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.....:	**4786488108-10**
Date of issue .....:	**2015-04-08**
Total number of pages.....:	**255**
CB Testing Laboratory.....:	**UL Camas**
Address .....:	**2600 NW Lake Road Camas, WA 98607 USA**
Applicant's name.....:	**XP Power LLC**
Address .....:	**15641 Red Hill Ave, Suite 100, Tustin, CA 92780, USA**
Test specification:	
Standard .....:	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (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

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.
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Test item description .....:	Component Switching Power Supply
Trade Mark .....:	
Manufacturer.....:	XP Power LLC Suite 100, 15641 Red Hill Ave, Tustin, CA 92780 USA
Model/Type reference.....:	XM4-MMMMM-PPSSNN, XM5-MMMMM-PPSSNN, XM7-MMMMM-PPSSNN, XM9-MMMMMM-PPSSNN, XM10-MMMMMMM-PPSSNN (Where M can be a combination of 1, 2, 3, 4, 5 or blank and a letter A-Z or blank; where P can be any number 0-9; where S can be any number 0-9; where N can be any number 0-9)
Ratings.....:	Input Rated: XM4-MMMMM-PPSSNN: ~100-240 Vac, 50/60 Hz, 5.6 A XM5-MMMMM-PPSSNN: ~100-240 Vac, 50/60 Hz, 7.0 A XM7-MMMMM-PPSSNN: ~100-240 Vac 50/60 Hz, 10.0 A XM9-MMMMMM-PPSSNN: ~100-240 Vac, 50/60 Hz, 12.7 A XM10-MMMMMMM-PPSSNN: ~100-240 Vac, 50/60 Hz, 14.2 A Output Rated: See Model Differences for module details.

Testing procedure and testing location:			
☐	**CB Testing Laboratory:**		
Testing location/ address ..... :			
☐	**Associated CB Testing Laboratory:**		
Testing location/ address ..... :			
Tested by (name + signature)..... :			
Approved by (name + signature) ..... :			
☐	**Testing procedure: TMP/CTF Stage 1:**		
Testing location/ address ..... :			
Tested by (name + signature)..... :			
Approved by (name + signature) ..... :			
☐	**Testing procedure: WMT/CTF Stage 2:**		
Testing location/ address ..... :			
Tested by (name + signature)..... :			
Witnessed by (name + signature) ..... :			
Approved by (name + signature) ..... :			
☒	**Testing procedure: SMT/CTF Stage 3 or 4:**		

Testing location/ address ..... :	XP Power LLC **15641 Red Hill Ave, Suite 100, Tustin, CA 92780, USA**	
Tested by (name + signature)..... :	Rodney Reyes	
Witnessed by (name + signature) ..... :	-	-
Approved by (name + signature) ..... :	Tac Pham	
Supervised by (name + signature)..... :	Melissa DeGuia	

List of Attachments (including a total number of pages in each attachment):

National Differences (9 pages)

Enclosures (238 pages)

Summary of testing: Unless otherwise indicated, all tests were conducted at XP POWER LLC, 15641 Red Hill Ave, Suite 100, Tustin, CA 92780, USA

Tests performed (name of test and test clause):	**Testing location:**
Power Input (4.11)	XP POWER LLC, 15641 Red Hill Ave, Suite 100, Tustin, CA 92780, USA
Humidity Conditioning (5.7)	
Working Voltage Measurements (8.5.4)	
Leakage Current Tests (8.7)	
Earth Leakage Current (8.7.4.5)	
Touch Leakage Current (8.7.4.6)	
Dielectric Strength (8.8.3)	
Temperature Test (11.1)	
Abnormal Operation Testing (13)	
Transformer Short-Circuit and Overload (15.5.1.2 and 15.5.1.3)	

Summary of compliance with National Differences

List of countries addressed: Austria, Canada, Republic of Korea, Sweden, UK, USA

☒ The product fulfils the requirements of IEC 60601-1: 2005, Third Edition with Am. 1

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. Label below is considered representative of models covered by this report.

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	Building-in
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location) :	Provide regulated power to medical devices as part of their internal construction
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) .....:	2015-01-16, 2012-03-01, 2011-12-02, 2011-11-16, 2010-09-05, 2006-10-31
Dates tests performed .....:	2015-03-16 to 2015-03-24, 2012-04-18 to 2012-06-06, 2011-12-02, 2011-11-17 to 2011-11-27, 2010-09-15 to 2010-09-28, 2007-11-29, 2007-07-09, 2007-06-19
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement.....:	Pass (P)
- test object was not evaluated for the requirement ..... :	N/E (collateral standards only)
- test object does not meet the requirement.....:	Fail (F)
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
General remarks: "(See Attachment #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. 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 ☐ comma / ☒ point is used as the decimal separator.**	
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..... :	☒ **Yes** ☐ **Not applicable**

When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies)..... :	XP POWER LLC 990 BENECIA AVE SUNNYVALE CA 94085 UNITED STATES XP POWER (KUNSHAN) LTD 230 BIN JIANG NAN RD ZHANGPU TOWN KUNSHAN JIANGSU 215300 CHINA

General product information:

The equipment is a modular ac to dc power supply for building-in. The power supply consists of an input power platform and various factory installed plug-in Output Modules. Each plug-in Output Module is either 2 or 3 slot width.

Model Differences:

All models provided with a power platform and maybe provided with various combinations of Output Modules.

Models within Model XM4, XM5, and XM7 Series are identical, with exception to the output wattage rating. and provided Plug-in output Modules. See output rating table provided below.

Model XM9 Series is similar to XM7 Series with exception to the power platform, number of Output Modules, and the output wattage rating. See output rating table provided below.

Model XM10 Series is similar to XM7 Series with exception to the power platform, number of Output Modules, and the output wattage rating. See output rating table provided below.

Model Series XM7, XM9 and XM10 may be provided with an optional fan control module to vary the fan speed based upon temperature feedback from a temperature sensor IC surface mounted to the fan control module board.

Output Rating:
XM4 Series: Max 400 W (For Input Range: 100-180 Vac) / Max 600 W (For Input Range: 180-240 Vac); up to 5 output modules provided.
XM5 Series: Max 500 W (For Input Range: 100-180 Vac) / Max 700 W (For Input Range: 180-240 Vac); up to 5 output modules provided.
XM7 Series: Max 700 W (For Input Range: 100-180 Vac) / Max 900 W (For Input Range: 180-240 Vac); up to 5 output modules provided.
XM9 Series: Max 900 W (For Input Range: 100-180 Vac) /Max 1100 W (For Input Range: 180-240 Vac); up to 6 output modules provided.
XM10 Series: Max 1000 W (For Input Range: 100-180 Vac) /Max 1200 W (For Input Range: 180-240 Vac); up to 7 output modules provided.

Output Module Ratings:
Modules 1A-1Z: 2 Slot Module, 3.3 to 60 Vdc, Max. 20 A, Max.126 W
Modules 2A-2Z: 2 Slot Module, 3.3 to 60 Vdc, Max. 40 A, Max.252 W
Modules 3A-3Z: 3 Slot Module, 3.3 to 60 Vdc, Max. 60 A, Max.420 W
Modules 4A-4Z: 4 Slot Module, 12.0 to 60 Vdc, Max 62.5A, Max 756W
Modules 5A-5Z: 2 Slot Module, Dual Output: V1=3.3 to 24 Vdc, Max. 10 A, Max, 150 W; V2 = 2.0 to 24 Vdc, Max. 10 A, Max. 150 W (V1+V2=150W Max.)
Modules 6A-6Z: 2 Slot Module, Dual Output: V1=5V dc to 24 Vdc, Max 10 A, Max, 175 W: V2=5 Vdc to 24 Vdc, Max 10 A, Max, 175 W (V1+V2=175W Max.)

Model Nomenclature for Model XM4-MMMMM-PPSSNN, XM5-MMMMM-PPSSNN, XM7-MMMMM-PPSSNN, XM9-MMMMMM-PPSSNN, and XM10-MMMMMMM-PPSSNN Series as follows:
M - indicates module designation

PPSSNN - indicates manufacturer configuration code (non-safety related)

Additional Information:

Nameplate marking provided is considered representative of all models.

CB Test certificates for components are included in Licenses Enclosure. In accordance with the current rules of CB Scheme, CB Test certificate is effective for 3 years. Recognizing NCB may challenge the CBTC when certificates are more than 3 years old.

When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.

CB Scheme investigation to IEC 60601-1, 3rd Edition issued under CBTR No. 11CA52235 and CBTC No. US-18323-UL.

This report is a reissue of CBTR Ref. No.: 4786488108-10, CB Test Certificate Ref. No. US-23802-UL, Issued 2014-08-22. Based on the conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, it has been determined that the product continues to comply with the standard.

Technical Considerations:

- The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)+AM1 (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States), CAN/CSA-C22.2 No. 60601-1 (2008) +AM1 (2014) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada), EN 60601-1 + AM1 (2013) (Medical electrical equipment Part 1: General requirements for basic safety and essential performance)
- 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; Flammable Anesthetic Mixtures Protection: Annex G
- The degree of protection against harmful ingress of water is:: Ordinary
- The mode of operation is:: Continuous
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:: No
- The product is evaluated only to the following hazards: Casualty, Fire, Shock
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- 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)

Engineering Conditions of Acceptability

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

- The component shall be considered for compliance with the Marking (clause 7) and Separation (clause 8) requirements as part of the end use application evaluation.
- This power supply was evaluated with Two MOPP between Primary and Secondary; One MOPP primary and Earth.
- The power supply was evaluated for use in 50°C ambient at Full Rated Output and 50% of the Rated Output in 70°C ambient.
- Consideration shall be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment. The end use product shall ensure that the power supply is used within its ratings.
- Repeat of leakage current testing and consideration of non-frequency weighted leakage current (clause 8.7.3) to be considered as part of the end product.

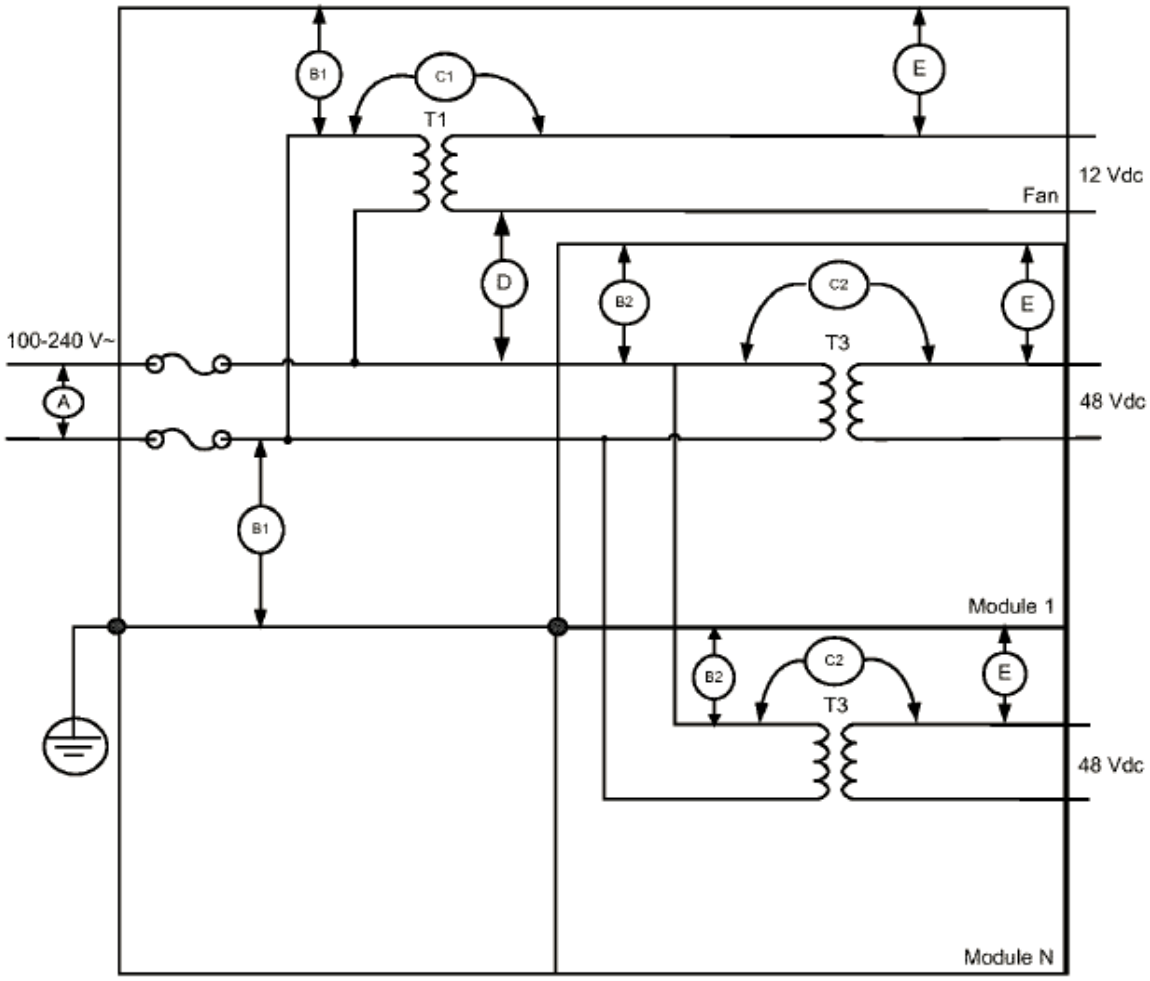
- This power supply has been evaluated as a continuous operation, ordinary equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- The end product shall ensure that the requirements related to accompanying documents, clause 7.9, are met.
- The available voltage for the secondary outputs does not exceed 25 Vac, 42.4Vpk, or 60 Vdc, under normal and single fault conditions.
- The secondary output circuits exceed 240 VA.
- The output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of the end-use equipment.
- The supply terminal (J1) is suitable for factory wiring. The output terminals and/or, connectors have not been investigated for field wiring. Terminal block (J1) is suitable for copper, wire only, 22-14 AWG, 10lbs. torque, 110°C.
- The Dielectric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal: 438 Vpk, 240 Vrms; Primary-SEC: 588 Vpk, 249.6 Vrms.
- Proper bonding to the end-product main protective earthing termination is required. Protective earthing testing shall be conducted in the end product application.
- Primary side heat sinks are floating and considered live. They should not be accessible in the end product.
- Cleaning test shall be considered as part of end product evaluation.
- The need for Marking Durability and Marking Legibility Testing shall be considered as part of the end product installation.
- Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
- 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): Platform: T1, Output Modules: T1, T2, and T3 (Class F, 155°C)
- Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation.
- The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- Compliance of adequate breaking capacity of the fuse per Clause 8.11.5 to be verified when installed in an end product.
- Printed Wiring Board rated 130°C.
- . For Model XM4 Series, the maximum continuous output power shall not to exceed 400 W for input voltages 100-180 Vac or 600 W when the supply voltage is 180-240 Vac, when used with any combination of output modules.
- For Model XM5 Series, the maximum continuous output power shall not to exceed 500 W for input voltages 100-180 Vac or 700 W when the supply voltage is 180-240 Vac, when used with any combination of output modules.
- For Model XM7 Series, the maximum continuous output power shall not to exceed 700 W for input voltages 100-180 Vac or 900 W when the supply voltage is 180-240 Vac, when used with any combination of output modules.
- For Model XM9 Series, the maximum continuous output power shall not to exceed 900 W for input voltages 100-180 Vac or 1100 W when the supply voltage is 180-240 Vac, when used with any combination of output modules.
- For Model XM10 Series, the maximum continuous output power shall not to exceed 1000 W for input voltages 100-180 Vac or 1200 W when the supply voltage is 180-240 Vac, when used with , any

combination of output modules.

- End product Risk Management to consider acceptability of automatic resetting thermal switch.
- Protective Earthing Test (Clause 8.6.4) was conducted at 30A. The need for additional Protective Earthing Test at 40A shall to be determined as part of end product evaluation.

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

INSULATION DIAGRAM



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

TABLE: INSULATION DIAGRAM		P
Pollution degree ..... :	2	—
Overvoltage category ..... :	II	—
Altitude..... :	3000m	—
Additional details on parts considered as applied parts ..... :	☒ None ☐ Areas _____ (See Clause 4.6 for details)	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			V_{rms}	V_{pk}					
A	BOP	IIIb	243	350	3	1.6	6.4	6.4	
B1	1 MOPP	IIIb	240*	438	4	2.5	6.4	6.4	For Model XM7 Series Platform: Aa1, Primary to Earth (Switching FET, D3-2 to TB1-2). Measurements on Model XM7 Platform represent Models XM4 and XM5 Series Platforms based upon similar platform construction
B1	1 MOPP	IIIb	240*	356	4	2.5	4.2	4.2	For Model XM10 Series Platform: Aa1, Primary to Earth (TB-1-3 to TB1-2). Measurements on Model XM10 Series Platform represent Model XM9 Series Platform based upon similar

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

									platform construction
B2	1 MOPP	IIIb	240*	344	4	2.5	6.4	6.4	For Modules 1A-1Z and Modules 2A-2Z: A-a1, Primary to Earth (Module Chassis)
B2	1 MOPP	IIIb	240*	289	4	2.5	7.8	7.8	For Modules 3A-3Z: A-a1, Primary to Earth (Module Chassis)
B2	1 MOPP	IIIb	240*	212	4	2.5	29	4	For Modules 4A-4Z: Primary to Earth (P1 to Chassis)
B2	1 MOPP	IIIb	240*	342	4	2.5	8.2	8.2	For Modules 5A-5Z: A-a1, Primary to Earth (Module Chassis)
C1	2 MOPP	IIIb	240*	366	8	5	8.1	8.1	For Model XM7 Series Platform: A-e, Primary to Secondary (R85 trace to D26 trace). Measurements on Model XM7 Series Platform represent Models XM4 and XM5 Series Platform based upon similar platform construction
C1	2 MOPP	IIIb	240*	350	8	5	8.2	8.2	For Model XM10 Series Platform: A-e, Primary to Secondary

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Clause	Requirement + Test	Result - Remark	Verdict

									(E2 to D25 trace). Measurements on Model XM10 represent Model XM9 Series Platform
C2	2 MOPP	IIIb	240*	588	8	5	8.3	8.3	All Modules: Across T3 (also Represents T1 and T2)
C2	2 MOPP	IIIb	240*	625	12	7	23	23	Module 4A-4Z: Across T1
C2	2 MOPP	IIIb	240*	553	8	5	8.9	8.9	Module 4A-4Z: T1 (Pin 1 to R70)
C2	2 MOPP	IIIb	240*	484	8.5	7	9.2	9.2	Module 4A-4Z: T2 Primary to Secondary (Across T2)
C2	2 MOPP	IIIb	240*	447	8	5	8.5	8.5	Module 4A-4Z: T3 Primary to Secondary (Also represents T4)
C2	2 MOPP	IIIb	240*	206	8	5	8.6	5.5	Module 4A-4Z: Primary to Secondary (J3 to P2)
D	2 MOPP	IIIb	240*	-	8	5	8.1	8.1	For Model XM7 Series Platform: Primary to Secondary (Fan). Measurements on Model XM7 Series Platform represent Models XM4 and XM5 Series Platform based upon similar platform

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

									construction
D	2 MOPP	IIIb	240*	-	8	5	30.1	30.1	For Model XM10 Series Platform: Primary to Secondary (Fan). Measurements on Model XM10 represent Model XM9 Series Platform based upon similar platform construction
E	Operational	IIIb	60Vdc	-	-	-	-	-	All Modules: Secondary to Earth
Supplementary Information: * 240 Vrms based on actual working voltage lower than highest rated input voltage. PRI = Primary, SEC = Secondary, BOP = Between Opposite Polarity, GND = Ground									

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

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