

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:	Switching Medical Power Supply
Model:	MINT3110VXXWWYZZ
Rating:	where V is A (Class I construction) or B (Class II construction), where Y represents A to Z, where XX is 05, 17, 19, 20, 21, 22, 23 (See below for output rating), WW or ZZ is any number 00 through 99, designates additional configurations indicating non-safety related options. Input: 100-240V~, 50-60Hz, 1.5-0.8A Output: Please see enclosure 7-03 for details.
Applicant Name and Address:	SL POWER ELECTRONICS CORP BLDG A 6050 KING ST VENTURA CA 93003 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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Reviewed by: Jimmy Deng

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

Product covered is an open frame power supply intended for building-in, to be used with Medical Electrical Equipment.

Model Differences

The models differ in output ratings which require different turns and gage in transformers T200 and secondary circuitry component values to accommodate the rated output.

Each model has two output ratings:

- 1.Max. 110W with 200LFM air flow or
- 2.Max. 80W with convection.

Technical Considerations

- Classification of installation and use : Building-in
- Device type (component/sub-assembly/ equipment/ system) : Component, Power Supply
- Intended use (Including type of patient, application location) : To supply regulated power to end products.
- Mode of operation : Continuous
- Supply connection : 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/C1:2009 (includes National Differences for USA); CAN/CSA-C22.2 No. 60601-1:08 (includes National Differences for Canada), EN 60601-1: 2006 + CORR: 2012., ,
- The product was not investigated to the following standards or clauses:: 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 degree of protection against harmful ingress of water is:: IPX0
- 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

- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- Manufacturer's Recommended Ambient: 50°C
- The product is Classified only to the following hazards: Casualty, Fire, Shock
- Power Supply was considered Overvoltage Category II - (OVCI)

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 end product should ensure that the requirements related to accompanying documents, clause 7.9, are met.
- This power supply has been evaluated for 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 Risk Management requirements of the standard were not evaluated and must be considered in the end use.
- End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Components: Fuses (F100, F102), Optocouplers (U1, U201, U202, U203).
- Under normal and single fault conditions, the DC output does not exceed 25 V ac or 60 V dc.
- 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. Earth Leakage and Touch Current testing was conducted as a component, and the results are in this report. End product application to also consider Leakage Testing per Clause 8.7.3e using a non-frequency-weighted

device.

- The expected service life of this product is 5 years.
- This power supply was evaluated with two MOPP between Primary and Secondary; one MOPP between Primary and Ground.
- The Interruption of the Power Supply Test was not conducted and shall be conducted in the end use application.
- The component shall be installed in compliance with the enclosure, mounting, spacings, casualty markings, and segregation requirements of the end-use application.
- Transformer (T200) uses a previously investigated Insulation System with Class B (130 deg. C) limits.
- Capability of the equipment to withstand cleaning, sterilization or disinfection without deterioration has not been evaluated. Additional evaluation may be required as part of end product investigation.
- The Electric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary to Secondary - 456 Vpk, 274 Vrms.
- Single fault testing was conducted without dielectric breakdown. End product Risk Management Process to consider the need for simultaneous fault condition testing.
- The supply input connectors, and the output connectors are acceptable for factory wiring only - internal wiring connections to be made inside the end product.
- Tests have been conducted with 20 A Branch Circuit rated devices located in the test circuit, located external to the unit.
- The component shall be installed in compliance with the Enclosure (clauses 9 & 11.3), Marking and Installation Instructions (clause 7), Mounting and Separation (clause 8) requirements of the end use application.
- The unit was evaluated for a maximum altitude of 3000 meters.
- Both Line 1 and Line 2 of the power supplies are fused, fuses designated F100, and F101, respectively.
- End product Risk Management to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
- The Voltage or Charge Limitation Test per 8.4.3 was not conducted, and shall be conducted in the

end product. ,

- End product should evaluate sub-clause 8.6 of this standard.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- The input and output connectors are not suitable for field connection.
- Proper bonding to the end-product main protective earthing termination is required.
- End product Risk Management Process to consider the need for simultaneous fault condition testing.
- End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- End product to determine the acceptability of risk in conjunction to the movement of components and conductors as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply.
- The usability of earthing connection pin (J101) need to be considered in end product.

Additional Information

Supervised Manufacturer's Testing (SMT): All original testing was conducted at SL Power Electronics - Ventura, CA, USA. Additional testing as part of this evaluation was conducted at Ault (Shanghai) Electronics, Shanghai, China.

The Applicant has requested that electrical schematics not be provided in this test report. The electrical schematics for these models are kept in file at the CB Testing Laboratory mentioned in the first page of this test report, and will be provided by the Applicant upon request by NCB's/CBTL's.

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.


Nameplate marking in this report represents all models in the series.

The company trademark may be applied to the exterior of the product, product literature or product packaging.

Additional Standards

The product fulfills the requirements of: ANSI/AAMI ES60601-1: 2005; CAN/CSA C22.2 No. 60601-1:08; EN 60601-1: 2006 + CORR: 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
Fuses	Ratings (current and voltage) and type. (located adjacent to fuse OR as a diagram inside enclosure)

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
MINT3110 Series	Exempt	Test	N/A

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			