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. ..... :	E321744-D1032-1/A0/C0-UL
Date of issue ..... :	2022-11-14
Total number of pages ..... :	126
Testing Laboratory ..... : Address ..... :	15 International Business Park, TÜV SÜD @ IBP, Singapore 609937
Applicant's name ..... :	XP Power
Address ..... :	15641 RED HILL AVE, SUITE 100 TUSTIN, CA, 92780 US
Test specification:	
Standard ..... :	IEC 60601-1:2005, AMD1:2012
Test procedure ..... :	UL Certification
Non-standard test method…….. :	N/A
Test Report Form No. ..... :	IEC60601_1S

General disclaimer:

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

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Test item description:	Switching power supply unit (AC-DC Power Supply)
Trade Mark:	Trademark image(s): 
Manufacturer:	Same as Applicant
Model/Type reference:	MCE10US03; MCE10US05; MCE10US09; MCE10US12; MCE10US15, MCE10US24; MCE10US48; MCE10US03-P; MCE10US05-P; MCE10US09-P; MCE10US12-P; MCE10US15-P, MCE10US24-P; MCE10US48-P
Ratings:	Input: 100-240V, 0.3-0.1A, 50/60Hz Output: MCE10US03, MCE10US03-P: 3.3VDC, 2.40A; MCE10US05, MCE10US05-P: 5VDC, 2.00A; MCE10US09, MCE10US09-P: 9VDC, 1.11A; MCE10US12, MCE10US12-P: 12VDC, 0.83A; MCE10US15, MCE10US15-P: 15VDC, 0.67A; MCE10US24, MCE10US24-P: 24VDC, 0.42A MCE10US48, MCE10US48-P: 48VDC, 0.21A

Testing procedure and testing location:		
[X] UL/DAP Testing Laboratory:		
Testing location/ address:	15 International Business Park, TÜV SÜD @ IBP, Singapore 609937	
Tested by (name, function, signature):	Brian Smith / James Gochman, Project Handler	
Approved by (name, function, signature):	Brian Burgess, Reviewer	
[ ] Testing procedure: WMT:		
Testing location/ address:		
Tested by (name, function, signature):		
Approved by (name, function, signature):		

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List of Attachments (including a total number of pages in each attachment):
Refer to Appendix A of this report. All attachments are included within this report.
Summary of testing
Tests performed (name of test and test clause): Testing location:
Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.

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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 owners of these marks.

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

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GENERAL INFORMATION	
Test item particulars(see also Clause 6):	
Classification of Installation and Use:	For building in
Supply Connection:	None
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location):	Power supply for medical equipment
Mode of Operation:	Continuous
Accessories and detachable parts included:	None
Other Options Include:	None
Testing	
Date of receipt of test item(s) .....:	2022-07-13
Dates tests performed .....:	N/A
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
- 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 Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. Throughout this report a point is used as the decimal separator.	

GENERAL PRODUCT INFORMATION:

Report Summary

The results of this investigation, including construction review, indicate that the products evaluated comply with referenced standard(s).

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

Product Description

AC-DC Power Supply

Model Differences

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.

Additional Information

N/A

Technical Considerations

- The product was investigated to the following standards:

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Main Standard(s):

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14

From Country Differences:

- USA: ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14

Additional Standards:

None

- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:
  - Clause 4.2: Rosk Management Process
  - Clause 11.7 Biocompatibility
  - Clause 12.2, 15.1: Usability evaluations
  - Clause 17 Electromagnetic Compatibility
- The following accessories were investigated for use with the product:
- The MCE10 series is a switching mode power supply intended for use as sub-assembly part of a system. The power supply does not provide any therapeutic support.

  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.

  The dimension of the encapsulated power supply with is 50.8 mm (L) x 29.2 mm (W) x 23.1 mm (H).

  Unless otherwise specified, all tests were conducted on unpotted sample (model: MCE10US48-P) as a representative of other models.

Engineering Conditions of Acceptability

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

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:

1. No essential performance has been considered.
2. The input/output connectors are not acceptable for field connections.
3. The power supply has been evaluated for use up to a max altitude 5000 meters.
4. The power supply provides the following Means of Protection:
   - 1 MOPP based upon a working voltage of 240 Vrms and 352 Vpk between Line and Neutral
   - 2 MOPP based upon a working voltage of 258 Vrms and 472 Vpk between Mains and Secondary

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5. The dielectric strength test was conducted based on the peak working voltages and means of protection above.
6. Marking legibility (Cl 7.1.2) has not been evaluated.
7. Printed Wiring Board(s) in the power supply are rated a minimum of 130 Degrees C and a minimum flame rating of V-0
8. Transformer T1 employs a R/C Class B (130 degrees C) Insulation System.
9. The power supplies covered in this report were tested on a 20 A branch circuit.
10. Testing was conducted with fuses rated 250 Vac, 10 A with an interrupt rating of 100A
11. Additional Overcurrent releases of adequate breaking capacity must be employed in the end product
12. The power supply was subjected to an elevated humidity test at 40°C, 93% RH for 168 h
13. 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.
14. The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.
15. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
16. End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
17. End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the final unit.
18. End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the final unit.

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