

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1:2005 (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:	Component Recognition																		
CCN:	QQHM2, QQHM8																		
Product:	Switching Power Supply																		
Model:	GSM11-10PP-104G, GSM11-10PP-108G, and GSM11-XYZ-XXXG, where X may be any number from 3 thru 28; where Y may be the letters A, B, P or T; where Z may be the letters A through Z; Models may also be followed by -XXX, where -XXX is any number from 001 to 999																		
Rating:	<p>Input: 100-240 V ac, 0.3 A, 50/60 Hz</p> <p>Output: 2.2 A or 11 W maximum output. See below for example of standard output voltage models.</p> <table style="margin-left: auto; margin-right: auto; border: none;"> <thead> <tr> <th style="text-align: left;">MODEL</th> <th style="text-align: left;">OUTPUT</th> </tr> </thead> <tbody> <tr> <td>GSM11-3</td> <td>3.3 Vdc, 2.2A</td> </tr> <tr> <td>GSM11-5</td> <td>5.1 Vdc, 2.2A</td> </tr> <tr> <td>GSM11-10PP-104G</td> <td>10 Vdc, 1.1A</td> </tr> <tr> <td>GSM11-10PP-108G</td> <td>10 Vdc, 1.1A</td> </tr> <tr> <td>GSM11-12</td> <td>12 Vdc, 0.92A</td> </tr> <tr> <td>GSM11-15</td> <td>15 Vdc, 0.74A</td> </tr> <tr> <td>GSM11-24</td> <td>24 Vdc, 0.46A</td> </tr> <tr> <td>GSM11-28</td> <td>28 Vdc, 0.4 A</td> </tr> </tbody> </table>	MODEL	OUTPUT	GSM11-3	3.3 Vdc, 2.2A	GSM11-5	5.1 Vdc, 2.2A	GSM11-10PP-104G	10 Vdc, 1.1A	GSM11-10PP-108G	10 Vdc, 1.1A	GSM11-12	12 Vdc, 0.92A	GSM11-15	15 Vdc, 0.74A	GSM11-24	24 Vdc, 0.46A	GSM11-28	28 Vdc, 0.4 A
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Applicant Name and Address:	SL POWER ELECTRONICS CORP 6050 KING DRVIE, BLDG. A VENTURA, CA 93003, 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 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.

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 Underwriters Laboratories Inc. (UL) or any authorized licensee of UL.

Prepared by: David Feusier
Underwriters Laboratories Inc.

A handwritten signature in black ink that reads "David Feusier". The signature is written in a cursive style with a large, stylized 'D' and 'F'.

Reviewed by: David Alma
Underwriters Laboratories Inc.

A handwritten signature in black ink that reads "David Alma". The signature is written in a cursive style.

Supporting Documentation – For UL Field Representative’s Use

The following documents 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

Products covered are open frame power supplies intended for building-in, to be used with Medical Electrical Equipment. Units are intended for used with Class II end-products. All models have a single DC output.

Model Differences

The GSM11-XYZ-XXXG Series, GSM11-10PP-104G, and GSM11-10PP- are Class II power supplies and differ only in secondary circuits for the different outputs.

GSM11-XYZ-XXXG, where X represents the output voltage which may be any number from 3 thru 28; Y indicates the type of input connector used which may be the letters A, B, P or T; Z indicates the type of output connector used which may be the letters A through Z; Models may also be followed by -XXX, where -XXX is any number from 001 to 999, which is used to designate value added configurations that have no impact on safety.

Models GSM11-10PP-104G, and GSM11-10PP-108G are identical to GSM11 Series units, except for output ratings, and supplementary Fuse, F1 is not provided (jumpered at that location on the PWB). Models GSM11-10PP-104G, and GSM11-10PP-108G are identical to each other, except for value added configurations that have no impact on safety.

Suffix G indicates compliance to RoHS. RoHS compliance has not been evaluated by UL.

Technical Considerations – For engineering use

The product was investigated to the following additional standards: ANSI/AAMI ES60601-1, CAN/CSA-C22.2 No. 60601-1:08, (includes National Differences for Canada), EN 60601-1: 1990 + A1:1993 + A2:1995, (except EMC limitations, EN 60601-1-2, Biocompatibility, EN 10993-1, Programmable Electronic Systems, IEC 60601-1-4)

Scope of Power Supply evaluation defers the following clauses to the be determined as part of the end product: Clause 4.2 (Risk Management), Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems)

The product is Classified only to the following hazards: Casualty, Fire, Shock

The degree of protection against harmful ingress of water is: Ordinary

Manufacturer's Recommended Ambient: 50°C

The mode of operation is: Continuous

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 anaesthetics mixture with air or oxygen or with nitrous oxide: No

Power Supply was considered Overvoltage Category II (OVCI)

Classification of installation and use : Building-in

Supply connection : Building-in

Accessories and detachable parts included in the evaluation: None

Engineering Conditions of Acceptability – For engineering use

For use only in or with complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc. When installed in an end-product, consideration must be given to the following:

- 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.
- Inductor (T1) and main Transformer (T2) are provided with a Class F (155°) insulation system
- The end product should ensure that the requirements related to accompanying documents, clause 7.9, are met.
- This power supply has been evaluated as continuous operation, ordinary equipment and has not been evaluated for use in the presence of a flammable anaesthetic mixture with air, oxygen, or nitrous oxide. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- 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.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- Single fault testing was conducted without dielectric breakdown, however end product Risk Management Process to consider the need for simultaneous fault condition testing.
- End product Risk Management Process to consider the need for different orientations of installation during testing.
- Humidity testing was conducted, however the end product Risk Management Process to determine risk acceptability criteria.

- Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk with respect to insulation's resistance to heat, moisture, and dielectric strength per 8.8.4.
- End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply.
- Leakage current testing should be considered in the end product application.
- End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Components: Fuse (F1), and Optocoupler (U4). Fuse (F1) is not provided for Models GSM11-10PP-106G and GSM11-10PP-108G.
- Models GSM11-10PP-104G and GSM11-10PP-108G are not provided with an input fuse (F1). These models were added without testing, based on similarity to previous models in this report. As noted in Model Differences, Models GSM11-10PP-104G and GSM11-10PP-108G are the same as previous models in this report, except for output DC voltage rating, and the elimination of supplementary input fuse, F1, rated 250 Vac, 1 A - location on PWB is jumpered with a conductor. Refer to the Critical Component table for the fuse originally used during testing. Abnormal Operation (Component Fault) testing was originally conducted on Model GSM11-15, considered representative of all models in the series. Component Fault testing of Models GSM11-10PP-104G and GSM11-10PP-108G was not repeated without the supplementary input fuse F1, based on the Applicant's request to waive this testing at the component level and have component fault testing conducted in the end product. Unless the end product is provided with a 1A or lower current rated input fuse with equivalent to original or faster acting characteristics, taking into account the suitability of the fuse type and fuse location. Component Single Fault testing shall be conducted in the end product device. Original component fault testing (shorts/opens) resulted in the opening of fuse F1 a total 32 times. The results of Table 13.2 – Single Fault Conditions - shall be reviewed to determine the number of component faults that need to be repeated on the power supply during the end product evaluation.
- The expected service life of this product is 5 years.
- All Models are Class II products. The need for IEC symbol 60417-5172 should be considered in the end use product.
- This power supply was evaluated with Two MOOP between Primary and Secondary.
- The maximum investigated branch circuit rating is: 20 A
- The Electric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary-SEC: 579 Vpk, 247 Vrms.
- Units are rated for operation at a maximum altitude of 4000 m. The applicable multiplication factor from Table 8 for MOOP was applied for Clearances.

Additional Information

Markings and instructions – For UL Field Representative Use

Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number
Fuses	Ratings (current and voltage) and type. (located adjacent to fuse OR as a diagram inside enclosure)