UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES 60601-1:2005 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance) CSA C22.2 No. 60601-1:08 (Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance)
Certification Type:	Power Supplies, Medical and Dental
CCN:	QQHM2, QQHM8
Product:	Medical Power Supply
Model:	ECM100USXX, ECM100USXX*, ECM100US12-C, ECM100US33>2413, ECM100US12>2516, ECM100US12>2662 and ECM100USXX 3X5, where XX can be any number between 03 and 48 designating the output voltage.
***Rating:**	All Models (Except Models ECM100US12-C, ECM100US12>2516 and ECM100US12>2662): Input: 100-240 V~, 50/60 Hz, 2.2 A Output: **See Model Differences section for details** Models ECM100US12>2516 and ECM100US12>2662: Input: 100-240 V~, 50-60 Hz, 2.2 A Output: **See Model Differences section for details** Model ECM100US12-C: Input: 100-240 V~, 50-60 Hz, 1.0 A Output: 12 Vdc, 3.75 A, 45 W **Model ECM100US33-C:** **Input: 100-240 V~, 50/60 Hz, 1.4 A** **Output: 33 Vdc, 1.97 A, 65 W**
Applicant Name and Address:	XP POWER INC SUITE 150 1241 E DYER RD SANTA ANA CA 92705 UNITED STATES

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 Underwriters Laboratories Inc. ('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.

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Underwriters Laboratories Inc.

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

Component Medical Power Supply intended for use in Medical Electrical Equipment. The need for the additional testing and evaluation shall be determined in the end product evaluation. Magnetic device, transformer T1, employs an (OBJY3) electrical insulation system designated Class F.

The open frame power supply, no enclosure or chassis, is for building-in Class I or Class II end-products.

Model Differences

All models in the Model ECS100USXX 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 for up to 50°C ambient:

Model No.	Output Voltage (Vdc)	Max. Output Current		Max. Power (W)
		Convection Cooled	5 CFM	
ECM100US03	3 to 4	16.0	20.0	100
ECM100US05	4.1 to 6	16.0	20.0	
ECM100US07	6.1 to 8	11.0	14.3	
ECM100US09	8.1 to 10	8.8	11.1	
ECM100US12	10.1 to 13.5	7.5	8.3	
ECM100US15	13.6 to 17	6.0	6.6	
ECM100US18	17.1 to 21	5.0	5.5	
ECM100US24	21.1 to 26	4.1	4.1	
ECM100US28	26.1 to 31	3.5	3.5	
ECM100US33	31.1 to 33	3.0	3.0	
ECM100US36	33.1 to 42	2.7	2.7	
ECM100US48	42.1 to 54	2.1	3.0	

Model ECM100USXX 3X5 is identical to model ECM100USXX except the PWB size is larger (3x5 inches) and changes to the trace layout and secondary circuitry.

Model ECM100USXX* is identical to model ECM100USXX except for changes to the trace layout and secondary circuitry.

Model ECM100US33>2413 is identical to model ECM100US33 except the input and output connectors are reversed on the PCB.

Models ECM100US12>2516 is identical to Model ECM100US12 with exception to having an input frequency rating of 50-60Hz, instead of 50/60Hz.

Models ECM100US12>2662 is identical to Model ECM100US12 (3 X 5) with exception to having an input frequency rating of 50-60Hz, instead of 50/60Hz.

Model ECM100US12-C is identical to ECM100US12 except for provided with a cover and the input and output electrical ratings.

Model ECM100US33-C is identical to ECM100US12-C except for input and output electrical ratings.

Technical Considerations – For engineering use

- The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1:2005/C1:2009 **+ AM1 (2012)** (includes National Differences for USA); CAN/CSA-C22.2 No. 60601-1:08 **+ AM1 (2014)** (includes National Differences for Canada), EN 60601-1:2006 **+ AM1 (2013)**
- 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
- Classification of installation and use: Component, building-in
- Supply connection: OVC II
- The product is Classified 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 manufacturer's recommended ambient was considered: 50°C at Full Output Rating (with Output De-rated linearly to 50% Full Output Rating at 70°C)

Risk Controls/ Engineering Conditions of Acceptability

- The component shall be installed in compliance with the Marking (clause 7) and Separation (clause 8) requirements of the end use application.
- Consideration should 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.
- **The Legibility of Markings (7.1.2) and Durability of Markings (7.1.3) tests shall be considered in an end product investigation.**
- Dielectric and Leakage current testing should be conducted in the end product application.
- Protective Earthing Test should be conducted in the end product for Class I end-product applications.
- This power supply was evaluated with Two MOPP between primary and secondary; One MOPP primary and Earth.
- This power supply has been evaluated as with a functional earth, 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 should 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 or 60 Vdc, under normal and single fault conditions.
- The input/output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of internal wiring inside the end-use machine.
- The power supply was tested with and without an externally powered 5 cfm fan.
- Heatsinks were considered floating live and should not be connected to earth in the end-product.
- The power supply should be mounted on insulating posts when installed in a Class II end product.
- For Models ECM100USXX and ECM100USXX*, the "floating" mounting hole near Capacitor (C1) shall be mounted on insulating post or properly earthed for Class I end-product.
- For units provided with input lead connection, the acceptability of the input leads with respect to termination, spacing and isolation shall be determined as part of the end product installation.
- Capacitors (C2, C3, C22, C22A, C43) may have various capacitance ratings and options. The end-product evaluation shall make determination whether or not additional control of capacitor values are required.

Additional Information

Models ECM100USXX 3X5 and ECM100USXX are intended for building-in Class I or Class II end-products, whereas Model ECM100USXX* **and ECM100US12-C are** intended for building-in Class I end-products only.

Marking plate covers all models.

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
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Alternating current	
Direct current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.
Serial or lot or batch number	**Eight alpha numeric characters (A BB CC DDD where A = factory code; BB = year; CC=week; DDD = serial number)**
Date of manufacturer	**Provided as part of serial number**

Special Instructions to UL Representative

IEC 60417-5019, Protective earth ground symbol, should only appear on Class I power supplies.

Production-Line Testing Requirements

Test Exemptions - The following models are exempt from the indicated test

Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
All	Exempt	Test	Exempt

Solid-State Component Test Exemptions - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:

N/A

Sample and Test Specifics for Follow-Up Tests at UL

The following tests shall be conducted in accordance with the Generic Inspection Instructions

Model	Samples	Test	Test Details
N/A	N/A	N/A	N/A