Description

UL TEST REPORT AND PROCEDURE

Standard:	AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021, CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14
Certification Type:	Component Recognition
CCN:	QQHM2 / QQHM8
Complementary CCNs:	
Product:	Component Power Supply
Model:	GCS150PSxxyy and GCS150PSxxKyy (where xx can be any number between 12 and 48 and yy is "-C", "-TF", "-EF" or blank and may be preceded by "-R"; all "-" considered optional; may also be provided with additional suffix "SF" or "S") GCS180PSxxyy(where xx can be any number between 12 and 48 and yy is "-C", "-TF", "-EF", or blank and may be preceded by "-R"; all "-" considered optional; may also be provided with additional suffix "SF" or "S")
Rating:	GCS150PSxxyy and GCS150PSxxKyy series Input: 100-240 Vac, 50/60 Hz, 1.8A Output: See Model Differences for details GCS180PSxxyy series Input: 100-240 Vac, 50/60 Hz, 2.2A Output: See Model Differences for details
Applicant Name and Address:	XP Power LLC 340 Commerce, Suite 100 Irvine, CA 92602, 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 as applicable.

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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Reviewed by: David V. Alma, Project 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 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.
Refer to the Report Modifications page for any modifications made to this report.

Model Differences

Model GCS150PSxx series and Model GCS180PSxx are identical with the exception to input ratings, power output, the shape of the Primary Heatsink, and minor differences in the PWB layout.
All models in the Model GCS150PSxx series and Model GCS180PSxx 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 Table Below. The values below are max power output with forced air cooling with a 7cfm fan at 50°C, See report enclosure Miscellaneous - (002) for Output Rating Table.

See report enclosure Miscellaneous - (001) for de-rated output values for higher ambient.
See report enclosure Miscellaneous - (002) for max Power Outputs based on model, ambient, and forced air cooling.

Units provided with suffix "R" is remote inhibit.
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 with suffix "K" can operate at full power at an ambient of 40°C.
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.

Additional Information

Marking Plates are considered representative of all models covered under this Report.
The clearance distances have additionally been assessed for suitability up to 5000 m elevation.
When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.
Manufacturer to provide up to date IEC Licenses for component licenses greater than 3 years upon request.

Technical Considerations

- The product was investigated to the following additional standards: EN 60601-1:2006, EN 60601-1:2006/A12:2014, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A2:2021
- The following additional investigations were conducted: -
- 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)·
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), Usability

- 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:

- 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, Report enclosure - (001) for details)

  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 test (Clause 8.7.3e) shall be considered in the end product application.

  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 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 Dielectric Strength Test conducted on this power supply was based upon a maximum working voltage of 353 Vpk, 250 Vrms from Primary-Earthed Dead Metal, 528 Vpk, 298 Vrms from Primary-Secondary for Models GCS180PSxx series; and 356 Vpk, 244 Vrms for Primary-Earthed Dead Metal; 509Vpk, 287Vrms from Primary-secondary for Model GCS150PSxx series.

  • The output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of the end-use equipment.

  • The maximum investigated branch circuit rating is: 20 A

  • Model GCS180PSxx series: Power supply provides the following MOPP (means of patient protection):

  o Two MOPP based upon a working voltage 298 Vrms, 528 Vpk between Primary to Secondary, one MOPP based upon a working voltage 250 Vrms, 353 Vpk between Primary and Earth/Enclosure, two MOPP based on a working voltage 48Vdc between secondary to floated earth trace on PWB for BF output consideration, one MOPP based upon a working voltage 250 Vrms between secondary and earthing trace or chassis for BF output consideration.

  • Model GCS150PSxx series: Power supply provides the following MOPP (means of patient protection):
  o Two MOPP based upon a working voltage 287 Vrms, 509 Vpk between Primary to Secondary, one MOPP based upon a working voltage 244 Vrms, 356 Vpk between Primary and Earth/Enclosure, two MOPP based upon a working voltage 48Vdc between secondary to floated earth trace on PWB for BF output consideration, one MOPP based upon a working voltage 250 Vrms between secondary and earthing trace or chassis for BF output consideration.

- For Class I applications: Unit to be properly bonded to end product main protective earth.

- 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

- 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)

- Printed Wiring Board rated 130°C.

- 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.

- Unit provided with additional suffix "-SF" are provided with only one fuse in the line side. Consideration for the need for additional fusing 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

- Unit has been subjected to 5 day (120 Hrs) humidity condition test at 93%, 40°C.