Underwriters Laboratories (UL LLC) Safety Report



Model: CHD250PSXXYY, (where the "XX" can be any number between 12 to 48

indicating main output voltage, "YY" can be SF or blank indicating Single Fuse),

may also be provided with additional suffixes "-S", "-C", "-L", and/or "A"

Device Description: Component power supply

Applicant: XP POWER LLC

15641 Red Hill Ave., Ste. 100

Tustin, CA 97280 USA

Manufacturer: Same as Applicant

Manufacturing Facility(ies):

XP Power Inc

990 Benecia Ave

Sunnyvale CA 94085-2804 USA

XP POWER (VIETNAM) CO LTD

LOT D - 4Q - CN MY PHUOC 3 INDUSTRIAL PARK BEN CAT DISTRICT BINH DUONG VIETNAM

XP POWER (KUNSHAN) LTD

230 BIN JIANG NAN RD ZHANGPU TOWN

KUNSHANJIANGSU, 215321 CHINA

Report No.: E146893-D1002-1-ULCB

Report (Re)Issue

Date:

2015-03-31

Base Standard(s): ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14,

IEC 60601-1 Edition 3.1 (2012)

Report Types: This report consists of the following report types:

[Yes] US Certification (UL Recognition)
[Yes] CAN Certification (cUL Recognition)

[Yes] CB Report & Certificate IEC/EN Informative Report

This report covers the Safety evaluation of the referenced model(s) according to the standard(s) specified above.

The **CB Certificate** is provided as a separate enclosure to this report and not provided in the body of this report.

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Report Modifications Summary

The following changes were made to this report. If none listed in the below table, this report is the originally issued report.

Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By
< ReportMod >		

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Test Report issued under the responsibility of:



IEC 60601-1 Medical electrical equipment

Part 1: General requirements for basic safety and essential performance

Report Reference No...... E146893-D1002-1-ULCB

Total number of pages...... 343

CB Testing Laboratory...... UL Camas

Applicant's name XP POWER LLC

Address...... 15641 Red Hill Ave., Ste. 100

Tustin, CA 97280 USA

Test specification:

(or IEC 60601-1: 2012 reprint)

Test procedure...... CB Scheme

Non-standard test method.....: N/A

Test Report Form No...... IEC60601_1J

Test Report Form Originator...... UL(US)

Master TRF....... 2014-07

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If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

The test results presented in this report relate only to the object tested.

This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

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Test item description:	Compo	onent power supply	
Trade Mark:	Refer t	o Marking Label enclosure	
Manufacturer:	Same	as Applicant	
Model/Type reference:	to 48 in indicati	50PSXXYY, (where the "XX" candicating main output voltage, 'ing Single Fuse), may also be s "-S", "-C", "-L", and/or "A"	"YY" can be SF or blank
Ratings:	Input: 1	100-240Vac, 50/60Hz, 3.1A Ma nces & Miscellaneous Enclosu	ax; Output: See Model re for details
Testing procedure and testing location	,-		
[] CB Testing Laboratory:		UL Camas	
Testing location/ address:		2600 N.W. Lake Road, Cama	s. WA. 98607. USA
[] Associated CB Testing Laborato	ry:		
Testing location/ address:			
Tested by (name + signature):		Bernadette Matsuoka	Belett Hatruske
Approved by (name + signature):		Melissa DeGuia	Belitt Hatriska
[] Testing procedure: TMP/CTF St	age 1:		
Testing location/ address:			
Tested by (name + signature):			
Approved by (name + signature):			
[] Testing procedure: WMT/CTF S	tage 2:		
Testing location/ address:			
Tested by (name + signature):			
Witnessed by (name + signature):			
Approved by (name + signature):			
[X] Testing procedure: SMT/CTF Stage 3 or 4:			
Testing location/ address:		XP POWER LLC, 15641 Red 97280, USA	Hill Ave., Ste. 100, Tustin, CA
Tested by (name + signature):		RODNEY REYES	Rodney Reyes
Witnessed by (name + signature):			

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Approved by (name + signature):	TAC PHAM	Taulan_
Supervised by (name + signature):	MELISSA DEGUIA	melissa J. of
	·	·

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List of Attachments (including a total number of pages in each	ch attachment):
Refer to Appendix A of this report. All attachments a	re included within this report.
Summary of tes	ting
Tests performed (name of test and test clause):	Testing location:
Refer to the Test List in Appendix D of this report if testing was per	formed as part of this evaluation.
Summary of compliance with National Differences List of countries addressed: Austria, Korea, Republic of, USA, C	Canada, United Kingdom, Sweden

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Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Refer to the enclosure(s) titled Marking Plate in the Enclosures section in Appendix A of this report for a copy.

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GENERAL INFORMATION Test item particulars: Classification of Installation and Use: Building-in Device Type: Component Intended Use Statement: Component power supply intended to provided regulated power to medical equipment Mode of Operation: Continuous Supply Connection: For building-in Accessories and detachable parts included: None Other Options Include: None **Testing** Date of receipt of test item(s): 2014-06-06, 2015-02-25 Dates tests performed: 2014-06-13 to 2015-03-25 Possible test case verdicts: - test case does not apply to the test object N/A - test object does meet the requirement.....: Pass (P)

Abbreviations used in the report:

- normal condition: N.C. - single fault condition: S.F.C.

- means of Operator protection: MOOP - means of Patient protection: MOPP

N/E

Yes

Fail (F)

General remarks:

"(See Attachment #)" refers to additional information appended to the report.

"(See appended table)" refers to a table appended to the report.

- test object was not evaluated for the requirement:

- test object does not meet the requirement.....:

The tests results presented in this report relate only to the object tested.

This report shall not be reproduced except in full without the written approval of the testing laboratory.

List of test equipment must be kept on file and available for review.

Additional test data and/or information provided in the attachments to this report.

Throughout this report a point is used as the decimal separator.

The Critical Component Table is located at the end of the Test Tables.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the

Manufacturer stating that the sample(s) submitted for evaluation

is (are) representative of the products from each factory has been provided:

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies) XP Power Inc

990 Benecia Ave

Sunnyvale CA 94085-2804 USA

XP POWER (VIETNAM) CO LTD

LOT D - 4Q - CN MY PHUOC 3 INDUSTRIAL

PARK

BEN CAT DISTRICT BINH DUONG VIETNAM

XP POWER (KUNSHAN) LTD

230 BIN JIANG NAN RD ZHANGPU TOWN KUNSHAN JIANGSU, 215321 CHINA

GENERAL PRODUCT INFORMATION:

Report Summary

All applicable tests according to the referenced standard(s) have been carried out.

Refer to the Report Modifications page for any modifications made to this report.

Product Description

The product is a component AC-DC power supply for building-in, open frame type provided with a metal chassis, incorporating primary and SELV components.

Model Differences

All models in the Model CHD250PSXXYY Series are identical with exception to the Mains Transformer (T1) and minor secondary components that allow for different output voltage ratings. See below for Model Ratings at 50°C.

Output Ratings:

CHD250PS12: 10.1Vdc to 13.5Vdc, 20.8A Max., 250 W Max.

CHD250PS15: 13.6Vdc to 17Vdc, 16.7A Max. 250 W Max.

CHD250PS18: 17.1Vdc to 21Vdc, 13.9A Max. 250 W Max.

CHD250PS24: 21.1Vdc to 26Vdc, 10.4A Max. 250 W Max.

CHD250PS28: 26.1Vdc to 31Vdc, 8.93A Max. 250 W Max.

CHD250PS33: 31.1Vdc to 33Vdc, 7.58A Max. 250 W Max.

CHD250PS36: 33.1Vdc to 42Vdc, 6.94A Max. 250 W Max.

CHD250PS48: 42.1Vdc to 54Vdc, 5.2A Max. 250 W Max.

See Miscellaneous enclosure Power Output Table for additional information regarding power output and the various configurations.

Suffix "SF" indicates single fuse provided in the line side of the primary.

Units provided with suffix "-C" provided with cover.

Units provided with suffix "-S" provided with screw terminal.

Units provided with suffix "-L" provided with input leads.

Units provided with suffix "-A" provided with 5V Stand-by output rated 5Vdc, 1A.

Additional Information

Marking label is representative of all models.

Licenses older than 3 years to be provided by the manufacturer upon request.

The required clearance values have been assessed for suitability up to 5000 m elevation

The testing was conducted at XP POWER LLC, 1241 E DYER RD, SUITE 150, SANTA ANA, CA 92705,

USA. The client moved to 15641 Red Hill Ave., Ste. 100, Tustin, CA 97280 in December 2014 and has been re-audited as an SMT at this location.

Technical Considerations

- The product was investigated to the following additional standards:
 ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, EN 60601-1:2006/A1:2013/A12:2014
- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)
- The following accessories were investigated for use with the product: None
- Scope of Power Supply evaluation defers the following clauses to the be determined as part
 of the end product: Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents),
 Clause 9 (ME Hazard), Clause 10 Radiation), Clause 14 (PEMS), Clause 16 (ME Systems)
- Scope of Power Supply evaluation excludes the following: ☐ Patient applied parts clauses: 4.6, 7.2.10, 8.3, 8.5.2, 8.5.5, 8.7.4.7-8.7.4.9, 8.9.1.15; Battery related clauses: 7.3.3, 15.4.3; Hand Control related clauses: 8.10.4; Oxygen related clauses: 11.2.2, Fluids related clauses: 11.6.2 − 11.6.4, Sterilization clause: 11.6.7, Biocompatibility Clause: 11.7 (ISO 10993), Motor related clauses: 13.2.13.3, 13.4, Heating Elements related clause: 13.2
- The product is evaluated only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: Ordinary
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The power supply was evaluated for use in 50°C ambient at Full Rated Output and see Enclosure Miscellaneous for additional ratings and various configurations

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-Secondary: 292 Vrms, 478 Vpk, Primary-Earthed Dead Metal: 240 Vrms, 420 Vpk and for Models CHD250PSXXYY, where XX is 5 to 36, Secondary to Ground at 250Vrms, 354Vpk

The power supply terminals and/or connectors are: Not investigated for field wiring

The maximum investigated branch circuit rating is: 20A

The investigated Pollution Degree is: 2

Proper bonding to the end-product main protective earthing termination is: Required

An investigation of the protective bonding terminals has: Not been conducted

The following input terminals/connectors must be connected to the end-product supply neutral: Input

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Connector (CON1) N terminal.

The following magnetic devices (e.g. transformers or inductor) are provided with an OBJY2 insulation system with the indicated rating greater than Class A (105°C): T1, T2, T3, T1-Standby (Class F, 155°C)

The following end-product enclosures are required: Mechanical, Fire, Electrical

Suitable disconnect device is to be provided in the end system

Temperature, Leakage and Dielectric Strength testing shall be considered in the end system

Printed Wiring Board rated 130°C.

Heatsinks are floating and considered live. They should not be accessible in the end-product

Heating test was not conducted on unit with input/output leads. If unit is provided with input and/or output leads, then temperature on leads must be measured and cannot exceed 105°C

These components have been judged on the basis of the required spacings in the ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10 +A1:2012) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance), CAN/CSA-C22.2 No. 60601-1 (2008) + CSA C22.2 No. 60601-1:2014 (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance), which covers the end-use product for which the component was designed, IEC 60601-1, Edition 3.1, EN 60601-1:2006/A1:2013/A12:2014

Clearance spacing evaluated for 5000 m altitude. Additional consideration maybe necessary in the end-use product

Units provided with additional suffix "SF", provided with only one fuse. The need for additional fusing shall be determined as part of the end product

The power supplies were evaluated as having 2 MOPP between primary-to-secondary for 292Vrms, 478Vpk, and 1 MOPP between primary-to-ground for 240Vac and 420Vpk. Models CHD250PSXX-YY where XX is 12 to 36 only were also evaluated for 2 MOPP between secondary to ground for working voltage of 42Vdc and 1 MOPP for a working voltage of 250Vrms between secondary and earth for BF output considerations.

Overcurrent releases of adequate breaking capacity must be employed in the end product

The legibility and durability of Marking Test shall be conducted as part of the end product investigation.

	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

Insulation Diagram - (01) Insulation Diagram

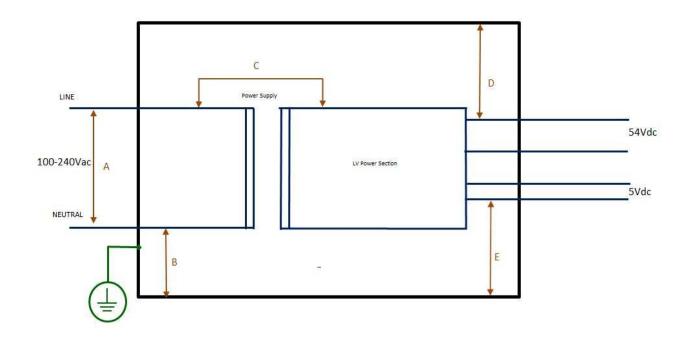


TABLE:	TABLE: INSULATION DIAGRAM							Pass	
Polluti	Pollution Degree:								-
Overvo	oltage category	:		II					-
Altitud	Altitude:			5000					-
	Additional details on parts considered as applied parts:			[X] None [] Areas: (See Clause 4.6 for details)				-	
Area	Number and type of Means of Protection: MOOP, MOPP	СТІ	Working Voltage V _{rms}	Working Voltage V _{pk}	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
Α	MOOP (1)	IIIb	240	339	2.96	2.96	3	3	PWB trace at Input Connector
В	MOPP (1)	IIIb	240	420	4	3.225	4	4	AC line traces to earth traces*
С	MOPP (2)	IIIb	292	478	9.2	9.03	9.2	9.2	PWB across T1
С	MOPP (2)	IIIb	240	324	7.9	6.45	10	10	T3 Pin 1 to 4
С	MOPP (2)	IIIb	240	324	7.9	6.45	8	8	Across the optoisolator
D	MOPP (1)	IIIb	250	354	4	3.2	4	4	From secondary to Ground on PWB for Models CHD250PSXX-YY where XX is 12 to 36 only

TRF No. IEC60601_1J

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4

4

4

4

From CON4 to Ground

From CON4 to Ground

on PWB

on PWB

Clause		Re	equirement -	+ Test		R	esult - Remai	rk	Verdict	
D	MOPP (2)	IIIb		42	4	2.6	4	4	From seconda Ground on P\ Models CHD2 where XX is 1 only	WB for 50PSXX-YY

2.1

3.2

3.4

4

IEC 60601-1

Supplementary Information: Refer to Appendix A for the Insulation Diagram.

250

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified. Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.

5

354

- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

For Model CHD250PS48, items D & E are operational insulation

Ε

Ε

MOPP (2)

MOPP (1)

IIIb

IIIb

^{*}Working voltage derived from Test Report Reference E139109-A144-CB-1

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Ī		IEC 60601-1		
	Clause	Requirement + Test	Result - Remark	Verdict

4	GENERAL REQUIREMENTS		Pass
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		Pass
4.2	RISK MANAGEMENT PROCESS FOR ME EQUIPM	ENT OR ME SYSTEMS	Pass
4.2.2	General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007):	See Appended RM Results Table 4.2.2.	Pass
4.2.3	Evaluating RISK		Pass
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level		Pass
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN:	RISK MANAGEMENT PLAN Document:10018357 Rev A	Pass
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		Pass
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		Pass
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.		Pass
4.3	Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.	See Document No: 10018357 Rev A	Pass
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.		Pass
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		Pass
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE:	See Appended Table 4.3	Pass
	- RISK CONTROL measures implemented		Pass
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		Pass
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE:	600khours; see RM Doc No. 10018357 Rev A	Pass
4.5	Alternative RISK CONTROL methods utilized:		N/A
	RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A

	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

	Alternative means based scientific data or clinical opinion or comparative studies:		N/A
4.6	RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10:	Component power supply intended for building-in, to be determined as part of end product	N/A
	MANUFACTURER assesses the risk of accessible parts coming into contact with the patient: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	Assessment identified the APPLIED PART TYPE requirements:		N/A
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2:	See appended table 13.2	Pass
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested: (ISO 14971 Cl. 4.2-4.4)	RISK ANALYSIS reference: 10018357 Rev A, Single Fault Condition (4.7) (ISO 14971 Cl.4.2 to 4.2)	Pass
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically:	See appended Table 13.2 for simulated physical test	Pass
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified:		Pass
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS		N/A
	RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION:		N/A
	Components determined to be acceptable where used as a MEANS OF PROTECTION:		N/A
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following		Pass
	a) Applicable safety requirements of a relevant IEC or ISO standard	See appended table 8.10	Pass

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		Pass
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately:	No such parts	N/A
	RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:		N/A
4.10	Power supply		Pass
4.10.1	ME EQUIPMENT is suitable for connection to indicated power source (select applicable):	Component, to be determined as part of the end product evaluation.	N/A
		Power supply is rated 100-240 V ac	
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:		Pass
	- 250 V for HAND-HELD ME EQUIPMENT (V):		N/A
	- 250 V d.c. or single-phase a.c., or 500 V poly- phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V):		Pass
	- 500 V for all other ME EQUIPMENT and ME SYSTEMS		N/A
4.11	Power input		Pass
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%:	See appended Table 4.11	Pass
5	GENERAL REQUIREMENTS FOR TESTING ME EC	QUIPMENT	Pass
5.1	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods:		N/A
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. (ISO 14971 Cl. 4.2-4.4)		N/A
5.3	Tests conducted within the environmental conditions specified in technical description		Pass
	Temperature (°C), Relative Humidity (%):	25degC, 50degC and 70degC, 30-75% RH	-

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Clause	Requirement + Test	Result - Remark	Verdict

	Atmospheric Pressure (kPa):	54-106	-
5.5	a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V):	Rated: 100-240 Vac; Tested: 90 Vac and 264 Vac	Pass
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz):	Rated: 50-60 Hz, Tested: 50 Hz and 60 Hz	Pass
	c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current:	Tested at 90 Vac and 264 Vac	Pass
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered:		N/A
	e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions:		N/A
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use		N/A
5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3:		Pass
	ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +32°C for indicated time	T =40°C Time: 120h	-
5.9	Determination of APPLIED PARTS and ACCESSIBL	E PARTS	N/A
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS:10018357 Rev A	Component for building-in; to be evaluated in end product	N/A
5.9.2	ACCESSIBLE PARTS		N/A
5.9.2.1	Accessibility determined using standard test finger of Fig. 6		N/A
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s		N/A
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS:		N/A

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	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL:		N/A
6	CLASSIFICATION OF ME EQUIPMENT AND ME S	YSTEMS	Pass
6.2	CLASS I ME EQUIPMENT, externally powered	Component, to be also determined in end-product evaluation	Pass
	CLASS II ME EQUIPMENT, externally powered		N/A
	INTERNALLY POWERED ME EQUIPMENT		N/A
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements		N/A
	TYPE B APPLIED PART		N/A
	TYPE BF APPLIED PART		N/A
	TYPE CF APPLIED PART		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS		N/A
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529:	Power Supply not evaluated for protection against ingress of water and particulate matter	N/A
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use:		N/A
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2		N/A
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION:	Intended for Continuous operation	Pass
7	ME EQUIPMENT IDENTIFICATION, MARKING, AN	D DOCUMENTS	Pass
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6:	Component for building-in; to be evaluated in end product	N/A
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE	Component for building-in; to be evaluated in end product	N/A
7.2	Marking on the outside of ME EQUIPMENT or ME E	QUIPMENT parts	Pass
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings:	See attached copy of Marking Plate	Pass
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS:	Component only, to be evaluated in end product	N/A

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	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT		N/A
	Single use item marked:		N/A
7.2.2	ME EQUIPMENT marked with:		Pass
	 the name or trademark and contact information of the MANUFACTURER 		Pass
	– a MODEL OR TYPE REFERENCE	See attached copy of Marking Plate	Pass
	- a serial number or lot or batch identifier; and		Pass
	- the date of manufacture or use by date	Provided as part of the serial number	Pass
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or		N/A
	RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts: (ISO 14971 Cl. 4.2-4.4, 5, 6.4)		N/A
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and		N/A
	– a MODEL OR TYPE REFERENCE		N/A
	Software forming part of a PEMS identified with a unique identifier:		N/A
7.2.3	Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS	Component, Accompanying Documents to be provided as part of end product	N/A
	Safety sign 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted		N/A
7.2.4	ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and:	No such parts	N/A
	- with a MODEL or TYPE REFERENCE		N/A
	– a serial number or lot or batch identifier		N/A
	- the date of manufacture or use by date		N/A
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		N/A
7.2.5	ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following	Component, to be determined in end-product evaluation	N/A

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	- the name or trademark of the manufacturer of the other electrical equipment and type reference		N/A
	marked adjacent to the relevant connection point; or		
	 Table D.2, safety sign No. 10 adjacent to the relevant connection point and listing of the required details in the instructions for use; or 		N/A
	 Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use. 		N/A
7.2.6	Connection to the Supply Mains		Pass
	Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point	(see attached marking plate)	Pass
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT		N/A
	 RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V): 	100-240vac	Pass
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V):		N/A
	- Nature of supply and type of current :		Pass
	Symbols 1-5, Table D.1 (used for same parameters:	(see attached marking plate)	Pass
	 RATED supply frequency or RATED frequency range in hertz: 		Pass
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT:		N/A
7.2.7	RATED input in amps or volt-amps, (A, VA):	(see attached marking plate)	Pass
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W):	(see attached marking plate)	Pass
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W):		N/A
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W):		N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA):		N/A
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W):		N/A

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7.2.8	Output connectors		Pass
7.2.8.2	Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment	Output rating provided for DC output connector. Component for building-in, also to be determined as part of the end product	Pass
	Rated Voltage (V), Rated Current (A):	(see attached marking plate & model differences)	-
	Rated Power (W), Output Frequency (Hz):	(see attached marking plate & model differences)	-
7.2.9	ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2), marking optional for ME EQUIPMENT or parts rated IPX0.:		N/A
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols :	No such parts	N/A
	TYPE B APPLIED PARTS with symbol 19 of Table D.1		N/A
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1:		N/A
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1:		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1:		N/A
	Proper symbol marked adjacent to or on connector for APPLIED PART:		N/A
	Safety sign 2 of Table D.2 placed near relevant outlet:		N/A
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use:		N/A
7.2.11	ME EQUIPMENT suitable for CONTINUOUS OPERATION		Pass
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time:		N/A
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder	Component only; to be evaluated in end product	N/A
	Fuse type:		-
	Voltage (V) and Current (A) rating:		-
	Operating speed (s) and Breaking capacity:		-
7.2.13	Physiological effects – safety sign and warning statements:		N/A

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	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use: (ISO 14971 Cl. 4.2-4.4, 5, 6.3)		N/A
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1		N/A
7.2.15	Requirements for cooling provisions marked:		N/A
7.2.17	Packaging marked with special handling instructions for transport and/or storage:	Component for building-in; to be evaluated in end product	N/A
	Permissible environmental conditions marked on outside of packaging:		N/A
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK:		N/A
	RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK.:		N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.3-6.4)		
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization		N/A
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and :		N/A
	- the RATED flow rate also marked		N/A
7.2.19	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL:		N/A
7.2.20	Removable protective means marked to indicate the necessity for replacement when the function is no longer needed:		N/A
7.2.21	MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms:		N/A
7.3	Marking on the inside of ME EQUIPMENT or ME EQ	UIPMENT parts	N/A
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W):	No such parts	N/A
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.3.2	Symbol 24 of Table D.1, or safety sign No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts:		N/A
7.3.3	Type of battery and mode of insertion marked:	No batteries	N/A
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL:		N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK:		N/A
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an unacceptable RISK if replaced incorrectly: (ISO 14971 Cl. 4.2-4.4, 5, 6.3)		N/A
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARD:		N/A
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified:	Fuses are not replaceable	N/A
	Voltage (V) and Current (A) rating:		-
	Operating speed(s), size & breaking capacity:		-
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1	Component for building-in, to be determined as part of the end product	N/A
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		N/A
7.3.6	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS		N/A
7.3.7	Terminals for supply conductors marked adjacent to terminals:		N/A
	Terminals for supply connections are not marked, the RISK MANAGEMENT FILE includes an assessment of the RISKS resulting from misconnections: (ISO 14971 Cl. 4.3)		N/A
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings		N/A

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	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3		N/A
	Marking for connection to a 3-phase supply, complies with IEC 60445		N/A
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		N/A
7.3.8	"For supply connections, use wiring materials suitable for at least X °C" or equivalent, marked at the point of supply connections		N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		N/A
7.4	Marking of controls and instruments		N/A
7.4.1	The "on" & "off" positions of switch to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 or	No such parts	N/A
	- indicated by an adjacent indicator light, or		N/A
	- indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with bistable positions marked with symbol 14 of Table D.1, and		N/A
	- status indicated by adjacent indicator light		N/A
	- status indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or		N/A
	- status indicated by adjacent indicator light		N/A
	- status indicated by other unambiguous means		N/A
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means		N/A
	RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK: (ISO 14971 Cl. 4.2-4.4, 5, 6.2, 6.3)		N/A
	(100 1407 1 01. 4.2-4.4, 3, 0.2, 0.3)		
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE:		N/A
	 or an indication of direction in which magnitude of the function changes 		N/A
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	Control device or switch that brings the ME		N/A
	EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009		. 4/1
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units	No such markings	N/A
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units		N/A
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3:		N/A
7.5	Safety signs		N/A
	Safety sign with established meaning used	Component only, to be determined in the end product	N/A
	RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR:		N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.3)		
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT		N/A
	Specified colours in ISO 3864-1 used for safety signs:		N/A
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		N/A
	Safety signs including any supplementary text or symbols described in instructions for use		N/A
	- and in a language acceptable to the intended OPERATOR		N/A
7.6	Symbols		N/A
7.6.1	Meanings of symbols used for marking described in instructions for use:	Component, Accompanying Documents to be provided by the end product	N/A
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable		N/A
7.7	Colours of the insulation of conductors		N/A
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation	Component only; to be evaluated in end product	N/A
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations		N/A

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7.7.3	Green and yellow insulation identify only following conductors:	Component only, to be determined in the end product	N/A
	- PROTECTIVE EARTH CONDUCTORS		N/A
	- conductors specified in 7.7.2		N/A
	- POTENTIAL EQUALIZATION CONDUCTORS		N/A
	- FUNCTIONAL EARTH CONDUCTORS		N/A
7.7.4	Neutral conductors of POWER SUPPLY CORDS are "light blue"		N/A
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1		N/A
7.8	Indicator lights and controls		N/A
7.8.1	Red indicator lights used only for Warning	No such parts	N/A
	Yellow indicator lights used only for Caution		N/A
	Green indicator lights used only for Ready for use		N/A
	Other colours: Meaning other than red, yellow, or green (colour, meaning):		N/A
7.8.2	Red used only for emergency control		N/A
7.9	ACCOMPANYING DOCUMENTS		N/A
7.9.1	ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description	Component, to be determined in end-product evaluation	N/A
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		N/A
	 Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to: 		N/A
	- MODEL or TYPE REFERENCE:		N/A
	When ACCOMPANYING DOCUMENTS provided electronically, USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT		N/A
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use		N/A
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended		N/A
7.9.2	Instructions for use include the required information		N/A
7.9.2.1	 use of ME EQUIPMENT as intended by the MANUFACTURER: 	Component, to be determined in end-product evaluation	N/A
-	- frequently used functions,		N/A

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	– known contraindication(s) to use of ME EQUIPMENT		N/A
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient		N/A
	 name or trademark and address of the MANUFACTURER 		N/A
	– MODEL OR TYPE REFERENCE		N/A
	Instruction for use included the following when the PATIENT is an intended OPERATOR:		N/A
	- the PATIENT is an intended OPERATOR		N/A
	 warning against servicing and maintenance while the ME EQUIPMENT is in use 		N/A
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and		N/A
	-maintenance the PATIENT can perform		N/A
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT		N/A
	Instructions for use are in a language acceptable to the intended operator		N/A
.9.2.2	Instructions for use include all warning and safety notices	Component, to be determined in end-product evaluation	N/A
	Warning statement for CLASS I ME EQUIPMENT included		N/A
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments		N/A
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference		N/A
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided		N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS		N/A
.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions		N/A
.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source		N/A

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	1	-
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries: (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	N/A
	Where the RISK is unacceptable, the IFU includes a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time:	N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided:	N/A
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK:	N/A
7.9.2.5	Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE	N/A
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to	N/A
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected	N/A
	APPLIED PARTS specified	N/A
7.9.2.6	Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation	N/A
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device	N/A
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation	N/A
7.9.2.9	Information provided to operate ME EQUIPMENT	N/A
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	N/A
7.9.2.10	A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message	N/A
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	N/A

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7.9.2.12	Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified		N/A
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use		N/A
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency		N/A
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT		N/A
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application		N/A
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL		N/A
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided		N/A
	Other equipment providing power to ME SYSTEM sufficiently described		N/A
7.9.2.15	Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for use:		N/A
7.9.2.16	Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)		N/A
7.9.2.17	Instruction for use for ME EQUIPMENT emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation		N/A
7.9.2.18	The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile indicate that they have been sterilized and the method of sterilization		N/A
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization		N/A
7.9.2.19	The instructions for use contain a unique version identifier:		N/A
7.9.3	Technical description		N/A

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7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use		N/A
	Technical description separable from instructions for information, as follows	use contains required	N/A
	 all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT 		N/A
	 a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and 		N/A
	a unique version identifier:		N/A
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description		N/A
7.9.3.2	The technical description contains the following requi	red information	N/A
	-type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT:	Component, to be determined in end-product evaluation	N/A
	 a statement for ME EQUIPMENT with a non- DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and 		N/A
	 instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and 		N/A
	RISK MANAGEMENT FILE includes an assessment to determine if replacement of components results in any unacceptable RISKS: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component		N/A
7.9.3.3	Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair		N/A
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description		N/A
8	PROTECTION AGAINST ELECTRICAL HAZARDS I	FROM ME EQUIPMENT	Pass

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8.1	Limits specified in Clause 8.4 not exceeded for	Component, also to be	Pass
	ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS	determined as part of the end product	
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a	RMF Reference to specific RISKS:	Pass
	HAZARDOUS SITUATION:	10018357 Rev A, (8.1b[3])	
	(ISO 14971 Cl. 4.3)	(ISO 14971 Cl. 4.2 to 5)	
8.2	Requirements related to power sources		N/A
8.2.1	Connection to a separate power source		N/A
	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM		N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		N/A
8.2.2	Connection to an external d.c. power source		N/A
	No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source		N/A
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE		N/A
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset		N/A
8.3	Classification of APPLIED PARTS		N/A
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	No applied parts	N/A
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART		N/A
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF		N/A
8.4	Limitation of voltage, current or energy		Pass
8.4.2	ACCESSIBLE PARTS and APPLIED PARTS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

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	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT:	No applied parts	N/A
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT:	Component only, to be determined in the end product	N/A
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed	Component only, to be determined in the end product	N/A
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.):		N/A
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J):		N/A
	d) Voltage and energy limits specified in c) above also applied to the following:		N/A
	 internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and 		N/A
	 internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre- set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL 		N/A
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		N/A
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N		N/A
	Test repeated with a TOOL specified in instructions for use		N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE		N/A
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION		N/A
	A TOOL is required when it is possible to prevent the devices from operating		N/A

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8.4.3	Worst case voltage between sine of slug and	Soo appended Table 9.4.2	Poss
ช.4. 3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one sec after disconnecting the plug of ME EQUIPMENT or its parts (V):	See appended Table 8.4.3	Pass
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 μC:	Did not exceed 60Vdc	N/A
8.4.4	Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC:	Component for building-in, to be determined as part of the end product	N/A
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description:		N/A
8.5	Separation of parts		Pass
8.5.1	MEANS OF PROTECTION (MOP)		Pass
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4	See Insulation Diagram and Table	Pass
	Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION		Pass
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		Pass
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		Pass
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test:	See appended Table 8.8.3	Pass
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		Pass
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6		N/A
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION:		N/A
	Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c.:		N/A
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	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N/A
	Voltage Total Working (V) and C Nominal (µF):		-
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)		Pass
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		N/A
	- dielectric strength test:		N/A
	 requirements of IEC 60950-1 for INSULATION CO-ORDINATION 		N/A
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:	see insulation diagram and table	Pass
	- limits of Tables 13 to 16 (inclusive); or		Pass
	 requirements of IEC 60950-1 for INSULATION CO-ORDINATION 		N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6		N/A
	 or with requirements and tests of IEC 60950-1 for protective earthing: 		N/A
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION:		N/A
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION:		N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N/A
	Voltage Total Working (V) and C Nominal (µF):		-
	Points and applied parts at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 were examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION		N/A
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION:		N/A
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION:		N/A
8.5.2	Separation of PATIENT CONNECTIONS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAX. MAINS VOLTAGE:	No patient connections	N/A
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		N/A
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		N/A
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS:		N/A
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4:		N/A
	Dielectric strength test conducted per 8.8.3:		N/A
	CREEPAGE and CLEARANCES measured :		N/A
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s		N/A
8.5.2.2	PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED:		N/A
	except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and		N/A
	RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4:		N/A
	Dielectric strength test conducted per 8.8.3:		N/A
	Relevant CREEPAGE and CLEARANCES measured		N/A
	RISK MANAGEMENT FILE includes an assessment of the RISK of metal ACCESSIBLE PARTS contacting a source of voltage or LEAKAGE CURRENT above the limits: (ISO 14971 Cl. 4.2-4.4, 5)		N/A

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8.5.2.3	A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE		N/A
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT:	No patient connections	N/A
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter		N/A
	 CLEARANCE between connector pins and a flat surface is at least 0.5 mm 		N/A
	 conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1 		N/A
	 required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N, 		N/A
	Test finger test (10 N):		N/A
	Except when RISK MANAGEMENT PROCESS includes an assessment of RISKS resulting from contact with objects other than mains sockets or flat surfaces: (ISO 14971 Cl. 4.2-4.4, 5)		N/A
8.5.4	WORKING VOLTAGE		Pass
	 Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V): 	Tested at 240Vac	Pass
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak- to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V):	Considered for dc outputs	Pass
	- WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V):	See Insulation Diagram and Insulation Table	Pass
	Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth	No applied parts	N/A

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	- WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V):	No applied parts	N/A
	WORKING VOLTAGE for DEFIBRILLATION- PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages		N/A
	 WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V): 	No such parts	N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	No such parts	N/A
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety		N/A
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		N/A
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator:		N/A
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS:		N/A
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load:		N/A
8.6	Protective and functional earthing and potential equa	lization of ME EQUIPMENT	N/A
8.6.1	Requirements of 8.6.2 to 8.6.8 applied	Component only; to be evaluated in end product	N/A
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8		N/A
8.6.2	PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR:	Component only; to be evaluated in end product	N/A
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL		N/A

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	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside:		N/A
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		N/A
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		N/A
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part,	No such parts	N/A
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop:	Component only, to be determined in the end product	N/A
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits:		N/A
8.6.5	Surface coatings		N/A
	Poorly conducting surface coatings on conductive elements removed at the point of contact		N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		N/A
8.6.6	Plugs and sockets		N/A
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections		N/A
	- applied also where interchangeable parts are PROTECTIVELY EARTHED		N/A
8.6.7	Terminal for connection of a POTENTIAL EQUALIZA	ATION CONDUCTOR	N/A
	Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE	No such parts	N/A
	-accidental disconnection avoided in NORMAL USE		N/A
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		T	
	 Terminal allows conductor to be detached without a TOOL 		N/A
	- Terminal not used for a PROTECTIVE EARTH CONNECTION		N/A
	- Terminal marked with symbol 8 of Table D.1		N/A
	 Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard 		N/A
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		N/A
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION		N/A
8.6.9	Class II ME EQUIPMENT	,	N/A
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow		N/A
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.		N/A
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS		N/A
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY C	CURRENTS	Pass
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3:	See appended Tables 8.7	Pass
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7:	See appended Tables 8.7	Pass
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		Pass
	where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		Pass
	the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		Pass
	- LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		Pass

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	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		N/A
8.7.3	Allowable Values		Pass
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b:	See appended Table 8.7	Pass
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz:	See appended Table 8.7	Pass
	c) TOUCH CURRENT did not exceed 100 μA in NORMAL CONDITION and 500 μA in SINGLE FAULT CONDITION (ITNC, ITSFC):	Component only; to be evaluated in end product	N/A
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (IENC, IESFC):	See appended Table 8.7	Pass
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710:		N/A
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device:	Component only; to be evaluated in end product	N/A
	f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non- PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION:		N/A
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements:	See appended Table 8.7	Pass
8.8	Insulation		Pass
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing		Pass
	Insulation exempted from test (complies with clause 4.8)	See appended table 8.10	N/A
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		N/A
8.8.2	Distance through solid insulation or use of thin sheet	material	Pass

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Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		Pass
a) 0.4 mm, min, distance through insulation, or	Considered as part of Optocoupler UL Recognition	N/A
b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		N/A
at least two layers of material, each passed the appropriate dielectric strength test:		N/A
 or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test: 		N/A
Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		N/A
Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		N/A
BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		N/A
c) Wire with solid insulation, other than solvent based enamel, complying with a)		N/A
d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		N/A
e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	Evaluated as part of component evaluation	Pass
BASIC INSULATION: minimum two wrapped layers or one extruded layer		N/A
- SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		N/A
REINFORCED INSULATION: minimum three layers, wrapped or extruded		Pass
In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values	Evaluated as part of component evaluation	N/A

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	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension :		N/A
	Finished component complied with routine dielectric strength tests of 8.8.3:	Evaluated as part of component evaluation	Pass
	Tests of Annex L not repeated since material data sheets confirm compliance:	See Table 8.10	Pass
8.8.3	Dielectric Strength		Pass
	Solid insulating materials with a safety function withstood dielectric strength test voltages:	See appended Table 8.8.3	Pass
8.8.4	Insulation other than wire insulation		Pass
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		Pass
	ME EQUIPMENT and design documentation examined:		N/A
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: 10018357 Rev A (8.8.4.1) (ISO 14971 CI.Cl. 4.2-4.4, 5, 6.2-6.5)	Pass
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat:	See enclosure Miscellaneous	Pass
	Tests conducted in absence of satisfactory evidence for resistance to heat:	See appended table 8.8.4.1	Pass
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus:		N/A
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C):	See appended Table 8.8.4.1	Pass
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION		Pass
8.8.4.2	Resistance to environmental stress		N/A
	1		

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	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9	Component for building-in; to be evaluated in end product	N/A
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION		N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION		N/A
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples		N/A
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h		N/A
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		Pass
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive):	Refer to Insulation Diagram	Pass
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1		N/A
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION, min CREEPAGE and CLEARANCES not applied:		N/A
8.9.3	Spaces filled by insulating compound		N/A
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound		N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests		N/A
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage):		N/A
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		N/A

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8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint		N/A
	A winding of solvent-based enamelled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		N/A
	 One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage : 		N/A
	- The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage		N/A
8.10	Components and wiring		Pass
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely:		Pass
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components: (ISO 14791 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: 10018357 Rev A (8.10.1) (ISO 14971 Cl.4.2-4.4, 5, 6.2-6.5)	Pass
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment:		Pass
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS		N/A
8.10.3	Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken:	No such parts	N/A
8.10.4	Cord-connected HAND-HELD parts and cord-connected devices	cted foot-operated control	N/A
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION	No such parts	N/A
8.10.4.2	Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3		N/A

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	Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3		N/A
8.10.5	Mechanical protection of wiring		N/A
	 a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges: 	Component only, to be determined in the end product	N/A
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS		N/A
8.10.6	Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead	No such parts	N/A
8.10.7	a) Insulating sleeve adequately secured:		N/A
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics		N/A
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C:		N/A
8.11	MAINS PARTS, components and layout		Pass
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles:	Component for building-in; to be evaluated in end product	N/A
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)		N/A
	PERMANENTLY INSTALLED ME EQUIPMENT provided with means to isolate its circuits electrically from the SUPPLY MAINS are capable of being locked in the off position		N/A
	- the isolation device specified in the ACCOMPANYING DOCUMENTS		N/A
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description:	Component only, to be determined in the end product	N/A
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV:		N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead		N/A

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	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		N/A
	f) A suitable plug device used in non- PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH:		N/A
	g) A fuse or a semiconductor device not used as an isolating means		Pass
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device		N/A
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering		N/A
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage		N/A
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		N/A
	Standard test finger applied		N/A
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	No such parts	N/A
8.11.3	POWER SUPPLY CORDS		N/A
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD	Component for building-in, to be determined as part of the end product	N/A
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design 53):		N/A
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE:		N/A
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17:		N/A

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8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6:		N/A
8.11.3.5	Cord anchorage		N/A
	a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage	Component for building-in to be determined as part of the end product	N/A
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or		N/A
	 metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or 		N/A
	 metal provided with an insulating lining affixed to cord anchorage 		N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components		N/A
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals		N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18:		N/A
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests		N/A
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position		N/A
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N/A
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged		N/A
8.11.3.6	POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment		N/A

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	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N/A
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D2 gram attached to the free end of cord (g):		N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		N/A
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D:		N/A
8.11.4	MAINS TERMINAL DEVICES		N/A
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection	Component for building-in to be determined as part of the end product	N/A
	Terminals alone are not used to keep conductors in position		N/A
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors		N/A
	Screws and nuts clamping external conductors do not serve to secure any other component		N/A
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N/A
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection		N/A
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		N/A
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction		N/A
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced after fastening and loosening a conductor of largest cross-sectional area 10 times	No such parts	N/A
8.11.4.4	Terminals with clamping means for a rewireable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened		N/A

8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewireable POWER SUPPLY CORD to allow for connection of conductors		N/A
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test		N/A
8.11.5	Mains fuses and OVER-CURRENT RELEASES		Pass
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection:	Each supply conductor is provided with a fuse. Suffix "SF" models provided with single fuse, consideration to be given in end product. See appended Table 8.10	Pass
	- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT:		N/A
	 neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT 		N/A
	 fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART 		N/A
	Protective devices have adequate breaking capacity to interrupt the max. fault current:	Component only, to be determined in the end product	N/A
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		Pass
	Justification for omission of fuses or OVER-CURRENT RELEASES documented:		N/A
8.11.6	Internal wiring of the MAINS PART		Pass
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable:		Pass
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient:	See appended Table 8.10 for details	Pass
9	PROTECTION AGAINST MECHANICAL HAZARDS SYSTEMS	OF ME EQUIPMENT AND ME	Pass
9.2	HAZARDS associated with moving parts		N/A
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level:	Component, to be determined as part of end product	N/A
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)		N/A

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	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and		N/A
	RISK CONTROLS implemented:		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	All RISKS associated with moving parts have been reduced to an acceptable level		N/A
9.2.2	TRAPPING ZONE		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:	Component, to be determined as part of end product	N/A
	- Gaps in Clause 9.2.2.2, or		N/A
	- Safe distances in Clause 9.2.2.3, or		N/A
	- GUARDS and other RISK CONTROL measures in 9.2.2.4, or		N/A
	- Continuous activation in Clause 9.2.2.5		N/A
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM		N/A
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20:	Component, to be determined as part of end product	N/A
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008:	Component, to be determined as part of end product	N/A
9.2.2.4	GUARDS and other RISK CONTROL measures		N/A
9.2.2.4.1	A TRAPPING ZONE do not to present a MECHANICAL HAZARD when GUARDS or other RISK CONTROL measures are of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK:	Component, to be determined as part of end product	N/A
9.2.2.4.2	FIXED GUARDS held in place by systems that can only be dismantled with a TOOL		N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open		N/A

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	 they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened, 		N/A
	absence or failure of one of their components prevents starting, and stops moving parts		N/A
	Movable GUARDS complied with any applicable tests		N/A
9.2.2.4.4	Other RISK CONTROL designed and incorporated into to the control system stops movement and		N/A
	- SINGLE FAULT CONDITIONS have a second RISK CONTROL, or		N/A
	ME EQUIPMENT is SINGLE FAULT SAFE		N/A
9.2.2.5	Continuous activation		N/A
	Continuous activation used as a RISK CONTROL, complies with the following	Component, to be determined as part of end product	N/A
	a) movement was in OPERATOR'S field of view		N/A
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR		N/A
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or		N/A
	- the continuous activation system is SINGLE FAULT SAFE		N/A
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement	Component, to be determined as part of end product	N/A
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		N/A
9.2.3	Other MECHANICAL HAZARDS associated with mo	ving parts	N/A
9.2.3.1	Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated		N/A
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or		N/A
	- activation does not result in an unacceptable RISK		N/A
9.2.3.2	Over travel past range limits of the ME EQUIPMENT prevented:		N/A
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse:		N/A
9.2.4	Emergency stopping devices		N/A

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	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power:	No such parts	N/A
	a) Emergency stopping device reduced RISK to an acceptable level		N/A
	RISK MANAGEMENT FILE indicates the use of an emergency stopping device reduces the RISK to an acceptable level: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.6)		N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N/A
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD		N/A
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N/A
	g) Means for stopping of movements operate as a result of one single action		N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or "STOP"		N/A
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed		N/A
	k) Emergency stopping device is suitable for its application		N/A
9.2.5	Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping:	No such parts	N/A

N/A

N/A

N/A

N/A

N/A

N/A

N/A

. .

placed in different positions of NORMAL USE,:

A warning provided when overbalance occurred

a) ME EQUIPMENT or its parts with a mass of 25kg

or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it

Surfaces of ME EQUIPMENT or its parts where a

RISK of overbalancing exists from pushing, etc., permanently marked with a warning of the RISK

ME EQUIPMENT did not overbalance when tested

b) ME EQUIPMENT, for use on the floor or on a

on a table, where RISK of overbalancing exists, permanently marked with the RISK warning:

table, did not overbalance due to sitting or stepping

ME EQUIPMENT or its parts, for use on the floor or

Instability from horizontal and vertical forces

during 10° inclined plane test

according to Cl. 9.4.2.3 a)

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	 and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented 		N/A
	 Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented 		N/A
	Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered:	All edges are sufficiently rounded or smooth	Pass
9.4	Instability HAZARDS	•	N/A
9.4.1	ME EQUIPMENT and its parts, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE		N/A
9.4.2	Instability – overbalance	•	N/A
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested:		N/A
9.4.2.2	Instability excluding transport	1	N/A
	ME EQUIPMENT or its did not overbalance when		N/A

9.4.2.3

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	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b):		N/A
9.4.2.4	Castors and wheels		N/A
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE		N/A
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT did not exceed 200 N:		N/A
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold:		N/A
9.4.3	Instability from unwanted lateral movement (including	g sliding)	N/A
9.4.3.1	a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control		N/A
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements		N/A
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1		N/A
9.4.3.2	Instability excluding transport		N/A
	a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test:		N/A
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test		N/A
9.4.4	Grips and other handling devices		N/A
	a) ME EQUIPMENT with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method	No such parts	N/A
	Handles, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS		N/A
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying		N/A
	c) Carrying handles and grips and their means of attachment withstood loading test:		N/A
9.5	Expelled parts HAZARD		N/A

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9.5.1	Suitability of means of protecting against expelled	No such parts	N/A
	parts determined by assessment and examination of RISK MANAGEMENT FILE: (ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)	·	
	(130 1497 1 Cl. 4.3, 4.4, 5, 6.2-6.5)		
	All identified RISKS associated with expelled parts mitigated to an acceptable level		N/A
9.5.2	Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965:	No such parts	N/A
9.6	Acoustic energy (including infra- and ultrasound) and	vibration	N/A
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and	No such parts	N/A
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity:		N/A
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and		N/A
	(ISO 14971 Cl. 4.2-44, 5, 6.2-6.5)		
	All identified RISKS mitigated to an acceptable level		N/A
9.6.2	Acoustic energy		N/A
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE	No such parts	N/A
	 - 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA): 		-
	- 83 dBA (when halving the cumulative exposure time) (dBA):		-
	 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB): 		-
9.6.2.2	RISK MANAGEMENT FILE examined: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
9.6.3	Hand-transmitted vibration	<u> </u>	N/A
	Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values	No such parts	N/A
	- 2.5 m/s2 for a cumulative time of 8 h during a 24 h period (m/s2):		N/A
	Accelerations for different times, inversely		N/A

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9.7	Pressure vessels and parts subject to pneumatic and	l hydraulic pressure	N/A
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE: (ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)	No such parts	N/A
	No unacceptable RISK resulted from loss of pressure or loss of vacuum		N/A
	 No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure 		N/A
	 Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects 		N/A
	 Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply 		N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N/A
	 All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity 		N/A
9.7.3	Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:	No such parts	N/A
	a) RATED maximum supply pressure from an external source		N/A
	b) Pressure setting of a pressure-relief device provided as part of assembly		N/A
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device		N/A
9.7.4	Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests:	No such parts	N/A
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was more than 50 kPa, and product of pressure and volume was more than 200 kPal:	No such parts	N/A

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9.7.6	Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE:	No such parts	N/A
9.7.7	Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests:	No such parts	N/A
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair		N/A
	c) Could be adjusted or rendered inoperative without a TOOL		N/A
	d) With discharge opening located and directed as to not to release material towards any person		N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		N/A
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure		N/A
	g) No shut-off valve provided between a pressure- relief device and parts it is to protect		N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N/A
	RISK MANAGEMENT FILE includes an assessment of the risks associated with the discharge opening of the pressure relief device: (ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)		N/A
9.8	HAZARDS associated with support systems		N/A
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK:	No such parts	N/A
	 Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD 		N/A
	 Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK 		N/A

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	- RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	 RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES 		N/A
	 Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials 		N/A
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		N/A
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest	No such parts	N/A
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing:		N/A
	RISK MANAGEMENT FILE includes an assessment of the structural integrity of support system: (ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)		N/A
	All identified RISKS are mitigated to an acceptable level		N/A
	When test were conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK:		N/A
	Where the equipment is not at equilibrium after 1 min, the RISK MANAGEMENT FILE includes an assessment of the test results: (ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)		N/A

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9.8.3	Strength of PATIENT or OPERATOR support or susp	pension systems	N/A
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints:	No such parts	N/A
	RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts		N/A
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER		N/A
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications		N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		N/A
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS		N/A
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance :		N/A
9.8.3.2	a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR:	No such parts	N/A
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests:		N/A
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK		N/A
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test:		N/A

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9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE maintained BASIC SAFETY and ESSENTIAL PERFORMANCE confirmed test	No such parts	N/A
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICE	ES .	N/A
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided for the support system	No such parts	N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		N/A
	Designed based on TOTAL LOAD		N/A
	Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N/A
	Activated before travel produced an unacceptable RISK		N/A
	- Takes into account Clauses 9.2.5 and 9.8.4.3		N/A
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests:		N/A
9.8.4.2	Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE	No such parts	N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		N/A
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to f	unction once	N/A
	–use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE:	No such parts	N/A
	 ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal 		N/A
	 ME EQUIPMENT permanently marked with safety sign 2 of Table D. 		N/A
	Marking is adjacent to MECHANICAL PROTECTIVE DEVICE		N/A
	Compliance confirmed by examination and following test:		N/A
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT		N/A

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Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		N/A
No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		N/A
Systems without MECHANICAL PROTECTIVE DEVI	CES	N/A
Support Systems does not require MECHANICAL PROTECTIVE DEVICES:	No such parts	N/A
RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system: (ISO 14971 Cl. 4.3,4.4,5,6.2-6.5)		N/A
PROTECTION AGAINST UNWANTED AND EXCES	 SIVE RADIATION HAZARDS	N/A
X-Radiation		N/A
The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT:	No such parts	N/A
Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE		N/A
RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or:		N/A
RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2	No such parts	N/A
Microwave radiation is propagated intentionally		N/A
Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.	No such parts	N/A
	when system was capable of supporting a PATIENT or OPERATOR No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function Systems without MECHANICAL PROTECTIVE DEVICES: RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system: (ISO 14971 Cl. 4.3,4.4,5,6.2-6.5) PROTECTION AGAINST UNWANTED AND EXCES X-Radiation The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT: Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or: RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5) RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT FILE: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5) The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2 Microwave radiation is propagated intentionally Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a	when system was capable of supporting a PATIENT or OPERATOR No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function Systems without MECHANICAL PROTECTIVE DEVICES Support Systems does not require MECHANICAL PROTECTIVE DEVICES: RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system: (ISO 14971 CI. 4.3,4.4,5,6.2-6.5) PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS X-Radiation The air kerma did not exceed 5 μGy/hat 5 cm from surface of ME EQUIPMENT: Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or: RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE: (ISO 14971 CI. 4.2-4.4, 5, 6.2-6.5) RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT FILE: (ISO 14971 CI. 4.2-4.4, 5, 6.2-6.5) The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2 Microwave radiation is propagated intentionally Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a No such parts

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10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE:	No such parts	N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		
10.6	RISK associated with infrared radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE:	No such parts	N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such parts	N/A
11	PROTECTION AGAINST EXCESSIVE TEMPERATE	LUDIES AND OTHER HAZARDS	Pass
11.1	Excessive temperatures in ME EQUIPMENT		Pass
11.1.1	Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and:	See appended Table 11.1.1	Pass
	Surfaces of test corner did not exceed 90 °C	Component for building-in; to be evaluated in end product	N/A
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION		N/A
	RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Component only, to be determined in the end product	N/A
11.1.2	Temperature of APPLIED PARTS		N/A
11.1.2.1	APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply:	No such parts	N/A
	Clinical effects determined and documented in the RISK MANAGEMENT FILE		N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use		N/A
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in NORMAL CONDITION and SINGLE FAULT CONDITION:		N/A

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	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:		N/A
	Maximum Temperature:		-
	Conditions for safe contact, e.g. duration or condition of the PATIENT:		-
	Clinical effects with respect to characteristics taken or surface pressure documented in the RISK MANAGEMENT FILE		N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		
	APPLIED PARTS surface temperature of equal to or less than 41°C		N/A
	Analysis documented in the RISK MANAGEMENT FILE show that APPLIED PART temperatures are not affected by operation of the ME EQUIPMENT including SINGLE FAULT CONDITIONS. Measurement of APPLIED PART temperature according to 11.1.3 is not conducted:		N/A
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
1.1.3	Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Component for building-in, to be determined as part of the end product	N/A
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE:		N/A
1.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL		N/A

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11.2	Fire prevention		N/A
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3	Component only, to be determined in the end product	N/A
11.2.2	2.2 Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		N/A
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of:	Not intended for oxygen rich environments	N/A
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions		N/A
	when temperature of material raised to its ignition temperature		N/A
	when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature		N/A
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating		N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively:		N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three:		N/A
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A

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	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3:		N/A
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%):		N/A
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes		N/A
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE:		N/A
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases:		N/A
11.2.2.2	RISK of ignition did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT		N/A
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks		N/A
	 Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques 		N/A
	 Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means 		N/A
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN F EQUIPMENT and ME SYSTEMS considered	RICH ENVIRONMENTS ME	N/A
	 Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2): 		N/A

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	- Failure of a barrier constructed in accordance with 11.2.2.1 b) 3):		N/A
	 Failure of a component creating a source of ignition (as defined in 11.2.2.1 a): 		N/A
	 Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a): 		N/A
	Failure of a pneumatic component resulting in leakage of oxygen-enriched gas:		N/A
11.3	Constructional requirements for fire ENCLOSURES	of ME EQUIPMENT	N/A
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2:	Component intended for building-in, be determined as part of the end product	N/A
	Constructional requirements were met, or		N/A
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	Justification, when requirement not met:		N/A
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials:	Component for building-in; t be evaluated in end product	N/A
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of materials data:		N/A
	If no FV Certification, FV tests based on IEC 60695- 11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings		N/A
	b) Fire ENCLOSURE met following:		N/A
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm		N/A
	2) No openings on the sides within the area included within the inclined line C in Fig 39		N/A
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials:		N/A
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11.4	ME EQUIPMENT and ME SYSTEMS intended for us	se with flammable anaesthetics	N/A
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G	Not evaluated for use in the presence of flammable anesthetics	N/A
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		N/A
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE: (ISO 14971 CI. 4.2-4.4, 5, 6.2-6.5)	Not evaluated for use in the presence of flammable agents	N/A
11.6	Overflow, spillage, leakage, ingress of water or particular disinfection, sterilization and compatibility with substated EQUIPMENT		N/A
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT:	Component for building-in; to be evaluated in end product	N/A
11.6.2	Overflow in ME EQUIPMENT		N/A
	ME EQUIPMENT incorporates a reservoir or liquid storage that did not wet any MEANS OF PROTECTION, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE:	Component only, to be determined in the end product	N/A
	Maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.		N/A
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.		N/A
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM		N/A

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	ME EQUIPMENT and ME SYSTEMS handling liquids constructed that spillage does not wet parts as determined by review of the RISK MANAGEMENT FILE and test: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill:		N/A
11.6.5	Ingress of water or particulate matter into ME EQUIP	MENT and ME SYSTEMS	N/A
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code):		N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION:		N/A
11.6.6	Cleaning and disinfection of ME EQUIPMENT and M	E SYSTEMS	N/A
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use:	Component only, to be determined in the end product	N/A
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER:		N/A
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests:	No such parts	N/A
	RISK MANAGEMENT FILE includes an assessment of the RISKS associated with any deterioration following sterilization: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented		N/A
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		N/A

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12	ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS		N/A
12.1	RISKS associated with accuracy of controls and instruments stated: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such parts	N/A
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING:		N/A
12.3	MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8. :		N/A
12.4	Protection against hazardous output		N/A
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
12.4.2	- need for indication associated with hazardous output addressed in RISK MANAGEMENT PROCESS: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit addressed in RISK MANAGEMENT PROCESS : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
12.4.4	RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
12.4.5	Diagnostic or therapeutic radiation		N/A
12.4.5.1	Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation		N/A
	Radiation safety ensured by compliance with requirements of appropriate standards		N/A
12.4.5.2	ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3		N/A

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12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as:		N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		
12.4.5.4	RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as:		N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		
12.4.6	RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT:		N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		
13	HAZARDOUS SITUATIONS AND FAULT CONDITION	DNS	Pass
13.1	Specific HAZARDOUS SITUATIONS		Pass
13.1.2	2 Emissions, deformation of ENCLOSURE or exceeding maximum temperature		Pass
	 Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur 		Pass
	Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		N/A
	 Temperatures of APPLIED PARTS did not exceed allowable values in Table 24: 		N/A
	 Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23: 		N/A
	 Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 °C were not exceeded 		Pass
	Limits for windings in Tables 26, 27, and 31 not exceeded		Pass
	Table 22 not exceeded in all other cases		Pass
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		N/A
13.1.3	- limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed:	see appended table	Pass
	 voltage limits for ACCESSIBLE PARTS including APPLIED PARTS did not exceed: 	see appended table 13.2	N/A
13. 2	SINGLE FAULT CONDITIONS		Pass

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40.04	During the application of the OINIOLE FALLET		Dana
13.2.1	During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination		Pass
	ME EQUIPMENT complied with 13.2.2 -13.2.12:	See appended Table 13.2	Pass
	RISK MANAGEMENT FILE includes and assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	RISK MANAGEMENT FILE defines the appropriate test conditions:		N/A
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of the temperature in the test environment	No heating elements or motors used	N/A
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		N/A
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION, the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		N/A
13.2.13.2	ME EQUIPMENT with heating elements		N/A
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	No heating elements provided	N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests		N/A
	a 3) other ME EQUIPMENT with heating elements met test		N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		N/A
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF- RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration		N/A
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		N/A

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	<u>, </u>	-	
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself		N/A
	b) ME EQUIPMENT with heating elements without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V):		N/A
	Operating period stopped when a non-SELF- RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY		N/A
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION		N/A
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and		N/A
	Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUTOUTS		N/A
	2) When more than one control provided, they were disabled in turn		N/A
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		N/A
13.2.13.3	ME EQUIPMENT with motors		N/A
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable	No motors	N/A
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		N/A
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition		N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		N/A
	b) Motor met running overload protection test of this clause when:		N/A

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	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N/A
	it is likely to be subjected to CONTINUOUS OPERATION while unattended		N/A
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C):		N/A
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		N/A
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload		N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		N/A
	Test not conducted based on other justifications (justification):		N/A
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10		N/A
13.2.13.4	ME EQUIPMENT RATED for NON-CONTINUOUS C	PERATION	N/A
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated	Unit intended for continuous operation	N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle		N/A
	Motor winding temperatures did not exceed values in 13.2.10:		N/A
	Insulation Class:		-
	Maximum temperature measured (°C):		-
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTE	MS (PEMS)	N/A
14.1	Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE, or	No PESS or PEMS	N/A
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK:		N/A

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	RISK MANAGEMENT FILE contains an	N/A	
	assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 4.2-4.4, 5)		
	(100 1497 1 01. 4.2-4.4, 0)		
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK	N/A	
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304:	N/A	
	Software development process applied according to Clause 5 of IEC 62304:	N/A	
	Software development process for Software risk management applied according to Clause 7 of IEC 62304:	N/A	
	Software development process Configuration Management applied according to Clause 8 of IEC 62304:	N/A	
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304:	N/A	
14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process:	N/A	
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan	N/A	
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented	N/A	
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	N/A	
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	N/A	
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules	N/A	
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	N/A	
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained	N/A	
14.6	RISK MANAGEMENT PROCESS	N/A	

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14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS:		N/A
	RISK MANAGEMENT FILE includes known or foreseeable HAZARDS associated with software, hardware, incorporation of the PEMS into an IT-NETWORK, components of 3rd party origin and legacy subsystems: (ISO 14971 Cl. 4.3)		N/A
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2:		N/A
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure: (ISO 14971 Cl. 6.1)		N/A
14.7	A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem: (ISO 14971 Cl. 6.3)		N/A
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems: (ISO 14971 Cl. 6.3)		N/A
14.9	Design is broken up into sub systems and descriptive data on design environment documented:		N/A
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures: (ISO 14971 Cl. 6.3)		N/A
	- milestone(s) when VERIFICATION is to be performed for each function		N/A

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	 selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION 	N/A
	- selection and utilization of VERIFICATION tools	N/A
	- coverage criteria for VERIFICATION	N/A
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented	N/A
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE:	N/A
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented	N/A
	The person with overall responsibility for PEMS VALIDATION is independent	N/A
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 6.3)	N/A
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE	N/A
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304:	N/A
	Software Process for Software changes applied according to Clause 5 of IEC 62304:	N/A
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304:	N/A
	Configuration management of software changes applied per Clause 8 of IEC 62304:	N/A
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304:	N/A
14.13	For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following:	N/A
	a) Purpose of the PEMS connection to an IT- NETWORK	N/A
	b) required characteristics of the IT-NETWORK	N/A
_	c) required configuration of the IT-NETWORK	N/A

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	d) technical specifications of the network connection, including security specifications		N/A
	e) intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK		N/A
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the characteristics required (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)		N/A
	ACCOMPANYING DOCUMENTS for the RESPONS the following:	IBLE ORGANIZATION include	N/A
	 statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties 		N/A
	 Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS 		N/A
	 Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis 		N/A
	- Changes to the IT-NETWORK include: - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment		N/A
15	CONSTRUCTION OF ME EQUIPMENT		Pass
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS:	Component to be evaluated in the end product	N/E
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance		N/A
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		N/A
15.3	Mechanical strength		N/A
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15.3.1	Manual stress relief much inspect dues and remak	Component only to be	N1/A
15.3.1	Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	Component only, to be determined in the end product	N/A
15.3.2	Push test conducted:		N/A
	No damage resulting in an unacceptable RISK sustained		N/A
15.3.3	Impact test conducted:		N/A
	No damage resulting in an unacceptable RISK sustained		N/A
15.3.4	Drop test		N/A
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested:	Component only, to be determined in the end product	N/A
	No unacceptable RISK resulted		N/A
15.3.4.2	Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test:		N/A
	No damage resulting in an unacceptable RISK sustained		N/A
15.3.5	MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests:		N/A
	No damage resulting in an unacceptable RISK sustained		N/A
15.3.6	Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK		N/A
	Mould-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C:		N/A
	No damage resulting in an unacceptable RISK		N/A
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT		N/A

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	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK		N/A
15.4	ME EQUIPMENT components and general assembly	/	N/A
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists,: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Component only, to be determined in the end product	N/A
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions,:	No patient leads or cables	N/A
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection:	No gas connections	N/A
15.4.2	Temperature and overload control devices		N/A
15.4.2.1	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION: (ISO 14971 Cl. 4.2-4.4, 5)	No such parts	N/A
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT	No such parts	N/A
	c) An additional independent non-SELF- RESETTING THERMAL CUT-OUT is provided: (ISO 14971 Cl. 4.2-4.4)	No such parts	N/A
	d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION or loss of ESSENTIAL PERFORMANCE: (ISO 14971 Cl. 4.2-4.4)	No such parts	N/A
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS	No such parts	N/A
	f) Use of THERMAL CUT-OUTS or OVER- CURRENT RELEASES do not affect safety as verified by following tests:		N/A

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	- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17		N/A
	- ME EQUIPMENT containing THERMAL CUT- OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13:		N/A
	- SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards		N/A
	- In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions operated 200 times		N/A
	Manual reset THERMAL CUT-OUTS and OVER- CURRENT RELEASES Certified in accordance with appropriate IEC standards		N/A
	manual reset THERMAL CUT-OUTS and OVER- CURRENT RELEASES operated 10 times		N/A
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		N/A
	g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating		N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating: (ISO 14971 Cl. 4.2-4.4)		N/A
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS		N/A
15.4.3	Batteries	1	N/A
15.4.3.1	Battery housings provided with ventilation: (ISO 14971 Cl. 4.2-4.4)	No batteries	N/A
	Battery compartments designed to prevent accidental short circuiting		N/A
15.4.3.2	Means provided to prevent incorrect connection of polarity:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict	

	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries: (ISO 14971 Cl. 4.2-4.4)		N/A
15.4.3.3	Overcharging of battery prevented by virtue of design:		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries: (ISO 14971 Cl. 4.2-4.4)		N/A
15.4.3.4	Primary lithium batteries comply with IEC 80086-4		N/A
	Secondary lithium batteries comply with IEC 62133		N/A
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire:		N/A
	Protective device has adequate breaking capacity		N/A
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented		N/A
	Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPs provided, or		N/A
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION		N/A
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for:	No indicators	N/A
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,		N/A
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with the use of indicator lights for EQUIPMENT incorporating non-luminous heaters: (ISO 14971 Cl. 4.2-4.4)		N/A
	Requirement not applied to heated stylus-pens for recording purposes		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	Indicator lights provided on ME EQUIPMENT to indicate an output exists		N/A
	Colours of indicator lights complied with 7.8.1		N/A
	Charging mode visibly indicated		N/A
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
15.4.6	Actuating parts of controls of ME EQUIPMENT		N/A
15.4.6.1	a) Actuating parts cannot be pulled off or loosened during NORMAL USE	No such parts	N/A
	b) Controls secured so that the indication of any scale always corresponds to the position of the control		N/A
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL		N/A
	When torque values per Table 30 applied knobs did not rotate :		N/A
	Tests conducted with no unacceptable RISK:		N/A
15.4.6.2	Stops on rotating/ movable parts of controls are of adequate mechanical strength:		N/A
	Torque values in Table 30 applied:		N/A
	No unexpected change of the controlled parameter when tested:		N/A
15.4.7	Cord-connected HAND-HELD and foot-operated con	trol devices	N/A
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1	No such parts	N/A
	b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage:		N/A
15.4.7.2	Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface:		N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		N/A
15.4.7.3	a) Foot-operated control device is at least rated IPX1:		N/A
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6:		N/A
15.4.8	Aluminum wires less than 16 mm2 in cross- sectional area are not used	No such parts	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

		1	
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed	No such parts	N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		N/A
	A pressure-release device operating during NORMAL USE is provided		N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		N/A
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPN providing separation in accordance with 8.5	MENT and transformers	Pass
15.5.1	Overheating		Pass
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating:	See appended Tables 15.5.1.2 and 15.5.1.3	Pass
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		Pass
	Dielectric strength test conducted after short circuit and overload tests:	see appended table 15.5.1.2 and 15.5.1.3	Pass
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved:	See appended Table 15.5.1.2	Pass
	Short circuit applied directly across output windings		Pass
15.5.1.3	Multiple overload tests conducted on windings:	See appended Table 15.5.1.3	Pass
15.5.2	Transformers operating at a frequency above 1kHz tested according to clause 8.8.3:		Pass
	Transformer windings provided with adequate insulation		Pass
	Dielectric strength tests were conducted :	Only short-circuit of the secondary winding insulation considered to create potential hazardous situation. Test not considered necessary based upon short-circuit of transformer secondary, use of triple insulated wire, and dielectric strength test from Primary to Core and Primary to Secondary	N/A
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with:	See appended Table 8.10	Pass

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Clause	Requirement + Test	Result - Remark	Verdict		

	- Means provided to prevent displacement of end turns		Pass
	- protective earth screens with a single turn have insulated overlap		N/A
	- Exit of wires form internal windings of toroid transformers protected with double sleeving		N/A
	- insulation between primary and secondary windings complies with 8.8.2		Pass
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4		Pass
16	ME SYSTEMS		N/A
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK	Component, to be determined in the end product	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with installation and modification of an ME SYSTEM: (ISO 14971 Cl. 4.2-4.4, 5)		N/A
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered		N/A
	 ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard 		N/A
	 ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards 		N/A
	 tests performed in NORMAL CONDITION, except as specified 		N/A
	 tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM 		N/A
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated		N/A
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR		N/A
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards		N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM		N/A
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM	M	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

Documents containing all da		N/A
SYSTEM to be used as inte MANUFACTURER including accompany ME SYSTEM or	g a contact address	
ACCOMPANYING DOCUM part of ME SYSTEM	ENTS regarded as a	N/A
a) ACCOMPANYING DOCU each item of ME EQUIPMENT MANUFACTURER		N/A
b) ACCOMPANYING DOCU each item of non-ME EQUIF MANUFACTURER		N/A
c) the required information is	s provided:	N/A
 specifications, instructions MANUFACTURER, and a little ME SYSTEM 		N/A
 instructions for installation modification of ME SYSTEM compliance with this standa 	I to ensure continued	N/A
 instructions for cleaning are disinfecting and sterilizing error equipment part forming p 	ach item of equipment	N/A
 additional safety measure installation of ME SYSTEM 	s to be applied during	N/A
 identification of parts of M use within the PATIENT EN 		N/A
 additional measures to be preventive maintenance 	applied during	N/A
 a warning forbidding place SOCKET-OUTLET, when p separate item, on the floor 		N/A
 a warning indicating an ac SOCKET-OUTLET or exten connected to ME SYSTEM 		N/A
 a warning to connect only specified as part of ME SYS being compatible with ME S 	TEM or specified as	N/A
maximum permissible load SOCKET-OUTLET(S) used		N/A
 instructions indicating MU OUTLETS provided with the used only for supplying pow intended to form part of ME 	ME SYSTEM to be er to equipment	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

		1
	 an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer 	N/A
	 an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET 	N/A
	 permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage 	N/A
	 instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT 	N/A
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:	N/A
	 adjustment, cleaning, sterilization, and disinfection PROCEDURES 	N/A
	 assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard 	N/A
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements	N/A
	Transient currents restricted to allowable levels for the specified IPS or UPS:	N/A
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified	N/A
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)	N/A
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed	N/A
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION	N/A
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V):	N/A
16.6	LEAKAGE CURRENTS	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
16.6.1	TOUCH CURRENT in NORMAL CONDITION did not exceed 100 μA:		N/A
	TOUCH CURRENT did not exceed 500 μA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR:		N/A
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA:		N/A
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values:		N/A
16.7	ME SYSTEM complied with applicable requirements of Clause 9:		N/A
16.8	Interruption and restoration power to the ME SYSTEM or any part of the ME SYSTEM did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		N/A
16.9	ME SYSTEM connections and wiring		N/A
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result:		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with plugs for connection of PATIENT leads or cables likely to be located in the PATIENT ENVIRONMENT: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	- Plugs for connection of PATIENT leads or PATIENT cables could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no unacceptable RISK results		N/A
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable		N/A
16.9.2	MAINS PARTS, components and layout		N/A
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or		N/A
	MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		N/A
	MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		N/A
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 visible in NORMAL USE, and		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		N/A
	 marked to indicate the equipment or equipment parts it may safely be attached to 		N/A
	 MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT 		N/A
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:		N/A
	CREEPAGE and CLEARANCES complied with 8.9		N/A
	It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets		N/A
	- PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:		N/A
	- ENCLOSURE complied with 8.4.2 d)		N/A
	MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable		N/A
	 RATINGS of components are not in conflict with conditions of use: 		N/A
	Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL		N/A
	- POWER SUPPLY CORD complied with 8.11.3		N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:		N/A
	 Separating transformer complied with this standard or IEC 61558-2-1,: 		N/A
	- Separating transformer is CLASS I		N/A
	 Degree of protection against ingress of water specified as in IEC 60529 		N/A
	Separating transformer assembly marked according to 7.2 and 7.3		N/A
	MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083		N/A
16.9.2.2	The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED did not exceed 200 $m\Omega$		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part		N/A
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL		N/A
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage		N/A
17	ELECTROMAGNETIC COMPATIBILITY OF ME EQ	UIPMENT AND ME SYSTEMS	N/E
	RISKS associated confirmed by review:	Not evaluated by UL LLC	N/E
	electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS:		N/E
	RISK MANAGEMENT FILE includes an assessment of risks associated with the introduction of electromagnetic phenomena into the environment by the EQUIPMENT or SYSTEM: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/E
	 introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems 		N/E
ANNEX G	PROTECTION AGAINST HAZARDS OF IGNITION OF MIXTURES	OF FLAMMABLE ANESTHETIC	N/A
G.2	Locations and basic requirements		N/A
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5	No intended for use with flammable anesthetic mixtures	N/A
G.2.2	FLAMMABLE AESTHETIC MIXTURE WITH		N/A
G.2.3	A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE		N/A
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5		N/A
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE comply with G.4 and G.6		N/A
	ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7		N/A
G.3	Marking, ACCOMPANYING DOCUMENTS		N/A
G.3.1	CATEGORY APG ME EQUIPMENT prominently marked "APG" (symbol 23 in Table D.1):		N/A
	•		

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	Length of green-coloured band is □ 4 cm, and size of marking is as large as possible for particular case	N/A
	When above marking not possible, relevant	N/A
	information included in instructions for use: Marking complied with tests and criteria of 7.1.2 and	N/A
G.3.2	7.1.3 CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle "AP" (symbol 22 in Table D.1):	N/A
	Marking is as large as possible for the particular case	N/A
	When above marking not possible, the relevant information included in instructions for use:	N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3	N/A
G.3.3	The marking placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts	N/A
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts	N/A
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG	N/A
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT	N/A
G.4.1	a) CREEPAGE and CLEARANCES are according to Table 12 for one MEANS OF PATIENT PROTECTION	N/A
	b) Connections protected against accidental disconnection	N/A
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD,	N/A
G.4.2	Construction details	N/A
	a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL	N/A
	b) ENCLOSURE complies with:	N/A
	– no openings on top covers of ENCLOSURE,	N/A
	openings in side-covers prevented penetration of a solid cylindrical test rod	N/A
	openings in base plates prevented penetration of a solid cylindrical test	N/A

N/A

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	c) Short circuiting conductor(s) to a conductive part (when no explosive gasses) did not result in loss of integrity of the part, an unacceptable temperature, or any HAZARDOUS SITUATION		N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures		N/A
	 Use of antistatic materials with a limited electrical resistance: 		N/A
	 Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor 		N/A
	b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882:		N/A
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5		N/A
G.5	Requirements and tests for CATEGORY AP ME EQU components	JIPMENT, parts and	N/A
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5		N/A
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5:		N/A
G.5.2	Temperature limits:		N/A
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and Umax and Imax occurring in their circuits, and complied as follows:		N/A
	Measured Umax ≤ UzR with IzR as in Fig. G.1:		N/A
	Measured Umax ≤ Uc with Cmax as in Fig. G.2 :		N/A
	Measured Imax ≤ IzR with UzR as in Fig G.1 :		N/A
	Measured Imax ≤ IzL with Lmax and a Umax ≤ 24 V as in Fig G.3:		N/A
	- Combinations of currents and corresponding		N/A

voltages within the limitations IzR.UzR ≤ 50 W

No extrapolation made for voltages above 42 V

extrapolated from Fig G.1

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T-			
	 Combinations of capacitances and corresponding voltages within limitations of C/2U2 ≤ 1.2 mJ extrapolated from Fig G.2 		N/A

	 Combinations of capacitances and corresponding voltages within limitations of C/2U2 ≤ 1.2 mJ extrapolated from Fig G.2 	N/A	i
	No extrapolation made for voltages above 242V	N/A	ı
	Umax determined using actual resistance R	N/A	
	 Combinations of currents and corresponding inductances within limitations L/2I2 ≤ 0.3 mJ extrapolated from Fig G.3 	N/A	
	No extrapolation made for inductances larger than 900 mH	N/A	ı
	 Umax was the highest supply voltage occurring in circuit under investigation with sparking contact open 	N/A	
	 Imax was the highest current flowing in circuit under investigation with sparking contact closed 	N/A	ı
	 Cmax and Lmax taken as values occurring at the component under investigation producing sparks 	N/A	ı
	- Peak value considered when a.c. supplied	N/A	
	 An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent Umax and Imax, either as d.c. or a.c. peak values in case of a complicated circuit: 	N/A	ı
	Temperature measurements made according to 11.1, and Umax, Imax, R, Lmax, and Cmax determined with application of Figs G.1-G.3:	N/A	ı
	Alternatively, compliance was verified by examination of design data:	N/A	
G.5.4	External ventilation with internal overpressure	N/A	
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:	N/A	
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR t removed by ventilation before EQUIPMENT energized,	N/A	ı
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa):	N/A	
	Overpressure maintained at the site of potential ignition	N/A	
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE	N/A	
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present	N/A	ı

	rtoquilonient i rest		
	c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa):		N/A
	d) External surface of ENCLOSURE did not exceed 150 °C in 25 °C:		N/A
G.5.5	ENCLOSURES with restricted breathing	1	N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:		N/A
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing		N/A
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h:		N/A
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained		N/A
	Cords are fitted with adequate anchorages to limit stresses as determined by test		N/A
	Overpressure not reduced below 200 Pa		N/A
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		N/A
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C):		N/A
	Steady state operating temperature of ENCLOSURE also measured (°C):		N/A
G.6	CATEGORY APG ME EQUIPMENT, parts and comp	ponents thereof	N/A
G.6.1	ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION		N/A
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test		N/A
G.6.2	Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION:		N/A
G.6.3	Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

Oladoo	110941101111111111111111111111111111111	
	a) no sparks produced and temperatures did not exceed 90 °C, or	N/A
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except Umax and Imax occurring in their circuits complied with requirements, taking Cmax and Lmax into consideration:	N/A
	Measured Umax ≤ UzR with IzR as in Fig. G.4 :	N/A
	Measured Umax ≤ UzC with Cmax as in Fig. G.5:	N/A
	Measured Imax ≤ IzR with UzR as in Fig G.4 :	N/A
	Measured Imax ≤ IzL with Lmax and a Umax ≤ 24 V as in Fig G.6 :	N/A
	Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated	N/A
	Umax was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10	N/A
	 Imax was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10 	N/A
	Cmax and Lmax are values occurring in relevant circuit	N/A
	– Umax additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω	N/A
	- Peak value considered when a.c. supplied	N/A
	An equivalent circuit calculated to determine max capacitance, inductance, and Umax and Imax, either as d.c. or a.c. peak values in case of a complicated circuit:	N/A
	When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components	N/A
	- requirement not applied to transformers complying with this standard	N/A
	- requirement not applied to wire-wound current- limiting resistors provided with a protection against unwinding of the wire in case of rupture	N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or	N/A
	Temperature measurements made in accordance with 11.1:	N/A

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	- or Umax, Imax, R, Lmax and Cmax determined together with application of Figs G.4-G.6:		N/A
	Alternatively, compliance verified by comparison with design data:		N/A
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUTOUT and complied with 15.4.2.1:		N/A
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE		N/A
G.7	Test apparatus for flammable mixtures according to this Clause and Fig G.7		N/A
ANNEX L	INSULATED WINDING WIRES FOR USE WITHOUT	TINTERLEAVED INSULATION	Pass
L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex	Evaluated as part of the component evaluation	Pass
L.2	Wire construction		Pass
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component	Extruded type only	Pass
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		Pass
L.3	Type Test		Pass
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified	Evaluated as part of component evaluation	Pass
	Temperature (°C):		-
	Humidity (%):		-
L.3.1	Dielectric strength		Pass
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted with no breakdown:	Evaluated as part of the component evaluation	Pass
	- 3000 V for BASIC and SUPPLEMENTARY INSULATION (V):		N/A
	- 6000 V for REINFORCED INSULATION (V):	Evaluated as part of the component evaluation	Pass
L.3.2	Flexibility and adherence		Pass
	Sample subjected to flexibility and adherence	Evaluated as part of the component evaluation	Pass

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	Sample examined per IEC 60851-3: 1997, cl. 5.1.1.4, followed by dielectric test of cl. 8.8.3, with no breakdown		Pass
	Test voltage was at least the voltage in Tables 6 and 7 but not less than the following:		Pass
	- 1500 V for BASIC and SUPPLEMENTARY INSULATION (V):		N/A
	- 3000 V for REINFORCED INSULATION (V):	Evaluated as part of the component evaluation	Pass
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 Mpa:		Pass
L.3.3	Heat Shock	•	Pass
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3		Pass
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		Pass
	 1500 V for BASIC and SUPPLEMENTARY INSULATION (V): 		N/A
	- 3000 V for REINFORCED INSULATION (V):	Evaluated as part of the component evaluation	Pass
	Oven temperature based on Table L.2 (°C):		-
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm2):	Evaluated as part of component evaluation	Pass
	Dielectric strength test conducted at room temperature after removal from the oven	Evaluated as part of component evaluation	Pass
L.3.4	Retention of electric strength after bending		Pass
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests		Pass
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		Pass
	- 1500 V for BASIC and SUPPLEMENTARY INSULATION (V):		N/A
	- 3000 V for REINFORCED INSULATION (V):	Evaluated as part of the component evaluation	Pass
	Test voltage applied between the shot and conductor		Pass
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm2):	Evaluated as part of component evaluation	Pass
L.4	Tests during manufacture		Pass
L.4.1	Production line dielectric strength tests done by the manufacture per L.4.2 and L.4.3:	See attached manufacturer's routine testing verification	Pass

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L.4.2	Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:		Pass
	 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V): 		N/A
	- 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V):	Evaluated as part of the component evaluation	Pass
L.4.3	Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1):	See manufacturer's routine testing verification	Pass
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:		Pass
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION:		N/A
	- 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION:	See manufacturer's routine testing verification	Pass

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESU	JLTS TABLE: General requirements for RISK I	MANAGEMENT	Pass
Clause of ISO	Document Ref. in RMF (I	Oocument No. paragraph/clause, version)	Result - Remarks	Verdict
14971	General process	Particular Medical Device		
3.1	XP-04-04 Rev B (1.0)	-	Risk Management Process (excluding production and post-production)	Pass
3.2	XP-04-04 Rev B (1.1)	-	Adequate Resources	Pass
3.2	XP-04-04 Rev B (1.1)	-	Adequate Resources	Pass
3.2	XP-04-04 Rev B (1.1)	-	Adequate Resources	Pass
3.3	-	XP-18-01 Rev B (4.0)	Qualification of personnel	Pass
3.4a	-	XP-04-04 Rev B (1.1), XP-04-02 Rev D, XP- 04-04 Rev B (1.1)		Pass
3.4b	-	XP-04-02 Rev D (Fig 1), XP-04-04 Rev B (1.1)		Pass
3.4c	-	XP-04-02 Rev D (FMEA report), XP-04-04 Rev B (1.1)		Pass
3.4d	-	XP-04-02 Rev D (FMEA report), XP-04-04 Rev B (1.1)		Pass
3.4e	-	XP-04-02 Rev D (III), XP-04-04 Rev B (1.1)		Pass
3.5	-	XP-04-02 Rev D, Analysis Checklist		Pass
4.1	-	XP-04-02 Rev D (FMEA Report)		Pass
4.2	-	XP-04-02 Rev D (FMEA Report)		Pass
4.3	-	XP-04-02 Rev D (FMEA Report)		Pass
4.4	-	XP-04-04 Rev B (1.2), XP-04-04 Rev B (1.3), TRF, XP-04-02 Rev D (FMEA Report), XP-04-04 Rev B		Pass
5	-	TRF, XP-04-02 Rev D (FMEA Report), XP- 04-04 Rev B, XP-14-02 Rev G (CAR)		Pass
6.2	-	XP-04-01 Rev M, XP-04-02 Rev D, XP-04- 04 Rev B, XP-09-01 Rev B, XP-14-02 Rev G		Pass
6.3	-	XP-14-02 Rev G (CAR), XP-05-02 Rev B		Pass
6.4	-	XP-04-01 Rev M (5.6), XP-04-04 Rev B		Pass
6.5	-	XP-09-01 Rev B, XP-14-02 Rev G		Pass
6.6a	-	XP-05-02 Rev B, ECR/ECO		Pass
6.6b	-	XP-05-02 Rev B, ECR/ECO		Pass
6.7	-	XP-04-04 Rev B, XP-04-01 Rev M, XP-16- 01 Rev E		Pass
7	-	XP-04-01 Rev M, XP-16-01 Rev E		Pass
8	-	XP-04-04 Rev B, XP-04-02 Rev D, XP-05- 02 Rev B, XP-14-02 Rev G		Pass

Supplementary Information:

Document Ref should be with regards to the policy/procedure documents and documents containing device specific output.

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Clause	Requirement + Test	Result - Remark	Verdict

4.3	TABLE: ESSENTIAL PERF	ORMANCE		Pass
List of E	of ESSENTIAL PERFORMANCE reference or reference from this standard or collateral or particular standard(s) MANUFACTURER'S document number reference from this standard or collateral or particular standard(s)			
•	provide 2MOPP between and Secondary	10018357 Rev A		
-	provide 1MOPP between and Ground	10018357 Rev A		
•	provide 1MOPP between ry and Ground	10018357 Rev A		

Supplementary Information:

ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.

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Clause	Requirement + Test	Result - Remark	Verdict

4.11	TABLE: Input Test				,	Pass
	Operating Conditions	Voltage (V)	Frequency (Hz)	Current (A)	Power (W or VA)	Power Factor (φ
CHD250PS12	: 12V/20.8A, 5V/1A	90	60	3.0	272.0	1.004
CHD250PS12	: 12V/20.8A, 5V/1A	100	60	2.7	271.0	1.004
CHD250PS12: 12V/20.8A, 5V/1A		240	60	1.2	266.0	0.931
CHD250PS12: 12V/20.8A, 5V/1A		264	60	1.2	266.0	0.819
CHD250PS12	: 12V/20.8A, 5V/1A	90	50	3.0	272.0	1.007
CHD250PS12	: 12V/20.8A, 5V/1A	100	50	2.7	271.0	0.996
CHD250PS12	: 12V/20.8A, 5V/1A	240	50	1.2	265.0	0.936
CHD250PS12: 12V/20.8A, 5V/1A		264	50	1.3	267.0	0.760
CHD250PS24: 24V/10.4A, 5V/1A		90	60	3.01	270.0	0.997
CHD250PS24	: 24V/10.4A, 5V/1A	100	60	2.7	269.0	0.996
CHD250PS24: 24V/10.4A, 5V/1A		240	60	1,17	264.0	0.940
CHD250PS24: 24V/10.4A, 5V/1A		264	60	1.21	264.0	0.826
CHD250PS24: 24V/10.4A, 5V/1A		90	50	3.01	270.0	0.997
CHD250PS24	: 24V/10.4A, 5V/1A	100	50	2.69	269.0	1.000
CHD250PS24	: 24V/10.4A, 5V/1A	240	50	1.17	264.0	0.940
CHD250PS24	: 24V/10.4A, 5V/1A	264	50	1.27	265.0	0.790
CHD250PS48	1:48V/5.2A, 5V/1A	90	60	3.0	270.0	0.997
CHD250P\$48	:48V/5.2A, 5V/1A	100	60	2.7	269.0	0.993
CHD250PS48:48V/5.2A, 5V/1A		240	60	1.2	264.0	0.932
CHD250PS48:48V/5.2A, 5V/1A		264	60	1.2	265.0	0.810
CHD250P\$48	:48V/5.2A, 5V/1A	90	50	3.0	271.0	0.997
CHD250PS48	:48V/5.2A, 5V/1A	100	50	3.0	271.0	0.897
CHD250PS48	:48V/5.2A, 5V/1A	240	50	1.2	265.0	0.936
CHD250PS48	:48V/5.2A, 5V/1A	264	50	1.3	266.0	0.781

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Clause	Requirement + Test	Result - Remark	Verdict

Test Tables

Supplementary Information:

Data above may include voltage measurement takes outside the device ratings for reference purposes. These will be indicated by an N/A Verdict because they are not required to meet the below criteria per this clause.

5.9.2	TABLE: Determination of ACCESSIBLE parts			
Location		Determination method (NOTE1)	Comments	

Supplementary Information:

NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.

NOTE To Lab: This test is performed in order to identify which parts of the device are accessible. Results of this test will determine which parts of the device can be accessed by the operator, patient, maintenance personnel, etc. and will be used as points for testing within clause 8.4 of the standard.

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Test Tables

7.1.2	.1.2 TABLE: Legibility of Marking			
	Markings tested	Ambient Illuminance (IX)	Remarks	

Supplementary Information:

Ambient illuminance derived from following recommended illumination levels for use in interior lighting design. See Annex A, cl. 7.1.2.

- 100 lx to 200 lx is recommended for working spaces where visual tasks are performed only occasionally;
- -500 lx to 1000 lx is recommended for visual tasks of small size or reading medium-pencil handwriting;
- 1,000 lx to 2,000 lx is recommended for visual tasks of low contrast or very small size: e.g., reading handwriting in hard-pencil on poor-quality paper

Any text or symbols that are excluded from this test are either identified in the table above or specified here:

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<u>Test Tables</u>

7.1.3	TABLE: Durability of marking test	N/A
	Characteristics of the Marking Label tested:	Remarks
Materia Label :	(composition) of Marking	
Ink/othe	er printing material or process :	
Method Label :	of application of ink to the	
Other:		
	Marking Label Certif	fication:
		T-w= , T-m= , T-i=
		74 500 P00-1007-1000 W0-15-00
		<u> </u>
		-
Sunnlen	nentary Information:	i.
	ne with distilled water	
	with methylated spirit	
	rith is opropyl alcohol	
For testing o	purposes, a methylated spirit is considered to be any commercia	ally available denatured alcohol containing a
	6% ethanol by volume.	

ly voltage/	frequency	(V/Hz)¹:					
						240V/60	
· ·		41-	Measured Valu	es			
Location From/To		Vpk or Vdc	Peak-to-peak ripple	Power W/VA	Energy (J)	Rema	rks
utral	242	344	E			12V/20.8A, 5\	//1A
ound	242	344	<u> </u>		·	12V/20.8A, 5\	//1A
ondary	292	478	¥ **			12V/20.8A, 5\	//1A
o Gnd		12 Vdc	0.180			12V/20.8A, 5\	//1A
	226	268	8			12V/20.8A, 5\	//1A
	utral ound ondary	vrms utral 242 pund 242 indary 292 o Gnd -	Vrms Vdc utral 242 344 pund 242 344 indary 292 478 g Gnd - 12 Vdc	Vrms Vdc ripple utral 242 344 - pund 242 344 - indary 292 478 - 6 Gnd - 12 Vdc 0.180	Vrms Vdc ripple W/VA utral 242 344 - pund 242 344 - indary 292 478 - 6 Gnd - 12 Vdc 0.180	Vrms Vdc ripple W/VA Energy (J) utral 242 344 - pund 242 344 - indary 292 478 - 6 Gnd - 12 Vdc 0.180	Vrms Vdc ripple W/VA Energy (J) utral 242 344 - 12V/20.8A, 5\ pund 242 344 - 12V/20.8A, 5\ indary 292 478 - 12V/20.8A, 5\ 0 Gnd - 12 V/20.8A, 5\ 12V/20.8A, 5\

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<u>Test Tables</u>

T1 Pin 9 to 11	12	15		12V/20.8A, 5V/1A
T1 Pin 10 to 12	12	15	6	12V/20.8A, 5V/1A
T1 Pin 13 to 15	13	14	H:	12V/20.8A, 5V/1A
T1 Pin 14 to 16	13	15	#:	12V/20.8A, 5V/1A
T1 Pin 1 to 9	186	390	<u> </u>	12V/20.8A, 5V/1A
T1 Pin 1 to 10	186	392		12V/20.8A, 5V/1A
T1 Pin 1 to 11	188	392		12V/20.8A, 5V/1A
T1 Pin 1 to 12	186	392		12V/20.8A, 5V/1A
T1 Pin 1 to 13	186	392		12V/20.8A, 5V/1A
T1 Pin 1 to 14	186	392	i i	12V/20.8A, 5V/1A
T1 Pin 1 to 15	188	391		12V/20.8A, 5V/1A
T1 Pin 1 to 16	186	396		12V/20.8A, 5V/1A
T1 Pin 6 to 9	289	475		12V/20.8A, 5V/1A
T1 Pin 6 to 10	171	453		12V/20.8A, 5V/1A
T1 Pin 6 to 11	171	396	1	12V/20.8A, 5V/1A
T1 Pin 6 to 12	280	453		12V/20.8A, 5V/1A
T1 Pin 6 to 13	273	453		12V/20.8A, 5V/1A
T1 Pin 6 to14	282	466		12V/20.8A, 5V/1A
T1 Pin 6 to 15	264	441		12V/20.8A, 5V/1A
T1 Pin 6 to 16	292	478		12V/20.8A, 5V/1A
T2 Pin 1 to 2	1	9		12V/20.8A, 5V/1A
T2 Pin 3 to 4	2	11		12V/20.8A, 5V/1A
T2 Pin 1 to 3	168	260		12V/20.8A, 5V/1A
T2 Pin 1 to 4	167	258		12V/20.8A, 5V/1A
T2 Pin 2 to 3	94	258		12V/20.8A, 5V/1A
T2 Pin 2 to 4	167	257	3	12V/20.8A, 5V/1A

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T3 Pin 1 to 2	ī	9	12V/20.8A, 5V/1A
T3 Pin 3 to 4	0.74	4	12V/20.8A, 5V/1A
T3 Pin 1 to 3	68	323	12V/20.8A, 5V/1A
T3 Pin 1 to 4	70	324	12V/20.8A, 5V/1A
T3 Pin 2 to 3	131	323	12V/20.8A, 5V/1A
T3 Pin 2 to 4	119	323	12V/20.8A, 5V/1A
T1-A Pin 1 to 2-SB	25	78	12V/20.8A, 5V/1A
T1-B Pin 3 to 4-SB	100	468	12V/20.8A, 5V/1A
T1-C Pin 1 to 2-SB	6	33	12V/20.8A, 5V/1A
T1-A Pin 1 to 1-SB	165	284	12V/20.8A, 5V/1A
T1-A Pin 1 to 2-SB	167	284	12V/20.8A, 5V/1A
T1 Pin 2 to 1-\$B	158	272	12V/20.8A, 5V/1A
T1-A Pin 2 to 2-SB	181	312	12V/20.8A, 5V/1A
T1-A Pin 3 to 1-SB	172	324	12V/20.8A, 5V/1A
T1-A Pin 3 to 2-SB	175	328	12V/20.8A, 5V/1A
T1-A Pin 4 to 1-SB	180	308	12V/20.8A, 5V/1A
T1-A Pin 4 to 2-SB	128	224	12V/20.8A, 5V/1A
OPT1 Pin 1 to 2	162	283	12V/20.8A, 5V/1A
OPT1 Pin 3 to 4	169	292	12V/20.8A, 5V/1A
OPT2 Pin 1 to 2	165	288	12V/20.8A, 5V/1A
OPT2 Pin 3 to 4	143	252	12V/20.8A, 5V/1A
OPT3 Pin 1 to 2	130	240	12V/20.8A, 5V/1A
OPT3 Pin 3 to 4	146	268	12V/20.8A, 5V/1A
OPT 4 Pin 1 to 2	147	263	12V/20.8A, 5V/1A
OPT 4 Pin 3 to 4	168	284	12V/20.8A, 5V/1A
A: Line to Neutral	242	344	24V/10.4, 5V/1A

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B: Line to Ground	242	344	24V/10.4, 5V/1A
D: Second. to Gnd	8	24 Vdc	24V/10.4, 5V/1A
T1 Pin 1 to 6	218	252	24V/10.4, 5V/1A
T1 Pin 3 to 7	28	33	24V/10.4, 5V/1A
T1 Pin 9 to 11	24	28	24V/10.4, 5V/1A
T1 Pin 10 to 12	24	28	24V/10.4, 5V/1A
T1 Pin 13 to 15	12	15	24V/10.4, 5V/1A
T1 Pin 14 to 16	12	15	24V/10.4, 5V/1A
T1 Pin 1 to 9	164	380	24V/10.4, 5V/1A
T1 Pin 1 to 10	150	336	24V/10.4, 5V/1A
T1 Pin 1 to 11	156	354	24V/10.4, 5V/1A
T1 Pin 1 to 12	156	354	24V/10.4, 5V/1A
T1 Pin 1 to 13	149	340	24V/10.4, 5V/1A
T1 Pin 1 to 14	150	336	24V/10.4, 5V/1A
T1 Pin 1 to 15	151	352	24V/10.4, 5V/1A
T1 Pin 1 to 16	161	368	24V/10.4, 5V/1A
T1 Pin 6 to 9	126	244	24V/10.4, 5V/1A
T1 Pin 6 to 10	127	252	24V/10.4, 5V/1A
T1 Pin 6 to 11	126	244	24V/10.4, 5V/1A
T1 Pin 6 to 12	126	244	24V/10.4, 5V/1A
T1 Pin 6 to 13	127	252	24V/10.4, 5V/1A
T1 Pin 6 to14	126	244	24V/10.4, 5V/1A
T1 Pin 6 to 15	126	252	24V/10.4, 5V/1A
T1 Pin 6 to 16	126	244	24V/10.4, 5V/1A

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Clause	Requirement + Test	Result - Remark	Verdict

T2 Pin 1 to 2	ı	9	24V/10.4, 5V/1A
T2 Pin 3 to 4	2	11	24V/10.4, 5V/1A
T2 Pin 1 to 3	168	260	24V/10.4, 5V/1A
T2 Pin 1 to 4	167	258	24V/10.4, 5V/1A
T2 Pin 2 to 3	94	258	24V/10.4, 5V/1A
T2 Pin 2 to 4	167	257	24V/10.4, 5V/1A
T3 Pin 1 to 2	1	9	24V/10.4, 5V/1A
T3 Pin 3 to 4	0.74	4	24V/10.4, 5V/1A
T3 Pin 1 to 3	68	323	24V/10.4, 5V/1A
T3 Pin 1 to 4	70	324	24V/10.4, 5V/1A
T3 Pin 2 to 3	131	323	24V/10.4, 5V/1A
T3 Pin 2 to 4	119	323	24V/10.4, 5V/1A
T1-A Pin 1 to 2-SB	25	78	24V/10.4, 5V/1A
T1-B Pin 3 to 4-SB	100	468	24V/10.4, 5V/1A
T1-C Pin 1 to 2-SB	6	33	24V/10.4, 5V/1A
T1-A Pin 1 to 1-SB	165	284	24V/10.4, 5V/1A
T1-A Pin 1 to 2-SB	167	284	24V/10.4, 5V/1A
T1 Pin 2 to 1-SB	158	272	24V/10.4, 5V/1A
T1-A Pin 2 to 2-SB	181	312	24V/10.4, 5V/1A
T1-A Pin 3 to 1-SB	172	324	24V/10.4, 5V/1A
T1-A Pin 3 to 2-SB	175	328	24V/10.4, 5V/1A
T1-A Pin 4 to 1-SB	180	308	24V/10.4, 5V/1A
T1-A Pin 4 to 2-SB	128	224	24V/10.4, 5V/1A
OPT1 Pin 1 to 2	162	283	24V/10.4, 5V/1A

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Clause	Requirement + Test	Result - Remark	Verdict

OPT1 Pin 3 to 4	169	292	24V/10.4, 5V/1A
OPT2 Pin 1 to 2	165	288	24V/10.4, 5V/1A
OPT2 Pin 3 to 4	143	252	24V/10.4, 5V/1A
OPT3 Pin 1 to 2	130	240	24V/10.4, 5V/1A
OPT3 Pin 3 to 4	146	268	24V/10.4, 5V/1A
OPT4 Pin 1 to 2	147	263	24V/10.4, 5V/1A
OPT4 Pin 3 to 4	168	284	24V/10.4, 5V/1A
A: Line to Neutral	242	344	48V/5.2A, 5V/1A
B: Line to Ground	242	344	48V/5.2A, 5V/1A
D: Second. to Gnd	8	48 ∀dc	48V/5.2A, 5V/1A
T1 Pin 1 to 6	215	316	48V/5.2A, 5V/1A
T1 Pin 3 to 7	27	35	48V/5.2A, 5V/1A
T1 Pin 9 to 11	47	57	48V/5.2A, 5V/1A
T1 Pin 10 to 12	47	62	48V/5.2A, 5V/1A
T1 Pin 13 to 15	12	21	48V/5.2A, 5V/1A
T1 Pin 14 to 16	12	16	48V/5.2A, 5V/1A
T1 Pin 1 to 9	169	388	48V/5.2A, 5V/1A
T1 Pin 1 to 10	144	328	48V/5.2A, 5V/1A
T1 Pin 1 to 11	156	364	48V/5.2A, 5V/1A
T1 Pin 1 to 12	156	364	48V/5.2A, 5V/1A
T1 Pin 1 to 13	143	320	48V/5.2A, 5V/1A
T1 Pin 1 to 14	170	384	48V/5.2A, 5V/1A
T1 Pin 1 to 15	146	324	48V/5.2A, 5V/1A
T1 Pin 1 to 16	167	380	48V/5.2A, 5V/1A

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T1 Pin 6 to 9	127	256	48V/5.2A, 5V/1A
T1 Pin 6 to 10	128	260	48V/5.2A, 5V/1A
T1 Pin 6 to 11	126	248	48V/5.2A, 5V/1A
T1 Pin 6 to 12	126	248	48V/5.2A, 5V/1A
T1 Pin 6 to 13	129	272	48V/5.2A, 5V/1A
T1 Pin 6 to14	127	264	48V/5.2A, 5V/1A
T1 Pin 6 to 15	128	264	48V/5.2A, 5V/1A
T1 Pin 6 to 16	127	252	48V/5.2A, 5V/1A
T2 Pin 1 to 2	1	9	48V/5.2A, 5V/1A
T2 Pin 3 to 4	2	11	48V/5.2A, 5V/1A
T2 Pin 1 to 3	168	260	48V/5.2A, 5V/1A
T2 Pin 1 to 4	167	258	48V/5.2A, 5V/1A
T2 Pin 2 to 3	94	258	48V/5.2A, 5V/1A
T2 Pin 2 to 4	167	257	48V/5.2A, 5V/1A
T3 Pin 1 to 2	1	9	48V/5.2A, 5V/1A
T3 Pin 3 to 4	0.7	5	48V/5.2A, 5V/1A
T3 Pin 1 to 3	68	323	48V/5.2A, 5V/1A
T3 Pin 1 to 4	70	324	48V/5.2A, 5V/1A
T3 Pin 2 to 3	131	323	48V/5.2A, 5V/1A
T3 Pin 2 to 4	119	323	48V/5.2A, 5V/1A
T1-A Pin 1 to 2-SB	25	78	48V/5.2A, 5V/1A
T1-B Pin 3 to 4-SB	100	468	48V/5.2A, 5V/1A
T1-C Pin 1 to 2-SB	6	33	48V/5.2A, 5V/1A
T1-A Pin 1 to 1-SB	165	284	48V/5.2A, 5V/1A

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Test Tables

T1-A Pin 1 to 2-SB	167	284	48V/5.2A, 5V/1A
T1 Pin 2 to 1-SB	158	272	48V/5.2A, 5V/1A
T1-A Pin 2 to 2-SB	181	312	48V/5.2A, 5V/1A
T1-A Pin 3 to 1-SB	172	324	48V/5.2A, 5V/1A
T1-A Pin 3 to 2-SB	175	328	48V/5.2A, 5V/1A
T1-A Pin 4 to 1-SB	180	308	48V/5.2A, 5V/1A
T1-A Pin 4 to 2-SB	128	224	48V/5.2A, 5V/1A
OPT1 Pin 1 to 2	162	283	48V/5.2A, 5V/1A
OPT1 Pin 3 to 4	169	292	48V/5.2A, 5V/1A
OPT2 Pin 1 to 2	165	288	48V/5.2A, 5V/1A
OPT2 Pin 3 to 4	143	252	48V/5.2A, 5V/1A
OPT3 Pin 1 to 2	130	240	48V/5.2A, 5V/1A
OPT3 Pin 3 to 4	146	268	48V/5.2A, 5V/1A
OPT4 Pin 1 to 2	147	263	48V/5.2A, 5V/1A
OPT4 Pin 3 to 4	168	284	48V/5.2A, 5V/1A

Supplementary Information:

The input supply voltage to the ME EQUIPMENTTT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 3.5.4.
 If the d.c. peak-to-peak ripple > 10%, waveform considered as a.c. See clause 3.4.2.2.

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8.4.3	TABLE: ME Equipmes voltage or calculation of supply			5070		23 50 35	\$311000 SANGE			p:	ass
Maxim	l um allowable voltage (V):								60		
		.e. :	Volt	age mea	sured (\	1)	0	.2		H4.	V.
Voltage	Measured Between:	1	2	3	4	5	6	7	8	9	10
ine pins 1	and 2	0	0	0	0	0	0	0	0	0	0
Pin 1 and	earth pin	0	0	0	0	0	0	2	0	0	0
Pin 2 and earth pin		0	0	0	0	6	0	0	0	4	0
	495	8	-	0	0	4	2	0	0	0	0
Line pin 1	and enclosure	4	2	U	100	20	50	757-	196		
68255 MB495 LTV	and enclosure	0	0	0	0	0	0	0	0	0	0
Line pin 2		0	0	0	0			0	0 45	0	0
Line pin 2	and enclosure	0 ge when	0 measur	0	0 ge excee	eded 60 y		0		0	0
ine pin 2	and enclosure	0 ge when	0 measur	o ota	0 ge excee	eded 60 y		7		9	10
Maximu Voltage	and enclosure um allowable stored char	ge when	0 measur	ed volta	ge excee	eded 60 γ	· (µс):		45		
Maximu Voltage Line pin 2	and enclosure um allowable stored char Measured Between:	ge when	0 measur	ed volta	ge excee	eded 60 γ	· (µс):		45		
Maximu Voltage Line pin Pin 1 an	um allowable stored char Measured Between: s 1 and 2	ge when	0 measur	ed volta	ge excee	eded 60 γ	· (µс):		45		
Maximu Voltage Line pin 1 an Pin 2 an	and enclosure um allowable stored char Measured Between: is 1 and 2 id earth pin	ge when	0 measur	ed volta	ge excee	eded 60 γ	· (με):		45		

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8.4.4		acitive circuits - measurement of re apacitive circuits (i.e., accessible ca IPMENT		SULTED STATES OF THE STATES OF	
Maximur	m allowable residual voltag	60 V			
Maximur 60 V:	m allowable stored charge	45 μC			
	n of the capacitive circuit ssible capacitor or circuit parts)	Calculated stored charge (µC)	Remarks		
Supplem None	entary Information:	,			

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8.5.5. 1a	TABLE: defibrillation-pro	o of applied parts - m	easurement of haza	rdous electrical ene	ergies	N/A
Test Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Rem	arks
	SIPs/SOPs		Normal/Rever se	xx/xx		
	Metal foil at base of equipment		Normal/Rever se	xx/xx		
	Unearthed Accessible Part		Normal/Rever se	xx/xx		
	Foil in contact with non-conductive Enclosure Part		Normal/Rever se	xx/xx		
	Patient Connections of other Applied Parts		Normal/Rever se	xx/xx		

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Clause	Requirement + Test	Result - Remark	Verdict

Applied	part with test voltage	Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks
		Normal/Rever se			
		Normal/Rever			
		Normal/Rever			
		Normal/Rever se			
		Normal/Rever			
Supplem None	entary Information:	1.			

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8.5.5.2	TABLE: DEFIBRILLATION-PRO DEFIBRILLATION-PROOF APPLII delivered to a 100 Ω load	()		105k	N/A
T	est Voltage applied to	Measured Energy E1 (mJ)	Measured Energy E2 (mJ)	Energy I as % of E2	
with PATIEN	CONNECTION 1 or APPLIED PART T CONNECTIONS 2, 3, and 4 of PLIED PART connected to earth				
with PATIEN	CONNECTION 2 or APPLIED PART T CONNECTIONS 1, 3, and 4 of PLIED PART connected to earth				
with PATIEN	CONNECTION 3 or APPLIED PART T CONNECTIONS 1, 2, and 4 of PLIED PART connected to earth				
with PATIEN	CONNECTION 4 or APPLIED PART T CONNECTIONS 1, 2, and 3 of PUIED PART connected to earth				
F050	ary Information: d energy delivered to 100 Ω with MEE innected.	quipment connected; EX	2= Measured energy deliver	red to 100 0 with	out ME

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Test Tables

8.6.4	TABLE: Impedance and current-carr	ying capability of	PROTECTIVE EART	H	N/A
Туре	of ME EQUIPMENT & impedance measured between parts	Test current (A)/Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)
impedance	ently installed ME equipment, between protective earth terminal ost remote protectively earthed part				100
impedance	pment with an appliance inlet, between earth pin in the appliance ne most remote protectively earthed				100
supply core earth pin ir	pment with a non-detachable power d, impedance between the protective n the mains plug and the most remote ly earthed part				200

Supplementary Information:

1 In accordance with Subclause 8.6.4a) (25 A or 1.5 x Ratings) (Note: CEC in Canada requires minimum 40 A for 2 min)

2 In accordance with Subclause 8.6.4a) (R = V / I)

3 See 8.6.4b for exceptions

ME equipment with a DETACHABLE SUPPLY CORD supplied or specified by the manufacturer is tested with the cord supplied or specified. When a DETACHABLE POWER SUPPLY CORD is neither supplied nor specified, testing shall be carried out using a 3m long cord of appropriate cross sectional area based on 8.11.3.3. and table 17. [60601-1: 2005 + AM1]

Alternatively, d.c. may be used for this test. [60601-1; 2005 + AM1]

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Clause	Requirement + Test	Result - Remark	Verdict

Test Tables

8.7	TABLE: leakage current				Pas
Type of I	eakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μΑ)	Remarks
13 - Earth (PE & FE) Leakage Current (NC)	264	60	174.8	
13 - Earth (PE & FE) Leakage Current (SFC)	264	60	345.3	
14 - Touch	Leakage Current (NC)	N/A	N/A	0.0	
14 - Touch	Leakage Current (SFC)	N/A	N/A	0.0	
15 - Patient	t Leakage Current (NC)	N/A	N/A	0.0	
15 - Patient	t Leakage Current (SFC)	N/A	N/A	0.0	
16 - Patient	: Leakage Current (Voltage on AP) (NC)	5)	15	0.0	N/A - No NC Tests
16 - Patient	t Leakage Current (Voltage on AP) (SFC)	N/A	N/A	0.0	
17 - Patient	t Leakage Current (Voltage on SIP/SOP) (NC)	N/A	N/A	0.0	
17 - Patient	t Leakage Current (Voltage on SIP/SOP) (SFC)	N/A	N/A	0.0	
18 - Patient Leakage Current (Voltage on Accessible Part) (NC)		<u> </u>	12	0.0	N/A - No NC Tests
18 - Patient	t Leakage Current (Voltage on Accessible Part) (SFC)	N/A	N/A	0.0	
19 - Patient	: Auxiliary Leakage Current (NC)	N/A	N/A	0.0	
19 - Patient	t Auxiliary Leakage Current (SFC)	N/A	N/A	0.0	
15 & 20 - T	otal Patient Leakage Current (Same AP Tied Together) (NC)	N/A	N/A	0.0	
15 & 20 - T (SFC)	otal Patient Leakage Current (Same AP Tied Together)	N/A	N/A	0.0	
16 & 20 - T	otal Patient Leakage Current (Voltage on AP) (NC)	==	a.	0.0	N/A - No NC Tests
16 & 20 - T	otal Patient Leakage Current (Voltage on AP) (SFC)	N/A	N/A	0.0	
17 & 20 - T	otal Patient Leakage Current (Voltage on SIP/SOP) (NC)	N/A	N/A	0.0	
17 & 20 - T	otal Patient Leakage Current (Voltage on SIP/SOP) (SFC)	N/A	N/A	0.0	
18 & 20 - T (NC)	otal Patient Leakage Current (Voltage on Accessible Part)	<u>a</u> ;	<u>@</u>	0.0	N/A - No NC Tests
18 & 20 - T (SFC)	otal Patient Leakage Current (Voltage on Accessible Part)	N/A	N/A	0.0	

Supplementary Information: Test conducted before and after humidity test, worst case results recorded

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;

Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7

Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The Individual APPLIED PARTS compiled with the PATIENT LEAKAGE CURRENT values.

Note 5: in addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7,

EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110% of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

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Test Tables

ER - Earth leakage current

PE - Protective Earthing

FE - Functional Earthing

TC - Touch (leakage) current

P - Patient leakage current

PM - Patient leakage current with mains on the applied parts

PSM - Patient leakage current with mains on SIP/SOPS

PA - Patient auxiliary current

TPL - Touch Patient Leakage Current

IP - Internally powered leakage current

MD - Measuring device

Fig. 12 - Refers to Fig. 12 in IEC 60601-1 (8.7.3)

A - After humidity conditioning

B - Before humidity conditioning

1 - Switch closed or set to normal polarity

0 - Switch open or set to reversed polarity

NC - Normal condition

SFC - Single fault condition

AA - After Abnormal

S1 - Mains neutral conductor

S5 - Mains polarity

S7 - Protective Earth Conductor

S9 - Mains on patient polarity

S12 - Grounded patient leads

(area fro	on under test om insulation agram)	Insulation Type (1 or 2 MOOP/MOPP)	PEAK WORKING VOLTAGE (U) V peak	PEAK WORKING VOLTAGE (U) V d.c.	A.C. test voltages in V r.m.s1	Dielectric breakdown after 1 minute Yes/No2
Primary to	Ground (1)	1 MOPP	344	s	1973 Vrms	No
Primary to	Secondary (1)	2 МОРР	475	22	4343 Vrms	No
Secon dary	to Ground (1)	1 МОРР	22	12 ∀dc	1500 Vrms	No
Primary to	Ground (2)	1 МОРР	344	: :=	1973 Vrms	No
Primary to	Secondary (2)	2 MOPP	475	3	4343 Vrms	No
Se con dary	to Ground (2)	1 МОРР	122	12 ∀dc	1500 Vrms	No
Primary to	Ground (3)	1 МОРР	344	ia ia	1973 Vrms	No
Primary to	Secondary (3)	2 MOPP	475	Ø	4352 Vrms	No
Se con dary	to Ground (3)	1 MOPP	e e	12 Vdc	1500 Vrms	No
100000000000000000000000000000000000000		ion: (1) Test conducted after C12 Short	l ted after humidity	condition and Te	l st (2) conducted a	fter the

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8.8.4.1	TABLE: Resistance to heat - Ball pressure to	est of thermoplastic parts	Pass
	Allowed impression diameter (mm):	≤2 mm	17
	Force (N):	20	
	Part/material	Test temperature (°C)	Impression diameter (mm)
Insulating m	aterial supporting insulated Mains Parts		
Conn 3 POS 0.3	.56 CTR HEADER VERT LOCK-Molex 26-60-4030	125	1.12
Transformer B	obbin - Ryton R-4-230BL, 1mm thick	125	0.9
Supplementar	y Information:	1	

8.9.2	TABLE: Short circuiting of each CLEARANCES for insulation in the complying with the required mean	MAINS PART between		lieu of N/A
Specific a	reas of circuits short-circuited and test conditions	Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE1	HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No	Remarks
0.000	entary Information: US SITUATION DESCRIBED IN 13.1: [60601	1:2005 + am1]		

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Test Tables

8.9.3.2	TABLE: Thermal cycling tests on one sa insulation between conductive parts	imple of insulating	s compound forming solid	N/A
Part Test	8.9.3.4 - Test duration and temperature fo cycles after which the sample was subject to Humidity Preconditioning per Cl. 5.7	ed Dielectric	Dielectric strength test after humidity preconditioning per ci. 5.7 except for 48 h only, Breakdown: Yes/No	Crack or volds in the insulating compound: Yes/No
	68 h at T1 ± 2 °C = °C 1			
Solid insulation	n 1 h at 25 °C ± 2 °C			
under test	2 h at 0 °C ± 2 °C			
	1 or more h at 25 °C ± 2 °C			

Supplementary Information:

 $1\,\text{T1} = 10\,^{\circ}\text{C}$ above the maximum temperature of relevant part determined per 11.1.1, or 85 $^{\circ}\text{C}$, the higher of the two. $10\,^{\circ}\text{C}$ not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

8.9.3.3	TABLI (see 8.9	E: Thermal cycling tests on one sample of cement 3.3)	ed joint with other insulating p	arts	N/A
Part Test	Sample	Each test duration and temperature	Dielectric test voltage	test,	ctric strength Breakdown: Yes/No
		1D Cycles conducted of the following:			
		1 - 68 h at T1 ± 2 °C = °C1			
Test Sample	1	2 -1 h at 25 °C ± 2 °C			
#1: Cemented Joint under		3 - 2 h at 0 °C ± 2 °C			
test		4 -1 or more h at 25 °C ± 2 °C			
	2	Humidity Conditioning per 5.7			
	3	Humidity Conditioning per 5.7	25	3	

Supplementary Information:

 $1\,\mathrm{T1}$ = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

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Test Tables

TABLE: List of critical	I components			p		
Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity 1		
		S	5			
	Manufacturer/	Manufacturer/ No./model	Manufacturer/ Type No./model Technical data	Manufacturer/ Type Standard No./,		

Supplementary Information:

Refer to Table 8.10 (cont.) at the end of these Test Tables for a list of all critical components associated with this device.

1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

8.10 b	TABLE: List of identi CHARACTERISTICS	N/A			
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity ¹

Supplementary Information:

Refer to Table 8:10 (cont.) at the end of these Test Tables for a list of all High Integrity components associated with this device.

1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

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Cord und	ler test	Mass of equipment (kg)	Pull (N)	Torque	Remarks	
				(Nm)	Remarks	
		*				
Supplementa	y Information	:	,			
From Table 18 o	f the standard:					
1 kg: 30 N Pull, 0.:		- Water				
over 1 through 4 k >4 kg: 100 N Pull,						
1 kg = 2.205 lbs. 1						
1 N = 0.225 lbs. Fo	rce 1 lb force = 4 i. Force 1 ft lb fo					

8.11.3 .6	TABLE: Cord guard	¥*	· · · · · · · · · · · · · · · · · · ·		N/A
Co	ord under test	Test mass (kg)	Measured curvature	Remarks	
Test met	hod per 3rd ed	H	*	*	
Test method per IEC 60335-1		E .	181	188	
			(4)		
Supplemen None	tary Information:	-to			

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Clause	Requirement + Test	Result - Remark	Verdict

Part of body	Allowable adult gap1, mm	Measured adult gap, mm	Allowable children gap1, mm	Measured childrei gap, mm
Body	>500		> 500	2
Head	>300 or <120		> 300 or < 60	
Leg	>180		> 180	
Foot	>120 or < 35		> 120 or < 25	
Toes	>50		> 50	š.
Arm	>120		> 120	
Hand, wrist, fis	t >100		> 100	
Finger	>25 or <8		> 25 or < 4	

9.2.3.	TABLE: Over-travel End	Stop Test	N/A
MEE	QUIPMENT end stop	Test Condition (cycles, load, speed)	Remarks
Supplem	entary Information:		
1 kg = 2.2	05 bs, 1 b = 0.454 kg		

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Clause	Requirement + Test	Result - Remark	Verdict	

9.4.2. l	TABLE: Instability - o	overbalance in transport position	N,
ME EQUIP	MENT preparation	Test Condition (transport position)	Remarks
Supplem	entary Information:		

TABLE: Instability	- overbalance excluding transport position	N/A
MENT preparation	Test Condition [excluding transport position] Test either 5 "incline and verify Warning marking or 10 "incline]	Remarks
entary Information:	-75	
	MENT preparation	

9.4.2. 3	TABLE: Instability	ity - overbalance from horizontal and vertical forces		
ME EQUIP	MENT preparation	Test Condition (force used, direction of force, weight of equipment, location of force)	Remarks	
1000	entary Information:	tice is present. Otherwise all are subjected to a 10° inclin		

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IEC 60601-1				
Clause	Requirement + Test	Result - Remark	Verdict	

9.4.2. 4.2	TABLE: Castors and wheels - Force for propulsion		
ME EQUIP	MENT preparation	Test Condition (force location and height)	Remarks
Supplem	entary Information:		
None			

1.3	TABLE: Castors and	wheels - Movement over a threshold	8 8	N/A
ME EQUIPM	MENT preparation	Test Condition (speed of movement)	Remarks	
Suppleme	ntary Information:			

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9.4.3. 1	TABLE: Instability position	TABLE: Instability from unwanted lateral movement (including sliding) in transport position		N/A
ME EQUII	PMENT preparation	Test Condition (transport position, working load, locking device(s), caster position)	Remarks	
Supplen	nentary Information:	g		
None				

IENT preparation	Test Condition (working load, locking device(s), caster position, force, force location, force direction)	Remarks
ntary Information:		
3.5 Sec 10 - 10 - 10 Sec		
r	ntary Information:	

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9.4.4	TABLE: Grips and other handling devices		
Clause and Name of Test		Test Condition	Remarks
Supplem	entary Information:		
N	•		
None			

9.7.5	TABLE:	Pressure vessels					N/A
Hydr Pneum Suitable N Test Pr	atic or Aedia and	Vessel Burst	Permanent Deformation	Leaks	Vessel fluid substance	Re	marks
	3		i V				
Supplem	entary Info	rmation:		, .			
None							

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9.8.3. 2	TABLE: PATIENT support/suspension system - Statis forces					
ME EQUIPN	MENT part or area	Position	Load	Area	Remarks	
					3	
	ē			2		
Supplem	entary Information:				5	

9.8.3. 3	TABLE: Support/Suspension System - Dynamic forces due to loading from persons					N/A
MEEQUIF	MENT part or area	Position	Safe Working Load	Area	Remarks	
	,,					
	entary Information:			.,		
None						

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Test Tables

10.1.1 TABLE: Measurement of X - radiation					
Maximur	n allowable radiation pA/kg (μSv/h) (mR/h):				
	Surface area under test Surface no./ Description1	Measured Radiation, pA/kg (μSv/h) (mR/h)	Remarks		

Supplementary Information:

¹ Measurements made at a distance of 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with the means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access (pA/kg).

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11.1.1 T	ABLE: Exces	sive temperature	Pass		
Model No.:		See below			
Test ambient (°C):	See below			
Test supply volta (V/Hz)4:	ge/frequen	sy See below			
Model No.:	Thermo- couple No.	Thermocouple location3	Max allowable temperature1 from Table 22, 23 or 24 or RM file for APS (*C)	Max measured temperature2, [°C]	Remarks
CHD250PS12: 12V/20.8A (250W) Convection	1	T AMBIENT	50.0	50	Tested at 90 Vac, 50Hz; duration:2h
CHD250PS12: 12V/20.8A (250W) Convection	2	FS1 BODY	125.0	103	
CHD250PS12: 12V/20.8A (250W) Convection	3	L1 COIL	130.0	108	
CHD250PS12: 12V/20.8A (250W) Convection	4	L2 COIL	130.0	115	
CHD250PS12: 12V/20.8A (250W) Convection	.5	C64 BODY	105.0	88	
CHD250PS12: 12V/20.8A (250W) Convection	6	орто 1 вору	105.0	87	
CHD250PS12: 12V/20.8A (250W) Convection	7	PCB @ TR5,D5	130.0	111	
CHD250P\$12: 12V/20.8A (250W) Convection	8	D24 BODY	140.0	120	
CHD250PS12: 12V/20.8A (250W) Convection	9	L4 COIL	130.0	113	
CHD250PS12: 12V/20.8A (250W) Convection	10	L3 COIL	130.0	109	
CHD250PS12: 12V/20.8A (250W) Convection	11	L5 COIL	130.0	111	

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Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS12: 12V/20.8A (250W) Convection	12	PCB @ TR27	130.0	100	
CHD250PS12: 12V/20.8A (250W) Convection	13	T1 COIL	130.0	105	
CHD250PS12: 12V/20.8A (250W) Convection	14	T1 CORE	130.0	98	
CHD250PS12: 12V/20.8A (250W) Convection	15	T2 BODY	130.0	100	
CHD250PS12: 12V/20.8A (250W) Convection	16	тз воду	130.0	92	
CHD250PS12: 12V/20.8A (250W) Convection	17	C34 BODY	105.0	97	
CHD250PS12: 12V/20.8A (250W) Convection	18	L9 COIL	130.0	104	
CHD250PS12: 12V/20.8A (250W) Convection	19	PBC @ TR16	130.0	111	
CHD250PS12: 12V/20.8A (250W) Convection	20	CON1 BODY	105.0	76	
CHD250PS12: 12V/20.8A (250W) Convection	1	T AMBIENT	50.0	50	Tested at 100Vac, 50Hz, duration:2h
CHD250PS12: 12V/20.8A (250W) Convection	2	FS1 BODY	125.0	91	
CHD250P\$12: 12V/20.8A (250W) Convection	3	L1 COIL	130.0	95	
CHD250PS12: 12V/20.8A (250W) Convection	4	L2 COIL	130.0	104	
CHD250PS12: 12V/20.8A (250W) Convection	5	C64 BODY	105.0	83	
CHD250PS12: 12V/20.8A (250W) Convection	6	орто 1 вору	105.0	85	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS12: 12V/20.8A (250W) Convection	7	PCB @ TR5,D5	130.0	105	
CHD250PS12: 12V/20.8A (250W) Convection	8	D24 BODY	140.0	112	
CHD250PS12: 12V/20.8A (250W) Convection	9	L4 COIL	130.0	108	
CHD250PS12: 12V/20.8A (250W) Convection	10	L3 COIL	130.0	104	
CHD250PS12: 12V/20.8A (250W) Convection	11	L5 COIL	130.0	109	
CHD250PS12: 12V/20.8A (250W) Convection	12	PCB @ TR27	130.0	98	
CHD250P\$12: 12V/20.8A (250W) Convection	13	T1 COIL	130.0	104	
CHD250PS12: 12V/20.8A (250W) Convection	14	T1 CORE	130.0	94	
CHD250PS12: 12V/20.8A (250W) Convection	15	T2 BODY	130.0	98	
CHD250PS12: 12V/20.8A (250W) Convection	16	тз вору	130.0	90	
CHD250PS12: 12V/20.8A (250W) Convection	17	C34 BODY	105.0	96	
CHD250PS12: 12V/20.8A (250W) Convection	18	L9 COIL	130.0	103	
CHD250PS12: 12V/20.8A (250W) Convection	19	PBC @ TR16	130.0	104	
CHD250PS12: 12V/20.8A (250W) Convection	20	CON1 BODY	105.0	71	
CHD250PS12: 12V/20.8A (250W) Convection	1	T AMBIENT	50.0	50	Tested at 240Vac, 50Hz; duration:2h

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS12: 12V/20.8A (250W) Convection	2	FS1 BODY	125.0	68
CHD250PS12: 12V/20.8A (250W) Convection	3	L1 COIL	130.0	70
CHD250PS12: 12V/20.8A (250W) Convection	4	L2 COIL	130.0	79
CHD250PS12: 12V/20.8A (250W) Convection	5	C64 BODY	105.0	71
CHD250PS12: 12V/20.8A (250W) Convection	6	OPTO 1 BODY	105.0	79
CHD250PS12: 12V/20.8A (250W) Convection	7	PCB @ TR5,D5	130.0	85
CHD250PS12: 12V/20.8A (250W) Convection	8	D24 BODY	140.0	87
CHD250PS12: 12V/20.8A (250W) Convection	9	L4 COIL	130.0	86
CHD250PS12: 12V/20.8A (250W) Convection	10	L3 COIL	130.0	85
CHD250PS12: 12V/20.8A (250W) Convection	11	L5 COIL	130.0	105
CHD250PS12: 12V/20.8A (250W) Convection	12	PCB @ TR27	130.0	95
CHD250PS12: 12V/20.8A (250W) Convection	13	T1 COIL	130.0	101
CHD250PS12: 12V/20.8A (250W) Convection	14	T1 CORE	130.0	91
CHD250PS12: 12V/20.8A (250W) Convection	15	T2 BODY	130.0	92
CHD250PS12: 12V/20.8A (250W) Convection	16	ТЗ ВОДУ	130.0	85

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

9	9-	¥ ×		(4)	30
CHD250PS12: 12V/20.8A (250W) Convection	17	C34 BODY	105.0	92	
CHD250PS12: 12V/20.8A (250W) Convection	18	L9 COIL	130.0	100	
CHD250PS12: 12V/20.8A (250W) Convection	19	PBC @ TR16	130.0	108	
CHD250PS12: 12V/20.8A (250W) Convection	20	CON1 BODY	105.0	60	
CHD250PS12: 12V/20.8A (250W) Convection	1	T AMBIENT	50.0	50	Tested at 264Vac, 50Hz; duration:2h
CHD250PS12: 12V/20.8A (250W) Convection	2	FS1 BODY	125.0	70	
CHD250PS12: 12V/20.8A (250W) Convection	3	L1 COIL	130.0	73	
CHD250PS12: 12V/20.8A (250W) Convection	4	L2 COIL	130.0	81	
CHD250PS12: 12V/20.8A (250W) Convection	.5	C64 BODY	105.0	73	
CHD250PS12: 12V/20.8A (250W) Convection	6	OPTO 1 BODY	105.0	80	
CHD250PS12: 12V/20.8A (250W) Convection	7	PCB @ TR5,D5	130.0	85	
CHD250P\$12: 12V/20.8A (250W) Convection	8	D24 BODY	140.0	89	
CHD250P\$12: 12V/20.8A (250W) Convection	9	L4 COIL	130.0	86	
CHD250P\$12: 12V/20.8A (250W) Convection	10	L3 COIL	130.0	86	
CHD250PS12: 12V/20.8A (250W) Convection	11	L5 COIL	130.0	106	

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Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS12: 12V/20.8A (250W) Convection	12	PCB @ TR27	130.0	96	
CHD250PS12: 12V/20.8A (250W) Convection	13	T1 COIL	130.0	103	
CHD250PS12: 12V/20.8A (250W) Convection	14	T1 CORE	130.0	93	
CHD250PS12: 12V/20.8A (250W) Convection	15	T2 BODY	130.0	94	
CHD250PS12: 12V/20.8A (250W) Convection	16	тз вору	130.0	86	
CHD250PS12: 12V/20.8A (250W) Convection	17	C34 BODY	105.0	.93	
CHD250PS12: 12V/20.8A (250W) Convection	18	L9 COIL	130.0	101	
CHD250PS12: 12V/20.8A (250W) Convection	19	PBC @ TR16	130.0	109	
CHD250PS12: 12V/20.8A (250W) Convection	20	CON1 BODY	105.0	61	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	1	T AMBIENT	50.0	50	Tested at 90 Vac, 50 Hz, duration:2h
CHD250PS12: 12V/18.1A (217W) Convection with Cover	2	FS1 BODY	125.0	95	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	3	L1 COIL	130.0	98	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	4	L2 COIL	130.0	112	

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Clause	Requirement + Test	Result - Remark	Verdict			

CHD250PS12: 12V/18.1A (217W) Convection with Cover	5	C64 BODY	105.0	92	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	6	орто 1 вору	105.0	91	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	7	PCB @ TR5,D5	130.0	124	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	8	D24 BODY	140.0	127	i i
CHD250PS12: 12V/18.1A (217W) Convection with Cover	9	L4 COIL	130.0	121	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	10	L3 COIL	130.0	113	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	11	L5 COIL	130.0	109	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	12	PCB @ TR27	130.0	96	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	13	T1 COIL	130.0	105	
CHD250P\$12: 12V/18.1A (217W) Convection with	14	T1 CORE	130.0	107	

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Clause	Requirement + Test	Result - Remark	Verdict		

Cover		Ĭ			
CHD250PS12: 12V/18.1A (217W) Convection with Cover	15	T2 BODY	130.0	97	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	16	тз вору	130.0	88	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	17	C34 BODY	105.0	94	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	18	L9 COIL	130.0	98	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	19	PBC @ TR16	130.0	95	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	20	CON1 BODY	105.0	75	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	1	T AMBIENT	50.0	50	Tested at 264Vac, 50Hz; duration:2h
CHD250PS12: 12V/18.1A (217W) Convection with Cover	2	FS1 BODY	125.0	72	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	3	L1 COIL	130.0	74	
CHD250PS12: 12V/18.1A (217W)	4	L2 COIL	130.0	86	

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30	Į.	34	2	9	13
Convection with Cover					
CHD250PS12: 12V/18.1A (217W) Convection with Cover	5	C64 BODY	105.0	79	:
CHD250PS12: 12V/18.1A (217W) Convection with Cover	6	OPTO 1 BODY	105.0	81	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	7	PCB @ TR5,D5	130.0	95	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	8	D24 BODY	140.0	96	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	9	L4 COIL	130.0	93	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	10	L3 COIL	130.0	90	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	11	L5 COIL	130.0	102	
CHD250P\$12: 12V/18.1A (217W) Convection with Cover	12	PCB @ TR27	130.0	92	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	13	T1 COIL	130.0	101	

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CHD250PS12: 12V/18.1A (217W) Convection with Cover	14	T1 CORE	130.0	102	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	15	T2 BODY	130.0	90	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	16	тз вору	130.0	82	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	17	C34 BODY	105.0	88	1
CHD250PS12: 12V/18.1A (217W) Convection with Cover	18	L9 COIL	130.0	94	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	19	PBC @ TR16	130.0	92	
CHD250PS12: 12V/18.1A (217W) Convection with Cover	20	CON1 BODY	105.0	63	
CHD250PS12: 12V/10.4A (125W) Convection	1	TAMBIENT	70.0	70	Tested at 90 Vac, 50Hz; duration:2h
CHD250PS12: 12V/10.4A (125W) Convection	2	FS1 BODY	125.0	87	
CHD250PS12: 12V/10.4A	3	L1 COIL	130.0	89	

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O	-	-		25	4
(125W) Convection					
CHD250PS12: 12V/10.4A (125W) Convection	4	L2 COIL	130.0	95	
CHD250PS12: 12V/10.4A (125W) Convection	.5	C64 BODY	105.0	87	
CHD250PS12: 12V/10.4A (125W) Convection	6	OPTO 1 BODY	105.0	87	
CHD250P\$12: 12V/10.4A (125W) Convection	7	PCB @ TR5,D5	130.0	98	
CHD250PS12: 12V/10.4A (125W) Convection	8	D24 BODY	140.0	101	
CHD250PS12: 12V/10.4A (125W) Convection	9	L4 COIL	130.0	100	
CHD250PS12: 12V/10.4A (125W) Convection	10	L3 COIL	130.0	97	
CHD250PS12: 12V/10.4A (125W) Convection	11	L5 COIL	130.0	96	
CHD250PS12:	12	PCB @ TR27	130.0	93	

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Clause	Requirement + Test	Result - Remark	Verdict

	-	Ŷ	25	i i
	*			
13	T1 COIL	130.0		
			92	
			i i	
	T. 5555	120		
14	11 CORE	130.0		
			89	
X	30			
10.00	T 0.000	1000000		
15	12 BODY	130.0		
			91	
	38	5	25	1,
Sacrano		275.07.0		
16	13 BODY	130.0		
			89	
			3	
	634 8684	105.0		
17	C34 BODY	103:0		
			88	
1.0	Le COII	:120:0		
1.0	ES COIL	130.0		
			90	
1.9	PRC @ TR16	130.0		
13	-DC@ 1810	130.0		
			92	
20	CONT BODY	105.0		
20	COMT BODA	103.0		
	13 14 15 16 17	14 T1 CORE 15 T2 BODY 16 T3 BODY 17 C34 BODY 18 L9 COIL 19 PBC @ TR16	14 T1 CORE 130.0 15 T2 BODY 130.0 16 T3 BODY 130.0 17 C34 BODY 105.0 18 L9 COIL 130.0	14 T1 CORE 130.0 89 15 T2 BODY 130.0 91 16 T3 BODY 130.0 89 17 C34 BODY 105.0 88 18 L9 COIL 130.0 90 19 PBC @ TR16 130.0 92

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Clause	Requirement + Test	Result - Remark	Verdict	

8.	46	60	2	99	<u>=</u>
CHD250PS12: 12V/10.4A (125W) Convection	1	T AMBIENT	70.0	70	Tested at 264Vac, 50Hz; duration:2h
CHD250PS12: 12V/10.4A (125W) Convection	2	FS1 BODY	125.0	81	
CHD250PS12: 12V/10.4A (125W) Convection	3	L1 COIL	130.0	83	
CHD250PS12: 12V/10.4A (125W) Convection	4	L2 COIL	130.0	88	
CHD250PS12: 12V/10.4A (125W) Convection	5	C64 BODY	105.0	85	1
CHD250PS12: 12V/10.4A (125W) Convection	6	OPTO 1 BODY	105.0	84	
CHD250PS12: 12V/10.4A (125W) Convection	7	PCB @ TR5,D5	130.0	93	
CHD250PS12: 12V/10.4A (125W) Convection	8	D24 BODY	140.0	94	
CHD250PS12: 12V/10.4A (125W)	9	L4 COIL	130.0	90	1

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Clause	Requirement + Test	Result - Remark	Verdict	

·	-	ş <u>.</u>	¥	gg s	<u> </u>
Convection					
CHD250PS12: 12V/10.4A (125W) Convection	10	L3 COIL	130.0	89	
CHD250PS12: 12V/10.4A (125W) Convection	11	L5 COIL	130.0	95	
CHD250PS12: 12V/10.4A (125W) Convection	12	PCB @ TR27	130.0	92	
CHD250PS12: 12V/10.4A (125W) Convection	13	T1 COIL	130.0	92	
CHD250PS12: 12V/10.4A (125W) Convection	14	T1 CORE	130.0	88	
CHD250PS12: 12V/10.4A (125W) Convection	15	T2 BODY	130.0	90	
CHD250PS12: 12V/10.4A (125W) Convection	16	тз вору	130.0	87	
CHD250PS12: 12V/10.4A (125W) Convection	17	C34 BODY	105.0	87	
CHD250PS12: 12V/10.4A	18	L9 COIL	130.0	89	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

(125W)	Ť			112-	1
Convection					
CHD250PS12: 12V/10.4A (125W) Convection	19	PBC @ TR16	130.0	91	
CHD250PS12: 12V/10.4A (125W) Convection	20	CON1 BODY	105.0	77	
CHD250PS12: 12V/10.4A (125W) Convection	Ĩ	TAMBIENT	70.0	70	At 90Vac, 50Hz; duration 2h
CHD250PS12: 12V/10.4A (125W) Convection	2	FS1 BODY	125.0	88	
CHD250PS12: 12V/10.4A (125W) Convection	3	L1 COIL	130.0	90	
CHD250PS12: 12V/10.4A (125W) Convection	4	L2 COIL	130.0	100	
CHD250PS12: 12V/10.4A (125W) Convection	1.5	C64 BODY	105.0	92	
CHD250PS12: 12V/10.4A (125W) Convection	6	орто 1 вору	105.0	90	
CHD250PS12:	7	PCB @	130.0	107	7

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

431//40 44	î	TR5,D5	ý.	95	i
12V/10.4A (125W)		185,05			
Convection					
convection					
CHD250PS12:		ľ			
12V/10.4A		D24 B0D34	140.0		
(125W)	8	D24 BODY	140.0		
Convection				108	
CHD250PS12:	9				
12V/10.4A	9	L4 COIL	130.0		
(125W)	9	L4 COIL	130.0		
Convection				106	
CHD250PS12:	0.5				
12V/10.4A	10	L3 COIL	130.0		
(125W)	10	L COIL	130.0		
Convection				101	
CHD250PS12:	St.	4		S	2,
12V/10.4A	11	L5 COIL	130.0		
(125W)	11	LI COIL	130.0		
Convection				98	
CHD250PS12:	5		<u> </u>	8	
12V/10.4A	12	PCB @ TR27	130.0		
(125W)	12	PCB @ TRZ7	130.0		
Convection				95	
CHD250PS12:	3				
12V/10.4A	13	T1 COIL	130.0		
(125W)	13	11 COIL	130.0		
Convection				96	
CHD250PS12:	3				
12V/10.4A	14	T1 CORE	130.0		
(125W)	1.46	12 COME	130.0		
Convection				97	
CHD250PS12:	1.7				
12V/10.4A	15	T2 BODY	130.0		
(125W)	(1.3)	12 BODT	130.0		
Convection	1	1		94	I

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

CHD250PS12: 12V/10.4A (125W) Convection	16	тэ вору	130.0	92	
CHD250PS12: 12V/10.4A (125W) Convection	17	C34 BODY	105.0	90	
CHD250PS12: 12V/10.4A (125W) Convection	18	L9 COIL	130.0	91	
CHD250PS12: 12V/10.4A (125W) Convection	19	PBC @ TR16	130.0	92	
CHD250PS12: 12V/10.4A (125W) Convection	20	CON1 BODY	105.0	81	
CHD250PS12: 12V/10.4A (125W) Convection with cover	1	TAMBIENT	70.0	70	Tested at 264Vac, 50Hz; duration:2h
CHD250PS12: 12V/10.4A (125W) Convection with cover	2	FS1 BODY	125.0	83	
CHD250PS12: 12V/10.4A (125W) Convection with cover	3	L1 COIL	130.0	85	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS12: 12V/10.4A (125W) Convection with cover	4	L2 COIL	130.0	92	
CHD250PS12: 12V/10.4A {125W} Convection with cover	.5	C64 BODY	105.0	87	
CHD250PS12: 12V/10.4A (125W) Convection with cover	6	OPTO 1 BODY	105.0	87	
CHD250PS12: 12V/10.4A (125W) Convection with cover	7	PCB @ TR5,D5	130.0	99	
CHD250PS12: 12V/10.4A (125W) Convection with cover	8	D24 BODY	140.0	99	
CHD250PS12: 12V/10.4A (125W) Convection with cover	9	L4 COIL	130.0	94	
CHD250PS12: 12V/10.4A (125W) Convection with cover	10	L3 COIL	130.0	93	
CHD250PS12: 12V/10.4A	11	L5 COIL	130.0	97	1.0

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

(125W) Convection with cover					
CHD250PS12: 12V/10.4A (125W) Convection with cover	12	PCB @ TR27	130.0	93	
CHD250PS12: 12V/10.4A (125W) Convection with cover	13	T1 COIL.	130.0	94	
CHD250PS12: 12V/10.4A (125W) Convection with cover	14	T1 CORE	130.0	95	
CHD250PS12: 12V/10.4A (125W) Convection with cover	15	T2 BODY	130.0	91	
CHD250PS12: 12V/10.4A (125W) Convection with cover	16	ТЗ ВОДУ	130.0	89	
CHD250PS12: 12V/10.4A (125W) Convection with cover	17	C34 BODY	105.0	88	
CHD250PS12: 12V/10.4A (125W) Convection with	18	L9 COIL	130.0	90	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

		ş	92	<u>ge</u> 3	4 X
cover					
CHD250PS12: 12V/10.4A (125W) Convection with cover	19	PBC @ TR16	130.0	91	
CHD250PS12: 12V/10.4A (125W) Convection with cover	20	CON1 BODY	105.0	79	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	1 00 € 50 € 50 € 50 € 50 € 50 € 50 € 50 €	TAMBIENT	50.0	50	Tested at 90 Vac, 50 Hz; duration 2h
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	2	FS1 BODY	125.0	98	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	3	L1 COIL	130.0	98	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	4	L2 COIL	130.0	107	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	.5	C64 BODY	105.0	89	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	6	OPTO 1 BODY	105.0	97	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	7	PCB @ TR5,D5	130.0	104	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	8	D24 BODY	140.0	118	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	9	L4 COIL	130.0	114	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	10	L3 COIL	130.0	121	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	11	L5 COIL	130.0	105	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	12	PCB @ TR27	130.0	98	
CHD250PS12: 12V/18.33A,	13	T1 COIL	130.0	117	:

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

		-	¥		4 %
5V/1A (225W)					
Convection with					
5V Standby					
CHD250PS12:	13	Î			
12V/18.33A,					
5V/1A (225W)	14	T1 CORE	130.0		
Convection with					
5V Standby				113	
CHD250PS12:					
12V/18.33A,					
5V/1A (225W)	15	T2 BODY	130.0		
Convection with					
5V Standby				118	
CHD250PS12:					
12V/18.33A,					
5V/1A (225W)	16	T3 BODY	130.0		
Convection with				000007	
5V Standby				112	
CHD250PS12:				1	
12V/18.33A,					
5V/1A (225W)	17	C34 BODY	105.0		
Convection with				SECTOR	
5V Standby				102	
CHD250PS12:					
12V/18.33A,					
5V/1A (225W)	18	L9 COIL	130.0		
Convection with				00	
5V Standby				93	
CHD250PS12:					
12V/18.33A,	1190607		VIETE VIET 14		
5V/1A (225W) Convection with	19	PBC@TR16	130.0		
5V Standby				105	
TO THE PERSON OF				3.500	
CHD250PS12:	Viskiniti	1010 (409) 6855, 12 1000 (49	00000040004		
12V/18.33A, 5V/1A (225W)	20	CON1 BODY	105.0		
Convection with				82	
CONTROL OF THE PROPERTY OF THE				l	

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IEC 60601-1						
	Clause	Requirement + Test	Result - Remark	Verdict		

ř.		<u> </u>	Ø.	25	2
5V Standby					
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	21	T1 COIL-SB	130.0	110	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	22	T1 CORE-SB	130.0	104	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	23	C7 BODY-SB	105.0	97	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	24	L1 COIL-SB	130.0	105	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	25	C14 BODY-SB	105.0	105	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	Ţ.	TAMBIENT	50.0	50	Tested at 264Vac, 50Hz, duration:2h
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	2	FS1 BODY	125.0	67	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	3	L1 COIL	130.0	72	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	4	L2 COIL	130.0	81	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	5	C64 BODY	105.0	75	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	6	OPTO 1 BODY	105.0	87	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	ž	PCB @ TR5,D5	130.0	85	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	8	D24 BODY	140.0	91	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	9	L4 COIL	130.0	92	
CHD250PS12: 12V/18.33A,	10	L3 COIL	130.0	93	14

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

8		\$	W.	9	4 70
5V/1A (225W)					
Convection with					
5V Standby					
CHD250PS12:					
12V/18.33A,					
5V/1A (225W)	11	L5 COIL	130.0		
Convection with					
5V Standby				99	
CHD250PS12:					
12V/18.33A,					
5V/1A (225W)	12	PCB @ TR27	130.0		
Convection with	H.	PCB @ THEF	130.0		
5V Standby				94	
100100 - 1000 5-64000 510 - 10				93	
CHD250PS12:					
12V/18.33A,					
5V/1A (225W)	13	T1 COIL	130.0		
Convection with				993	
5V Standby				113	
CHD250PS12:					
12V/18.33A,					
5V/1A (225W)	14	T1 CORE	130.0		
Convection with				Post 0.5 %	
5∨ Standby				109	
CHD250PS12:					
12V/18.33A,					
5V/1A (225W)	15	T2 BODY	130.0		
Convection with					
5V Standby				110	
CHD250PS12:					-
12V/18.33A,					
5V/1A (225W)	16	T3 BODY	130.0		
Convection with					
5V Standby				101	
CHD250PS12:					:
12V/18.33A,	17	C34 BODY	105.0		
5V/1A (225W)		- AND DEFENDENCE OF THE SECOND	1000 A 100 A 100 A 100 A	97	
Convection with				30	

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IEC 60601-1				
Clause	Requirement + Test	Result - Remark	Verdict	

		62	W.	95	e X
5V Standby					
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	18	L9 COIL	130.0	90	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	19	PBC @ TR16	130.0	102	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	20	CON1 BODY	105.0	62	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	21	T1 COIL-SB	130.0	102	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	22	T1 CORE-SB	130.0	95	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	23	C7 BODY-SB	105.0	92	
CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	24	L1 COIL-SB	130.0	85	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS12: 12V/18.33A, 5V/1A (225W) Convection with 5V Standby	25	C14 BODY-SB	105.0	94	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	1	T AMBIENT	50.0	50	Tested at 90Vac, 50Hz; duration:2h
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	2	FS1 BODY	125.0	80	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	3	L1 COIL	130.0	84	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	4	L2 COIL	130.0	96	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	5	C64 BODY	105.0	82	
CHD250PS12: 12V/13.33A,	6	OPTO 1 BODY	105.0	81	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

Certain takenan - I			Ť	34 3 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	i
5V/1A (165W) Convection with					
5V Standby and					
Cover					
CHD250PS12: 12V/13.33A,					
5V/1A (165W)	7	PCB @	130.0		
Convection with		TR5,D5	130.0		
5V Standby and				***	
Cover				104	
CHD250PS12:					
12V/13.33A,					
5V/1A (165W)	8	D24 BODY	140.0		
Convection with 5V Standby and					
Cover				107	
TREES (28)				(13%)	
CHD250PS12:				5)	
12V/13.33A, 5V/1A (165W)					
Convection with	9	L4 COIL	130.0		
5V Standby and					
Cover				107	
CHD250PS12:					-
12V/13.33A,					
5V/1A (165W)					
Convection with	10	L3 COIL	130.0		
5V Standby and					
Cover				103	
CHD250PS12:	8				
12V/13.33A,					
5V/1A (165W)	11	L5 COIL	130.0		
Convection with	(04040)		12010		
5V Standby and					
Cover				95	
CHD250PS12:				₽	
12V/13.33A,	12	PCB @ TR27	130.0	88	
5V/1A (165W)				89288	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

4		ş	¥		4 70
Convection with					
5∨ Standby and					
Cover					
CHD250PS12:					
12V/13.33A,					
5V/1A (165W)		170/01 04044000	SUPPLIES AND SUPPL		
Convection with	13	T1 COIL	130.0		
5V Standby and					
Cover				91	
CHD250PS12:	,				
12V/13.33A,					
5V/1A (165W)					
Convection with	14	T1 CORE	130.0		
5V Standby and					
Cover				93	
				55	
CHD250PS12:		32			1.
12V/13.33A,					
5V/1A (165W)	15	T2 BODY	130.0		
Convection with		3	- NESSYS-1		
5V Standby and				% PF 3 MF	
Cover				98	
CHD250PS12:					
12V/13.33A,					
5V/1A (165W)	16	тз вору	130.0		
Convection with	10	13 8001	150.0		
5V Standby and					
Cover				97	
CHD250PS12:		4			
12V/13.33A,					
5V/1A (165W)	18/25	0.500-0.000-0.000	7612233		
Convection with	17	C34 BODY	105.0		
5V Standby and					
Cover				86	
CHD250PS12:				:	- 57
12V/13.33A,	1.9	19 001	130.0		
THE PROPERTY OF THE PARTY OF TH	1.0	LJ COIL	130.0		
Convection with				82	I
5V Standby and Cover CHD250PS12: 12V/13.33A, 5V/1A (165W)	18	L9 COIL	130.0	86	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

5V Standby and Cover					
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	19	PBC @ TR16	130.0	89	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	20	CON1 BODY	105.0	68	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	21	T1 COIL-SB	130.0	94	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	22	T1 CORE-SB	130.0	93	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	23	C7 BODY-SB	105.0	77°	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and	24	L1 COIL-SB	130.0	83	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

8	66	<u> </u>	÷		g X3
Cover					
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	25	C14 BODY-SB	105.0	100	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	ì	TAMBIENT	50.0	50	Tested at 264Vac, 50Hz; duration: 2h
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	2	FS1 BODY	125.0	70	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	3	L1 COIL	130.0	72	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	4	L2 COIL	130.0	83	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	.5	C64 BODY	105.0	77	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	6	OPTO 1 BODY	105.0	76	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	7	PCB @ TR5,D5	130.0	92	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	8	D24 BODY	140.0	94	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	9	L4 COIL	130.0	93	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	10	L3 COIL	130.0	91	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	11	L5 COIL	130.0	91	
CHD250PS12:	12	PCB @ TR27	130.0	85	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

0		\$		ge g	4 X
12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover					
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	13	T1 COIL	130.0	89	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	14	T1 CORE	130.0	90	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	15	T2 BODY	130.0	93	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	16	тз вору	130.0	91	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	17	C34 BODY	105.0	83	
CHD250PS12: 12V/13.33A,	18	L9 COIL	130.0	80	1

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

-		-	Ť	up.	i i
5V/1A (165W) Convection with 5V Standby and Cover					
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	19	PBC @ TR16	130.0	87	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	20	CON1 BODY	105.0	62	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	21	T1 COIL-SB	130.0	89	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	22	T1 CORE-SB	130.0	88	
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	23	C7 BODY-SB	105.0	75	
CHD250PS12: 12V/13.33A, 5V/1A (165W)	24	L1 COIL-SB	130.0	81	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

8	£1	<u> </u>	· ·	120 D	x x
Convection with 5V Standby and Cover					
CHD250PS12: 12V/13.33A, 5V/1A (165W) Convection with 5V Standby and Cover	25	C14 BODY-SB	105.0	91	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	1	T AMBIENT	70.0	50	Tested at 90Vac, 50Hz, duration 2h
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	2	FS1 BODY	125.0	85	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	3	L1 COIL	130.0	88	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	4	L2 COIL	130.0	96	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W)	.5	C64 BODY	105.0	90	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

S	6	<u> </u>	ý.	ggg	9 70
Convection with 5V Standby					
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	6	OPTO 1 BODY	105.0	92	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	7	PCB@ TR5,D5	130.0	.98	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	8	D24 BODY	140.0	103	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	9	L4 COIL	130.0	101	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	10	L3 COIL	130.0	105	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with	11	L5 COIL	130.0	96	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

<i>S</i> 2	65	<u> </u>	300	92:	g x3
5V Standby					
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	12	PCB @ TR27	130.0	94	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	13	T1 COIL	130.0	100	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	14	T1 CORE	130.0	98	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	15	T2 BODY	130.0	102	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	16	ТЗ ВОДУ	130.0	100	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	17	C34 BODY	105.0	93	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	18	L9 COIL	130.0	89	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	19	PBC @ TR16	130.0	93	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	20	CON1 BODY	105.0	100	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	21	T1 COIL-SB	130.0	97	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	22	T1 CORE-SB	130.0	93	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	23	C7 BODY-SB	105.0	89	
CHD250PS12:	24	L1 COIL-SB	130.0	96	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby					
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	25	C14 BODY-SB	105.0	96	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	í	T ambient	70	70	Tested at 90 Vac, 50Hz, duration 2h
CHD250P\$12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	2	FS1 BODY	125.0	85	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	3	L1 COIL	130.0	88	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	4	L2 COIL	130.0	96	
CHD250PS12: 12V/9.17A,	.5	C64 BODY	105.0	90).

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

33	66	<u> </u>	<u> </u>	ag-	2 W
5V/0.5A (112.5W) Convection with 5V Standby					
CHD250PS12: 12V/9.17A,					
5V/0.5A (112.5W) Convection with 5V Standby	6	OPTO 1 BODY	105.0	92	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	7.	PCB @ TR5,D5	130.0	98	
3v Standby	27		ε	98	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with	80	D24 BODY	140.0		
5V Standby				103	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	9	L4 COIL	130.0	101	
CHD250PS12:	9				,
12V/9.17A, 5V/0.5A (112.5W) Convection with	10	L3 COIL	130.0	405	
5V Standby				105	
CHD250PS12: 12V/9.17A, 5V/0.5A	11	L5 COIL	130.0	96	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

(112.5W) Convection with 5V Standby					
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	12	PCB @ TR27	130.0	94	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	13	TI COIL	130.0	100	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	14	T1 CORE	130.0	98	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	15	T2 BODY	130.0	102	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	16	тз вору	130.0	100	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W)	17	C34 BODY	105.0	93	1

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

*	#56				20
Convection with 5V Standby					
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	18	L9 COIL	130.0	89	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	19	PBC @ TR16	130.0	93	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	20	CON1 BODY	105.0	100	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	21	T1 COIL-SB	130.0	97	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	22	T1 CORE-SB	130.0	93	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with	23	C7 BODY-SB	105.0	89	

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IEC 60601-1						
Clause Requirement + Test		Result - Remark	Verdict			

5V Standby					,
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	24	L1 COIL-SB	130.0	96	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	25	C14 BODY-SB	105.0	96	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	1	T ambient	70	70	Tested at 264Vac, 50Hz, duration 2h
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	2	FS1 BODY	125.0	81	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	3	L1 COIL	130.0	84	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	4	L2 COIL	130.0	91	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	5	C64 BODY	105.0	89	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	6	OPTO 1 BODY	105.0	88	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	7.	PCB @ TR5,D5	130.0	93	,
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	8	D24 BODY	140.0	95	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	9	L4 COIL	130.0	92	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	10	L3 COIL	130.0	96	
CHD250PS12:	11	L5 COIL	130.0	94	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby					
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	12	PCB @ TR27	130.0	93	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	13	T1 COIL	130.0	98	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	14	T1 CORE	130.0	97	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	15	T2 BODY	130.0	99	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	16	ТЗ ВОДУ	130.0	96	
CHD250PS12: 12V/9.17A,	17	C34 BODY	105.0	.91	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

5V/0.5A (112.5W) Convection with 5V Standby					
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	18	L9 COIL	130.0	88	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	19	PBC @ TR16	130.0	92	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	20	CON1 BODY	105.0	78	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	21	T1 COIL-SB	130.0	97	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	22	T1 CORE-SB	130.0	94	
CHD250PS12: 12V/9.17A, 5V/0.5A	23	C7 BODY-SB	105.0	.91	

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IEC 60601-1						
	Clause Requirement + Test		Result - Remark	Verdict		

The state of the s	ie:		ř	95	¥ %
(112.5W) Convection with					
5V Standby					
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	24	L1 COIL-SB	130.0	87	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby	25	C14 BODY-SB	105.0	.91	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	1	T ambient	70	70	Tested at 90Vac, 50Hz, duration 2h
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	ž	FS1 BODY	125.0	86	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	.3	L1 COIL	130.0	88	
CHD250PS12:	4	L2 COIL	130.0	96	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

	66	<u> </u>	8		e X
12V/9.17A,					
5V/0.5A					
(112.5W)					
Convection with					
5V Standby with					
cover					
CHD250PS12:					
12V/9.17A,					
5V/0.5A					
(112.5W)	5	C64 BODY	105.0		
Convection with					
5V Standby with					
cover				90	
CHD250PS12:		3	<u> </u>		
12V/9.17A,					
5V/0.5A					
(112.5W)	6	OPTO 1 BODY	105.0		
Convection with					
5V Standby with					
cover				89	
CHD250PS12:	ġ.	Sp 9			-
12V/9.17A,					
5V/0.5A					
(112.5W)	7	PCB @	130.0		
Convection with	~~	TR5,D5			
5V Standby with					
cover				104	
CUD 2 FARCA 2	9				
CHD250PS12: 12V/9.17A,					
5V/0.5A					
(112.5W)	8	D24 BODY	140.0		
Convection with	77	32.030			
5V Standby with					
cover				104	
CHD250PS12:	=		1	5	
12V/9.17A,		14600	130.0		
5V/0.5A	9	L4 COIL	130.0	2000271	
(112.5W)				103	
/TTC. 2041				7	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

	-	Vi		4 X
	-0			
1.0	13 COII	130.0		
+6	Beoil	130.0		
			101	
			100	
	ľ			
11	L5 COIL	130.0		
			614003	
			96	
	35		3	(
12	PCB @ TR27	130.0		
	11270 11270			
			94	
	*		9	
13	T1 COIL	130.0		
		Secretary April 1971		
			94	
14	T1 COPE	130.0		
1.9	IT COKE	130.0		
			94	
	12	11 L5 COIL 12 PCB @ TR27	11 L5 COIL 130.0 12 PCB @ TR27 130.0	11 L5 COIL 130.0 96 12 PCB @ TR27 130.0 94 13 T1 COIL 130.0 94

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

cover					
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	15	T2 BODY	130.0	98	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	16	ТЗ ВОДУ	130.0	97	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	17	C34 BODY	105.0	90	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	18	L9 COIL	130.0	87	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	19	PBC @ TR16	130.0	91	
CHD250PS12:	20	CON1 BODY	105.0	80	

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IEC 60601-1				
Clause	Requirement + Test	Result - Remark	Verdict	

2					2
12V/9.17A,]
5V/0.5A					
(112.5W)					
Convection with					
5V Standby with					
cover					
CHD250PS12:					
12V/9.17A,					
5V/0.5A					
(112.5W)	21	T1 COIL-SB	130.0		
Convection with					
5V Standby with					
cover				94	
CHD250PS12:	5		>	5	5
12V/9.17A,					
5V/0.5A					
(112.5W)	22	T1 CORE-SB	130.0		
Convection with					
5V Standby with					
cover				94	
CHD250PS12:			<u> </u>		:
12V/9.17A,					
5V/0.5A					
(112.5W)	23	C7 BODY-\$B	105.0		
Convection with					
5V Standby with					
cover				86	
CHD250PS12:		1			
12V/9.17A,					
5V/0.5A					
(112.5W)	24	L1 COIL-SB	130.0		
Convection with		10000000000000000000000000000000000000	Constitute.		
5V Standby with					
cover				89	
CHD250PS12:	E			E- 12	
12V/9.17A,	25	C14 BODY-SB	105.0		
5V/0.5A	1000001		en natiff	00	
(112.5W)				99	

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

29	£66				g 79
Convection with 5V Standby with cover					
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	1	T ambient	70	70	Tested at 264Vac, 50Hz, duration 2h
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	2	FS1 BODY	125.0	83	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	3	L1 COIL	130.0	85	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	4	L2 COIL	130.0	92	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with	5	C64 BODY	105.0	88	

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

ê O		<u> </u>	2	up.	
cover					
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	6	OPTO 1 BODY	105.0	86	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	7	PCB @ TR5,D5	130.0	99	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	8	D24 BODY	140.0	99	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	9	L4 COIL	130.0	97	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	10	13 CO L	130.0	95	
CHD250PS12:	11	L5 COIL	130.0	95	

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IEC 60601-1				
Clause	Requirement + Test	Result - Remark	Verdict	

80		<u> </u>	W	ate of	2 30
12V/9.17A,]
5V/0.5A					
(112.5W)					
Convection with					
5V Standby with					
cover					
CHD250PS12:	-				
12V/9.17A,					
5V/0.5A					
(112.5W)	12	PCB @ TR27	130.0		
Convection with					
5V Standby with					
cover				92	
CHD250PS12:					
12V/9.17A,					
5V/0.5A					
(112.5W)	13	T1 COIL	130.0		
Convection with	113	IT COIL	130.0		
5V Standby with					
cover				93	
		40		- 33	
CHD250PS12:					
12V/9.17A,					
5V/0.5A					
(112.5W)	14	T1 CORE	130.0		
Convection with					
5V Standby with					
cover				93	
CHD250PS12:		*		8	
12V/9.17A,					
5V/0.5A					
(112.5W)	15	T2 BODY	130.0		
Convection with					
5V Standby with					
cover				96	
CHD250PS12:				9	
12V/9.17A,	16	T3 BODY	130.0		
5V/0.5A	S. M. C.	and the second s	A STATE MANY	OF.	
(112.5W)				95	l

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IEC 60601-1				
Clause	Requirement + Test	Result - Remark	Verdict	

S. Paraconaldo anticipado de paraco	ê	7	Y	gs-	
Convection with					
5V Standby with					
cover					
CHD250PS12:		+			
12V/9.17A,					
5V/0.5A					
(112.5W)	17	C34 BODY	105.0		
Convection with	94400	1000 and and and an and an and	5-400-00-00-00-00-00-00-00-00-00-00-00-00		
5V Standby with					
cover				89	
384C7050C				1896	
CHD250PS12:		Ĭ		ĺ	
12V/9.17A,					
5V/0.5A					
(112.5W)	18	L9 COIL	130.0		
Convection with					
5V Standby with				Same a	
cover				86	
CHD250PS12:	er En	3:		3	
12V/9.17A,					
5V/0.5A					
(112.5W)	19	PBC @ TR16	130.0		
Convection with					
5V Standby with					
cover				90	
CHD250PS12:	5	+			
12V/9.17A,					
5V/0.5A					
(112.5W)	20	CON1 BODY	105.0		
Convection with	20	CONT BODY	103.0		
5V Standby with					
cover				79	
PO ACI				13	
CHD250PS12:	**	SV.		20	
12V/9.17A,					
5V/0.5A	21	T1 COIL-SB	130.0		
(112.5W)					
Convection with				92	
5V Standby with				V3(47)	

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IEC 60601-1				
Clause	Requirement + Test	Result - Remark	Verdict	

	266	2	û	95	2 X
cover					
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	22	T1 CORE-S8	130.0	92	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	23	C7 BODY-\$B	105.0	84	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	24	L1 COIL-SB	130.0	87	
CHD250PS12: 12V/9.17A, 5V/0.5A (112.5W) Convection with 5V Standby with cover	25	C14 BODY-\$B	105.0	95	
CHD250PS24: 24V/10.4A (250W) Convection	Ĭ.	TAMBIENT	50.0	50	Tested at 90Vac, 50Hz, duration:2h
CHD250PS24: 24V/10.4A (250W) Convection	2	FS1 BODY	125.0	91	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS24: 24V/10.4A (250W) Convection	3	L1 COIL	130.0	99	
CHD250PS24: 24V/10.4A (250W) Convection	4	L2 COIL	130.0	111	
CHD250PS24: 24V/10.4A (250W) Convection	:5	C64 BODY	105.0	82	
CHD250PS24: 24V/10.4A (250W) Convection	6	OPTO 1 BODY	105.0	87	
CHD250PS24: 24V/10.4A (250W) Convection	7	PCB @ TR5,D5	130.0	108	
CHD250PS24: 24V/10.4A (250W) Convection	8	D24 BODY	140.0	119	
CHD250PS24: 24V/10.4A (250W) Convection	g	L4 COIL	130.0	103	
CHD250PS24: 24V/10.4A (250W) Convection	10	B COIL	130.0	113	
CHD250PS24: 24V/10.4A (250W)	11	L5 COIL	130.0	105	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

	_6:	62			X X
Convection					
CHD250PS24: 24V/10.4A (250W) Convection	12	PCB @ TR27	130.0	91	
CHD250PS24: 24V/10.4A (250W) Convection	13	T1 COIL	130.0	103	
CHD250PS24: 24V/10.4A (250W) Convection	14	T1 CORE	130.0	104	
CHD250PS24: 24V/10.4A (250W) Convection	15	T2 BODY	130.0	99	
CHD250PS24: 24V/10.4A (250W) Convection	16	тз вору	130.0	.95	
CHD250PS24: 24V/10.4A (250W) Convection	17	C34 BODY	105.0	84	
CHD250P\$24: 24V/10.4A (250W) Convection	18	L9 COIL	130.0	82	
CHD250PS24: 24V/10.4A (250W) Convection	19	PBC @ TR16	130.0	90	
CHD250PS24: 24V/10.4A	20	CON1 BODY	105.0	.71	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

- Vallagerium	-	ş	<u> </u>	ap.	S4:
(250W) Convection					
CHD250PS24: 24V/10.4A (250W) Convection	1, 200	TAMBIENT	50.0	50	Tested at 100 Vac, 50 Hz; duration 2 h
CHD250PS24: 24V/10.4A (250W) Convection	2	FS1 BODY	125.0	83	
CHD250PS24: 24V/10.4A (250W) Convection	3	L1 COIL	130.0	90	
CHD250PS24: 24V/10.4A (250W) Convection	4	L2 COIL	130.0	105	
CHD250PS24: 24V/10.4A (250W) Convection	.5	C64 BODY	105.0	79	
CHD250PS24: 24V/10.4A (250W) Convection	6	OPTO 1 BODY	105.0	86	
CHD250PS24: 24V/10.4A (250W) Convection	7	PCB @ TR5,D5	130.0	104	
CHD250PS24: 24V/10.4A (250W) Convection	8	D24 BODY	140.0	113	
CHD250PS24:	9	L4 COIL	130.0	100	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

	266				2 27
24V/10.4A (250W) Convection					
CHD250PS24: 24V/10.4A (250W) Convection	10	13 COIL	130.0	110	
CHD250PS24: 24V/10.4A (250W) Convection	11	L5 COIL	130.0	104	
CHD250PS24: 24V/10.4A (250W) Convection	12	PCB @ TR27	130.0	90	
CHD250PS24: 24V/10.4A (250W) Convection	13	T1 COIL	130.0	102	
CHD250PS24: 24V/10.4A (250W) Convection	14	T1 CORE	130.0	103	
CHD250PS24: 24V/10.4A (250W) Convection	15	T2 BODY	130.0	98	
CHD250PS24: 24V/10.4A (250W) Convection	16	тэ вору	130.0	94	
CHD250PS24: 24V/10.4A (250W) Convection	17	C34 BODY	105.0	83	

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IEC 60601-1				
Clause	Requirement + Test	Result - Remark	Verdict	

CHD250P524: 24V/10.4A (250W) Convection	18	L9 COIL	130.0	82	
CHD250PS24: 24V/10.4A (250W) Convection	19	PBC@TR16	130.0	89	
CHD250PS24: 24V/10.4A (250W) Convection	20	CON1 BODY	105.0	68	Tested at 240 vac, 50Hz; Duration 2h
CHD250PS24: 24V/10.4A (250W) Convection	1	T AMBIENT	50.0	50	Tested at 240 Vac, .50 Hz, duration:2h
CHD250PS24: 24V/10.4A (250W) Convection	2	FS1 BODY	125.0	65	
CHD250PS24: 24V/10.4A (250W) Convection	3	L1 COIL	130.0	69	
CHD250PS24: 24V/10.4A (250W) Convection	4	L2 COIL	130.0	79	
CHD250PS24: 24V/10.4A (250W) Convection	5	C64 BODY	105.0	70	
CHD250PS24: 24V/10.4A (250W)	6	ОРТО 1 ВОДУ	105.0	72	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

	66				2 2
Convection					
CHD250PS24: 24V/10.4A (250W) Convection	7.	PCB @ TR5,D5	130.0	84	
CHD250PS24: 24V/10.4A (250W) Convection	8	D24 BODY	140.0	86	
CHD250PS24: 24V/10.4A (250W) Convection	9	L4 COIL	130.0	79	
CHD250PS24: 24V/10.4A (250W) Convection	10	L3 COIL	130.0	83	,
CHD250PS24: 24V/10.4A (250W) Convection	11	L5 COIL	130.0	101	
CHD250PS24: 24V/10.4A (250W) Convection	12	PCB @ TR27	130.0	88	
CHD250PS24: 24V/10.4A (250W) Convection	13	T1 COIL	130.0	99	
CHD250PS24: 24V/10.4A (250W) Convection	14	T1 CORE	130.0	100	
CHD250PS24: 24V/10.4A	15	T2 BODY	130.0	84	8

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

(250W) Convection					
CHD250PS24: 24V/10.4A (250W) Convection	16	тз вору	130.0	78	
CHD250PS24: 24V/10.4A (250W) Convection	17	C34 BODY	105.0	77	
CHD250PS24: 24V/10.4A (250W) Convection	18	L9 COIL	130.0	79	
CHD250PS24: 24V/10.4A (250W) Convection	19	PBC@TR16	130.0	89	
CHD250PS24: 24V/10.4A (250W) Convection	20	CON1 BODY	105.0	59	
CHD250PS24: 24V/10.4A (250W) Convection	1	TAMBIENT	50.0	50	Tested at 264Vac, 50Hz, Duration 2h
CHD250PS24: 24V/10.4A (250W) Convection	2	FS1 BODY	125.0	66	
CHD250PS24: 24V/10.4A (250W) Convection	3	L1 COIL	130.0	70	
CHD250PS24:	4	L2 COIL	130.0	79	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

æ	26	<u> </u>	2	pt:	g 27
24V/10.4A (250W) Convection					
CHD250PS24: 24V/10.4A (250W) Convection	5	C64 BODY	105.0	71	
CHD250PS24: 24V/10.4A (250W) Convection	6	орто 1 вору	105.0	72	
CHD250PS24: 24V/10.4A (250W) Convection	ž	PCB @ TR5,D5	130.0	84	
CHD250PS24: 24V/10.4A (250W) Convection	8	D24 BODY	140.0	86	
CHD250PS24: 24V/10.4A (250W) Convection	9	L4 COIL	130.0	77	
CHD250PS24: 24V/10.4A (250W) Convection	10	L3 COIL	130.0	82	
CHD250PS24: 24V/10.4A (250W) Convection	11	L5 COIL	130.0	102	
CHD250PS24: 24V/10.4A (250W) Convection	12	PCB @ TR27	130.0	88	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

CHD250PS24: 24V/10.4A (250W) Convection	13	T1 COIL	130.0	99	
CHD250PS24: 24V/10.4A (250W) Convection	14	T1 CORE	130.0	100	
CHD250PS24: 24V/10.4A (250W) Convection	15	T2 BODY	130.0	83	
CHD250PS24: 24V/10.4A (250W) Convection	16	тз вору	130.0	77	
CHD250PS24: 24V/10.4A (250W) Convection	17	C34 BODY	105.0	77°	
CHD250PS24: 24V/10.4A (250W) Convection	18	L9 COIL	130.0	79	
CHD250PS24: 24V/10.4A (250W) Convection	19	PBC @ TR16	130.0	88	
CHD250PS24: 24V/10.4A (250W) Convection	20	CON1 BODY	105.0	59	
CHD250PS24: 24V/9.04A (217W) Convection with	1	TAMBIENT	50.0	50	Tested at 9DVac, 5DHz, duration 2 h

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

		-	9	2	- X
Cover					
CHD250PS24: 24V/9.04A (217W) Convection with Cover	2	FS1 BODY	125.0	86	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	3	L1 COIL	130.0	93	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	4	L2 COIL	130.0	109	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	5	C64 BODY	105.0	88	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	6	OPTO 1 BODY	105.0	84	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	7	PCB @ TR5,D5	130.0	118	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	8	D24 BODY	140.0	122	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

CHD250PS24: 24V/9.04A (217W) Convection with Cover	9	L4 COIL	130.0	107	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	10	L3 COIL	130.0	118	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	11	L5 COIL	130.0	102	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	12	PCB @ TR27	130.0	89	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	13	T1 COIL	130.0	99	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	14	T1 CORE	130.0	99	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	15	T2 BODY	130.0	98	
CHD250PS24: 24V/9.04A	16	тз вору	130.0	96	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

	46	<u> </u>	V6	99	2 22
(217W) Convection with Cover					
CHD250PS24: 24V/9.04A (217W) Convection with Cover	17	C34 BODY	105.0	84	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	18	L9 COIL	130.0	80	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	19	PBC @ TR16	130.0	87	1
CHD250PS24: 24V/9.04A (217W) Convection with Cover	20	CON1 BODY	105.0	71	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	ĭ	T AMBIENT	50.0	50	Tested at 264Vac, 50Hz, duration 2h
CHD250PS24: 24V/9.04A (217W) Convection with Cover	2	FS1 BODY	125.0	68	
CHD250PS24: 24V/9.04A (217W) Convection with	3	L1 COIL	130.0	72	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

		62 0		25	· · ·
Cover					
CHD250PS24: 24V/9.04A (217W) Convection with Cover	4	L2 COIL	130.0	84	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	5	C64 BODY	105.0	76	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	6	OPTO 1 BODY	105.0	75	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	7	PCB @ TR5,D5	130.0	94	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	8	D24 BODY	140.0	95	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	9	L4 COIL	130.0	85	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	10	L3 COIL	130.0	92	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS24: 24V/9.04A (217W) Convection with Cover	11	L5 COIL	130.0	96	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	12	PCB @ TR27	130.0	85	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	13	T1 COIL	130.0	95	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	14	T1 CORE	130.0	95	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	15	T2 BODY	130.0	90	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	16	T3 BODY	130.0	85	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	17	C34 BODY	105.0	79	
CHD250PS24: 24V/9.04A	18	L9 COIL	130.0	777	i

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

9			ű.	25	4 %
(217W) Convection with Cover					
CHD250PS24; 24V/9.04A (217W) Convection with Cover	19	PBC @ TR16	130.0	84	
CHD250PS24: 24V/9.04A (217W) Convection with Cover	20	CON1 BODY	105.0	61	
CHD250PS24: 24V/5.2A (125W) Convection	1	T AMBIENT	70.0	70	Tested at 90Vac, 50Hz, duration 2 h
CHD250PS24: 24V/5.2A (125W) Convection	2	FS1 BODY	125.0	84	1
CHD250PS24: 24V/5.2A (125W) Convection	3	L1 COIL	130.0	87	
CHD250PS24: 24V/5.2A (125W) Convection	4	L2 COIL	130.0	96	
CHD250PS24: 24V/5.2A (125W) Convection	.5	C64 BODY	105.0	87	
CHD250PS24: 24V/5.2A (125W) Convection	6	орто 1 вору	105.0	88	
CHD250PS24: 24V/5.2A (125W) Convection	7	PCB @ TR5,D5	130.0	99	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS24: 24V/5.2A (125W) Convection	8	D24 BODY	140.0	103	
CHD250PS24: 24V/5.2A (125W) Convection	9	L4 COIL	130.0	96	
CHD250PS24: 24V/5.2A (125W) Convection	10	L3 COIL	130.0	101	
CHD250PS24: 24V/5.2A (125W) Convection	11	L5 COIL	130.0	95	
CHD250PS24: 24V/5.2A (125W) Convection	12	PCB @ TR27	130.0	90	
CHD250PS24: 24V/5.2A (125W) Convection	13	T1 COIL	130.0	92	
CHD250PS24: 24V/5.2A (125W) Convection	14	T1 CORE	130.0	93	
CHD250PS24: 24V/5.2A (125W) Convection	15	T2 BODY	130.0	93	
CHD250PS24: 24V/5.2A (125W) Convection	16	тз вору	130.0	92	
CHD250PS24: 24V/5.2A (125W) Convection	17	C34 BODY	105.0	85	
CHD250PS24: 24V/5.2A (125W) Convection	18	L9 COIL	130.0	84	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

CHD250PS24: 24V/5.2A (125W) Convection	19	PBC@TR16	130.0	87	
CHD250PS24: 24V/5.2A (125W) Convection	20	CON1 BODY	105.0	78	
CHD250PS24: 24V/5.2A (125W) Convection	1	TAMBIENT	70.0	70	Tested at 264 Vac, 50 Hz, duration 2h
CHD250PS24: 24V/5.2A (125W) Convection	2	FS1 BODY	125.0	80	
CHD250PS24: 24V/5.2A (125W) Convection	3	L1 COIL	130.0	82	
CHD250PS24: 24V/5.2A (125W) Convection	4	L2 COIL	130.0	89	
CHD250PS24: 24V/5.2A (125W) Convection	5	C64 BODY	105.0	85	
CHD250PS24: 24V/5.2A (125W) Convection	6	орто 1 вору	105.0	84	
CHD250PS24: 24V/5.2A (125W) Convection	Ž	PCB @ TR5,D5	130.0	92	
CHD250PS24: 24V/5.2A (125W) Convection	8	D24 BODY	140.0	93	
CHD250PS24: 24V/5.2A (125W) Convection	9	L4 COIL	130.0	86	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS24: 24V/5.2A (125W) Convection	10	L3 COIL	130.0	91	
CHD250PS24: 24V/5.2A (125W) Convection	11	L5 COIL	130.0	94	
CHD250PS24: 24V/5.2A (125W) Convection	12	PCB @ TR27	130.0	89	
CHD250PS24: 24V/5.2A (125W) Convection	13	T1 COIL	130.0	.91	
CHD250PS24: 24V/5.2A (125W) Convection	14	T1 CORE	130.0	93	:
CHD250PS24: 24V/5.2A (125W) Convection	15	T2 BODY	130.0	91	1
CHD250PS24: 24V/5.2A (125W) Convection	16	тз вору	130.0	88	
CHD250PS24: 24V/5.2A (125W) Convection	17	C34 BODY	105.0	84	
CHD250PS24: 24V/5.2A (125W) Convection	18	L9 COIL	130.0	83	
CHD250PS24: 24V/5.2A (125W) Convection	19	PBC @ TR16	130.0	87	
CHD250PS24: 24V/5.2A (125W) Convection	20	CON1 BODY	105.0	76	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

	£	12	Ø.	up t	2 X
CHD250PS24: 24V/4.52A (109W) Convection with Cover	1	TAMBIENT	70.0	70	Tested at 9DVac, 5DHz, Duration:2h
CHD250PS24: 24V/4.52A (109W) Convection with Cover	2	FS1 BODY	125.0	82	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	3	L1 COIL	130.0	84	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	4	L2 COIL	130.0	91	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	5	C64 BODY	105.0	88	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	6	OPTO 1 BODY	105.0	84	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	7	PCB @ TR5,D5	130.0	96	
CHD250PS24: 24V/4.52A	8	D24 BODY	140.0	96	i)

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

	66	<u> </u>	vii		2 20
(109W) Convection with Cover					
CHD250PS24; 24V/4.52A (109W) Convection with Cover	9	L4 COIL	130.0	89	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	10	L3 COIL	130.0	.94	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	11	L5 COIL	130.0	95	1
CHD250PS24: 24V/4.52A (109W) Convection with Cover	12	PCB @ TR27	130.0	90	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	13	T1 COIL	130.0	91	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	14	T1 CORE	130.0	.92	
CHD250PS24: 24V/4.52A (109W) Convection with	15	T2 BODY	130.0	92	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

		-	¥	98:	¥ X
Cover					
CHD250PS24: 24V/4.52A (109W) Convection with Cover	16	ТЗ ВОДУ	130.0	90	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	17	C34 BODY	105.0	85	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	18	L9 COIL	130.0	84	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	19	PBC @ TR16	130.0	87	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	20	CON1 BODY	105.0	78	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	1	T AMBIENT	70.0	70	Tested at 264Vac, 5DHz; duration:2h
CHD250PS24: 24V/4.52A (109W) Convection with Cover	2	FS1 BODY	125.0	86	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS24: 24V/4.52A (109W) Convection with Cover	3	L1 COIL	130.0	89	
CHD250PS24: 24V/4.52A {109W} Convection with Cover	4	L2 COIL	130.0	98	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	.5	C64 BODY	105.0	91	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	6	OPTO 1 BODY	105.0	88	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	Ž	PCB @ TR5,D5	130.0	106	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	8	D24 BODY	140.0	107	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	9	L4 COIL	130.0	99	
CHD250PS24: 24V/4.52A	10	L3 COIL	130.0	105	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

Ø	200	<u> </u>	300	945:	2 20
(109W) Convection with Cover					
CHD250PS24; 24V/4.52A (109W) Convection with Cover	11	L5 COIL	130.0	97	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	12	PCB @ TR27	130.0	92	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	13	T1 COIL	130.0	92	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	14	T1 CORE	130.0	92	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	15	T2 BODY	130.0	93	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	16	ТЗ ВОДУ	130.0	.95	
CHD250PS24: 24V/4.52A (109W) Convection with	17	C34 BODY	105.0	94	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

0		-	W.	up. p	X X
Cover					
CHD250PS24: 24V/4.52A (109W) Convection with Cover	18	L9 COIL	130.0	87	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	19	PBC @ TR16	130.0	88	
CHD250PS24: 24V/4.52A (109W) Convection with Cover	20	CON1 BODY	105.0	80	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	1	TAMBIENT	50.0	50	Tested at 9DVac, 5DHz, Duration:2h
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	2	FS1 BODY	125.0	85	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	3	L1 COIL	130.0	92	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	4	L2 COIL	130.0	105.	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	5	C64 BODY	105.0	79	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	6	OPTO 1 BODY	105.0	88	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	7	PCB @ TR5,D5	130.0	104	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	8	D24 BODY	140.0	113	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	9	L4 COIL	130.0	105	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	10	L3 COIL	130.0	114	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	11	L5 COIL	130.0	99	
CHD250PS24: 24V/9.17A,	12	PCB @ TR27	130.0	85	10

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

		<u> </u>		up d	<u> </u>
5V/1A (220.5W) Convection with 5V Stdby					
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	13	T1 COIL	130.0	97	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	14	T1 CORE	130.0	99	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	15	T2 BODY	130.0	106	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	16	тз вору	130.0	101	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	17	C34 BODY	105.0	87	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	18	L9 COIL	130.0	81	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with	19	PBC @ TR16	130.0	85	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

2		ş	Ý	9	4
5V Stdby					
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	20	CON1 BODY	105.0	70	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	21	T1 COIL-SB	130.0	107	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	22	T1 CORE-SB	130.0	77	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	23	C6 BODY-SB	105.0	83	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	24	L1 COIL-SB	130.0	81	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	25	C14 BODY-SB	125.0	109	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	1	T AMBIENT	50.0	50	Tested at 264Vac, 50Hz, Duration 2h

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IEC 60601-1					
	Clause Requirement + Test		Result - Remark	Verdict	

CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	2	FS1 BODY	125.0	66	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	3	L1 COIL	130.0	70	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	4	L2 COIL	130.0	82	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	.5	C64 BODY	105.0	71	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	6	OPTO 1 BODY	105.0	79	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	7	PCB @ TR5,D5	130.0	86	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	8	D24 BODY	140.0	90	
CHD250PS24: 24V/9.17A,	9	L4 COIL	130.0	86	32

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

÷	65	82	300	945:	g x
5V/1A (220.5W) Convection with 5V Stdby					
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	10	L3 COIL	130.0	92	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	11	L5 COIL	130.0	95	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	12	PCB @ TR27	130.0	83	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	13	T1 COIL	130.0	94	
CHD250PS24; 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	14	T1 CORE	130.0	97	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	15	T2 BODY	130.0	99	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with	16	тз вору	130.0	93	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

	66	<u> </u>	X2		2 8
5V Stdby					
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	17	C34 BODY	105.0	82	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	18	L9 COIL	130.0	78	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	19	PBC @ TR16	130.0	83	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	20	CON1 BODY	105.0	60	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	21	T1 COIL-SB	130.0	99	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	22	T1 CORE-SB	130.0	70	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	23	C6 BODY-SB	105.0	80	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	24	L1 COIL-SB	130.0	79	
CHD250PS24: 24V/9.17A, 5V/1A (220.5W) Convection with 5V Stdby	25	C14 BODY-SB	125.0	95	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	1	T AMBIENT	50.0	50	Tested at 9DVac, 5DHz, Duration:2h
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	2	FS1 BODY	125.0	87	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	3	L1 COIL	130.0	94	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	4	L2 COIL	130.0	107	
CHD250PS24: 24V/6.67A, 5V/1A (165W)	.5	C64 BODY	105,0	81	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

	200	<u> </u>	2	35	- W
Convection with Cover and 5V Stdby					
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	6	OPTO 1 BODY	105.0	90	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	7	PCB @ TR5,05	130.0	106	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	g	D24 BODY	140.0	115	5
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	9	L4 COIL	130.0	107	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	10	13 COIL	130.0	117	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with	11	L5 COIL	130.0	102	1

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

					g 20
Cover and 5V Stdby					
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	12	PCB @ TR27	130.0	88	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	13	TI COIL	130.0	100	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	14	T1 CORE	130.0	101	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	15	T2 BODY	130.0	108	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	16	ТЗ ВОДУ	130.0	103	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V	17	C34 BODY	105.0	89	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

O. C.	i i		¥	10.	8
Stdby					
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	18	L9 COIL	130.0	84	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	19	PBC@TR16	130.0	89	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	20	CON1 BODY	105.0	72	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	21	T1 COIL-SB	130.0	110	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	22	T1 CORE-SB	130.0	80	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	23	C6 BODY-SB	105.0	85	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	24	L1 COIL-SB	130.0	84	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	25	C14 BODY-SB	125.0	112	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	1	T AMBIENT	50.0	50	Tested at 264Vac, 50Hz; duration:2h
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	2	FS1 BODY	125.0	67	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	3	L1 COIL	130.0	72	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	4	L2 COIL	130.0	83	
CHD250PS24:	5	C64 BODY	105.0	75	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

æ		2	va	98:	2 79
24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby					
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	6	ОРТО 1 ВОДУ	105.0	81	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	7	PCB @ TR5,D5	130.0	92	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	8	D24 BODY	140.0	.92	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	9	L4 COIL	130.0	89	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	10	L3 COIL	130.0	95	
CHD250PS24: 24V/6.67A,	11	L5 COIL	130.0	98	į.

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IEC 60601-1						
Clause Requirement + Test		Result - Remark	Verdict			

		-	Y	98: P	4 X
5V/1A (165W) Convection with Cover and 5V Stdby					
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	12	PCB @ TR27	130.0	86	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	13	T1 COIL	130.0	96	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	14	T1 CORE	130.0	99	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	15	T2 BODY	130.0	102	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	16	ТЗ ВОДУ	130.0	95	
CHD250PS24: 24V/6.67A, 5V/1A (165W)	17	C34 BODY	105.0	84	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

8		82	· · · · · · · · · · · · · · · · · · ·	up d	g XX
Convection with Cover and 5V Stdby					
CHD250PS24; 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	18	L9 COIL	130.0	81	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	19	PBC @ TR16	130.0	85	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	20	CON1 BODY	105.0	63	1
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	21	T1 COIL-SB	130.0	101	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	22	T1 CORE-SB	130.0	73	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with	23	C6 BODY-SB	105.0	82	

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IEC 60601-1							
Clause	Requirement + Test	Result - Remark	Verdict				

20	#56				9 27
Cover and 5V Stdby					
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	24	L1 COIL-SB	130.0	80	
CHD250PS24: 24V/6.67A, 5V/1A (165W) Convection with Cover and 5V Stdby	25	C14 BODY-SB	125.0	97	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	1	T AMBIENT	70.0	70	Tested at 90Vac, 50Hz, Duration: 2h
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	2	FS1 BODY	125.0	84	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	3	L1 COIL	130.0	87	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with	4	L2 COIL	130.0	98	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

	65				g W
5V Stdby					
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	5	C64 BODY	105.0	90	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	6	OPTO 1 BODY	105.0	88	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	7.	PCB @ TR5,D5	130.0	105	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	8	D24 BODY	140.0	106	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	9	L4 COIL	130.0	101	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	10	L3 COIL	130.0	107	

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IEC 60601-1							
Clause	Requirement + Test	Result - Remark	Verdict				

CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	11	L5 COIL	130.0	96	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	12	PCB @ TR27	130.0	91	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	13	T1 COIL	130.0	92	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	14	T1 CORE	130.0	93	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	15	T2 BODY	130.0	99	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	16	ТЗ ВОДУ	130.0	98	
CHD250PS24:	17	C34 BODY	105.0	89	1

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IEC 60601-1						
	Clause	Requirement + Test	Result - Remark	Verdict		

24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby					
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	18	L9 COIL	130.0	85	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	19	PBC@TR16	130.0	87	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	20	CON1 BODY	105.0	79	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	21	T1 COIL-SB	130.0	100	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	22	T1 CORE-SB	130.0	84	
CHD250PS24: 24V/4.52A,	23	C6 BODY-SB	105.0	.87	j.

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

8	26				27
5V/0.5A (112.5W) Convection with 5V Stdby					
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	24	L1 COIL-SB	130.0	86	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	25	C14 BODY-SB	105.0	101	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	1	T AMBIENT	70.0	70	Tested at 264 Vac, 50 Hz; Duration:2h
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	2	FS1 BODY	125.0	81	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	3	L1 COIL	130.0	83	
CHD250PS24: 24V/4.52A, 5V/0.5A	4	L2 COIL	130.0	93	

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IEC 60601-1					
	Clause	Requirement + Test	Result - Remark	Verdict	

(112.5W) Convection with 5V Stdby					
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	×5	C64 BODY	105.0	87	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	6	OPTO 1 BODY	105.0	85	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	7	PCB@ TR5,D5	130.0	99	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	8	D24 BODY	140.0	99	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	g	L4 COIL	130.0	95	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W)	10	L3 COIL	130.0	97	*

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

Convection with 5V Stdby					
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	11	L5 COIL	130.0	94	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	12	PCB @ TR27	130.0	90	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	13	T1 COIL	130.0	91	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	14	T1 CORE	130.0	92	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	15	T2 BODY	130.0	97	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with	16	ТЗ ВОДУ	130.0	95	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

	65				g w
5V Stdby					
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	17	C34 B0DY	105.0	87	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	18	L9 COIL	130.0	84	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	19	PBC @ TR16	130.0	86	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	20	CON1 BODY	105.0	78	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	21	T1 COIL-SB	130.0	97	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	22	T1 CORE-SB	130.0	81	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	23	C6 BODY-\$B	105.0	86	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	24	L1 COIL-SB	130.0	86	
CHD250PS24: 24V/4.52A, 5V/0.5A (112.5W) Convection with 5V Stdby	25	C14 BODY-SB	105.0	96	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	1	T AMBIENT	70.0	70	Tested at 90Vac, 50Hz; Duration 2h
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	2	FS1 BODY	125.0	84	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	3	L1 COIL	130.0	87	
CHD250PS24:	4	L2 COIL	130.0	98	0

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

e Head revisitions individue		i i	<u> </u>	20	
24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby					
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	% 5	C64 BODY	105.0	90	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	6	OPTO 1 BODY	105.0	88	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	7	PCB @ TR5,D5	130.0	105	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	8	D24 BODY	140.0	106	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	9	L4 COIL	130.0	101	
CHD250PS24: 24V/3.33A,	10	L3 COIL	130.0	107	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

æ :		<u> </u>	Võ	20 P	2 20
5V/0.5A (82.5W) Convection with Cover and 5V Stdby					
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	11	L5 COIL	130.0	96	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	12	PCB @ TR27	130.0	91	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	13	T1 COIL	130.0	92	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	14	T1 CORE	130.0	93	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	15	T2 BODY	130.0	99	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W)	16	тз вору	130.0	98	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

Convection with Cover and 5V Stdby					
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	17	C34 BODY	105.0	89	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	18	L9 COIL	130.0	85	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	19	PBC @ TR16	130.0	87	1
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	20	CON1 BODY	105.0	79	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	21	T1 COIL-SB	130.0	100	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with	22	T1 CORE-SB	130.0	87	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

Cover and 5V Stdby					
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	23	C6 BODY-SB	105.0	88	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	24	L1 COIL-SB	130.0	88	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	25	C14 BODY-SB	105.0	103	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	1	T AMBIENT	70.0	70	Tested at 264Vac, 50Hz; duration:2h
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	2	FS1 BODY	125.0	81	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V	3	L1 COIL	130.0	83	,

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IEC 60601-1						
Clause Requirement + Test		Result - Remark	Verdict			

and the second s	6		Ø .	T	X X
Stdby					
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	4	L2 COIL	130.0	93	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	5	C64 BODY	105.0	87	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	6	ОРТО 1 ВОДУ	105.0	85	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	7	PCB @ TR5,D5	130.0	99	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	Q	D24 BODY	140.0	99	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	9	L4 COIL	130.0	95	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

CHD250P524: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	10	L3 COIL	130.0	97	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	11	L5 COIL	130.0	94	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	12	PCB @ TR27	130.0	90	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	13	T1 COIL	130.0	91	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	14	T1 CORE	130.0	92	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	15	T2 BODY	130.0	97	
CHD250PS24:	16	тз вору	130.0	95	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby					
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	17	C34 BODY	105.0	87	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	18	L9 COIL	130.0	84	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	19	PBC @ TR16	130.0	86	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	20	CON1 BODY	105.0	78	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	21	T1 COIL-SB	130.0	97	
CHD250PS24: 24V/3.33A,	22	T1 CORE-SB	130.0	84	32

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

÷					2 20
5V/0.5A (82.5W) Convection with Cover and 5V Stdby					
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	23	C6 BODY-SB	105.0	86	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	24	L1 COIL-SB	130.0	87	
CHD250PS24: 24V/3.33A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	25	C14 BODY-SB	105.0	.98	2
CHD250PS48: 48V/5.2A (250W) Convection	1	T AMBIENT	50	50	Tested at 90Vac, 50Hz; Duration:2h
CHD250PS48: 48V/5.2A (250W) Convection	2	FS1 BODY	125.0	96	
CHD250PS48: 48V/5.2A (250W) Convection	3	L1 COIL	130.0	99	
CHD250PS48: 48V/5.2A (250W) Convection	4	L2 COIL	130.0	107	
CHD250PS48: 48V/5.2A (250W)	.5	C64 BODY	105.0	83	

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

Convection					
CHD250PS48: 48V/5.2A (250W) Convection	6	OPTO 1 BODY	105.0	87	
CHD250PS48: 48V/5.2A (250W) Convection	7	PC8 @ TR5,D5	130.0	109	
CHD250PS48: 48V/5.2A (250W) Convection	8	D24 BODY	140.0	117	
CHD250PS48: 48V/5.2A (250W) Convection	9	L4 COIL	130.0	101	
CHD250PS48: 48V/5.2A (250W) Convection	10	L3 COIL	130.0	110	
CHD250PS48: 48V/5.2A (250W) Convection	11	L5 COIL	130.0	107	
CHD250PS48: 48V/5.2A (250W) Convection	12	PCB @ TR27	130.0	100	
CHD250PS48: 48V/5.2A (250W) Convection	13	T1 COIL	130.0	109	
CHD250PS48: 48V/5.2A (250W) Convection	14	T1 CORE	130.0	119	
CHD250PS48: 48V/5.2A (250W) Convection	15	T2 BODY	130.0	96	
CHD250PS48: 48V/5.2A (250W)	16	тз вору	130.0	87	

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

Convection				1820	
CHD250PS48: 48V/5.2A (250W) Convection	17	C34 BODY	105.0	87	
CHD250PS48: 48V/5.2A (250W) Convection	18	L9 COIL	130.0	88	
CHD250PS48: 48V/5.2A (250W) Convection	19	PBC@TR16	130.0	95	
CHD250PS48: 48V/5.2A (250W) Convection	20	CON1 BODY	105.0	73	
CHD250PS48: 48V/5.2A (250W) Convection	1	T AMBIENT	50	50	Tested at 100 Vac, 50 Hz: Duration:2h
CHD250PS48: 48V/5.2A (250W) Convection	2	FS1 BODY	125.0	90	
CHD250PS48: 48V/5.2A (250W) Convection	3	L1 COIL	130.0	93	
CHD250PS48: 48V/5.2A (250W) Convection	4	L2 COIL	130.0	99	
CHD250PS48: 48V/5.2A (250W) Convection	.5	C64 BODY	105.0	80	
CHD250PS48: 48V/5.2A (250W) Convection	6	ОРТО 1 ВОДУ	105.0	85	
CHD250PS48: 48V/5.2A (250W)	7	PCB @ TR5,D5	130.0	101	

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

Convection				4	
CHD250PS48: 48V/5.2A (250W) Convection	8	D24 BODY	140.0	108	
CHD250PS48: 48V/5.2A (250W) Convection	9	L4 COIL	130.0	96	
CHD250PS48: 48V/5.2A (250W) Convection	10	L3 COIL	130.0	104	
CHD250PS48: 48V/5.2A (250W) Convection	11	L5 COIL	130.0	106	
CHD250PS48: 48V/5.2A (250W) Convection	12	PCB @ TR27	130.0	100	
CHD250PS48: 48V/5.2A (250W) Convection	13	T1 COIL	130.0	109	
CHD250PS48: 48V/5.2A (250W) Convection	14	T1 CORE	130.0	118	
CHD250PS48: 48V/5.2A (250W) Convection	15	T2 BODY	130.0	95	
CHD250PS48: 48V/5.2A (250W) Convection	16	T3 BODY	130.0	86	
CHD250PS48: 48V/5.2A (250W) Convection	17	C34 BODY	105.0	86	
CHD250PS48: 48V/5.2A (250W)	18	L9 COIL	130.0	88	

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

Convection				100	40
CHD250PS48: 48V/5.2A (250W) Convection	19	PBC @ TR16	130.0	95	
CHD250PS48: 48V/5.2A (250W) Convection	20	CON1 BODY	105.0	71	
CHD250PS48: 48V/5.2A (250W) Convection	1	T AMBIENT	50	50	Tested at 240 Vac, 50 Hz, duration:2h
CHD250PS48: 48V/5.2A (250W) Convection	2	FS1 BODY	125.0	68	
CHD250PS48: 48V/5.2A (250W) Convection	3	L1 COIL	130.0	70	
CHD250PS48: 48V/5.2A (250W) Convection	4	L2 COIL	130.0	78	
CHD250PS48: 48V/5.2A (250W) Convection	.5	C64 BODY	105.0	70	
CHD250PS48: 48V/5.2A (250W) Convection	6	OPTO 1 BODY	105.0	78	
CHD250PS48: 48V/5.2A (250W) Convection	7	PC8 @ TR5,D5	130.0	83	
CHD250PS48: 48V/5.2A (250W) Convection	8	D24 BODY	140.0	86	
CHD250PS48: 48V/5.2A (250W)	9	L4 COIL	130.0	79	

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

Convection					
CHD250PS48: 48V/5.2A (250W) Convection	10	L3 COIL	130.0	83	
CHD250PS48: 48V/5.2A (250W) Convection	11	L5 COIL	130.0	102	
CHD250PS48: 48V/5.2A (250W) Convection	12	PCB @ TR27	130.0	98	
CHD250PS48: 48V/5.2A (250W) Convection	13	T1 COIL	130.0	108	
CHD250PS48: 48V/5.2A (250W) Convection	14	T1 CORE	130.0	116	
CHD250PS48: 48V/5.2A (250W) Convection	15	T2 BODY	130.0	91	
CHD250PS48: 48V/5.2A (250W) Convection	16	тз вору	130.0	81	
CHD250PS48: 48V/5.2A (250W) Convection	17	C34 BODY	105.0	83	
CHD250PS48: 48V/5.2A (250W) Convection	18	L9 COIL	130.0	86	
CHD250PS48: 48V/5.2A (250W) Convection	19	PBC @ TR16	130.0	94	
CHD250PS48: 48V/5.2A (250W)	20	CON1 BODY	105.0	60	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

Convection					
CHD250PS48: 48V/5.2A (250W) Convection	ĩ	T AMBIENT	50	50	Tested at 264 Vac, 50 Hz; Duration 2h
CHD250PS48: 48V/5.2A (250W) Convection	2	FS1 BODY	125.0	68	
CHD250PS48: 48V/5.2A (250W) Convection	3	L1 COIL	130.0	70	
CHD250PS48: 48V/5.2A (250W) Convection	4	L2 COIL	130.0	78	
CHD250PS48: 48V/5.2A (250W) Convection	.5	C64 BODY	105.0	70	
CHD250PS48: 48V/5.2A (250W) Convection	6	OPTO 1 BODY	105.0	77	
CHD250PS48: 48V/5.2A (250W) Convection	Ž	PCB @ TR5,D5	130.0	83	
CHD250PS48: 48V/5.2A (250W) Convection	8	D24 BODY	140.0	86	
CHD250PS48: 48V/5.2A (250W) Convection	9	L4 COIL	130.0	78	
CHD250PS48: 48V/5.2A (250W) Convection	10	L3 COIL	130.0	81	
CHD250PS48: 48V/5.2A (250W)	11	L5 COIL	130.0	103	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

S		<u> </u>	000	into the state of	2 8
Convection					
CHD250PS48: 48V/5.2A (250W) Convection	12	PCB @ TR27	130.0	98	
CHD250PS48: 48V/5.2A (250W) Convection	13	T1 COIL	130.0	108	
CHD250PS48: 48V/5.2A (250W) Convection	14	T1 CORE	130.0	116	
CHD250PS48: 48V/5.2A (250W) Convection	15	T2 BODY	130.0	91	
CHD250PS48: 48V/5.2A (250W) Convection	16	T3 BODY	130.0	80	
CHD250PS48: 48V/5.2A (250W) Convection	17	C34 BODY	105.0	83	
CHD250PS48: 48V/5.2A (250W) Convection	18	L9 COIL	130.0	86	
CHD250PS48: 48V/5.2A (250W) Convection	19	PBC @ TR16	130.0	94	
CHD250PS48: 48V/5.2A (250W) Convection	20	CON1 BODY	105.0	60	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	1	T AMBIENT	50	50	Tested at 90Vax, 50Hz Duration:2h

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

CHD250PS48: 48V/4.52A (217W) Convection with Cover	2	FS1 BODY	125.0	85	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	3	L1 COIL	130.0	97	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	4	L2 COIL	130.0	112	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	.5	C64 BODY	105.0	93	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	6	OPTO 1 BODY	105.0	85	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	7	PCB @ TR5,D5	130.0	122	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	8	D24 BODY	140.0	96	
CHD250PS48: 48V/4.52A	9	L4 COIL	130.0	103	i i

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

(217W) Convection with Cover					
CHD250PS48: 48V/4.52A (217W) Convection with Cover	10	L3 COIL	130.0	106	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	.11	L5 COIL	130.0	107	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	12	PCB @ TR27	130.0	99	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	13	T1 COIL	130.0	106	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	14	T1 CORE	130.0	108	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	15	T2 BODY	130.0	.97	
CHD250PS48: 48V/4.52A (217W) Convection with	16	тз вору	130.0	88	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

0		ş	100	98: 3	4 X
Cover					
CHD250PS48: 48V/4.52A (217W) Convection with Cover	17	C34 BODY	105.0	86	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	18	L9 COIL	130.0	86	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	19	PBC @ TR16	130.0	93	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	20	CON1 BODY	105.0	74	1
CHD250PS48: 48V/4.52A (217W) Convection with Cover	1	TAMBIENT	50	50	Tested at 264 Vac, 50 Hz, Duration:2h
CHD250PS48: 48V/4.52A (217W) Convection with Cover	2	FS1 BODY	125.0	67	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	3	L1 COIL	130.0	72	

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IEC 60601-1					
	Clause	Requirement + Test	Result - Remark	Verdict	

CHD250PS48: 48V/4.52A (217W) Convection with Cover	4	L2 COIL	130.0	84	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	.5	C64 BODY	105.0	78	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	6	OPTO 1 BODY	105.0	76	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	7	PCB @ TR5,D5	130.0	93	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	8	D24 BODY	140.0	79	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	9	L4 COIL	130.0	83	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	10	L3 COIL	130.0	86	
CHD250PS48: 48V/4.52A	11	L5 COIL	130.0	102	1

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

(217W) Convection with Cover					
CHD250PS48: 48V/4.52A (217W) Convection with Cover	12	PCB @ TR27	130.0	96	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	13	T1 COIL	130.0	105	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	14	T1 CORE	130.0	106	
CHD250P548: 48V/4.52A (217W) Convection with Cover	15	T2 BODY	130.0	91	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	16	ТЗ ВОДУ	130.0	81	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	17	C34 BODY	105.0	82	
CHD250PS48: 48V/4.52A (217W) Convection with	18	L9 COIL	130.0	84	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

&					9 99
Cover					"
CHD250PS48: 48V/4.52A (217W) Convection with Cover	19	PBC @ TR16	130.0	92	
CHD250PS48: 48V/4.52A (217W) Convection with Cover	20	CON1 BODY	105.0	63	
CHD250PS48: 48V/2.6A (125W) Convection	1	T AMBIENT	1927	70	Tested at 90Vac, 50Hz; Duration:2h
CHD250PS48: 48V/2.6A (125W) Convection	2	FS1 BODY	125.0	87	
CHD250PS48: 48V/2.6A (125W) Convection	3	L1 COIL	130.0	88	
CHD250PS48: 48V/2.6A (125W) Convection	4	L2 COIL	130.0	94	
CHD250PS48: 48V/2.6A (125W) Convection	5	C64 BODY	105.0	86	
CHD250PS48: 48V/2.6A (125W) Convection	6	OPTO 1 BODY	105.0	88	
CHD250PS48: 48V/2.6A (125W) Convection	7	PCB @ TR5,D5	130.0	.97	
CHD250P\$48: 48V/2.6A (125W)	8	D24 BODY	140.0	100	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

Convection			8		
CHD250PS48: 48V/2.6A (125W) Convection	9	L4 COIL	130.0	93	
CHD250PS48: 48V/2.6A (125W) Convection	10	L3 COIL	130.0	98	
CHD250PS48: 48V/2.6A (125W) Convection	11	L5 COIL	130.0	97	
CHD250PS48: 48V/2.6A (125W) Convection	12	PCB @ TR27	130.0	95	
CHD250PS48: 48V/2.6A (125W) Convection	13	T1 COIL	130.0	96	
CHD250PS48: 48V/2.6A (125W) Convection	14	T1 CORE	130.0	99	
CHD250PS48: 48V/2.6A (125W) Convection	15	T2 BODY	130.0	93	
CHD250PS48: 48V/2.6A (125W) Convection	16	тз вору	130.0	89	
CHD250PS48: 48V/2.6A (125W) Convection	17	C34 BODY	105.0	88	
CHD250PS48: 48V/2.6A (125W) Convection	18	L9 COIL	130.0	88	
CHD250PS48: 48V/2.6A (125W)	19	PBC @ TR16	130.0	90	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

8		62	2		<u>at</u>
Convection					
CHD250PS48: 48V/2.6A (125W) Convection	20	CON1 BODY	105.0	79	
CHD250PS48: 48V/2.6A (125W) Convection	1	TAMBIENT	(20)	70	Tested at 100 Vac, 50 Hz, Duratio:2h
CHD250PS48: 48V/2.6A (125W) Convection	2	FS1 BODY	125.0	81	
CHD250PS48: 48V/2.6A (125W) Convection	3	L1 COIL	130.0	82	
CHD250PS48: 48V/2.6A (125W) Convection	4	L2 COIL	130.0	88	
CHD250PS48: 48V/2.6A (125W) Convection	5	C64 BODY	105.0	85	
CHD250PS48: 48V/2.6A (125W) Convection	6	OPTO 1 BODY	105.0	85	
CHD250PS48: 48V/2.6A (125W) Convection	Ž	PCB @ TR5,D5	130.0	92	
CHD250PS48: 48V/2.6A (125W) Convection	8	D24 BODY	140.0	94	
CHD250PS48: 48V/2.6A (125W) Convection	9	L4 COIL	130.0	86	
CHD250PS48: 48V/2.6A (125W)	10	L3 COIL	130.0	89	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

Convection					
CHD250PS48: 48V/2.6A (125W) Convection	11	L5 COIL	130.0	96	
CHD250PS48: 48V/2.6A (125W) Convection	12	PCB @ TR27	130.0	94	
CHD250PS48: 48V/2.6A (125W) Convection	13	T1 COIL	130.0	94	
CHD250PS48: 48V/2.6A (125W) Convection	14	T1 CORE	130.0	98	
CHD250PS48: 48V/2.6A (125W) Convection	15	T2 BODY	130.0	91	
CHD250PS48: 48V/2.6A (125W) Convection	16	тз вору	130.0	86	
CHD250PS48: 48V/2.6A (125W) Convection	17	C34 BODY	105.0	86	
CHD250PS48: 48V/2.6A (125W) Convection	18	L9 COIL	130.0	86	
CHD250PS48: 48V/2.6A (125W) Convection	19	PBC @ TR16	130.0	89	
CHD250PS48: 48V/2.6A (125W) Convection	20	CON1 BODY	105.0	76	
CHD250PS48: 48V/2.26A (108.5W)	1	T AMBIENT	927	70	Tested at 90Vac, 50Hz, Duration:2h

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

80	266		2	10 m	2 20
Convection with Cover					
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	2	FS1 BODY	125.0	85	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	3	L1 COIL	130.0	90	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	4	L2 COIL	130.0	100	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	75	C64 BODY	105.0	92	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	6	OPTO 1 BODY	105.0	89	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	7	PCB @ TR5,D5	130.0	106	
CHD250PS48: 48V/2.26A (108.5W) Convection with	8	D24 BODY	140.0	98	ř

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

0	5	\$	¥	98:	¥ X
Cover					
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	9	L4 COIL	130.0	101	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	10	L3 COIL	130.0	104	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	11	L5 COIL	130.0	101	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	12	PCB @ TR27	130.0	98	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	13	T1 COIL	130.0	98	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	14	T1 CORE	130.0	99	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	15	T2 BODY	130.0	97	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	16	тэ вору	130.0	93	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	17	C34 BODY	105.0	90	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	18	L9 COIL	130.0	89	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	19	PBC @ TR16	130.0	92	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	20	CON1 BODY	105.0	82	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	1	T AMBIENT		70	Tested at 264Vac, 50Hz, duration:2h
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	2	FS1 BODY	125.0	81	
CHD250PS48: 48V/2.26A	.3	L1 COIL	130.0	85	,,

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

(108.5W) Convection with Cover					
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	4	L2 COIL	130.0	93	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	5	C64 BODY	105.0	89	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	6	OPTO 1 BODY	105.0	86	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	7	PCB @ TR5,D5	130.0	100	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	8	D24 BODY	140.0	94	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	9	L4 COIL	130.0	.93	
CHD250PS48: 48V/2.26A (108.5W) Convection with	10	L3 COIL	130.0	94	1

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

Cover	8			10-	X.
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	11	L5 COIL	130.0	99	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	.12	PCB @ TR27	130.0	96	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	13	T1 COIL	130.0	96	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	14	T1 CORE	130.0	97	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	15	T2 BODY	130.0	94	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	16	ТЗ ВОДУ	130.0	90	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	17	C34 BODY	105.0	88	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	18	L9 COIL	130.0	88	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	19	PBC @ TR16	130.0	90	
CHD250PS48: 48V/2.26A (108.5W) Convection with Cover	20	CON1 BODY	105.0	79	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	1	TAMBIENT	*	50	Tested at 9DVac, 5DHz, duration:2h
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	2	FS1 BODY	125.0	85	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	3	L1 COIL	130.0	97	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	4	L2 COIL	130.0	110	
CHD250PS48: 48V/4.58A,	.5	C64 BODY	105.0	87	ı

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

5V/1A (225W) Convection with 5V Stdby					
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	6	OPTO 1 BODY	105.0	93	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	7	PCB @ TR5,D5	130.0	108	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	8	D24 BODY	140.0	119	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	9	L4 COIL	130.0	112	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	10	L3 COIL	130.0	118	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	11	L5 COIL	130.0	105	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with	12	PCB @ TR27	130.0	96	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

5V Stdby				25. 2	70
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	13	T1 COIL	130.0	102	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	14	T1 CORE	130.0	109	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	15	T2 BODY	130.0	110	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	16	тз вору	130.0	105	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	17	C34 BODY	105.0	92	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	18	L9 COIL	130.0	89	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	19	PBC @ TR16	130.0	92	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

	és .	<u> </u>	ý.	up d	2
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	20	CON1 BODY	105.0	75	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	21	T1 COIL-SB	130.0	105	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	22	T1 CORE-SB	130.0	101	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	23	C6 BODY-SB	105.0	83	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	24	L1 COIL-SB	130.0	84	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	25	C14 BODY-SB	125.0	114	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	1	TAMBIENT		50	Tested at 264Vac, 50Hz; duration:2h
CHD250PS48: 48V/4.58A,	2	FS1 BODY	125.0	65	

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IEC 60601-1						
	Clause	Requirement + Test	Result - Remark	Verdict		

					2 2
5V/1A (225W) Convection with 5V Stdby					A
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	3	L1 COIL	130.0	72	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	4	L2 COIL	130.0	84	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	5	C64 BODY	105.0	74	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	6	OPTO 1 BODY	105.0	83	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	7.	PCB @ TR5,D5	130.0	86	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	8	D24 BODY	140.0	.91	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with	9	L4 COIL	130.0	89	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

5V Stdby					
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	10	L3 COIL	130.0	91	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	11	L5 COIL	130.0	100	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	12	PCB @ TR27	130.0	95	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	13	T1 COIL	130.0	102	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	14	T1 CORE	130.0	109	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	15	T2 BODY	130.0	104	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	16	ТЗ ВОДУ	130.0	97	

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IEC 60601-1						
Clause Requirement + Test		Result - Remark	Verdict			

CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	17	C34 BODY	105.0	88	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	18	L9 COIL	130.0	88	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	19	PBC @ TR16	130.0	92	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	20	CON1 BODY	105.0	62	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	21	T1 COIL-SB	130.0	99	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	22	T1 CORE-SB	130.0	94	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	23	C6 BODY-SB	105.0	81	
CHD250P\$48: 48V/4.58A,	24	L1 COIL-SB	130.0	83	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

8	56	<u> </u>	<u> </u>	100 de 100 d	e 20
5V/1A (225W) Convection with 5V Stdby					
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with 5V Stdby	25	C14 BODY-SB	125.0	99	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	Î	T AMBIENT	t a si	50	Tested at 9DVac, 5DHz, Duration:1h:15 min
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	2	FS1 BODY	125.0	76	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	3	L1 COIL	130.0	86	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	4	L2 COIL	130.0	102	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V	5	C64 BODY	105.0	80	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

Stdby					
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	6	орто 1 воду	105.0	80	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	7	PCB@ TR5,D5	130.0	94	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	g.	D24 BODY	140.0	103	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	9	L4 COIL	130.0	100	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	10	L3 COIL	130.0	105	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	11	L5 COIL	130.0	110	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	12	PCB @ TR27	130.0	102	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	13	T1 COIL	130.0	97	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	14	T1 CORE	130.0	101	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	15	T2 BODY	130.0	101	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	16	ТЗ ВОДУ	130.0	97	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	17	C34 BODY	105.0	84	
CHD250PS48:	18	L9 COIL	130.0	82	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

	25				2 2
48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby					
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	19	PBC @ TR16	130.0	86	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	20	CON1 BODY	105.0	68	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	21	T1 COIL-SB	130.0	101	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	22	T1 CORE-SB	130.0	98	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	23	C6 BODY-SB	105.0	82	
CHD250PS48: 48V/4.58A,	24	L1 COIL-\$B	130.0	83	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

	26				2 20
5V/1A (225W) Convection with Cover and 5V Stdby					
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	25	C14 BODY-SB	125.0	103	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	î,	TAMBIENT	576	50	Tested at 264 Vac, 50 Hz, duration:1h:15 min
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	2	FS1 BODY	125.0	67	1
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	.3	L1 COIL	130.0	72	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	4	L2 COIL	130.0	87	
CHD250PS48: 48V/4.58A, 5V/1A (225W)	5	C64 BODY	105.0	76	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

Ø	266	62 4	2	100	2 79
Convection with Cover and 5V Stdby					
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	6	OPTO 1 BODY	105.0	75	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	7	PCB @ TR5,D5	130.0	86	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	8	D24 BODY	140.0	90	2
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	9	L4 COIL	130.0	87	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	10	L3 COIL	130.0	89	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with	11	L5 COIL	130.0	105	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

Cover and 5V Stdby					
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	12	PCB @ TR27	130.0	99	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	13	TI COIL	130.0	95	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	14	T1 CORE	130.0	99	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	15	T2 BODY	130.0	97	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	16	тз вору	130.0	92	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V	17	C34 BODY	105.0	82	

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IEC 60601-1						
Clause Requirement + Test		Result - Remark	Verdict			

2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	ř	-	Ŷ	15 D	4
Stdby					
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	18	L9 COIL	130.0	80	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	19	PBC@TR16	130.0	84	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	20	CON1 BODY	105.0	85	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	21	T1 COIL-SB	130.0	96	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	22	T1 CORE-SB	130.0	93	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	23	C6 BODY-SB	105.0	80	

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IEC 60601-1						
Clause Requirement + Test		Result - Remark	Verdict			

CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	24	L1 COIL-SB	130.0	81	
CHD250PS48: 48V/4.58A, 5V/1A (225W) Convection with Cover and 5V Stdby	25	C14 BODY-SB	125.0	94	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	ĭ	T AMBIENT	<i>i</i> #1	70	Tested at 90Vac, 50Hz, duration:2h
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	2	FS1 BODY	125.0	83	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	3	L1 COIL	130.0	89	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	4	L2 COIL	130.0	99	
CHD250PS48:	5	C64 BODY	105.0	88	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby					
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	6	OPTO 1 BODY	105.0	92	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	7	PCB @ TR5,D5	130.0	99	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	g	D24 BODY	140.0	103	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	9	L4 COIL	130.0	100	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	10	13 COIL	130.0	103	
CHD250PS48: 48V/2.29A,	11	L5 COIL	130.0	99	13

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

5V/0.5A (112.5W) Convection with 5V Stdby					
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	12	PCB @ TR27	130.0	96	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	13	TI COIL	130.0	96	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	14	T1 CORE	130.0	100	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	15	T2 BODY	130.0	102	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	16	ТЗ ВОДУ	130.0	99	
CHD250P\$48: 48V/2.29A, 5V/0.5A	17	C34 BODY	105.0	92	

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IEC 60601-1						
Clause Requirement + Test		Result - Remark	Verdict			

(112.5W) Convection with 5V Stdby					
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	18	L9 COIL	130.0	90	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	19	PBC @ TR16	130.0	90	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	20	CON1 BODY	105.0	80	1
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	21	T1 COIL-SB	130.0	100	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	22	T1 CORE-SB	130.0	97	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W)	23	C6 BODY-SB	105.0	88	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

	#56				9 27
Convection with 5V Stdby					
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	24	L1 COIL-SB	130.0	88	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	25	C14 BODY-5B	105	103	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	1	T AMBIENT		70	Tested at 264 Vac, 50 Hz, duration 2h
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	2	FS1 BODY	125.0	80	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	3	LI COIL	130.0	85	
CHD250P548: 48V/2.29A, 5V/0.5A (112.5W) Convection with	4	L2 COIL	130.0	94	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

3	6	<u> </u>	Ø	ng-	a a
5V Stdby					
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	.51	C64 BODY	105.0	88	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	6	OPTO 1 BODY	105.0	89	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	7.	PCB @ TR5,D5	130.0	95	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	8	D24 BODY	140.0	97	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	9	L4 COIL	130.0	93	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	10	L3 COIL	130.0	96	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	11	L5 COIL	130.0	98	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	12	PCB @ TR27	130.0	95	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	13	T1 COIL	130.0	95	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	14	T1 CORE	130.0	99	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	15	T2 BODY	130.0	99	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	16	ТЗ ВОДУ	130.0	96	
CHD250PS48:	17	C34 BODY	105.0	90	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby					
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	18	L9 COIL	130.0	89	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	19	PBC @ TR16	130.0	90	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	20	CON1 BODY	105.0	78	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	21	T1 COIL-SB	130.0	98	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	22	T1 CORE-SB	130.0	95	
CHD250PS48: 48V/2.29A,	23	C6 BODY-SB	105.0	.87	- 1

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

æ					200
5V/0.5A (112.5W) Convection with 5V Stdby					
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	24	L1 COIL-SB	130.0	88	
CHD250PS48: 48V/2.29A, 5V/0.5A (112.5W) Convection with 5V Stdby	25	C14 BODY-SB	105	99	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	1	T AMBIENT	24	70	Tested at 9DVac, 5DHz, Duration: 1h:15min
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	2	FS1 BODY	125.0	84	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	ຶກ	L1 COIL	130.0	89	
CHD250P\$48: 48V/1.67A, 5V/0.5A (82.5W)	4	L2 COIL	130.0	100	

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IEC 60601-1					
Clause Requirement + Test		Result - Remark	Verdict		

8.	66	£2		110-	2 20
Convection with Cover and 5V Stdby					
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	5	C64 BODY	105.0	89	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	6	OPTO 1 BODY	105.0	89	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	7	PCB @ TR5,D5	130.0	98	1
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	g	D24 BODY	140.0	101	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	9	L4 COIL	130.0	99	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with	10	L3 COIL	130.0	102	ř

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

Cover and 5V Stdby					
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	11	L5 COIL	130.0	106	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	12	PCB @ TR27	130.0	102	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	13	T1 COIL	130.0	97	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	14	T1 CORE	130.0	100	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	15	T2 BODY	130.0	101	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V	16	тз вору	130.0	99	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

Stdby					
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	17	C34 BODY	105.0	91	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	18	L9 COIL	130.0	89	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	19	PBC @ TR16	130.0	91	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	20	CON1 BODY	105.0	81	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	21	T1 COIL-SB	130.0	100	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	22	T1 CORE-SB	130.0	99	

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Clause	Requirement + Test	Result - Remark	Verdict		

CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	23	C6 BODY-SB	105.0	89	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	24	L1 COIL-SB	130.0	89	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	25	C14 BODY-SB	105	102	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	1	T AMBIENT		70	Tested at 264Vac, 50Hz, Duration:1h:15min
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	2	FS1 BODY	125.0	83	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	3	L1 COIL	130.0	86	
CHD250PS48:	4	L2 COIL	130.0	96	

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Clause	Requirement + Test	Result - Remark	Verdict		

	266				<u>u</u> 20
48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby					
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	%5	C64 BODY	105.0	90	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	6	OPTO 1 BODY	105.0	87	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	7	PCB @ TR5,05	130.0	.96	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	8	D24 BODY	140.0	98	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	9	L4 COIL	130.0	94	
CHD250PS48: 48V/1.67A,	10	L3 COIL	130.0	97	3

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Ī	IEC 60601-1					
	Clause Requirement + Test		Result - Remark	Verdict		

		<u> </u>	vii	St	2 20
5V/0.5A (82.5W) Convection with Cover and 5V Stdby					
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	11	L5 COIL	130.0	105	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	12	PCB @ TR27	130.0	102	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	13	T1 COIL	130.0	.96	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	14	T1 CORE	130.0	99	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	15	T2 BODY	130.0	100	
CHD250P\$48: 48V/1.67A, 5V/0.5A (82.5W)	16	тз вору	130.0	97	

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Clause Requirement + Test		Result - Remark	Verdict		

8	66	<u> </u>	V6	100 P	2 20
Convection with Cover and 5V Stdby					
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	17	C34 BODY	105.0	90	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	18	L9 COIL	130.0	88	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	19	PBC @ TR16	130.0	90	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	20	CON1 BODY	105.0	80	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	21	T1 COIL-SB	130.0	98	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with	22	T1 CORE-SB	130.0	97	

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IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict			

8		ş	Ý.	2	¥ X
Cover and 5V Stdby					
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	23	C6 BODY-SB	105.0	88	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	24	L1 COIL-SB	130.0	89	
CHD250PS48: 48V/1.67A, 5V/0.5A (82.5W) Convection with Cover and 5V Stdby	25	C14 BODY-SB	105	100	
CHD250PS12: 12V/16.67A (200W) Convection	1	TAMBIENT	70.0	70.0	Tested at 90Vac, 50Hz, duration: 2h
CHD250PS12: 12V/16.67A (200W) Convection	2	FS1 BODY	125.0	84.1	
CHD250PS12: 12V/16.67A (200W) Convection	3	L1 COIL	130.0	89.2	
CHD250PS12: 12V/16.67A (200W) Convection	4	L2 COIL	130.0	99.7	

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Clause	Requirement + Test	Result - Remark	Verdict

CHD250PS12: 12V/16.67A (200W) Convection	5	C64 BODY	105.0	80.8	
CHD250PS12: 12V/16.67A (200W) Convection	6	OPTO 1 BODY	105.0	92.0	
CHD250PS12: 12V/16.67A (200W) Convection	7	PCB @ TR5,D5	130.0	101.4	
CHD250PS12: 12V/16.67A (200W) Convection	8	D24 BODY	140.0	108.6	
CHD250PS12: 12V/16.67A (200W) Convection	9	L4 COIL	130.0	104.2	1
CHD250PS12: 12V/16.67A (200W) Convection	10	L3 COIL	130.0	107.7	
CHD250PS12: 12V/16.67A (200W) Convection	11	L5 COIL	130.0	106.4	
CHD250PS12: 12V/16.67A (200W) Convection	12	PCB @ TR27	130.0	99.5	
CHD250PS12: 12V/16.67A (200W)	13	T1 COIL	130.0	108.0	

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IEC 60601-1				
Clause	Requirement + Test	Result - Remark	Verdict	

	- [e	ř	Ť	ag.	541
Convection					
CHD250PS12: 12V/16.67A (200W) Convection	14	T1 CORE	130.0	108.9	
CHD250PS12: 12V/16.67A (200W) Convection	15	T2 BODY	130.0	99.0	
CHD250PS12: 12V/16.67A (200W) Convection	16	тз вору	130.0	95.8	
CHD250PS12: 12V/16.67A (200W) Convection	17	C34 BODY	105.0	98.6	
CHD250PS12: 12V/16.67A (200W) Convection	18	L9 COIL	130.0	100.0	
CHD250PS12: 12V/16.67A (200W) Convection	19	PBC @ TR16	130.0	107.2	
CHD250PS12: 12V/16.67A (200W) Convection	20	CON1 BODY	105.0	95.5	
CHD250PS12: 12V/16.67A (200W) Convection	1	T AMBIENT	70.0	70.0	Tested at 264Vac, 50Hz, duration: 2h
CHD250PS12: 12V/16.67A	2	FS1 BODY	125.0	69.6	

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IEC 60601-1				
Clause	Requirement + Test	Result - Remark	Verdict	

(200W) Convection					
CHD250PS12: 12V/16.67A (200W) Convection	3	L1 COIL	130.0	73.4	
CHD250PS12: 12V/16.67A (200W) Convection	4	L2 COIL	130.0	83.3	
CHD250PS12: 12V/16.67A (200W) Convection	5	C64 BODY	105.0	74.6	
CHD250PS12: 12V/16.67A (200W) Convection	6	OPTO 1 BODY	105.0	85.2	
CHD250PS12: 12V/16.67A (200W) Convection	7	PCB @ TR5,D5	130.0	84.9	
CHD250PS12: 12V/16.67A (200W) Convection	8	D24 BODY	140.0	88.8	
CHD250PS12: 12V/16.67A (200W) Convection	9	L4 COIL	130.0	85.5	
CHD250PS12: 12V/16.67A (200W) Convection	10	L3 COIL	130.0	86.3	
CHD250PS12:	11	L5 COIL	130.0	105.0	

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

	46	62	W.	100 de 100 d	e X2
12V/16.67A (200W) Convection					
CHD250PS12: 12V/16.67A (200W) Convection	12	PCB @ TR27	130.0	98.2	
CHD250PS12: 12V/16.67A (200W) Convection	13	T1 COIL	130.0	109.0	
CHD250PS12: 12V/16.67A (200W) Convection	14	T1 CORE	130.0	108.1	
CHD250PS12: 12V/16.67A (200W) Convection	15	T2 BODY	130.0	92.7	1
CHD250PS12: 12V/16.67A (200W) Convection	16	тз вору	130.0	87.5	
CHD250PS12: 12V/16.67A (200W) Convection	17	C34 BODY	105.0	98.1	
CHD250PS12: 12V/16.67A (200W) Convection	18	L9 COIL	130.0	103.0	
CHD250PS12: 12V/16.67A (200W) Convection	19	PBC @ TR16	130.0	110.0	

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IEC 60601-1				
Clause	Requirement + Test	Result - Remark	Verdict	

9	_6	62	<u> </u>		<u>ar</u>
CHD250PS12: 12V/16.67A (200W) Convection	20	CON1 BODY	105.0	84.8	
CHD250PS48: 48V/4.17A (200W) Convection	1	T AMBIENT	No.	70.0	Tested at 90 Vac, 50Hz, duration 2h
CHD250PS48: 48V/4.17A (200W) Convection	2	FS1 BODY	125.0	105.0	
CHD250PS48: 48V/4.17A (200W) Convection	3	L1 COIL	130.0	115.0	
CHD250PS48: 48V/4.17A (200W) Convection	4	L2 COIL	130.0	120.0	
CHD250PS48: 48V/4.17A (200W) Convection	.5	C64 BODY	105.0	99.0	
CHD250PS48: 48V/4.17A (200W) Convection	6	OPTO 1 BODY	105.0	94.0	
CHD250PS48: 48V/4.17A (200W) Convection	7	PCB @ TR5,D5	130.0	122.0	
CHD250PS48: 48V/4.17A (200W)	8	D24 BODY	140.0	127.0	

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IEC 60601-1				
Clause	Requirement + Test	Result - Remark	Verdict	

Convection	1				
CHD250PS48: 48V/4.17A (200W) Convection	9	L4 COIL	130.0	117.0	
CHD250PS48: 48V/4.17A (200W) Convection	10	L3 COIL	130.0	108.0	
CHD250P\$48: 48V/4.17A (200W) Convection	11	L5 COIL	130.0	119.0	
CHD250PS48: 48V/4.17A (200W) Convection	12	PCB @ TR27	130.0	110.0	
CHD250PS48: 48V/4.17A (200W) Convection	13	T1 COIL	130.0	111.0	
CHD250PS48: 48V/4.17A (200W) Convection	14	T1 CORE	130.0	120.0	
CHD250PS48: 48V/4.17A (200W) Convection	15	T2 BODY	130.0	103.0	
CHD250PS48: 48V/4.17A (200W) Convection	16	тз вору	130.0	98.0	
CHD250PS48: 48V/4.17A	17	C34 BODY	105.0	95.0	

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Clause	Requirement + Test	Result - Remark	Verdict

(200W) Convection					551
CHD250PS48: 48V/4.17A (200W) Convection	18	L9 COIL	130.0	99.0	
CHD250P\$48: 48V/4.17A (200W) Convection	19	PBC@TR16	130.0	106.0	
CHD250PS48: 48V/4.17A (200W) Convection	20	CON1 BODY	105.0	95.0	
CHD250PS48: 48V/4.17A (200W) Convection	1	T AMBIENT		70.0	Tested at 264Vac, 50; duration 2h
CHD250PS48: 48V/4.17A (200W) Convection	2	FS1 BODY	125.0	98.0	
CHD250PS48: 48V/4.17A (200W) Convection	3	L1 COIL	130.0	114.0	
CHD250P\$48: 48V/4.17A (200W) Convection	4	L2 COIL	130.0	112.0	
CHD250PS48: 48V/4.17A (200W) Convection	.5	C64 BODY	105.0	91.0	
CHD250PS48:	6	OPTO 1 BODY	105.0	88.0	

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	201				2 27
48V/4.17A (200W) Convection					
CHD250PS48: 48V/4.17A (200W) Convection	7	PCB @ TR5,D5	130.0	101.0	
CHD250PS48: 48V/4.17A (200W) Convection	8	D24 BODY	140.0	105.0	
CHD250PS48: 48V/4.17A (200W) Convection	9	L4 COIL	130.0	96.0	
CHD250PS48: 48V/4.17A (200W) Convection	10	L3 COIL	130.0	92.0	
CHD250PS48: 48V/4.17A (200W) Convection	11	L5 COIL	130.0	116.0	
CHD250PS48: 48V/4.17A (200W) Convection	12	PCB @ TR27	130.0	107.0	
CHD250PS48: 48V/4.17A (200W) Convection	13	T1 COIL	130.0	108.0	
CHD250PS48: 48V/4.17A (200W) Convection	14	T1 CORE	130.0	116.0	

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Clause	Requirement + Test	Result - Remark	Verdict

Test Tables

CHD250P\$48: 48V/4.17A (200W) Convection	15	T2 BODY	130.0	99.0	
CHD250PS48: 48V/4.17A (200W) Convection	16	тз вору	130.0	92.0	
CHD250PS48: 48V/4.17A (200W) Convection	17	C34 BODY	105.0	93.0	
CHD250PS48: 48V/4.17A (200W) Convection	18	L9 COIL	130.0	97.0	
CHD250PS48: 48V/4.17A (200W) Convection	19	PBC @ TR16	130.0	104.0	
CHD250PS48: 48V/4.17A (200W) Convection	20	CON1 BODY	105.0	89.0	

Supplementary Information:

Where:

tm = measured temperature

tc = tm corrected (tm-ta+ 40 °C or max. RATED ambient).

tmax = maximum permitted temperature Max allowable temperature from Table 22, 23, or RM2

- 1 When thermocouples used to determine temperature of windings, temperature limits of Table 22 reduced by 10 °C.
- 2 Maximum allowable temperature on surfaces of test corner is 90 ℃
- 3 Max temperature determined in accordance with 11.1.3 e) 4 Record duration time for each test run.

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11.1.3d	TABLE: Te	mperature of	windings by	change-of-re	sistance met	hod	-	N/A
	iture T of ding:	t1 (°C)	R1 (Ω)	t2 (°C)	R2 (Ω)	ΔT (°C)	Allowed Tmax (°C)	Insulation class
				3				

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	Areas where sparking might cause ignition:	Remarks	
1	Areas where sparking might cause ghition.	Remarks	
2			
3		+	
4		Ť	
5			
6			
Materials	of the parts between which sparks could occur (Comp Designation, Manufacturer):	position, Grade Remarks	
1			
2			
3			
4			
5			
6			
Test param	neters selected representing worst case conditions for and location/material tested:	ME EQUIPMENT Remarks	
Oxygen con	ncentration (%):		
Fuel:			
Current (A)			
Voltage (V)			
Capacitance	e (μF):		
nductance	or resistance (h or Ω):		
No. of trials	s (300 Min) :		
Sparks resu	Ited in ignition (Yes/No):		
Sunnlam	entary Information:		

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Clause	Requirement + Test	Result - Remark	Verdict

	compatibility with subs	tances		
Cli	ause / Test Name	Test Condition	Part under test	Remarks
Cl. 11.6	.2, Overflow			
	V1.			
Suppler	nentary Information:		Lt	
00000	•			
Suppler Vone	nentary information:			

compatibility with subst	tances	er, cleaning, disinfection, ster	N/A
se / Test Name	Test Condition	Part under test	Remarks
	3		
entary Information:		e e	
	se / Test Name	se / Test Name Test Condition	se / Test Name Test Condition Part under test

	compatibility with subs	3		
Cla	use / Test Name	Test Condition	Part under test	Remarks
			10	
Supplen	nentary Information:		*	

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Clause	Requirement + Test	Result - Remark	Verdict

Cl=	compatibility with subst	Test Condition	Part under test	Remarks
CIG	ruse y reservante	resecondition	rare under test	iiciiidik3
· · · · · · · · · · · · · · · · · · ·	ant sur to form ation.	ů.	,	
uppien	nentary Information:			

Clau	se / Test Name	Test Condition	Part under test	Remarks
			5.	
			5	
Suppleme	entary Information:			
lone				

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Clause	Requirement + Test	Result - Remark	Verdict

	ompatibility with subs	500 000 000		
Claus	e / Test Name	Test Condition	Part under test	Remarks
		Ú.	E. C.	
Sup plem er	tary Information:			

13.1.2	SINGLE FAL		8.1 b), 8.7.2, and 13.2.	n parts & components to w .2 relative to emission of fla	
Power o	lissipated less	than (W):		15	
Energy	dissipated les	s than (I):	261	900	
	omponent ited	Measured power dissipated (W)	Calculated energy dissipated (J)	SINGLE FAULT CONDITIONS waived (Yes/No)	Remarks
	-				
	7		3	S 6	
Sunnler	nentary Infor	rmation:	1	<u> </u>	

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Clause	Requirement + Test	Result - Remark	Verdict

13.2	TABLE: SINGLE FAULT CONDITIONS in accord	ance with 13.2.2 to 13.2.13, inclusive	Pass
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No
13.2,2	Electrical single fault conditions according to 8.1:	Res.	-
13.2.2	SHORT: TR15, D/S	NB,NT,NC-Output shutdown when short was applied. Recovered after short was removed. Monitored for SELV, voltage was 0V < 0.2 sec. T1: 41 °C, T2: 39 °C, T3: 38 °C, T1 Stdby: 60 °C, TA: 25 °C; Tested at 264Vac/60Hz, Duration: 2h Leakage: NC: 180 uA; SFC: 353 uA	No
13.2.2	SHORT: OPTO 1, PIN 1 to 2	NB,NT,NC- Unit remained stable during short. T1: 112°C, T2: 105°C, T3: 99°C, T1 Stdby: 99°C, TA: 25°C Tested at 264Vac/60Hz, Duration:2h:0m:0s Leakage:NC: 138 uA; SFC: 264 uA	No
13.2.2	SHORT: OPTO 1, PIN 3 to 4	NB,NT,NC- Unit remained stable during short. T1: 34°C, T2: 41°C, T3: 42°C, T1 Stdby: 51°C, TA: 25°C Tested at 264Vac/60Hz, Duration: 2h Leakage: NC: 191 uA; SFC: 368 uA	No
13.2.2	SHORT: L3, PIN 1 to 2	NB,NT,NC-Unit remained stable during short. T1: 115°C, T2: 111°C, T3: 106°C, T1 Stdby: 105°C, TA: 25°C Tested at 264Vac/60Hz, Duration: 2h Leakage: NC: 131 uA; SFC: 255uA	No
13.2.2	SHORT: C12, (+ to -)	NB,NT,NC- FS1,FS2 opened immediately. T1: 31°C, T2: 30°C, T3: 29°C, T1 Stdby: 30°C, TA: 25°C, Tested at 264Vac/60Hz, Duration:1s Leakage:NC: 138 uA; SFC:258uA (*)	No

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Clause	Requirement + Test	Result - Remark	Verdict

13,2,2	SHORT: C12	NB,NT,NC-Both FS1,FS2 opened immediately. T1: 29°C, T2: 29°C, T3: 28°C, T1 Stdby: 29°C, TA: 25°C; Tested at 264Vac/60Hz, Duration:1s Leakage:NC: 135 uA; SFC: 254 uA	No
13.2.2	SHORT: TR2, D/S	NB,NT,NC-Both FS1,FS2 opened immediately. T1:30°C, T2: 29°C, T3: 29°C, T1 Stdby: 29°C, TA: 25°C; Tested at 264Vac/60Hz, Duration:1s Leakage:NC: 138 uA; SFC: 257 uA	No
13.2.2	SHORT: D24, A/C	NB,NT,NC-Both FS1,FS2 opened immediately. T1:30°C, T2:30°C, T3: 29°C, T1 Stdby: 28°C, TA: 25°C, Tested at 264Vac/60Hz, Duration:1s Leakage:NC: 137 uA; SFC: 255 uA	No
13.2.2	SHORT: TR4, D/S	NB,NT,NC-Both FS1,FS2 opened immediately. T1: 29°C, T2: 29°C, T3: 29°C, T1 Stdby: 27°C, TA: 25°C, Tested at 264Vac/60Hz, Duration:1s Leakage:NC: 134 uA; SFC: 253 uA	No

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Clause	Requirement + Test	Result - Remark	Verdict

Test Tables

13.2.6	Leakage of liquid - risk management file examined to determine the appropriate test conditions (sealed rechargeable batteries exempted):	920	N/A
13.2.6			N/A
13.2.6			N/A
13.2.6			N/A
13.2.6	Ÿ.	ž.	N/A
13.2.11	Fallures of components in ME equipment used in conjunction with oxygen rich environments: See 11.2.2	fex.	N/A
13.2.12	Fallure of parts that might result in a mechanical hazard: See 9 & 15.3 - [AM1: including RISK CONTROLS to address moving parts (9.2.2.4.4)]	act	N/A
15.4.3.5	Short circuit on battery	t.	N/A

${\bf Supplementary\,Information:}$

See Table 11 for Temperatures obtained during the indicated Abnormal Operation tests.

Where: NB:No indication of dielectric breakdown; NT - Tissue paper remained intact; NC - Cheesecloth remained intact *Dielectric Test conducted at 4352Vac from Primary to Secondary

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Clause	Requirement + Test	Result - Remark	Verdict

<u>Test Tables</u>

13.2	TABLE: SINGLE FAULT CONDITIONS in accorda	ance with 13.2.2 to 13.2.13, inclusive,	continued N/A
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No
13.2.4	Fallure of thermostats according to 13.2.13 & 15.4.2, overloading - thermostats short circuited or interrupted, the less favorable of the two:	100 H	N/A
13.2.4			N/A
13.2.4	-3		N/A
13.2.4			N/A
13.2.4			N/A
13.2.5	Fallure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, thermostats short circuited or interrupted, the less favorable of the two:	SIRS	N/A
13.2.5			N/A
See Table 11 for Temperatures obtained during the indicated Abnormal Operation tests.		See Tables above	Pass

Supplementary Information:

See Table 11 for Temperatures obtained during the indicated Abnormal Operation tests.

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Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed		ZARDOUS ION (Yes/No)
13.2.7	Impairment of cooling that could result in a hazard using test method of 11.1:	85g		N/A
13.2.7	Single ventilation fans locked consecutively			N/A
13.2.7	Ventilation openings on top and sides impaired by covering openings on top of enclosure or positioning of me equipment against walls			N/A
13.2.7	Blocking of filters simulated			N/A
13.2.7	Flow of a cooling agent interrupted		ı,	N/A
13.2.7				N/A
13.2.7 13.2.7 Supplemen	Flow of a cooling agent interrupted			

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Clause	Requirement + Test	Result - Remark	Verdict

13.2	TABLE: SINGLE FAULT CONDITIONS in accorda continued	nce with 13.2.2 to 13.2.13, inclusive,	N/A
Clause N	o. Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION [Yes/No]
13.2.8	Locking of moving parts - Only one part locked at a time - Also see 13.2.10 below:	Resi	N/A
13.2.8			N/A
13.2.8			N/A
13.2.8	9		N/A
13.2.8			N/A
13.2.1D	Additional test criteria for motor operated ME equipment in 13.2.8 & 13.2.9:	987	N/A
13.2.10	For every test in single fault condition of 13.2.8 and 13.2.9, except as stated in 13.1.2, motor-operated NiE equipment started from cold condition at rated voltage or at the upper limit of rated voltage range for the following periods of time:	H2	N/A
13.2.10	a) 30 s for: - hand-held ME equipment - ME equipment that has to be kept switched on by hand - ME equipment that has to be kept under physical load by hand	150	N/A
13.2.10	b) 5 min for other ME equipment intended only for attended use (excluding automated or remotely controlled ME equipment operating when operator is not present)	es.	N/A
13.2.10	c) for maximum period of a timer when such a device terminates operation for me equipment not listed under a) or b) above	ies.	N/A
13.2.10	d) as long as necessary to establish thermal stability for all remaining me equipment	85g	N/A
13.2.10	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, thermal cut-outs, motor protective devices and the like		N/A
13.2.10	Temperatures measured as specified in 11.1.3 d)		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

13.2.10	Temperatures did not exceed limits of Table 26	N/A
Suppleme	ntary Information:	
See Table 1	L for Temperatures obtained during the indicated Abnormal Operation tests	Includes details from clause 13,7,10 fe
	tion remperatores obtained during the maleaced Abnormal operation tests	"HICITAGE A GETAILS HAILL CLAUSE TS'S'TA I

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Clause	Requirement + Test	Result - Remark	Verdict

J. H. Martin		nce with 13.2.2 to 13.2.13, inclusive,	continued N/A
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION [Yes/No]
13.2.9	Interruption and short circuiting of motor capacitors - Motor capacitors short & open circuited 1. Also see SUPPLEMENTARY INFORMATION note 1 below and 13.2.10 below.	342	N/A
13.2.9			N/A
13.2.10	Additional test criteria for motor operated ME equipment in 13.2.8 & 13.2.9:	852	N/A
13,2,10	For every test in single fault condition of 13.2.8 and 13.2.9, except as stated in 13.1.2, motor-operated ME equipment started from cold condition at rated voltage or at the upper limit of rated voltage range for the following periods of time:	525	N/A
13.2 ,10	a) 30 s for: - hand-held ME equipment - ME equipment that has to be kept switched on by hand - ME equipment that has to be kept under physical load by hand	250	N/A
13.2.10	b) 5 min for other ME equipment intended only for attended use (excluding automated or remotely controlled ME equipment operating when operator is not present)	es .	N/A
13.2.10	c) for maximum period of a timer when such a device terminates operation for me equipment not listed under a) or b) above	A53	N/A
13.2.10	d) as long as necessary to establish thermal stability for all remaining me equipment	200	N/A
13.2,10	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, thermal cut-outs, motor protective devices and the like		N/A
13.2.10	Temperatures measured as specified in 11.1.3 d)		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

13.2.10	Temperatures did not exceed limits of Table 26	N/A
Suppleme	ntary Information:	
equipment not Table 11 for Te	is short-circuited capacitor not performed when motor provided with a capa intended for unattended use including automatic or remote control. See A imperatures obtained during the indicated Abnormal Operation tests. Inclu- motor operated equipment.	Attachment # and appended Table 8,10.See

			1 2
Clause No	b. Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION [Yes/No]
13.2.13	Overload: See 13.2.13.2 to 13.2.13.4 (Inclusive)	(4)	N/A
13.2.13	ME equipment remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to roomtemperature		N/A
13.2.13	ME equipment examined for compilance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		N/A
13.2.13	For insulation of thermoplastic materials relied upon as a means of protection (see 8.8), the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		N/A
	nentary Information: = 11 for Temperatures obtained during the indicated Abr	ormal Operation tests.	<u>.</u>

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Clause	Requirement + Test	Result - Remark	Verdict

Clause No	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOU: SITUATION [Yes/No]
13.2.13	Overload: See 13.2.13.2 to 13.2.13.4 (Inclusive)	187	N/A
13.2.13	ME equipment remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to room temperature		N/A
13.2.13	ME equipment examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		N/A
13.2.13	For insulation of thermoplastic materials relied upon as a means of protection (see 8.8), the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 % higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		N/A
535	 nentary Information: : 11 for Temperatures obtained during the indicated Abn	ormal Operation tests.	at a

15.3	TABLE: Mechanical Strengt	h tests	N/A
Clause	Name of Test	Test Conditions	Observed results/Remarks
Supplementa	ary Information:		

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Clause	Requirement + Test	Result - Remark	Verdict

15.3	TABLE: Mechanical Strengt	h tests, continued	N/A
Clause	Name of Test	Test Conditions	Observed results/Remarks
upplementa Jone	ry Information:		

15.3	TABLE: Mechanical Strength	tests, continued	N/A
Clause	Name of Test	Test Conditions	Observed results/Remarks
From Table 2		access ories and parts (kg) Drop	hairbt (cm)
From Table 2	2000	accessories and parts (kg) Drop	height (cm) 5
From Table 2	19: of PORTABLE ME EQUIPMENT or its	accessories and parts (kg) Drop	height (cm) 5 3

15.3	TABLE: Mechanical Stren	TABLE: Mechanical Strength tests, continued	
Clause	Name of Test	Test Conditions	Observed results/Remarks
NOTE: After			as determined by inspection of the RISK parts that are MOBILE, constitutes a failure.

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Clause	Requirement + Test	Result - Remark	Verdict

Test Tables

15.3	TABLE: Mechanical Strength tests, continued		N/
Clause	Name of Test	Test Conditions	Observed results/Remarks
Supplementa: + 70°C or Max. ⁻	ry Information: Temp. + 10°C		

Rotating control under test	Gripping diameter "d" of control knob (mm)1	Torque from Table 30 (Nm)	Axial force applied (N)	Unacceptable RISK occurred Yes/No	Remarks
	5		2	<u> </u>	
				E	
			-		

Supplementary Information:

¹ Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)

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Clause	Requirement + Test	Result - Remark	Verdict

Test Tables

15.5.1 .2	3750735		mer short circuit te e short circuited ur				r at the first	Pass
Primary	voltage	e (most adve	erse value from 90 %	6 to 110 % o	f RATED voltage)(\	/)1:	264Vac	
RATED input frequency (Hz):							60	-
Winding te	ested	Class of Insulation [A, B, E, F, or H]	Type of protective device [fuse, circuit breaker] /Ratings	Protective device operated Yes/No	Time to THERMAL STABILITY (when protective device did not operate)[Min]	Maximum allowed temp from Table 31 [°C]	Maximum winding temp measured °C]	Amblent (°C)
CHD 250PS Pln 9 to 12, S		F	Fuse 250V/5A	No	120 min	180	T1: 53°C, T2: 54°C, T3: 54°C, T1 5tdby: 58°C (1)	25
CHD250PS Pin3 to 4	512: 12,	Œ	Fuse 25DV/5A	No	120 min	180	T1: 116°C; T2: 103°C; T3: 97°C; T1 Stdby: 95°C (2)	25
CHD 250PS Pin 3 to 4	S12: T3,	F	Fuse 25DV/5A	No	120 mln	180	T1: 115°C; T2: 101°C; T3: 97°C; T1 Stdby; 97°C (3)	25
CHD250PS Stdby: FL1 to		F	Fuse 250V/5A	No	120 mln	190	T1: 103°C; T2: 99°C; T3: 93°C; T1 Stdby: 88°C (4)	25
CHD 250PS Pln 9 to 12	548: 11 ,	F	Fuse 25DV/5A	No	120 min	180	T1: 53°C, T2: 54°C, T3: 54°C, T1 Stdby: 58°C (5)	25
CHD 250P5 Pln 3 to 4	548: 12:	}F	Fuse 250V/5A	No	120 mln	.18D	T1: 116°C, T2: 103°C, T3: 97°C, T1 Stdby: 95°C (6)	25
CHD250PS Pln 3 to 4	548; 13 ;	F	Fuse 250V/5A	No	120 mln	180	T1: 115°C, T2: 101°C, T3: 97°C, T1 Stdby: 97°C (7)	25
CHD250PS Pin FL1 to FL2 Standby		F	Fuse 25DV/SA	No	120 min	180	T1: 103°C, T2: 99°C, T3: 93°C, T1 51dby: 88°C (8)	25

Supplementary Information:

¹ Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.

⁽¹⁾ NB,NT,NC- Main output shutdown when short was applied. 5V output remained stable. V1 output recovered after short was removed. Leakage: NC: 175Ua; SFC: 345uA

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Clause	Requirement + Test	Result - Remark	Verdict

Test Tables

- (2) NB,NT,NC-Unit remained stable during short-circuit. Leakage: NC:130uA; SFC:256uA
- (3) NB,NT,NC,CD-TR15. V1 output was intermittent after 45 minutes. 5V stdby remained stable. V1 output did not recovered after short was removed. Output shorted. Leakage: NC: 155Ua, SFC: 303uA
- (4) NB,NT,NC- 5V standby output shutdown when short was applied. Main output remained stable. 5V standby output recovered after short was removed. Leakage: NC: 139uA; SFC: 269uA
- (5) NB,NT,NC- Main output shutdown when short was applied. 5V output remained stable. V1 output recovered after short was removed. Leakage: NC: 175uA, SFC: 345uA
- (6) NB,NT,NC-Unit remained stable during short-circuit. Leakage: NC: 130uA, SFC: 256uA
- (7) NB,NT,NC,CD-TR15. V1 output was intermittent after 45 minutes. 5V stdby remained stable. V1 output did not recovered after short was removed. Output shorted. Leakage: NC: 155uA, SFC: 303uA
- (8) NB,NT,NC- 5V standby output shutdown when short was applied. Main output remained stable. 5V standby output recovered after short was removed. Leakage: NC: 139uA, SFC: 269uA

 $Where: NB: No\ indication\ of\ dielectric\ breakdown;\ NT-Tissue\ paper\ remained\ intact;\ NC-Cheese cloth\ remained\ intact;$

15.5.1 .3	5.1 TABLE: transformer overload test – conducted only when protective device under she circuit test operated						
Primary	Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)1:						c
RATED I	RATED input frequency (Hz):						
	rrent just below STABILITY unde		that would activate protect	ive device & a	chieve	Foldback	
		able 32 when prot nd it was shunted	tective device that operated (A):	under metho	d a) is		
wir	nding tested	Class of Insulation [A, B, E, F, H]	Type of protective device used [fuse, circuit breaker]/Ratings	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured [°C]	Ambi	ent (°C)
CHD250PS C39	612: T1: Across	F	Fuse: 250V/5A	180	T1: 129°C, T2: 118°C, T3: 110°C, T1 Stdby: 110°C (1)		25
CHD250PS C34	512; T2: Across	F	Fuse: 250V/5A	180	T1: 114°C, T2: 108°C, T3: 101°C, T1 Stdby: 101°C (2)		25
CHD250PS C41	S12: T3: Across	F	Fuse: 250V/5A	180	T1: 123°C, T2: 112°C,	;	25

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			100	T3: 105°C, T1 Stdby: 104°C (3)	
CHD250PS12: T1 Standby: Across C6	F	Fuse: 250V/5A	180	T1: 97°C, T2: 104°C, T3: 99°C, T1 Stdby: 102°C (4)	25
CHD250PS48: T1 Across C39	F	Fuse: 250V/5A	180	T1: 130°C, T2: 108°C, T3: 96°C, T1 Stdby: 100°C (5)	25
CHD250PS48: T2 Across C34	E	Fuse: 250V/5A	180	T1: 134°C, T2: 109°C, T3: 94°C, T1 Stdby: 99°C (6)	25
CHD250PS48: T3 Across C41	F	Fuse: 250V/5A	180	T1: 129°C, T2: 109°C, T3: 94°C, T1 Stdby: 99°C (7)	25
CHD250PS48: T1 Standby: Across C6	F	Fuse: 250V/5A	180	T1: 105°C, T2: 101°C, T3: 92°C, T1 Stdby: 111°C (8)	25

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Clause	Requirement + Test	Result - Remark	Verdict

Test Tables

Supplementary Information:

- 1 Loads on other windings between no load and their NORMAL USE load. Time durations:
- Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved.
- IEC 60127-1 fuse: 30 min at current from Table 32.
- Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a).

This portion concluded at specified time or when a second protective device opened.

- (1) NB,NT,NC-Unit was stable during overload. Leakage: NC: 135 uA, SFC: 259 uA
- (2) NB,NT,NC-Unit was stable during overload. Leakage: NC: 133 uA, SFC: 258 uA
- (3) NB,NT,NC-Unit was stable during overload. Leakage: NC: 128 uA, SFC: 252 uA
- (4) NB,NT,NC-Unit was stable during overload. Leakage: NC: 138 uA, SFC: 271 uA
- (5) NB,NT,NC-Unit was stable during overload. Leakage: NC: 140 uA, SFC: 278 uA
- (6) NB,NT,NC-Unit was stable during overload. Leakage: NC: 136 uA, SFC: 270 uAA
- (7) NB,NT,NC-Unit was stable during overload. Leakage: NC: 130 uA, SFC: 255 uA
- (8) NB,NT,NC-Unit was stable during overload. Leakage: NC: 145 uA; SFC: 286 uA

Where: NB:No indication of dielectric breakdown; NT - Tissue paper remained intact; NC - Cheesecloth remained intact

15.5.2	TABLE:	Transformer dielectric	strength after h	umidity precond	ditioning of 5.7	N/A
Transfo Model/Ty No	pe/ Part	Test voltage applied between	Test voltage, (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No

Supplementary Information:

Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Subclause 15.5.2 for test parameters & other details

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<u>Test Tables</u>

Specific area where TOUCH CURRENT measured [l.e., from or between parts of MESYSTEM within PATIENT ENVIRONMENT]		Allowable TOUCH CURRENT IN NORMAL CONDITION [µA]	Measured TOUCH CURRENT In NORMAL CONDITION [µA]	Allowable TOUCH CURRENT in event of Interruption of PROTECTIVE EARTH CONDUCTOR, [µA]	Measured TOUCH CURREN in event of interruption of PROTECTIVE EARTH CONDUCTOR, [µA]
		100		500	
		100		500	8
		100		500	8
		100		500	
		100		500	
Supplemo	entary Information:				

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SP	TABLE: Additional or special tests conducted			N/A	
Clause and Name of Test		Test type and condition	Observed results		
Supplementary information:					

This table is used to identify test results for tests other than referenced in the above test tables. Refer to Appendix D for all tests performed within this report.

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Clause	Requirement + Test	Result - Remark	Verdict

8.10 T	ABLE: List of cr	itical component	ts		Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
Bottom Cover – for models with suffix "-C"	Interchangeable	Interchangeable	Metal, L-shaped, overall approx. 14 by 8.8 by 4.3 cm, min. 0.9 mm thick. See Enclosure 4-13 for details.		
Top Cover – for models with suffix "-C"	Interchangeable	Interchangeable	Metal, L-shaped, overall approx. 14 by 8.8by 4.3 cm, min. 0.6 mm thick. Provided with numerous ventilation openings. Secured to Bottom Cover by screws. See Enclosure 4-13 for details.		
Insulator Sheet – for models with suffix "-C"	Formex Inc	Formex GK-10BK	Cover and PWB. Rated min. V-1, 115°C, approx. 136 by 84 mm., min 0.25 mm thick.	UL 94 (QMFZ2 (E121855))	UL
Printed Wiring Board	Interchangeable	Interchangeable	Overall approx. 12.6 by 7.5 cm, min. 2 mm thick. Rated min. V-1, min. 130°C	UL 796 (ZPMV2)	UL
Primary Connector (CON1)	Molex	41791 Series (P/N 26-60- 4030)	2 pos. Rated min. 250 V, 7.0 A, 105°C	UL 1977 (ECBT2 (E29179)), CSAC22.2 NO 182.3-M1987	UL, CSA
Terminal Block (CON1) - for Models provided with suffix "-S"	Dinkle Enterprise	EK381V Series (EK381V- 03P)	Rated min. 7A, 250V, min. 105°C. May be mounted on top or bottom of PWB.	UL 1054, CSA C22.2 No. 158 (XCFR2,8 (E102914))	UL, cUL, TUV
Primary Connector (CON1) - Alternate	Interchangeable	Interchangeable	Not provided, when provided with Input Leads, (AVLV2), rated min. 18 AWG, min. 60°C, min. VW-1, soldered and mechanically secured through the PWB.	UL 758 (AVLV2)	UL
Input Leads – Optional – For Models with –L suffix	Interchangeable	Interchangeable	When not provided with primary connector or terminal block (CON1), provided with Input Leads, (AVLV2), rated min. 18 AWG, min. 105°C, min. VW-1, soldered and mechanically secured through the PWB.	UL 758 (AVLV2)	UL
Primary Connector (CON1) - Alternate	Interchangeable	Interchangeable	2 pos. Rated min. 250 V, 7.0 A, 105°C	UL 1977 (ECBT2), or UL 498 (RTRT2) or UL 746C (QMFZ2)	UL
Fuse (FS1, FS2)	Bel Fuse Inc.	5HFP Series	Rated 5A, min. 250V,	UL 248, CSA-C22.2 No.	UL, cUL, VDE

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Clause	Requirement + Test	Result - Remark	Verdict

8.10 T	ABLE: List of cri	tical component	ts		Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
			min. 125°C. Mounted vertically with leads soldered through Main PWB. Provided with fuse carrier. (IR rating:1500 A at 250 V ac)	248 (JDYX2, 8 (E20624)), IEC 60127-2	
Fuse (FS1, FS2) - Alternate	Littelfuse (Wickmann Werke)	216 Series (0216005XEP)	Rated 5A, min. 250V, min. 125°C, Time Lag (Non-operator replaceable). (IR rating: 1500A at 250Vac)	UL 248-14, CSAC22.2 No. 248.14, ((JDYX2,8(E10480)), IEC 60127-2	UL, cUL, SEMKO
Fuse holder (FS1,FS2)	El Dupont De Nemours & Co Inc	FR530	Overall approx. 29 by 17.75 by min. 0.8 mm thick. Rated V-0, min. 155°C	UL 94, (QMFZ2, 8) (E41938))	UL, cUL
Fuseholder (FS1,FS2) - Alternate	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Overall approx. 29 by 17.75 by min. 0.8 mm thick. Rated V-0, min. 155°C.	UL 94 (QMFZ2 (E95746))	UL
X-Capacitor (C1)	Xiamen Faratronic Co Ltd	MKP62 Series (Type C42)	Rated max. 0.47 uF, min. 250 V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2, 8 (E186600)), IEC60384- 14	UL, cUL, VDE
Capacitor (C5)	Xiamen Faratronic Co Ltd	MKP62 Series (Type C42)	Rated max. 1.5 uF, min. 250 V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2, 8 (E186600)), IEC60384- 14	UL, cUL, VDE
X-Capacitor (C6)	Xiamen Faratronic Co Ltd	MKP62 Series (Type C42)	Rated max. 2.2 uF, min. 250 V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2, 8 (E186600)), IEC60384- 14	UL, cUL, VDE
X-Capacitor (C6) - Alternate	Epcos/Siemens	B3292 Series	Rated max. 2.2 uF, min. 250 V, marked "X2"	UL 60384-14, CSA E60384-14:09 (FOWX2, 8 (E97863)), IEC60384- 14	UL, cUL, VDE
Film Capacitors (C29,C30) (PRI)	Interchangeable	Interchangeable	Rated max. 0.068 uF, min. 400 Vdc.		
Thermistor (TH1)	Epcos OHG	B57236 Series	NTC. Rated 20 Ohm, 25°C min, 2.8A min. steady state current (Not relied upon for safety).	UL 1434, IEC 60730- 1:1999+A1:2003, Annex J (XGPU2) (E69802))	UL, cUL
Thermistor (TH1) - Alternate	Interchangeable	Interchangeable	NTC. Rated 20 Ohm, 25°C min, 2.8A min. steady state current (Not relied upon for safety).	UL 1434 (XGPU2), IEC60730, EN60730-1	UL
X-Capacitor (C67,C68)	Vishay Capacitors Belgium N V	338 2 Series	Rated max. 0.1 uF, min. 250V, marked	UL 60384-14, CSA E60384-1:03, CSA	UL, cUL, FI

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Clause	Requirement + Test	Result - Remark	Verdict

8.10	TABLE: List of cri	tical componen	ts		Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates conformity ¹
			"X2".	E60384-14:09 ((FOWX2, 8), (E354331)), IEC 60384-14	
X-Capacitor (C67,C68) - Alternate	Kemet Electronics Corp (Evox-Rifa)	PHE840 Series	Rated max. 0.1uF, min. 250V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 ((FOWX2, 8) E73869)), IEC 60384- 14	UL, cUL, SEMKO
X-Capacitor (C67,C68) - Alternate	Kemet Electronics Italia SRL	R.46 Series	Rated max. 0.1 uF, min. 250V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2,8(E97797)), IEC60384-14	UL, cUL, VDE
X-Capacitor (C67,C68) - Alternate	Winday Electronic Ind Co Ltd	MPX Series	Rated max. 0.1 uF, min. 250V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2,8 (E302125)), IEC 60834-14	UL, cUL, VDE
Diodes (D1,D2,D23,D24)	Vishay	1N5627GP	Rated min. 800V, min. 3A. Soldered and secured to PWB using Diode Support. See diode support for details		
Diodes (D1,D2,D23,D24)	Interchangeable	Interchangeable	Rated min. 800V, min. 3A. Soldered and secured to PWB using Diode Support. See diode support for details		
Diode Support (D1,D2,D23,D24)	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Overall approx. 28 by 11 by min. 0.8 mm thick. Rated V-0, min. 155°C.	UL 94 (QMFZ2 (E95746))	UL
Diode Support (D1,D2,D23,D24) Alternate	EI Dupont De Nemours & Co Inc	FR530	Overall approx. 28 by 11 by min. 0.8 mm thick. Rated V-0, min. 155°C.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Y-Capacitor (C4,C45,C76)	Kemet Electronics OY (Evox-Rifa)	ERP610 Series	Rated max. 1000 pF, min. 250 V, marked "Y1".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2,8 (E356389)), IEC60384-14	UL, cUL, VDE
Y-Capacitor (C4,C45,C76) – Alternate	Murata Mfg Co Ltd	KX Series	Rated max. 1000 pF, min. 250 V, marked "Y1".	UL 60384-14, (FOWX2 (E37921)), CAN/CSA- E60384-14:09, IEC 60834-14	UL, CSA, VDE
Y-Capacitor (C4,C45,C76) – Alternate	Vishay Electronic GmbH	VY1 or VKP Series	Rated max. 1000 pF, min. 250 V, marked "Y1".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2, 8 (E183844)), IEC60384- 14	UL, cUL, VDE

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Clause	Requirement + Test	Result - Remark	Verdict

8.10 T	ABLE: List of cri	tical component	:S		Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
Electrolytic Capacitors (C14,C25,C112,C11 3) (PRI)	Interchangeable	Interchangeable	Rated max 100 uF, min. 63 V, min. 105°C. Provided with integral pressure relief.		
MOSFET (TR13) (PRI)	ST Microelectronics	STP10NK60Z	Rated min. 600 V, min. 10A, min. 150°C.		
MOSFET (TR13) (PRI) - Alternate	Interchangeable	Interchangeable	Rated min. 600 V, min. 10A, min. 150°C.		
Electrolytic Capacitor (C64) (PRI)	Interchangeable	Interchangeable	Rated max 150 uF, min. 450 V, min. 105°C. Provided with integral pressure relief		
Relay (RL1)	Xiamen Hongfa Electroacoustic Co	HF32F Series (HF32F-012-HSLQ)	Rated min. 12V, min. 10A (Non-isolating).	UL 60947-4-1A, CSA C22.2, No. 60947-4-1 (NLDX2, NLDX8 (E134517)), IEC61810	UL, cUL, TUV
MOSFET (TR2- TR5,TR27,TR28)	Fairchild Semiconductor	IRFB18N50KPBF	Rated min. 600 V, min. 13A, min. 150°C. TR2- TR5 secured to MOSFET Heat Sink by screw, nut and washer.		
MOSFET (TR2- TR5,TR27,TR28) - Alternate	Interchangeable	Interchangeable	Rated min. 600 V, min. 13A, min. 150°C. TR2- TR5 secured to MOSFET Heat Sink by screw, nut and washer.		
MOSFET Heatsink (TR2-TR5) (PRI)	Interchangeable	Interchangeable	Two provided. Aluminum, L-shaped, Overall approx. 33 by 31 by 6.8 by min. 1 mm thick. See Enclosure Diagrams (11) for details.		
Rectifier Diodes (D5,D6) (PRI)	Philips Semiconductors	BYV29 Series	Rated min. 9A, min. 500V. Secured to Rectifier Diode Heatsink using screw, washer, and nut.		
Rectifier Diodes (D5,D6) (PRI) - Alternate	Interchangeable	Interchangeable	Rated min. 9A, min. 500V. Secured to Rectifier Diode Heatsink using screw, washer, and nut.		
Rectifier Diode Heatsink (D5,D6) (PRI)	Interchangeable	Interchangeable	Aluminum, L-shaped, Overall approx. 33 by 31 by min. 1 mm thick. See enclosure Diagrams (12) for details.		
Rectifier Diode Heatsink (D5,D6) (PRI) – for Models	Interchangeable	Interchangeable	Aluminum, L-shaped, Overall approx. 33 by 31 by 18.6 by min. 1		

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Clause	Requirement + Test	Result - Remark	Verdict	

8.10 T	ABLE: List of cri	tical component	S		Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
with –A suffix			mm thick. Provided with screw opening to secure 5V Stand-by PWB.		
Inductor (L1)	XP Power LLC	Interchangeable (100xxxxx where x can be any number between 0 and 9). Construction of Inductor 10016094 represents entire series.	Toroidal. Copper Magnet Wire, (OBMW2), rated min. 130°C, wound on ferrite core. Overall approx. 25 mm dia. by 11 mm wide. See Enclosure Diagrams (01) for details.		
Inductor (L1) Base	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C. Provided between Inductor L1 and PWB. Overall approx. 25 by 11.6 by min. 1 mm thick.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Inductor (L1) Base – Alternate	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C. Provided between Inductor L1 and PWB. Overall approx. 25 by 11.6 by min. 1 mm thick	UL 94 (QMFZ2 (E95746))	UL
Inductor (L2)	XP Power LLC	Interchangeable (100xxxxx where x can be any number between 0 and 9). Construction of Inductor 10014243 represents entire series.	Toroidal. Copper Magnet Wire, (OBMW2), rated min. 130°C, wound on ferrite core. Overall approx. 29 mm dia. by 13 mm wide. See Enclosure Diagrams (02) for details.		
Inductor (L2) Base	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C. Provided between Inductor L1 and PWB. Overall approx. 25 by 15.4 by min. 1 mm thick	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Inductor (L2) Base – Alternate	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C. Provided between Inductor L1 and PWB. Overall approx. 25 by 15.4 by min. 1 mm thick.	UL 94, UL 746C (QMFZ2 (E95746))	UL
Inductors (PFC) (L3,L4)	XP Power LLC	Interchangeable (100xxxxxwhere x can be any number between 0 and 9. Construction of transformer 10013071 represents the entire series)	Open-type. Concentrically wound magnet wire, (OBWM2), rated min. 130°C. Overall approx. 41 by 26 by 20 mm. Core/Bobbin: See Transformer – Bobbin Material for details. See Enclosure Diagrams (03) for		

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Clause	Requirement + Test	Result - Remark	Verdict	

8.10 T	ABLE: List of cri	tical component	S		Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
			details.		
Inductors (PFC) (L3,L4) - Base	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C. Provided between Inductor L3,L4 assembly and PWB. L- shaped, overall approx. 43 by 29.5 by min. 1 mm thick.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Inductors (PFC) (L3,L4) – Base - Alternate	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C. Provided between Inductor L3,L4 assembly and PWB. L- shaped, overall approx. 43 by 29.5 by min. 1 mm thick.	UL 94, UL 746C (QMFZ2 (E95746))	UL, cUL
Inductor (L5)	XP Power LLC	Interchangeable (100xxxxx where x can be any number between 0 and 9. Construction of Inductor 10015645 represents the entire series)	Open-type. Concentrically wound magnet wire, (OBWM2), rated min. 130°C. Overall approx. 20.3 by 18 by 16.5 mm, min. 1 mm thick. Provided with Bobbin Base. See Inductor – Bobbin Base. See Enclosure Diagram (04) for details.	-	Evaluated as part of this investigation
Inductor (L5) – Bobbin	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C, approx. 14.65 by 8.25 by min. 0.5 mm thick.	QMFZ2 (E233198)	UL
Inductor (L5) — Bobbin - Alternate	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Inductor (L5) – Bobbin Base	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C, min. 1 mm thick. See Enclosure Diagram (04) for details.	UL 94, UL 746C (QMFZ2 (E95746))	UL
Inductor (L5) – Bobbin Base - Alternate	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C, min. 1 mm thick. See Enclosure Diagram (04) for details.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Transformer (T1)	XP Power LLC	Interchangeable (100xxxxx where x can be any number between 0 and 9. Construction of Transformer 10013075 represents entire series.)	Open-type. Provided with a Class F insulation system, see Transformer—Insulation System for details. Overall approx. 33 by 27 by 26 mm. Bobbin: Overall approx.16.8 by 11.2 by 11. 2 mm, min. 1.0 mm thick, see Transformer — Bobbin Material for details. See Enclosures Diagrams (06) to (10)	-	Evaluated as part of this investigation

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Clause Requirement + Test Result - Remark Verdict

8.10 TA	ABLE: LIST OT C'I	tical componen	ıs		Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
			and (14) for details.		
Transformer (T1) – Insulation System	XP Power LLC	Designated F	Rated 155°C	UL 1446 (OBJY3 (E139109S))	
Transformer – Bobbin	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C, min. 0.90 mm thick.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Transformer (T1) - Bobbin - Alternate	Sumitomo Bakelite Co Ltd	Sumikon PM9820 & PM9630	Rated V-0, min. 155°C, min. 0.90 mm thick.	UI 94, UL 746C, QMFZ2 (E41429)	UL
Transformer (T1) - Bobbin - Alternate	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C, min. 0.90 mm thick.	UL 94, UL 746C (QMFZ2 (E95746))	UL
Transformer (T1) - Core Washer	Dupont	Nomex 410	Rated V-0, approx. 22.5 mm OD, 12.5 mm ID, min. 0.08 mm thick.	UL 746C, UL 94 (QMFZ2 (E34739))	UL
Transformer (T1) - Insulator Sheet	Dupont	Nomex 410	Rated V-0, approx. 45 by 16 mm, min. 0.08 mm thick.	UL 746C, UL 94 (QMFZ2 (E34739))	UL
Transformer (T1) - Insulating Tape	3М Со	1350	Polyester film tape, min. 2.5 mils thick (Passed 2500 V ac dielectric)	UL 510 (OANZ2 (E17385))	UL
Transformer (T1) – Magnet Wire (Winding 2, 3, 6, and 7)	Interchangeable	Interchangeable	Rated min. 155°C, 0.20 mm, MW80.	UL 1446 (OBMW2)	UL
Transformer (T1) – Triple Insulated Wire (Winding 1, 4, 5 and 8)	Great Leoflon Industrial Co., Ltd	TRW (F)	Reinforced Insulation. Rated 155°C, min. 600 Vpk (Passed 6k Vpk dielectric as part of component evaluation, also passed 10kV dielectric for twist pair test as part of Test Report E146893-A32 report); and suitable for reinforced insulation)	UL 2353 (OBJT2 (E211989))	UL
Transformer (T1) – Triple Insulated Wire (Winding 1, 4, 5 and 8) - Alternate	Kuo Kuang Electronic Wire Co., Ltd	REFU-F	Reinforced Insulation, rated 155°C, min. 600 Vpk (15kV Dielectric test during component evaluation).	UL 2353 (OBJT2 (E222087))	UL
Transformer (T1) – Support	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C. Overall approx. 32.4 by 30 by 10.5 by min. .090 mm thick.	UL 94, UL 746C (QMFZ2 (E95746))	UL
Transformer (T1) – Support	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C. Overall approx. 32.4 by 30 by 10.5 by min. .090 mm thick.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
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Clause Requirement + Test Result - Remark Verdict

8.10 T	ABLE: List of cri	ticai component	.5		Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
T3)		(100xxxxx, where x can be any number between 0 and 9. Construction of Transformer 10013074 represents entire series)	Provided with a Class F insulation system, see Transformer— Insulation System for details. Secured to board using Transformer Base. See enclosure Diagrams (11) for details.		
Transformer (T2, T3) – Base	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C. Overall approx. 13 by 12.5 by 18 by min. .090 mm thick.	UL 94, UL 746C (QMFZ2 (E95746))	UL
Transformer (T2, T3) – Base - Alternate	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C. Overall approx. 13 by 12.5 by 18 by min. .090 mm thick.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Transformer (T2, T3) – Insulation System	XP Power LLC	Designated F	Rated 155°C	UL 1446 OBJY3 (E139109S)	
Transformer (T2, T3) – Triple Insulated Wire (Winding 2)	Rubadue Wire Co. Inc.	T24A01T090-2	Reinforced Insulation. Rated 155°C,min. 1000 Vpk, 23 AWG (14kV Dielectric test during component evaluation).	UL 2353, (OBJT2 (E206198))	UL
Transformer (T2, T3) – Magnet Wire (Winding 1)	Interchangeable	Interchangeable	Rated 130°C, 0.30 mm, MW80.	UL 1446 (OBMW2)	UL
Optical Isolator (OPT1-OPT4)	Lite-On	LTV-816 Series	Double protection, isolation voltage min. 5000 V. DTI min 0.4mm	UL 1577, CSA Component Acceptance Service No. 5A (FPQU2, 8 (E113898)), IEC 607047-5-2,VDE 0884	UL, cUL, VDE
Optical Isolator (OPT1- OPT4) - Alternate	Renesas Electronics Corp (NEC)	PS2561L-1 Series	Double protection, isolation voltage min. 5000 V. DTI min 0.4mm	UL 1577 (FPQU2 (E72422)), CSA Std. 1, 60950-1,CA5A,E60065, IEC 60950-1, 60065 7th Ed. , IEC 607047-5-2, VDE 0884	UL, CSA, VDE
Optical Isolator (OPT1- OPT4) - Alternate	Vishay Infared Components Inc	SFH6156 Series (Systems H and J)	Double protection, isolation voltage 4420 V. DTI min 0.4mm	UL 1577, CSA Component Acceptance Service No. 5A (FPQU2 (E52744)), IEC 60747-5- 2, VDE0884E	UL, cUL, VDE
Y-Capacitor (C110)	Murata Mfg Co Ltd	KX Series	Rated max. 680 pF, min. 250 V, marked "Y1".	UL 60384-14 (FOWX2(E37921)), CSA Std. CAN/CSA-E60384- 14:09, IEC60384-14	UL, CSA, VDE
Y-Capacitor (C110) – Alternate	TDK-EPC Corp	CD Series	Rated max. 680 pF, min. 250 V, marked "Y1".	UL 60384-14, CSA E60384-1:03 (FOWX2,8) (E37861)), IEC60384-14,	UL, cUL, VDE
Y-Capacitor (C110)	Vishay Electronic GmbH	VY1 or VKP Series	Rated max. 680 pF,	UL 60384-14, CSA	UL, cUL, VDE

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Clause Requirement + Test Result - Remark Verdict					

8.10 T	ABLE: List of cr	itical component	S		Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity 1
– Alternate			min. 250 V, marked "Y1".	E60384-1:03, CSA E60384-14:09 (FOWX2, 8 (E183844)), IEC60384- 14	
Electrolytic Capacitors (SEC)	Interchangeable	Interchangeable	Rated min. 16 V, 105°C. Provided with integral pressure relief.	-	-
Output Inductor (L9)	XP Power LLC	Interchangeable (100xxxxx, where x can be any number between 0 and 9. Construction of inductor 10013080 represents the entire series)	Magnet Wire, (OBWM2) min. 105°C, wound on ferrite core. Overall approx. 8 mm dia. by 15.2 mm high. See Enclosure Diagrams (05) for details.	-	Evaluated as part of this investigation
Ceramic Capacitor (C23)	Interchangeable	Interchangeable	Rated max. 0.1 uF, min. 50V.	-	-
MOSFET (TR15, TR16) (SEC)	Interchangeable	Interchangeable	Rated min. 40V, max. 120 A. Secured to output connector (CON2) by screw and nut.	-	-
Output Connector (CON2) (SEC)	Interchangeable	Interchangeable	U-shaped, tin plated brass, overall approx. 31.8 by 13 by 11.4 by min. 1 mm thick. Secured to PWB by solder.	-	-
Output Connector (CON3) (SEC)	Interchangeable	Interchangeable	U-shaped, tin plated brass, overall approx. 15.3 by 13 by 4.5 by min. 1 mm thick. Secured to PWB by solder.	-	-
Output Connector (CON3) (SEC) – for Models with suffix - A	Interchangeable	Interchangeable	U-shaped, tin plated brass, overall approx. 26.85 by 12.8 by 5 by min. 1 mm thick. Secured to PWB by solder.	-	-
Output Connector (CON4) (SEC)	Japan Solderless Terminal Mfg Co Ltd (JST)	PHD Series (B10B- PHDSS(LF)(SN))	Rated min. 7A, min. 250V, min. 105°C.	UL 1977, (ECBT2 (E60389)), C22.2 No. 182.3	UL, CSA
Electrolytic Capacitor (C36, C64, C113)	Interchangeable	Interchangeable	May be provided with optional heat-shrink tubing. See Insulating Tubing/Sleeving for details.	-	-
5V Stand-by - Printed Wiring Board – for Models with suffix -A	Interchangeable	Interchangeable	Overall approx. 6.9 by 3.2 cm, min. 1 mm thick. Rated min. V-1, min. 130°C. Input side secured to Rectifier Diode Heatsink	U:L 796 (ZPMV2)	UL

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Clause	Requirement + Test	Result - Remark	Verdict	

8.10 T	ABLE: List of cri	tical component	ts		Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
			(D5,D6) (PRI) by screw and nut. Output side secured to Output Connector (CON3) (SEC) by solder.		
X-Capacitor (C9) - 5V Stand-by	Xiamen Faratronic Co Ltd	MKP62 Series (Type C42)	Rated max. 0.1 uF, min. 250 V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2, 8 (E186600)), IEC60384- 14	UL, cUL, VDE
Transformer (T1) – 5V Stand-by	XP Power LLC	10015566	Open-type. Provided with a Class F insulation system, see Transformer – Insulation System for details. Overall approx. 17.8 by 16.4 by 11 mm See enclosure diagram (15) for details.	-	-
Transformer (T1) – Insulation System - 5V Stand-by	XP Power LLC	Class F	Rated 155°C	UL 1446 (OBJY3 (E139109SP)	
Transformer – Bobbin - 5V Stand- by	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C, min. 0.90 mm thick.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Transformer (T1) - Bobbin – 5V Stand- by - Alternate	Sumitomo Bakelite Co Ltd	Sumikon PM9820 & PM9630	Rated V-0, min. 155°C, min. 0.90 mm thick.	UL 94, UL 746C (QMFZ2 (E41429))	UL
Transformer (T1) - Bobbin - 5V Stand- by -Alternate	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C, min. 0.90 mm thick.	UL 94, UL 746C (QMFZ2 (E95746))	UL
Transformer (T1) – Magnet Wire (Winding 1, 2) - 5V Stand-by	Interchangeable	Interchangeable	Rated min. 155°C, 0.20 mm, MW80.	UL 1446 (OBMW2)	UL
Transformer (T1) – Triple Insulated Wire (Winding 3) - 5V Stand-by	Great Leoflon Industrial Co., Ltd	TRW (F)	Reinforced Insulation. Rated 155°C, min. 600 Vpk(Passed 6k Vpk dielectric as part of component evaluation, also passed 10kV dielectric for twist pair test as part of Test Report E146893-A32 report); and suitable for reinforced insulation)	UL 2353 ((OBJT2 (E211989))	UL
Transformer (T1) – Triple Insulated Wire (Winding 3) - 5V Stand-by - Alternate	Kuo Kuang Electronic Wire Co., Ltd	REFU-F	Reinforced Insulation, rated 155°C, min. 600 Vpk (15kV Dielectric test during component evaluation).	UL 2353 (OBJT2 (E222087))	UL

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IEC 60601-1				
Clause	Requirement + Test	Result - Remark	Verdict	

8.10	TABLE: List of crit	tical componen	ts			Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	٠,	& Certificates of onformity ¹
Transformer (T1) - Outerwrap - 5V Stand-by	- 3M Co	1350	Polyester film tape, 1mm thick. (Not relied upon for reinforced insulation)	UL 510 OANZ2 (E17385)	UL	
Transformer (T1) - Outerwrap - 5V Stand-by - Alternate	Jingjiang Yahua Pressure Sensitive Glue Co Ltd	CT (CT286)	Rated 130°C. Tape Polyester Film, 1mm thick. (Not relied upon for reinforced insulation)	UL 510 (OANZ2 (E165111))	UL	
Inductor (L1) - 5V Stand-by	XP Power	10015586	Copper Magnet Wire, (OBMW2), rated min. 130°C, wound on ferrite core. Overall approx. 2.6 mm dia. by 15 mm long. See Enclosure Diagrams (16) for details.	-	-	
Electrolytic Capacitors - 5V Stand-by	Interchangeable	Interchangeable	Rated min. 16 V, 105°C. Provided with integral pressure relief.	-	-	
Insulating Tubing/Sleeving	Interchangeable	Interchangeable	FEP, PTFE, PVC, TFE, neoprene, polyimide or marked VW-1; 130 ºC, 240 V	UL 224 (UZFT2, YDPU2, YDRY2, YDTU2)	UL	
RTV	Interchangeable	Interchangeable	Rated min. V-2, min. 130°C	UL 746C (QMFZ2)	UL	

Supplementary information:

The (CB) Test Laboratory has verified the component information.

- 1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.
- 2) Identify the UL Product Category CCN(s)/File Number in brackets "()" if component is a UL Certified component and this report includes a UL Certification. This is useful for the UL Follow-Up Service Inspection associated with the UL Mark.

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

National Differences

The following National Differences are included in this Report. If not 'Selected', the device was not evaluated to these Differences.

Selected? (y/n)	Country	Standard	Abbreviation
Yes	Austria	EN 60601-1:2006/A1:2013	AU
Yes	Korea, Republic of	KS C IEC 60601-1	КО
Yes	USA	ANSI/AAMI ES60601-1:2005/(R)2012	US
Yes	Canada	CSA CAN/CSA-C22.2 NO. 60601-1:14	CAN
Yes	United Kingdom	BS EN 60601:2006 A1	UK
Yes	Sweden	SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014	SW

	Austria (EN 60601-1:2006/A	1:2013)	
	No specific National Differences for this Country		N/A
	Korea, Republic of (KS C IEC 6	50601-1)	
	No specific National Differences for this Country		N/A
	USA (ANSI/AAMI ES60601-1:200	05/(R)2012)	
	Replacement: where there was no relevant IEC/ISO standard, the relevant US ANSI standard applied	see appended table 8.10	Pass
	- when no relevant US ANSI standard existed, the requirements of this standard applied	see appended table 8.10	Pass
	Replacement: Rated voltage not exceeding 250V dc or single phase ac. or 600V poly-phase ac for me equipment and me systems up to 4kVA		Pass
	Rated voltage not exceeding 600 V for all other me equipment and me systems		N/A
	Addition: To comply with NFPA 70, X-Ray systems are classified as long time operation (> 5 min) or momentary operation (< 5 sec)	No such parts	N/A
	Addition: To comply with NFPA 70, X-Ray systems are marked as long time operation or momentary operation		N/A
7.2.22	New Sub-clause: Colors of medical gas cylinders		N/A
	To comply with NFPA 99: Cylinders containing medical gases and their connection points are colored in accordance with the requirements of NFPA 99		N/A

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

Addition: All fixed me equipment & permanently installed me equipment are class I me equipment		N/A
Addition: To comply with NFPA 99, the enclosure of X-ray ME EQUIPMENT operating over 600 Vac, 850Vdc MAINS VOLTAGE, or containing voltages up to 50 V peak and enclosed in protectively earthed enclosure as well as connections to X-ray tubes and other high voltage components that include high voltage shielded cables are PROTECTIVELY EARTHED.		N/A
To comply with NFPA 99, non-current carrying conductive parts of X-Ray ME EQUIPMENT likely to become energized are PROTECTIVELY EARTHED		N/A
Earth leakage current values are not higher than the stated values		Pass
5 mA in normal condition		Pass
10 mA in single fault condition		Pass
Addition prior to the first paragraph: a) To comply with the NEC, add the following requirements to this clause:	Component only, to be determined in the end product	N/A
Addition at the end of the clause: b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, 250 V/20 A "Hospital Grade" mains plug is provided and the POWER SUPPLY CORD is marked	Component only, to be determined in the end product	N/A
Addition: permanently connected me equipment provided with field wiring provision in accordance with NEC		N/A
Installation of connecting cords between equipment parts comply with NEC		N/A
Cable used as external interconnection between units		N/A
1) Exposed to abuse: Type SJT, SJTO, SJO, ST, SO, STO, or equivalent, or similar multiple-conductor appliance-wiring material,		N/A
2) Not exposed to abuse: The cable was as in item 1) above, or		N/A
i) Type SPT-2, SP-2, or SPE-2, or equivalent		N/A
ii) Type SVr, SVRO, SVE, or equivalent or similar multiple- conductor appliance wiring material,		N/A
iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more,		N/A

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

	- enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more		N/A
	Receptacles provided as part of me equipment and me systems for use in the patient care areas of pediatric wards, rooms, or areas are Listed tamper resistant	No such parts	N/A
	- or employ a Listed tamper resistant cover in accordance with NEC		N/A
	- and it is acceptable for use at a voltage not less than the rated voltage of the appliance		N/A
	- and has an ampacity as in NEC, not less than the current rating of the appliance		N/A
	Addition: To comply with NFPA 99, for X-Ray ME EQUIPMENT with an attachment plug, the current rating on a hospital grade plug is 2X the maximum input current of the equipment		N/A
	Canada (CSA CAN/CSA-C22.2 NO.	60601-1:14)	
1	Scope, object and related documents		Pass
1.1	Scope		Pass
	This standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be installed in accordance with CSA C22.1 and CAN/CSA-Z32.		Pass
1.3	Collateral standards		N/A
	Applicable Canadian collateral standards become normative at the date of their publication and apply together with this standard.	Noted	N/A
1.4	Particular standards		N/A
	Applicable Canadian 60601/80601 particular standards may modify, replace, or delete requirements contained in this standard. Requirements in the Canadian particular takes priority of this standard.	Noted	N/A
3	Terminology and definitions		N/A
3.41	HIGH VOLTAGE - voltage above 750 V, as defined in the Canadian Electrical Code Part I		N/A
	General Requirements		Pass
4.1A	General requirements applicable to ME EQUIPMENT and ME SYSTEMS are provided in CAN/CSA C22.2 No. 0		Pass
	a) the applicable safety requirements of a relevant CSA,Group, IEC, or ISO standard; or	see appended table 8.10	Pass
	b) where there is no relevant CSA Group, IEC or ISO standard, requirements of this standard applied		Pass

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	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

	ME EQUIPMENT intended for connection to SUPPLY MAINS in accordance with the Canadian Electrical Code Part I, CSA C22.1 and the following RATED voltage not exceeded:	Pass
	ME EQUIPMENT identification, markings and documents	Pass
7	ME EQUIPMENT identification, markings and documents	Pass
7.7.1-7.7.5	Replaced by 7.7 below	N/A
7.7	Colours of insulation on conducts in accordance with Canadian Electric Code, Part 1	N/A
	A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION of any insulation identified by either green or green and yellow colour at least at the termination of the conductors	N/A
	Identification by green or green and yellow insulation only used for: - PROTECTIVE EARTH CONDUCTORS; - Conductors as specified in 7.7.2 - POTENTIAL EQUALIZATION CONDUCTORS; - FUNCTIONAL EARTH CONDUCTORS	N/A
	Colours of neutral conductors and POWER SUPPLY CORD conductors in accordance with Canadian Electric Code, Part 1, CSA C22.2 No. 21 and CSA C22.2 No. 49	N/A
	Allowable values in accordance with the Canadian Electrical Code, Part I	Pass
	POWER SUPPLY CORDS comply with the following:	N/A
	a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall be	N/A
	i) molded-on type, hospital grade mains plug complying with CSA C22.2 No. 21:	N/A
	ii) hospital grade disassembly attachment plug type complying with CSA C22.2 No. 42; or	N/A
	iii) Class II equipment having fuses on the line side/sides and neutral may use a non-polarized attachment plug or a polarized attachment plug. CSA configuration type 1-15P shall be required and shall meet all applicable requirements in CSA C22.2 No. 21 and CSA C22.2 No. 42. Where a polarized attachment plug is used, the POWER SUPPLY CORD shall be connected to the wiring of the EQUIPMENT on the ungrounded side of the line when any of the following devices are used in the primary circuit:	N/A
	1- the centre contact of an Edison base lampholder;	N/A
	<u>l</u>	<u> </u>

	IEC 60601-1		
Clause	Requirement + Test	Result - Remark	Verdict

2- a single pole switch;	N/A
3- an automatic control with a marked off position;	N/A
4- a solitary fuse/fuse holder; or	N/A
5- any other single pole overcurrent protective device	N/A
b) Detachable POWER SUPPLY CORD for non- PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) shall be of a type that	N/A
i) can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety HAZARD to a PATIENT or OPERATOR;	N/A
ii) can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety HAZARD to a PATIENT or OPERATOR; and	N/A
iii) has a terminal configuration or other constructional feature that will minimize the possibility of its replacement by a detachable POWER SUPPLY CORD which could create a HAZARDOUS SITUATION	N/A
c) A detachable POWER SUPPLY CORD shall	N/A
i) comply with the applicable requirements of CSA C22.2 No. 21; and	N/A
ii) not be smaller than No. 18 AWG, and the mechanical serviceability shall be not less than	N/A
1) Type SJ or equivalent for mobile or exposed to abuse ME EQUIPMENT; and	N/A
2) Type SV or equivalent for ME EQUIPMENT not exposed to abuse (or Type HPN if required because of temperature)	N/A
d) Power supply cords shall meet the requirements of the Canadian Electrical Code, Part I, as applicable	N/A
Mains fuses and OVER-CURRENT RELEASES shall be in accordance with the Canadian Electrical Code, Part I,	Pass
Pressure vessels shall comply with the requirements of CSA B51, as applicable	N/A
A pressure-relief device shall also comply as applicable to the requirements of ASME PTC 25 or equivalent Canadian requirements:	N/A
bA) The point of connection of gas cylinders to ME EQUIPMENT shall be gas specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on EQUIPMENT shall be	N/A

		IEC 60601-1						
Clause	Requirement + Test	Result - Remark	Verdict					

i) gas specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1 380 kPa (200 psi); or :	N/A
ii) DISS type complying with CGA V-5 for pressures 1 380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA-Z5359	N/A
Flexible cords and equipment wire of ME EQUIPMENT shall be in accordance with the Canadian Electrical Code, Part I,	N/A
General requirements for the ME SYSTEMS	N/A
An ME SYSTEM shall provide	N/A
- within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with the CSA Group standard; and	N/A
- outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA Group, IEC, or ISO safety standards	N/A
Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with CSA Group, IEC, or ISO safety standards that are relevant to that equipment.	N/A
d) The MULTIPLE SOCKET-OUTLET combined with a separating transformer, the following additional requirements apply:	N/A
- The separating transformer shall comply with the requirements of this standard; or	N/A
- The separating transformer complied with CAN/CSA- E61558-2-1, except that the requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 do not apply	N/A
-Separating transformer was CLASS 1 construction	N/A
-Degree of protection against ingress of water is specified:	N/A
Separating transformer assembly market according to 7.2 and 7.3	N/A
MULTIPLE SOCKET-OUTLET permanently connected to the separating transformer or	N/A
socket- outlet of separating transformer assembly of the type the cannot accept MAINS PLUGS of any of the kinds in Canadian Electrical Code, Part 1	N/A
United Kingdom (BS EN 60601	:2006 A1)
No specific National Differences for this Country	N/A

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

Sweden (SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014)				
	No specific National Differences for this Country		N/A	

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

Collateral/Particular Standard Enclosures

Enclosures

Supplement ID	<u>Description</u>
N/A	No Collateral or Particular standards apply.

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IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		

FND OF MAIN REPORT

APPENDIX A: Enclosures

All Enclosures associated with this report are shown below.

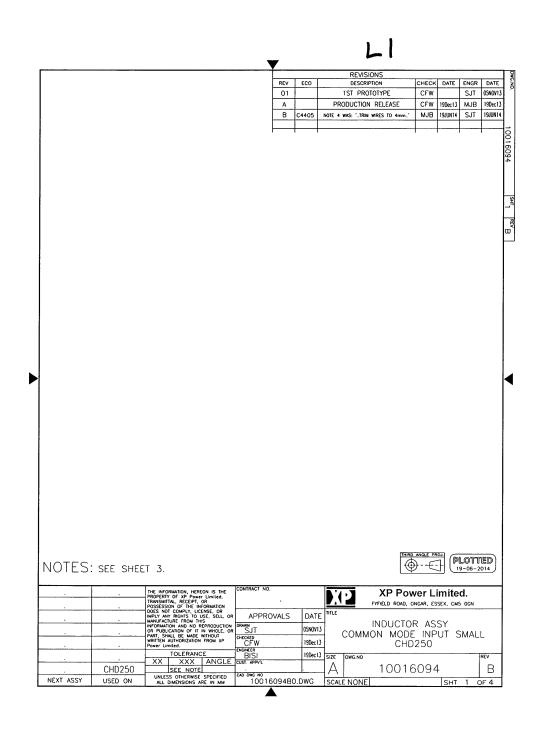
Enclosures

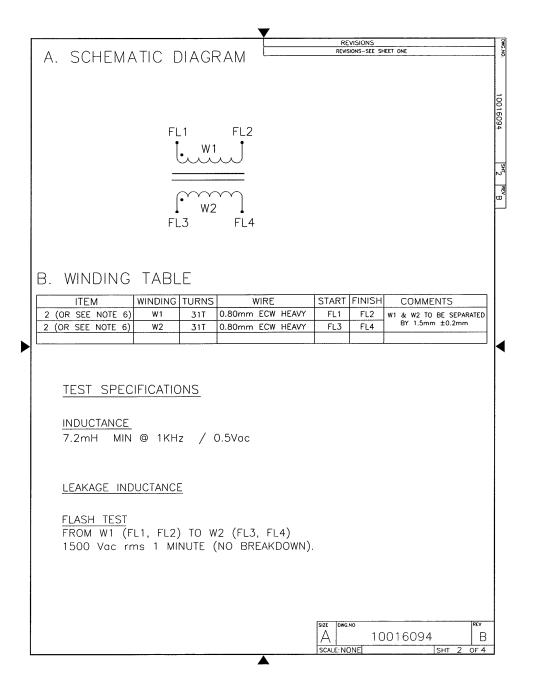
Supplement - (ID)	<u>Description</u>
Diagrams - (01)	: Inductor (L1)
Diagrams - (02)	: Inductor (L2)
Diagrams - (03)	: Inductor (L3, L4)
Diagrams - (04)	: Inductor (L5)
Diagrams - (05)	: Inductor (L9)
Diagrams - (06)	: CHD250PSXXYY - Transformer (T1)
Diagrams - (07)	: Alternate - Transformer (T1)
Diagrams - (08)	: Alternate - Transformer (T1)
Diagrams - (09)	: Alternate - Transformer (T1)
Diagrams - (10)	: Alternate - Transformer (T1)
Diagrams - (11)	: CHD250PSXXYY - Transformer (T2, T3)
Diagrams - (12)	: Heatsinks - Mosfet (TR2-TR5), Diode (D5, D6)
Diagrams - (13)	: CHD250PSXXYY: Cover Top/Bottom
Diagrams - (14)	: CHD250PSXXYY - Transformer (T1)
Diagrams - (15)	: Stand-by Output Transformer (T1) - For models with suffix "A"
Diagrams - (16)	: Stand-by Output Inductor (L1) - For models with suffix "A"
Licenses - (01)	: Optocoupler - Lite On, Type LTV-816 Series
Licenses - (02)	: Optocoupler - Renesas (NEC), Type PS2561 Series
Licenses - (03)	: Optocoupler - Vishay, Type SFH6156 series
Marking Label - (01)	: Marking Plate
Marking Label - (02)	: Trade name
Miscellaneous - (01)	: Letter of Assurance
Miscellaneous - (02)	: Output Ratings
Miscellaneous - (03)	: Rationale for waiving the ball pressure test
Photographs - (01)	: Top View with Cover
Photographs - (02)	: Input Side View with Cover
Photographs - (03)	: Output Side View with Cover
Photographs - (04)	: Internal View
Photographs - (05)	: Top View without Cover
Photographs - (06)	: Bottom view of the PWB
Schematics + PWB - (01)	: Component/PWB Trace Layout
Schematics + PWB - (02)	: PWB Component Layout - Standby Board (For models with "A"suffix)
Schematics + PWB - (03)	: Electrical Schematics

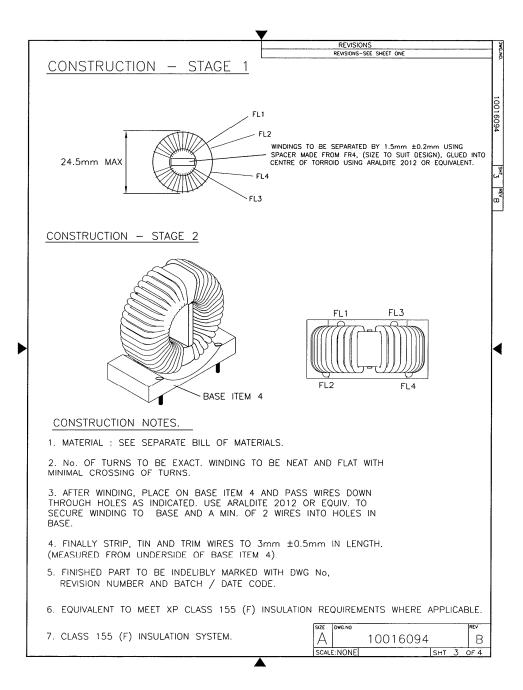
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Schematics + PWB - (04)	: Electrical Schematics
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Diagrams - (01) Inductor (L1)

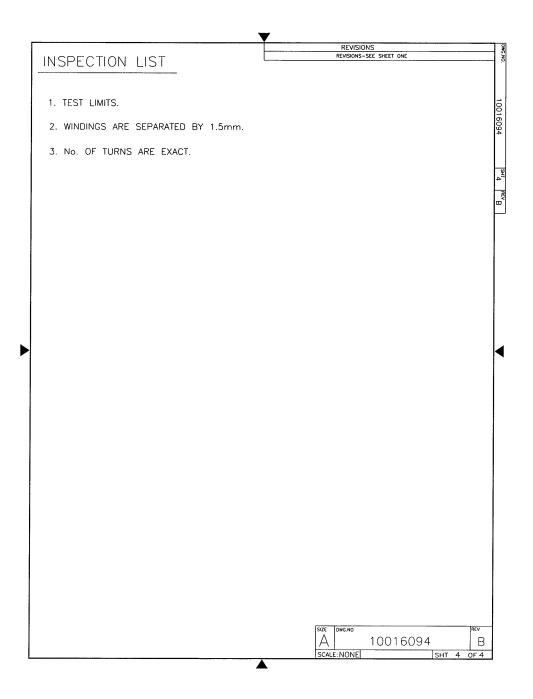




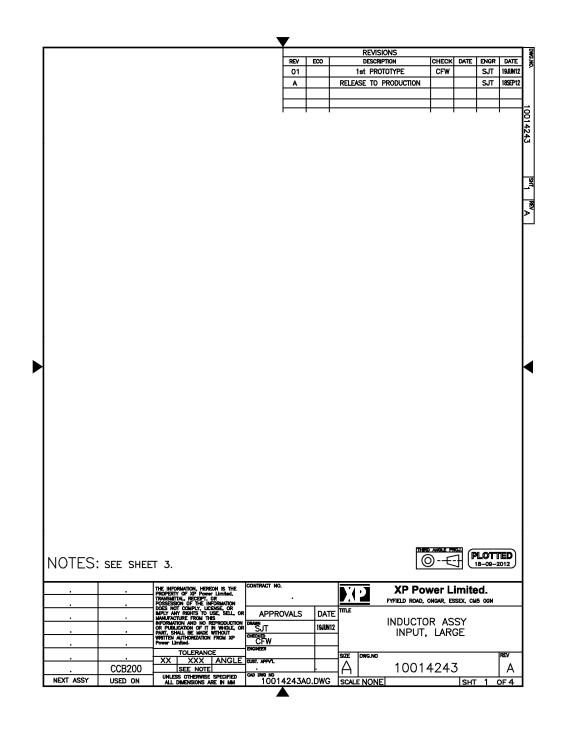


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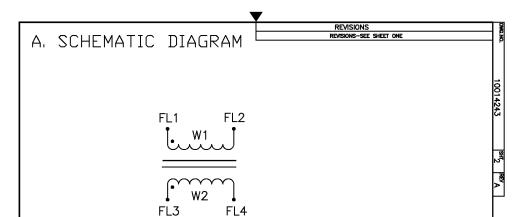
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Diagrams - (02) Inductor (L2)



Diagrams - (02) Inductor (L2)



B. WINDING TABLE

ITEM	WINDING	TURNS	WIRE	START	FINISH	COMMENTS
2 (OR SEE NOTE 6)	W1	32T	0.8mm ECW HEAVY	FL1	FL2	W1 & W2 TO BE SEPARATED
2 (OR SEE NOTE 6)	W2	32T	0.8mm ECW HEAVY	FL3	FL4	BY 4mm +/-0.2mm

TEST SPECIFICATIONS

INDUCTANCE

6.22mH MIN @ 1KHz / 0.5Vac INDUCTANCE FOR BOTH WINDINGS TO BE WITHIN 0.35mH MAX.

LEAKAGE INDUCTANCE

> 45uH

FLASH TEST

FROM W1 (FL1, FL2) TO W2 (FL3, FL4) 1500 Vac rms 1 MINUTE (NO BREAKDOWN).

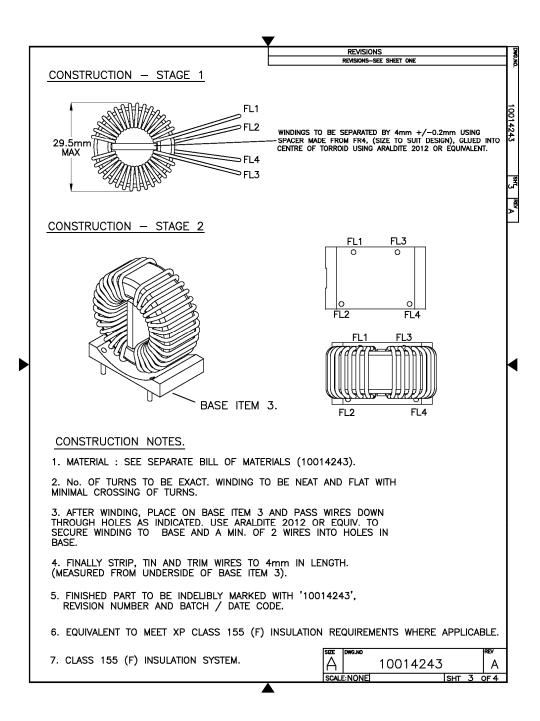
DC RESISTANCE TEST (TOTAL W1 & W2)

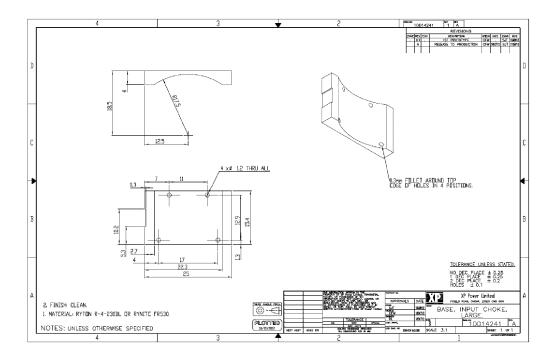
CONNECT FL2-FL3

MEASURE FL1 TO FL4 95m OHMS MAX

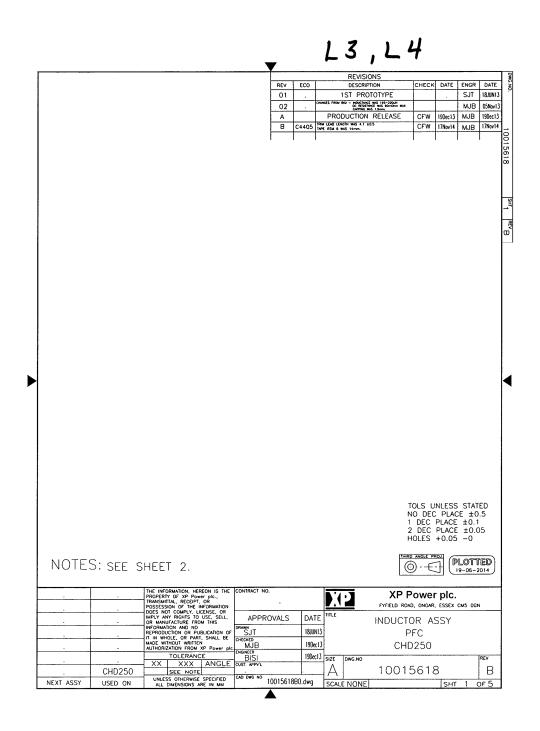
SIZE	DWG.NO				REV
ΙΑ		10014243			A
SCALE	NONE		SHT	2	OF 4

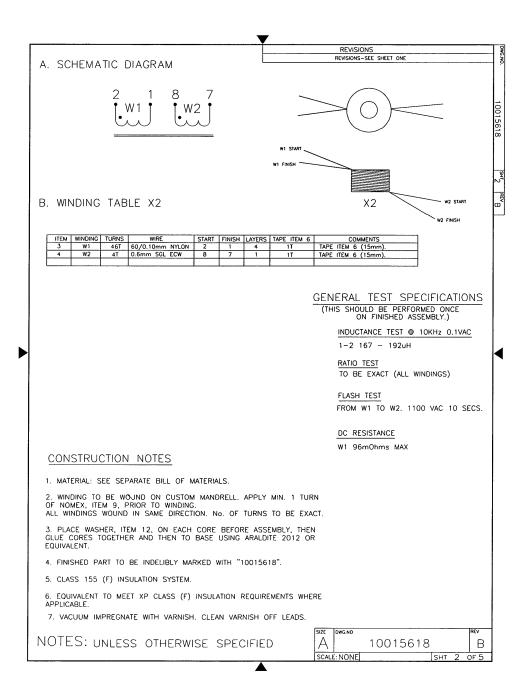
Ā

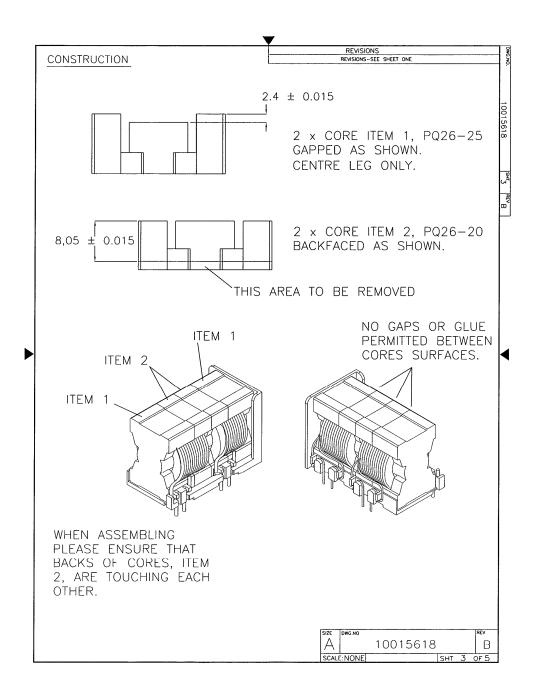


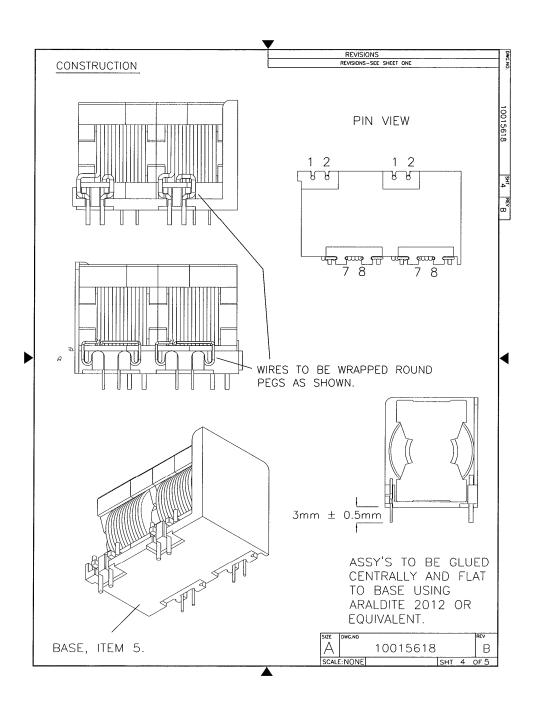


Diagrams - (03) Inductor (L3, L4)



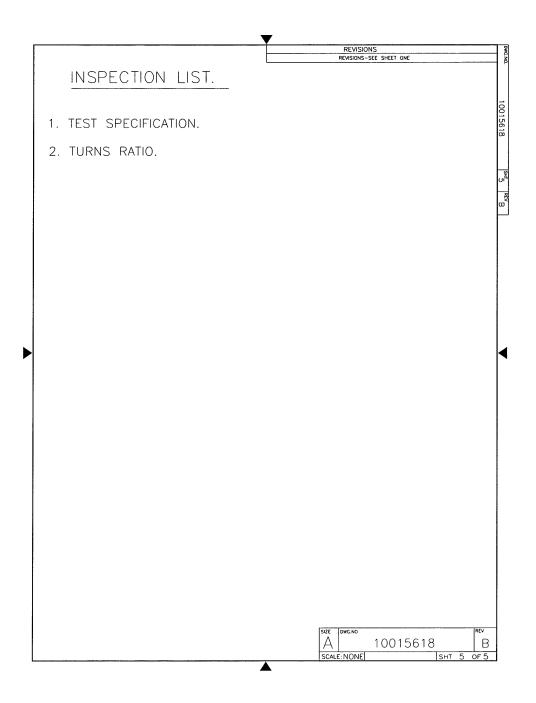






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Diagrams - (03) Inductor (L3, L4)



Diagrams - (04) Inductor (L5)

Diagrams - (04) Inductor (L5)

			1		DEVISIONS				
			REV	ECO	REVISIONS DESCRIPTION	CHECK	DATE	ENGR	DATE
			01	.	1ST PROTOTYPE			JRB	31Jul1
			A		PRODUCTION RELEASE	мјв	200ec13	JRB	20Dec1
					A14-3-4490	+			
						.h			ı
					7	TOLS UN	JI FSS	STAT	FD
					١	NO DEC	PLAC	CE ±0	.5
						DEC F			
						HOLES +),)
	S. CEE 6	CHECT O			THIR	ANGLE PRO		LOTT	ED
NOTE	J. SEE S	SHEEL Z.				<i>)</i> - ' -	IJĽ		
NOTES									
NOTE:		THE INFORMATION, HEREON IS THE	CONTRACT NO.		XP XP	Power	plc.		
NOTES		PROPERTY OF XP Power pic.				D, ONGAR,		CHE OCK	
NOTE:		PROPERTY OF XP Power pic., TRANSMITTAL, RECEIPT, OR POSSESSION OF THE INFORMATION					CODEN	CM2 OO	ı
NOTES		PROPERTY OF XP Power plc., TRANSMITTAL, RECEIPT, OR POSSESSION OF THE INFORMATION DOES NOT COMPLY, LICENSE, OR IMPLY ANY RIGHTS TO USE, SELL,	APPROVALS	DATE	TITLE)D ^C		CM3 001	ı
NOTES		PROPERTY OF XP Power plc. TRANSMITTAL RECEIPT, OR POSSESSION OF THE INFORMATION DOES NOT COMPLY, LICENSE, OR IMPLY ANY RIGHTS TO USE, SELL, OR MANUFACTURE FROM THE INFORMATION AND NO REPRODUCTION	APPROVALS	DATE	INDUCTO			CM3 001	ı
NOTES		PROPERTY OF XP Power pic., TRANSMITTAL, RECEIP! OR POSSESSION OF THE INFORMATION DOES NOT COMPLY, LUCENSE OR IMPLY ANY RIGHTS TO USE, SELL, OR MANUFACTURE FROM THIS INFORMATION AND NO REPRODUCTION OR PUBLICATION OF IT IN WHOLE, OR PART, SHALL BE MADE WITHOUT WOTETS. MITHOUTE SECON UPON	APPROVALS DRAWN JRB CHECKED	31,101.13	INDUCTO BO	OST			ı
NOTES		PROPERTY OF XP Power pic. TRANSMITHA, RECEPT, OR, POSSESSION OF THE INFORMATION DOES NOT COMPLY, LICENSE, OR OUSS NOT COMPLY, LICENSE, OR AMULFACTURE, FROM THIS INFORMATION AND NO REPRODUCTION OR PUBLICATION OF IT IN WHOLE, OR PART, SHALL BE MADE WITHOUT WRITTER MUTHORIZATION FROM XP POWER PIC.	APPROVALS DRAWN JRB CHECKED MJB ENGINEER	31JUL13 20Dec13	INDUCTO BO CHE				ı
NOTES		THE INFORMATION, HEREON IS THE PROPERTY OF XP POWER PIC. TRANSMITTAL, RECEIPT, OR POWER PIC. POSSESSION OF THE INFORMATION POSSESSION OF THE INFORMATION OF THE INFORMATION OF THE POWER PIC. OR MANUFACTURE FROM THIS INFORMATION AND NO REPRODUCTION OR PUBLICATION OF IT IN WHOLE, OR PART, SHALL BE MADE WITHOUT WRITTEN MUTHORIZATION FROM XP POWER PIC. TOLERANCE XY. XY.Y. ANCLE	BISI	31,101.13	INDUCTO BO CHE	OST			REV
NOTES		XX XXX ANGLE SEE NOTE	CUST. APPV'L	31JUL13 20Dec13	INDUCTO BO CHE	OST)250			REV
NOTES	CHD250	XX XXX ANGLE	BISI	31JUL13 20Dec13 20Dec13	INDUCTO BO CHE	OST)250			

Diagrams - (04) Inductor (L5)

A. SCHEMATIC DIAGRAM

FL1 • W1 }

B. WINDING TABLE

ITEM	WINDING	TURNS	WIRE	START	FINISH	LAYERS	TAPE ITEM 7 (SEE NOTE 8)	COMMENTS
3	W1	98T	31 x 0.07mm ECW	FL1	FL2		1T	

TEST SPECIFICATIONS

(THIS SHOULD BE PERFORMED ONCE ON FINISHED ASSEMBLY.)

FLASH TEST

REVISIONS
REVISIONS-SEE SHEET ONE

FROM W1 TO CORE 550 Vac rms 10 SECS (NO BREAKDOWN).

INDUCTANCE TEST

677 - 779uH +/- 7% @ 1KHz.

DC RESISTANCE TEST 0.58 OHMS MAX.

FINISHED PART TO BE INDELIBLY MARKED WITH "DWG.NO. & REV"
 VACUUM IMPREGNATE WITH VARNISH. CLEAN VARNISH OFF LEADS.

2. NUMBER OF TURNS TO BE EXACT. ALL WINDINGS TO BE IN SAME DIRECTION.

3. ONLY LEADOUT PART OF W1 IS TWISTED. SLEEVE WIRES AFTER WINDING, BEFORE ASSEMBLY WITH SLEEVING,

6. FIT ONE WASHER, ITEM 5, INTO EACH CORE, ITEM 2.

1. MATERIAL: SEE SEPARATE BILL OF MATERIALS.

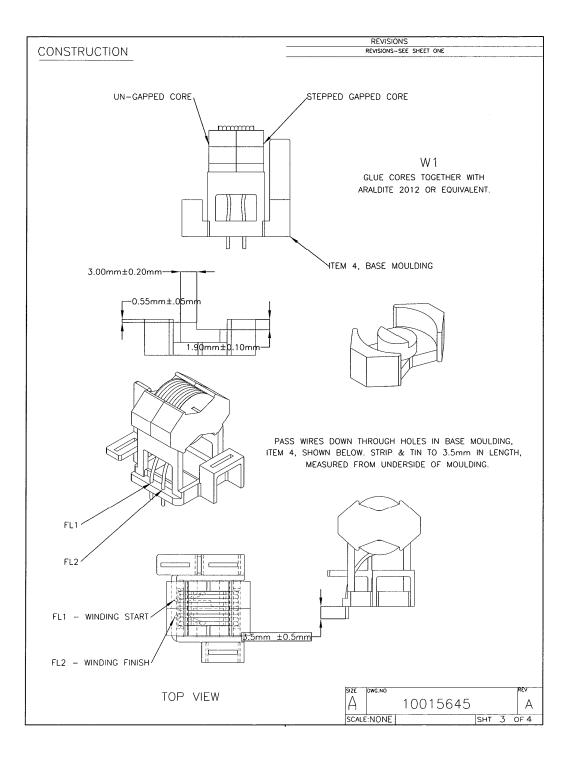
ITEM 1 (OR SEE NOTE 8).

7. CORES GLUED AND CORES TO BASE USING ARALDITE 2012 OR EQUIVALENT. (SEE NOTE 8).

8. EQUIVALENT TO MEET XP CLASS (F) INSULATION REQUIREMENTS WHERE APPLICABLE.

NOTES: unless otherwise specified

Diagrams - (04) Inductor (L5)

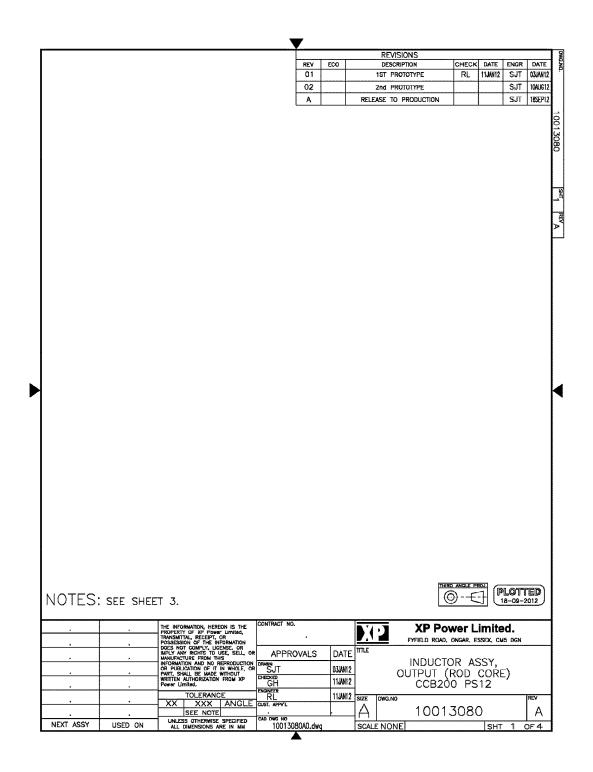


Diagrams - (04) Inductor (L5)

	REVISIONS
	REVISIONS-SEE SHEET ONE
INSPECTION LIST.	
1. TEST SPECIFICATION.	
2. TURNS RATIO.	
	SIZE DWG.NO REV
	A 10015645 A
	SCALE:NONE SHT 4 OF 4

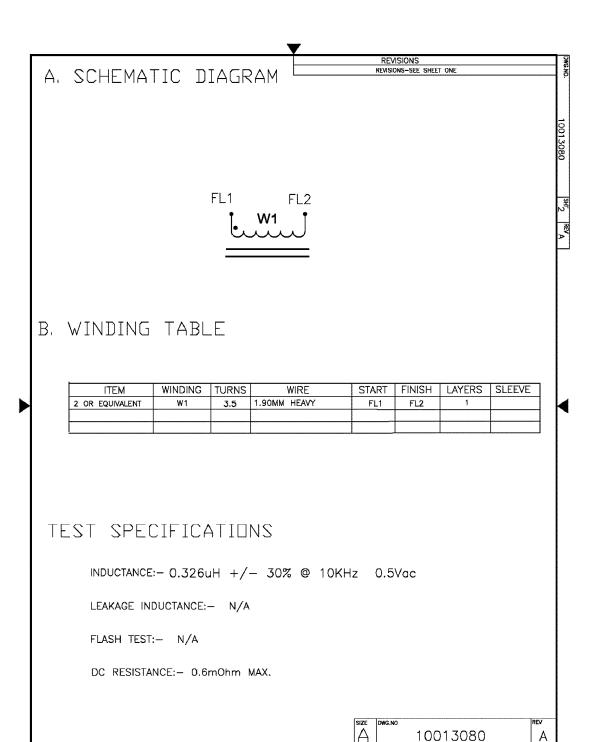
Diagrams - (05) Inductor (L9)

Diagrams - (05) Inductor (L9)

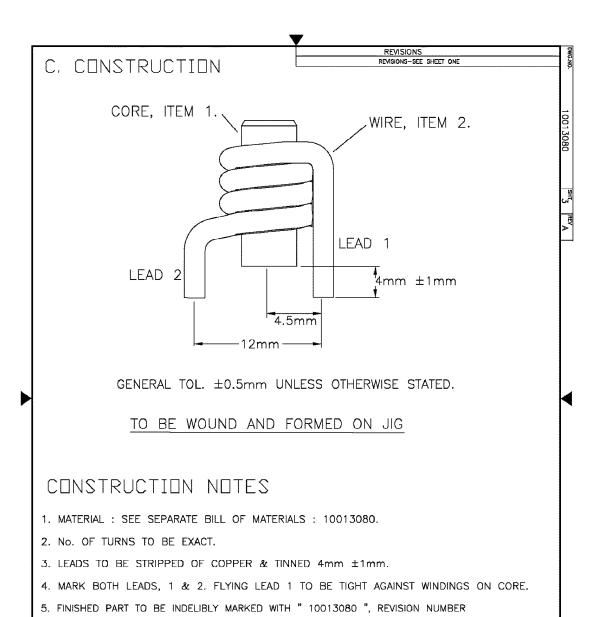


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Diagrams - (05) Inductor (L9)



Diagrams - (05) Inductor (L9)



6. ROD CORE GLUED INTO WINDING WITH ARALDITE 2012 OR EPOXY RESIN EQUIVALENT. SEE NOTE 7.
7. EQUIVALENT TO MEET XP CLASS 155 (F) INSULATION REQUIREMENTS WHERE APPLICABLE.

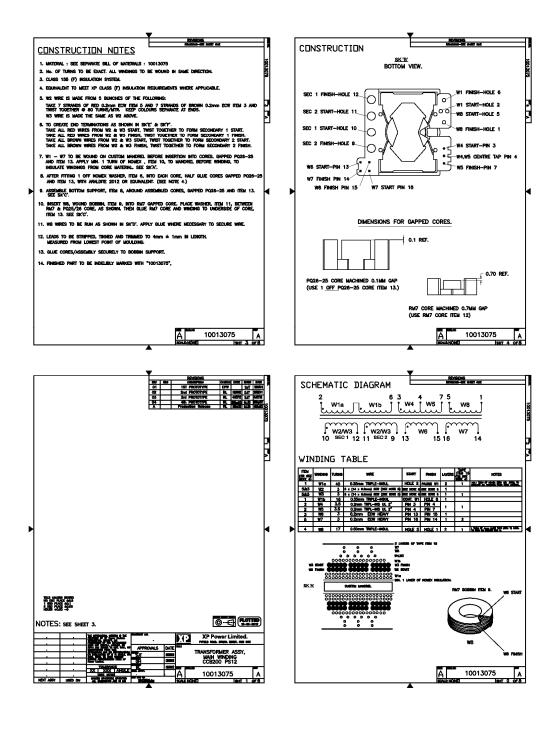
10013080

Α

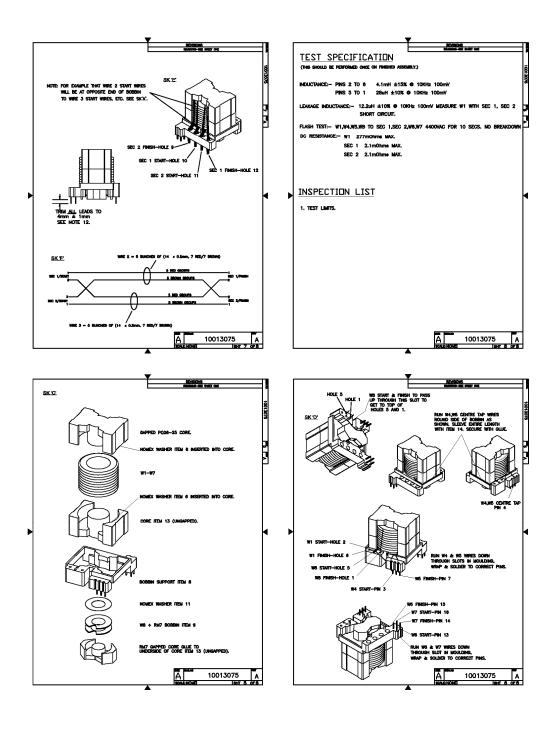
AND BATCH / DATE CODE OR BAG AND TAG.

Diagrams - (06) CHD250PSXXYY - Transformer (T1)

Diagrams - (06) CHD250PSXXYY - Transformer (T1)

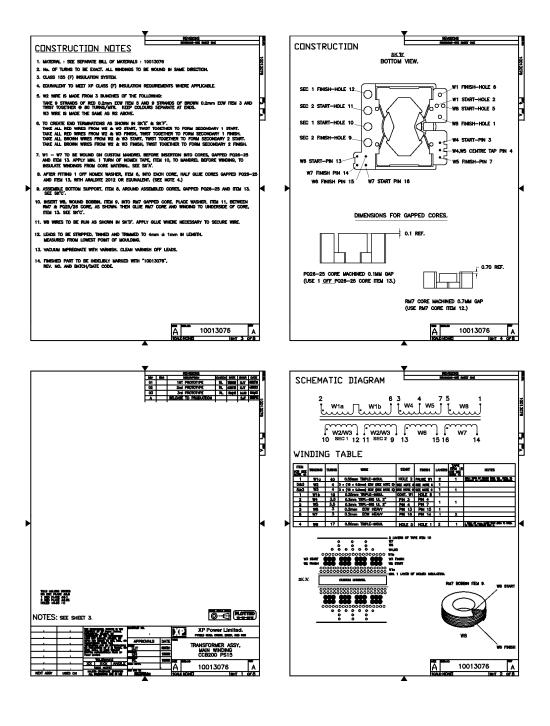


<u>Diagrams - (06) CHD250PSXXYY - Transformer (T1)</u>

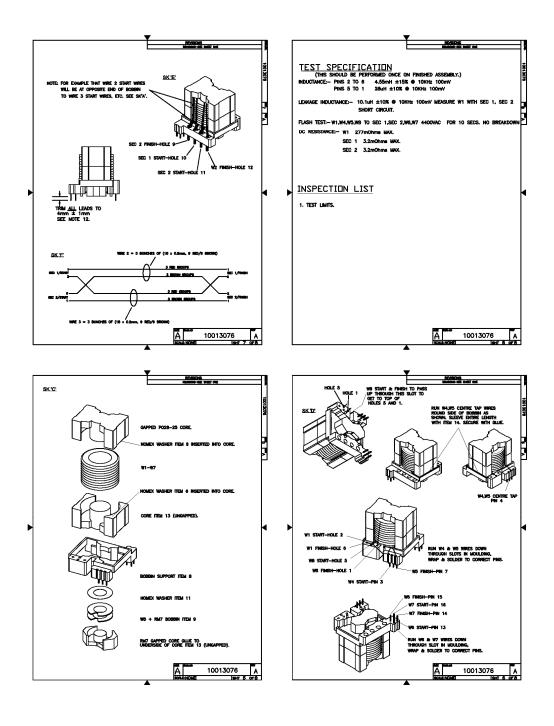


Diagrams - (07) Alternate - Transformer (T1)

<u>Diagrams - (07) Alternate - Transformer (T1)</u>

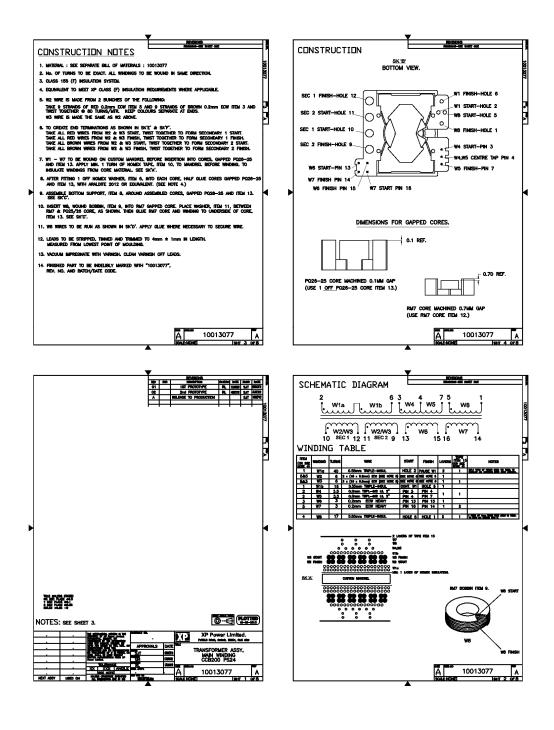


<u>Diagrams - (07) Alternate - Transformer (T1)</u>

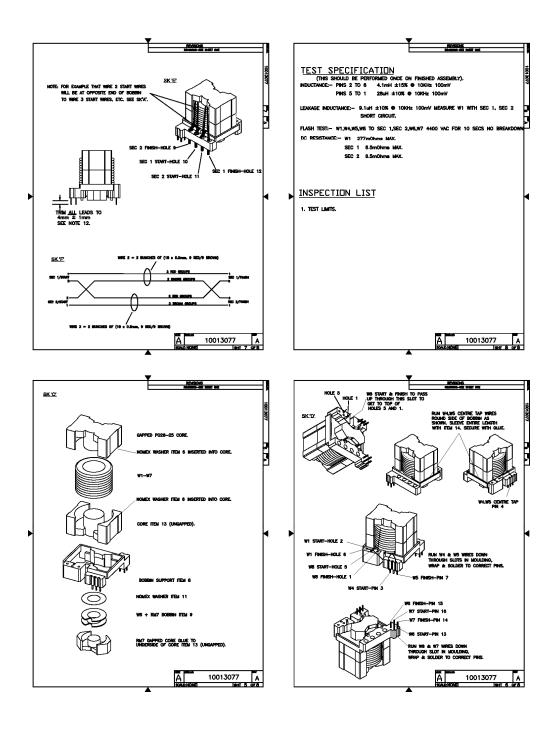


Diagrams - (08) Alternate - Transformer (T1)

Diagrams - (08) Alternate - Transformer (T1)

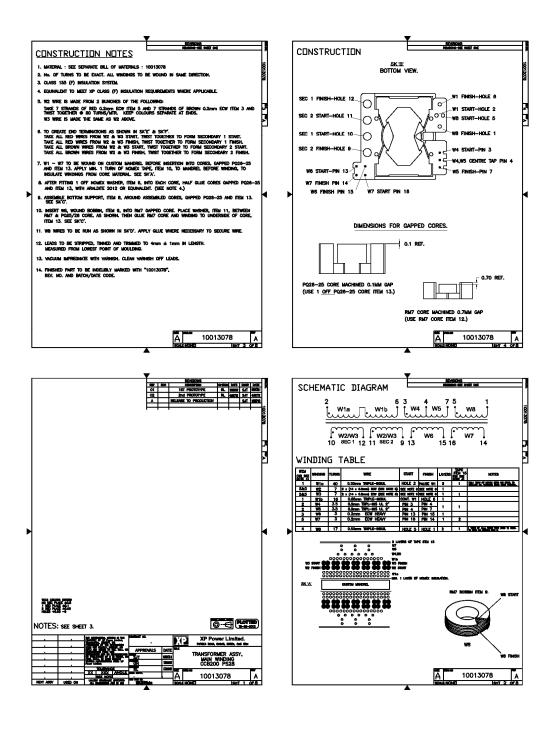


Diagrams - (08) Alternate - Transformer (T1)

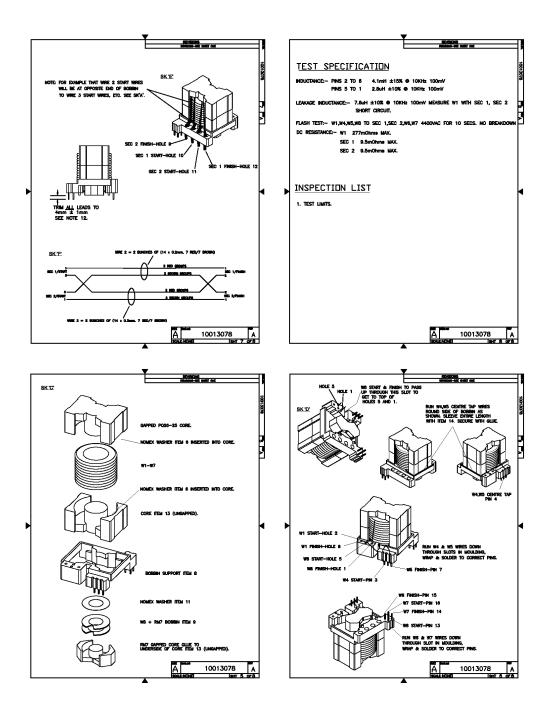


Diagrams - (09) Alternate - Transformer (T1)

<u>Diagrams - (09) Alternate - Transformer (T1)</u>

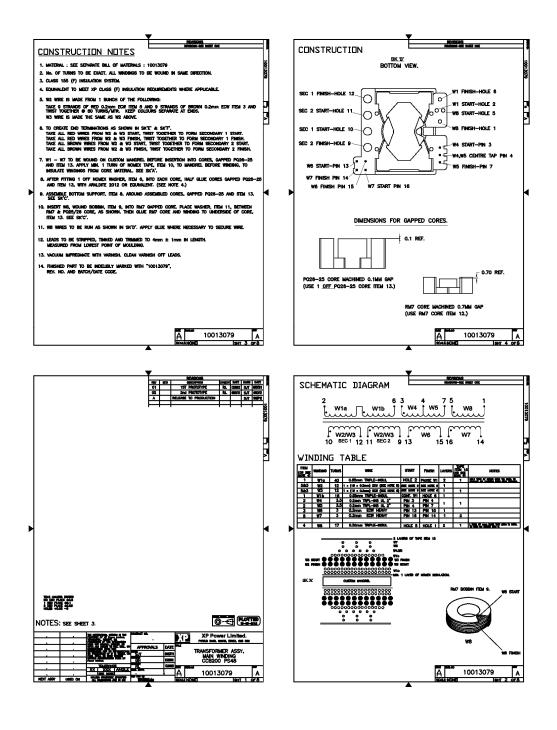


<u>Diagrams - (09) Alternate - Transformer (T1)</u>

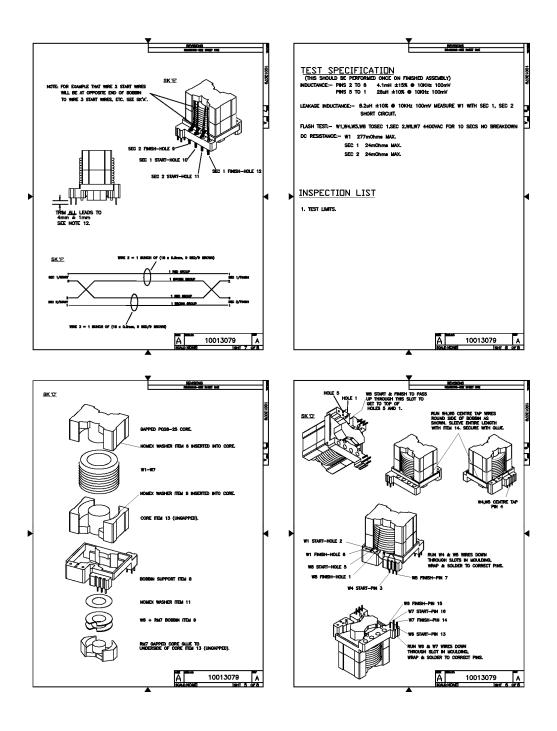


Diagrams - (10) Alternate - Transformer (T1)

Diagrams - (10) Alternate - Transformer (T1)



<u>Diagrams - (10) Alternate - Transformer (T1)</u>

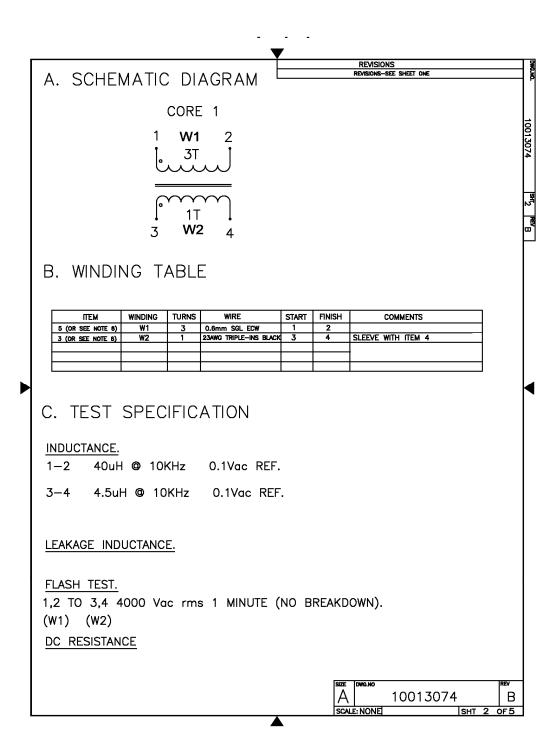


Diagrams - (11) CHD250PSXXYY - Transformer (T2, T3)

Diagrams - (11) CHD250PSXXYY - Transformer (T2, T3)

			<u> </u>			VISIONS				
			REV	ECO		SCRIPTION	CHECK	DATE		
			01			PROTOTYPE	CFW		SJT	11AUG11
			02			PROTOTYPE	RL	C9JAN12	SJT	03JAN12
			03			PROTOTYPE	CFW		SJT	28MAR12
			A B	C3971	RELEASE	TO PRODUCTION ETA CHANGES	CFW	180CT12 05Apr13	SJT RL	18SEP12 30APR13
				W8/II	PUSI	EIA CHANGES	UF#	U3MDF13	KL	JOHENIO
NOTES:	SEE SHEE	ET 3.)E	-1 (P	LOTI 19-03-:	TED
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_		TOLERANCE	CUST. APPV'L	CSJANT						REV
· ·	CCB200	SEE NOTE UNLESS OTHERWISE SPECIFIED ALL DIMENSIONS ARE IN MM	CAD DING NO		JA I	10013	3074	4		В

Diagrams - (11) CHD250PSXXYY - Transformer (T2, T3)

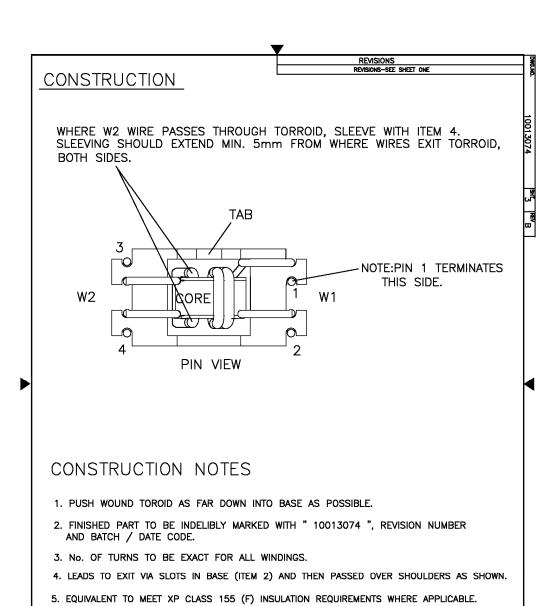


10013074

В

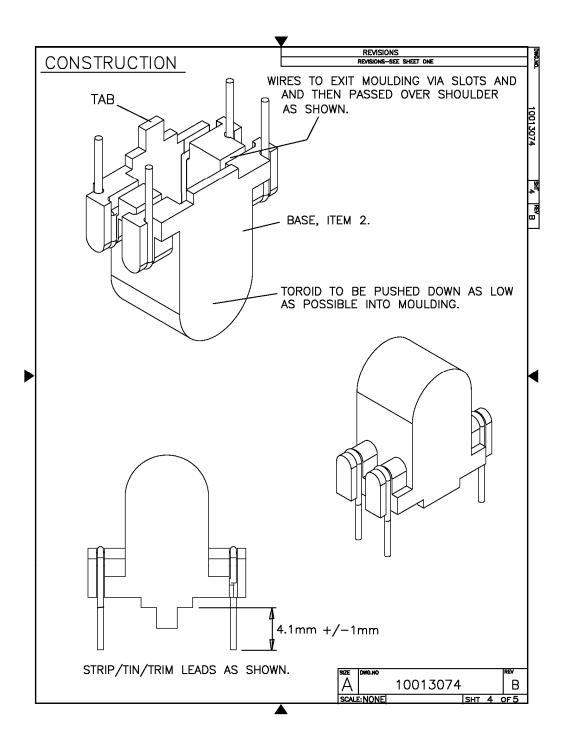
SHT 3

Diagrams - (11) CHD250PSXXYY - Transformer (T2, T3)

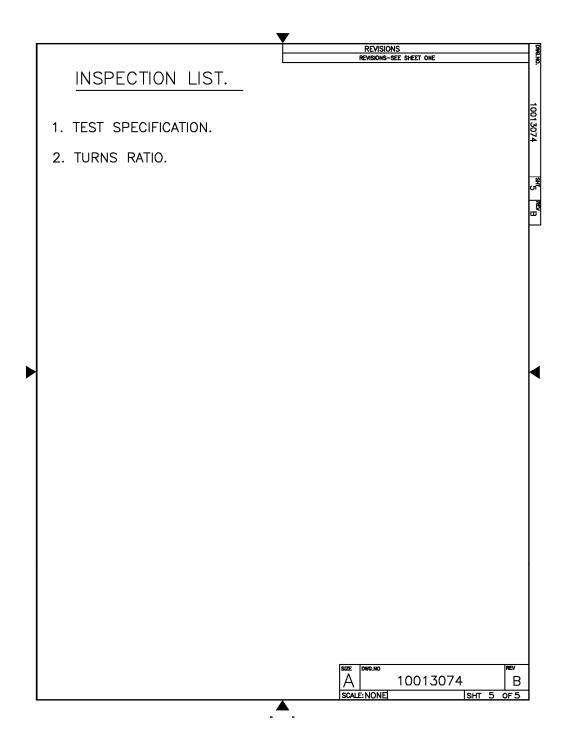


6. CLASS 155 (F) INSULATION SYSTEM.

Diagrams - (11) CHD250PSXXYY - Transformer (T2, T3)

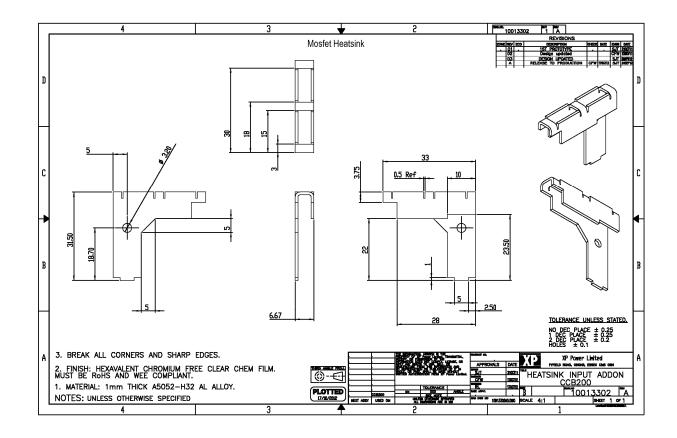


<u>Diagrams - (11) CHD250PSXXYY - Transformer (T2, T3)</u>

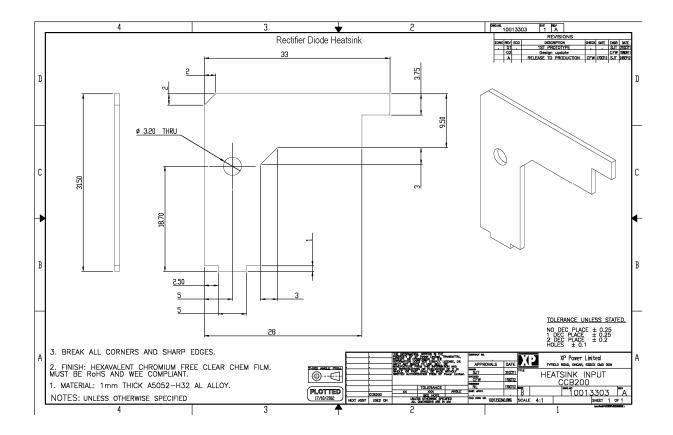


Diagrams - (12) Heatsinks - Mosfet (TR2-TR5), Diode (D5, D6)

Diagrams - (12) Heatsinks - Mosfet (TR2-TR5), Diode (D5, D6)

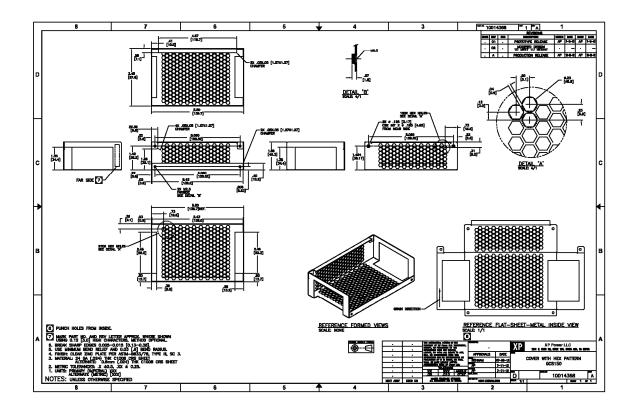


Diagrams - (12) Heatsinks - Mosfet (TR2-TR5), Diode (D5, D6)

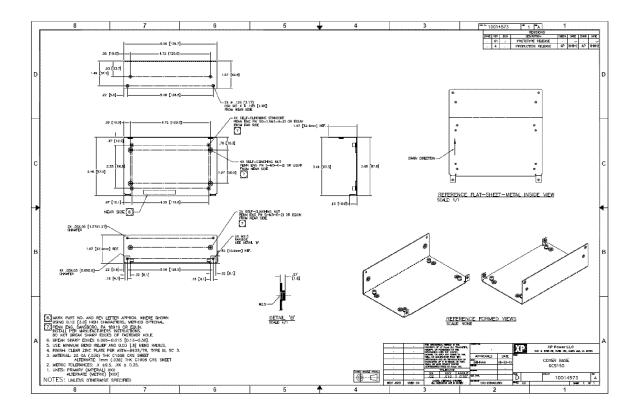


Diagrams - (13) CHD250PSXXYY: Cover Top/Bottom

<u>Diagrams - (13) CHD250PSXXYY: Cover Top/Bottom</u>

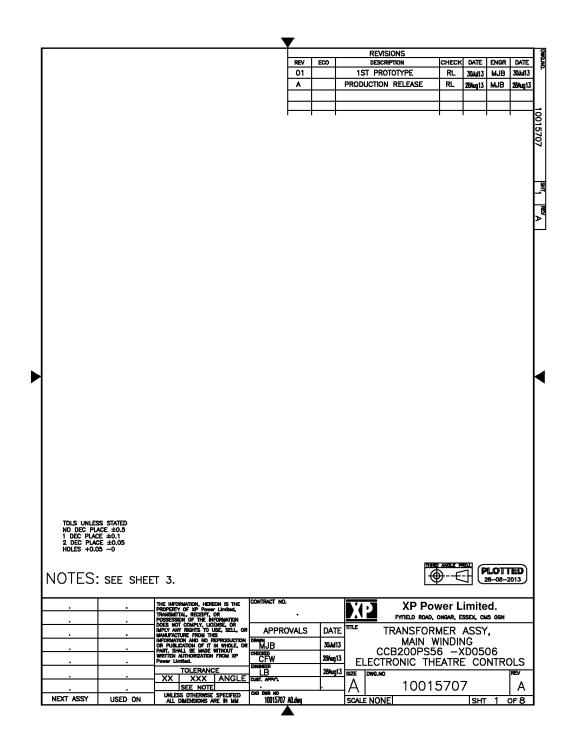


Diagrams - (13) CHD250PSXXYY: Cover Top/Bottom

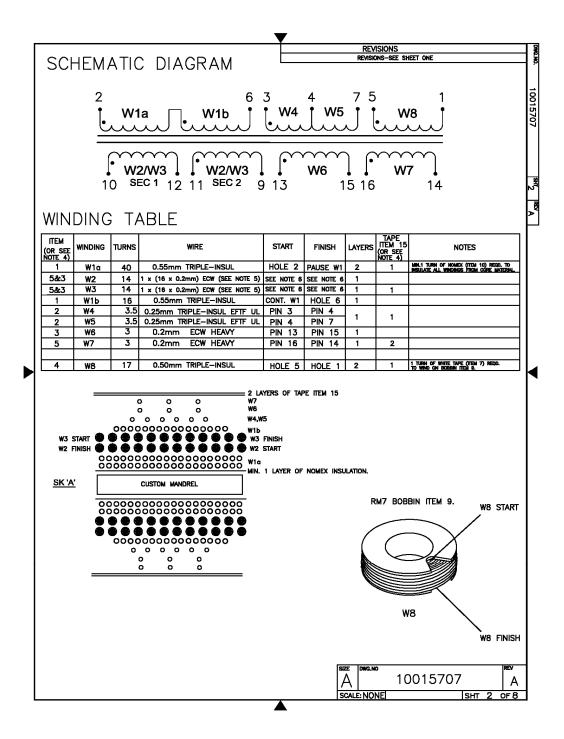


Diagrams - (14) CHD250PSXXYY - Transformer (T1)

Diagrams - (14) CHD250PSXXYY - Transformer (T1)



Diagrams - (14) CHD250PSXXYY - Transformer (T1)



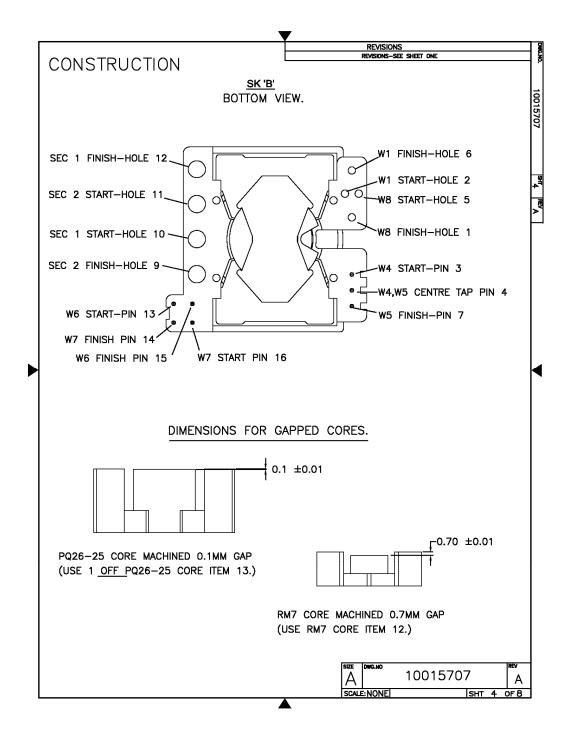
Diagrams - (14) CHD250PSXXYY - Transformer (T1)

REVISIONS -SEE SHEET ONE CONSTRUCTION NOTES 1. MATERIAL : SEE SEPARATE BILL OF MATERIALS : 10015707 2. No. OF TURNS TO BE EXACT. ALL WINDINGS TO BE WOUND IN SAME DIRECTION. 3. CLASS 155 (F) INSULATION SYSTEM. 4. EQUIVALENT TO MEET XP CLASS (F) INSULATION REQUIREMENTS WHERE APPLICABLE. 5. W2 WIRE IS MADE FROM 1 BUNCH OF THE FOLLOWING: TAKE 8 STRANDS OF RED 0.2mm ECW ITEM 5 AND 8 STRANDS OF BROWN 0.2mm ECW ITEM 3 AND TWIST TOGETHER @ 80 TURNS/MTR. KEEP COLOURS SEPARATE AT ENDS. W3 WIRE IS MADE THE SAME AS W2 ABOVE. 6. TO CREATE END TERMINATIONS AS SHOWN IN SK'E' & SK'F'. TAKE ALL RED WIRES FROM W2 & W3 START, TWIST TOGETHER TO FORM SECONDARY 1 START. TAKE ALL RED WIRES FROM W2 & W3 FINISH, TWIST TOGETHER TO FORM SECONDARY 1 FINISH. TAKE ALL BROWN WIRES FROM W2 & W3 START, TWIST TOGETHER TO FORM SECONDARY 2 START. TAKE ALL BROWN WIRES FROM W2 & W3 FINISH, TWIST TOGETHER TO FORM SECONDARY 2 FINISH. 7. W1 - W7 TO BE WOUND ON CUSTOM MANDREL BEFORE INSERTION INTO CORES, GAPPED PQ26-25 AND ITEM 13. APPLY MIN. 1 TURN OF NOMEX TAPE, ITEM 10, TO MANDREL BEFORE WINDING, TO INSULATE WINDINGS FROM CORE MATERIAL. SEE SK'A'. 8. AFTER FITTING 1 OFF NOMEX WASHER, ITEM 6, INTO EACH CORE HALF, GLUE CORES, GAPPED PQ26-25 AND ITEM 13, WITH ARALDITE 2012 OR EQUIVALENT. (SEE NOTE 4.) 9. ASSEMBLE BOBBIN SUPPORT, ITEM 8, AROUND ASSEMBLED CORES, GAPPED PQ26-25 AND ITEM 13. SEE SK'C'. 10. INSERT W8, WOUND BOBBIN, ITEM 9, INTO RM7 GAPPED CORE. PLACE WASHER, ITEM 11, BETWEEN RM7 & PQ25/26 CORE, AS SHOWN. THEN GLUE RM7 CORE AND WINDING TO UNDERSIDE OF CORE, ITEM 13 SEE SK'C' 11. W8 WIRES TO BE RUN AS SHOWN IN SK'D'. APPLY GLUE WHERE NECESSARY TO SECURE WIRE. 12. LEADS TO BE STRIPPED, TINNED AND TRIMMED TO 4.1mm \pm 1mm IN LENGTH. MEASURED FROM LOWEST POINT OF MOULDING. 13. GLUE CORES/ASSEMBLY SECURELY TO BOBBIN SUPPORT, ENSURING THEY ARE MOUNTED SQUARELY. 14. VACUUM IMPREGNATE WITH VARNISH. CLEAN VARNISH OFF LEADS. 15. FINISHED PART TO BE INDELIBLY MARKED WITH "10015707", REV. NO. AND BATCH/DATE CODE.

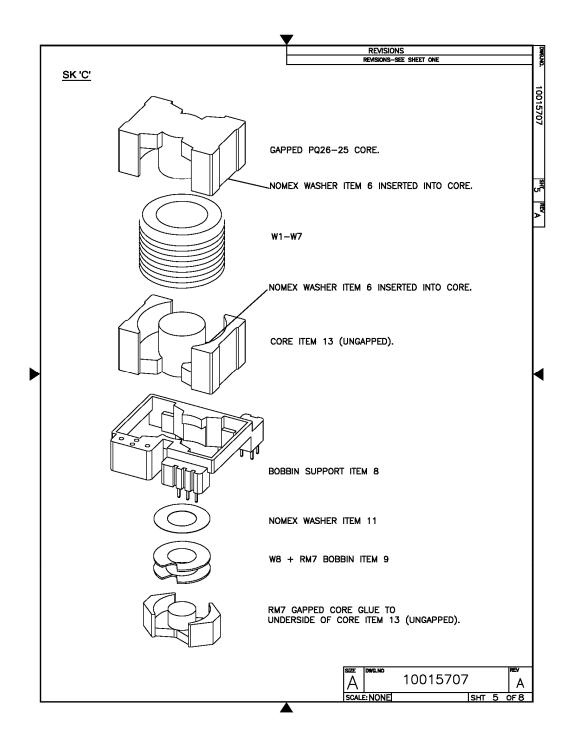
| SCALE:NONE | SHT 3 0F8

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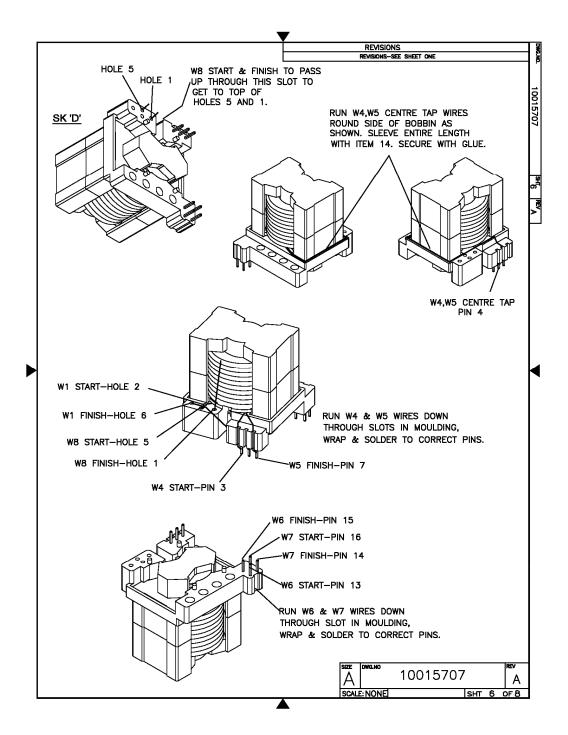
<u>Diagrams - (14) CHD250PSXXYY - Transformer (T1)</u>



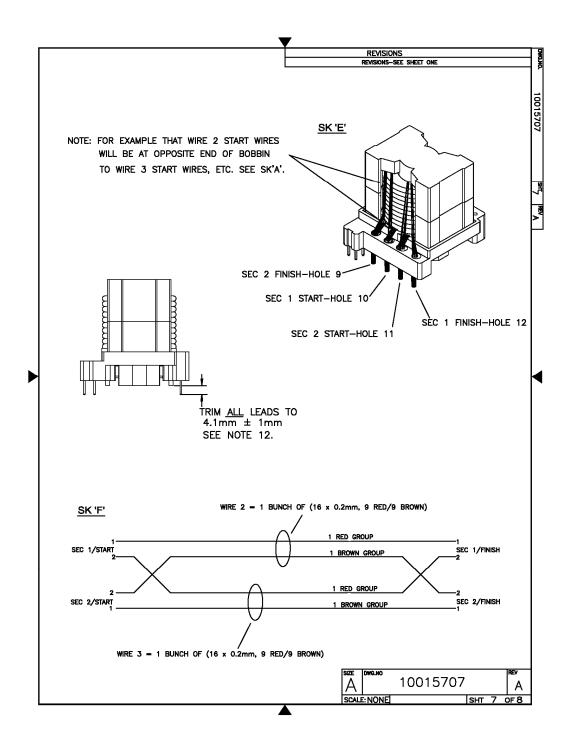
<u>Diagrams - (14) CHD250PSXXYY - Transformer (T1)</u>



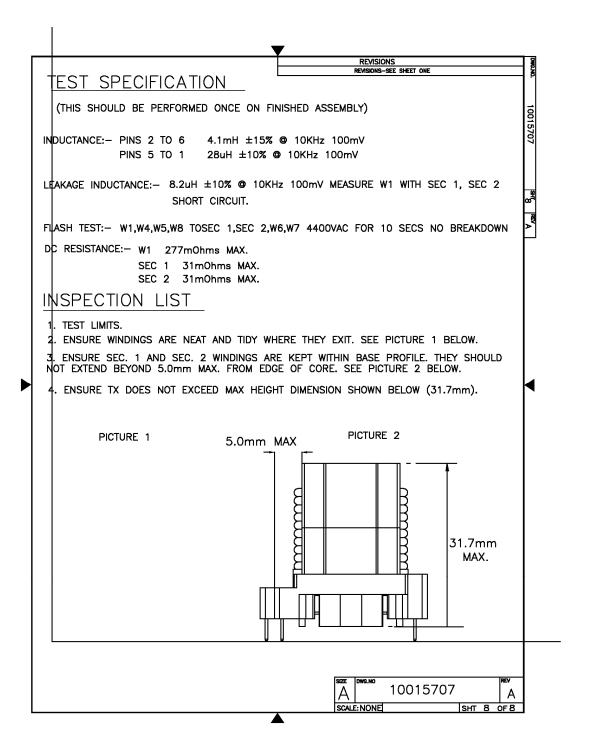
Diagrams - (14) CHD250PSXXYY - Transformer (T1)



<u>Diagrams - (14) CHD250PSXXYY - Transformer (T1)</u>



<u>Diagrams - (14) CHD250PSXXYY - Transformer (T1)</u>



Diagrams - (15) Stand-by Output Transformer (T1) - For models with suffix "A"

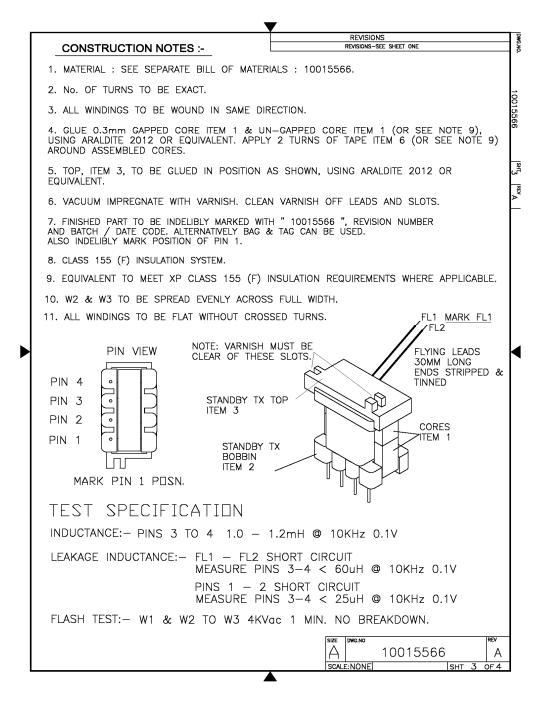
<u>Diagrams - (15) Stand-by Output Transformer (T1) - For models with suffix "A"</u>

					Ť			REV	/ISIONS				
						REV	ECO	DES	CRIPTION	CHECK	DATE	ENGR	DATE
						01	. [IST P	ROTOTYPE			SJT	29MAY13
						Α		PRODUC	TION RELEASE	CFW	23SEP13	RL	23SEP13
										1			
						ı	ı			- 1			
TOLS UNLESS NO DEC PLA	s Stated DE ±0.5												
TOLS UNLESS NO DEC PLA 1 DEC PLAC 2 DEC PLAC	S STATED CE 40.5 E 40.05												
TOLS UNLESS NO DEC PLAC 1 DEC PLAC 2 DEC PLAC HOLES +-O.O.	S STATED CE ±0.5 E ±0.1 E ±0.05 S −0												
TOLS UNLESS NO DEC PLAC 10 DEC PLAC 2 DEC PLAC HOLES +0.01	S SIATED CE ±0.5 E ±0.5 E ±0.05 5 −0												
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	S SIMIED DE #40.5 E #40.1 E #40.1 E #40.5 5 = 50.05 5 = 50.05 E E SHEE										~ ⊮	LOT1 23-09-2	ED 2013
			maaton, herec	on, is, the	CONTRACT NO.					⊚-€	<u> </u>	3-09-2	*ED
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		THE INFORPROPERTY TRANSMITT POSSESSIK DOES NOT IMPLY ANY MANUFACT INFORMATI OR PUBLII PART, SHA POWER LIT	TOLERANCE	Ε	CONTRACT NO. APPROV DOWN CFW DOWN CFW DOWN RICH		28WAY13	SIZE DWG.N	XP Po	O-E OWER L O, ONGAR, E RMER OBY P CB200	imite ssex, cw ASS) CB	ed. 15 OGN	"ED" (15013)
		THE INFORPROPERTY TRANSMITT POSSESSIK DOES NOT IMPLY ANY MANUFACT INFORMATI OR PUBLI PART, SHA POWER LITT		Ε	CONTRACT NO. APPROV DOMENT TO CHECKED TO CH		28MAY13 23SEP13	TITLE	XP Po	OWER LO, ONGAR, E	imite ssex, cw ASS) CB	ed. 15 OGN	2013

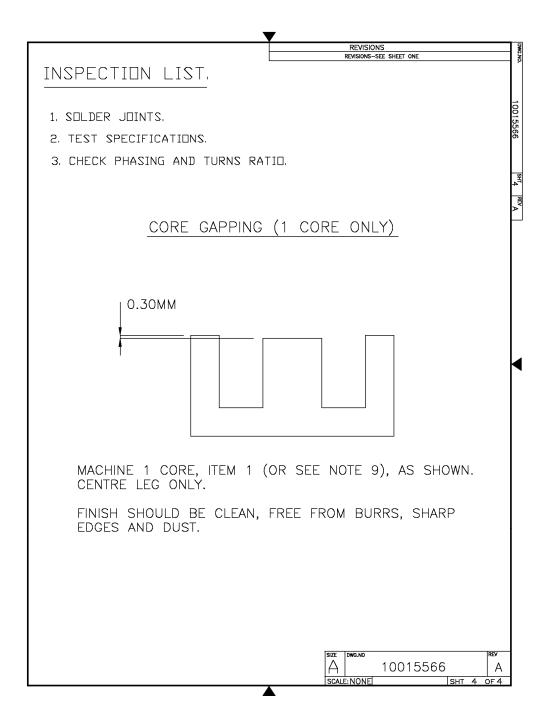
<u>Diagrams - (15) Stand-by Output Transformer (T1) - For models with suffix "A"</u>

SCHEMATIC DIAGRAM 4 W1 3 FL2 W2 2 WINDING TABLE TEM WINDING TURNS WIRE START FINISH LAYERS TAPE TIEM 6 (OR SEE NOTE 9) W1 105T 0.2mm ECW HEAVY 3 4 3 1 4 (OR SEE NOTE 9) W2 18T 2 x 0.2mm ECW HEAVY 2 1 1 1 WIND BIFILAR. SEE NOTE 10 5 (OR SEE NOTE 9) W3 7T 0.65mm TRIPLE INS. FL1 FL2 1 2 LAYERS LAYERS	WINDING TABLE WINDING TURNS WIRE START FINISH LAYERS TAPE (COMMENTS (TREE (CREE (CR	WINDING TABLE WINDING TURNS WIRE START FINISH LAYERS TAPE (COMMENTS (TREE (CREE (CR							RI	EVISIONS			
W1 W2 VINDING TABLE WINDING TURNS WIRE START FINISH LAYERS TAPE (IFEM 6 (IFEM 6 (IFEM 6 (NOTE 9))) 4 (OR SEE NOTE 9) W1 105T 0.2mm ECW HEAVY 3 4 3 1 4 3 1 4 4 (OR SEE NOTE 9)) 4 (OR SEE NOTE 9) W2 18T 2 x 0.2mm ECW HEAVY 2 1 1 1 WIND BIFILAR. SEE NOTE 10	W1 START FINISH LAYERS TAPE (TEM 6 (TEM 6 (NOTE 9)) 4 (OR SEE NOTE 9) W1 105T 0.2mm ECW HEAVY 3 4 3 1 4 (OR SEE NOTE 9) W2 18T 2 x 0.2mm ECW HEAVY 2 1 1 1 WIND BIFILAR. SEE NOTE 10	W1 START FINISH LAYERS TAPE (TEM 6 (TEM 6 (NOTE 9)) 4 (OR SEE NOTE 9) W1 105T 0.2mm ECW HEAVY 3 4 3 1 4 (OR SEE NOTE 9) W2 18T 2 x 0.2mm ECW HEAVY 2 1 1 1 WIND BIFILAR. SEE NOTE 10	SCHEMA	4TIC	C D	IAGRAM			REVI	ISIONS—SEE SH	EET ONE		
WINDING TABLE ITEM WINDING TURNS WIRE START FINISH LAYERS TAPE (FITEM 6 (OR SEE NOTE 9) W1 105T 0.2mm ECW HEAVY 3 4 3 1 4 4 4 (OR SEE NOTE 9) W2 18T 2 x 0.2mm ECW HEAVY 2 1 1 1 WIND BIFILAR. SEE NOTE 10	WINDING TABLE ITEM WINDING TURNS WIRE START FINISH LAYERS TAPE (COMMENTS (DESSERVED)) 4 (OR SEE NOTE 9) W1 105T 0.2mm ECW HEAVY 3 4 3 1 4 (OR SEE NOTE 9) W2 18T 2 x 0.2mm ECW HEAVY 2 1 1 1 WIND BIFILAR. SEE NOTE 10	WINDING TABLE ITEM WINDING TURNS WIRE START FINISH LAYERS TAPE (COMMENTS (DESSERVED)) 4 (OR SEE NOTE 9) W1 105T 0.2mm ECW HEAVY 3 4 3 1 4 (OR SEE NOTE 9) W2 18T 2 x 0.2mm ECW HEAVY 2 1 1 1 WIND BIFILAR. SEE NOTE 10				4•		W3					
WINDING TABLE ITEM WINDING TURNS WIRE START FINISH LAYERS TAPE (FITEM 6 (OR SEE NOTE 9) W1 105T 0.2mm ECW HEAVY 3 4 3 1 4 4 4 (OR SEE NOTE 9) W2 18T 2 x 0.2mm ECW HEAVY 2 1 1 1 WIND BIFILAR. SEE NOTE 10	WINDING TABLE ITEM WINDING TURNS WIRE START FINISH LAYERS TAPE (OR SEE NOTE 9) W1 105T 0.2mm ECW HEAVY 3 4 3 1 4 4 0R SEE NOTE 9) W2 18T 2 x 0.2mm ECW HEAVY 2 1 1 1 WIND BIFILAR. SEE NOTE 10	WINDING TABLE ITEM WINDING TURNS WIRE START FINISH LAYERS TAPE (OR SEE NOTE 9) W1 105T 0.2mm ECW HEAVY 3 4 3 1 4 4 0R SEE NOTE 9) W2 18T 2 x 0.2mm ECW HEAVY 2 1 1 1 WIND BIFILAR. SEE NOTE 10				1	$\frac{3}{2}$						
ITEM	ITEM	ITEM				W2 -	<u> </u>						
ITEM	ITEM	ITEM				2•••)						
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TEM	TEM	TEM											
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5 (OR SEE NOTE 9) W3 7T 0.65mm TRIPLE INS. FL1 FL2 1 2 LAYERS	5 (OR SEE NOTE 9) W3 7T 0.65mm TRIPLE INS. FL1 FL2 1 2 LAYERS	5 (OR SEE NOTE 9) W3 7T 0.65mm TRIPLE INS. FL1 FL2 1 2 LAYERS	ITEM	WINDING	TURNS	WIRE				TAPE ITEM 6 (OR SEE NOTE 9)	СОММЕ	NTS	
			ITEM 4 (or see note 9)	WINDING W1	TURNS	WIRE 0.2mm ECW HEAVY	3	4	3	1			DTE 10
			4 (or see note 9) 4 (or see note 9)	WINDING W1 W2	TURNS 105T 18T	WIRE 0.2mm ECW HEAVY 2 x 0.2mm ECW HEAVY	3 2	4	3	1			DTE 10
			4 (or see note 9) 4 (or see note 9)	WINDING W1 W2	TURNS 105T 18T	WIRE 0.2mm ECW HEAVY 2 x 0.2mm ECW HEAVY	3 2	4	3	1			DTE 10
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			4 (OR SEE NOTE 9) 4 (OR SEE NOTE 9)	WINDING W1 W2	TURNS 105T 18T	WIRE 0.2mm ECW HEAVY 2 x 0.2mm ECW HEAVY	3 2	4	3	1			DTE 10
			4 (or see note 9) 4 (or see note 9)	WINDING W1 W2	TURNS 105T 18T	WIRE 0.2mm ECW HEAVY 2 x 0.2mm ECW HEAVY	3 2	4	3	1			DTE 10
			4 (or see note 9) 4 (or see note 9)	WINDING W1 W2	TURNS 105T 18T	WIRE 0.2mm ECW HEAVY 2 x 0.2mm ECW HEAVY	3 2	4	3	1			DIE 10
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Diagrams - (15) Stand-by Output Transformer (T1) - For models with suffix "A"



<u>Diagrams - (15) Stand-by Output Transformer (T1) - For models with suffix "A"</u>



Diagrams - (16) Stand-by Output Inductor (L1) - For models with suffix "A"

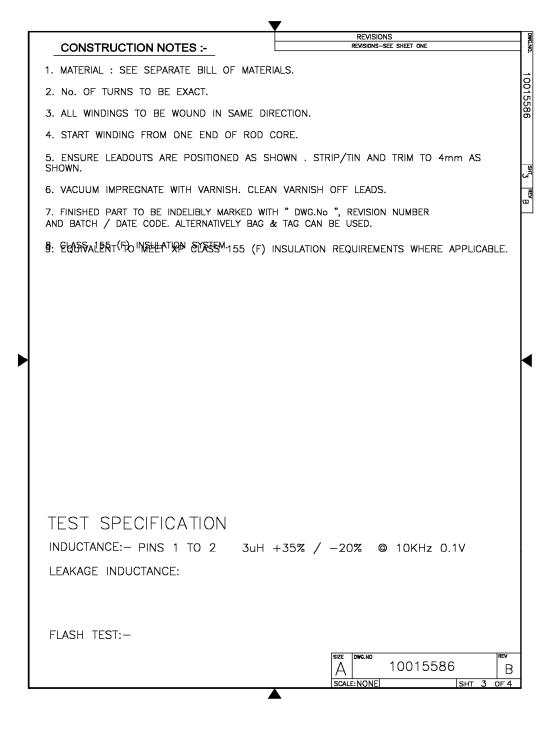
<u>Diagrams - (16) Stand-by Output Inductor (L1) - For models with suffix "A"</u>

					- 		R	EVISIONS				
					REV	ECO	D	ESCRIPTION	CHECK	DATE	ENGR	DATE
					01		IST	PROTOTYPE			MJB	O6June 13
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					CONTRACT NO.	; NAT		XP Pov	wer L	imite	23-09-2 ed.	ED 013
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NO ⁻	TES:	SEE		THE INFORMATION, HEREON IS THE PROPERTY OF 'AP Power Limited, TRANSMITTAL, RECEIPT, OR THE PROPERTY OF 'AP POWER LIMITAL, RECEIPT, OR THE PROPERTY LIEDENS, OR MAPLY ANY RIGHTS TO USE, SELL, OR MAPLY ANY RIGHTS TO USE, SELL, OR MAPLY ANY RIGHTS TO USE, SELL, OR MAPLY ANY RIGHTS TO WASTERN ANY TO BE THE PROPERTY OF THE	ENGINEER RI	23SEF 23SEF	E TITLE 13 13	XP POV PPFELD ROAD, I INDUCTO OUTPUT F CCB200 STA	Wer L ONGAR, E DIR AS ROD NDBY	imite ssex, cw SSY, CORE / BO,	23-09-2 2 d. 45 DGN	013)

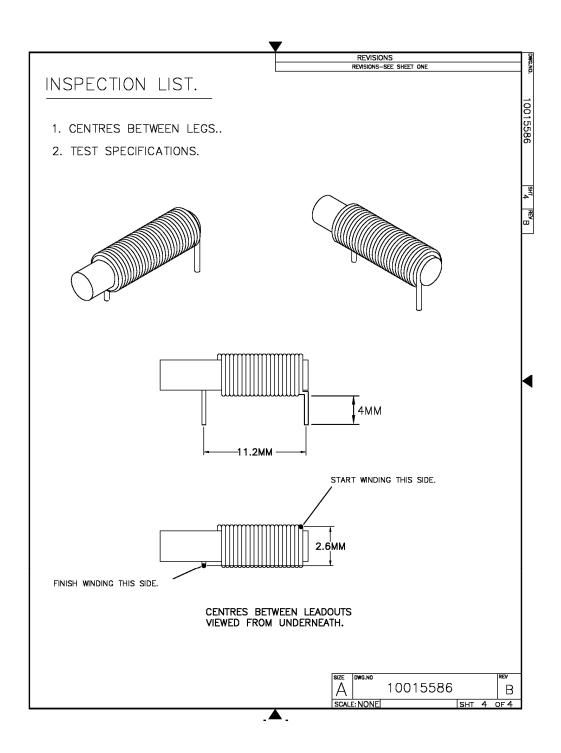
<u>Diagrams - (16) Stand-by Output Inductor (L1) - For models with suffix "A"</u>

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ITEM	WINDING	TURNS	V						COMMENTS	
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ITEM	WINDING	TURNS	V						COMMENTS	
ITEM	WINDING	TURNS	V					(OR SEE NOTE 9)	COMMENTS	REV

<u>Diagrams - (16) Stand-by Output Inductor (L1) - For models with suffix "A"</u>



<u>Diagrams</u> - (16) Stand-by Output Inductor (L1) - For models with suffix "A"



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<u>Licenses</u> - (01) Optocoupler - Lite On, Type LTV-816 Series

Details Page 1 of 4 Testing Standards Conferences InSite Login E Notes VDE VDE > Institute > Online Service > VDE approved products > Details DetailCertifiedProductsWebPart Institute Approval no.: 40015248 Online Service Product: Optocoupler VDE approved products Productgroup: Optocouplers Online Search Company: Lite-On Technology Corporation 90 Chien I Road 235 CHUNGHO CITY, TAIPEI HSIEN TAIWAN Unlawful use Mark: VDE Mark LTV-4N25 Type: Technical data: LTV-702V Type: Technical data: LTV-713F Type: Technical data: LTV-713V Type: Technical data: Type: LTV-703F Technical data: LTV-703V Type: Technical data: Type: LTV-814 Technical data: LTV-8141 Technical data: LTV-814H Type: Technical data: LTV-815 Type: Technical data: LTV-816 Type: Technical data: Type: LTV-4N26 Technical data: Type: LTV-817 Technical data: LTV-819-1 Type: Technical data: LTV-819-2 Type:

http://www.vde.com/en/Institute/OnlineService/VDE-approved-products/Pages/Details.aspx?vdeProduct... 03/03/2010

Page 2 of 4

<u>Licenses</u> - (01) Optocoupler - Lite On, Type LTV-816 Series

	Technical data:	
note the second	Type:	LTV-821
	Technical data:	
	Type:	LTV-824
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Technical data: LTV-852

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Technical data: LTV-8Q52 Type:

Technical data: Type: LTV-845 Technical data:

Type: LTV-846 Technical data: LTV-847 Type:

Technical data: LTV-4N28 Type:

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Type: LTV-715F Technical data:

LTV-724F Type: Technical data:

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LTV-851

<u>Licenses - (01) Optocoupler - Lite On, Type LTV-816 Series</u>

Details			Page 3 of 4
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Type:

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Details Page 4 of 4

Technical data: LTV-932 Type: Technical data: Type: MOC3041 Technical data: Type: MOC3042 Technical data: Type: MOC3043 Technical data: Type: LTV-4N35 Technical data: Type: MOC3051 Technical data: MOC3052 Type: Technical data: MOC3061 Type: Technical data: Type: MOC3062 Technical data: Type: MOC3063 Technical data: Type: MOC3081 Technical data: MOC3082 Type: Technical data: MOC3083 Technical data: LTV-4N37 Type: Technical data: LTV-702F Type: Technical data:

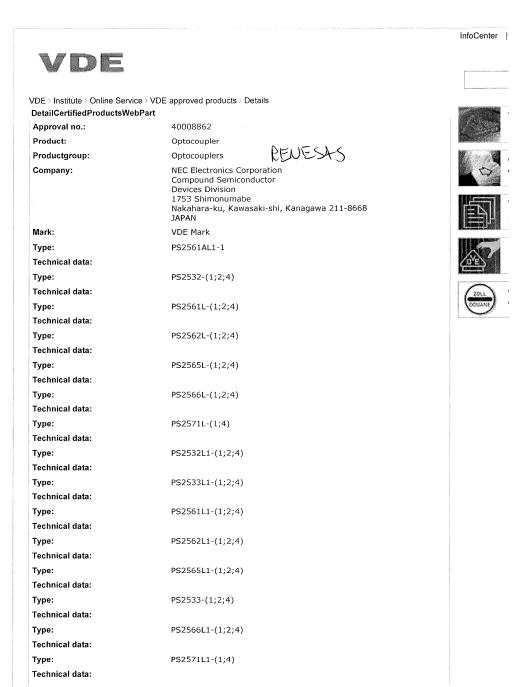


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Details Page 1 of 3



<u>Licenses</u> - (02) Optocoupler - Renesas (NEC), Type PS2561 Series

Details

Page 2 of 3

Type:	PS2532L2-(1;2;4)	
Technical data:		
Туре:	PS2533L2-(1;2;4)	
Technical data:		
Type:	PS2561L2-(1;2;4)	
Technical data:		
Туре:	PS2562L2-(1;2;4)	
Technical data:	, , , ,	
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Type:	PS2561AL-1	
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Type:	PS2561AL2-1	
Technical data:	732301AL2*1	
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	PS2581AL1	
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Type:	PS2581AL2	
Technical data:	PG0505 (4.9.4)	
Type:	PS2535-(1;2;4)	
Technical data:	PC25251 (4.0.4)	
Type:	PS2535L-(1;2;4)	
Technical data:	20050514 (4.0.4)	
Type:	PS2535L1-(1;2;4)	
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Гуре:	PS2561B-1	
Technical data:		
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Details Page 3 of 3

PS2561BL1-1 Type: Technical data: Type: PS2561BL2-1 Technical data: PS2581BL1 Type: Technical data: Type: PS2581BL2 Technical data: PS2513-1 Type: Technical data: Type: PS2513L-1 Technical data: Type: PS2513L1-1 Technical data: PS2565-(1;2;4) Type: Technical data: PS2513L2-1 Type: Technical data: Type: PS2566-(1;2;4) Technical data: PS2571-(1;4) Type: Technical data: PS2532L-(1;2;4) Technical data: Type: PS2533L-(1;2;4) Technical data:

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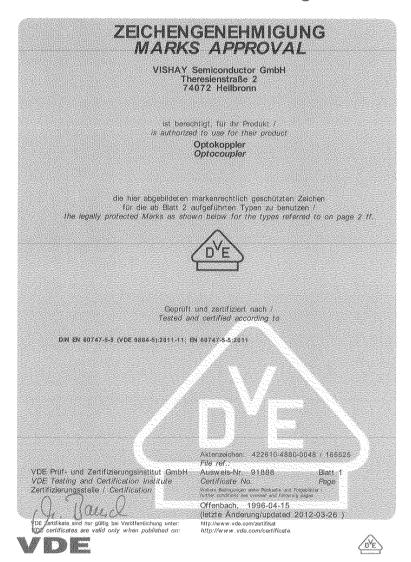


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Vishay Semiconductors

Optocoupler

VDE Prüf- und Zertifizierungsinstitut



Revision: 16-May-12 1 Document Number: 83576

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Ausweis-Nr. / Blat Certificate No. pag 91888 2

Name und Sitz des Genehmigungs-Inhabers I Name and registered seat of the Certificate holder VISHAY Semiconductor GmbH, Theresienstraße 2, 74072 Heilbronn

Aktenzeichen / File ref. 422610-4880-0048 / 165525 / FG34 / SCT letzte Änderung / updated Datum / Date 2012-03-26 1996-04-15

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Optokoppler Optocoupler

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Typ(en) / Type(s):
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1] SFH 6106...X001 / -X01(6;7;8;9)
2] SFH 6116...X001 / -X01(6;7;8;9)
3] SFH 6116...X001 / -X01(6;7;8;9)
4] SFH 6136...X001 / -X01(6;7;8;9)
5] SFH 610A...X001 / -X01(6;7;8;9)
6] SFH 611A...X001 / -X01(6;7;8;9)
7] SFH 615A...X001 / -X01(6;7;8;9)
8] SFH 615A...X001 / -X01(6;7;8;9)
9] SFH 616A...X001 / -X01(6;7;8;9)
10] SFH 610A...E. -X001 / -X01(6;7;8;9)
11] SFH 615AGR-X001 / -X01(6;7;8;9)
12] SFH 615AGR-X001 / -X01(6;7;8;9)
13] SFH 615AGR-X001 / -X01(6;7;8;9)
14] SFH 615AGR-X001 / -X01(6;7;8;9)
15] SFH 615AGR-X001 / -X01(6;7;8;9)
16] SFH 615AGR-X001 / -X01(6;7;8;9)
17] SFH 615AGR-X001 / -X01(6;7;8;9)
18] SFH 615AGR-X001 / -X01(6;7;8;9)
19] SFH 615AGR-X001 / -X01(6;7;8;9)
19] SFH 615AGR-X001 / -X01(6;7;8;9)
20] SFH 615AGR-X001 / -X01(6;7;8;9)
21] SFH 615AGR-X001 / -X01(6;7;8;9)
22] SFH 615AGR-X001 / -X01(6;7;8;9)
23] SFH 620A-..X001 / -X01(6;7;8;9)
24] SFH 620AGR-X001 / -X01(6;7;8;9)
25] SFH 620AR-X001 / -X01(6;7;8;9)
26] SFH 620AGR-X001 / -X01(6;7;8;9)
27] SFH 620AGR-X001 / -X01(6;7;8;9)
28] SFH 620AGR-X001 / -X01(6;7;8;9)
29] ILD 1-X001 / -X01(6;7;8;9)
31] ILD 2-X001 / -X01(6;7;8;9)
32] ILD 5-X001 / -X01(6;7;8;9)
33] ILD 74-X001 / -X01(6;7;8;9)
34] ILD 645-..-X001 / -X01(6;7;8;9)
35] ILD 645-..-X001 / -X01(6;7;8;9)
36] ILD 621-..-X001 / -X01(6;7;8;9)
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VDE Prüf- und Zertiftzierungeinstitut Grebh * Testing and Gertifizzien institut Merzinstrasse 28 D-63089 Offestisch

Telefon + 45 (0) 69 63 06-0 Yelefon + 49 (0) 69 83 06-355

Revision: 16-May-12 **2** Document Number: 83576
For technical questions, contact: optocoupleranswers@vishay.com

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VDE Prüf- und Zertifizierungsinstitut Zeichengenehmigung

Ausweis-Nr. / Certificate No. 91888

Name und Sitz des Genehmigungs-Inhabers / Name and registered seat of the Certificate holder VISHAY Semiconductor GmbH, Theresienstraße 2, 74072 Heilbronn

422610-4880-0048 / 165525 / FG34 / SCT

letzte Änderung / updated Datum / Date 2012-03-26

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Typ(en) / Type(s)

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37] ILD 621GB-X001 / -X01(6;7;8;9)
         38] ILCT 6-X001 / -X01(6;7;8;9)
39] MCT 6-X001 / -X01(6;7;8;9)
  39] MCT 6-X001 / -X01(6;7;8;9)
40] ILD 616-X001 / -X01(6;7;8;9)
41] ILD 30-X001 / -X01(6;7;8;9)
42] ILD 31-X001 / -X01(6;7;8;9)
43] ILD 32-X001 / -X01(6;7;8;9)
44] ILD 55-X001 / -X01(6;7;8;9)
45] ILD 66---X001 / -X01(6;7;8;9)
46] ILD 250-X001 / -X01(6;7;8;9)
47] ILD 251-X001 / -X01(6;7;8;9)
48] ILD 252-X001 / -X01(6;7;8;9)
49] ILD 255-X001 / -X01(6;7;8;9)
50] ILD 620-GB-X001 / -X01(6;7;8;9)
51] ILD 620-GB-X001 / -X01(6;7;8;9)
49] ILD 255-X001 / -X01(6;7;8;9)
50] ILD 620 X001 / -X01(6;7;8;9)
51] ILD 620 GB-X001 / -X01(6;7;8;9)
52] ILD 755-..-X001 / -X01(6;7;8;9)
53] ILD 766-..-X001 / -X01(6;7;8;9)
54] ILQ 1-X001 / -X01(6;7;8;9)
55] ILQ 2-X001 / -X01(6;7;8;9)
56] ILQ 3-X001 / -X01(6;7;8;9)
57] ILQ 5-X001 / -X01(6;7;8;9)
58] ILQ 615-..-X001 / -X01(6;7;8;9)
60] ILQ 621-X001 / -X01(6;7;8;9)
61] ILQ 621 GB-X001 / -X01(6;7;8;9)
62] ILQ 30-X001 / -X01(6;7;8;9)
63] ILQ 31-X001 / -X01(6;7;8;9)
64] ILQ 32-X001 / -X01(6;7;8;9)
65] ILQ 55-X001 / -X01(6;7;8;9)
66] ILQ 65-..-X001 / -X01(6;7;8;9)
67] ILQ 620 GB-X001 / -X01(6;7;8;9)
69] SFH1617A-y-X001 / -X01(6;7;8;9)
69] SFH1617A-y-X001 / -X01(6;7;8;9)
70] ILD1615-y-X001 / -X01(6;7;8;9)
71] ILD1615-y-X001 / -X01(6;7;8;9)
```

Fortsetzung siehe Blatt 4 / continued on page 4

VDE Prüf- und Zertifleierungsinstitut GmitH * Testing and Certification institute

Muriamstrasso 28, D-63069 Offenbach

Telefon + 49 (0) 69 83 06-0 Telefox + 49 (0) 69 83 06-555

Revision: 16-May-12 Document Number: 83576 3

Licenses - (03) Optocoupler - Vishay, Type SFH6156 series



VDE Certificate 91888

www.vishay.com

Vishay Semiconductors

VDE Prüf- und Zertifizierungsinstitut Zeichengenehmigung

Ausweis-Nr. / Certificate No. 91888

Name und Sitz des Genehmigungs-Inhabers / Name and registered seat of the Certificate holder VISHAY Semiconductor GmbH, Theresienstraße 2, 74072 Heilbronn

Aktenzeichen / File ref. 422610-4880-0048 / 165525 / FG34 / SCT

letzte Änderung / updated Datum / Date 2012-03-26

Dieses Blatt gilt nur in Verbindung mit Blatt 1 des Zeichengenehmigungsausweises Nr. 91888 This supplement is only valid in conjunction with page 1 of the Certificate No. 91888.

Typ(en) / Type(s)

72] TCED1100 73] TCED1100G

74] TCET1600 75] TCET1600G

76] TCET1600G 76] TCET2200 77] TCET2200G 78] TCET2100 79] TCET2100G 80] TCET2600

81] TCET2600G 82] TCET4100

83] TCET4100G 84] TCET4600

85] TCET4600 86] SFH 6156-3078

87] V0615A-X015 / -X15(6;7;8;9) 88] V0617A-X015 / -X15(6;7;8;9) 89] V0618A-X015 / -X15(6;7;8;9)

Weitere Angaben

Anlage Nr.: 1_100A ; 1_200A Appendix No.: 1_100A ; 1_200A

VDE Prüf- und Zertifizierungsinstitut GmbH VDE Testing and Certification Institute Fachgebiet FG34 Section FG34

VDE Prof- und Zeitlibeierungsinstitut Grobit * Testing and Certification institute

Merianstrasse 28, D-63069 CHN

Telefon + 49 (0) 69 83 06-0 Telefon + 49 (0) 69 83 06-555

Revision: 16-May-12 Document Number: 83576 4 For technical questions, contact: optocoupleranswers@vishav.com

Licenses - (03) Optocoupler - Vishay, Type SFH6156 series



VDE Certificate 91888

www.vishay.com

Vishay Semiconductors

VDE Prüf- und Zertifizierungsinstitut Zeichengenehmigung

Ausweis-Nr. / Beiblatt / Certificate No. Supplement 91888

Name und Sitz des Genehmigungs-Inhabers / Name and registered seat of the Certificate holder VISHAY Semiconductor GmbH, Theresienstraße 2, 74072 Heilbronn

Aktenzeichen / File ref. 422610-4880-0048 / 165525 / FG34 / SCT

letzte Änderung / updated Datum / Date 2012-03-26 1996-04-15

Dieses Beiblatt ist Bestandteil des Zeichengenehmigungsausweises Nr. 91888. This supplement is part of the Certificate No. 91888.

Optokoppler Optocoupler

Fertigungsstätte(n) Place(s) of manufacture

Referenz/Reference 30009952

Vishay Semiconductor Malaysia Sdn. Bhd. 1710-1 Krubong Ind. Park Mukim Krubong 75250 MELAKA, MELAKA

MALAYSIA

VDE Prüf- und Zertifizierungsinstitut GmbH VDE Testing and Certification Institute Fachgebiet FG34 Section FG34

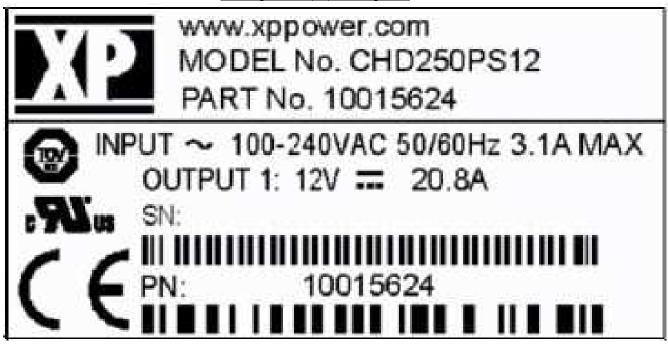
VDE Priif- und Zertifizierungsinstitut GmbH * Yesting and Certification Institut-

Merianstrause 28, D-63069 Offenback

Telefost + 49 (0) 69 83 06-9 Telefost + 49 (0) 69 63 06-555

Marking Label - (01) Marking Plate

Marking Label - (01) Marking Plate



Marking Label - (02) Trade name

Marking Label - (02) Trade name



Miscellaneous - (01) Letter of Assurance

Miscellaneous - (01) Letter of Assurance



THE XPERTS IN POWER

XP Power, 1241 E. Dyer Road, Suite 150, Santa Ana, California 92705 USA Tel: +1 714-597-7100 Fax: +1 714-597-7143 Website: www.xppower.com

August 21, 2012

Underwriters Laboratories LLC. 2929 E Imperial Hwy Suite 100 Brea, CA 92821

Attn: Mr. Linus Park

Email: linus.park@ul.com

Subject: National Differences

Dear Mr. Park,

This document confirms that XP Power Inc will provide the following items needed to the accepting National Certification Bodies (NCBs) along with the CB test report.

Markings and Safety Instructions – Safety instructions and markings in the language suitable for the countries listed in the attached reports will be provided at the same time the CB test report is submitted to the NCB.

EMC Test Report – Where detailed in the National Differences, an EMC test report or Declaration of Conformity will accompany this product when sent to countries that require EMC test results as part of their certification process.

RoHS - Restriction of the use of certain hazardous substances in electrical and electronic equipment. The substances to which the RoHS directive applies are: Lead, Mercury, Cadmium, Hexavalent chromium, Polybrominated biphenyls, Polybrominates diphenyl ethers.

Power Supply Cords and Plugs – All power cords and plug assemblies provided with the unit will be certified and suitable for use in the countries listed in the attached CB test report.

Multiple Factories - This confirms that samples submitted for certification are representative of the products from each factory. The factories are as noted in this CB Test Report.

Tac Pham

Manager, Product Compliance

XP Power LLC

Miscellaneous - (02) Output Ratings

Miscellaneous - (02) Output Ratings

Model	Convection	nal Cooling	Convectional Cooling With 5V Standby		Convectional Con		Convectional Cooling With Cover and and 5V Standby		
	Max Output @50°C	Max Output @70°C	Max Output @50°C	Max Output @70°C	Max Output @50°C	Max Output @70°C	Max Output @50°C	Max Output @70°C	
CHD250PS12	250W; 20.8A	200W; 16.67A	255W; 20.8A, 1A	127.3W; 10.4A, 0.5A	217W; 18.1A	108.5W; 9.04A	165W; 13.33A, 1A	82.5W; 6.67A, 0.5A	
CHD250PS15	250W; 16.7A	200W; 13.33A	255W; 16.7; 1A	127.3W; 8.33A; 0.5A	217W; 14.5A	108.5W; 7.23A	165W; 10.7A; 1A	82.5W; 5.33A, 0.5A	
CHD250PS18	250W; 13.9A	200W; 11.11A	255W; 13.9A; 1A	127.3W; 6.94A, 0.5A	217W; 12.1A	108.5W; 6.03A	165W; 8.89A; 1A	82.5W; 4.44A; 0.5A	
CHD250PS24	250W; 10.4A	200W; 8.33A	255W; 10.4A, 1A	127.3W; 5.2A, 0.5A	217W; 9.04A	108.5W; 4.52A	165W; 6.67A, 1A	82.5W; 3.33A, 0.5A	
CHD250PS28	250W; 8.93 A	200W; 7.14A	255W; 8.93A; 1A	127.3W; 4.46A, 0.5A	217W; 7.75A	108.5W; 3.88A	165W; 5.71A; 1A	82.5W; 2.86A; 0.5A	
CHD250PS33	250W; 7.58A	200W; 6.1A	255W; 7.58A; 1A	127.3W; 3.79A, 0.5A	217W; 6.58A	108.5W; 3.29A	165W; 4.84A, 1A	82.5W; 2.42A, 0.5A	
CHD250PS36	250W; 6.94A	200W; 5.56A	255W; 6.94A, 1A	127.3W; 3.47A; 0.5A	217W; 6.03A	108.5W; 3.01A	165W; 4.44A, 1A	82.5W; 2.22A, 0.5A	
CHD250PS48	250W; 5.2A	200W; 4.17A	255W; 5.2A, 1A	127.3W; 2.6A; 0.5A	217W; 4.52A	108.5W; 2.26A	165W; 3.33A, 1A	82.5W; 1.67A, 0.5A	

Miscellaneous - (03) Rationale for waiving the ball pressure test

Miscellaneous - (03) Rationale for waiving the ball pressure test

Clause 8.8.4.1 of ANSI/AAMI ES6060-1 (Use of UL Recognized Plastics instead of Ball Pressure Test)

Clauses 8.8.4.1 a) and 8.8.4.1b) requires external plastic enclosures and insulating materials which support uninsulated Mains Parts be subjected to the Ball Pressure Test to determine the softening point of thermoplastic materials.

Since the plastic material used are UL Recognized Plastic with the following Relative Thermal Indexes (RTI), the Ball Pressure Test was waived for the following plastics. See below for explanation of how RTIs are established for plastics.

Transformer bobbin -

Sumitomo Bakelite Co., Ltd"; Type: PM-9630; RTI: Electrical: 170°C, Mechanical with Impact: 150°C, Mechanical without Impact: 150°C. Flammability: V-0.

Sumitomo Chemical Co., Ltd"; Type: PM-9820; RTI: Electrical: 150°C, Mechanical with Impact: 150°C, Mechanical without Impact: 150°C. Flammability: V-0.

El Duport DeNemours & Co., Inc., Type FR530 RTI: Electrical: 155°C, Mechanical with Impact: 155°C, Mechanical without Impact: 155°C. Flammability: V-0

The Relative Thermal Index of a material is an indication of the plastic's ability to retain its electrical and mechanical properties when exposed to elevated temperatures for an extended period of time. It is the maximum temperature below which a material maintains its characteristics over a period of time. There may be up to three independent RTIs assigned to a material: electrical; mechanical with impact; and mechanical without impact.

The RTI of a material is established on the basis of either accelerated aging experiments or on a generic basis from field experience with specific facilities of materials. UL 746B "Standard for Polymeric Materials -Long Term Property Evaluations" gives details on how these RTIs are established.

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Miscellaneous - (03) Rationale for waiving the ball pressure test

Generic Indices: RTIs assigned to a material using the generic indices is based upon acceptable service experience with families of materials (e.g., ABS, polycarbonate, etc.). RTIs established on a generic basis are conservative temperatures limits.

Long-Term Thermal-Aging: The prime cause of polymeric material degrade with time is due to exposure to heat. Although it would be preferable to evaluate material performance by aging at normal operating temperature for a long time period, it is not very practical to do so. Instead, the desired information is obtained through an accelerated aging process in which the materials are aged at elevated temperatures. This involves measuring the pertinent properties of the material as functions of time and temperature, and using appropriate mathematical techniques to determine the time to "end of useful service" for each temperature. The "end of useful life" is defined as the time at which a material property has degraded to 50 percent of its original value. It is not expected that a 50% loss of property due to thermal degradation results in premature risk of electric shock, fire, or personal injury.

The long-term material performance is determined relative to that of a reference or control material, thus the term "relative temperature index" is used. For this method, samples of the new and control materials are placed in ovens which are kept at predetermined constant temperatures. Samples of both materials are taken from the ovens at various times and tested to determine mechanical and electrical properties. The data permits determination of the time at which the property values for each material fall to 50 percent of the original values.

The primary properties that are monitored to determine when they have fallen to 50% of its original values are as followed for each of the RTIs.

Mechanical RTI:

Thermoplastics use Tensile Strength test per UL 746A Thermosets use Flexural test per UL 746A Page A-76 of A-94

Miscellaneous - (03) Rationale for waiving the ball pressure test

Report No.: E146893-D1002-1-ULCB

Mechanical with Impact RTI:

Thermoplastics use Tensile Strength test per UL 746A

Thermosets use Izod test per UL 746A

Electrical RTI:

Thermoplastics use Dielectric test per UL 746A

Thermosets use Dielectric test per UL 746A

The Tensile Strength and Flexural Strength of a plastic material are measures of the material's ability to withstand stresses without breakage or rupture.

The Tensile and Izod Impact Tests determine the relative ability of a material to resist impact in its molded form. A single blow is used to determine energy required to rupture the sample.

The Dielectric-Strength Test determines the materials ability to resist electrical breakdown under high-voltage conditions at normal operating frequencies.

Since the plastic materials have gone through the above mentioned long-term aging test which take 9 to 18 months to complete under UL's Plastic Recognition Program, we have determined that it provides an equivalent degree of safety to that prescribed by the Ball Pressure Test.

Rationale: This clarification reduces the volume of testing required when the enclosure or mains-supporting subcomponent has already been evaluated for resistance to heat.

Photographs - (01) Top View with Cover

Photographs - (01) Top View with Cover



Photographs - (02) Input Side View with Cover

Photographs - (02) Input Side View with Cover

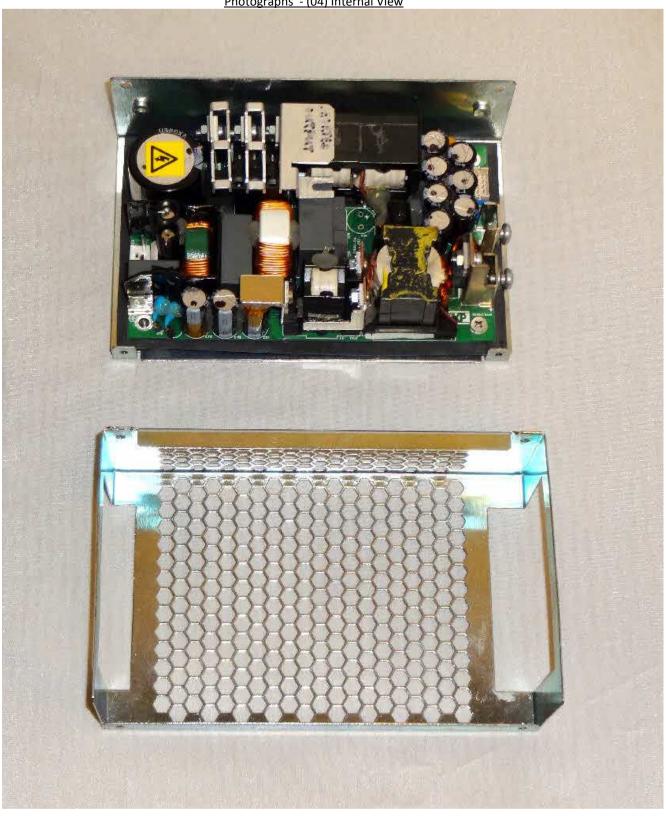


Photographs - (03) Output Side View with Cover



Photographs - (04) Internal View

Photographs - (04) Internal View



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Photographs - (05) Top View without Cover

Photographs - (05) Top View without Cover



Photographs - (06) Bottom view of the PWB

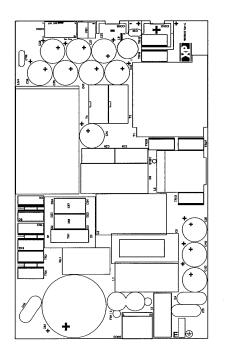
Photographs - (06) Bottom view of the PWB



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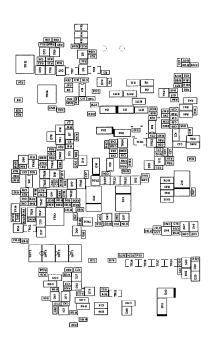
Report No.: E146893-D1002-1-ULCB

Schematics + PWB - (01) Component/PWB Trace Layout

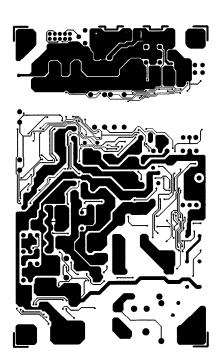


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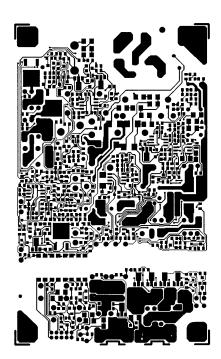
Report No.: E146893-D1002-1-ULCB



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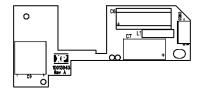


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Schematics + PWB - (02) PWB Component Layout - Standby Board (For models with "A"suffix)

Schematics + PWB - (02) PWB Component Layout - Standby Board (For models with "A"suffix)



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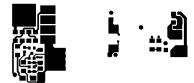
Schematics + PWB - (02) PWB Component Layout - Standby Board (For models with "A"suffix)



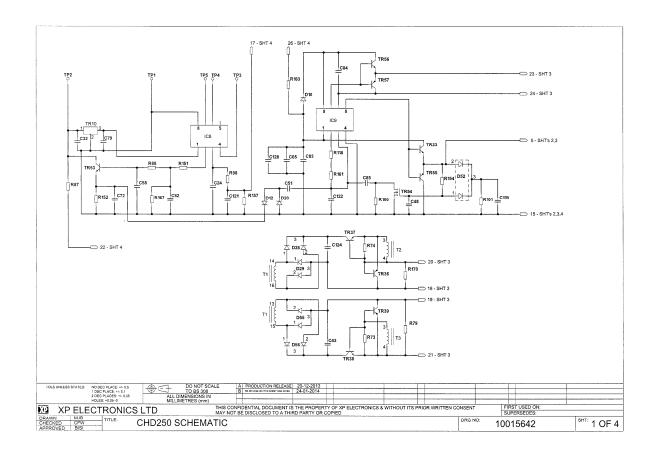


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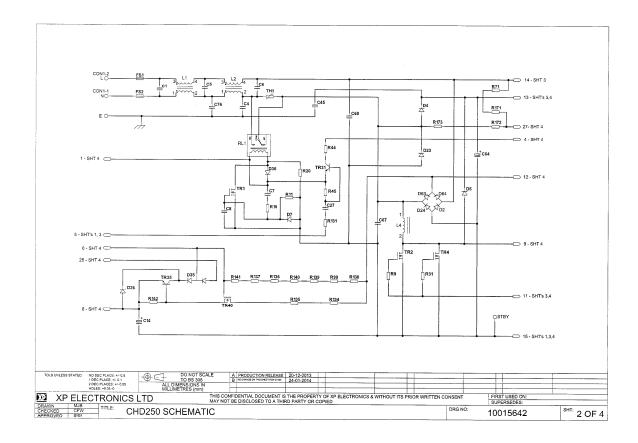
Schematics + PWB - (02) PWB Component Layout - Standby Board (For models with "A"suffix)

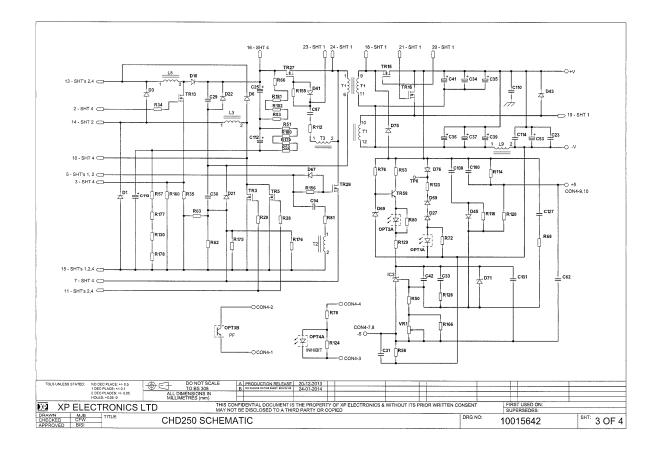


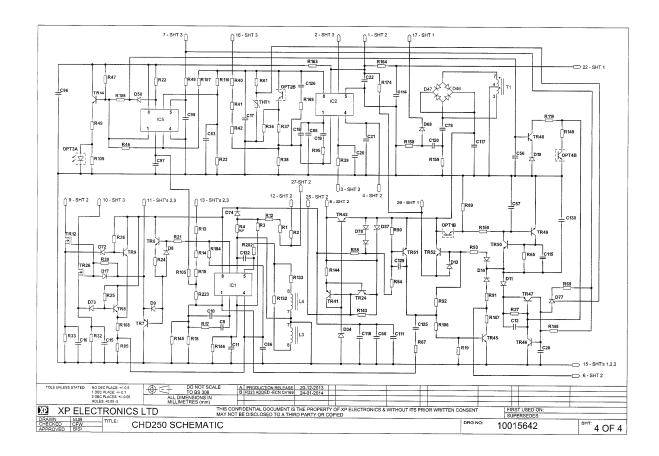
Schematics + PWB - (03) Electrical Schematics



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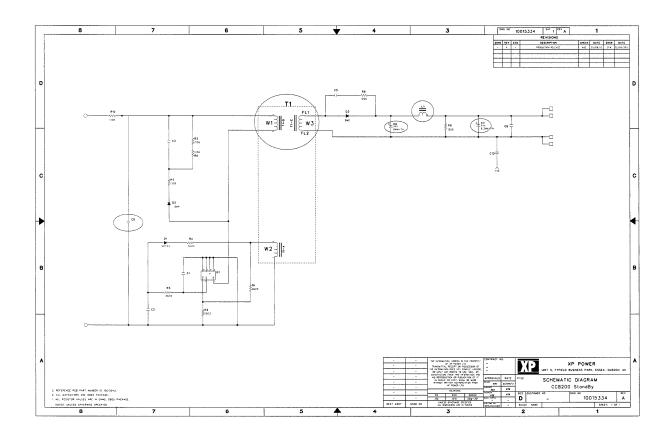






Schematics + PWB - (04) Electrical Schematics

<u>Schematics + PWB - (04) Electrical Schematics</u>



-----END OF APPENDIX A-----

Page B-1 of B-2 Report No.: E146893-D1002-1-ULCB

UL CERTIFICATION DOCUMENTATION:

APPENDIX B: UL Certification Documentation

This Appendix includes additional documentation for the UL Certification report only.

This report from this point below is associated with the UL Certification report only and NOT the CB Report (if applicable).

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Test Record

Models CHD250PS12, CHD250PS24 CHD250PS48 were used for test purposes and considered representative of the entire series.

All applicable tests according to the referenced standard(s) have been carried out.

The following tests were conducted:

Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.

Test results are valid only for the tested equipment. These tests are considered representative of the products covered by this Test Report. The test methods and results of the above tests have been reviewed and found to be in accordance with the requirements in the Standard(s) referenced at the beginning of this Test Report.

The following supplements are provided as a part of this Test Record. NOTE: These supplements are only available to the Applicant via the CDA system.

Refer to the Enclosures, which is located in Appendix A of this report.		
END OF APPENDIX B		

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APPENDIX C: Follow-Up Service Documentation

Follow-Up Service Procedure

It is important to keep UL Procedures and Test Reports up-to-date as new or revised pages are received. Correct maintenance will decrease the amount of time the UL Representative spends when visiting your facility.

UL LLC offers MyHome @UL, a dedicated website providing secure access to online tools and databases that can help simplify your compliance activities. You can customize your personal MyHome @UL page to include the content needed most, including timely information about certification updates and links to other Web sites you visit regularly. Visit http://my.home.ul.com/ to sign up today!

PAGES (in content order)	FUNCTION	HOW TO UPDATE	
Authorization Page	Displays the Product Category, the type of Follow-Up Service (Type R=Reexamination / Type L=Label), the File Number and the Volume Number associated with each Applicant's, Manufacturer's and Listee's company name and address.	Replace existing page by matching the UL File Number and Volume Number. Discard the older page (refer to "Issued" or "Revised" date).	
Addendum to Authorization Page*	Lists the additional names and addresses of manufacturing locations, when multiple locations exist	Replace existing page by matching the UL File Number and Volume Number. Discard the older page (refer to "Issued" or "Revised" date).	
Listing Mark Data (LMD), Classification Mark Data (CMD) or Recognized Component Mark Data (RCMD) Pages* #	Used only for products covered under Type R Service. Displays the correct LMD, CMD, or RCMD Mark, the Control Number for Listed and Classified categories and additional information regarding minimum size, application, procurement, and any other optional markings, in addition to the UL Mark.	Replace existing page by matching the UL File Number and Volume Number. Discard the older page (refer to "Issued" or "Revised" date).	
		Replace, add or delete page(s) with most current "Issued" or "Revised" date.	
Index*	Catalogs the contents of the Procedure by some logical means, i.e. Section Number, Report Reference Number, or Issue Date.	Replace present page by matching the UL File Number, Volume Number, Page Number and most current "Revised" date.	
Appendices* # (App.)	Contains instructions for the Manufacturer and UL Representative concerning specific responsibilities and required periodic tests. May also outline tests to be conducted on samples to be forwarded to UL's facilities.	Replace present page by matching the UL File Number, Volume Number, Appendix letter (eg. App. A), Page Number and most current "Revised" date.	
(Арр.)	Standardized Appendix Pages are the same for all manufacturers within a particular product category.	Replace present page by matching the Appendix letter (eg. App. A), Page Number and most current "Revised" date.	
Follow-Up Inspection Instructions (FUII) Pages*	Contains information similar to that in the Appendices. FUII Pages are issued as part of the Procedure when a UL Standard is used in conjunction with the Procedure, and are the same for all manufacturers within a particular category.	Replace present pages by matching the Page Number and most current "Issued" or "Revised" date.	
Section General* # (Sec. Gen.)	Contains description, requirements, identifications and/or specifications that are common to all products covered by the entire volume and supplements the information provided in the Description Section.	ucts covered by the	
Description, or Section systems. This includes written text supplemented by File Number, Volume Number		Replace present page by matching the UL File Number, Volume Number, Section Number, Page Number and most current "Issued" date.	

^{*} The above page(s) may not appear in all UL Follow-Up Service Procedures; UL's Conformity Assessment Services staff determines their inclusion.

PLEASE NOTIFY YOUR LOCAL UL OFFICE OF ANY CHANGES IN CONTACT NAME, COMPANY NAME OR ADDRESS, SO THIS MATERIAL AND IMPORTANT INFORMATION CONTINUES TO BE DELIVERED TO YOUR FACILITY WITHOUT INTERRUPTION.

[#] These pages are combined in the **Generic Inspection Instructions** for International Style Reports, identified, as example by Vol. X1, X2, etc.

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UL Authorization Page



UL File Number: E146893 Volume: D1 Issue Date:

FOLLOW-UP SERVICE PROCEDURE

(TYPE R)

PRODUCT CATEGORY NAME (QQHM2 / QQHM8)

Manufacturer: SEE ADDENDUM FOR MANUFACTURING LOCATIONS

Applicant: 35701 (Party Site) 100565739 XP POWER LLC

15641 Red Hill Ave., Ste. 100 Tustin, CA 97280 USA

Listee/Classified/ S

Same as Applicant (unless specified differently below)

Recognized Co.:

This Follow-Up Service Procedure authorizes the above Manufacturer(s) to use the marking specified by UL LLC, or any authorized licensee of UL LLC, including the UL Contracting Party, only on products when constructed, tested and found to be in compliance with the requirements of this Follow-Up Service Procedure and in accordance with the terms of the applicable service agreement with UL Contracting Party and any applicable Service Terms. The UL Contracting Party for Follow-Up Services is listed on addendum to this Follow-Up Service Procedure ("UL Contracting Party"). UL Contracting Party and UL LLC are referred to jointly herein as "UL."

UL further defines responsibilities, duties and requirements for both Manufacturers and UL representatives in the document titled, "UL Mark Surveillance Requirements" that can be located at the following web-site: http://www.ul.com/fus and in the document titled "UL and Subscriber Responsibilities" that can be located at the following website: http://www.ul.com/responsibilities. Manufacturers without Internet access may obtain the current version of these documents from their local UL customer service representative or UL field representative. For assistance, or to obtain a paper copy of these documents or the applicable Service Terms, please contact UL's Customer Service at http://www.ul.com/global/eng/pages/corporate/contactus, select a location and enter your request, or call the number listed for that location.

The Applicant, the specified Manufacturer(s) and any Listee/Classified/Recognized Co. in this Follow-Up Service Procedure must agree to receive Follow-Up Services from UL Contracting Party. If your applicable agreement is a Global Services Agreement ("GSA") with an effective date of January 1, 2012 or later and this Follow-Up Service Procedure is issued on or after that effective date, the Applicant, the specified Manufacturer(s) and any Listee/Classified/Recognized Co. will be bound to a Service Agreement for Follow-Up Services upon the earliest by any Subscriber of use of the prescribed UL Mark, acceptance of the factory inspection, or payment of the Follow-Up Service fees which will incorporate such GSA, this Follow-Up Service Procedure and the Follow-Up Service Terms which can be accessed by clicking here: www.ul.com/contracts/Terms-After-12-31-2011. In all other events, Follow-Up Services will be governed by and incorporate the terms of your applicable service agreement and this Follow-Up Service Procedure.

It is the responsibility of the Listee/Classified/Recognized Co. to make sure that only the products meeting the aforementioned requirements bear the authorized Marks of UL LLC, or any authorized licensee of UL LLC.

This Follow-Up Service Procedure contains information for the use of the above Manufacturer(s) and representatives of UL and is not to be used for any other purpose. It is provided to the Manufacturer with the understanding that it will be returned upon request and is not to be copied in whole or in part.

Page C-4 of C-43

Report No.: E146893-D1002-1-ULCB

This Follow-Up Service Procedure, and any subsequent revisions, is the property of UL and is not transferable. This Follow-Up Service Procedure contains confidential information for use only by the above named Manufacturer(s) and representatives of UL and is not to be used for any other purpose. It is provided to the Subscribers with the understanding that it is not to be copied, either wholly or in part unless specifically allowed, and that it will be returned to UL, upon request.

Capitalized terms used but not defined herein have the meanings set forth in the GSA and the applicable Service Terms or any other applicable UL service agreement.

UL shall not incur any obligation or liability for any loss, expense or damages, including incidental, consequential or punitive damages arising out of or in connection with the use or reliance upon this Follow-Up Service Procedure to anyone other than the above Manufacturer(s) as provided in the agreement between UL LLC or an authorized licensee of UL LLC, including UL Contracting Party, and the Manufacturer(s).

UL LLC has signed below solely in its capacity as the accredited entity to indicate that this Follow-Up Service Procedure is in compliance with the accreditation requirements.

Bruce A. Mahrenholz Director North American Certification Program Page C-5 of C-43 Report No.: E146893-D1002-1-ULCB

Addendum to Authorization Page

LOCATION

Manufacturing Factory(ies)
Information:

XP Power Inc 990 Benecia Ave

Sunnyvale CA 94085-2804 USA

Party Site: 12864

Subscriber No.: 407169001

Factory ID: FS

UL Contracting Party: UL LLC

XP POWER (VIETNAM) CO LTD LOT D - 4Q - CN MY PHUOC 3 INDUSTRIAL PARK BEN CAT DISTRICT BINH DUONG VIETNAM

Party Site: 38034

Subscriber No.: 100574113

Factory ID:

UL Contracting Party: UL AG

XP POWER (KUNSHAN) LTD 230 BIN JIANG NAN RD ZHANGPU TOWN KUNSHAN JIANGSU, 215321 CHINA

Party Site: 33779

Subscriber No.: 100101437

Factory ID: K

UL Contracting Party: UL AG

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UL Appendix:

GENERIC INSPECTION INSTRUCTIONS

Product Category	Product Category CCN
Power Supplies, Medical and Dental - Component	QQHM

These instructions consist of the following Parts:

Part	Description
AA	Instructions and Responsibilities for UL Representative
AB	Instructions for Follow-Up Tests at UL
AC	Responsibilities and Requirements for Manufacturer
AD	General Terminology
AE	General Product Construction Requirements
AF	UL Certification Marks

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PART AA

INSTRUCTIONS AND DUTIES FOR UL REPRESENTATIVE

AA1.0	UL REPRESENTATIVE'S DUTIES		
AA1.1	The UL Representative's duties include, but are not limited to: A. Examining the construction of production intended to bear the UL Mark or Marking to determine compliance with the description of the product and any other requirements expressed in this Procedure.		
	B. Where so specified in each Test Report, forwarding samples to UL for Follow-Up tests.		
	C. Where so specified by Part AC, inspecting the test records and facilities of the manufacturer t ensure that:		
	The proper number of samples are undergoing the required tests, and		
	2. The required tests are being performed correctly, and		
	3. The proper information is being recorded and is up-to-date, and		
	 The instruments being used for the tests have been calibrated at the prescribed interval and are in good working order. 		

AA2.0	PROCEDURE IN CASE OF NONCONFORMANCE
AA2.1	Report to the manufacturer and UL LLC by means of a Variation Notice (VN) if:
	A. Variations in construction are found, or
	B. The manufacturer's method and/or frequency of testing is not as described, or
	C. The test records maintained by the manufacturer are not as described, or
	D. The manufacturer's inspection program is not being performed as described, or
	E. Nonconforming test results are witnessed during tests conducted specifically for the UL Representative.
AA2.2	Explain to the manufacturer that a VN is a means of communication with the manufacturer and applicant and forms a record of those items where nonconformance to the Procedure has been found. Reference is to be made to "Information for Manufacturer's Variation Notices" on the back of the VN.
AA2.3	When a product does not conform with the Procedure, require that the manufacturer:
	A. Remove any markings referencing UL from the product, or obliterate these markings where the marking is imprinted, die-stamped, molded, etc., or
	B. Suitably modify all products that do not comply with the Procedure, or
	C. Hold shipment pending further instructions from UL LLC
	D. Demonstrate that one of the conditions shown below exist and be able to provide any of the referenced information or documentation. Under the following conditions, variations from Procedure described constructions shall be noted on a Variation Notice, however, the manufacturer is not required to remove UL markings, rework the product or hold shipment.
	 A part is called out as Listed and the manufacturer or part number is not as described and the alternate part being used is Listed and all other attributes for the part are met.
	 A part is called out as a Recognized Component (R/C) and the manufacturer or part number is not as described and the alternate part being used is Recognized under the described category and all other attributes for the part are met.

	3. Internal wiring is identified by UL Style Number and the manufacturer is using (R/C) Appliance Wiring Material (AWM) with Style Numbers not referenced in the Procedure description. The manufacturer must be able to provide documentation that the voltage and temperature ratings of the alternate Style Number are equal to or greater than the ratings of the Style Numbers specified in the Procedure. AWM with Style Numbers not specified in the Procedure must be rated VW-1.
AA2.4	It is the manufacturer's responsibility to forward a copy of the Variation Notice to the Applicant.
AA2.5	If the manufacturer or Applicant question the rejection of the product, the material may be held at the point of inspection, typically at the factory, pending an appeal. The manufacturer has the right to appeal a decision with which they disagree. Provide the name of the UL engineer to whom the appeal is to be made. To resolve issues involving variations in construction, the manufacturer and Applicant may also be offered the option of contacting their New Work assignment engineer. Held shipment appeals involving Follow-Up Services issues (e.gimproper labeling, etc.) should be directed to an appropriate staff member designated by the Reviewing Office for the product category. Should UL grant temporary authorization for the continued use of the UL Mark, such temporary authorization shall only be for the time needed to review and/or process the Procedure revisions, or as otherwise specified to cover a particular lot or production run. The manufacturer shall satisfy the UL Representative that all marks referencing UL are removed from the rejected material. Those marks referencing UL not destroyed during their removal from the product shall be turned over to the UL Representative for destruction.

AA3.0	EXAMINATIONS TO BE WITNESSED BY UL REPRESENTATIVE			
AA3.1	Inspection of Printed Wiring Boards and Printed Wiring Board Assemblies			
AA3.1.1	The UL Representative shall determine that the printed wiring board is as specified in the Procedure.			
AA3.1.2	If the soldering operation is performed at the Original Equipment Manufacturer's factory (OEM) and the soldering temperature and dwell time are given in the Procedure, the temperature and dwell time shall also be checked to determine that they do not exceed the limits specified.			
AA3.1.3	The UL Representative shall determine that the printed wiring board is as specified in the Procedure. The UL Representative then shall make a visual inspection of the printed wiring board assemblies for any mechanical damage or evidence of exposure to excessive temperatures that may have occurred during the soldering operation. The base material and the conductors shall examined for nonconforming features as indicated below:			
	A. Conductors, Terminal Pads, and Tabs			
	 Reduction in cross-section, such as scratches, nicks, pin holes, tearing. 			
	2. Loosening or lifting of printed wiring conductor, pad, or tab from the base material.			
	3. Sections missing or damaged.			
	4. Blistering			
	5. Breaks			
	B. Base Material			
	1. Warping			
	2. Cracking			
	3. Charring, blistering, or other heat damage due to solder process			
	4. Delamination			

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AA3.1.4	With respect to printed wiring boards using Surface Mounted Technology (SMT), if the SMT assembly process is done at temperatures and times below the soldering limits, the UL Representative will accept the boards. If the assembly process is conducted on-site with temperatures/times in excess of soldering limits or if the process is conducted off-site and the temperatures/times cannot be verified, a visual inspection will be conducted by the UL Representative in accordance with the guidelines shown above. If any instructions for SMT
	components are specified in the Procedure, then these SMT instructions are superseded.

AA4.0	SAMPLE SELECTION FOR TESTS CONDUCTED AT MANUFACTURER AND UL		
AA4.1	Standard Follow-Up Tests for Plastic Enclosures and Parts		
AA4.1.1	Each Test Report indicates the plastics enclosures or parts that may require Follow-Up Service testing. The UL Representative shall consult Table AA1 to determine which tests are required.		
AA4.1.2	With respect to Table AA1, Access to Molding Operation shall be determined in accordance with the following:		
	A. UL is considered to have access to the plastic molding operation if the molding takes place in the end-product assembly location and the operation complies with the requirements below.		
	B. The UL Representative shall have free, unannounced, and immediate access to the factory and the storage facility during all business hours of the factory or storage facility. The UL Representative shall also have access to the records required below.		
	C. The manufacturer shall mark each enclosure, cartons containing enclosures, or a tag accompanying the enclosure in a manner such that the UL Representative can trace the origin of each enclosure to a specific batch.		
	D. The manufacturer shall keep records for each batch of plastic enclosures molded, in accordance with the below requirements.		
	E. The records shall be thorough, so that the UL Representative may determine the composition of the enclosure. The records shall be maintained for at least six months from the date of production, and shall be accurate. All of the following items are to be covered:		
	The records shall indicate the base material. The manufacturer may not blend resins. Exception: The manufacturer may blend resins provided it is specifically stated in the Procedure.		
	2. The records shall include the amount of regrind used. Thermoplastic regrind shall not exceed 25 percent by weight. UL does not authorize the use of thermoset regrind. Exception: Thermoplastic regrind may exceed 25 percent provided it is specifically stated in the Procedure and does not exceed the percent stated in the Procedure.		
	3. The composition of the enclosures shall not include recycled plastics, color concentrates, flame retardants, or mold release lubricants. Exception: One or more of the elements indicated in 3) may be included, provided the Procedure specifically acknowledges its use.		
	F. However, if a minor discrepancy (such as a mathematical error or a bookkeeping oversight) occurs, the manufacturer shall discuss the error with the responsible individual. If necessary, the manufacturer shall correct the error on the records. To prevent recurrence of the error, the error shall be documented on a Variation Notice, and the UL Representative shall pay particular attention to this area during future inspections.		
	G. If a major discrepancy appears in the records, or if the records are not complete, or UL no longer has access to the molding operation, the UL Representative shall issue a Variation Notice so that the Procedure will be modified accordingly		

AA4.1.3	Where testing is required, samples are to be selected no less than once per year in accordance with each Test Report. All samples are to be handled in accordance with the requirements of this section.
AA4.1.4	Enclosure samples shall be chosen in a manner such that each enclosure material in use by the manufacturer is represented by tests no less than once over a two-year period. Enclosure materials that are used infrequently (i.e. less than once in a two year period) shall be selected whenever they are used.
AA4.1.5	Impact Test at Manufacturer
AA4.1.5.1	Where indicated in Table AA1, the UL Representative shall conduct the Impact Test as part of the product inspection at the manufacturer's facility and shall determine if the manufacturer records the test data in compliance with the requirements of this document
	Exception: As noted in Table AA1 footnote (d), the Impact Test shall be conducted at UL if the manufacturer does not have the ability to conduct the test.
AA4.1.5.2	Each enclosure sample fabricated with the material specified in the Test Report shall be subjected to a single impact. The impact shall be directed onto the surface most likely to demonstrate a nonconformance when the Basis of Acceptability of AA4.1.5.3 is applied. The impact is to be produced by dropping a steel sphere 2 inches (50.8 mm) in diameter and weighing 1.18 pounds (0.536 kg mass) a height of 50.85 in. (129.2 cm). For surfaces other than the top of an enclosure the steel sphere is to be suspended by a cord and swung as a pendulum, dropping through the 50.85 in. (129.2 cm) vertical distance before striking the surface
AA4.1.5.3	Each sample shall withstand the impact of AA4.1.5.2 without being affected to the extent that:
	A. Uninsulated, live parts are accessible to contact, or
	B. The mechanical performance of the product is adversely affected so as to create a risk of injury to persons, or
	C. A condition is produced that can cause a risk of electric shock.
AA4.1.5.4	To determine compliance with AA4.1.5.3 (A), the UL Representative shall apply the articulate probe to verify that the probe cannot contact an uninsulated, live part. It is the manufacturer's responsibility to order and purchase the probe through UL's Corporate Standards Department, at the Northbrook Office.
AA4.1.5.5	To determine compliance with AA4.1.5.3 (B), the UL Representative shall give consideration to the functioning of safety devices and constructional features (such as thermostats, overload protective devices and strain relief). Cracking or denting of the enclosure shall not result in the exposure of moving parts that could cause a risk of injury to persons.
AA4.1.5.6	To determine compliance with AA4.1.5.3 (C), the product shall be subjected to a Dielectric Voltage-Withstand Test as described in AC2.3 without dielectric breakdown.
AA4.1.5.7	If the Impact Test sample produces any one of the conditions specified in AA4.1.5.3, the test is to be repeated on three previously untested samples from the same lot. The results are considered acceptable if all three samples comply with the requirements. If a nonconformance occurs on any one of the additional samples, then the lot shall be considered rejected.
AA4.1.6	ID and Flammability Tests
AA4.1.6.1	Samples selected in accordance with Table AA1 shall be tagged with all the following information, and the manufacturer shall forward them to the Reviewing Office:
	A. Material
	B. Manufacturer
	C. Model number
	D. Follow-Up Test(s) required

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E. Test parameters (if any)

TABLE AA1 FOLLOW-UP TESTING FOR PLASTIC ENCLOSURES AND PARTS

	Molding location			
Enclosure	Recognized Component molder or evaluated component molder other than Recognized ^a	Not evaluated molding		
plastic		UL has access to molding operation ^b	UL does not have access to molding operation b	
Recognized Component	No tests required	Annual Impact Test at Mfg. OR Annual ID Tests at UL ^{c, d}	Annual Impact and ID Tests at UL	
Unlisted Component ^e	Annual Impact Test at Mfg. ^d AND Annual ID and Flame Tests at UL	Annual Impact Test at Mfg. ^d AND Annual ID and Flame Tests at UL	Bi-annual Impact and ID Tests at UL	

- The reference to evaluated component molder other than Recognized is in regard to a molder of plastic fabricated parts which has been authorized by UL to mold plastic for the end-use product, but for which no Recognition has been established.
- Access to molding operation means the molding takes place in the end-product assembly location and the manufacturer follows the requirements in AA4.1.2.
- The manufacturer may elect either an Impact Test or ID Tests. The UL Representative shall act accordingly.
- If the manufacturer does not have the ability to perform the Impact Test in accordance with AA4.1.5, the required test samples are to be forwarded to UL for testing.
- The reference to Unlisted component plastic is in regard to a component plastic used in a Listed or Recognized product which is separately investigated in accordance with applicable requirements for the end-use product, and for which no coverage has been requested or established.

PART AB

INSTRUCTIONS FOR FOLLOW-UP TESTS AT UL

AB1.0	GENERAL
AB1.1	The samples forwarded by the UL Representative shall be subjected to the tests indicated on the sample tags in accordance with any indicated test specifics (e.g. oven temperature).
AB1.2	Unless otherwise notes, all references are to the Generic Inspection Instructions.

TABLE AB1 TEST PARAMETERS

Test	Method	Basis for Acceptability
Impact	AA4.1.5.2	AA4.1.5.3 – AA4.1.5.7
Identification		
Qualitative Infrared Analysis (IR)	UL 746A	Compare to original spectrum in Test Report
Differential Scanning Calorimetry (DSC)	UL 746A	Compare to original thermogram in Test Report
Thermogravimetry (TGA)	UL 746A	Compare to original thermogram in Test Report
Flammability		
3/4 Inch Flame	UL 746C	UL 746C
5 Inch Flame	UL 746C	UL 746C

PART AC

RESPONSIBILITIES AND REQUIREMENTS FOR MANUFACTURER

AC1.0	MANUFACTURER'S RESPONSIBILITIES (INCLUDING BUT NOT LIMITED TO)
AC1.1	Control of UL Mark - Restrict the use of markings that reference UL (either directly or by use of the name, an abbreviation of it, or the UL symbol or Classification Mark, or indirectly by means of agreed-upon markings that are understood to indicate acceptance by UL) to those products that are found by the manufacturer's own inspection to comply with the Procedure description. Such restrictions apply to packaging, brochures or other means of advertising that reference UL. Use of such markings is further limited by the agreements that have been executed by the subscriber and UL. Markings shall be confined to the locations authorized in these Generic Inspection Instructions or in individual Test Reports.
AC1.2	Access to Factory - During hours in which the factory is in operation, provide the UL Representative with free access to any portion of the premises where the product or components thereof are being fabricated, processed, finished or stored, and to the test area assigned for the UL Representative's use. The UL Representative shall be permitted to inspect and subject to prescribed tests, prior to shipment, any product bearing or intended to bear markings referencing UL.
AC1.3	Production-Line Tests - Conduct the tests detailed in Part AC2.0.
AC1.4	Required Records - Maintain records of test performance. The records shall include the model or catalog designation of the product, the date of production, the tests performed, number of units tested, test results and action taken on rejections. Records for test performance shall be retained for six (6) months and shall be readily available for review by the UL Representative.
	Exception - Records of test results need not be maintained for 100% Production-Line Tests.
AC1.5	Test Equipment and Personnel - Provide, at a convenient location, all required test equipment and facilities and any required personnel for conducting all tests that are to be performed at the factory. These shall be available when needed so that the inspection work can proceed without undue delay.
AC1.6	Test Equipment Calibration - Determine that the test equipment is functioning properly daily, and have it calibrated at least annually, or whenever it has been subject to abuse (such as being dropped or struck with an object) or its accuracy is questionable. The test equipment and instruments shall be calibrated either by the manufacturer or by an outside laboratory. In either case, it shall be calibrated by comparison with a standard that is traceable to the applicable U.S. or foreign National Standard. A letter from the outside laboratory or from an off-site manufacturer's calibration lab stating that their lab standards are directly traceable to their country's National Standard and outlining their traceability pathway is considered adequate proof of traceability. For in-house calibrations, the Standard (weight and gauge blocks, etc.) used shall be calibrated every three years, or whenever the Standard has been subject to some form of abuse that may affect the Standard's fitness for use. The Standard shall be stored to protect it from damage or deterioration per the Standard manufacturer's recommendations. Records of the calibration of the test equipment and Standard(s) shall be maintained until the next required calibration is completed and recorded, and shall be readily available for review by the UL Representative.

AC2.0	REQUIREMENTS FOR PRODUCTION-LINE TESTS	
AC2.1	The following Production-Line Tests shall be conducted on the products covered by this Procedure. During production, the test equipment shall be checked for proper operation at least once during each shift. When the tests are not performed concurrently, it is preferred that the Grounding Continuity Test be performed before either Dielectric Voltage-Withstand Test.	
AC2.2	Production-Line Grounding Continuity Test	
AC2.2.1	General - Except as may be noted under "Exceptions" in each Test Report, the manufacturer shall subject 100 percent of production of all of the following products to a routine Production-Line Grounding Continuity Test as described in section AC2.2.3:	
	A. Products that are provided with a grounding type power supply cord, or	
	B. Fixed products that are for permanent connection to the branch circuit.	
	Exception: This test is not required for permanent connection to the branch circuit by fixed wiring if the design does not employ bonding jumpers or grounding wiring to remote units.	
AC2.2.2	<u>Test Equipment</u> - Any suitable continuity-indicating device (such as an ohmmeter, a battery and buzzer combination, or the like) may be used to determine compliance with the Grounding Continuity Test requirements.	
AC2.2.3	Method - Continuity shall be determined between the grounding conductor of the attachment plug cap, and/or the designated main grounding point, and accessible dead-metal parts of the product, using the test equipment indicated above.	
	A single test is sufficient if the accessible metal selected is conductively connected by design to all other accessible metal.	
AC2.2.4	Basis for Acceptability - There shall be grounding continuity between the parts specified.	
AC2.3	Production-Line Dielectric Voltage-Withstand Test	
AC2.3.1	<u>General</u> - Except as may be noted under "Exceptions" in each Test Report, the manufacturer shall subject 100 percent of production of all products to a routine Production-Line Dielectric Voltage-Withstand Test as described in section AC2.3.3.	
AC2.3.2	<u>Test Equipment</u> - The test equipment shall include a means of indicating the test potential, an audible or visual indicator of electrical breakdown, and either a manually operated reset device to restore the equipment after electrical breakdown or an automatic feature that rejects any unacceptable unit. If an ac test potential is applied, the test equipment shall also include a transformer having an essentially sinusoidal output.	
	If the output of the test-equipment transformer is less than 500 volt-amperes, the equipment shall include a voltmeter in the output circuit to indicate the test potential directly.	
	If the output of the test-equipment transformer is 500 volt-amperes or more, the test potential may be indicated (1) by a voltmeter in the primary circuit or in a tertiary-winding circuit, (2) by a selector switch marked to indicate the test potential, or (3), in the case of equipment having a single test-potential output, by a marking in a readily visible location to indicate the test potential. When marking is used without an indicating voltmeter, the equipment shall include a positive means, such as an indicator lamp, to indicate that the manually operated reset switch has been reset following a dielectric breakdown.	
	Test equipment other than that described above may be used when it can be shown that UL has previously confirmed in writing that the equipment complies with the above requirements and is deemed suitable for use for this test.	

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AC2.3.3 Method - Each product shall withstand without electrical breakdown, as a routine production-line test, the application of an ac potential at a frequency within the range of 40-70 Hz or DC potential between the primary wiring, including connected components, and accessible dead metal parts that are likely to become energized. The test potential and duration shall be in accordance with Table AC1. The manufacturer's test conditions may be higher than those shown in Table AC1 when necessary to comply with other international product safety certifications. The product may be in a heated or unheated condition for the test. The test shall be conducted when the product is complete (fully assembled), and it is not intended that the product be unwired, modified, or disassembled for the test, unless otherwise permitted below: A. A part, such as a snap cover or a friction-fit knob, that would interfere with conducting the test need not be in place. B. The test may be conducted before final assembly if the test parameters represent that for the completed product. During the test, the primary switch is to be in the on position, both sides of the primary circuit of the product are to be connected together and to one terminal of the test equipment, and the second test-equipment terminal is to be connected to accessible dead metal. Electromagnetic interference filter capacitors connected to the primary circuit shall not be disconnected during the test. AC2.3.4 Basis for Acceptability - All products shall withstand the applied potential without an indication of

TABLE AC1 DIELECTRIC VOLTAGE-WITHSTAND TEST CONDITIONS

electrical breakdown.

Product Voltage Rating (V)	Test Potential (V rms / dc)	Time
120	840 V rms / 1200 V dc	2 sec
240	1390 V rms / 1970 V dc	2 sec
120/240	0.9 times of clamping voltage*	2 sec

Comment: *If a transient limiting device is provided, see individual description for details and values.

PART AD

GENERAL TERMINOLOGY

AD1.0	ABBREVIATIONS / DEFINITIONS		
AD1.1	IEC	Component provided with a testing agency's mark as indicated in Table II	
AD1.2	PRI	Primary circuit (mains)	
AD1.3	PWB	Printed wiring board	
AD1.4	SEC	Secondary circuit	
AD1.5	CN	Component provided with CSA or CUL Marking	
AD1.6	LC	Supplied by source limited to the values specified Table 17 (see below)	

S

Table 17 - Limits of maximum available current

Open-circuit output voltage (<i>U or Û</i>)			Maximum available current
a.c. r.m.s.	d.c.	Peak ^a	a.c. r.m.s. or d.c.
U ≤ 2	<i>U</i> ≤ 2	Û ≤ 2,8	50
2 < <i>U</i> ≤ 12,5	2 < <i>U</i> ≤ 12,5	$2.8 < \hat{U} \le 17.6$	100 / <i>U</i>
12,5 < <i>U</i> ≤ 18,7	12,5 < <i>U</i> ≤ 18,7	$17,6 < \hat{U} \le 26,4$	8
18,7 < <i>U</i> ≤ 30	18,7 < <i>U</i> ≤ 60	$26,4 < \hat{U} \le 42,4$	150 / <i>U</i>

^a The peak value (\hat{U}) applies to non-sinusoidal a.c. and to d.c. with ripple exceeding 10 %, and is provided for convenience. The r.m.s. value of the maximum available current shall be determined as that value is related to heating.

PART AE

GENERAL PRODUCT CONSTRUCTION REQUIREMENTS

AE1.0	CONSTRUCTION DETAILS		
AE1.1	Unless otherwise described or supplemented in individual Test Reports, the following requirements apply to all equipment included in this Procedure. It is the manufacturer's responsibility to assure the compliance of production with these requirements.		
AE1.1.1	Accessories Parts and Accessories - Such items packaged with the product shall be specifically described in a Test Report.		
AE1.1.2	Adapters – Three or two wire grounding type adapters shall not be furnished with the product unless specifically authorized by a Test Report.		
AE1.1.3	Bonding - Except where specifically noted in a Test Report, bonding of internal dead-metal parts to the enclosure for grounding purposes shall be accomplished by a positive means such as clamping, riveting, bolting or screwed connection. The bonding connection shall reliably penetrate any nonconductive coatings such as paint or vitreous enamel.		
AE1.1.4	<u>Casualty Considerations</u> - Except as described, or as necessary for normal operation of the equipment, there shall be no sharp edges, burrs, points, or spikes inside or outside the device that may cause injury during use or during cleaning operations.		
AE1.1.5	<u>Connectors</u> - Connectors shall be applied so as to ensure that all bare strands are contained and insulated.		
AE1.1.6	Grounding - The following guidelines shall be observed:		
	A. <u>Non-Detachable Cord Connected Appliance</u> - The equipment-grounding conductor of the flexible cord:		
	Shall be connected to the grounding member of the attachment-plug cap.		
	Note: The grounding member of the attachment-plug shall be fixed in position with respect to the cap.		
	2. Shall be conductively connected to all dead-metal parts of the product that are specified in the description as being connected to the grounding conductor. The grounding-conductor shall be connected by either (1) a screw or other reliable means which serves no other purpose and which is not liable to be removed during any servicing operation, or (2) a threaded grounding stud on which a closed ring connector secured to the ground conductor is the first conductor mounted and secured by a nut and split ring lockwasher. Solder alone shall not be used for securing this conductor.		
	Note: The screw or stud and nut shall: (1) be provided with a means to penetrate nonconductive coatings, such as paint or enamel; (2) be of a corrosion-resistant metal or shall be protected against corrosion; and (3) be marked on or adjacent with a grounding symbol or the IEC417 Grounding Symbol 5019 " — ". The installation instructions shall identify the meaning of the symbol.		
	B. <u>Detachable Cord Connected Appliance</u> - Polarization shall be maintained through the load fitting of the cord (appliance coupler) and the mating connector (appliance inlet) on the product. The load fitting shall be a three wire ANSI configuration.		
	Exception: The load fitting need not be an ANSI configuration provided it is wired as follows (the description applies when viewing the face of the connector on the product, with the center contact down):		

1. The right contact shall be connected to the grounded conductor (neutral) of the cord. 2. The center contact shall be connected to the grounding conductor of the cord. Permanently-Connected Products - In a permanently connected product (1) all exposed metal parts, and (2) all dead-metal parts within the enclosure, which are specified in the description as being connected (see "Bonding") to the grounding conductor, shall be conductively connected to: 1. The point of the enclosure at which the metal raceway of the power supply circuit will be connected, and 2. The equipment-grounding field-wiring terminal or lead. The equipment-grounding terminal or grounding lead shall be connected to the frame or enclosure by a positive means, such as by a bolted or screwed connection. The grounding connection shall reliably penetrate nonconductive coatings, such as paint or vitreous enamel. The grounding point shall be so located that it is unlikely that the grounding means will be removed during normal servicing. A wire-binding screw intended for the connection of an equipment-grounding conductor shall be identified by the protective earth symbol. The head shall be either hexagonal shaped or slotted, or both. A pressure wire connector intended for connection of an equipment grounding conductor shall be identified by the protective earth symbol " 🖃 ". The wire-binding screw or pressure wire connector shall be so located that it is unlikely to be removed during normal servicing of the unit. Grounding Terminal:- The grounding conductor shall be the first conductor terminated on a grounding terminal and secured by a separate nut. Other grounding conductors may be secured to this terminal if they are secured on top of the first nut by a second nut. AE1.1.7 Indicators - Indicator lights shall be clearly visible to the equipment operator. AE1.1.8 Internal Plastic Parts - For each type of plastic material the manufacturer shall review the Recognized Component Directory and Supplement or UL Online Certification Directory (http://www.ul.com/database) in order to insure that the plastic material in question meets all the material characteristics specified (i.e. flammability rating, Relative Thermal Index (RTI), and color) at the thickness specified. Alternatively, a copy of the Plastic Manufacturer's Component Recognition Report or Recognition Card may be used as a traceability pathway only if these materials were issued after the latest publication of the Recognized Component Directory. AE1.1.9 Internal Wiring - Conductors shall be routed away or protected from sharp edges and moving parts. Exception: LC that are reliably separated from PRI and SEC circuits need not be Recognized AWM. AE1.1.10 Lampholder Connections - All screw shells of lampholders shall be connected to the same conductor of the supply circuit. Loose Strands - Ends of stranded conductors shall have all strands contained to prevent contacting AE1.1.11 of, or reduction of spacing to, other live parts and dead metal. This can be accomplished by: A. Tinning B. Inserting properly into suitable wire connectors. C. Crimped connectors and/or eyelets with the crimp containing all strands Solder lugs. D. AE1.1.12 Markings - Required information shall be legibly marked on the product, in the manner and minimum height specified.

AE1.1.13 Multiple Voltage - Cord-connected multiple voltage products shall be provided with an attachment plug that is suitable for the voltage for which the product is set. AE1.1.14 Polarity - An appliance intended for permanent connection to the source of supply and having an identified terminal or lead; and an appliance employing a power supply cord with a polarized attachment plug cap (excluding 250 volt, 2-pole and 250 volt, 3-pole, 3-phase), utilizing the components indicated, shall have the components wired as follows: Lampholders and Receptacles - The screw shell or identified terminal or lead of a lampholder and the identified terminal or lead of a receptacle, shall be connected to the identified grounded conductor or terminal within the product. Switches (Single Pole) - Unless otherwise specified in the Procedure, a manual single pole switch, and an automatic control with a marked "off" position, shall not be connected to the identified grounded conductor. AE1.1.15 Power Supply Cords Non-Detachable Power Supply Cord – A non-detachable power supply cord as described in each Test Report must be provided and shipped with the unit in all cases. The power supply cord and any alternatives must be described in each Test Report. Each conductor of a nondetachable power supply cord shall have only one color, except the conductor identified by a combination of green and yellow. B. Detachable Power Supply Cord – The detachable power supply cord as described in each Test Report may or may not be shipped with the unit. Follow the guidelines in Table AE1 to apply the alternatives under each of the situations described in the notes to Table AE1. Table AE1 also includes alternative detachable power supply cords that may be shipped with units intended for use outside the USA. C. For Equipment Intended For Sale Outside of the USA and Canada Only - A marking must be provided adjacent to the appliance coupler or at an equivalent location either to inform the user on proper selection of the power supply cord or to see the instruction manual for this information. This marking may be in the form of a tag, nonpermanent label, or product insert that is provided on or packaged with the product so that the marking is visible at the time of installation. The marking (tag, label, or product insert) or instruction manual must contain complete instructions concerning selection of the proper power supply cord as noted in the individual section. D. For Equipment Included For Sale Outside of the USA and Canada - Verify that the detachable power supply cord is either: (1) Certified by one of the agencies listed in Table AE3 or (2) Comprised of cordage marked with an agency marking per Table AE3 or marked per

Table AE4. The fittings are to be marked with at least one of the agencies listed in

Table AE3

AE1.1.16 Printed Wiring Boards (PWBs) - PWBs shall show no burning, bubbling or other visible evidence of damage to their conductors or substrate material as a result of the fabrication process.

With respect to PWBs using Surface Mounted Technology (SMT), it is acceptable if the SMT assembly process is done at temperatures and times below the soldering limits. If the SMT assembly process is conducted on-site with temperatures/times in excess of soldering limits or if the process is conducted off-site and the temperatures/times cannot be verified, a visual inspection shall be conducted by the UL Representative.

The PWBs shall be inspected by the manufacturer for mechanical damage or evidence of exposure to excessive temperatures that may have occurred during the soldering operation. If any nonconforming features (defined below) are found after visual inspection, the manufacturer shall reject the lot (as defined in Table AA1). Otherwise, the use of PWBs may continue without any interruption.

The base material and the conductors shall be examined for nonconforming features as indicated below.

- A. Conductors, Terminal Pads, and Tabs
 - 1. Reduction in cross-section, such as scratches, nicks, pin holes, tearing.
 - 2. Loosening or lifting of printed wiring conductor, pad, or tab from the base material.
 - 3. Sections missing or damaged.
 - 4. Blistering
 - 5. Breaks
- B. Base Material
 - 1. Warping
 - 2. Cracking
 - 3. Charring, blistering, or other heat damage due to solder process
 - 4. Delamination

AE1.1.17 Protection of Wiring - All wire and wire insulation in the product shall be protected from damage. This is commonly achieved by securement, segregation, and routing to keep the wire away from parts or assemblies which can damage the wire or insulation. Internal wiring that might make contact with metal parts shall be protected from sharp metal edges. This can be accomplished by rounding or deburring the metal, using a Recognized Component bushing, or through other construction features described in the Test Report.

If the wiring is located where it may be in proximity to combustible material, it shall be protected by the method(s) described in the individual Test Report.

Conductors shall be examined for evidence of damage. Faulty practices which can cause damage to conductors and/or insulation include:

- A. Improper application of crimped connectors, including but not limited to, use of crimping tool and dies not recommended by the manufacturer of the connector.
- B. Improper insulation removal.
- Overheating of conductor insulation because of routing or contact with hot surfaces during or after installation.
- D. Use of wire in which the insulation has been cut, cracked, crushed, abraded, etc.

	Constructions which may cause damage to conductors and/or insulation include:
	A. Moving parts such as rotating or reciprocating cams, shafts, and the like, as well as removable or sliding covers, hinged doors.
	B. Sharp edges and corners (including screw threads, burrs, points, stamped metal edges).
	C. Heat sources (including lamps, heating elements, etc.).
	D. Assemblies that clamp or squeeze wire insulation, unless described in the Test Report.
AE1.1.18	Securement of Parts - Screws or other fastenings used to mount or support small, fragile, insulating parts shall not be tight enough to cause cracking or breaking of these parts. Uninsulated live parts, components which support live parts, and dead metal parts, that are normally intended to remain stationary, shall be prevented from rotating or shifting if movement will result in twisting or stress of internal wiring or connections, or spacings being reduced below that specified in the Test Report. Similar parts that are normally intended to move or rotate shall be prevented from excessive movement if such movement will result in twisting or stress of internal wiring or connections, or spacings being reduced below that specified in the Test Report.
	A switch, lampholder, attachment plug receptacle, motor attachment plug cap, or other components subject to handling by the user shall be mounted securely and prevented from rotating.
	Exception: Based on engineering considerations certain constructions of securely mounted push button or plunger type switches, and lampholders of the type in which the lamp cannot be replaced (such as a neon pilot or indicator light in which the lamp is sealed in a non-removable jewel) may be excluded from the above. These constructions are described in the Procedure. However, in no case will nonconforming spacings be allowed.
	Some means commonly used to prevent rotation are:
	A. Lock washer.
	B. Matched keying of the component and its mounting.
	C. Two or more fasteners (screws, rivets, pins, etc.).
	D. Strap, clip, or pin fitted into an adjacent part.
	E. Physical barrier (molded boss, side of enclosure, adjacent component, etc.) that bears against the component.
AE1.1.19	Sharpness of edges - All edges and corners of the frame, enclosure, guards, etc. exposed during normal use or maintenance or that may be contacted by internal wiring are smooth and well rounded.
AE1.1.20	Solder Connections - All solder connections shall be made mechanically secure before soldering. Some typical examples of mechanical securement are:
	A. Twisting wire around a solder post that has a change in dimension or restriction so unsoldered wire will not slip off post.
	B. Inserting wire through an opening, and bending over the free end.
AE1.1.21	Strain Relief - Strain Relief methods such as tying the supply cord into a knot or tying the ends of the cord with string shall not be used.
AE1.1.22	<u>Usage Markings</u> - There shall be no marking in the instruction manual, or on the carton or package that is, or could be construed to be, in conflict with or an extension of the use covered in the Test Report.

AE1.1.23	<u>Documentation</u> - Handling of hazardous substances and correct disposal procedure, field-installed devices, explanation of warning symbols.
	A. Documentation such as an instruction manual shall be provided with these products. No attachments or accessories are mentioned in the instruction manual unless specifically mentioned in a particular section.
	B. For products where attachments are specifically mentioned in a particular section, which are packaged and sold separately, the instruction manual packaged with the basic appliance identifies each separately available attachment by attachment name and model number. In addition, the manual packaged with the attachment indicates by name and model number the basic appliance with which it is to be used.
	 C. Documentation shall also include the complete electrical rating of the device as described in the electrical rating section of the Procedure; a description of all input/output connections; assembly, location and mounting requirements; supply connection and earthing requirements, ventilation requirements; identification of operating controls, instructions for cleaning, replacement of consumable materials, interconnecting accessories, indication of suitable accessories, instructions for use, technical specifications, name and address of manufacturer or supplier and as statement of range of environmental conditions as noted below. Indoor use or outdoor use;
	 Altitude up to 2000 m or above 2000 m if specified by the manufacturer Temperature 0 to 40°C, or outside this range if specified by the manufacturer. Maximum relative humidity 80 percent for temperatures up to 31°C decreasing linearly to
	 50 percent relative humidity at 40°C; Mains supply voltage fluctuations not to exceed ± 10 percent of the nominal voltage;
	 Transient overvoltages according to INSTALLATION CATEGORIES (OVERVOLTAGE CATEGORIES) I, II, III and IV. For mains supply the minimum and normal category is II; POLLUTION DEGREE 1 2, 3 or 4.

TABLE AE1 DETACHABLE POWER SUPPLY CORD REQUIREMENTS

Detachable Power Supply Cord		
Provided	Not Provided	
A or B (C and D) or (C and E)		

- A. The power supply cord should be as described in the Test Report.
- B. The detachable power supply cord is either:
 - 1. Certified by one of the agencies listed in Table AE3; or
 - 2. Comprised of cordage marked with an agency marking per Table AE3 or marked per Table AE4. The fittings are to be marked with at least one of the agencies listed in Table AE3.

Units provided with detachable power supply cords, which are certified by one of the agencies listed in Table AE3 or AE4, shall be considered to be intended for use outside of the USA.

- C. A marking must be provided adjacent to the appliance coupler or at an equivalent location either to inform the user on proper selection of the power supply cord or to see the instruction manual for this information. This marking may be in the form of a tag, nonpermanent label, or product insert that is provided on or packaged with the product so that the marking is visible at the time of installation.
- D. The marking (tag, label, or product insert) or instruction manual must contain complete instructions concerning selection of the power supply cord. It shall include either Option 1, 2, or 3 as follows:
 - 1. Reference to a power supply cord must be as a UL Listed detachable power supply cord consisting of the specific configuration of appliance coupler, the cord type, and the electrical rating of the power supply cord as described in each Test Report. Refer to Table AE2 for equivalent cord types.
 - 2. Reference to a power supply cord may be made to a Listed field installed accessory kit containing a suitable Listed power supply cord. Authorization for use of a Listed field installed accessory kit must be included in the individual Test Reports.
 - Reference to a power supply cord may be made to a cord that is not Listed and not intended for use in the United States or Canada. In this case, the manufacturer is to supply the UL Representative with information to verify that the referenced cord is certified or similarly appropriate for use in the destination country.
- E. The reference to the power supply cord (see Note C) shall include instruction for selection of the proper power supply cord as described in Note B above.

TABLE AE2 EQUIVALENT CORDS

Basis Cord Type	Equivalent Types
SP-2	SPE-2, SPT-2
SP-3	SPE-3, SPT-3
SV	SVE, SVO, SVOO, SVT, SVTO, SVTOO
SJ	SJE, SJO, SJOO, SJT, SJTO, SJTOO
S	SE, SO, SOO, ST, STO, STOO

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TABLE AE3 CERTIFICATION MARKINGS

Country	Cert. Agency	Mark	Country	Cert. Agency	Mark
Argentina	IRAM		Ireland	NSAI	
Australia	SAA	****	Italy	IMQ	(A)
Austria	OVE	©VĒ	Japan	JET, JQA	PS
Belgium	CEBEC	CEBEC	Netherlands	KEMA	KEMA
Canada	CSA	(F)	Norway	NEMKO	Ŋ
China	CCC	(W)	Spain	AEE	(9ee)
Denmark	DEMKO	D	Sweden	SEMKO	0
Finland	FEI	(F)	Switzerland	SEV	⊕
France	UTE	(X S 0)	United Kingdom	ASTA	ĀĪĀ
Germany	VDE	ØE .		BSI	\Diamond

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TABLE AE4 HAR FLEXIBLE CORDS APPROVAL ORGANIZATIONS AND CORDAGE HARMONIZATION MARKING METHODS

Approval Organization	Printed or Embossed Harmonization Marking (May be Located On Jacket or Insulation of Internal Wiring)		Alternative Marking Utilizing Black-Red Yellow Thread (Length of color Section, mm)		
Comite Electrotechnique Belge (CEBEC)	CEBEC	<har></har>	10	30	10
Verband Deutscher Elektrotechniker (VDE) e.V. Prufstelle	<vde></vde>	<har></har>	30	10	10
Union technique de l'Electricite (UTE)	UTE	<har></har>	30	10	30
Instituto Italiano del Marchio di Qualita (IMQ)	IEMMEQU	<har></har>	10	30	50
British Approvals Service for Electric Cables (BASEC)	BASEC	<har></har>	10	10	30
N.V. KEMA	KEMA-KEUR	<har></har>	10	30	30
SEMKO AB Svenska Elektriska materielkontrollanstalter	SEMKO	<har></har>	10	10	50
Österreichischer Verband fur Elektrotechnik (ÖVE)	<ÖVE>	<har></har>	30	10	50
Danmarks Elektriske Materialkontroll (DEMKO)	<demko></demko>	<har></har>	30	10	30
National Standards Authority of Ireland (NSAI)	<nsai></nsai>	<har></har>	30	30	50
Norges Elektriske Materiellkontroll (NEMKO)	NEMKO	<har></har>	10	10	70
Asociacion Electrotecnica Y Electronica Espanola (AEE)	<uned></uned>	<har></har>	30	10	70
Hellenic Organization for Standardization (ELOT)	ELOT	<har></har>	30	30	70
Instituto Portages da Qualidade (IPQ)	np	<har></har>	10	10	90
Schweizerischer Elektro Technischer Verein (SEV)	SEV	<har></har>	10	30	90
Elektriska Inspektoratet	SETI	<har></har>	10	30	90

PART AF UL CERTIFICATION MARK

Product Category: Power Supplies, Medical and Dental - Component
Product Category CCN: QQHM2 / QQHM8

UL Recognition Mark:

OL IXCO	ognition mark.			
AF1.1	Products Recognized under UL's Component Recognition Service are identified by marking elements			
7 4 1.1	consisting of:			
AF1.1.1	The Recognized Company's identification specified in this document.			
AF1.1.2	A catalog, model or other applicable product designation specified in the descriptive sections of this document.			
AF1.1.3	The UL Recognized Component Mark shown below.			
AF1.2	Only those components, which actually bear the Marking, should be considered as being covered under the Recognition Program. The UL Listing or Classification Mark is not authorized for use on or in connection with Recognized Components.			
Recogniz	ed Component Mark			
AF2.2	Recognized only to United States safety requirements:			
AF2.3	Recognized only to Canadian safety requirements:			
AF2.4	Recognized to both U.S. and Canadian safety requirements:			
AF2.5	Minimum size of the Recognized Component Mark is not specified as long as it is legible. Minimum height of the registered symbol ® shall be 3/64 inch but may be omitted if it is out of proportion to the Recognized Component Mark or not legible to the naked eye.			
AF2.6	The manufacturer may reproduce the Mark electronically. Any decision regarding the acceptability of the manufacturer's Mark reproduction will be made at the Reviewing Office.			

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Description

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012)
Certification Type: CCN:	Component Recognition QQHM2 / QQHM8
Product:	Component power supply
Model:	E146893-D1002-1-ULCB
Rating:	Input: 100-240Vac, 50/60Hz, 3.1A Max; Output: See Model Differences & Miscellaneous Enclosure for details
Applicant Name and Address:	XP POWER LLC 15641 Red Hill Ave., Ste. 100 Tustin, CA 97280, USA

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Bernadette Matsuoka Reviewed by: Melissa DeGuia

Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

A. Authorization - The Authorization page may include additional Factory Identification Code markings.

B. Generic Inspection Instructions -

- i. Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.
- ii. **Part AE** details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.
- iii. **Part AF** details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

Product Description

The product is a component AC-DC power supply for building-in, open frame type provided with a metal chassis, incorporating primary and SELV components.

Refer to the Report Modifications page for any modifications made to this report.

Model Differences

All models in the Model CHD250PSXX-YY Series are identical with exception to the Mains Transformer (T1) and minor secondary components that allow for different output voltage ratings. See below for Model Ratings at 50°C.

Output Ratings:

CHD250PS12: 10.1Vdc to 13.5Vdc, 20.8A Max., 250 W Max.

CHD250PS15: 13.6Vdc to 17Vdc, 16.7A Max. 250 W Max.

CHD250PS18: 17.1Vdc to 21Vdc, 13.9A Max, 250 W Max.

CHD250PS24: 21.1Vdc to 26Vdc, 10.4A Max. 250 W Max.

CHD250PS28: 26.1Vdc to 31Vdc, 8.93A Max. 250 W Max. CHD250PS33: 31.1Vdc to 33Vdc, 7.58A Max. 250 W Max.

CHD250PS36: 33.1Vdc to 42Vdc, 6.94A Max. 250 W Max.

CHD250PS48: 42.1Vdc to 54Vdc, 5.2A Max. 250 W Max.

See Miscellaneous enclosure Power Output Table for additional information regarding power output and the various configurations.

Suffix "SF" indicates single fuse provided in the line side of the primary.

Units provided with suffix "-C" provided with cover.

Units provided with suffix "-S" provided with screw terminal.

Units provided with suffix "-L" provided with input leads.

Units provided with suffix "-A" provided with 5V Stand-by output rated 5Vdc, 1A.

Additional Information

Marking label is representative of all models.

Licenses older than 3 years to be provided by the manufacturer upon request.

The required clearance values have been assessed for suitability up to 5000 m elevation

The testing was conducted at XP POWER LLC, 1241 E DYER RD, SUITE 150, SANTA ANA, CA 92705, USA. The client moved to 15641 Red Hill Ave., Ste. 100, Tustin, CA 97280 in December 2015 and has been re-audited as an SMT at this location.

Technical Considerations

- The product was investigated to the following additional standards: ANSI/AAMI ES60601-1:2005 (R2012), CSA C22.2 No. 60601-1:2014, EN 60601-1:2006/A1:2013/A12:2014
- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: Electromagnetic

Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)

- The following accessories were investigated for use with the product: None
- Scope of Power Supply evaluation defers the following clauses to the be determined as part of the end product: Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME Hazard), Clause 10 Radiation), Clause 14 (PEMS), Clause 16 (ME Systems)
- Scope of Power Supply evaluation excludes the following: Patient applied parts clauses: 4.6, 7.2.10, 8.3, 8.5.2, 8.5.5, 8.7.4.7-8.7.4.9, 8.9.1.15; Battery related clauses: 7.3.3, 15.4.3; Hand Control related clauses: 8.10.4; Oxygen related clauses: 11.2.2, Fluids related clauses: 11.6.2 − 11.6.4, Sterilization clause: 11.6.7, Biocompatibility Clause: 11.7 (ISO 10993), Motor related clauses: 13.2.13.3, 13.4, Heating Elements related clause: 13.2
- The product is evaluated only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: Ordinary
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The power supply was evaluated for use in 50°C ambient at Full Rated Output and see Enclosure Miscellaneous for additional ratings and various configurations

Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. When installed in an end-product, consideration must be given to the following:

- The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-Secondary: 292 Vrms, 478 Vpk, Primary-Earthed Dead Metal: 240 Vrms, 420 Vpk and for Models CHD250PSXXYY, where XX is 5 to 36, Secondary to Ground at 250Vrms, 354Vpk
- The power supply terminals and/or connectors are: Not investigated for field wiring
- The maximum investigated branch circuit rating is: 20A
- The investigated Pollution Degree is: 2
- Proper bonding to the end-product main protective earthing termination is: Required
- An investigation of the protective bonding terminals has: Not been conducted
- The following input terminals/connectors must be connected to the end-product supply neutral: Input Connector (CON1) N terminal.
- The following magnetic devices (e.g. transformers or inductor) are provided with an OBJY2 insulation system with the indicated rating greater than Class A (105°C): T1, T2, T3, T1-Standby (Class F, 155°C)
- The following end-product enclosures are required: Mechanical, Fire, Electrical
- Suitable disconnect device is to be provided in the end system
- Temperature, Leakage and Dielectric Strength testing shall be considered in the end system
- Printed Wiring Board rated 130°C.
- Heatsinks are floating and considered live. They should not be accessible in the end-product
- Heating test was not conducted on unit with input/output leads. If unit is provided with input and/or output leads, then temperature on leads must be measured and cannot exceed 105°C

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■ These components have been judged on the basis of the required spacings in the ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10 +A1:2012) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance), CAN/CSA-C22.2 No. 60601-1 (2008) + CSA C22.2 No. 60601-1:2014 (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance), which covers the end-use product for which the component was designed, IEC 60601-1, Edition 3.1, EN 60601-1:2006/A1:2013/A12:2014

- Clearance spacing evaluated for 5000 m altitude. Additional consideration maybe necessary in the end-use product
- Units provided with additional suffix "SF", provided with only one fuse. The need for additional fusing shall be determined as part of the end product
- The power supplies were evaluated as having 2 MOPP between primary-to-secondary for 292Vrms, 478Vpk, and 1 MOPP between primary-to-ground for 240Vac and 420Vpk. Models CHD250PSXX-YY where XX is 12 to 36 only and were also evaluated for 2 MOPP between secondary to ground for working voltage of 42Vdc and 1 MOPP for a working voltage of 250Vrms between secondary and earth for BF output considerations.
- Overcurrent releases of adequate breaking capacity must be employed in the end product
- The legibility and durability of Marking Test shall be conducted as part of the end product investigation.

Markings and instructions						
Clause Title	Marking or Instruction Details					
Company identification	Classified or Recognized company's name, Trade name, Trademark or File					
Model	Model number					
Serial number or lot or batch identifier	Serial number or lot or batch identifier					
Date of manufacture or use by date	Date of manufacture or use by date					
Supply Connection	Voltage range, ac/dc, phases if more than single phase					
Alternating current	\sim					
Direct current						
Direct current and alternating current	\sim					
Supply Frequency	Rated frequency range in hertz					
Power Input	Amps, VA, or Watts					
Output	Rated output voltage, power, frequency.					

Special Instructions to UL Representative

None

Production-Line Testing Requirements Test Exemptions - The following models are exempt from the indicated test Test **Exemption Specifics** Details **Grounding Continuity** The following models are exempt from CHD250PSXXYY series the indicated test: Dielectric Voltage Withstand The following models are exempt from the indicated test: Patient Circuit Dielectric The following models are exempt from CHD250PSXXYY series Voltage Withstand the indicated test: Solid-State Components The following solid-state components CHD250PSXXYY series may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test: Sample and Test Specifics for Follow-Up Tests at UL

The following tests shall be conducted in accordance with the Generic Inspection Instructions							
Plastic Enclosure or Part	Test	Sample(s)	Test Specifics				
None	NA	NA	NA				

TABLE: List of Critical Components

8.10 TA	ABLE: List of critical	components				Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²		& Certificates of nformity 1
Bottom Cover – for models with suffix "-C"	Interchangeable	Interchangeable	Metal, L-shaped, overall approx. 14 by 8.8 by 4.3 cm, min. 0.9 mm thick. See Enclosure 4-13 for details.			
Top Cover – for models with suffix "-C"	Interchangeable	Interchangeable	Metal, L-shaped, overall approx. 14 by 8.8by 4.3 cm, min. 0.6 mm thick. Provided with numerous ventilation openings. Secured to Bottom Cover by screws. See Enclosure 4-13 for details.			
Insulator Sheet – for models with suffix "-C"	Formex Inc	Formex GK-10BK	Cover and PWB. Rated min. V-1, 115°C, approx. 136 by 84 mm., min 0.25 mm thick.	UL 94 (QMFZ2 (E121855))	UL	
Printed Wiring Board	Interchangeable	Interchangeable	Overall approx. 12.6 by 7.5 cm, min. 2 mm thick. Rated min. V-1, min. 130°C	UL 796 (ZPMV2)	UL	
Primary Connector (CON1)	Molex	41791 Series (P/N 26-60- 4030)	2 pos. Rated min. 250 V, 7.0 A, 105°C	UL 1977 (ECBT2 (E29179)), CSAC22.2 NO 182.3-M1987	UL, CSA	
Terminal Block (CON1) - for Models provided with suffix "-S"	Dinkle Enterprise	EK381V Series (EK381V- 03P)	Rated min. 7A, 250V, min. 105°C. May be mounted on top or bottom of PWB.	UL 1054, CSA C22.2 No. 158 (XCFR2,8 (E102914))	UL, cUL,	τυν
Primary Connector (CON1) - Alternate	Interchangeable	Interchangeable	Not provided, when provided with Input Leads, (AVLV2), rated min. 18 AWG, min. 60°C, min. VW-1, soldered and mechanically secured through the PWB.	UL 758 (AVLV2)	UL	
Input Leads – Optional – For Models with –L suffix	Interchangeable	Interchangeable	When not provided with primary connector or terminal block (CON1), provided with Input Leads, (AVLV2), rated min. 18 AWG, min. 105°C, min. VW-1, soldered and mechanically secured through the PWB.	UL 758 (AVLV2)	UL	
Primary Connector (CON1) - Alternate	Interchangeable	Interchangeable	2 pos. Rated min. 250 V, 7.0 A, 105°C	UL 1977 (ECBT2), or UL 498 (RTRT2) or UL 746C (QMFZ2)	UL	

8.10 TA	ABLE: List of critical o	components			Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
Fuse (FS1, FS2)	Bel Fuse Inc.	5HFP Series	Rated 5A, min. 250V, min. 125°C. Mounted vertically with leads soldered through Main PWB. Provided with fuse carrier. (IR rating:1500 A at 250 V ac)	UL 248, CSA-C22.2 No. 248 (JDYX2, 8 (E20624)), IEC 60127-2	UL, cUL, VDE
Fuse (FS1, FS2) - Alternate	Littelfuse (Wickmann Werke)	216 Series (0216005XEP)	Rated 5A, min. 250V, min. 125°C, Time Lag (Non-operator replaceable). (IR rating: 1500A at 250Vac)	UL 248-14, CSAC22.2 No. 248.14, ((JDYX2,8(E10480)), IEC 60127-2	UL, cUL, SEMKO
Fuse holder (FS1,FS2)	El Dupont De Nemours & Co Inc	FR530	Overall approx. 29 by 17.75 by min. 0.8 mm thick. Rated V-0, min. 155°C	UL 94, (QMFZ2, 8) (E41938))	UL, cUL
Fuseholder (FS1,FS2) - Alternate	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Overall approx. 29 by 17.75 by min. 0.8 mm thick. Rated V-0, min. 155°C.	UL 94 (QMFZ2 (E95746))	UL
X-Capacitor (C1)	Xiamen Faratronic Co Ltd	MKP62 Series (Type C42)	Rated max. 0.47 uF, min. 250 V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2, 8 (E186600)), IEC60384- 14	UL, cUL, VDE
Capacitor (C5)	Xiamen Faratronic Co Ltd	MKP62 Series (Type C42)	Rated max. 1.5 uF, min. 250 V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2, 8 (E186600)), IEC60384- 14	UL, cUL, VDE
X-Capacitor (C6)	Xiamen Faratronic Co Ltd	MKP62 Series (Type C42)	Rated max. 2.2 uF, min. 250 V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2, 8 (E186600)), IEC60384- 14	UL, cUL, VDE
X-Capacitor (C6) - Alternate	Epcos/Siemens	B3292 Series	Rated max. 2.2 uF, min. 250 V, marked "X2"	UL 60384-14, CSA E60384-14:09 (FOWX2, 8 (E97863)), IEC60384- 14	UL, cUL, VDE
Film Capacitors (C29,C30) (PRI)	Interchangeable	Interchangeable	Rated max. 0.068 uF, min. 400 Vdc.		
Thermistor (TH1)	Epcos OHG	B57236 Series	NTC. Rated 20 Ohm, 25°C min, 2.8A min. steady state current (Not relied upon for safety).	UL 1434, IEC 60730- 1:1999+A1:2003, Annex J (XGPU2) (E69802))	UL, cUL
Thermistor (TH1) - Alternate	Interchangeable	Interchangeable	NTC. Rated 20 Ohm, 25°C min, 2.8A min. steady state current (Not relied upon for safety).	UL 1434 (XGPU2), IEC60730, EN60730-1	UL
X-Capacitor (C67,C68)	Vishay Capacitors Belgium N V	338 2 Series	Rated max. 0.1 uF, min. 250V, marked	UL 60384-14, CSA E60384-1:03, CSA	UL, cUL, FI

8.10	BLE: List of critical c	omponents			Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
			"X2".	E60384-14:09 ((FOWX2, 8), (E354331)), IEC 60384-14	
X-Capacitor (C67,C68) - Alternate	Kemet Electronics Corp (Evox-Rifa)	PHE840 Series	Rated max. 0.1uF, min. 250V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 ((FOWX2, 8) E73869)), IEC 60384- 14	UL, cUL, SEMKO
X-Capacitor (C67,C68) - Alternate	Kemet Electronics Italia SRL	R.46 Series	Rated max. 0.1 uF, min. 250V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2,8(E97797)), IEC60384-14	UL, cUL, VDE
X-Capacitor (C67,C68) - Alternate	Winday Electronic Ind Co Ltd	MPX Series	Rated max. 0.1 uF, min. 250V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2,8 (E302125)), IEC 60834-14	UL, cUL, VDE
Diodes (D1,D2,D23,D24)	Vishay	1N5627GP	Rated min. 800V, min. 3A. Soldered and secured to PWB using Diode Support. See diode support for details		
Diodes (D1,D2,D23,D24)	Interchangeable	Interchangeable	Rated min. 800V, min. 3A. Soldered and secured to PWB using Diode Support. See diode support for details		
Diode Support (D1,D2,D23,D24)	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Overall approx. 28 by 11 by min. 0.8 mm thick. Rated V-0, min. 155°C.	UL 94 (QMFZ2 (E95746))	UL
Diode Support (D1,D2,D23,D24) - Alternate	El Dupont De Nemours & Co Inc	FR530	Overall approx. 28 by 11 by min. 0.8 mm thick. Rated V-0, min. 155°C.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Y-Capacitor (C4,C45,C76)	Kemet Electronics OY (Evox-Rifa)	ERP610 Series	Rated max. 1000 pF, min. 250 V, marked "Y1".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2,8 (E356389)), IEC60384-14	UL, cUL, VDE
Y-Capacitor (C4,C45,C76) – Alternate	Murata Mfg Co Ltd	KX Series	Rated max. 1000 pF, min. 250 V, marked "Y1".	UL 60384-14, (FOWX2 (E37921)), CAN/CSA- E60384-14:09, IEC 60834-14	UL, CSA, VDE
Y-Capacitor (C4,C45,C76) – Alternate	Vishay Electronic GmbH	VY1 or VKP Series	Rated max. 1000 pF, min. 250 V, marked "Y1".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2, 8 (E183844)), IEC60384- 14	UL, cUL, VDE
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8.10	ABLE: List of critical c	omponents			Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
Capacitors (C14,C25,C112,C1 3) (PRI)	1		min. 63 V, min. 105°C. Provided with integral pressure relief.		
MOSFET (TR13) (PRI)	ST Microelectronics	STP10NK60Z	Rated min. 600 V, min. 10A, min. 150°C.		
MOSFET (TR13) (PRI) - Alternate	Interchangeable	Interchangeable	Rated min. 600 V, min. 10A, min. 150°C.		
Electrolytic Capacitor (C64) (PRI)	Interchangeable	Interchangeable	Rated max 150 uF, min. 450 V, min. 105°C. Provided with integral pressure relief		
Relay (RL1)	Xiamen Hongfa Electroacoustic Co	HF32F Series (HF32F-012- HSLQ)	Rated min. 12V, min. 10A (Non-isolating).	UL 60947-4-1A, CSA C22.2, No. 60947-4-1 (NLDX2, NLDX8 (E134517)), IEC61810	UL, cUL, TUV
MOSFET (TR2- TR5,TR27,TR28)	Fairchild Semiconductor	IRFB18N50KPBF	Rated min. 600 V, min. 13A, min. 150°C. TR2- TR5 secured to MOSFET Heat Sink by screw, nut and washer.		
MOSFET (TR2- TR5,TR27,TR28) - Alternate	Interchangeable	Interchangeable	Rated min. 600 V, min. 13A, min. 150°C. TR2- TR5 secured to MOSFET Heat Sink by screw, nut and washer.		
MOSFET Heatsink (TR2-TR5) (PRI)	Interchangeable	Interchangeable	Two provided. Aluminum, L-shaped, Overall approx. 33 by 31 by 6.8 by min. 1 mm thick. See Enclosure Diagrams (11) for details.		
Rectifier Diodes (D5,D6) (PRI)	Philips Semiconductors	BYV29 Series	Rated min. 9A, min. 500V. Secured to Rectifier Diode Heatsink using screw, washer, and nut.		
Rectifier Diodes (D5,D6) (PRI) - Alternate	Interchangeable	Interchangeable	Rated min. 9A, min. 500V. Secured to Rectifier Diode Heatsink using screw, washer, and nut.		
Rectifier Diode Heatsink (D5,D6) (PRI)	Interchangeable	Interchangeable	Aluminum, L-shaped, Overall approx. 33 by 31 by min. 1 mm thick. See enclosure Diagrams (12) for details.		
Rectifier Diode Heatsink (D5,D6) (PRI) – for Models with –A suffix	Interchangeable	Interchangeable	Aluminum, L-shaped, Overall approx. 33 by 31 by 18.6 by min. 1 mm thick. Provided with screw opening to secure 5V Stand-by		

8.10 TA	BLE: List of critical o	components				Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data PWB.	Standard No./ Edition ²		& Certificates of informity ¹
Inductor (L1)	XP Power LLC	Interchangeable (100xxxxx where x can be any number between 0 and 9). Construction of Inductor 10016094 represents entire series.	Toroidal. Copper Magnet Wire, (OBMW2), rated min. 130°C, wound on ferrite core. Overall approx. 25 mm dia. by 11 mm wide. See Enclosure Diagrams (01) for details.			
Inductor (L1) Base	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C. Provided between Inductor L1 and PWB. Overall approx. 25 by 11.6 by min. 1 mm thick.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL	
Inductor (L1) Base – Alternate	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C. Provided between Inductor L1 and PWB. Overall approx. 25 by 11.6 by min. 1 mm thick	UL 94 (QMFZ2 (E95746))	UL	
Inductor (L2)	XP Power LLC	Interchangeable (100xxxxx where x can be any number between 0 and 9). Construction of Inductor 10014243 represents entire series.	Toroidal. Copper Magnet Wire, (OBMW2), rated min. 130°C, wound on ferrite core. Overall approx. 29 mm dia. by 13 mm wide. See Enclosure Diagrams (02) for details.			
Inductor (L2) Base	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C. Provided between Inductor L1 and PWB. Overall approx. 25 by 15.4 by min. 1 mm thick	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL	
Inductor (L2) Base – Alternate	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C. Provided between Inductor L1 and PWB. Overall approx. 25 by 15.4 by min. 1 mm thick.	UL 94, UL 746C (QMFZ2 (E95746))	UL	
Inductors (PFC) (L3,L4)	XP Power LLC	Interchangeable (100xxxxxwhere x can be any number between 0 and 9. Construction of transformer 10013071 represents the entire series)	Open-type. Concentrically wound magnet wire, (OBWM2), rated min. 130°C. Overall approx. 41 by 26 by 20 mm. Core/Bobbin: See Transformer – Bobbin Material for details. See Enclosure Diagrams (03) for details.			
Inductors (PFC) (L3,L4) - Base	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C. Provided between Inductor L3,L4	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL	

8.10 T	ABLE: List of critical c	omponents			Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
			assembly and PWB. L-shaped, overall approx. 43 by 29.5 by min. 1 mm thick.		
Inductors (PFC) (L3,L4) – Base - Alternate	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C. Provided between Inductor L3,L4 assembly and PWB. L- shaped, overall approx. 43 by 29.5 by min. 1 mm thick.	UL 94, UL 746C (QMFZ2 (E95746))	UL, cUL
Inductor (L5)	XP Power LLC	Interchangeable (100xxxxx where x can be any number between 0 and 9. Construction of Inductor 10015645 represents the entire series)	Open-type. Concentrically wound magnet wire, (OBWM2), rated min. 130°C. Overall approx. 20.3 by 18 by 16.5 mm, min. 1 mm thick. Provided with Bobbin Base. See Inductor – Bobbin Base. See Enclosure Diagram (04) for details.	-	Evaluated as part of this investigation
Inductor (L5) – Bobbin	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C, approx. 14.65 by 8.25 by min. 0.5 mm thick.	QMFZ2 (E233198)	UL
Inductor (L5) — Bobbin - Alternate	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Inductor (L5) – Bobbin Base	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C, min. 1 mm thick. See Enclosure Diagram (04) for details.	UL 94, UL 746C (QMFZ2 (E95746))	UL
Inductor (L5) – Bobbin Base - Alternate	EI Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C, min. 1 mm thick. See Enclosure Diagram (04) for details.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Transformer (T1)	XP Power LLC	Interchangeable (100xxxxx where x can be any number between 0 and 9. Construction of Transformer 10013075 represents entire series.)	Open-type. Provided with a Class F insulation system, see Transformer— Insulation System for details. Overall approx. 33 by 27 by 26 mm. Bobbin: Overall approx.16.8 by 11.2 by 11. 2 mm, min. 1.0 mm thick, see Transformer — Bobbin Material for details. See Enclosures Diagrams (06) to (10) and (14) for details.	-	Evaluated as part of this investigation
Transformer (T1) - Insulation System	- XP Power LLC	Designated F	Rated 155°C	UL 1446 (OBJY3 (E139109S))	
Transformer – Bobbin	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C, min. 0.90 mm thick.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL

8.10	TABLE: List of critical o	components				Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²		& Certificates of onformity ¹
Transformer (T1) Bobbin - Alternat		Sumikon PM9820 & PM9630	Rated V-0, min. 155°C, min. 0.90 mm thick.	UI 94, UL 746C, QMFZ2 (E41429)	UL	
Transformer (T1) Bobbin - Alternat		R-4-230BL (Ryton)	Rated V-0, min. 155°C, min. 0.90 mm thick.	UL 94, UL 746C (QMFZ2 (E95746))	UL	
Transformer (T1) Core Washer	- Dupont	Nomex 410	Rated V-0, approx. 22.5 mm OD, 12.5 mm ID, min. 0.08 mm thick.	UL 746C, UL 94 (QMFZ2 (E34739))	UL	
Transformer (T1) Insulator Sheet	- Dupont	Nomex 410	Rated V-0, approx. 45 by 16 mm, min. 0.08 mm thick.	UL 746C, UL 94 (QMFZ2 (E34739))	UL	
Transformer (T1) Insulating Tape	- 3M Co	1350	Polyester film tape, min. 2.5 mils thick (Passed 2500 V ac dielectric)	UL 510 (OANZ2 (E17385))	UL	
Transformer (T1) Magnet Wire (Winding 2, 3, 6, and 7)	- Interchangeable	Interchangeable	Rated min. 155°C, 0.20 mm, MW80.	UL 1446 (OBMW2)	UL	
Transformer (T1) Triple Insulated Wire (Winding 1, 5 and 8)	Co., Ltd	TRW (F)	Reinforced Insulation. Rated 155°C, min. 600 Vpk (Passed 6k Vpk dielectric as part of component evaluation, also passed 10kV dielectric for twist pair test as part of Test Report E146893-A32 report); and suitable for reinforced insulation)	UL 2353 (OBJT2 (E211989))	UL	
Transformer (T1) Triple Insulated Wire (Winding 1, 5 and 8) - Alterna	Wire Co., Ltd	REFU-F	Reinforced Insulation, rated 155°C, min. 600 Vpk (15kV Dielectric test during component evaluation).	UL 2353 (OBJT2 (E222087))	UL	
Transformer (T1) Support	 Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co) 	R-4-230BL (Ryton)	Rated V-0, min. 155°C. Overall approx. 32.4 by 30 by 10.5 by min. .090 mm thick.	UL 94, UL 746C (QMFZ2 (E95746))	UL	
Transformer (T1) Support	– El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C. Overall approx. 32.4 by 30 by 10.5 by min. .090 mm thick.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL	
Transformer (T2, T3)	XP Power	Interchangeable (100xxxxx, where x can be any number between 0 and 9. Construction of Transformer 10013074 represents entire series)	Toroidal. 2 provided. Provided with a Class F insulation system, see Transformer— Insulation System for details. Secured to board using Transformer Base. See enclosure Diagrams	-	-	

8.10 T	ABLE: List of critical c	omponents			Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data (11) for details.	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
Transformer (T2, T3) – Base	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C. Overall approx. 13 by 12.5 by 18 by min. .090 mm thick.	UL 94, UL 746C (QMFZ2 (E95746))	UL
Transformer (T2, T3) – Base - Alternate	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C. Overall approx. 13 by 12.5 by 18 by min. .090 mm thick.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Transformer (T2, T3) – Insulation System	XP Power LLC	Designated F	Rated 155°C	UL 1446 OBJY3 (E139109S)	
Transformer (T2, T3) – Triple Insulated Wire (Winding 2)	Rubadue Wire Co. Inc.	T24A01T090-2	Reinforced Insulation. Rated 155°C,min. 1000 Vpk, 23 AWG (14kV Dielectric test during component evaluation).	UL 2353, (OBJT2 (E206198))	UL
Transformer (T2, T3) – Magnet Wire (Winding 1)	Interchangeable	Interchangeable	Rated 130°C, 0.30 mm, MW80.	UL 1446 (OBMW2)	UL
Optical Isolator (OPT1-OPT4)	Lite-On	LTV-816 Series	Double protection, isolation voltage min. 5000 V. DTI min 0.4mm	UL 1577, CSA Component Acceptance Service No. 5A (FPQU2, 8 (E113898)), IEC 607047-5-2,VDE 0884	UL, cUL, VDE
Optical Isolator (OPT1- OPT4) - Alternate	Renesas Electronics Corp (NEC)	PS2561L-1 Series	Double protection, isolation voltage min. 5000 V. DTI min 0.4mm	UL 1577 (FPQU2 (E72422)), CSA Std. 1, 60950-1,CA5A,E60065, IEC 60950-1, 60065 7th Ed. , IEC 607047-5-2, VDE 0884	UL, CSA, VDE
Optical Isolator (OPT1- OPT4) - Alternate	Vishay Infared Components Inc	SFH6156 Series (Systems H and J)	Double protection, isolation voltage 4420 V. DTI min 0.4mm	UL 1577, CSA Component Acceptance Service No. 5A (FPQU2 (E52744)), IEC 60747-5- 2, VDE0884E	UL, cUL, VDE
Y-Capacitor (C110)	Murata Mfg Co Ltd	KX Series	Rated max. 680 pF, min. 250 V, marked "Y1".	UL 60384-14 (FOWX2(E37921)), CSA Std. CAN/CSA-E60384- 14:09, IEC60384-14	UL, CSA, VDE
Y-Capacitor (C110) – Alternate	TDK-EPC Corp	CD Series	Rated max. 680 pF, min. 250 V, marked "Y1".	UL 60384-14, CSA E60384-1:03 (FOWX2,8) (E37861)), IEC60384-14,	UL, cUL, VDE
Y-Capacitor (C110) — Alternate	Vishay Electronic GmbH	VY1 or VKP Series	Rated max. 680 pF, min. 250 V, marked "Y1".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2, 8 (E183844)), IEC60384- 14	UL, cUL, VDE
Electrolytic Capacitors (SEC)	Interchangeable	Interchangeable	Rated min. 16 V, 105°C. Provided with integral pressure relief.	-	-

8.10 T	ABLE: List of critical	components				Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²		& Certificates of onformity ¹
Output Inductor (L9)	XP Power LLC	Interchangeable (100xxxxx, where x can be any number between 0 and 9. Construction of inductor 10013080 represents the entire series)	Magnet Wire, (OBWM2) min. 105°C, wound on ferrite core. Overall approx. 8 mm dia. by 15.2 mm high. See Enclosure Diagrams (05) for details.	-	Evaluate investiga	d as part of this ation
Ceramic Capacitor (C23)	Interchangeable	Interchangeable	Rated max. 0.1 uF, min. 50V.	-	-	
MOSFET (TR15, TR16) (SEC)	Interchangeable	Interchangeable	Rated min. 40V, max. 120 A. Secured to output connector (CON2) by screw and nut.		-	
Output Connector (CON2) (SEC)	Interchangeable	Interchangeable	U-shaped, tin plated brass, overall approx. 31.8 by 13 by 11.4 by min. 1 mm thick. Secured to PWB by solder.	-	-	
Output Connector (CON3) (SEC)	Interchangeable	Interchangeable	U-shaped, tin plated brass, overall approx. 15.3 by 13 by 4.5 by min. 1 mm thick. Secured to PWB by solder.		-	
Output Connector (CON3) (SEC) – for Models with suffix A	_	Interchangeable	U-shaped, tin plated brass, overall approx. 26.85 by 12.8 by 5 by min. 1 mm thick. Secured to PWB by solder.	-	-	
Output Connector (CON4) (SEC)	Japan Solderless Terminal Mfg Co Ltd (JST)	PHD Series (B10B- PHDSS(LF)(SN))	Rated min. 7A, min. 250V, min. 105°C.	UL 1977, (ECBT2 (E60389)), C22.2 No. 182.3	UL, CSA	
Electrolytic Capacitor (C36, C64, C113)	Interchangeable	Interchangeable	May be provided with optional heat-shrink tubing. See Insulating Tubing/Sleeving for details.		-	
5V Stand-by - Printed Wiring Board – for Model with suffix -A	Interchangeable	Interchangeable	Overall approx. 6.9 by 3.2 cm, min. 1 mm thick. Rated min. V-1, min. 130°C. Input side secured to Rectifier Diode Heatsink (D5,D6) (PRI) by screw and nut. Output side secured to Output Connector (CON3) (SEC) by solder.	U:L 796 (ZPMV2)	UL	
X-Capacitor (C9) - 5V Stand-by	Xiamen Faratronic Co Ltd	MKP62 Series (Type C42)	Rated max. 0.1 uF, min. 250 V, marked "X2".	UL 60384-14, CSA E60384-1:03, CSA E60384-14:09 (FOWX2, 8 (E186600)), IEC60384-	UL, cUL,	VDE

8.10 TA	BLE: List of critical c	omponents			Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²	Mark(s) & Certificates of conformity ¹
Transformer (T1) – 5V Stand-by	XP Power LLC	10015566	Open-type. Provided with a Class F insulation system, see Transformer – Insulation System for details. Overall approx. 17.8 by 16.4 by 11 mm See enclosure diagram (15) for details.	-	-
Transformer (T1) – Insulation System - 5V Stand-by	XP Power LLC	Class F	Rated 155°C	UL 1446 (OBJY3 (E139109SP)	
Transformer – Bobbin - 5V Stand- by	El Dupont De Nemours & Co Inc	FR530	Rated V-0, min. 155°C, min. 0.90 mm thick.	UL 94, UL 746C, (QMFZ2, 8 (E41938))	UL, cUL
Transformer (T1) - Bobbin – 5V Stand- by - Alternate	Sumitomo Bakelite Co Ltd	Sumikon PM9820 & PM9630	Rated V-0, min. 155°C, min. 0.90 mm thick.	UL 94, UL 746C (QMFZ2 (E41429))	UL
Transformer (T1) - Bobbin - 5V Stand- by -Alternate	Solvay Specialty Polymers USA L L C (formerly Chevron Phillips Chemical Co)	R-4-230BL (Ryton)	Rated V-0, min. 155°C, min. 0.90 mm thick.	UL 94, UL 746C (QMFZ2 (E95746))	UL
Transformer (T1) – Magnet Wire (Winding 1, 2) - 5V Stand-by	Interchangeable	Interchangeable	Rated min. 155°C, 0.20 mm, MW80.	UL 1446 (OBMW2)	UL
Transformer (T1) – Triple Insulated Wire (Winding 3) - 5V Stand-by	Great Leoflon Industrial Co., Ltd	TRW (F)	Reinforced Insulation. Rated 155°C, min. 600 Vpk(Passed 6k Vpk dielectric as part of component evaluation, also passed 10kV dielectric for twist pair test as part of Test Report E146893-A32 report); and suitable for reinforced insulation)	UL 2353 ((OBJT2 (E211989))	UL
Transformer (T1) – Triple Insulated Wire (Winding 3) - 5V Stand-by - Alternate	Kuo Kuang Electronic Wire Co., Ltd	REFU-F	Reinforced Insulation, rated 155°C, min. 600 Vpk (15kV Dielectric test during component evaluation).	UL 2353 (OBJT2 (E222087))	UL
Transformer (T1) – Outerwrap - 5V Stand-by	ЗМ Со	1350	Polyester film tape, 1mm thick. (Not relied upon for reinforced insulation)	UL 510 OANZ2 (E17385)	UL
Transformer (T1) – Outerwrap - 5V Stand-by - Alternate	Jingjiang Yahua Pressure Sensitive Glue Co Ltd	CT (CT286)	Rated 130°C. Tape Polyester Film, 1mm thick. (Not relied upon for reinforced insulation)	UL 510 (OANZ2 (E165111))	UL

8.10	TABLE: List of critical of	components				Pass
Component, Part No.	/ Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./ Edition ²		& Certificates of onformity ¹
Inductor (L1) - 5 Stand-by	XP Power	10015586	Copper Magnet Wire, (OBMW2), rated min. 130°C, wound on ferrite core. Overall approx. 2.6 mm dia. by 15 mm long. See Enclosure Diagrams (16) for details.	-	-	
Electrolytic Capacitors - 5V Stand-by	Interchangeable	Interchangeable	Rated min. 16 V, 105°C. Provided with integral pressure relief.	-	-	
Insulating Tubing/Sleeving	Interchangeable	Interchangeable	FEP, PTFE, PVC, TFE, neoprene, polyimide or marked VW-1; 130 °C, 240 V	UL 224 (UZFT2, YDPU2, YDRY2, YDTU2)	UL	
RTV	Interchangeable	Interchangeable	Rated min. V-2, min. 130°C	UL 746C (QMFZ2)	UL	

Supplementary information:

The (CB) Test Laboratory has verified the component information.

- 1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.
- 2) Identify the UL Product Category CCN(s)/File Number in brackets "()" if component is a UL Certified component and this report includes a UL Certification. This is useful for the UL Follow-Up Service Inspection associated with the UL Mark.

END OF APPENDIX C

Page D-1 of D-52 Report No.: E146893-D1002-1-ULCB

TEST RESULTS:

APPENDIX D: Test Datasheets Enclosures

The following tests have been performed as part of this report:

Standard	Clause No.	Test Name	Testing Location / Comments
IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)	4.11	Power Input	XP POWER LLC, 15641 Red Hill Ave., Ste. 100, Tustin, CA 97280, USA
IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)	5.7	Humidity Conditioning	XP POWER LLC, 15641 Red Hill Ave., Ste. 100, Tustin, CA 97280, USA
IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)	8.4.3	Voltage or Charge Limitation	XP POWER LLC, 15641 Red Hill Ave., Ste. 100, Tustin, CA 97280, USA
IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)	8.5.4	Working Voltage Measurements	XP POWER LLC, 15641 Red Hill Ave., Ste. 100, Tustin, CA 97280, USA
IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)	8.7	Leakage Current Tests	XP POWER LLC, 15641 Red Hill Ave., Ste. 100, Tustin, CA 97280, USA
IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)	8.7.4.5	Earth Leakage Current	XP POWER LLC, 15641 Red Hill Ave., Ste. 100, Tustin, CA 97280, USA
IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)	8.8.3	Dielectric Voltage Withstand	XP POWER LLC, 15641 Red Hill Ave., Ste. 100, Tustin, CA 97280, USA
IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)	8.8.4.1	Ball Pressure	XP POWER LLC, 15641 Red Hill Ave., Ste. 100, Tustin, CA 97280, USA
IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)	11	Temperature	XP POWER LLC, 15641 Red Hill Ave., Ste. 100, Tustin, CA 97280, USA
IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)	13	Abnormal Operation Testing	XP POWER LLC, 15641 Red Hill Ave., Ste. 100, Tustin, CA 97280, USA
IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)	15.5.1.2	Transformer Short Circuit	XP POWER LLC, 15641 Red Hill Ave., Ste. 100,

			Tustin, CA 97280, USA
IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)	15.5.1.3	Transformer Overload	XP POWER LLC, 15641 Red Hill Ave., Ste. 100, Tustin, CA 97280, USA

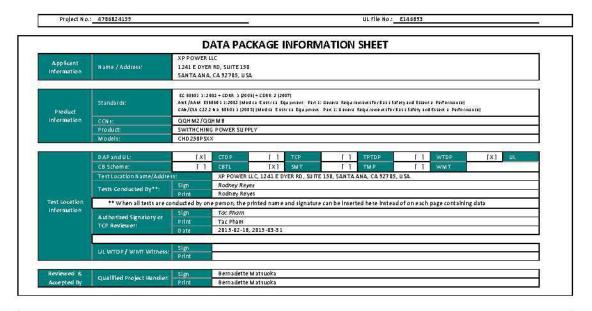
NOTE: If testing location is blank then the test was performed at the CB Testing Laboratory as specified at the beginning of this report.

The following datasheet enclosures are provided in this section of the report. If blank, no separate enclosures are attached.

Enclosures

Supplement ID	<u>Description</u>
Datasheets - (03)	: Datasheets

Datasheets - (03) Datasheets



Erwir on ment:	
Accommodations and Environmental conditions, including proper power source meet the requirements of the test standard or UL default criteria (ISO/IEC 17025 Clause 5.3.1, 5.3.2, 5.3.3)	t i
Equipment.	
Testing is being conducted within the test equipment calibration dates. (See Test instrument information Page and ISO/IEC 17025 5.6.2.2)	F-1
Citical Consumables:	46 -
Critical consumables are compliant with test standard requirements. (ISO/IEC 17025 Clause 4.6)	r i
Sample Identification:	
Identification of items to be tested has been made (e.g. model no., Serial No., etc.) (See Test Sample Identification page and ISO/IEC 17 025 Clause 5:8.2)	[]
Summary:	100 and
The testfacility was deemed to have the environment and capabilities necessary to perform the tests included in this data package.	1 1

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<u>Datasheets</u> - (03) <u>Datasheets</u>

Apl. [Yes/No]	Clause No.	Test Name	Test Notes
Yes	4.11	Power input	
Yes	5.7	Humidity Conditioning	
Yes	8.43	Voltage or Charge Limitation	
Yes	8.5.4	Working Voltage Measurements	
Yes	8.7	Leakage Current Tests	
Yes	8.7.4.5	Earth Leakage Current	
	8.7.4.7 b)	Patient Leakage Current, Mains on F-Type AP	
- 3	8.7.4.7 c)	Patient Leakage Current, Mains on I/O	
	8.7.4.7 d)	Patient Leakage Current, Mains on Non-PE Enclosure	
	8.7.4.7 h)	Total Patient Leakage Current	
	8.7.4.8	Patient Auxiliary Current	
Yes	8.8.3	Dielectric Voltage Withstand	
Yes	8.8.4.1	Ball Pressure	
Yes	11	Temperature	
Yes	13	Abnormal Operation Testing	
Yes	15.5.1.2	Transformer Short Circuit	
Yes	15.5.1.3	Transformer Overload	

Project No.: 4786824155 ULFIIe No.: E146853

TEST SAMPLE IDENTIFICATION

The table below is to provide correlation of sample numbers to specific product related information. Refer to this table when a test identifies a test sample by "Sample No." only.

Sample Number	Sample Card Number	Date Received	Storage Location	Manufacturer, Product Identification and Ratings
1	K14160036	2014-06-06	Safety Lab	XP Power LLC, CH D258 P512 Rated Input: 188-248Vac, 58/68Hz, 3.1A Rated Output: 18.1Vdcto 13.5Vdc 12V/28.8A, 5V/8.5A (258W)
2	K 14 180077	2014-06-06	Safety Lab	XP Power LLC, CH D250 P524 Rated Input: 100-240Vac, 50/60Hz, 3.1A Rated Output: 21.1 Vdcto 26Vdc 24V/10 AA 5V/0.5A (250W)
3	K 14190018	2014-06-06	Safety Lab	XP Power LLC, CH 0250 PS48 Rated Input: 100-240Vac, 50/6 0Hz, 3.1A Rated Output: 42.1Vdc to 54Vdc 48 V/5.2A, 5V/0.5A (250 W)
4	10013075	2014-06-06	Safety Lab	T1 Transformer
.5	09-65-2038	2014-06-06	Safety Lab	Conn 3 POS 8.15 6 CTR HEADER VERT LOCK Molex 26-60-4030
6		2014-06-06	Safety Lab	Transformer Bobbin - Ryton R-4 23 BBL, 1mm thick
7	10015334	2014-06-06	Safety Lab	T1 Standby Transformer
	Sampling Procedure (if used)			

Special instructions - Unless specified otherwise in the individual Methods, the tests shall be conducted under the following ambient conditions. Confirmation of these conditions shall be recorded at the time the test is conducted.

For 60601-1.3 rd edition tests use the 2 rd edition values unless the 3 rd edition fields are populated. This detail is based on the manufacturer's ACCOMPANYING DOCUMENTS and has been inserted by the project handler/reviewer.

Standard	Amblent Temperature, °C	Relative Humidity, %	Barometric Pressure, hPa or kPa
60065	25 +/- 10	Max 75	Not specified
6 0 6 0 1 - 1 2 n d E d	+10 to +40	30 to 75	700 to 1060 hPA
60 601-1 3rd Ed	+40 to +70	93	700 to 1060 hPA
60950	N ot specified	Not specified	Not specified
60950-1	Not specified	Not specified	Not specified

TEST INSTRUMENT REFERENCE LIST

The table below is to provide correlation of sample numbers to specific product related information. Refer to this table when a test identifies a test sample by "Sample No." only.

Istr. Code Intrument I.D.		Intrument I.D. Instrument Type Range Used OR ***		Make and Model **	Calibration Date	
att. code	microment.b.	Trati din encrype	Kange used OK	in also all dim odel	Last	Due
1	T452	AC Power Source	0-300 V ac	Associated Research Mode 1000	12/13/2013 _. 01/07/2015	12/13/201- 01/07/201
2	T442	AC Power Source	0-300 V ac	Caforn a nstruments Mode 5001 X	12/13/2013 09/18/2014	12/13/201 09/18/201
3	1322	Data Logger	Auto	Fuke Hydra Data Logger	12/13/2013 01/07/2015	12/13/201
4	T610	Osc ascape	Auto	Tektronx DOP3034 Phasphor Osc ascope	12/13/2013, 01/07/2015	12/13/201
5	T611	Current Camp	Auto	H ok 3284 C amp On AC/DC H Tester	12/13/2013, 01/07/2015	12/13/201 01/07/20
6	T436	Different a Probe	1/100	Leamy APOS1	12/13/2013; 01/07/2015	12/13/201
7	T444	Leakage Tester	0 3-10 M U	S mpson Made 228	12/26/2013, 08/21/2014	12/26/201 08/21/20
∃B	T451	Safety Ana yzer	Auto	Assoc Research Mode 8106 Omn a 6	12/13/2013 01/07/2015	12/13/201 01/07/20
5	T427	Baromet er	Auto	Davs Percepton	12/13/2013, 02/10/2015	12/13/201
10	T443	H gh Votage Probe	100 Mahm	Teltronx P80154	12/13/2013; 01/07/2015	12/13/201 01/07/20
11	1507	H gh Votage Probe	100 Mahm	Teltranx P80154	12/13/2013 01/07/2015	12/13/201 01/07/20
12	T424	Power Anayzer	Auto	Votech PM100 Power Anayzer	12/13/2013 01/07/2015	12/13/20 01/07/20
13	T453	Heat Chamber	Auto	Thermatron SM-16-3800	12/13/2013 01/07/2015	12/13/20
14	T441	Dgta Caper	0-150 mm/0-6 n	Da Caper	12/13/2013; 01/07/2015	12/13/20
15	T457	DC Power Suppy	0-500Vdd/0-5A	HP System Power Suppy 6035A	12/13/2013	12/13/20

16	T492	Ba Pressure Apparatus	20N	EO &O	12/26/2013 09/04/2014	12/26/2014, 09/04/2015
17	T600	Stop Watch	0-60 s ec	Se ko 8A20	12/13/2013, 01/07/2015	12/13/2014, 01/07/2016
18	T602	H pat Tester	10 KV ac/dc	K kus u TOS5101	12/13/2013, 01/07/2015	12/13/2014, 01/07/2016
19	T489	LCR Meter	A uto	HP LCR Precs on Meter 4284A	12/12/2013 01/23/2015	12/12/2014, 01/23/2016

Chamber setting(s) < was / were > monitored to ensure that the setting(s) < was / were > stable throughout the test time frame. Any deviations from the setting(s) are noted below.

Date	Test	Instrument Code	Time Period of deviation	Setting(s)
	6 -			10 - 01

** Information to be recorded when tests are conducted at a non-UL facility.

*** Refer to specific data she et for individual scale used.

11

The M. &TE used for tests have minimum required accuracy and range/functions, and were calibrated to assure these levels.

Test equipment information is recorded on UL's Laboratory Project Management (LPM)/Laboratory Equipment Management (LEM) database. (This statement may be selected only if databases are completed electronically at a UL facility)

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Tested By:	Rodney Reyes	Test Verdict:	77
Test Date(s):	2014-06-13-2014-10-22	Amb. Temp (°C):	25
Sample No.:	1, 2, 3	Amb. Humid (%):	41
Instrument Code/Range:	1, 5, 9	Amb. Pressure (mBar):	1019
Project No.:	4786824159	ULFile Na.;	E146893

INPUT TEST ((IEC 60601-1, 3rd Edition, Clause: 4.11)

METHOD

The unit was operated under the conditions specified in Table 4.11 until the input reached a stable value. The current or power input was measured and recorded for each operating condition.

The input current was measured with a true rms meter. The ratings of the device were compared to the measured values.

[N/A] Power factor was measured as indicated below (to facilitate the determination of whether the product is eligible to have a wattage rating instead of a VA or amperage rating).

PARAMETERS:

Device Voltage Ratings	Device Frequency Ratings	Device Current/Power Ratings	Current/Pawer Type
100-240 VAC	50/60 Hz	3.1	Α.

RESULTS:

The measurements and calculations are identified below.

Operating Conditions / Ratings	Set Voltage (V)	Freq. (Hz)	Current (A)	Measured Power (W)	Power (VA / W)	Calculated Power Factor (cosp)	Remarks	Verdict
CHD250P\$12: 12V/20.8A, 5V/1A	90	60	3.0	272.0	270 VA / 272 W	1,007	Ā	459
CHD250PS12: 12V/20.8A, 5V/1A	100	50	2.7	271.0	270 VA / 271 W	1.004	N	Pass
CHD250PS12: 12V/20.8A, 5V/1A	240	60	1.2	266.0	285.6 VA / 266 W	0.931	38	Pass
CHD250PS12: 12V/20.8A, 5V/1A	264	50	1.2	266.0	316.8 VA / 266 W	0.840		28
CHD250PS12: 12V/20.8A, 5V/1A	90	50	3.0	272.0	270 VA / 272 W	1.007		293
CHD250PS12: 12V/20.8A, 5V/1A	100	50	2.7	271.0	272 VA / 271 W	0.996	=	Pass
CHD250PS12: 12V/20.8A, 5V/1A	240	50	1.2	265.0	283.2 VA / 265 W	0.936	-	Pass
CHD250PS12: 12V/20.8A, SV/1A	264	50	1.3	267.0	343.2 VA / 267 W	0.778		8
CHD250PS24: 24V/10.4A, 5V/1A	90	60	3.01	270.0	270.9 VA / 270 W	0.997	-	
CHD250PS24; 24V/10.4A, SV/1A	100	60	2.7	269.0	270 VA / 269 W	0.996	-	Pass
CHD250PS24; 24V/10.4A, 5V/1A	240	60	1.17	264.0	280.8 VA / 264 W	0,940	25	Pass
CHD250PS24: 24V/10.4A, 5V/1A	264	60	1.21	264.0	319.44 VA / 264 W	0.826	<u> </u>	751
CHD250PS24: 24V/10.4A, 5V/1A	90	50	3.01	270.0	270.9 VA / 270 W	0.997	27	533
CHD250PS24: 24V/10.4A, 5V/1A	100	50	2.69	269.0	269 VA / 269 W	1,000	ā	Pass
CHD250PS24: 24V/10.4A, 5V/1A	240	50	1.17	264.0	280.8 VA / 264 W	0.940	zi.	Pass
CHD250PS24: 24V/10.4A, 5V/1A	264	50	1.27	265.0	335.28 VA / 265 W	0.790	2	
CHD250PS48:48V/5.2A, SV/1A	90	60	3.0	270.0	270 VA / 270 W	1.000	-:	
CHD250P\$48:48V/5.2A, 5V/1A	100	60	2.7	269.0	271 VA / 269 W	0.993	:	Pass
CHD250PS48:48V/5.2A, 5V/1A	240	60	1.2	264.0	283.2 VA / 264 W	0.932		Pass
CHD250P\$48:48V/5.2A, 5V/1A	264	60	1.2	265.0	316.8 VA / 265 W	0.836	==	120
CHD250PS48:48V/5.2A, 5V/1A	90	50	3.0	271.0	270 VA / 271 W	1,004		88

CHD250PS48:48V/5.2A, 5V/1A	100	50	3.0	271.0	302 VA / 271 W	0.897		Pass
CHD250PS48:48V/5.2A, 5V/1A	240	50	1.2	265.0	283.2 VA / 265 W	0,936	2	Pass
CHD250PS48:48V/5.2A, 5V/1A	264	50	1.3	266.0	343.2 VA / 266 W	0.775	28	***

SUPPLEMENTARY INFORMATION:

Data above may include voltage measurement takes outside the device ratings for reference purposes. These will be indicated by an N/A Verdict because they are not required to meet the below criteria per this clause.

CRITERIA.

The steady-state measured input of the device shall not exceed the marked rating by more than 10%.

NOTES TO/FROM THE LAB:

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Tested By:	Radney Reyes	Test Verdict:	왕
Test Date(s):	2014-07-02-2014-07-07	Amb. Temp (°C):	Not Required
Sample No.:	1.	Amb. Humid (%):	Not Required
Instrument Code/Range:	1, 8, 9, 13, 18	Amb. Pressure (mBar):	Nat Required
Praject Na.:	4786824159	ULFile No.;	E146893

HUMIDITY PRECONDITIONING TREATMENT: (IEC 60601-1, 3rd Edition, Clause 5.7)

METHOD:

ME EQUIPMENT or its parts was set up completely (or where necessary partially). Covers used during transport and storage were detached. This treatment was applied only to those ME EQUIPMENT parts which were influenced by the climatic conditions that were simulated by the test. Parts that can be detached without the use of a TOOL were detached but are treated simultaneously with the major part. ACCESS COVERS, as specified in the Result's table, that can be opened or detached without the use of a TOOL were opened and detached.

A humidity chamber having relative humidity of 93 +/- 3percent was set to any convenient Temperature T between 20 and 32°C. The unit, before being placed in the chamber was brought to a temperature between T + 4°C and kept at this temperature a minimum of 4 h. Then the sample was placed in the humidity chamber and kept there for the time specified in Table 5.7 (minimum 48 h). During this time the temperature of the air in the chamber was maintained at T±2°C.

Immediately after the treatment and while still in the chamber, the sample was subjected to Dielectric Voltage Withstand Test. Then the unit was removed from the chamber, placed in normal environment (temperature approximately T, humidity 45-65%) and at operating temperature, the Leakage Current Test was performed.

- [X] Risk Management Process determined MEEQUIPMENT can be exposed to high humidity for extended periods, please modify the above test procedure as indicated as follows: 120 hours @ 40°C, 93% Humidity
- [X] Immediately following the humidity preconditioning treatment, the ME equipment was subjected to a repeat of the dielectric with stand and leakage current tests.

RESULTS:

Test Type and Condition			Pre-chamber			Ch am ber					Post-chamber (Info only)			
	Part Under Test	Remarks	T (°C)	Start Time	Stap Time	Humidity (%)	T(°C)	Start Date & Time	Stop Date & Time	Duration (hrs)	Humidity (%)	T (°C)	Start Time	Stop Time
Humidity test: 120 hrs @ 40°C, 93% Humidity	CHD250P\$12	Passed Hipot and Leakage	32	7:00 AM	11:00 AM	93	40	2014-07- 02 / 11:00AM	2014-07- 07 / 11:00AM	120	45	25	11:05 PM	12:05 PM

SUPPLEMENTARY INFORMATION:

Refer and record Leakage Current and Dielectric Withstand in Tables 8.7 and 8.8.3 respectively for results.

In general all equipment must be kept in the humidity chamber for 48h unless the risk management process suggests a longer period (see clause 5.7 for details).

CRITERIA

The device shall pass the required Leakage and Dielectric Strength tests.

NOTES TO/FROM THE LAB:

None

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Tested Βγ:	Radney Reyes	Test Verdict:	PASS
Test Date(s):	2014-07-02	Amb. Temp (°C):	25
Sample No.:	1.	Amb. Humid (%):	41
Instrument Code/Range:	2, 4, 9, 10, 11	Amb. Pressure (mBar):	1019
Project No.:	4786824159	UL File Na.;	E146893

VOLTAGE OR CHARGE LIMITATION: (IEC 60601-1, 3rd Edition, Clause 8.4.3)

METHOD

The equipment was operated for 1 min at RATED voltage or at the upper limit of the RATED voltage.

Then the sample was either disconnected from the power source by means of the plug, in which case the test was performed as many times as necessary, up to 10 times, to allow the worst case to be measured or a triggering circuit was used (as specifically noted in the table below) to ensure that disconnection occurred at the peak of the supply writing waveform.

On a second after disconnection the voltage between points specified below was measured and recorded in Table 8.4.3a. A storage oscilloscope with probes having an impedance of at least 100 MQ or similar high impedance instrument which does not affect the measurement was used for this measurement.

If any value exceeded 60 V, then the stored charge between the points indicated was measured or calculated by any convenient method and added to Table 8.4.3b.

Calculate Residual Stored Charge (μ C) = [Capacitanæ Value (μ F)] X [Measured Residual Voltage (V)]

PARAMETERS:

Input Voltage (Vac)	In put Frequency (Hz)
240	60

RESULTS:

							M	aximum a	llow ab le v	oltage (V):	50	
	Measurements [V]											
Voltage Measured Between:	1	2		4	5	6	7	8	9	10	Remarks	Verdict
Line pins 1 and 2	0	0	0	0	0	. 0	0	0	0	0	Within limits	Pass
Pin 1 and earth pin	0	. 0	D	D	0	0	2	0	0	0	Within limits	Pass
Pin 2 and earth pin	0	D	0	0	6	0	0	0	4	0	Within limits	Pass
Line pin 1 and enclosure	4	2	0	0	4	2	0	0	0	0	With in limits	Pass
Line pin 2 and enclosure	0	0	0	0	0	0	0	0	0	0	Within limits	Pass

[] Voltage exceeds 60 V, Stored Charge was measured:

			Maximur	n allowabl	e stored c	harge whe	n measure	ed voltage	exceeded	б0 ∨ (μС):	Z	15	
	Measurements [μC												
Charge Measured Between:	1	2	3	4	5	5	7	8	9	10	Ren	arks	Verdict
Line pins 1 and 2	å -c	ê -						i i		- 1	7/5	1.5	7
Pin 1 and earth pin	. 2:	. 2:	. 8	8	. 8	. 8	- 8		. 12	2	7/2	7/2	7
Pin 2 and earth pin	. 8	S S	- 12	12	- 15	. 8	- 10	122	12	12	32	82	7
Line pin 1 and enclosure	23	29	197	24	- 81	19	- 19	- 12	12	12	- 22	1/2	?
Line pin 2 and enclosure	23	25	27	24	2	144	12	32	12	12	22	- 22	?

[] Voltage exceeds 60 V, Stored Charge was calculated:

			Maxim	um allowa	ble stare	d charge w	hen residu	al voltage	exceeded (50 V (μC)	4	45		
Location	Measure	d residual	Time at	ter discon	nection	Capacita	nce value	Calc, stor	ed charge		Remarks		Verdict	
Line pins 1 and 2	7.5	5.	- 5		- 15			- 15	15	:5	55	5.5	7	
Pin 1 and earth pin	9 52			5 5		-	-	-		25	- 1	1.5	7	
Pin 2 and earth pin		- 2:								- 125	A 75 -	1.5	7	
Line pin 1 and enclosure		2.	. 8	. 8	. 8	. 8	- 3	2		12	72	1/2	7	
Line nin 2 and enclosure	22	2.	- 8	8	- 8	- 8	-8	185	125	100	1/2	1/2	7	

SUPPLEMENTARY INFORMATION:

The values were calculated using the capacitance and voltage measurements in the formula Q =C*V where C is the capacitance, V is the voltage and the units of Q are Coulombs (in table 8.4.3b the values are to be expressed in micro Coulombs).

CRITERIA:

The highest voltage measurement shall not exceed 60 V.

The charge measurements shall not exceed 45 μC.

The residual stored charge shall not exceed 45 µC.

NOTES TO/FROM THE LAB:

None

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Tested By:	Rodney Reyes	Test Verdict:	\$§
Test Date(s):	2014-07-02	Amb. Temp (°C):	25
Sample No.:	1, 2, 3	Amb. Humid (%):	42
Instrument Code/Range:	1, 4, 9, 10, 11	Amb. Pressure (mBar):	1019
Project Na.:	4786824159	UL File Na.:	E146893

WORKING VOLTAGE MEASUREMENT: (IEC 60601-1, 3rd Edition, Clause 8.5.4)

METHOD

The unit was operated at RATED voltage or at the upper limit of the RATED voltage. The voltage at the measurement points was recorded in the table below. r.m.s measurement was made for non-d.c. voltage and peak-to-peak ripple measurement was made for d.c. voltage.

PARAMETERS:

Input Voltage (Vac)	In put Frequency (H				
240	60				

RESULTS:

Location From/ To (Insulation Diagram Designation)	Measured Voltage (Vrms)	ge Measured Voltage Measured Peak-to- (Vpk or Vdc) peak ripple (V) (mm)			Required Clearance (mm)	Meas. Creep. (mm)	Creep. Clear. Remarks (mm) (mm)			
A: Line to Neutral	242	344	-	4			6	12V/20.8A, 5V/1A		
8: Line to Ground	242	344	3		- 6	. 8	2	12V/20.8A, 5V/1A		
C; Prito Secondary	292	478	8	8	8	. 3	5	12V/20.8A, 5V/1A		
D: Secand, to Gnd	2):	12 Vdc	0.180	8	8		ā	12V/20.8A, 5V/1A		
T1 Pin 1 ta 6	226	268	a a		-	9	5	12V/20.8A, 5V/1A		
T1 Pin 9 ta 11	12	15		#	æ	9	5	12V/20.8A, 5V/1A		
T1 Pin 10 ta 12	12	15				i ii	-	12V/20.8A, 5V/1A		
T1 Pin 13 ta 15	13	14	¥	12	12	į į	2	12V/20.8A, 5V/1A		
T1 Pin 14 to 16	13	15	3		2	5	2	12V/20.8A, 5V/1A		
T1 Pin 1 ta 9	1.86	390			8		2	12V/20.8A, 5V/1A		
T1 Pin 1 ta 10	186	392				5 5	-	12V/20.8A, 5V/1A		
T1 Pin 1 ta 11	188	392	2		98	2	3	12V/20.8A, 5V/1A		
T1 Pin 1 ta 12	186	392	25				5	12V/20.8A, 5V/1A		
T1 Pin 1 ta 13	186	392	*	*	*		4	12V/20.8A, 5V/1A		
T1 Pin 1 ta 14	186	392	*	*	*	1	ú	12V/20.8A, 5V/1A		
T1 Pin 1 to 15	188	391	*	14	44	2		12V/20.8A, 5V/1A		
T1 Pin 1 ta 16	186	396	2	, a	2			12V/20.8A, 5V/1A		
T1 Pin 6 ta 9	289	475	3	8	8			12V/20.8A, 5V/1A		
T1 Pin 6 to 10	171	453	-				12V/20.8A, 5V/1A			
T1 Pin 6 ta 11	171	396	2		8			12V/20.8A, 5V/1A		
T1 Pin 6 to 12	280	453	5.		8 8 8		12V/20.8A, 5V/1A			
T1 Pin 6 ta 13	273	453	*	*	*	ж н		12V/20.8A, 5V/1A		
T1 Pin 6 ta14	282	466	*		*) is	-	12V/20.8A, 5V/1A		
T1 Pin 6 to 15	264	441	. 4	12	- 4	3	2	12V/20.8A, 5V/1A		
T1 Pin 6 ta 16	292	478	<u> </u>		2	2	2	12V/20.8A, 5V/1A		
T2 Pin 1 to 2	1	9	2	. 3	. 8	, 1	1	12V/20.8A, 5V/1A		
T2 Pin 3 ta 4	2	11	5	8		9	5	12V/20.8A, 5V/1A		
T2 Pin 1 to 3	168	260	5				5	12V/20.8A, 5V/1A		
T2 Pin 1 to 4	167	258	8		*		-	12V/20.8A, 5V/1A		
T2 Pin 2 to 3	94	258	98		*	_	=	12V/20.8A, 5V/1A		
T2 Pin 2 to 4	167	257		44	39		2	12V/20.8A, 5V/1A		
T3 Pin 1 ta 2	1	9		ž.		-	2	12V/20.8A, 5V/1A		
T3 Pin 3 to 4	0.74	- 4					2	12V/20.8A, 5V/1A		
T3 Pin 1 to 3	68	323	-			_	-	12V/20.8A, 5V/1A		
T3 Pin 1 ta 4	70	324				_	5	12V/20.8A, 5V/1A		
T3 Pin 2 to 3	131	323			.00		5	12V/20.8A, 5V/1A		
T3 Pin 2 to 4	119	323		*	*		-	12V/20.8A, 5V/1A		
T1-A Pin 1 ta 2-58	25	78	*	*	*	is	-	12V/20.8A, 5V/1A		
T1-8 Pin 3 to 4-58	100	468	¥	¥	16	9	2	12V/20.8A, 5V/1A		
T1-C Pin 1 to 2-58	- 6	33	25	15	8	i i	2	12V/20.8A, 5V/1A		

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gr gr		Sr	4			2	25
T1-A Pin 1 to 1-58	165	284	2	8	¥	32	12V/20.8A, 5V/1A
T1-A Pin 1 ta 2-58	167	284	25	ä	ä	22	12V/20.8A, 5V/1A
T1 Pin 2 ta 1-58	158	272	3	ē	ě	: :22	12V/20.8A, 5V/1A
T1-A Pin 2 to 2-SB	181	312	8	8	8	100 100 100	12V/20.8A, 5V/1A
T1-A Pin 3 to 1-\$8	172	324				Marie Title	12V/20.8A, 5V/1A
T1-A Pin 3 to 2-S8	175	328	9	2		. <u>.</u>	12V/20.8A, 5V/1A
T1-A Pin 4 to 1-SB	180	308				\$ 55	12V/20.8A, 5V/1A
T1-A Pin 4 to 2-SB	128	224	*				127/20.84, 57/14
***************************************	***************************************	77 0.000					
OPT1 Pin 1 to 2	162	283			.0	15	12V/20.8A, 5V/1A
OPTL Pin 3 to 4	169	292	8	#	*	(H	12V/20.8A, 5V/1A
OPT2 Pin 1 to 2	165	288	*	. *	*	lie .	12V/20.8A, 5V/1A
OPT2 Pin 3 ta 4	143	252	. 3	ž .	. 8	. 8	12V/20.8A, 5V/1A
OPT3 Pin 1 to 2	130	240				22	12V/20.8A, 5V/1A
OPT3 Pin 3 to 4	146	268				= ==	12V/20.8A, 5V/1A
OPT4 Pin 1 to 2	147	263				- 5	12V/20.8A, 5V/1A
OPT4 Pin 3 to 4	168	284		#			12V/20.8A, 5V/1A
			8	. *	*	(H	
A: Line to Neutral	242	344	*		*	l#	24V/10.4, 5V/1A
B: Line to Ground	242	344	34		*	122	24V/10.4, 5V/1A
D: Second, to Gnd	25	24 Vdc	33		20	, S	24V/10.4, 5V/1A
T1 Pin 1 to 6	218	252	. 3			25	24V/10.4, 5V/1A
T1 Pin 3 ta 7	28	33					24V/10.4, 5V/1A
T1 Pin 9 ta 11	24	28				85.	24V/10.4, 5V/1A
T1 Pin 10 to 12	24	28					24V/10.4, 5V/1A
T1 Pin 13 to 15	12	15	*		*) (H	24V/10.4, 5V/1A
T1 Pin 14 to 16	12	15	8:	*	*	læ.	24V/10.4, 5V/1A
T1 Pin 1 to 9	164	380	2	· ·	12	122	24V/10.4, 5V/1A
T1 Pin 1 to 10	150	336	2	E .	E .	12	24V/10.4, 5V/1A
T1 Pin 1 to 11	156	354		8	8	, E	24V/10.4, 5V/1A
T1 Pin 1 to 12	156	354		_	_	1.5	24V/10.4, 5V/1A
T1 Pin 1 ta 13	149	340	-			SE.	24V/10.4, 5V/1A
T1 Pin 1 to 14	150	336			-		24V/10.4, 5V/1A
T1 Pin 1 ta 15	151	352			*	lei	24V/10.4, 5V/1A
T1 Pin 1 to 16	161	368	2		19	12	24V/10.4, 5V/1A
T1 Pin 6 ta 9	126	244		E E		72	24V/10.4, 5V/1A
T1 Pin 6 to 10	127	252	8	8	8	0.05 0.05	24V/10.4, 5V/1A
T1 Pin 6 to 11	126	244		-		-	24V/10.4, 5V/1A
T1 Pin 6 to 12	126	244					24V/10.4, 5V/1A
T1 Pin 6 to 13	127	252				~	24V/10.4, 5V/1A
T1 Pin 6 ta 14	126	244					24V/10.4, 5V/1A
T1 Pin 6 to 15			8	#		(it	
Committee of the second	126	252	*			1/4	24V/10.4, 5V/1A
T1 Pin 6 to 16	126	244	÷.	*	- 4	32	24V/10.4, 5V/1A
T2 Pin 1 ta 2	1	9	2	, E	2	- F2	24V/10.4, 5V/1A
T2 Pin 3 to 4	2	11	20	8	8	125	24V/10.4, 5V/1A
T2 Pin 1 to 3	168	250	3			= ==	24V/10.4, 5V/1A
T2 Pin 1 to 4	167	258					24V/10.4, 5V/1A
T2 Pin 2 to 3	94	258				- 15	24V/10.4, 5V/1A
T2 Pin 2 to 4	167	257	8	*	*	æ	24V/10.4, 5V/1A
T3 Pin 1 to 2	81:	9	*		*	l#	24V/10.4, 5V/1A
T3 Pin 3 to 4	0.74	4	¥*	¥	- 10	22	24V/10.4, 5V/1A
T3 Pin 1 ta 3	68	323	2		ě.	. 2	24V/10.4, 5V/1A
T3 Pin 1 to 4	70	324				. Ha	24V/10.4, 5V/1A
T3 Pin 2 ta 3	131	323	3	5		5	24V/10.4, 5V/1A
T3 Pin 2 to 4	119	323	2	æ	.00	5	24V/10.4, 5V/1A
T1-A Pin 1 to 2-58	25	78	8	*	*	(H	24V/10.4, 5V/1A
T1-8 Pin 3 ta 4-58	100	468	*	*		(H	24V/10.4, 5V/1A
T1-C Pin 1 to 2-SB	б	33	2	- 4	**	32	24V/10.4, 5V/1A
				-			T 1/2 1/2 1/2 1/2 1/2 1/2 1/2 1/2 1/2 1/2

		ř	ř .	¥		T	
T1-A Pin 1 to 1-SB	165	284		*	*	. 12	24V/10.4, 5V/1A
T1-A Pin 1 to 2-SB	167	284	. 3		8	. 2	24V/10.4, 5V/1A
T1 Pin 2 to 1-58	158	272	3	, 8	8	E 15	24V/10.4, 5V/1A
T1-A Pin 2 to 2-SB	181	312	. 3				24V/10.4, 5V/1A
T1-A Pin 3 to 1-SB	172	324	2		- 5		24V/10.4, 5V/1A
T1-A Pin 3 to 2-58	175	328	8		*	114	24V/10.4, 5V/1A
T1-A Pin 4 to 1-S8	180	308	*		*	Æ	24V/10,4, 5V/1A
T1-A Pin 4 to 2-S8	128	224	4	- 4	4	12	24V/10.4, 5V/1A
OPT1 Pin 1 to 2	162	283	. 2	. 4	- E	. 2	24V/10.4, 5V/1A
OPT1 Pin 3 to 4	169	292	. 3	. 8	8	122	24V/10.4, 5V/1A
OPT2 Pin 1 to 2	165	288	8				24V/10.4, 5V/1A
OPT2 Pin 3 ta 4	143	252			5		24V/10.4, 5V/1A
OPT3 Pin 1 to 2	130	240	5.		#	:15	24V/10.4, 5V/1A
OPT3 Pin 3 to 4	146	268	8	. *	**	(=	24V/10.4, 5V/1A
OPT4 Pin 1 to 2	147	263	8:			16	24V/10.4, 5V/1A
OPT4 Pin 3 to 4	168	284	91	- 4	W.	12	24V/10.4, 5V/1A
0		Ú.	3		8	. 2	2
A: Line to Neutral	242	344	. 2	85	85	102 102	48V/5.2A, 5V/1A
8: Line to Ground	242	344				v 55	48V/5.2A, 5V/1A
D: Second. to Gnd	-:	48 Vdc				25	48V/5.2A, 5V/1A
T1 Pin 1 ta 6	215	316					48V/5.2A, 5V/1A
T1 Pin 3 ta 7	27	35			*	18	48V/5.2A, 5V/1A
T1 Pin 9 to 11	47	57	-	- 4	12	le le	48V/5.2A, 5V/1A
T1 Pin 10 to 12	47	62	*			12	48V/5.2A, 5V/1A
T1 Pin 13 to 15	12	21	3	8	8	12	48V/5.2A, 5V/1A
T1 Pin 14 to 16	12	16	-	-	_	_	48V/5.2A, 5V/1A
T1 Pin 1 to 9	169	388					48V/5.2A, 5V/1A
T1 Pin 1 to 10	144	- 90000				- 3	48V/5.2A, 5V/1A
		328			85		
T1 Pin 1 to 11	156	364	8:		*	(HE	48V/5.2A, 5V/1A
T1 Pin 1 ta 12	156	364	#		*	i#	48V/5.2A, 5V/1A
T1 Pin 1 to 13	143	320			*	192	48V/5.2A, 5V/1A
T1 Pin 1 to 14	170	384	25		ž.	. 2	48V/5.2A, 5V/1A
T1 Pin 1 to 15	146	324		15	15	12	48V/5.2A, 5V/1A
T1 Pin 1 to 16	167	380				E - 15	48V/5.2A, 5V/1A
T1 Pin 6 ta 9	127	256	5		5.	5	48V/5.2A, 5V/1A
T1 Pin 6 ta 10	128	260	5.	æ			48V/5.2A, 5V/1A
T1 Pin 6 ta 11	126	248	8:		#	18	48V/5.2A, 5V/1A
T1 Pin 6 ta 12	126	248	81		*	194	48V/5.2A, 5V/1A
T1 Pin 6 to 13	129	272	27	. 4	*	12	48V/5.2A, 5V/1A
T1 Pin 6 to14	127	264	. 2		22	. 12	48V/5.2A, 5V/1A
T1 Pin 6 to 15	128	264			8	12	48V/5.2A, 5V/1A
T1 Pin 6 ta 16	127	252	23		8	100	48V/5.2A, 5V/1A
T2 Pin 1 ta 2	1	9	5		5	35	48V/5.2A, 5V/1A
T2 Pin 3 to 4	2	11	S:		.5	.5	48V/5.2A, 5V/1A
T2 Pin 1 to 3	168	260	85		*	(100	48V/5.2A, 5V/1A
T2 Pin 1 to 4	167	258	9	9	12	12	48V/5.2A, 5V/1A
T2 Pin 2 ta 3	94	258	2	E	ž.	122	48V/5.2A, 5V/1A
T2 Pin 2 to 4	167	257	8	8	8	12	48V/5.2A, 5V/1A
T3 Pin 1 to 2	1	9			-		48V/5.2A, 5V/1A
T3 Pin 3 ta 4	0.7	5			-	-	48V/5.2A, 5V/1A
T3 Pin 1 to 3	68	323				-	48V/5.2A, 5V/1A
T3 Pin 1 to 4	70	324	88	**************************************	**	-	48V/5.2A, 5V/1A
T3 Pin 2 to 3	131	323	*	12	12		48V/5.2A, 5V/1A
T3 Pin 2 to 4	119	323	9			- 12	48V/5.2A, 5V/1A
T1-A Pin 1 to 2-SB	25	78	3			2	
T1-8 Pin 3 to 4-S8	100	468	8		8		48V/5.2A, 5V/1A 48V/5.2A, 5V/1A
	1999						
T1-C Pin 1 to 2-SB	6	33	3		-		48V/5.2A, 5V/1A
T1-A Pin 1 to 1-SB	165	284	2	-		15	48V/5.2A, 5V/1A
T1-A Pin 1 to 2-SB	167	284	5.		£7.	.5	48V/5.2A, 5V/1A
T1 Pin 2 to 1-58	158	272	*	*	*	(=	48V/5.2A, 5V/1A
T1-A Pin 2 to 2-SB	181	312	82	. *	18	i/ii	48V/5.2A, 5V/1A
T1-A Pin 3 to 1-SB	172	324	9	. 9	19	2 2	48V/5.2A, 5V/1A
T1-A Pin 3 to 2-SB	175	328	3	- E	ž.	. 12	48V/5.2A, 5V/1A
T1-A Pin 4 to 1-SB	180	308	8		8		48V/5.2A, 5V/1A

T1-A Pin 4 to 2-SB	128	224) #F	(Fig. 1)	· · · · · · · · · · · · · · · · · · ·	122	48V/5.2A, 5V/1A
OPT1 Pin 1 to 2	162	283	2	. 4	- 4	. 22	48V/5.2A, 5V/1A
OPT1 Pin 3 to 4	169	292	8		8	12	48V/5.2A, 5V/1A
OPT2 Pin 1 to 2	165	288	2			15	48V/5.2A, 5V/1A
OPT2 Pin 3 ta 4	143	252	9			- 25	48V/5.2A, 5V/1A
OPT3 Pin 1 ta 2	130	240	*		*	æ	48V/5.2A, 5V/1A
OPT3 Pin 3 to 4	146	268	æ	*	*	ie.	48V/5.2A, 5V/1A
OPT4 Pin 1 to 2	147	263	¥	12	12	122	48V/5.2A, 5V/1A
OPT4 Pin 3 to 4	168	284	2	2	- 4	12 12	48V/5.2A, 5V/1A

SUPPLEMENTARY INFORMATION:

The following information from the Standard is provided for reference purposes:

The WORKING VOLTAGE for each MEANS OF PROTECTION shall be determined as follows:

- -The input supply voltage to the ME EQUIPMENT shall be the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value.
- For d.c. voltages with superimposed ripple, the WORKING VOLTAGE is the average value if the peak to peak ripple does not exceed 10 % of the average value or the peak voltage if the peak to peak ripple exceeds 10 % of the average value.
- voltage if the peak to peak ripple exceeds 10 % of the average value.

 —The WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION is the voltage to which the DOUBLE INSULATION as a whole is subjected.
- For WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth, the situation in which the PATIENT is earthed (intentionally or accidentally) is regarded as a NORMAL CONDITION.
- -The WORKING VOLTAGE between the PATIENT CONNECTION(S) of an FTYPE APPLIED PART and the ENCLOSURE is taken as the highest voltage appearing across the insulation in NORMAL USE including earthing of any part of the APPLIED PART. See also 8.5.2.1.
- For DEFIBRILLATIONPROOF APPLIED PARTS, the WORKING VOLTAGE is determined without regard to the possible presence of defibrillation voltages. See also 8.5.5 and
- In the case of motors provided with capacitors where a resonance voltage can occur between the point where a winding and a capacitor are connected to gether on the one hand and any terminal for external conductors on the other hand, the WORKING VOLTAGE shall be equal to the resonance voltage.

CRITERIA

X.

NOTES TO/FROM THE LAB:

None

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Datasheets - (03) Datasheets

		Test Verdict:	PASS	- 23
Praject Na.:_	4786824159	ULFile Na.;	E146893	7,5

LEAKAGE CURRENT TEST: (IEC 60601-1, 3rd Edition, Clause 8.7)

METHOD:

A. Measuring Condition:

- Testing was conducted after thermal stabilization and was repeated following Humidity Preconditioning. Following the humidity conditioning (see Humidity Conditioning Test for further details), the equipment was located in an environment with a temperature approximately equal to twhere t is the temperature of the humidity cabinet and a relative humidity between 45% and 65% and was conducted 1 hour after the end of the humidity preconditioning treatment.
- In Normal Condition and in the specified Single Fault Conditions (8.7.2)
- With the Equipment energized in stand-by and fully operating and with any switch in the Mains Part in any position.
- With the equipment connected to a supply source with the highest rated supply frequency and 110% of the highest rated Mains Voltage as indicated in the RESULTS table.

8. The measuring supply circuit was connected to the indicated supply mains: (see 8.7.4.2)

- [X] Annex F, Fig. F.1 Supply circuit with one side of the supply at ground potential.
- [| Annex F, Fig. F.2 Supply circuit symmetrical to ground potential.
- Annex F, Fig. F.3 Supply Circuit for polyphase equipment specified for connection to a polyphase Supply Main s.
- Annex F, Fig. F.4 Supply Circuit for single phase equipment specified for connection to a polyphase Supply Mains. (Center Tap Leakage-DO NOT USE SWITCH BOX)
- Annex F, Fig. F.S Supply Circuit for ME equipment having a separate power supply unit or intended to receive its power from another equipment in an ME system.

Measurements which do not energize the equipment were made first.

C. Connection of Equipment to the Measuring Supply Circuit:

- [] Equipment provided with a Power Supply Cord Tested using the cord provided.
- Equipment provided with an Appliance Inlet Use Detachable power supply cord having a length of 3 M or Type , Length as specified by manufacturer.
- [X] Equipment specified for Permanent Installation Tested while connected to the supply via the shortest possible connection.

D. Measuring Arrangement:

The supply circuit and each measuring circuit were positioned as far as possible from unscreened power supply leads.

External parts of the Applied Parts, including Patient cords, were placed on an insulating surface with a dielectric constant of approximately 1 (e.g. expanded polystyrene) and approximately 200 mm above an earth of metal surface.

E. Measuring Device (MD) and Instrument:

- The leakage current tests are conducted using a modified Measuring Device (MD). The MD as shown in Fig. 12 was used without the 10 kΩ resistor (R1) and 0.015 μf capacitor (C1). This is used to satisfy the testing within clause 8.7.3 e) and is also used for all other leakage testing to replace the MD identified in Fig. 12. If any of the leakage results are above the limits specified in clause 8.7.3 a) through d) using this modified MD then they are to be repeated using the MD specified in Fig. 12 and a separate Datasheet('Non-Frequency-Weighted Leakage Current') shall identify the test results for the 1 kOhm MD only.
- [X] The Measuring Device (MD) shown in Fig. 12 was used. It consisted of a 1 kg resistor (R2) in parallel of a 10 kg resistor (R1) which is in series with a 0.015 µf capacitor (C1).

The measuring instrument had an impedance of approximately 1 MQ or more for frequencies from d.c. up and including 1 MHz. It shall indicate the true r.m.s, value of the voltage across the MD. Review Clause 8.7.4.4 for appropriate Measuring Device (MD),

[] A suitably rated oscilloscope with probe having an impedance > 1.M Q was used. The capacitance of the measuring device and its connecting leads to earth and to the body of the equipment was kept as low as possible.

All recorded leakage current measurements were in microamperes unless otherwise specified.

RESULTS:

The following Table is a summary of all the Leakage Current testing performed, identifying the maximum measurements for all switch positions. Refer to the individual Leakage Current test for additional details.

Test Type	Figure	Cand.	Supply Voltage (V)	Supply Freq. (Hz)	Max Meas. (uA a.c.)	Max Meas. (uAd.c.)	Max (uA [8,8F	aici)	Max ! (uA t [8, 8 f	l.c.)	R em arks	Verdict
Earth Leakage Current	13	NC	264	60	174.8	- 0	5,0	00	45		5	Pass
Carrii Ceakage Current		SFC	264	60	345.3		10,1	000			45	Pass
Touch Leakage Current	14	NC	264	60	0.0	0.0	10	00	10	0	- 5\:	7
Tobbit Leakage Corrent		SFC	264	60	0.0	0.0	50	00	50	0	viz: 3	7
Patient Leakage Current	15	NC.	264	60	0.0	0.0	100	10	1	0	7	7
Patient Leakage Current	123	SFC	264	60	0.0	0.0	500	50	5	0	J-	7
Patient Leakage Current (Voltage on	16	NC.	-	-	-	-					N/A - No NC Tests	N/A
AP)	10	SFC	264	60	0.0	0.0	5,000	50	5,000	50	-	7
atient Leakage Current (Voltage on	17	NC.	264	60	0.0	0.0	100	10	1	0		7
SIP/SOP)	13	SFC	264	60	0.0	0.0	500	50	5	0	-	7
Patient Leakage Current (Voltage on	18	NC.	-		- 5	-		-			N/A - Na NC Tests	N/A
Accessible Part)	18	SFC	264	60	0.0	0.0	50	00	50	0	5	7
Patient Auxiliary Leakage Current	19	NC.	264	60	0.0	0.0	100	10	10		1	7
Patient Auxiliary Leakage Current	13	SFC	264	60	0.0	0.0	500	50	5	0	26	7
Total Patient Leakage Current (Same	15 & 20	NC	264	60	0.0	0.0	500	50	5	0	3.	7
AP Tied Together)	13 8 20	SFC	264	60	0.0	0.0	1,000	100	10	0		7
Total Patient Leakage Current	16 & 20	NC			*				13		N/A - Na NC Tests	N/A
(Voltage on AP)	15 8: 20	SFC	264	60	0.0	0.0	5,000	100	5,000	100		7
Total Patient Leakage Current	47.0.20	NC	264	60	0.0	0.0	500	50	5	0	5.	7
(Voltage on SIP/SOP)	17 & 20	SFC	264	60	0.0	0.0	1,000	100	10	0		7
Total Patient Leakage Current	400.20	NC		-		- 1			17		N/A - Na NC Tests	N/A
(Voltage on Accessible Part)	18 & 20	SFC	264	60	0.0	0.0	1,000		1,000			7

SUPPLEMENTARY INFORMATION:

Abbreviations used:

- ER Earth leakage current TC -Touch (leakage) current
- P Patient leakage current
- PM Patient leakage current with mains on the applied parts
- PSM Patient leakage current with mains on SIP/SOPS
- PA Patient auxiliary current
- TPL Touch Patient Leakage Current
- IP -Internally powered leakage current
- MD Measuring device
- Fig. 12 Refers to Fig. 12 in IEC 60601-1 (8.7.3)

- A After humidity conditioning
- B Before humidity conditioning
- 1 Switch closed or set to normal polarity
- 0 Switch open or set to reversed polarity
- NC Normal condition SFC - Single fault condition
- AA -After Abnormal
- S1 Mains neutral conductor
- SS Mains polarity S7 Protective Earth Conductor
- S9 Mains on patient polarity

CRITERIA:

Measured leakage currents shall be within the specified limits.

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Tested By:	Radney Reyes	Test Verdict:	PASS
Test Date(s):	2014-07-02-2014-07-07	Amb. Temp (°C):	25
Sample No.:	1	Amb. Humid (%):	41
Instrument Code/Range:	1, 8, 9	Amb. Pressure (mBar):	10
Project No.:	4786824159	ULFile Na.:	E146893

EARTH LEAKAGE CURRENT TEST (IEC 60601-1, 3rd Edition, CLAUSE: 8.7.4.5)

METHOD.

The equipment was connected to the indicated voltage and frequency. Earth leakage current was measured through the indicated Figure of IEC 60601-1.

- [X] Fig. 13 Class Lequipment with or without an Applied Part.
- [| Switch S12 was connected between earth and F-Type Applied Part _____
- Equipment has more than one Protective Conductor (i.e. one connected to the main enclosure and one to a separate power supply unit), the current was the aggregate current that follow into the protective earthing system of the installation.
- [] Fixed equipment that can have connections to earth through the building structure, Earth Leakage Current was measured per test procedure specified by manufacturer______.
- [| Switch S10 was connected between earth and the Functional Earth Terminal.

PARAMETERS:

Supply Voltage	Supply Frequency	Operating Conditions
264	60	No load

RESULTS:

Switt	h Pasitlan			S1=1 ured uA			SFC: S1=0 Measured u.A			. Remark	
		Bef	Before		After		Before		er	T. COURT	
\$5	51.0	512	AC	DC	AC	DC	AC	DC	AC	DC	11
0	0	D	153.90		174.70	4	302.40	-	343.00	-	. Pi
0	0	1	-	- 2	-	2	2	- 94	4	34	2
0	1	0	25	20	0	2	0	- 12		82	2
0	1	1	25	26	2	2	2	- 2		32	27
1	0	0	155.20	- 74	174.80	- 5	302.80		345.30	577	27
1	0	1	5 70	5 76					0 5 6	875	4 7/
1	1	0			-		-		1 . 3		5.
1	1	1		- 53						-	-

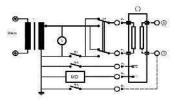
[] The following Leakage Current tests were performed, in addition to those referenced above. (NOTE: This can be used for devices that are mains connected and internally powered, deviced with external power source using switches \$2 & \$3 from Fig. F.5, etc.).

Type of Leakage Current and Test Condition	Supply Voltage (V)	Supply Frequency (Hz)	Canditian (NC/SFC)	Measured Max. Value AC (uA)	Measured Max. Value DC (uA)	Remarks
	33	23	2			35

SUPPLEMENTARY INFORMATION:

For Battery Operated only equipment, the neutral condctor and SL not used; SL=1 above indicates NC and SL=9 is not used in this case.

Refer to the Leakage Current Summary for a summary of the maximum measurements for this test and verdict results.



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None

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Tested By:	Radney Reyes	Test Verdict:	PASS
Test Date(s):	2014-07-02	Amb. Temp (°C):	25
Sample No.:	1.	Amb. Humid (%):	40
Instrument Code/Range:	9, 18	Amb. Pressure (mBar):	1018
Project No.:	4786824159	UL File Na.;	E146893

DIELECTRIC VOLTAGE WITHSTAND: (IEC 60601-1, 3rd Edition, Clause 8.8.3)

METHOD

The equipment was brought to the steady state operating temperature reached during the Normal Temperature Test. Initially not more than 50 percent of the test voltage was applied. The test voltage was raised to its full value within a period of 10 s. The test voltage was held at full value for 1 min. The test voltage was lowered over a period of 10 s to less than 50 percent of the full value.

Alternatively, a d.c. test voltage equal to the peak value of the a.c. test voltage may be used.

During the test, breakdown constitutes a failure. Insulation breakdown is considered to have occurred when the current which flows as a result of the application of the test voltage rapidly increases in an uncontrolled manner, that is, the insulation does not restrict the flow of the current. Corona discharge or a single momentary flashover is not regarded

as insulation breakdown.

Where an ENCLOSURE or part of ENCLOSURE consists of nonconductive surfaces, metal foil is applied. Care is taken that the metal foil is positioned in such a manner that flashover does not occur at the edges of insulation linings. If applicable, the metal foil is moved so as to test all parts of the surface.

The circuits on either side of the insulation under test should be connected or short circuited such that components within these circuits do not get stressed during the test.

For example, the terminals of the MAINS PART, the SIGNAL INPUT/OUTPUT PART and the PATIENT CONNECTION (\$) (if applicable) respectively are short circuited during the test.

Where there are capacitors across the insulation under test (e.g. radiofrequency filter capacitors), they may be disconnected during the test, if they are certified to IEC 60384-

- [X] Dielectric test was repeated immediately following the Humidity pre-conditioning test.
- [| Dielectric test was repeated immediately following Sterilization test.
- [X] Dielectric test was repeated immediately following Abnormal Operation and Single Fault Conditions test.

RESULTS:

Insulation under Test (Area from Insulation Diagram)	Insulation Type (1 or 2 M OOP /M OPP)	Reference Voltage					
		Peak Working Voltage (U) Vpeak	Peak Working Voltage (U) Vdc	Test Voltage (Vrms or Vdc)	Dielectric breakdown before 1 min. (Yes/No)	Remark	Verdict
Line to Neutral	BOP	344				-	(50)
Primary to Ground	1 MOPP	344		1973 Vrms	Na	After Humidity	Pass
Primary to Secondary	2 MOPP	475	· ·	4343 Vrms	No	After Humidity	Pass
Secondary to Ground	1 MOPP		12 Vdc	1500 Vrms	No	After Humidity	Pass
Primary to Ground	1 MOPP	344	9	1973 Vrms	Na	After Abnormals	Pass
Primary to Secondary	2 MOPP	475	¥	4343 Vrms	Na	After Abnormals	Pass
Primary to Secondary	2 MOPP	475	8	4343 Vrms	Na	After Abnormals	Pass
Secondary to Ground	1 MOPP	- 2:	12 Vdc	1500 Vrms	Na	After Abnormals	Pass

SUPPLEMENTARY INFORMATION: None

....

CRITERIA:

There shall be no indication of dielectric breakdown.

NOTES TO/FROM THE LAB:

None

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Tested By:	Radney Reyes	Test Verdict:	PASS
Test Date(s):	2014-06-07	Amb. Temp (°C):	25
Sample No.:	1.	Amb. Humid (%):	41
Instrument Code/Range:	9, 13, 16	Amb. Pressure (m Bar):	1020
Project No.:	4786824159	UL File Na.;	E146893

BALL PRESSURE: (IEC 60601-1, 3rd Edition, Clause 8.8.4.1)

METHOD

A sample of each insulating material indicated in the table was tested using the test apparatus shown in Fig. 21 of IEC 60601-1, 3rd Edition. (In this apparatus, a steel ball of 5 mm diameter exerts a force of 20 N when pressed against a surface). The apparatus and a fire (or sand) brick were placed in an air-circulating oven. Once the apparatus and brick attained the oven temperature, the sample was placed in the oven on top of the brick. The steel ball was then positioned such that the apparatus was balanced on the surface of the sample. After 1 h, it was removed and the diameter of the impression made by the ball was measured.

- Enclosures and Other External Insulating Parts (d. 8.8.4.1.a) The oven temperature was higher of either 75°C ± 2°C or the sum of the specified ambient and the temperature rise of relevant part during the Temperature Test;
- [X] Insulating Parts supports uninsulated Mains Parts (cl. 8.8.4.1.b) The oven temperature was higher of either 125°C ± 2°C or the sum of the specified ambient and the temperature rise of relevant part during the Temperature Test;

RESULTS:

Part/Material	Test temperature (°C)	Impression diameter (mm)	Remarks	Verdict
Enclosure/External insulating parts	÷	*	-	888
Conn 3 POS 0.156 CTR HEADER VERT LOCK-Malex 26-60- 4030	125	1.12	Impression was less than 2mm.	Pass
Transformer Bobbin - Ryton R-4-2308L, 1mm thick	125	9,0	Impression was less than 2mm.	Pass
Insulating material Supporting insulated Mains Parts	21	12	-	88

SUPPLEMENTARY INFORMATION:

None

CRITERIA:

The results shall be less than or equal to 2 mm.

NOTES TO/FROM THE LAB:

None

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Datasheets - (03) Datasheets

Test Verdict:	Tested By: Rodney Reyes
Amb. Temp (°C):	Test Date(s): 2014-06-13
Amb. Humld(%):	Sample No.: 1
Amb. Pressure (mBar):	Instrument Code/Range: 1, 3, 5, 9, 13
UL File No.:	Project No.: 4786824159

TEMPERATURE TEST: [IEC 60 601-1, 3rd Edition, Clause 11)

METHOD:

All necessary connections for the change-of-resistance measurement for the windings specified below were made, initial ambient temperature and a cold resistance of the windings were measured and recorded

Type \underline{K} thermocouples were placed at the locations noted below.

- The sample was placed in a test corner. The test corner consisted of two walls at right angles, [and] [a floor] [and] [a ceiling], all of dull black painted plywood of 20 mm thickness.

 The linear dimensions of the test corner were at least 115 percent of the linear dimensions of the unit. The unit was positioned [as near to the walls as possible] [on one wall as near as possible to the other wall] and to the [floor] [ceiling] [on the ceiling as near to the walls as possible] [suspended in its normal position].
- [X] The sample was positioned as in normal use. The unit was connected and operated as specified in Table 11.
- [] Hand-held equipment was suspended in _______ in still air:
- [] Equipment normally used on a floor or a table was placed as [] as near to [] _____In/mm from the walls as possible.
- [] Equipment normally fixed to a wall was mounted on one of the walls, [] as near to [] ____in/mm from the other wall and to the floor or ceiling as is likely to occur in NORMAL U.SE.
- [] Equipment normally fixed to a celling was fixed to the celling as near to the walls as is likely to occur in NORMAL U.S.E.
- [1 Other equipment was tested in the position of NORMAL USE:
- Equipment intended for installation in a cabinet or wall was built in as required by installation instructions, using dull black painted plywood walls, 10 mm thick when representing cabinet walls if the installation instructions so specify and 20 mm thick when representing building walls.
- [] Rechargeable batteries /battery packs were completely discharged at the beginning of the test.

The Test Duration was recorded.

Thermal Stabilization

- for MEEQUIPMENT Intended for non-CONTINUOUS OPERATION: After operating in standby/quiescent mode until THERMAL STABILITY is reached, the MEEQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for 7 h, whichever is shorter. The "on" and "off" periods for each cycle are the RATEO "on" and "off" neriods:
- [X] FOR MEEQUIPMENT for CONTINUOUS OPERATION, The MEEQUIPMENT is operated until THERMAL STABILITY is reached.

RESULTS:

Model/Part/	Type No.	()		CH D25 12V/20.8 Conve	A (25 DW)	12V/20.6	i0 P512: IA (250W) ection	12V/20.8	0PS12: A (250W) ection	CHD 25 12V/28.8. Conve	30000000000	12V/18.1 Convect	0P512: .A (217W) :lon with ver	12V/18.1 Convect		Remarks (Including	
dax. rated a	m blent o	perating temp T [°C):	. 5	0	- 1	0	5	0	. 5	0	5	0		0	Insulation class	
rest am blent	t temp t,	(°C):		5	0		0	5	0	5	0	5	U	5	0	and Classification	
Supply Volta	ge (V):			90 1	VAC	100	VAC	248	VAC	264	VAC	90	VAC	264	VAC	of Individual	Verdl
Supply Frequ		Se:		35	0	3	0	- 5	0	5	0	25	in	5	0	Insulating	
Outy Cycle (s						_	-0	× -		- 2			-3		2 6	materials or	
rest D uratio	n (himis):			21	0.05	_	hrs	2	hrs	21	nrs	. 21	hrs	21	0.05	Relative Thermal	
Model No.	Therm .	Thermocouple location	Limit t _{max (} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} *C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. im (°C)	Corr. t _e (°C)	Meas. tm (°C)	Corr. t _e (°C)	Index (°C))	
1	1	TAMBIENT	50.0	50	50.0	50	50.0	50	50.0	50	5 0.0	50	50.0	50	50.0		Pass
ï	2	FS1 BODY	125.0	103	103.0	91	91.0	68	68.0	70	70.0	95	95.0	72	72.0		Pass
1	3	LI COIL	130.0	108	108.0	95	95.0	70	70.0	73	73.0	98	98.0	74	74.0		Pass
I .	4	L2 COIL	130.0	115	115.0	104	104.0	79	79.0	81	81.0	112	112.0	96	86.0		Pass
1	. 5	C64 BODY	105.0	88	88.0	83	83.0	71	71.0	73	73.0	92	92.0	79	79.0		Pass
1	6	OPTO 1 BODY	105.0	87	87.0	85	85.0	79	79.0	80	8 0.0	91	91.0	81	81.0		Pas
1	7	PCB @ TR5,05	130.0	111	111.0	105	1 05.0	85	85.0	85	85.0	124	124.0	95	95.0		Pass
1	В	D24 B OD Y	140.0	120	120.0	112	112.0	87	87.0	89	8 9.0	127	127.0	.96	96.0		Pas
1	9	L4 COIL	130.0	113	113.0	108	108.0	86	86.0	86	86.0	121	121.0	.93	93.0		Pas
1	10	L3 COIL	130.0	109	109.0	104	104.0	85	85.0	86	86.0	113	113.0	90	90.0		Pass
Î	11	L5 COIL	130.0	111	111.0	109	189.0	105	105.0	106	106.0	109	109.0	102	102.0		Pass
1	12	PCB @ TR27	130.0	100	100.0	98	98.0	95	95.0	96	96.0	96	96.0	92	92.0		Pass
1	13	T1 COIL	130.0	105	105.0	104	104.0	101	101.0	103	103.0	105	105.0	101	101.0		Pas
1	14	T1 CORE	130.0	98	98.0	94	94.0	91	91.0	93	93.0	107	107.0	102	102.0		Pass
1	15	T2 BODY	130.0	100	100.0	98	98.0	92	92.0	94	94.0	97	97.0	90	90.0		Pass
1	16	YDOB ET	130.0	92	92.0	90	90.0	85	85.0	86	86.0	88	88.0	82	82.0		Pass
1	17	C34BODY	105.0	97	97.0	96	96.0	92	92.0	93	93.0	94	94.0	88	88.0		Pass
1	18	ra coir	130.0	104	104.0	103	103.0	100	100.0	101	101.0	98	98.0	94	94.0		Pass
1	15	PBC @ TR16	130.0	111	111.0	104	104.0	108	108.0	109	189.0	95	95.0	92	92.0		Pass
1	20	CON1 BODY	105.0	76	76.0	71	71.0	60	60.0	61	61.0	75	75.0	63	63.0		Pass

SUPPLEMENTARY INFORMATION:

t_m = measured temperature

 t_{m} = measureu unperacute $t_{m} = t_{m}$ corrected ($t_{m} - t_{m} + 40$ °C or max. RATED ambient). t_{mm} = maximum permitted temperature Max allowable temperature from Table 22, 23, or R M^{2,4}

When thermocouples used to determine temperature of windings, temperature limits of Table 22 reduced by 10 °C. 2 Maximum allowable temperature on surfaces of test corner is 90 °C.

**Max temperature determined in accordance with 11.1.3 e)

**See Attachment #s for RISK MANAGEMENT FILE containing temperatures 8. clinical effects. Also, see instructions for use.

* Record duration time for each test run.

The temperatures obtained shall not exceed the specified limits.
Thermal cutouts shall not operate.
Sealing or potting compound shall not flow out.

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Datasheets - (03) Datasheets

Tested By:	Rodney Reyes	Test Verdict:	PASS
Test Date(s):	2014-03-16, 2015-03-25	Amb. Temp (°C):	25
Sample No.:	1	Amb. Humld(%):	42
Instrument Code/Range:	1, 3, 5, 9, 13	Amb. Pressure (mBar):	1020
Project No.:	4786824159	UL File No.:	E146893

METHOD:

All necessary connections for the change-of-resistance measurement for the windings specified below were made. Initial ambient temperature and a cold resistance of the windings were TI

Type <u>K</u> thermocouples were placed at the locations noted below.

- The sample was placed in a test corner. The test corner consisted of two walls at right angles, [and] [a floor] [and] [a ceiling], all of dull black painted plywood of 20 mm thickness. The linear dimensions of the test corner were at least 115 percent of the linear dimensions of the unit. The unit was positioned [as near to the walls as possible] [on one wall as near as possible to the other wall] and to the [floor] [ceiling] [on the ceiling as near to the walls as possible] [suspended in its normal position].
- [X] The sample was positioned as in normal use. The unit was connected and operated as specified in Table 11.
- [] Hand-held equipment was suspended in _
- 1.1 Equipment normally used on a floor or a table was placed as [] as near to [] _____in/mm from the walls as possible.
- Equipment normally fixed to a wall was mounted on one of the walls, [] as near to [] _____in/mm from the other wall and to the floor or celling as is likely to occur in NOKMAL U.SE. 1.1
- 1.1 Equipment normally fixed to a celling was fixed to the celling as near to the walls as is likely to occur in NORMALUSE.
- [] Other equipment was tested in the position of NORMAL USE: __
- 13 Equipment intended for installation in a cabinet or wall was built in as required by installation instructions, using dull black painted plywood walls, 10 mm thick when representing cabinet walls if the installation instructions so specify and 20 mm thick when representing building walls.
- [] Rechargeable batteries /battery packs were completely discharged at the beginning of the test.

The Test Duration was recorded.

Thermal Stabilization

- 11 For ME EQUIPMENT Intended for non-CONTINUOUS OPERATION: After operating in standby/gulescent mode until THERMAL STABILITY is reached, the ME EQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for 7 h, whichever is shorter. The "on" and "off" periods for each cycle are the RATED "on" and "off"
- [X] FOR MEEQUIPMENT for CONTINUOUS OPERATION, The MEEQUIPMENT is operated until THERMAL STABILITY is reached.

THERMAL STABILITY is considered to exist only if temperatures did not increase in 1 hour by more than 2°C.

RESULTS:

Model/Part/	Туре N о	ti.		5000000	0P512: A (125W) ection	12V/10.4	0 P512: A (1 25W) ection	12V/9.05 Convect	0P512: A (109W) tion with ver	12V/9.05 Convect	OPS12: A (189W) ion with ver	12V/1	ow)	12V/1 (20)	0 PS12: (6.67A 0 W) ection	Remarks (including	
Max. rated a	m blent o	perating temp T (°C):	7	Ö	7	0	7	0	7	0	7	0	7	0	Insulation class and Classification	
Test am blent	t temp t,	(°C):			0	7	0	7	0	7	0	7	0	- 7	0	of Individual	Verdict
Supply Volta	ge (V):			50.3	VAC	264	VAC	5.0	VAC	264	VAC	50	VAC	264	VAC:	Insulating	VEILUILL
Supply Frequ	iency (Hz	8		. 5	0	5	0	5	0	5	0	- 5	а	- 5	0	materials or	
Duty Cycle (s	on soff):		j ,	. 4	18		2	5.			-				Relative Thermal	
Test D uratlo	n (himis):			21) is	21	hrs	2	hrs	2	hrs	2 1	hrs	21	hrs	Index (°C))	
Model No.	Therm . No.	Thermocouple location ¹	Limit t _{max} (°C)	Meas. tm (°C)	Corr, t _{e(} °C)	Meas. tm (℃)	Corr. t _{∈(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)		
1	1	TAMBIENT	70.0	70	70.0	70	70.0	70	70.0	70	70.0	70	70.0	70	70.0		Pass
1	2	FS1 BODY	125.0	87	87.0	81	81.0	88	88.0	83	0.EB	84	84.1	70	69.6		Pass
1	3	LI COIL	130.0	89	89.0	83	83.0	90	90.0	85	85.0	89	89.2	73	73.4		Pass
1	4	L2 COIL	130.0	95	95.0	**	88.0	100	100.0	92	92.0	100	99.7	83	B3.3		Pass
1	5	C64 BODY	105.0	87	87.0	85	85.0	92	92.0	87	87.0	81	80.8	75	74.6		Pass
1	6	OPTO 1 BODY	105.0	87	87.0	84	84.0	90	90.0	87	87.0	92	92.0	85	85.2		Pass
1	7	PCB @ TR5,D5	130.0	98	98.0	93	93.0	107	107.0	99	9 9.0	101	101.4	85	84.5		Pass
1	В	D24 BODY	140.0	101	101.0	94	94.0	108	108.0	99	99.0	109	108.6	89	88.8		Pass
1	9	L4 COIL	130.0	100	100.0	90	90.0	106	106.0	94	94.0	104	1042	96	85.5		Pass
1	10	L3 COIL	130.0	97	97.0	89	89.0	101	101.0	93	93.0	108	107.7	96	86.3		Pass
18	11	L5 COIL	130.0	96	96.0	95	95:0	98	98.0	97	57.0	106	106.4	105	105.0		Pass
1	12	PCB @ TR27	130.0	93	93.0	92	92.0	95	95.0	93	93.0	100	99.5	98	98.2		Pass
1	13	T1 COIL	130.0	92	92.0	92	92.0	96	96.0	94	94.0	108	108.0	109	109.0		Pass
1	14	T1 CORE	130.0	89	89.0	- 88	88.0	97	97.0	95	95.0	109	108.9	108	108.1		Pass
1	15	T2 BODY	130.0	91	51.0	90	98.0	94	94.0	91	91.0	99	99.0	93	92.7		Pass
1	16	T3 BODY	130.0	89	89.0	87	87.0	92	92.0	89	89.0	96	95.8	88	87.5		Pass
11	17	G14BODY	105.0	88	88.0	87	87.0	90	90.0	88	88.0	. 99	98.6	98	98.1		Pass
1	18	L9 COIL	130.0	90	90.0	89	89.0	91	91.0	90	9 0.0	100	100.0	103	103.0		Pass
1	19	PBC @ TR16	130.0	92	92.0	.91	91.0	92	92.0	91	91.0	107	107.2	110	110.0		Pass
1	20	CON1 BODY	105.0	79	79.0	77	77.0	81	81.0	79	75.0	96	95.5	85	84.8	I .	Pass

SUPPLEMENTARY INFORMATION: Test at 200W-70C represents entire series.

t_m = measured temperature

 $t_{\rm c}$ = $t_{\rm m}$ corrected ($t_{\rm m}$ - $t_{\rm s}$ + 40 °C or max. RATED ambient).

 t_{max} = maximum permitted temperature Max allowable temperature from Table 22, 23, or R $M^{P, \Phi}$

When thermocouples used to determine temperature of windings, temperature limits of Table 22 reduced by 10 $\,$ °C.

² Maximum allowable temperature on surfaces of test corner is 90 °C

^a Max temperature determined in accordance with 11.13 e)

See Attachment # s for RISK MANAGEMENT FILE containing temperatures & clinical effects. Also, see instructions for use:

* Record duration time for each test run.

CRITERIA:

The temperatures obtained shall not exceed the specified limits. Thermal cutouts shall not operate. Sealing or potting compound shall not flow out.

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Datasheets - (03) Datasheets

Tested By:	Rodney Reyes	Test Verdict:	PASS
Test Date(s):	2014-06-23 - 2014-06-27	Amb. Temp (℃):	25
Sample No.:	1	Amb. Humld(%):	40
Instrument Code/Range:	1, 3, 5, 9, 13	Amb. Pressure (mBar):	1020
Project No.:	4786824159	UL File No.:	E146893

METHOD:

All necessary connections for the change-of-resistance measurement for the windings specified below were made, initial ambient temperature and a cold resistance of the windings were TI

Type <u>K</u> thermocouples were placed at the locations noted below.

- The sample was placed in a test corner. The test corner consisted of two walls at right angles, [and] [a floor] [and] [a ceiling], all of dull black painted plywood of 20 mm thickness. The linear dimensions of the test corner were at least 115 percent of the linear dimensions of the unit. The unit was positioned [as near to the walls as possible] [on one wall as near as possible to the other wall] and to the [floor] [ceiling] [on the ceiling as near to the walls as possible] [suspended in its normal position].
- [X] The sample was positioned as in normal use. The unit was connected and operated as specified in Table 11.
- Hand-held equipment was suspended in _
- 1.1 Equipment normally used on a floor or a table was placed as [] as near to [] _____in/mm from the walls as possible.
- Equipment normally fixed to a wall was mounted on one of the walls, [] as near to [] _____in/mm from the other wall and to the floor or celling as is likely to occur in NOKMAL U.SE. 1.1
- 1.1 Equipment normally fixed to a celling was fixed to the celling as near to the walls as is likely to occur in NORMALUSE.
- [] Other equipment was tested in the position of NORMAL USE: _
- 13 Equipment intended for installation in a cabinet or wall was built in as required by installation instructions, using dull black painted plywood walls, 10 mm thick when representing cabinet walls if the installation instructions so specify and 20 mm thick when representing building walls.
 - Rechargeable batteries /battery packs were completely discharged at the beginning of the test.

The Test Duration was recorded.

Thermal Stabilization

- 11 For ME EQUIPMENT Intended for non-CONTINUOUS OPERATION: After operating in standby/quiescent mode until THERMAL STABILITY is reached, the ME EQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for 7 h, whichever is shorter. The "on" and "off" periods for each cycle are the RATED "on" and "off"
- [X] FOR MEEQUIPMENT for CONTINUOUS OPERATION, The MEEQUIPMENT is operated until THERMAL STABILITY is reached.

THERMAL STABILITY is considered to exist only if temperatures did not increase in 1 hour by more than 2°C.

RESULTS:

Model/Part/1	Type N o			CH D25 12V/20.8 (25) Convect 5V St	A, 5V/1A SW) lonwith	12V/20.8 (25) Convect	0 P512: (A, 5V/1A 5 W) don with and by	12V/13.3 (16 Convect	5W) Ion with dby and	5V Stan	3A, 5V/1A 5W) Ion with					Remarks (Including Insulation class	
		perating temp T (°C):	- 5			0	5	2	5	716					and Classification	
Fest am blent	SALES OF THE OWNER, TH	(°C):		. 5	-	5	Table 1	5	5	5	Tolon .					of Individual	Verdict
supply Voltag				90	100000	20001.00	VAC		VAC	264			55	5 8	2	Insulating materials or	
Supply Frequ	and the second			. 5	0	5		5	5	5	0			6		Relative Thermal	
Outy Cycle (s	on, s off	9						0	2	. 6						Index (°C))	
Fest D uration	n (hemes):			2 1	irs	21	ris	2	hrs	2 1	nrs						
Model No.	Therm. No.	Thermocouple location	Limit t _{max (} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)		
1	1	TAMBIENT	50.0	50	50.0	50	50.0	50	50.0	50	5 0.0		(5)); y			Pass
1	2	FSI BODY	125.0	98	98.0	67	67.0	80	80.0	70	70.0						Pass
1	3	LI COIL	130.0	98	98.0	72	72.0	84	84.0	72	7.2.0						Pass
1	4	LZ COIL	130.0	107	107.0	81	81.0	96	96.0	83	0.68						Pass
1	. 5	C64 BODY	105.0	89	89.0	75	75.0	82	82.0	77	77.0			G 6			Pass
1	6	OPTO 1 BODY	105.0	97	97.0	87	87.0	81	B1.0	76	76.0						Pass
1	7	PCB @ TR5,D5	130.0	104	104.0	85	85.0	104	104.0	92	92.0		00%	ě.			Pass
1	8	D24 BODY	140.0	118	118.0	91	91.0	107	107.0	94	94.0		3				Pass
1	9	L4 COIL	130.0	114	114.0	92	92.0	107	107.0	93	93.0)				Pass
1	10	L3 COIL	130.0	121	121.0	93	93.0	103	103.0	91	91.0						Pass
10 0	11	L5 COIL	130.0	105	105.0	.99	99.0	95	95.0	91	91.0						Pass
1	12	PCB @ TR27	130.0	98	98.0	94	94.0	88	0.88	85	85.0						Pass
1	13	T1 COIL	130.0	117	117.0	113	113.0	91	91.0	89	8 9.0		ĵ				Pass
1	14	T1 CORE	130.0	113	113.0	109	109.0	93	93.0	90	9 0.0						Pass
1	15	T2 BODY	130.0	118	118.0	110	110.0	98	98.0	93	93.0		d .	£ .			Pass
10	16	YDOB ET	130.0	112	112.0	101	101.0	97	97.0	91	91.0		J				Pass
1	17	C14BODY	105.0	102	102,0	97	97.0	86	86.0	83	83.0						Pass
1	18	L9 COIL	130.0	93	93.0	90	90.0	82	82.0	80	80.0		3				Pass
1	15	PBC @ TR16	130.0	105	105.0	102	102.0	89	89.0	87	87.0						Pass
1	20	CON1 BODY	105.0	82	82.0	62	62.0	68	68.0	62	62.0						Pass
1	21	T1 COIL-SB	130.0	110	110.0	102	102.0	94	94.0	89	89.0						Pass
1	22	T1 CORE-5B	130.0	104	104.0	95	95.0	93	93.0	88	88.0		3				Pass
f.	23	C7 BODY-58	105.0	97	97.0	92	92.0	77	77.0	75	75.0						Pass
16	24	L1 COIL-SB C14 BODY-SB	130.0	105	105.0	85 94	85.0 94.0	83 100	100.0	81 91	81.0 91.0						Pass Pass

SUPPLEMENTARY INFORMATION:

Where:

t_m = measured temperature

 $t_c = t_m$ corrected ($t_m - t_s + 40$ °C or max. RATED ambient).

 $t_{max} = maximum\ permitted\ temperature\ Max\ allowable\ temperature\ from\ Table\ 22, 23, or\ R\ M^{2,4}$

- 1 When thermocouples used to determine temperature of windings, temperature limits of Table 22 reduced by 10 $^{\circ}$ C.
- ² Maximum allowable temperature on surfaces of test corner is 90 °C
- ^a Max temperature determined in accordance with 11.13 e)
- 4 See Attachment # s for RISK MANAGEMENT FILE containing temperatures & clinical effects. Also, see instructions for use.
- * Record duration time for each test run.

- The temperatures obtained shall not exceed the specified limits.
- Thermal cutouts shall not operate.
 Sealing or potting compound shall not flow out.

NOTES TO/FROM THE LAB:

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Datasheets - (03) Datasheets

1	Tested By:	Rodney Reyes	Test Verdict:	PASS
	Test Date(s):	2014-06-23 -2014-06-27	Amb. Temp (°C):	2.5
	Sample No.:	1	Amb. Humld(%):	40
	Instrument Code/Range:	1, 3, 5, 9, 13	Amb. Pressure (mBar):	1020
100	Project No.:	4786824159	UL File No.:	E146893
TEMPERATUR	ETEST: [IEC 60 601-1, 3rd Edition, Clau	se 11)		
METHOD:				
1.0	All necessary connections for the ch measured and recorded.	ange-of-resistance measurement for the windings	specified below were made. Initial ambient temperature a	nd a cold resistance of the windings were
Type <u>K</u> th	hermocouples were placed at the locath	ons noted below.		
1.1	The linear dimensions of the test co	rner were at least 115 percent of the linear dimens	angles, [and] [a floor]	
1×1	The sample was positioned as in no	rmal use. The unit was connected and operated as	specified in Table 11.	
1/1	Hand-held equipment was suspend	ed in in still air.		
1.1	Equipment normally used on a floor	r or a table was placed as [] as near to []In	/mm from the walls as possible.	
1.1	Equipment normally fixed to a wall	was mounted on one of the walls, [] as near to []	In/mm from the other wall and to the floor or celling	g as is likely to occur in NORMAL USE.

[] Equipment normally fixed to a celling was fixed to the celling as near to the walls as is likely to occur in NORMAL U.S.E.

[1 Other equipment was tested in the position of NORMAL USE:

Equipment Intended for Installation in a cabinet or wall was built in as required by installation instructions, using dull black painted plywoodwalls, 10 mm thick when representing cabinet walls if the Installation instructions so specify and 20 mm thick when representing building walls.

[] Rechargeable batteries /battery packs were completely discharged at the beginning of the test.

The Test Duration was recorded.

Thermal Stabilization

[] FOR ME EQUIPMENT Intended for non-CONTINU OUS OPERATION: After operating in standby/quiescent mode until THERMAL STABILITY is reached, the ME EQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for 7 h, whichever is shorter. The "on" and "off" periods for each cycle are the RATED "on" and "off" net lods:

[X] For MEEQUIPMENT for CONTINUOUS OPERATION, The MEEQUIPMENT is operated until THERMAL STABILITY is reached.

RESULTS:

Model/Part/	Type No.:			CH D25 12V/1 5V/0.5 A Convect 5V St	0.4A, (127.5W) lonwith	12V/ 5V/0.5A Convect	0 P512: 10 AA, (1275W) tlonwith andby	12 V/I 5 V/II 5 A Convect 5 V Stan	0P512: i.67 A, (82.5W) ilon with dby and ver	12V/I 5V/II.5A Convect 5V Stan	0P512: 6.67A, (82.5W) (lon with dby and ver					Remarks (Including Insulation class	
day rateda	m blent o	perating temp T (°cv	7	n -	7	ű.	7	n .	- 7	0			0		and Classification	
rest am bleni				7	2	- 12	0	7		- 2	0			2		of Individual	Ve rdict
Supply Volta				90		- 2	VAC	35 25	VAC		VAC		3	1	9	Insulating materials or	
Supply Frequ				5	21.70	200000	0				0			-		Relative Thermal	
outy Cycle (s	20013			- 1		_	20	-		_	-				_	Index (°C))	
rest D uratlo				21		2		2	hrs	2					_		
Model No.	Therm.	Thermocouple location	Limit t _{max} ,°C)	Meas. tm (°C)	Corr.	Meas. tm (°C)	Corr. t _e /°C)	Meas. tm (°C)	Corr.	Meas. tm (°C)	Corr.	Meas. tm (°C)	Corr. t _e °C)	Meas. tm (°C)	Corr. t _c °C)		
F.	1	TAMBIENT	70.0	70	70.0	70	70.0	70	70.0	70	70.0			Description of the last			Pass
10	2	FS1 BODY	125.0	85	85.0	81	81.0	86	86.0	83	83.0			-	-		Pass
1	3	L1 COIL	130.0	- 88	88.0	84	84.0	88	88.0	85	85.0		4),				Pass
i	4	LZ COIL	130.0	96	96.0	91	91.0	96	96.0	92	92.0			-			Pass
1	5	C64 BODY	105.0	90	90.0	89	89.0	90	90.0	88	88.0						Pass
1	6	OPTO 1 BODY	105.0	92	52.0	- 88	88.0	89	89.0	86	86.0		9				Pass
1	7	PCB @ TR5,D5	130.0	98	98.0	93	93.0	104	104.0	99	59.0		8				Pass
1	В	D24 BODY	140.0	103	103.0	95	95.0	104	104.0	99	99.0						Pass
16	90	L4 COIL	130.0	101	101.0	92	92.0	103	103.0	97	97.0						Pass
i	10	L3 COIL	130.0	105	105.0	.96	96.0	101	101.0	95	95.0		7				Pass
1	11	L5 COIL	130.0	96	96.0	94	94.0	96	96.0	95	95.0						Pass
1	12	PCB @ TR27	130.0	94	94.0	93	93.0	94	94.0	92	92.0		ĵ				Pass
1	13	T1 COIL	130.0	100	100.0	98	98.0	94	94.0	93	93.0			20 20			Pass
1	14	T1 CORE	130.0	98	98.0	97	97.0	94	94.0	93	93.0		8	ė.			Pass
1	15	T2 BODY	130.0	102	102.0	99	99.0	98	98.0	96	9 6.0			4)			Pass
1	16	T3 800Y	130.0	100	100.0	96	96.0	97	97.0	95	95.0						Pass
1	17	C34 BODY	105.0	93	93.0	91	91.0	90	90.0	89	8 9.0		076				Pass
1	18	L9 COIL	130.0	89	89.0	- 88	88.0	87	87.0	86	8 6.0						Pass
1	19	PBC @ TR16	130.0	93	93.0	92	92.0	91	91.0	90	90.0						Pass
1	211	CON1 BODY	105.0	100	100.0	78	78.0	80	80.0	79	79.0						Pass
1	21	T1 COIL-SB	130.0	97	97.0	97	97.0	94	94.0	92	92.0		2				Pass
1	22	T1 CORE-SB	130.0	98	93.0	94	94.0	94	94.0	92	92.0		_				Pass
1	23	C7 BODY-5B	105.0	89	89.0	91	91.0	86	B6.0	84	84.0						Pass
1	24	L1 COIL-5B	130.0	96 96	96.0	87 91	87.0 91.0	89 99	89.0 99.0	97 95	87.0 95.0		2	0 3			Pass Pass

SUPPLEMENTARY INFORMATION:

 t_m = measured temperature t_s = t_m corrected (t_m = t_s + 40 °C or max. RATED ambient). t_{max} = maximum permitted temperature Max allowable temperature from Table 22, 23, or RM^{2,4}

- When thermocouples used to determine temperature of windings, temperature limits of Table 22 reduced by 10 °C.
- ² Maximum allowable temperature on surfaces of test corner is 90 °C
- *Max temperature determined in accordance with 11:13 e)

 See Attachment #s for RISK MANAGEMENT FILE containing temperatures & clinical effects. Also, see instructions for use.
- * Record duration time for each test run.

CRITERIA:

- The temperatures obtained shall not exceed the specified limits.
- Thermal cutouts shall not operate. Sealing or potting compound shall not flow out:

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Datasheets - (03) Datasheets

Tested By:	Rodney Reyes	Test Verdict:	PASS
Test Date(s):	2014-10-27-2014-11-04	Amb. Temp (°C):	25
Sample No.:	2	Amb. Humld(%):	42
Instrument Code/Range:	1, 3, 5, 9, 13	Amb. Pressure (mBar):	1020
Project No.:	4786824159	UL File No.:	E146893

METHOD:

All necessary connections for the change-of-resistance measurement for the windings specified below were made, initial ambient temperature and a cold resistance of the windings were TI

Type <u>K</u> thermocouples were placed at the locations noted below.

- The sample was placed in a test corner. The test corner consisted of two walls at right angles, [and] [a floor] [and] [a ceiling], all of dull black painted plywood of 20 mm thickness. The linear dimensions of the test corner were at least 115 percent of the linear dimensions of the unit. The unit was positioned [as near to the walls as possible] [on one wall as near as possible to the other wall] and to the [floor] [ceiling] [on the ceiling as near to the walls as possible] [suspended in its normal position].
- [X] The sample was positioned as in normal use. The unit was connected and operated as specified in Table 11.
- Hand-held equipment was suspended in _
- 1.1 Equipment normally used on a floor or a table was placed as [] as near to [] _____in/mm from the walls as possible.
- Equipment normally fixed to a wall was mounted on one of the walls, [] as near to [] _____in/mm from the other wall and to the floor or celling as is likely to occur in NOKMAL U.SE. 1.1
- 1.1 Equipment normally fixed to a celling was fixed to the celling as near to the walls as is likely to occur in NORMALUSE.
- [] Other equipment was tested in the position of NORMAL USE: _
- 13 Equipment intended for installation in a cabinet or wall was built in as required by installation instructions, using dull black painted plywood walls, 10 mm thick when representing cabinet walls if the installation instructions so specify and 20 mm thick when representing building walls.
- Rechargeable batteries /battery packs were completely discharged at the beginning of the test.

The Test Duration was recorded.

Thermal Stabilization

- 11 For ME EQUIPMENT Intended for non-CONTINUOUS OPERATION: After operating in standby/quiescent mode until THERMAL STABILITY is reached, the ME EQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for 7 h, whichever is shorter. The "on" and "off" periods for each cycle are the RATED "on" and "off"
- [X] FOR MEEQUIPMENT for CONTINUOUS OPERATION, The MEEQUIPMENT is operated until THERMAL STABILITY is reached.

THERMAL STABILITY is considered to exist only if temperatures did not increase in 1 hour by more than 2°C.

RESULTS:

viodel/Part/	Туре Но	()		CH D25 24V/18.4 Conve	A (25 DW)	24V/18.4	i0 P524: IA (250W) ection	24V/10.4	0PS24: A (250W) ection	CHD 25 24V/18 A Conve	A (250W)	24V/9.04 Convect	0P524: A (217W) Ion with ver	CH D25 24V/5.84 Convect Con	A (217W) lonwith	Remarks (Including	
dax. rated a	m blent o	perating temp T (°C):	. 5	0	- 32	0		0	5	0	5	0		0	Insulation class	
est am blen	t temp t.	(°C):		5	0		0	- 5	0	5	0	5	0	5	0	and Classification	
upply Volta	ge IV):			90 1	/AC	100	VAC	248	VAC	264	VAC	90	VAC	264	VAC	of Individual	Verdict
upply Frequ	iency (Hz	De l		. 5	0	3	0	25	0	5	0	.5	0	. 5	0	Insulating	
outy Cycle (s				-	, 1	_	->		es .				-			materials or	
est D uratlo				21	ırs		hrs	2	hrs	21	nrs .	2 hrs		2 hrs		Relative Thermal	
Model No.	Therm . No.	Thermocouple location	Limit t _{max (} °C)	Meas. tm (°C)	Corr. t _e (°C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas tm (°C)	Corr. t _{e(} *C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. im (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Index (°C))	
1	1	TAMBIENT	50.0	50	50.0	50	50.0	50	50.0	50	5 0.0	50	50.0	50	50.0		Pass
1	2	FS1 BODY	125.0	91	91.0	83	83.0	65	65.0	66	66.0	86	86.0	68	68.0		Pass
1	3	LI COIL	130.0	99	99.0	90	90.0	69	69.0	70	70.0	93	93.0	72	72.0		Pass
F	4	L2 COIL	130.0	111	111.0	105	105.0	79	79.0	79	79.0	109	109.0	84	84.0		Pass
1	. 5	C64 BODY	105.0	82	82.0	79	79.0	70	70.0	71	71.0	88	88.0	76	76.0		Pass
1	6	OPTO 1 BODY	105.0	87	87.0	86	86.0	72	72.0	72	72.0	84	84.0	75	75.0		Pass
1	7	PCB @ TR5,D5	130.0	108	108.0	104	104.0	84	84.0	84	84.0	118	118.0	94	94.0		Pass
1	В	D24 BODY	140.0	119	119.0	113	113.0	86	B6.0	86	8 6.0	122	122.0	95	95.0		Pass
1	9	L4 COIL	130.0	103	103.0	100	100.0	79	79.0	77	77.0	107	107.0	85	85.0		Pass
1	10	L3 COIL	130.0	113	113.0	110	110.0	83	B3 .0	82	82.0	118	118.0	92	92.0		Pass
Î	11	L5 COIL	130.0	105	105.0	104	104.0	101	101.0	102	102.0	102	102.0	96	96.0		Pass
1	12	PCB @ TR27	130.0	91	51.0	90	90.0	88	88.0	88	0.88	89	85.0	85	85.0		Pass
1	13	T1 COIL	130.0	103	103.0	102	102.0	99	99.0	99	99.0	99	99.0	95	95.0		Pass
1	14	T1 CORE	130.0	104	104.0	103	103.0	100	100.0	100	100.0	99	99.0	95	95.0		Pass
1	15	T2 BODY	130.0	99	99.0	98	98.0	84	84:0	83	83.0	98	98.0	90	90.0		Pass
1	16	YOO 8 ET	130.0	95	95.0	94	94.0	78	78.0	77	77.0	96	96.0	85	85.0		Pass
1	17	C34 BODY	105.0	84	84.0	83	83.0	77	77.0	77	77.0	84	84.0	79	75.0		Pass
1	18	ra coir	130.0	82	82.0	82	82.0	79	79.0	79	79.0	80	80.0	77	77.0		Pass
1	15	PBC @ TR16	130.0	90	90.0	89	89.0	89	89.0	88	88.0	87	87.0	84	84.0		Pass
1	20	CON1 BODY	105.0	71	71.0	68	68.0	59	59.0	59	59.0	.71	71.0	61	61.0		Pass

SUPPLEMENTARY INFORMATION:

- t_m = measured temperature
- t_{mm} = measureu unperature t_{mm} = aximum permitted temperature Max allowable temperature from Table 22, 23, or R M²⁴
- When thermocouples used to determine temperature of windings, temperature limits of Table 22 reduced by 10 °C. 2 Maximum allowable temperature on surfaces of test corner is 90 °C.

- **Max temperature determined in accordance with 11.1.3 e)

 **See Attachment #s for RISK MANAGEMENT FILE containing temperatures 8. clinical effects. Also, see instructions for use.
- * Record duration time for each test run.

- The temperatures obtained shall not exceed the specified limits.
 Thermal cutouts shall not operate.
 Sealing or potting compound shall not flow out.

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Datasheets - (03) Datasheets

Tested By:	Rodney Reyes	Test Verdict:	PASS
Test Date(s):	2014-11-05	Amb. Temp (°C):	2.5
Sample No.:	2	Amb. Humld(%):	42
Instrument Code/Range:	1, 3, 5, 9, 13	Amb. Pressure (mBar):	1020
Project No.:	4786824159	UL File No.:	E146893

TEMPERATURE TEST: [IEC 60 601-1, 3rd Edition, Clause 11)

METHOD:

[1] All necessary connections for the change-of-resistance measurement for the windings specified below were made, initial ambient temperature and a cold resistance of the windings were measured and recorded.

Type \underline{K} thermocouples were placed at the locations noted below.

- The sample was placed in a test corner. The test corner consisted of two walls at right angles, [and] [a floor] [and] [a celling], all of dull black painted plywood of 20 mm thickness.

 The linear dimensions of the test corner were at least 115 percent of the linear dimensions of the unit. The unit was positioned [as near to the walls as possible] [on one wall as near as possible to the other wall] and to the [floor] [celling] [on the celling as near to the walls as possible] [suspended in its normal position].
- [X] The sample was positioned as in normal use. The unit was connected and operated as specified in Table 11.
- [] Hand-held equipment was suspended in _______ in still air:
- [] Equipment normally used on a floor or a table was placed as [] as near to [] _____In/mm from the walls as possible.
- [] Equipment normally fixed to a wall was mounted on one of the walls, [] as near to [] ____in/mm from the other wall and to the floor or ceiling as is likely to occur in NORMAL U.SE.
- [] Equipment normally fixed to a celling was fixed to the celling as near to the walls as is likely to occur in NORMAL U.S.E.
- [] Other equipment was tested in the position of NORMAL USE: ______
- Equipment Intended for Installation in a cabinet or wall was built in as required by installation instructions, using dull black painted plywood walls, 10 mm thick when representing cabinet walls if the Installation instructions so specify and 20 mm thick when representing building walls.
- [] Rechargeable batteries /battery packs were completely discharged at the beginning of the test.

The Test Duration was recorded.

Thermal Stabilization

- for MEEQUIPMENT Intended for non-CONTINUOUS OPERATION: After operating in standby/quiescent mode until THERMAL STABILITY is reached, the MEEQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for 7 h, whichever is shorter. The "on" and "off" periods for each cycle are the RATEO "on" and "off" neriods:
- [X] FOR MEEQUIPMENT for CONTINUOUS OPERATION, The MEEQUIPMENT is operated until THERMAL STABILITY is reached.

RESULTS:

Model/Part/	Туре но.	6		CH D25 24V/5.2/ Conve	(125W)	24 V/5 2	0 P524: A (125W) ection	24V/4.52 Convect		CHD 25 24V/4.52 Convect Co	lon with					Remarks (Including	
Max. rated a	m blent o	perating temp T (°C):	7	0	7	0	7	0	7	0					Insulation class	
Test am blen	t temp t,	(°C):		7	0	7	0	7	0	7	0					and Classification	
supply Volta	ge (V):			98 1	VAC	264	VAC	90	VAC	264	VAC		3	9	2	of Individual	Verdict
Supply Frequ		55°		. 5	0	- 5	0	. 5	0	5	0			ř.		Insulating	
outy Cycle (s				- 1		3	-01		21						_	materials or	
Test D uratlo				21	nrs	21	hrs	2	hrs	21	irs .			-		Relative Thermal	
Model No.	Therm .	Thermocouple location	Limit t _{max (} °C)	Meas. tm (°C)	Corr. t _e (°C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Index (°C))	
1	1	TAMBIENT	70.0	70	70.0	70	70.0	70	70.0	70	70.0						Pass
1	2	FS1 BODY	125.0	84	84.0	80	80.0	82	82.0	86	86.0		38				Pass
1	3	L1 COIL	130.0	87	87.0	82	82.0	84	84.0	89	89.0						Pass
1	4	L2 COIL	130.0	96	96.0	89	89.0	91	91.0	98	98.0		0				Pass
1	5	C64 BODY	105.0	87	87.0	85	85.0	88	88.0	91	91.0						Pass
1	6	OPTO 1 BODY	105.0	88	88.0	84	84.0	84	84.0	88	8.8.0		3				Pass
1	7	PCB @ TR5,05	130.0	99	99.0	92	92.0	96	96.0	106	106.0						Pass
1	В	D24 BODY	140.0	103	103.0	93	93.0	96	96.0	107	107.0						Pass
1	9	L4 COIL	130.0	96	96.0	96	86.0	89	89.0	99	99.0						Pass
1	10	L3 COIL	130.0	101	101.0	91	91.0	94	94.0	105	105.0		0). y			Pass
1	11	L5 COIL	130.0	95	95.0	94	94.0	95	95.0	97	97.0						Pass
1	12	PCB @ TR27	130.0	90	90.0	89	89.0	90	90.0	92	92.0						Pass
1	13	T1 COIL	130.0	92	92.0	91	91.0	91	91.0	92	92.0		4				Pass
1	14	T1 CORE	130.0	93	93.0	93	93.0	92	92.0	92	92.0						Pass
1	15	T2 BODY	130.0	93	93.0	91	91.0	92	92.0	93	93.0						Pass
1	16	YDO8 ET	130.0	92	92.0	88	88.0	90	90.0	95	95.0		3	1			Pass
1	17	C14BODY	105.0	85	85.0	94	84.0	85	85.0	94	94.0		3				Pass
1	18	ra coir	130.0	84	84.0	83	83.0	84	84.0	87	87.0						Pass
18	19	PBC @ TR16	130.0	87	87.0	87	87.0	87	87.0	88	88.0		1				Pass
1	20	CON1 BODY	105.0	78	78.0	76	76.0	78	78.0	80	80.0			6			Pass

SUPPLEMENTARY INFORMATION:

- t_m = measured temperature
- $t_m = m_{\rm ext}$ currected ($t_m t_s + 40$ °C or max. RATED ambient). $t_{\rm max} = m_{\rm ext}$ more insured temperature Max allowable temperature from Table 22, 23, or R M^{2,4}
- When thermocouples used to determine temperature of windings, temperature limits of Table 22 reduced by 10 °C. 2 Maximum allowable temperature on surfaces of test corner is 90 °C.

- Max temperature determined in accordance with 11.1.3 e)

 See Attachment #s for RISK MANAGEMENT FILE containing temperatures & clinical effects. Also, see instructions for use.
- * Record duration time for each test run.

- The temperatures obtained shall not exceed the specified limits.
 Thermal cutouts shall not operate.
 Sealing or potting compound shall not flow out.

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Datasheets - (03) Datasheets

	Tested By:	Rodney Reyes	Test Verdict:	PASS
	Test Date(s):	2014-11-06	Amb. Temp (℃):	25
	Sample No.:	2	Amb. Humid(%):	42
	Instrument Code/Range:	1, 3, 5, 5, 13	Amb. Pressure (mBar):	1020
	Project No.:	4786824159	UL File No.:	E146893
ERATURE	E TEST: [IEC 60 601-1, 3rd Edition, Clau	se ii)		
HOD:				
1.0	All necessary connections for the ch measured and recorded.	ange-of-resistance measurement for the windings spe	cified below were made. Initial ambient temperature ar	nd a cold resistance of the windings wer
pe <u>K</u> th	ermocouples were placed at the locath	ons noted below.		
1.1	The linear dimensions of the test co		gles, [and] [afloor] [and] [a celling], all of duli bia s of the unit: The unit was positioned [as near to the w aas possible] [suspended in its normal position].	
1×1	The sample was positioned as in no	rmal use. The unit was connected and operated as spec	offied in Table 11.	
1.1	Hand-held equipment was suspend	ed in in still air:		
1.1	Equipment normally used on a floor	or a table was placed as [] as near to []In/mi	m from the walls as possible.	
1.1	Equipment normally fixed to a wall	was mounted on one of the walls, [] as near to []	In/mm from the other wall and to the floor or celling	as is likely to occur in NORMAL USE.
1.1	Equipment normally fixed to a cellin	ng was fixed to the celling as near to the walls as is likel	y to occur in NORMALUSE.	
1.1	Other equipment was tested in the	position of NORMAL USE:		
-1-010		in a cabinet or wall was built in as required by installat so specify and 20 mm thick when representing building	tion instructions, using dull black painted plywood walls gwalls.	, 10 mm thick when representing cable
10				
1.1	Rechargeable batteries /battery par	cks were completely discharged at the beginning of the	test.	

for MEEQUIPMENT Intended for non-CONTINUOUS OPERATION: After operating in standby/quiescent mode until THERMAL STABILITY is reached, the MEEQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for 7 h, whichever is shorter. The "on" and "off" periods for each cycle are the RATED "on" and "off"

[[]X] For MEEQUIPMENT for CONTINUOUS OPERATION, The MEEQUIPMENT is operated until THERMAL STABILITY is reached.

RESULTS:

Model/Part/	Type No.			24V/18.4 (25) Convect	0P524: A, 5V/1A 5W) lonwith tdby	24V/18.4 (25 Convec	18 P524: 14, 5V/14 5W) tlonwith itdby	24V/6.67 (16 Convect Cover	0P524: PA, 5V/1A 5W) tion with and 5V dby	(1 6. Convect	A,5V/1A 5W) Ion with and5V				i	Remarks (Including Insulation class	
wax. rated a	m blent o	perating temp T (°C):	. 5	o o	- 5	io		0	5	0			10		and Classification of Individual	Ve rdict
Test am blent	temp t,	(°C):		. 5	0		0		0	5	0			E		Insulating	Vertuitt
Supply Volta	ge (V):			90	VAC	264	VAC	9 0	VAC	264	VAC		3	1 3	9	materials or	
Supply Frequ	ency (Hz):		5	0		0	. 5	0	5	0				-	Relative Thermal	
Duty Cycle (s	on soff):			3	- 1	3);	-	Q.	- 9	- 1			1		Index (°C))	
Test D uration				21	nrs	2	hrs	2	hrs	2 1	ur.s				- 1	37.00	
Model No.	Therm.	Thermocouple location	Limit t _{max(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)		
F.	10	TAMBIENT	50.0	50	50.0	50	50.0	50	50.0	-50	50.0						Pass
16	2	FSI BODY	125.0	85	85.0	66	66.0	87	87.0	67	67.0						Pass
1	3	L1 COIL	130.0	92	92.0	70	70.0	94	94.0	72	72.0		(- /		Pass
1	4	LZ COIL	130.0	105	105.0	82	82.0	107	107.0	83	83.0						Pass
1	5	C64 BODY	105.0	79	79.0	71	71.0	81	B1.0	75.	75.0						Pass
1	6	OPTO 1 BODY	105.0	88	88.0	79	79.0	90	90.0	81	81.0		3				Pass
1	7	PCB @ TR5,D5	130.0	104	104.0	- 36	86.0	106	106.0	92	92.0		S.				Pass
1	В	D24 BODY	140.0	113	113.0	90	90.0	115	115.0	92	92.0)				Pass
1	9	L4 COIL	130.0	105	105.0	86	86.0	107	107.0	89	89.0		Ĭ				Pass
1	10	L3 COIL	130.0	114	114.0	92	92.0	117	117.0	95	95.0						Pass
1	11	L5 COIL	130.0	99	99.0	95	95.0	102	102.0	98	98.0						Pass
1	12	PCB @ TR27	130.0	85	85.0	83	83.0	88	88.0	86	86.0		1				Pass
1	13	T1 COIL	130.0	97	97.0	94	94.0	100	100.0	96	96.0		9				Pass
1	14	T1 CORE	130.0	99	99.0	97	97.0	101	101.0	99	59.0		ĝ.				Pass
1	15	T2 BODY	130.0	106	106.0	99	99.0	108	108.0	102	102.0						Pass
1	16	YDOB ET	130.0	101	101.0	93	93.0	103	103.0	95	95.0						Pass
1	17	G480DY	105.0	87	87.0	82	82.0	89	89.0	84	84.0		3	6 3			Pass
1	18	Fa COIF	130.0	81	81.0	78	78.0	84	84.0	81	81.0						Pass
1	19	P8C @ TR16	130.0	85	85.0	83	83.0	89	89.0	85	85.0		2	-			Pass
1	20	CON1 BODY	105.0	70 107	70.0	60	60.0	72	72.0	63 101	63.0		77				Pass
1	21	T1 COIL-SB	130.0	1.77	107.0	99 70	99.0	110	110.0	1000	101.0		2				Pass
1	22	T1 CORE-SB	130.0	77	77.0		70.0	80	80.0	73	73.0		0	1			Pass
	23	C6 BODY-5B	105.0	83	0.68	90	80.0	85	85.0	82	82.0						Pass Pass
- 30 - 4	0000000	A STATE OF THE PARTY OF THE PAR	CONTRACTOR OF		1000000		1000000		The state of the s		000000		2	E 2			Pass
1	24 25	L1 COIL-58 C14 BODY-58	130.0 125.0	81 109	81.0 109.0	79 95	75.0 95.0	84 112	84.0 112.0	80 97	8 0.0 97.0		8				

SUPPLEMENTARY INFORMATION:

 t_m = measured temperature t_s = t_m corrected (t_m = t_s + 40 °C or max. RATED ambient). t_{max} = maximum permitted temperature Max allowable temperature from Table 22, 23, or RM^{2,4}

- When thermocouples used to determine temperature of windings, temperature limits of Table 22 reduced by 10 °C.
- ³ Maximum allowable temperature on surfaces of test corner is 90 °C
- *Max temperature determined in accordance with 11.13 e)

 See Attachment #s for RISK MANAGEMENT FILE containing temperatures & clinical effects. Also, see instructions for use.
- * Record duration time for each test run.

CRITERIA:

- The temperatures obtained shall not exceed the specified limits.
- Thermal cutouts shall not operate. Sealing or potting compound shall not flow out:

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Datasheets - (03) Datasheets

	Tested By:	Rodney Reyes	Test Verdict:	PASS
	Test Date(s):	2014-11-07-2014-11-11	Amb. Temp (°C):	25
	Sample No.:	2	Amb. Humid(%):	42
	Instrument Code/Range:	1, 3, 5, 9, 13	Amb. Pressure (mBar):	1020
	Project No.:	4786824159	UL File No.:	E146893
RATURE	TEST: [IEC 60 601-1, 3rd Edition, Claus	ie 11)		
NOD:				
13	All necessary connections for the ch measured and recorded.	ange-of-resistance measurement for the winding	gs specified below were made. Initial amblent temperature a	nd a cold resistance of the windings wer
pe <u>K</u> the	ermocouples were placed at the locatio	ns noted below.		
1.1	The linear dimensions of the test co	rner were at least 115 percent of the linear dimer	ht angles, [and] [a floor]	
[x]	The sample was positioned as in nor	mal use. The unit was connected and operated a	s specified in Table 11.	
1.1	Hand-held equipment was suspende	ed in in still air.		
1.1	Equipment normally used on a floor	or a table was placed as [] as near to []	in/mm from the walls as possible.	
1.1	Equipment normally fixed to a walls	was mounted on one of the walls, [] as near to [[]In/mm from the other wall and to the floor or cellin	g as is likely to occur in NORMAL USE.
1.1	Equipment normally fixed to a cellin	gwas fixed to the celling as near to the walls as is	s likely to occur in NORMAL U.SE.	
1.1	Other equipment was tested in the	position of NORMAL USE:		
1.1		In a cabinet or wall was built in as required by ins to specify and 20 mm thick when representing bu	stallation instructions, using duli black painted plywood wall uilding walls.	s, 10 mm thick when representing cabin
	Bachargaahla hattarlar (hattan, nac	ks were completely discharged at the beginning o	of the test	
[1]	mechangeable batteries (battery pat	manage completely appearance or one or Summile		

for MEEQUIPMENT Intended for non-CONTINUOUS OPERATION: After operating in standby/quiescent mode until THERMAL STABILITY is reached, the MEEQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for 7 h, whichever is shorter. The "on" and "off" periods for each cycle are the RATED "on" and "off"

[[]X] For MEEQUIPMENT for CONTINUOUS OPERATION, The MEEQUIPMENT is operated until THERMAL STABILITY is reached.

THERMAL STABILITY is considered to exist only if temperatures did not increase in 1 hour by more than 2 °C.

RESULTS:

Model/Part/	Type No.	*		24 V/5 2A (127 Convect	0P524: , 5V/0.5A 5W} lonwith tdby	24V/5 <i>21</i> (127 Convec	10 P524: 1, 5 V/0 5A 15 W) tlon with itdby	24V/: 5V/05A Convect Cover	0P524: 3 33 A, (82.5W) tion with and 5V dby	24V/3 5V/8.5A Convect Cover	30000					Remarks (Including	
day rateda	m blant o	perating temp T (°cv	- 119	0		0	7		7	n					Insulation class and Classification	
est am blen					o .	- 72	0	2.3	0	- 2	0			E	_	of Individual	Verdi
iupply Volta		656:		1	VAC		VAC	A	VAC	264	22		33	E .	9	Insulating	
Supply Frequ		W.			0	(5)700	0		0		0		-	<u> </u>		materials or	
	2,513					_	.u.	-							_	Relative Thermal	
Duty Cycle (_			-					-	_	Index (°C))	
Test D uratlo	n (h:m:s):				n rs	1	hrs	g)	hrs	2	10.5						
Model No.	Therm.	Thermocouple location	Limit t _{max} (°C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)		
F	1	TAMBIENT	70.0	70	70.0	70	70.0	70	70.0	70	70.0						Pas
16:	-2	FS1 BODY	125.0	84	84.0	81	81.0	84	84.0	81	81.0		7				Pas
1	3	L1 COIL	130.0	87	87.0	83	83.0	87	87.0	83	83.0		f(1		Pas
1	4	LZ COIL	130.0	98	98.0	93	93.0	98	98.0	93	93.0						Pas
1	5	C64 BODY	105.0	90	90.0	87	87.0	90	90.0	87	87.0						Pas
1	6	OPTO 1 BODY	105.0	88	88.0	85	85.0	88	88.0	85	85.0		36	F I			Pas
1	7	PCB @ TR5,D5	130.0	105	105.0	99	99.0	105	105.0	99	5 9.0		3	£ 1			Pas
1	В	D24 BODY	140.0	106	106.0	99	99.0	106	106.0	99	99.0						Pas
1	9	L4 COIL	130.0	101	101.0	95	95.0	101	101.0	95	95.0						Pas
1	10	L3 COIL	130.0	107	107.0	97	97.0	107	107.0	97	97.0		8				Pas
1	11	L5 COIL	130.0	96	96.0	94	94.0	96	96.0	94	94.0						Pas
1	12	PCB @ TR27	130.0	91	91.0	90	90.0	91	91.0	90	9 0.0						Pas
1	13	T1 COIL	130.0	92	92.0	91	91.0	92	92.0	91	91.0		17	2: 1			Pas
1	14	T1 CORE	130.0	93	93.0	92	92.0	93	93.0	92	92.0		8				Pas
1	15	T2 BODY	130.0	99	99.0	97	97.0	99	99.0	97	97.0						Pas
16	16	T3 800Y	130.0	98	98.0	95	95.0	98	98.0	95	95.0						Pas
1	17	G14BODY	105.0	89	89.0	87	87.0	89	89.0	87	87.0		8				Pas
1	18	L9 COIL	130.0	85	85.0	84	84.0	85	85.0	84	84.0		4				Pas
Y	19	PBC @ TR16	130.0	87	87.0	96	86.0	87	87.0	86	8 6.0						Pas
1	20	CON1 BODY	105.0	79	75.0	78	78.0	79	79.0	78	78.0						Pas
1	21	T1 COIL-58	130.0	100	100.0	97	97.0	100	100.0	97	57.0		8				Pas
1	22	T1 CORE-SB	130.0	84	84.0	81	81.0	87	87.0	84	84.0						Pas
1	23	C6 BODY-5B	105.0	87	87.0	96	86.0	88	88.0	86	86.0						Pas
1	24	L1 COIL-5B	130.0	86	86.0	36	86.0	88	88.0	87	87.0		8				Pas
1	25	C14 B OD Y-SB	105.0	101	101.0	96	96.0	103	103.0	98	98.0		1				Pa

SUPPLEMENTARY INFORMATION:

 t_m = measured temperature t_s = t_m corrected (t_m = t_s + 40 °C or max. RATED ambient). t_{max} = maximum permitted temperature Max allowable temperature from Table 22, 23, or RM^{2,4}

- When thermocouples used to determine temperature of windings, temperature limits of Table 22 reduced by 10 °C.
- ² Maximum allowable temperature on surfaces of test corner is 90 °C
- **Max temperature determined in accordance with 11:1.3 e)

 **See Attachment #s for RISK MANAGEMENT FILE containing temperatures & clinical effects. Also, see instructions for use.
- * Record duration time for each test run.

CRITERIA:

- The temperatures obtained shall not exceed the specified limits.
- Thermal cutouts shall not operate. Sealing or potting compound shall not flow out:

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Datasheets - (03) Datasheets

	Tested By: Rodney Reyes	Test Verdict: PA	455
	Test Date(s): 2014-10-21, 2014-10-22	Amb. Temp (℃): 25	5
	Sample No.: 3	Amb. Humld(%): 42	
	Instrument Code/Range: 1, 3, 5, 9, 13	Amb. Pressure (mBar): 10	120
	Project No.: 4786824159	UL File No.: E1	46893
MPERATURE	ETEST: [IEC 60601-1, 3rd Edition, Clause 11)		
ETHOD:			
1.1	All necessary connections for the change-of-resistance measurement for measured and recorded.	r the windings specified below were made. Initial ambient temperature and a	cold resistance of the windings were
Type <u>K</u> th	ermocouples were placed at the locations noted below.		
1.1		owalis at right angles, [and] [a floor] [[and] [a celling], all of dull black po Il linear dimensions of the unit. The unit was postioned [as near to the walls as near to the walls as possible] [suspended in its normal postion].	
[X]	The sample was positioned as in normal use. The unit was connected an	d operated as specified in Table 11.	
[1	Hand-held equipment was suspended ini	n still air:	
1.1	Equipment normally used on a floor or a table was placed as [] as near	to []In/mm from the walls as possible.	
1.1	Equipment normally fixed to a wall was mounted on one of the walls, [as near to []In/mm from the other wall and to the floor or ceiling as !	s likely to occur in NORMAL USE.
1.1	Equipment normally fixed to a celling was fixed to the celling as near to t	the walls as is likely to occur in NORMALUSE.	
1.1	Other equipment was tested in the position of NORMAL USE:		
10	Equipment intended for installation in a cabinet or wall was built in as re walls if the installation instructions so specify and 20 mm thick when rep	equired by installation instructions, using dull black painted plywood walls, 10 oresenting building walls.	mm thick when representing cabine
[1	Rechargeable batteries /battery packs were completely discharged at the	e beginning of the test.	
The Test D	uration was recorded.		
Thermal St	abilization		
[]		operating in standby/quiescent mode until THERMALSTABILITY is reached, the achieved, or for 7 h, whichever is shorter. The "on" and "off" periods for each	

[[]X] FOR ME EQUIPMENT for CONTINUOUS OPERATION, The ME EQUIPMENT IS OPERATED UNTIl THERMAL STABILITY IS reached.

RESULTS:

Model/Part/	Туре н о.	()		CH D25 48V/5.2/ Conve	(250W)	48 V/5 2	0 PS48: 4 (250W) ection	48V/52	0P548: 4 (250W) ection	48V/5.2	i0PS48 : 4 (25 0W) ection	48V/452 Convect	10P548: (A (217W) (lon with ver	48V/4.52 Convect	0 PS48: A (2 17W) lonwith ver	Remarks (Including	
Max. rated a	m blent c	perating temp T (°C):	5	0	9	0		0		0		0		0	Insulation class	
Test am blen	t temp t.	(°C):			0	5	0	5	0	5	0	- 5	D	5	0	and Classification	
Supply Volta	ge (V):			90	VAC	100	VAC	248	VAC	264	VAC	90	VAC	264	VAC	of Individual	Verdict
Supply Frequ		Se:		- 5		35	0	- 5	0	5	0	2.5	10	. 5	0	Insulating	
Duty Cycle (s				1.00			-0)			-		-		-	-	materials or	
Test D uratlo				21	105	21		2	hrs	21	hrs	- 2	hrs	2	105	Relative Thermal	
Model No.	Therm.	Thermocouple location	Limit t _{max (} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} *C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _e °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Index (°C))	
1	1	TAMBIENT	FIER	50	50.0	50	50.0	50	50.0	50	5 0.0	50	50.0	50	50.0		Pass
1	2	FS1 BODY	125.0	96	96.0	90	90.0	68	68.0	68	68.0	85	85.0	67	67.0		Pass
1	3	LI COIL	130.0	99	99.0	93	93.0	70	70.0	70	70.0	97	97.0	72	72.0		Pass
1	4	L2 COIL	130.0	107	107.0	99	99.0	78	78.0	78	78.0	1.12	112.0	84	84.0		Pass
1	5	C64 BODY	105.0	83	83.0	80	88.0	70	70.0	70	7 0.0	93	93.0	78	78.0		Pass
1	6	OPTO 1 BODY	105.0	87	87.0	85	85.0	78	78.0	77	77.0	85	85.0	76	76.0		Pass
1	7	PCB @ TR5,D5	130.0	109	109.0	101	101.0	83	0.68	83	83.0	122	122.0	93	93.0		Pass
1	В	D24 B OD Y	140.0	117	117.0	108	188.0	86	B6:0	86	86.0	96	96.0	79	79.0		Pass
1	9	L4 COIL	130.0	101	101.0	96	96.0	79	79.0	78	78.0	103	103.0	83	83.0		Pass
1	10	L3 COIL	130.0	110	110.0	104	104.0	83	D. E8	81	81.0	106	106.0	96	86.0		Pass
1	11	L5 COIL	130.0	107	107.0	106	106.0	102	102.0	103	103.0	107	107.0	102	102.0		Pass
1	12	PCB @ TR27	130.0	100	100.0	100	1.00.0	98	98.0	98	98.0	99	99.0	96	96.0		Pass
1	13	T1 COIL	130.0	109	109.0	109	109.0	108	108.0	108	108.0	106	106.0	105	105.0		Pass
1	14	T1 CORE	130.0	1 19	119.0	118	118.0	116	116.0	116	116.0	108	108.0	106	106.0		Pass
1	15	T2 BODY	130.0	96	96.0	95	95.0	91	91.0	91	91.0	97	57.0	91	91.0		Pass
1	16	T3 BODY	130.0	87	87.0	36	86.0	81	81.0	80	80.0	88	88.0	81	81.0		Pass
1	17	C14BODY	105.0	87	87.0	96	86.0	83	0. E8	83	0.E8	86	86.0	82	82.0		Pass
1	18	L9 COIL	130.0	88	88.0	88	88.0	86	86.0	86	86.0	86	86.0	84	84.0		Pass
1	19	PBC @ TR16	130.0	95	95.0	95	95.0	94	94.0	94	94.0	93	93.0	92	92.0		Pass
1	20	CON1 BODY	105.0	73	73.0	71	71.0	60	60.0	60	60.0	.74	74.0	63	63.0		Pass

SUPPLEMENTARY INFORMATION:

t_m = measured temperature

 t_{mm} = measureu unperature t_{mm} = aximum permitted temperature Max allowable temperature from Table 22, 23, or R M²⁴

When thermocouples used to determine temperature of windings, temperature limits of Table 22 reduced by 10 °C. 2 Maximum allowable temperature on surfaces of test corner is 90 °C.

**Max temperature determined in accordance with 11.1.3 e)

**See Attachment #s for RISK MANAGEMENT FILE containing temperatures 8. clinical effects. Also, see instructions for use.

* Record duration time for each test run.

The temperatures obtained shall not exceed the specified limits.
Thermal cutouts shall not operate.
Sealing or potting compound shall not flow out.

NOTES TO/FROM THE LAB:

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Datasheets - (03) Datasheets

	Tested By: Ro	odney Reyes		<u> </u>	Test Verdict:	PASS
	Test Date(s): 20	014-10-22,2015-03-2	6		Amb. Temp (℃):	25
	Sample No.: 3				Amb. Hum ld(%):	42
	Instrument Code/Range: 1,	3, 5, 5, 13		i A	.mb. Pressure (mBar):	
	Project No.: 47	86824159			UL File No.:	E146893
ERATURE	TEST: [IEC 60 601-1, 3rd Edition, Clause 1	.1)				
ים סאד						
13	All necessary connections for the chang measured and recorded.	e-of-resistance meas	urement for the windings	specified below were made, initial a	n blent temperature a	nd a cold resistance of the windings wer
pe <u>K</u> the	ermocouples were placed at the locations i	noted below.				
13	The sample was placed in a test corner. The linear dimensions of the test corner possible to the other wall and to the [r were at least 115 pe	ercent of the linear dimens	ions of the unit. The unit was position	ned (as near to the w	
[X]	The sample was positioned as in norma	l use. The unit was co	onnected and operated as	specifie d in Table 11.		
1.1	Hand-held equipment was suspended in	o	In still air.			
1.1	Equipment normally used on a floor or :	a table was placed as	[] as near to []In	/mm from the walls as possible.		
1.1	Equipment normally fixed to a wall was	mounted on one of t	:he walls, [] as near to []	In/mm from the other wall an	ito the floor or celling	as is likely to occur in NORMAL USE.
1.1	Equipment normally fixed to a celling w	as fixed to the celling	g as near to the walls as Is I	lkely to occur in NORMAL USE.		
1.1	Other equipment was tested in the posi	Itlen of NORMAL USE	teer Project	- F		
101	Equipment intended for installation in a walls if the installation instructions so sp				painted plywoodwalls	, 10 mm thick when representing cabin
		vara complataki disch	harred at the beginning of	*ha tart		
[]	Rechargeable batteries /battery packs v	were completely distr	marken at the neguming or	INF LEST.		

for MEEQUIPMENT Intended for non-CONTINUOUS OPERATION: After operating in standby/quiescent mode until THERMAL STABILITY is reached, the MEEQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for 7 h, whichever is shorter. The "on" and "off" periods for each cycle are the RATED "on" and "off"

[X] For MEEQUIPMENT for CONTINUOUS OPERATION, The MEEQUIPMENT is operated until THERMAL STABILITY is reached.

RESULTS:

Model/Part/	Type No.			CH D25 48V/2.64 Conve	(125W)	48 V/2 .6/	0 P548: 4 (125W) ection	48V/ (188 Convect	0P548: 2.26A .5W) lon with ver	48V/. (108 Convect	0PS48 : 2.26A .5W) Ion with ver	48V/4.17	i0P548: 'A (200W) ection	48V/4.17	0 PS48: 'A (2 00W) ection	Remarks (Including	
Max. rated a	m blent o	perating temp T (°C):	7	0	7	0	. 7	0	7	0	- 5	0	7	0	Insulation class and Classification	
Test am blent	temp t	(°C):		7	0	7	0	7	0	7.	0	1.7	0	7	0	of Individual	Verdic
supply Volta	ge (V):			(90)	/AC	100	VAC	5.01	VAC	264	VAC	50	VAC	264	WAC	Insulating	VEIGIL
Supply Frequ	iency (Hz	e e		. 5	0	5	o .		0	5	0	.5	П	- 5	0	materials or	
Duty Cycle (s	on soff	1		j ,	. 4		91	2								Relative Thermal	
Test D uratio	n (himis):			21	rrs	21	nrs	2	hrs.	2 1	nr s	2	hrs	21	hrs	Index (°C))	
Model No.	Therm.	Thermocouple location	Limit t _{max} °C)	Meas. tm (°C)	Corr, t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{<(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)		
1	1	TAMBIENT	19981	70	70.0	70	70.0	70	70.0	70	70.0	70	70.0	70	70.0		Pass
1	2	F51 BODY	125.0	87	87.0	81	81.0	85	85.0	81	81.0	105	105.0	98	98.0		Pass
1	3	LI COIL	130.0	88	88.0	82	82.0	90	90.0	85	85.0	115	115.0	114	114.0		Pass
1	4	L2 COIL	130.0	94	94.0	88	88.0	100	100.0	93	93.0	120	120.0	112	112.0		Pass
1	5	C64 BODY	105.0	86	86.0	85	85.0	92	92.0	89	89.0	99	99.0	91	91.0		Pass
1	6	OPTO 1 BODY	105.0	88	88.0	85	85.0	89	89.0	86	86.0	94	94.0	88	88.0		Pass
1	7	PCB @ TR5,D5	130.0	97	97.0	92	92.0	106	186.0	100	100.0	122	122.0	101	101.0		Pass
1	В	D24 BODY	140.0	100	100.0	94	94.0	98	98.0	94	94.0	127	127.0	105	105.0		Pass
1	9	L4 COIL	130.0	93	93.0	96	86.0	101	101.0	93	93.0	117	117.0	96	96.0		Pass
1	10	L3 COIL	130.0	98	98.0	89	89.0	104	104.0	94	94.0	108	108.0	92	92.0		Pass
18	11	L5 COIL	130.0	97	97.0	96	96.0	101	101.0	99	99.0	119	115.0	116	116.0		Pass
1	12	PCB @ TR27	130.0	95	95.0	94	94.0	98	98.0	96	96.0	110	110.0	107	107.0		Pass
1	13	T1 COIL	130.0	96	96.0	94	94.0	98	98.0	96	96.0	111	111.0	108	108.0		Pass
1	14	T1 CORE	130.0	99	99.0	98	98.0	99	99.0	97	97.0	120	12 0.0	116	116.0		Pass
1	15	T2 BODY	130.0	93	93.0	91	91.0	97	97.0	94	94.0	103	103.0	99	99.0		Pass
1	16	YDOB ET	130.0	89	89.0	96	86.0	93	93.0	90	90.0	98	58.0	92	92.0		Pass
1	17	C34BODY	105.0	88	88.0	96	86.0	90	50.0	88	88.0	95	95.0	93	93.0		Pass
1	18	L9 COIL	130.0	88	88.0	96	86.0	89	89.0	88	88.0	99	99.0	97	97.0		Pass
1	19	PBC @ TR16	130.0	90	90.0	89	89.0	92	92.0	90	90.0	106	106.0	104	104.0		Pass
1	20	CON1 BODY	105.0	79	79.0	76	76.0	82	82.0	79	79.0	95	95.0	89	89.0		Pass

SUPPLEMENTARY INFORMATION:

Where:

t_m = measured temperature

 $t_{\rm c}$ = $t_{\rm m}$ corrected ($t_{\rm m}$ - $t_{\rm s}$ + 40 °C or max. RATED ambient).

 t_{max} = maximum permitted temperature Max allowable temperature from Table 22, 23, or R $M^{P, \Phi}$

When the mocouples used to determine temperature of windings, temperature limits of Table 22 reduced by 16 °C.
Maximum allowable temperature on surfaces of test corner is 90 °C.

^a Max temperature determined in accordance with 11.13 e)

See Attachment # s for RISK MANAGEMENT FILE containing temperatures & clinical effects. Also, see instructions for use:

* Record duration time for each test run.

CRITERIA:

The temperatures obtained shall not exceed the specified limits. Thermal cutouts shall not operate. Sealing or potting compound shall not flow out.

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Datasheets - (03) Datasheets

	Tested By: Rodney Reyes	Test Ver dict: PASS
	Test Date(s): 2014-11-06-2014-11-10	Amb. Temp (°C): 25
	Sample No.: 3	Amb. Hum ld(%): 42
	Instrument Code/Range: 1, 3, 5, 9, 13	Amb. Pressure (mBar): 1020
	Project No.: 4786824159	UL File No.: <u>E146893</u>
PERATURE	TEST: [IEC 60 601-1, 3rd Edition, Clause 11)	
ETHOD:		
10	All necessary connections for the change-of-resistance measurement for the windl measured and recorded.	ings specified below were made. Initial am blent temperature and a cold resistance of the windings wer
Type <u>K</u> th	ermocouples were placed at the locations noted below.	
L)		ight angles, [and][afloor] [and][a celling], all of dull black painted plywood of 20 mm thickness nensions of the unit. The unit was positioned [as near to the walls as possible][on one wall as near a he walls as possible][suspended in its normal position].
[×1	The sample was positioned as in normal use. The unit was connected and operates	das specified in Table 11.
[1]	Hand-held equipment was suspended in in still air:	
1.1	Equipment normally used on a floor or a table was placed as [] as near to []	In/mm from the walls as possible.
1.1	Equipment normally fixed to a wall was mounted on one of the walls, [] as near t	o [1]In/mm from the other wall and to the floor or celling as is likely to occur in NORMAL U.SE.
1.1	Equipment normally fixed to a celling was fixed to the celling as near to the walls a	s is likely to occur in NORMAL U.SE.
[]	Other equipment was tested in the position of NORMAL USE:	
1 1	Equipment intended for installation in a cabinet or wall was built in as required by walls if the installation instructions so specify and 20 mm thick when representing	installation instructions, using dull black painted plywood walls, 10 mm thick when representing cabin building walls.
[1	Rechargeable batteries /battery packs were completely discharged at the beginnin	g of the test.
The Test D	uration was recorded.	
-6 1 -4	STATES AT THE STATE OF THE STAT	

For MEEQUIPMENT Intended for non-CONTINUOUS OPERATION: After operating in standby/quiescent mode until THERMAL STABILITY is reached, the MEEQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for 7 h, whichever is shorter. The "on" and "off" periods for each cycle are the RATED "on" and "off"

[[]X] For MEEQUIPMENT for CONTINUOUS OPERATION, The MEEQUIPMENT is operated until THERMAL STABILITY is reached.

RESULTS:

Model/Part <i>)</i>	Туре N о.			48V/5.21 (25. Convect	0P548: .A, 5V/1A 5W) lon with tdby	48V/5.2: (25 Convec	i 0 PS48: LA, 5V/1A 5 W) tlon with itdby	48V/3.33 (16 Convect Cover	0PS48: IA, 5V/1A 5W) tlon with and 5V dby	48 V/3 33 (1 6. Convect Cover	0P548: IA, 5 V/1A 5 W) Ion with and 5 V Iby					Remarks (Including Insulation class	
dax, rated a	m blent o	perating temp T (°C):	. 5	0	-	0		0	5	0			0	- 1	and Classification	
est am blen				- 5	0		0		0	5	0			E		of Individual	Ve rdi
upply Volta	ge (V):			90	VAC	264	VAC	90	VAC	264	VAC		3	3	2	Insulating materials or	
upply Frequ		Y		- 5	0		0		0	5	0			1		Relative Thermal	
uty Cycle (_	20	-	-	9				1	-	Index (°C))	
Test D uratlo				2		_	hrs	200	5 mln		5 m ln				- 1		
Model No.	Therm.	Thermocouple location	Limit t _{max} ,°C)	Meas.	Corr. t _e °C)	Meas. tm (°C)	Corr. t _e /°C}	Meas. tm (°C)	Corr.	Meas tm (°C)	Corr. t _e °C)	Meas. tm (°C)	Corr. t _e (°C)	Meas. tm (°C)	Corr.		
F.	1	TAMBIENT	- 123	50	50.0	50	50.0	50	50.0	50	50.0			-			Pas
16:	2	F51 BODY	125.0	85	85.0	65	65.0	76	76.0	67	67.0		-	-			Pas
1	3	L1 COIL	130.0	97	97.0	72	72.0	86	86.0	72	72.0		7		- 0		Pas
1	4	LZ COIL	130.0	110	110.0	84	84.0	102	102.0	87	87.0			-	-		Pas
1	5	C64 BODY	105.0	87	87.0	74	74.0	80	80.0	76	76.0			-			Pas
1	6	OPTO 1 BODY	105.0	93	93.0	83	83.0	80	80.0	75	75.0		9	1 1			Pas
1	7	PCB @ TR5,D5	130.0	108	108.0	86	86.0	94	94.0	86	86.0		8				Pas
1	В	D24 BODY	140.0	119	119.0	91	91.0	103	103.0	90	90.0						Pas
16:	90	L4 COIL	130.0	112	112.0	89	89.0	100	100.0	87	87.0		1				Pas
ï	10	L3 COIL	130.0	118	118.0	91	91.0	105	105.0	89	89.0		Ť.				Pas
1	11	L5 COIL	130.0	105	105.0	100	100.0	110	110.0	105	105.0						Pas
Y	12	PCB @ TR27	130.0	96	96.0	95	95.0	102	102.0	99	9 9.0						Pas
1	13	T1 COIL	130.0	102	102.0	102	102.0	97	97.0	95	95.0			100			Pas
1	14	T1 CORE	130.0	109	109.0	109	109.0	101	101.0	99	99.0		ĝ.				Pas
1	15	T2 BODY	130.0	110	110.0	104	104.0	101	101.0	97	97.0						Pas
1	16	T3 800Y	130.0	105	105.0	97	97.0	97	97.0	92	92.0						Pas
1	17	C34 BODY	105.0	92	92.0	88	88.0	84	84.0	82	82.0						Pas
1	18	L9 COIL	130.0	89	89.0	- 88	88.0	82	82.0	80	80.0						Pas
I .	19	PBC @ TR16	130.0	92	92.0	92	92.0	86	86.0	84	84.0						Pas
1	211	CON1 BODY	105.0	75	75.0	62	62.0	68	68.0	85	8.5.0						Pas
1	21	T1 COIL-SB	130.0	105	105.0	99	99.0	101	101.0	96	9 6.0		3				Pa:
1	22	T1 CORE-SB	130.0	101	101.0	94	94.0	98	98.0	93	93.0		J				Pa:
1	23	C6 BODY-SB	105.0	83	0.68	81	81.0	82	B2.0	80	0.0						Pas
1	24	L1 COIL-5B	130.0	84	84.0	83	83.0	83	0. E8	81	81.0		25	8			Pas
1	25	C14 B OD Y-5B	125.0	114	114.0	99	99.0	103	103.0	94	94.0		10			1	Pa

SUPPLEMENTARY INFORMATION:

 t_m = measured temperature t_s = t_m corrected (t_m = t_s + 40 °C or max. RATED ambient). t_{max} = maximum permitted temperature Max allowable temperature from Table 22, 23, or RM^{2,4}

- When thermocouples used to determine temperature of windings, temperature limits of Table 22 reduced by 10 °C.
- ² Maximum allowable temperature on surfaces of test corner is 90 °C
- **Max temperature determined in accordance with 11:1.3 e)

 **See Attachment #s for RISK MANAGEMENT FILE containing temperatures & clinical effects. Also, see instructions for use.
- * Record duration time for each test run.

CRITERIA:

- The temperatures obtained shall not exceed the specified limits.
- Thermal cutouts shall not operate. Sealing or potting compound shall not flow out:

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Datasheets - (03) Datasheets

	Tested By: Rodney Re	yes:	Test	/erdict	: PASS
	Test Date(s): 2014-11-0	7-2014-11-11	Amb. Ter	np (°C):	25
	Sample No.: 1		Amb. Hu	m ld(%)	42
	Instrument Code/Range: 1, 3, 5, 9, 1	13	Amb. Pressure	(mBar)	: 1020
	Project No.: 47868241:	59	ULI	lle No.:	E146893
MPERATURE	ETEST: [IEC 60 601-1, 3rd Edition, Clause 11)				
ETHOD:					
1.1	All necessary connections for the change-of-res measured and recorded.	lstance measurement for the wir	ndings specified below were made. Initial ambient tempe	rature a	and a cold resistance of the windings were
Type <u>K</u> th	ermocouples were placed at the locations noted be	low.			
1.1	The linear dimensions of the test corner were at	t least 115 percent of the linear o	tright angles, [and] [a floor] [and] [a ceiling], all of dimensions of the unit. The unit was positioned [as near o the walls as possible] [suspended in its normal position	to the	
[X]	The sample was positioned as in normal use. Th	e unit was connected and operat	ed as specified in Table 11.		
1.1	Hand-held equipment was suspended in	In still air	race		
1.1	Equipment normally used on a floor or a table w	vas placedas [] as near to [] _	In/mm from the walls as possible.		
1.1	Equipment normally fixed to a wall was mounte	d on one of the walls, [] as near	r to []In/mm from the other wall and to the floor	r cellin	g as is likely to occur in NORMAL USE.
1.1	Equipment normally fixed to a celling was fixed	to the celling as near to the walls	as is likely to occur in NORMALUSE.		
1.1	Other equipment was tested in the position of N	ORMAL USE:			
1.1	Equipment intended for installation in a cabinet walls if the installation instructions so specify ar		by Installation Instructions, using dull black painted plywong building walls.	odwal	ls, 10 mm thick when representing cabiner
[1	Rechargeable batterles /battery packs were con	pletely discharged at the beginn	ling of the test.		
The Test D	uration was recorded.				
Thermal St	abilization				
ΓΊ			g in standby/quiescent mode until THERMAL STABILITY ! d, or for 7 h, whichever is shorter. The "on" and "off" per		

[[]X] For MEEQUIPMENT for CONTINUOUS OPERATION, The MEEQUIPMENT is operated until THERMAL STABILITY is reached.

RESULTS:

Model/Part/	Type No.:	8		CH D25 48 V/2 .6A (127 Convect 5V S	, 5V/8.5A 5W} lonwith	48V/2.67 (127 Convec	0 PS48: k, 5 V/0 5A 5 W) tlon with tdby	48 V/I 5 V/II 5 A Convect Cover	0P548: 1.67 A, . (82.5W) tlon with and 5V dby	48V/3 5V/0.5A Convect Cover	0PS48: 1.67A, (82.5W) Ion with and 5 V iby					Remarks (Including Insulation class	
Max rateda	m blent o	perating temp T (°cv	7	0	- 5	0	7	0	7	0			10	-	and Classification	
rest am blen		COLUMN TO SERVICE ASSESSMENT		7		- 22	0	7		- 2	0			E		of Individual	Verdict
Supply Volta					VAC		VAC	37	VAC	264	22		35	1 2	9	Insulating materials or	
Supply Frequ		VC		5	2075	-	0		0		0			1		Relative Thermal	
Duty Cycle (2000			3	_	_	20.		8					-	_	Index (°C))	
Fest Duratio				21		_	hrs		5 mln	1 hr 1				t	_ #	mack (sc//	
- House						1		g)			-		-	Farmer			
Model No.	Therm.	Thermocouple location	Limit t _{max (} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	Corr. t _{e(} °C)	Meas. tm (°C)	t _{e(°C)}		
F	1	TAMBIENT	188	70	70.0	70	70.0	70	70.0	70	70.0						Pass
16	2	F51 BODY	125.0	83	83.0	80	80.0	84	84.0	83	83.0						Pass
1	3	L1 COIL	130.0	89	89.0	85	85.0	89	89.0	86	8 6.0						Pass
1	4	L2 COIL	130.0	99	99.0	94	94.0	100	100.0	96	96.0						Pass
1	5	C64 BODY	105.0	88	88.0	- 88	88.0	89	B9.0	90	9 0 .0						Pass
1	6	OPTO 1 BODY	105.0	92	92.0	89	89.0	89	89.0	87	87.0		200				Pass
1	7	PCB @ TR5,D5	130.0	99	99.0	95	95.0	98	98.0	96	96.0		S.				Pass
1	В	D24 BODY	140.0	103	103.0	97	97.0	101	101.0	98	98.0)				Pass
18	9	L4 COIL	130.0	100	100.0	93	93.0	99	99.0	94	94.0						Pass
1	10	L3 COIL	130.0	103	103.0	96	96.0	102	102.0	97	97.0		3				Pass
1	11	L5 COIL	130.0	99	99.0	98	98.0	106	106.0	105	105.0						Pass
1	12	PCB @ TR27	130.0	96	96.0	95	95.0	102	102.0	102	102.0						Pass
1	13	T1 COIL	130.0	96	96.0	95	95.0	97	97.0	96	96.0		0	2			Pass
1	14	T1 CORE	130.0	100	100.0	99	99.0	100	100.0	99	99.0		9				Pass
1	1.5	T2 BODY	130.0	102	102.0	99	99.0	101	101.0	100	100.0						Pass
1	16	YDO8 ET	130.0	99	99.0	96	96.0	99	99.0	97	57.0						Pass
1	17	G480DY	105.0	92	92.0	90	90.0	91	91.0	90	90.0		8				Pass
1	18	L9 COIL	130.0	90	90.0	89	89.0	89	89.0	88	88.0						Pass
Y	19	PBC @ TR16	130.0	90	90.0	90	90.0	91	91.0	90	90.0						Pass
1	20	CON1 BODY	105.0	80	80.0	78	78.0	81	81.0	80	80.0						Pass
1	21	T1 COIL-58	130.0	100	100.0	98	98.0	100	100.0	98	58.0		3				Pass
1	22	T1 CORE-SB	130.0	97	97.0	95	95.0	99	99.0	97	97.0						Pass
1	23	C6 BODY-SB	105.0	88	88.0	87	87.0	89	B9.0	88	0.88						Pass
1	24	L1 COIL-5B	130.0	88	88.0	88	88.0	89	89.0	89	8 9.0		8	E :			Pass
1	25	C14 B OD Y-5B	105.0	103	103.0	99	99.0	102	102.0	100	100.0		17				Pass

SUPPLEMENTARY INFORMATION:

 t_m = measured temperature t_s = t_m corrected (t_m = t_s + 40 °C or max. RATED ambient). t_{max} = maximum permitted temperature Max allowable temperature from Table 22, 23, or RM^{2,4}

- When thermocouples used to determine temperature of windings, temperature limits of Table 22 reduced by 10 °C.
- ² Maximum allowable temperature on surfaces of test corner is 90 °C
- *Max temperature determined in accordance with 11:13 e)

 See Attachment #s for RISK MANAGEMENT FILE containing temperatures & clinical effects. Also, see instructions for use.
- * Record duration time for each test run.

CRITERIA:

- The temperatures obtained shall not exceed the specified limits.
- Thermal cutouts shall not operate. Sealing or potting compound shall not flow out:

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Tested By:	Radney Reyes	Test Verdict:	PASS
Test Date(s):	2014-07-02	Amb. Temp (°C):	25
Sample No.:	1.	Amb. Humid (%):	41
Instrument Code/Range:	1, 3, 5, 9, 18	Amb. Pressure (m Bar):	1019
Praject Na.:	4786824159	UL File Na.;	E146893

ABNORMAL OPERATION AND SINGLE FAULT CONDITIONS: (IEC 60601-1, 3rd Edition, Clause 13)

METHOD

The device was operated as indicated in Table 13 until ultimate results were obtained. All final results and the duration of each test were recorded in Table 13. If required, final temperatures were measured and recorded in Table 13. The normal conditions identified in 8.1a) were also applied in the least favorable combination unless otherwise noted in Table 13.

- $[X] \qquad \text{The unit was positioned in the same way as for the Temperature Test.}$
- [X] Failure of Components (4.7) The points indicated in Table 13 were short circuited or opened, one at a time.
- [X] For each fault condition, the Dielectric Voltage Withstand Test was repeated immediately following the conclusion of the test.
- [X] For each fault condition, the Leakage Current Test was repeated immediately following the conclusion of the test.

RESULTS:

Clause	Description of single fault condition	Results observed	Hazardous situation occurred (Yes/No)	Remarks (Input Condition & Test Duration (h:m:s)	Verdic
13.2.2	Electrical single fault conditions according to 8.1:		8	5	151
13.2.2	SHORT: TR15, D/S	NB,NT,NC-Output shutdown when shart was applied. Recovered after shart was removed. Manitared for SELV, voltage was 0V < 0.2 sec. T1: 41°C, T2: 39°C, T3: 38°C, T1 Stdby: 60°C, TA: 25°C	Na	264Vac/60Hz 2h:0m:0s Leakage: NC: 180 uA SFC: 353 uA	Pass
13.2.2	SHORT: OPTO 1, P IN 1 to 2	NB,NT,NC-Unit remained stable during short. T1: 112°C, T2: 105°C, T3: 99°C, T1 Stdby: 99°C, TA: 25°C	Na	264 Vac/60Hz 2h: 0m: 0s Leakage: NC: 138 uA SFC: 264 uA	Pass
13.2.2	SHORT: OPTO 1, PIN 3 to 4	NB,NT,NC-Unit remained stable during short. T1: 34°C, T2: 41°C, T3: 42°C, T1 Stdby: 51°C, TA: 25°C	∜Na ∵	264Vac/60Hz 1h:0m:0s Leakage: NC: 191 uA SFC: 368 uA	Pass
13.2.2	SHORT: L3, PIN 1 to 2	NB,NT,NC-Unit remained stable during short. T1: 115°C,T2: 111°C, T3: 106°C, T1 Stdby: 105°C, TA: 25°C	Na	264Vac/60Hz 2h:0m:0s Leakage: NC: 131 u.A SFC: 255 u.A	Pass
13.2.2	*SHORT: CL2, (+/-)	NB,NT,NC- FS1,FS2 opened immediately. T1: 31°C, T2: 30°C, T3: 29°C, T1 Stdby: 30°C, TA: 25°C	Na	264Vac/60Hz 0h:0m:1s Leakage; NC: 138 uA SFC: 258 uA	Pass
13.2.2	SHORT; C12	NB,NT,NC-Both F51,F52 opened immediately. T1: 29°C, T2: 29°C, T3: 28°C, T1. Stdby: 29°C, TA: 25°C	Na	264Vac/60Hz 0h:0m:1s Leakage: NC: 135 uA SFC: 254 uA	Pass
13.2.2	SHORT: TR2, D/S	NB,NT,NC-Both FS1,FS2 opened immediately. T1: 30°C, T2: 29°C, T3; 29°C, T1. Stdby: 29°C, TA: 25°C	Na	264Vac/60Hz 0h:0m:1s Leakage: NC: 138 uA SFC: 257 uA	Pass

13.2.2	SHORT: D24, A/C	NB,NT,NC-Bath FS1,FS2 opened immediately. TL: 30°C, T2: 30°C, T3: 29°C, T1 Stdby: 28°C, TA: 25°C	Na	264Var/60Hz 0h:0m:1s Leakage: NC: 137 uA SFC: 255 uA	Pas
13.2.2	SHORT: TR4, D/S	NB,NT,NC-Bath FS1,FS2 apened immediately. T1: 29°C, T2: 29°C, T3: 29°C, T1 Stdbγ: 27°C, TA: 25°C	No	264Vac/60Hz 0h:0m:1s Leakage: NC: 134 uA SFC: 253 uA	Pas

SUPPLEMENTARY INFORMATION: Test conducted with dielectric test voltage at 4352 Vac.

See Table 11 for Temperatures obtained during the indicated Abnormal Operation tests:

Self-resetting thermal cutouts shall not operate.

The setting of any thermostat, thermal cutout or overload release shall not change due to heating, vibration or other causes.

The measured temperatures shall not exceed those allowable.

In each case the hazardous situations described in Clauses 13.1.2 to 13.1.4 shall not occur.
Dielectric breakdown shall not occur. See Table above or Clause 8.8.3 a test results for details.

Excessive leakage currents shall not occur. See Table above or Claue 8.7 test results for details.

NOTES TO/FROM THE LAB:

BMM 2015-03-31:Where: NB:No indication of dielectric breakdown; NT - Tissue paper remained intact; NC - Cheesecloth remained intact

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Tested By:	Rodney Reyes	Test Verdict:	PASS
Test Date(s):	2014-07-01	Amb. Temp (°C):	25
Sample No.:	1,3	Amb. Humid (%):	40
Instrument Code/Range:	1, 3, 5, 9, 18	Amb. Pressure (mBar):	1018
Project No.:	4786824159	ULFile Na.:	E146893

TRANSFORMER SHORT-CIRCUIT TEST: (IEC 60601-1, 3rd Edition, Clause 15.5.1.2)

METHOD:

- [] All necessary connections for the change-of-resistance measurements for the windings indicated in Table 15.5.1.2 and 15.5.1.3 by Change of Resistance (COR) were made.
- [X] Thermocouples were placed at all [other | locations. Initial ambient temperature and a cold resistance of the windings were measured.

The power transformer was placed [on a softwood surface] in the appliance in the same location as that of the Temperature Test | and covered with cheesecloth.

PART I - SHORT CIRCUIT

[X] For transformers with multiple secondary windings, the above was repeated for each indicated remaining winding. The sample was allowed to cool to room temperature between each test.

Dielectric Voltage Withstand Tests (DWT) were repeated immediately after removing of the short condition on the winding and replacing all fuses and resetting all manual reset devices that opened as a result of the abnormal condition.

Thermal Stability -temperatures do not increase in 1 h by more than 2 °C.

RESULTS:

		Prim	ary voltage, most ac	lverse value betwee	n 90 % to 110 % of R	ATED voltage (V) ^L :	264 Vac	5	
					RATED in	out frequency (Hz):	60 Hz		
Winding tested	Class of insul. (A, 8, E, F, or H)	BEVICE ITUSE, CITCUIT	Protective device operated (Yes/No)	Time to THERMAL STABIUTY when protective device did not operate (Min)	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (*C)	Ambient (°C)	Remarks	Verdict
CHD250PS12: T1, Pin 9 ta 12, Shart	F	Fuse: 250V/5A	No	2 hrs	180	T1: 53°C T2: 54°C T3: 54°C T1 Stdby: 58°C	25	NB,NT,NC- Main output shutdown when short was applied. Sv output remained stable. V1 output recovered after short was removed. Leakage: NC: 175UA	Pass
CHD250PS12: T2, Pin 3 to 4	F	Fuse: 250V/5A	No	2.hrs	180	T1: 116°C T2: 103°C T3: 97°C T1 Stdby: 95°C	25	NB,NT,NC- Unit remained stable during short- circuit. Leakage: NC: 130uA SFC: 256uA	Pass

CHD250P512: T3, Pin 3 ta 4	ाह	Fuse: 250v/5A	Na	2 hrs	180	T1: 115°C T2: 101°C T3: 97°C T1 Stdby: 97°C	25	NB,NT,NC,CD- TRLS, VL output was intermittent after 45 minutes. SV stdbyr em ained stable. VL output did not recovered after short was removed. Output shorted. Leakage: NC: 155uA SFC: 303uA	Pass
CHD250PS12: T1, Stdby: FL1 to FL2	F	Fuse: 25 0V/SA	Nα	2 hrs	180	T1: 103°C T2: 99°C T3: 93°C T1 Stdby: 88°C	25	NB,NT,NC- SV standby output shutdown when short was applied. Main output remained stable. SV standby output recovered after short was removed. Leakage: NC: 139uA SFC: 269uA	Pass
CHD250P548: T1, Pin 9 to 12	F	Fuse: 250v/5A	No	2 hrs	180	T1: 53°C T2: 54°C T3: 54°C T1: 5tdby: 58°C	25	NB,NT,NC- Main output shutdown when short was applied. SV output remained stable. V1 output recovered after short was removed. Leakage: NC: 1754A SFC: 345uA	Pass
CHD250P\$48: T2: Pin 3 ta 4	F.	Fuse: 250v/SA	Nα	2 hrs	180	T1: 116°C T2: 103°C T3: 97°C T1 Stdby: 95°C	25	NB,NT,NC-Unit remained stable during short- circuit. Leakage: NC: 130UA SFC: 256UA	Pass

CHD250PS48: T3: Pin 3 to 4	F	Fuse: 250V/5A	≀N a	2 hrs	180	T1: 115°C T2: 101°C T3: 97°C T1 Stdby: 97°C	25%	NB,NT,NC,CD- TR15. V1 output was intermittent after 45 minutes. SV stdby remained stable. V1 output did not recovered after short was removed. Output shorted. Leakage: NC: 155uA SFC: 303uA	Pass
CHD250PS48: T1, Pin FL1 to FL2, 5V Standby	F	Fuse: 250V/SA	No	2 hrs	180	T1; 103°C T2; 93°C T3; 93°C T1 Stdby; 88°C	25	NB,NT,NC- SV standby output shutdown when short was applied. Main output remained stable. SV standby output recovered after short was removed. Leakage: NC: 139uA SFC: 269uA	Pass

SUPPLEMENTARY INFORMATION:

[] Short circuit test completed without operation of a protective device, overload test was not required.

CRITERIA

The measured temperatures shall not exceed the maximum allowable temperatures.

There shall be no dielectric breakdown. See dielectric with stand data sheet for detailed results.

The winding shall not open under test.

NOTES TO/FROM THE LAB:

BMM 2015-03-31: Where: NB:No indication of dielectric breakdown; NT - Tissue paper remained intact; NC - Cheesecloth remained intact

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Loads on other windings between no load and their NORM AL USE load. Short circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.

Tested By:	Rodney Reyes	Test Verdict:	PASS
Test Date(s):	2014-07-01-2014-10-27	Amb. Temp (°C):	25
Sample No.:	1,3	Amb. Humid (%):	43
Instrument Code/Range:	1, 3, 5, 9, 18	Amb. Pressure (mBar):	1018
Project Na.:	4786824159	ULFile Na.:	E146893

TRANSFORMER OVERLOAD TEST: (IEC 60601-1, 3rd Edition, Clause 15.5.1.3)

METHOD

- All necessary connections for the change-of-resistance measurements for the windings indicated in Table 15.5.1.2 and 15.5.1.3 by Change of Resistance (COR) were
- [6] Thermocouples were placed at all [other | locations. Initial ambient temperature and a cold resistance of the windings were measured.

The power transformer was placed [an a rollwood revises |] in the appliance in the same location as that of the Temperature Test | and covered with cheesed oth.

PARTIL - OVERLOAD

The unit was connected to a supply specified in Table 15.5.1.3. (Between 90% and 110% of the RATED supply voltage, whichever was the least favorable and at rated frequency.)

Source of supply protected by a [20-amp | (30-amp | fire apply circuit breaker.

With the transformer initially at room temperature, each secondary windings was overloaded one at a time and the sample was operated as indicated below. The remaining secondary winding loads were adjusted to (no load) [loaded as in normal use] [loaded as specified;

- [| Windings with more than one protective device required multiple overload tests in order to fully evaluate worst-case normal use loading and fusing.
 - [] (a) Current of Protective Device Not Specified: The winding under test is loaded to its normal use load until thermal stability is reached. The load is then progressively adjusted in appropriate steps to approach the minimum current at which the protective device operates, allowing sufficient time for thermal stability to be reached. Following operation of a protective device, b) is performed:
 - (b) Windings provided with overcurrent protection were loaded to the test current specified in the table and operated for the indicated test duration. The overcurrent protector was replaced by links of negligible impedance.
 - [| If protective device that operated in a) is external to transformer it was shunted.
 - [] Fuses in Accordance with IEC 60127-1 The transformer or power supply was overloaded for 30 minutes so that the test current in the fused circuit was as indicated under Result for the specific winding which was the fuse rating multiplying the ratio in accordance with the following table.

Test Current for Transformer

Marked Value of RATED Current of protecting fuse-link [A	Ratio between test current RATED current of the fuse-link		
Upto and including 4	2.1		
Over 4 up to and including 10	1.9		
Over 10 up to and including 25	1.75		
Over 25	1,6		

- Fuses Not in Accordance with IEC 60127-1 -
 - [] The transformer or power supply was overloaded for 30 minutes so that the test current in the fused circuit was as indicated under Result for the specific winding which, was as high as possible according to the characteristics supplied by the fuse manufacturer, but does not cause the fuse to operate (30 minute clearing time current).
 - [| No 30 minute clearing-time current data is available, test current per the above table was used until thermal stability was achieved.
- [X | Other protective device -
 - Windings protected by a thermal cutout were loaded to result in stable winding temperatures reaching approximately 85 percent of the thermal cutout temperature indicated in the table. The test current was then increased by 5 percent. When steady thermal conditions were again established, the load was again increased. These steps were continued until the thermal protector operated. The highest stable temperatures were recorded in the table.
 - [X] With the transformer for a switching type power supply operating at maximum specified load, each secondary winding was individually loaded after the rectifier (before the regulators). The winding was loaded starting from rated load and gradually adjusted, once temperatures were deemed to have stabilized. This process was continued until the maximum obtainable voltampere output was reached or just before foldback.
- [X] For transformers with multiple secondary windings, the above was repeated for each indicated remaining winding. The sample was allowed to cool to room temperature between each test.

Dielectric Voltage Withstand Tests (DWT) were repeated immediately after removing of the short condition on the winding and replacing all fuses and resetting all manual reset devices that opened as a result of the abnormal condition.

Thermal Stability - temperatures do not increase in 1 h by more than 2 °C.

RESULTS:

Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)*; RATED input frequency (He); Test current just below minimum current that would activate protective device & achieve THERMAL STABILITY under method a) (A); Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was									60 Hz		
Winding tested	Class of insulation (A, B, E, F, or H)	Type of protective device used (fuse, circuit breaker)/ Ratings	Maximum allowed temp from Table 31 (*C)			Test duration		R _L	R ₂ (Ω)	Remarks	Verdic
CHD250PS12: T1:	F	Fuse: 250V/5A	180	T1: 129°C T2: 118°C T3: 110°C T1 Stdby: 110°C	25	2 hrs	24	72	9	NB,NT,NC- Unit was stable during overload. Leakage: NC: 135 uA SFC: 259 uA	Pass
CHD250P\$12; T2; Acr ass C34	F	Fuse: 250V/5A	180	T1: 114°C T2: 108°C T3: 101°C T1 Stdby: 101°C	25	2 hrs	2.1	100	Ā	NB,NT,NC- Unit was stable during overload, Leakage; NC: 133 uA SFC: 258 uA	Pass
CHD250PS12; T3; Acrass C41	F	Fuse: 250v/5A	180	T1: 123°C T2: 112°C T3: 105°C T1 Stdby: 104°C	25	2 hrs	2.1	ie .) IS	NB,NT,NC- Unit was stable during overload. Leakage: NC: 128 uA SFC: 252 uA	Pass
HD250PS12: T1 tandby: Across C6	F	Fuse: 250V/5A	180	T1: 97°C T2: 104°C T3: 99°C T1 Stdby: 102°C	25	2 hrs	1,35	æ	¥	NB,NT,NC- Unit was stable during overload. Leakage: NC: 138 uA SFC: 271 uA	Pass
HD250PS48; T1 Icross C39	F	Fuse: 250V/5A	180	T1: 130°C T2: 108°C T3: 95°C T1 Stdby: 100°C	25	2 hrs	5.95		128	NB,NT,NC- Unit was stable during overload. Leakage: NC: 140 uA SFC: 278 uA	Pass
HD250PS48; T2 cr ass C34	F	Fuse: 250v/5A	180	T1: 134°C T2: 109°C T3: 94°C T1 Stdby: 99°C	25	2 hrs	1.45	1000 1000	原	NB,NT,NC- Unit was stable during overload, Leakage: NC: 136 uA SFC: 270 uA	Pass
HD250P\$48; T3 crass C41	F	Fuse: 250V/5A	180	T1: 129°C T2: 109°C T3: 94°C T1 Stdby: 99°C	25	2 hrs	1.45) IA	NB,NT,NC- Unit was stable during overload. Leakage: NC: 130 uA SFC: 255 uA	Pass
HD250PS48: T1 tandby: Across C6	⊘ E e	Fuse: 250V/SA	180	T1: 105°C T2: 101°C T3: 92°C T1: Stdby: 111°C	25	2 hrs	1,35	le ·	*	NB,NT,NC- Unit was stable during overload, Leakage: NC: 145 uA SFC: 286 uA	Pass

SUPPLEMENTARY INFORMATION:

 $^{^{\}rm L}$ Loads on other windings between no load and their NORMAL USE load.

Time durations:
- IEC 60127-1 fuse; 30 min at current from Table 32.

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Datasheets - (03) Datasheets

- Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing time current data available, test current from Table 32 used until THERMAL STABILITY achieved.

- Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a). This portion concluded at specified time or when a second protective device opened.

The measured temperatures shall not exceed the maximum allowable temperatures.

There shall be no dielectric breakdown. See dielectric with stand data sheet for detailed results.

The winding shall not open under test. Cheesecloth shall not char.

NOTES TO/FROM THE LAB:

BMM 2015-03-31:Where: NB:No indication of dielectric breakdown; NT - Tissue paper remained intact; NC - Cheesecloth remained intact

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<u>Datasheets</u> - (03) Datasheets

END OF DATASHEET PACKAGE

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CERTIFICATE OF COMPLIANCE

Certificate Number 20150331-E146893

Report Reference E146893-D1002-1-ULCB

Issue Date 2015-03-31

Issued to: XP POWER LLC

15641 Red Hill Ave., Ste. 100 Tustin, CA 97280 USA

This is to certify that representative samples of

Component power supply

CHD250PSXXYY, (where the "XX" can be any number between 12 to 48 indicating main output voltage, "YY" can be SF or blank indicating Single Fuse), may also be provided with additional

suffixes "-S", "-C", "-L", and/or "A"

Have been investigated by UL in accordance with the

Standard(s) indicated on this Certificate.

Standard(s) for Safety: ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2

NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012)

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