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# **UL TEST REPORT AND PROCEDURE**

Standard: ANSI/AAMI ES60601-1:2005, 3rd ed. (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: MINT1110AXYKZ Series, where MINT is Medical Internal Model, 1 is the number of outputs 110 is the output wattage i.e. 110 W, A: is any Alpha character A-Z which indicates changes not related to Safety X: is a 2 digit numeric character that represents the Output Voltage. Voltage Range is 12-24Vdc. Y: Output Connector Options K: Input Connector Options Z: Configuration: 01 is Standard, 02-99 Modifications which have no impact on Safety Model MINT1110A1808K02 Rating: Input: 100-240V~, 50-60Hz, 1.4A Output: MINT1110A1208K01 Series - Rated 12Vdc, 7.5A MINT1110A1508K01 Series - Rated 15Vdc, 6.5A MINT1110A1808K01 Series - Rated 18Vdc, 5.8A MINT1110A1808K02 Series - Rated 18Vdc, 5.8A MINT1110A1908K01 Series - Rated 19Vdc. 5.8A MINT1110A2408K01 Series - Rated 24Vdc, 4.6A **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.

Prepared by: Tom Scheuffele Reviewed by: David V. Alma

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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.

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## **Product Description**

The MINT1110A Series are open-frame AC/DC power supplies, designed for building-in.

MINT1110 A X Y K Z Series Model Number Guide

MINT: Medical Internal Model number prefix.

- 1: Signifies number of outputs: 1
- 110: Output wattage = 110 W.
- A: Signifies generational differences, not evaluated by UL or related to safety, such as energy star level changes, EMC level changes; may be any letter from A to Z.
- X: Output Voltage: Numeric indicator from 12 to 24; i.e. 12 = 12 Vdc
- Y: Output Connector Options
- K: Input Connector Options
- Z: Configuration: 01 = Standard, 02-99 Modifications, which have no impact on Safety.

#### **Model Differences**

The power supplies in the MINT1110 Series are similar to each other, and differ only in minor component changes in the secondary circuit and the number for windings for T1 to accommodate for the different output voltages.

Model MINT1110A1808K02 - Same as base model MINT1110A1808K01 except it has a shorter u-Channel chassis, has 2 L-shaped mounting brackets, has a Plastic Sheet top cover (not acting as an insulation materials), Tma = 65 C, requires additional airflow (Fan) in the end product to meet heating requirements, and includes a 100Mohm static bleed resistor string from output to chassis.

#### **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 : Build-in
- Accessories and detachable parts included : None
- Other options include : None
- 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:: Ordinary.

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- 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
- For all models except for Model MINT1110A1808K02 40°C. For Model MINT1110A1808K02 65°C.
- The product is Classified only to the following hazards: Casualty, Fire, Shock
- Power Supply was considered Overvoltage Category II (OVCII)

## **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:

- Both Line and Neutral of the power supply are fused.
- The products were tested on a 20A branch circuit, if use on a branch circuit greater than 20A, additional tests may be necessary.
- 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.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Components: Fuses (F1, F2), Optocouplers (ICP3, ICP4).
- Single fault testing was conducted without dielectric breakdown, however end product Risk Management Process to consider the need for simultaneous fault condition testing.

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 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.
- The expected service life of this product is 5 years.
- Two MOPP is provided between primary and secondary; One MOPP is provided between primary and earth (chassis), operational insulation provided between secondary and earth.
- 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.
- Limitation of Voltage/Energy test (8.4.3) should be considered in the end product evaluation.
- Model MINT1110A1808K02 is rated as follows: Output 18Vdc, 5.8A, the Tma is 65°C, and requires additional airflow (fan) in the end product. The unit was tested under the following parameters: Output loaded to 18Vdc, 3.6A, tested at an Ambient of 65°C, as noted in Tables 11.1.1 in this report, and additional airflow (fan) was used. The acceptability of this power supply for use in a 65°C ambient based on airflow provided in the end product shall be determined as part of the end product evaluation.
- Transformer (T1) is provided with a Class B (130 °C) insulation system for 12, 15, 18 and 24V models and a Class F (155 °C) insulation system for MINT1110A1908K01 models.
- Legibility of Marking Testing per clause 7.1.2 for all required power supply markings should be considered in the end product 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.
- 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

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power supply.

- The component shall be installed in compliance with the Marking (clause 7) and Separation (clause
   8) requirements of the end use application
- Earthing and Potential Equalization (8.6.4) may need to be conducted in the end use product.
- 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.
- The end-product Dielectric Strength Test is to be based upon a maximum working voltage of: 1
   MOPP Primary-Earthed Dead Metal: 317 Vrms, 452 Vpk; 2 MOPP Primary-SEC: 239 Vrms, 560 Vpk

#### **Additional Information**

The schematics for these models are kept in file at the CB Testing Laboratory mentioned in the first page of this test report, and can be provided by the manufacturer 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.

The Electrical and Nameplate Labels are representative of all models in the series.

This report is an update of CBTR Ref. No.: E116994-A48-CB-1, CB Test Certificate Ref. No. US-13757-A3-UL. Based on the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, has been determined that the product continues to comply with the standard.

#### **Additional Standards**

The product fulfills the requirements of: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (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) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada); EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

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		
Alternating current	$\sim$		

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Power Input	Amps, VA, or Watts		
	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		
All	Exempt	Test	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					