UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Product:	Power supply
Model:	GCS250PSxxyy (where xx can be any number between 12 and 56 and yy is "-C", "-TF", "-EF" or blank; all "-" considered optional; may also be provided with additional suffix "SF", "S", "R" or "L")
Rating:	GCS250PSxxyy series Input: 100-240 Vac, 50/60 Hz, 3A Output: See Model Differences for details
Applicant Name and Address:	XP POWER L L C 15641 RED HILL AVE, SUITE 100 TUSTIN CA 92780 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 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.

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

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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 model covered in this report is a component power supply intended for use in Medical Electrical Equipment. It is an open frame power supply intended for building-in Class I or Class II end-products. The Double insulated symbol (symbol 9 of Table D.1 - IEC 6017-5172) is optionally provided. Earthing (ground) symbol (Symbol 6 from Table D.1- IEC 60417-5017) may only be provided for Class I power supplies.

Model Differences

All models in the Model GCS250PSXX series are identical with exception to the Mains Transformer, T1, shape of Heatsink (SEC) and secondary components/circuitry that allow for different output voltage ratings. See below for minor variations within the series.

Models GCS250PS12 to GCS250PS18 are identical to models GCS250PS24 to GCS250PS56 except for secondary output circuitry and secondary heatsink.

Models GCS250PS24 to GCS250PS36 are identical to models GCS250PS48 to GCS250PS56 except for secondary heatsink.

See below for Model Ratings:

Model GCS250PS12: Output Rated: 10.1 Vdc - 13.5 Vdc, 18.7 A Max., 225 W Max.
Model GCS250PS15: Output Rated: 13.6 Vdc - 17 Vdc, 15 A Max., 225 W Max.
Model GCS250PS18: Output Rated: 17.1Vdc - 21 Vdc, 13.9A Max, 250V Max
Model GCS250PS24: Output Rated: 21.1 Vdc - 26 Vdc, 10.4 A Max., 250 W Max.
Model GCS250PS28: Output Rated: 26.1 Vdc - 31 Vdc, 8.9 A Max., 250 W Max.
Model GCS250PS33: Output Rated: 31.1 Vdc - 33 Vdc, 7.6 A Max., 250 W Max.
Model GCS250PS36: Output Rated: 33.1 Vdc - 42 Vdc, 6.9 A Max, 250 W Max.
Model GCS250PS48: Output Rated: 42.1 Vdc - 54 Vdc, 5.2 A Max., 250 W Max.
Model GCS250PS56: Output Rated: 54.1 Vdc - 63.2 Vdc, 4.5 A Max., 250 W Max.

Units provided with suffix "C" is provided with cover.
Units provided with suffix "TF" is provided with top fan.
Units provided with suffix "EF" is provided with end fan.
Units provided without suffix "C", "TF" or "EF" is open frame (without cover).
Units provided with additional suffix "SF" to indicate single pole fusing.
Units provided with additional suffix "S" to indicate screw terminal block.
Units provided with additional suffix "L" to indicate fly leads.
Units provided with suffix “R” is remote inhibit

See Enclosure - Miscellaneous for max Power Outputs based on model, ambient, and forced air cooling.

Technical Considerations

- Classification of installation and use : For building-in
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : Component power supply for use in medical products
- Mode of operation : Continuous
- Supply connection : For building-in
- Accessories and detachable parts included : None
- Other options include : None

- The product was investigated to the following additional standards:: EN 60601-1: 2006 + CORR: 2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance), CAN/CSA-C22.2 No. 60601-1 (2008) + A1 (2014)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada), ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10 +A1:2012) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States)
- The product was not investigated to the following standards or clauses:: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)
- 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 power supply was evaluated for use in 50°C ambient at Full Rated Output and 50% of the Rated Output in 70°C ambient. (See De-rating Curve, Enclosure 7-01 for details)
- 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)
- Device has been evaluated for a 5000 m altitude.

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:

- 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.
- Repeat of leakage current testing and consideration of non-frequency weighted leakage current (clause 8.7.3e) 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 or 60 Vdc, under normal and single fault conditions.
- The output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of the end-use equipment.
- The Dielectric Strength Test conducted on this power supply was based upon a maximum working voltage of 340 Vpk, 240 Vrms for Primary-Earthed Dead Metal; 340Vpk, 240Vrms from Primary-secondary for Model GCS250PSxx series.
- 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.
- 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.
- 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): L1, L4 and T1 (Class F, 155°C)
- The PWB is rated 130°C.
- For Class I applications: Unit to be properly bonded to end product main protective earth.
- Units provided with single fuse in Line side, end product to determine the need for additional double pole fusing as part of the end product.
- Unit has been subjected to 5 day humidity condition test at 93%, 40°C.
- When installed in a Class I end product, the power supply shall be mounted in a manner that provides, at a minimum, 3.2 mm Clearance/4 mm Creepage between the primary sides of power supply and protectively earthed accessible conductive parts. In addition, when installed in a Class I end product, the protective bonding terminal of the power supply shall be reliably connected to the main protective earthing terminal of the end product.
- When installed in a Class II end product, the power supply shall be mounted in a manner that provides sufficient clearance and creepage distance between the hazardous parts and accessible conductive parts.
- Proper bonding to the Class I end-product main protective earthing termination is required (via mounting holes on the PCB), unless for Class II applications. For Class II applications the primary side mounting pads are isolated from accessible conductive chassis by Reinforced Insulation
- Forced-air cooling with cover at 7 CFM shall be provided with the end product in order to achieve maximum power output.
- Model GCS250PSxx series: Power supply provides the following MOPP (means of patient protection): two MOPP based upon a working voltage 240 Vrms, 340 Vpk between Primary to Secondary, one MOPP based upon a working voltage 240Vrms, 340 Vpk between Primary and Earth/Enclosure, one MOPP based upon a working voltage 240 Vrms between secondary and earthing trace or chassis for BF output consideration.

Additional Information

The Marking Plate provided is representative of all models covered under this Report.

Additional Standards

The product fulfills the requirements of: ANSI/AAMI ES 60601-1, 1st ed + AM1 (2012), CSA C22.2 No. 60601-1:2008 +AM1 (2014), IEC 60601-1, Edition 3.1 (2012)

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	
Supply Frequency	Rated frequency range in hertz

Power Input	Amps, VA, or Watts
7.2.2 from AM1	Serial number or lot or batch number and Date of Manufacture (provided as part of serial number)

Special Instructions to UL Representative

N/A

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 models	Exempt	Exempt	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:

Component
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

Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
N/A			