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:	Component Switching Power Supply
Model:	GCS265PSxxyy (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", or "R"). **GCS265PS36-XB0599**
Rating:	Input: 100-240 Vac, 50/60 Hz, 3A Output: See Model Differences for details
Applicant Name and Address:	XP POWER LLC 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.

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

Prepared by: Haydee Gonzalez Reviewed by: Timothy L. Gambrell

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.

Model Differences

All models in the Model GCS265PSXX series are identical with exception to the Mains Transformer, T1, and secondary components/circuitry that allow for different output voltage ratings.

Model GCS265PS36-XB0599 is identical to Model GCS265PS36 except for larger PWB to accommodate Oring Diode (Q17) Heatsink. This model not provided with an enclosure.

See ILL. 19 (Enclosure – Miscellaneous (7-01)) for max Power Outputs based on model, ambient, and forced air cooling.

See below for Model Output Ratings:

Model GCS265PS12:
V1: 10.1 Vdc - 13.5 Vdc, 20.8 A Max. (250 W Max);
V2: 5 Vdc, 3A Max (15 W Max);
(Total Power: 265 W Max)

Model GCS265PS15:
V1: 13.6 Vdc - 17 Vdc, 16.7 A Max. (250 W Max);
V2: 5Vdc, 3A Max (15 W Max);
(Total Power: 265 W Max)

Model GCS265PS18:
V1: 17.1 Vdc - 21 Vdc, 13.9 A Max. (250 W Max);
V2: 5Vdc, 3A Max (15 W Max);
(Total Power: 265 W Max)

Model GCS265PS24:
V1: 21.1 Vdc - 26 Vdc, 10.4 A Max. (250 W Max);

V2: 5Vdc, 3A Max (15 W Max);
(Total Power: 265 W Max)

Model GCS265PS28:
V1: 26.1 Vdc - 31 Vdc, 8.9 A Max. (250 W Max);
V2: 5Vdc, 3A Max (15 W Max);
(Total Power: 265 W Max)

Model GCS265PS33:
V1: 31.1 Vdc - 33 Vdc, 7.6 A Max. (250 W Max);
V2: 5Vdc, 3A Max (15 W Max);
(Total Power: 265 W Max)

Model GCS265PS36:
V1: 33.1 Vdc - 42 Vdc, 6.9 A Max. (250 W Max);
V2: 5Vdc, 3A Max (15 W Max);
(Total Power: 265 W Max)

Model GCS265PS48:
V1: 42.1 Vdc - 54 Vdc, 5.2 A Max. (250 W Max);
V2: 5Vdc, 3A Max (15 W Max);
(Total Power: 265 W Max)

Model GCS265PS56:
V1: 54.1 Vdc - 63.2 Vdc, 4.5 A Max. (250 W Max);
V2: 5Vdc, 3A Max (15 W Max);
(Total Power: 265 W Max)

Model GCS265PS36-XB0599:
V1: 36 Vdc, 6.95A (250 W Max.)
V2: 5Vdc, 3A
(Total Power: 265W 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 suffix “R” is remote inhibit.

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 : Component only for building-in
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10+A1(R2012)) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States), 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), IEC 60601-1: Edition 3.1, 2012-08, EN 60601-1: 2006 + CORR: 2010+A1 (2013) (Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- The product was not investigated to the following standards or clauses:: Electromagnetic Compatibility (IEC 60601-1-2), Biocompatibility (ISO 10993-1)
- 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 product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:: No
- 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).

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 product was submitted and evaluated for use at the maximum ambient temperature (Tma) permitted by the manufacturer's specification of: 50°C at 100% of Output Rating, 70°C at 50% of Output Rating. See ILL. 19 (Miscellaneous enclosure 7-01) Power Output Table for additional information regarding power output and the various configurations.
- The maximum continuous power supply output (Watts) relied on forced air cooling from: 7 cfm fan applied 1 inch from input side, blowing inward.
- 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.
- 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)
- 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.
- The end product shall ensure that the requirements related to accompanying documents, clause 7.9, are met.
- The input/output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of the end-use equipment.
- Power supply provides the following MOPP (means of patient protection):2 MOPP based upon a working voltage 336 Vpk, 240 Vrms between Primary to Secondary, one MOPP based upon a working voltage 352Vpk, 244 Vrms between Primary and Earth/Enclosure, and 1 MOPP based upon a working voltage 250Vac between secondary to earth trace on PWB.
- The Dielectric Strength Test conducted on this power supply was based upon a maximum working voltage of 352Vpk, 244 Vrms from Primary-Earthed Dead Metal, 336 Vpk, 240 Vrms from Primary-Secondary.
- 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, T1 and 5V

Standby-Transformer (T1) are 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.
- Unit has been subjected to 5 day humidity condition test at 93%, 40°C.
- Fans: For models with the suffix "EF", the fan provided in this sub-assembly is not intended for operator access., For models with the suffix "TF", the fan provided in this sub-assembly is provided with a fan guard to reduce the risk of operator contact with the stator.
- Heatsinks are floating and considered live. They should not be accessible in the end-product.
- Clearance spacing evaluated for 5000 m altitude. Additional consideration maybe necessary in the end-use product.
- Heating test was not conducted on unit with input/output leads. If unit is provided with input and/or output leads, then temperature on leads must be measured and cannot exceed 105°C.
- The following components require special consideration during end-product Thermal (Heating) tests due to the indicated maximum temperature measurements during component-level testing: Model GC265PS12: PCB@Q1 coil (130°C); C22 (Stand-by board) (105°C); C27 (105°C).
- An investigation of the protective bonding terminals has: Not been conducted.
- Overcurrent releases of adequate breaking capacity must be employed in the end product.

Additional Information

The clearance distances have additionally been assessed for suitability up to 5000 m elevation (1.29 correction factor as per Table 8).

Marking label is representative of all models.

Additional Standards

The product fulfills the requirements of: IEC 60601-1:2012 (AM1)

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
Serial number or lot or batch identifier	Eight alpha numeric characters (A BB CC DDD where A = factory code; BB = year; CC=week; DDD = serial number)
Date of manufacture or use by date	Provided as part of the serial 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.
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	No test	Test	No test

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