

Description**UL TEST REPORT AND PROCEDURE**

| | |
|------------------------------------|--|
| Standard: | 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 |
| Certification Type: | Component Recognition |
| CCN: | QQHM2 / QQHM8 |
| Complementary CCNs: | |
| Product: | AC-DC Power Supply |
| Model: | MCE40US03, MCE40US05, MCE40US09, MCE40US12, MCE40US15, MCE40US24, MCE40US48, MCE40US03-P, MCE40US05-P, MCE40US09-P, MCE40US12-P, MCE40US15-P, MCE40US24-P, MCE40US48-P |
| Rating: | 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 |
| Applicant Name and Address: | XP Power L L C 15641 RED HILL AVE, SUITE 100 Tustin, CA 92780, 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.

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability as applicable.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: James Gochman, Project Handler
Reviewed by: David Alma, Reviewer

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 MCE40 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 88 mm (L) x 38.1 mm (W) x 29 mm (H).

Unless otherwise specified, all tests were conducted on unpotted sample (model: MCE40US48-P) as a representative of other models.

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

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, filled with potting compound.

Additional Information

Testing was not considered necessary based upon previous evaluation under the CB Scheme. The CB Scheme Test Certificate SG PSB-MD-00573 and Report Ref. No. 7191275605-EEC21 dated 06/09/2022 was prepared by TÜV SÜD PSB Pte Ltd., 15 International Business Park, Singapore 609937.

Technical Considerations

- The product was investigated to the following 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:
 - All clauses related to Risk Management
 - Clause 4.3 (Essential Performance)
 - Clause 7.4 (Marking of Controls and Instruments)
 - Clause 7.5 (Safety Signs),
 - Clause 7.8 (Indicator Lights and Controls),
 - Clause 7.9 (Accompanying Documents),
 - Clause 8.4.2 (Accessible Parts and Applied Parts),
 - Clause 9 (Mechanical Hazard),
 - Clause 10 (Radiation),
 - Clause 12 (Accuracy of Controls and Instruments and protection against Hazardous outputs),
 - Clause 14 (PEMS),
 - Clause 16 (ME Systems)
- Risk Management was excluded from this investigation.

- The following accessories were investigated for use with the product: N/A
- N/A

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:

- 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. The Risk Management requirements of this standard were not addressed and must be considered in the end product investigation.
 2. No essential performance has been considered.
 3. The input/output connectors are not acceptable for field connections.
 4. The power supply has been evaluated for use up to a max altitude 5000 meters.
 5. The power supply provides the following Means of Protection:
 - 1 MOPP based upon a working voltage of 240 Vrms and 339 Vpk between Line and Neutral
 - 2 MOPP based upon a working voltage of 258 Vrms and 600 Vpk between Mains and Secondary
 6. The dielectric strength test was conducted based on the peak working voltages and means of protection above.
 7. Marking legibility (CI 7.1.2) has not been evaluated.
 8. Printed Wiring Board(s) in the power supply are rated a minimum of 130 Degrees C and a minimum flame rating of V-0
 9. Transformer T1 employs a R/C Class B (130 degrees C) Insulation System.
 10. The power supplies covered in this report were tested on a 20 A branch circuit.
 11. Testing was conducted with fuses rated 250 Vac, 10 A with an interrupt rating of 100A
 12. Additional Overcurrent releases of adequate breaking capacity must be employed in the end product
 13. The power supply was subjected to an elevated humidity test at 40°C, 93% RH for 168 h
 14. 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.
 15. The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.
 16. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
 17. End product Risk Management Process to consider the need for simultaneous fault condition testing.
 18. End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
 19. End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the final unit.
 20. End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the final unit.

| | | | |
|---|---|---|---|
| - | - | - | - |
| - | - | - | - |