




Test Report issued under the responsibility of:






NCB TÜV SÜD PSB Pte Ltd
15 International Business Park,
TÜV SÜD @ IBP, Singapore 609937



PSB Singapore

TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1: General requirements for basic safety and essential performance
Report Number : 7191275605-EEC21
Date of issue : 09 June 2022
Total number of pages : 229
Name of Testing Laboratory : TÜV SÜD PSB Pte Ltd
preparing the Report : 15 International Business Park, TÜV SÜD @ IBP, Singapore 609937
Applicant's name : XP Power LLC
Address : 15641 Red Hill Ave., Suite 100, Tustin, CA 92780 USA
Test specification:
Standard : IEC 60601-1:2005, AMD1:2012
Test procedure : CB Scheme
Non-standard test method : N/A
TRF template used : IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No. : IEC60601\_1S
Test Report Form(s) Originator : UL(US)
Master TRF : 2020-12-17
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<b>Test item description</b> ..... :	AC-DC Power Supply
<b>Trade Mark(s)</b> ..... :	
<b>Manufacturer</b> ..... :	XP Power LLC 15641 Red Hill Ave., Suite 100, Tustin, CA 92780 USA
<b>Model/Type reference</b> ..... :	MCE40US03; MCE40US05; MCE40US09; MCE40US12; MCE40US15, MCE40US24; MCE40US48 MCE40US03-P; MCE40US05-P; MCE40US09-P; MCE40US12-P; MCE40US15-P, MCE40US24-P; MCE40US48-P
<b>Ratings</b> ..... :	Input: i) 100-240V~, 0.60-0.25A, 50/60Hz (for models MCE40US03 and MCE40US03-P only)  ii) 100-240V~, 0.80-0.32A, 50/60Hz (for models other than MCE40US03 and MCE40US03-P)  Output: MCE40US03, MCE40US03-P: 3.3VDC, 9.10A; MCE40US05, MCE40US05-P: 5VDC, 8.00A; MCE40US09, MCE40US09-P: 9VDC, 4.44A; MCE40US12, MCE40US12-P: 12VDC, 3.33A; MCE40US15, MCE40US15-P: 15VDC, 2.66A; MCE40US24, MCE40US24-P: 24VDC, 1.66A MCE40US48, MCE40US48-P: 48VDC, 0.82A

<b>Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):</b>		
<input checked="" type="checkbox"/>	<b>CB Testing Laboratory:</b>	TÜV SÜD PSB Pte Ltd
<b>Testing location/ address.....:</b>		15 International Business Park, TÜV SÜD @ IBP, Singapore 609937
<b>Tested by (name, function, signature).....:</b>		Yeo Eng Teong, Tester 
<b>Approved by (name, function, signature)....:</b>		Yeoh Wei Yee, Reviewer 
<hr/>		
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 1:</b>	
<b>Testing location/ address.....:</b>		
<b>Tested by (name, function, signature).....:</b>		
<b>Approved by (name, function, signature)....:</b>		
<hr/>		
<input checked="" type="checkbox"/>	<b>Testing procedure: CTF Stage 2:</b>	XP Power Limited
<b>Testing location/ address.....:</b>		i) 401 Commonwealth Drive, Haw Par Technocentre Lobby B, #02-02 Singapore 149598  ii) 19 Tai Seng Avenue, #07-01, Singapore 534054
<b>Tested by (name + signature) .....</b>		Lim Nixon, Tester 
<b>Witnessed by (name, function, signature)..:</b>		Yeo Eng Teong, Witness 
<b>Approved by (name, function, signature)....:</b>		Yeoh Wei Yee, Reviewer 
<hr/>		
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 3:</b>	
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 4:</b>	
<b>Testing location/ address.....:</b>		
<b>Tested by (name, function, signature).....:</b>		
<b>Witnessed by (name, function, signature)..:</b>		
<b>Approved by (name, function, signature)....:</b>		
<b>Supervised by (name, function, signature) :</b>		

<p><b>List of Attachments (including a total number of pages in each attachment):</b></p> <p>Attachment 1: Photographs (5 pages)</p> <p>Attachment 2: National differences for Canada and United States to IEC 60601-1: 2005/AMD1:2012 (13 pages)</p> <p>Attachment 3: Transformer Specifications (29 pages)</p>	
<p><b>Summary of testing:</b></p>	
<p><b>Tests performed (name of test and test clause):</b></p> <p>1) All applicable tests (except the clauses in below item 2) were performed</p> <p>2) Clause 7.1.3 - (Durability of marking test) Clause 8.9 - (Creepage distances and air clearances)</p> <p><b>Exceptions:</b> The following clauses were not part of the manufacturers order and therefore excluded from this testing: Clause 4.2: Risk Management Process Clause 11.7 Biocompatibility Clause 12.2, 15.1: Usability evaluations Clause 17 Electromagnetic Compatibility</p>	<p><b>Testing location:</b></p> <p>1) XP Power Limited 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598</p> <p>2) TÜV SÜD PSB Pte Ltd 15 International Business Park, TÜV SÜD @ IBP, Singapore 609937</p>
<p><b>Summary of compliance with National Differences (List of countries addressed):</b></p> <ul style="list-style-type: none"> <li>- European Union (EN) (no declared national differences)</li> <li>- Canada (CA)</li> <li>- United States (US)</li> <li>- Japan (JP)</li> </ul> <p><input checked="" type="checkbox"/> <b>The product fulfils the requirements of IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012); EN 60601-1:2006 + CORR. 1:2010 + A1:2013 + A12:2014; CAN/CSA-C22.2 No. 60601-1:14; ANSI/AAMI ES60601-1:2005/(R)2012; JIS T 0601-1:2017;</b></p>	
<p><b>Statement concerning the uncertainty of the measurement systems used for the tests</b> (may be required by the product standard or client)</p> <p><input type="checkbox"/> <b>Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:</b> <b>Procedure number, issue date and title:</b></p> <p>Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.</p> <p><input checked="" type="checkbox"/> <b>Statement not required by the standard used for type testing</b></p> <p>(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)</p>	

**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.



<b>Test item particulars .....</b>	
<b>Classification of installation and use.....</b>	Permanently Installed (For building-in)
<b>Supply Connection .....</b>	Permanently Installed (For building-in)
Device type (component/sub-assembly/ equipment/ system).....	Component
Intended use (Including type of patient, application location).....	See General Product Information and Other Remarks
Mode of operation.....	Continuous
Accessories and detachable parts included.....	None
Other options include.....	None
<b>Possible test case verdicts:</b>	
- test case does not apply to the test object.....	N/A
- test object does meet the requirement.....	P (Pass)
- test object was not evaluated for the requirement.....	N/E (collateral standards only)
- test object does not meet the requirement.....	F (Fail)
<b>Abbreviations used in the report</b>	
- normal condition.....	N.C.      - single fault condition ..... : S.F.C.
- means of Operator protection .....	MOOP      - means of Patient protection .... : MOPP
<b>Testing .....</b>	
<b>Date of receipt of test item.....</b>	11 October 2021
<b>Date (s) of performance of tests .....</b>	11 October 2021 to 07 March 2022
<b>General remarks:</b>	
"(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report.  Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	
<b>Manufacturer's Declaration per sub-clause 4.2.5 of IEC60601-1:</b>	
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.....	<input checked="" type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>Not applicable</b>

<p><b>When differences exist; they shall be identified in the General product information section.</b></p> <p><b>Name and address of factory (ies)..... :</b> 1) Dongguan Cincon Electronics Limited</p> <p style="text-align: right;">No. 1 Jing Xiang Rd., Dongcheng Foreign Trade Industrial Park, Zhushan, Dongcheng District 523128 Dongguan, People's Republic Of China</p> <p style="text-align: right;">2) Cincon Electronics Co., Ltd.</p> <p style="text-align: right;">8-1, Fu Kung Rd., Fu Hsing Park, 506 Fu Hsing Hsiang, Changhua Hsien, Taiwan</p>
<p><b>General product information and other remarks:</b></p> <p>The MCE40 series is a building-in switching mode power supply intended for use as sub-assembly part of a system. The power supply does not provide any therapeutic support.</p> <p>This power supply is evaluated for Means of Patient Protection (MOPP) only and is intended for building in with a maximum operating ambient temperature of 50°C (Full Load) and 70°C (50% Load) as specified by the manufacturer.</p> <p>The dimension of the encapsulated power supply with is 88 mm (L) x 38.1 mm (W) x 29 mm (H).</p> <p>Unless otherwise specified, all tests were conducted on unpotted sample (model: MCE40US48-P) as a representative of other models.</p> <p><b>Model Differences:</b></p> <p>All models are identical with exception to the mains transformer T1, and minor secondary components that allow for different output voltage ratings. The models name without suffix "-P" are models that are encapsulated filling with potting compound.</p> <p><b>Technical Considerations:</b></p> <p>1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:</p> <ul style="list-style-type: none"> <li>• Clause 4.3 (Essential Performance),</li> <li>• Clause 7.4 (Marking of Controls and Instruments),</li> <li>• Clause 7.5 (Safety Signs),</li> <li>• Clause 7.8 (Indicator Lights and Controls),</li> <li>• Clause 7.9 (Accompanying Documents),</li> <li>• Clause 8.4.2 (Accessible Parts and Applied Parts),</li> <li>• Clause 9 (ME Hazard),</li> <li>• Clause 10 (Radiation),</li> <li>• Clause 12 (Accuracy of Controls and Instruments and protection against Hazardous outputs),</li> <li>• Clause 14 (PEMS),</li> <li>• Clause 16 (ME Systems)</li> <li>• Clause 17 (Electromagnetic Compatibility of ME Equipment and ME Systems),</li> <li>• Risk Management was excluded from this investigation.</li> </ul>

## 2. Risk Controls/ Engineering Considerations for component power supply:

For use only in or with complete equipment where the acceptability of the combination is determined by the CB Testing Laboratory, when installed in an end-product, consideration must be given to the following:

- For Power Supplies with No RM: End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- For Power Supplies with No RM: End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1).
- For Power Supplies with No RM: End product Risk Management Process to consider the need for simultaneous fault condition testing.
- For Power Supplies with No RM: End product Risk Management Process to consider the need for different orientations of installation during testing.
- For Power Supplies with No RM with Exposure Condition outside of Humidity Range: Power Supply tested in 40°C, 93%RH. End product Risk Management Process to determine risk acceptability criteria.
- For Power Supplies with No RM and Insulating Materials: End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- For Power Supplies with No RM and Not tested with Test Corner: Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.
- For Power Supplies with No RM or Units without Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
- For Power Supplies with No RM or Units with Liquids: End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.
- For Power Supplies with No RM or Units with Indicators: End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.
- For Power Supplies with No RM or Units with Enclosures: End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply
- For Power Supplies with Thermal Cut-off and No RM: End product to determine the acceptability of risk in conjunction to the use of Thermal Cut-off and Overcurrent releases as part of the power supply
- For Power Supplies with Pre-set components and No RM: End product to determine the acceptability of risk in conjunction to the use of Pre-set controls as part of the power supply.



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

## INSULATION DIAGRAM

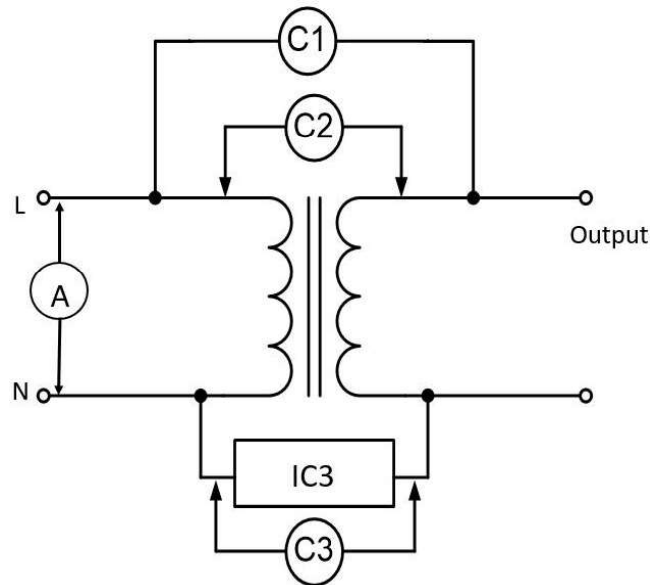


TABLE: INSULATION DIAGRAM									P
Pollution degree.....: 2									—
Overvoltage category.....: II									—
Altitude.....: < 5000m									—
Additional details on parts considered as applied parts.....: <input checked="" type="checkbox"/> None <input type="checkbox"/> Areas _____ (See Clause 4.6 for 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 <sub>rms</sub>	V <sub>pk</sub>					
A	1 MOOP	IIIb	240	346	3.0	3.0	14.0	14.0	L to N before fuse
C1	2 MOPP	IIIb	240	358	8.0	6.5	16.0	16.0	CY1 to CY2
C2	2 MOPP	IIIb	258	600	9.1	9.1	21.9	21.9	Transformer T1 (Trace across PCB)
C2	2 MOPP	IIIb	258	600	9.1	9.1	13.0	13.0	T1 primary to secondary (triple insulated wire used)
C3	2 MOPP	IIIb	240	391	8.0	6.5	8.3	8.3	Opto-coupler Pin 1 - 4

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

Supplementary Information:

Note 1: Multiplication factor of 1.48 used for Air Clearance for MOOP

Note 2: Multiplication factor of 1.29 used for Air Clearance for MOPP

**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.