

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:	Component - Power Supply
Model:	MINT1065WX75YZ where W = C or D; X = any number 12 through 48 Y = C or K; Z = any number 01 through 99, designates additional configurations indicating non-safety related options
Rating:	Input: 100-240Vac, 50-60Hz, 1.3A Output: See Enclosure - Miscellaneous for various ratings
Applicant Name and Address:	SL POWER ELECTRONICS CORP BLDG A 6050 KING ST VENTURA CA 93003 UNITED STATES

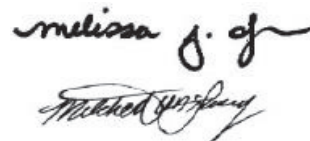
This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up 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 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.

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

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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.

Product Description

The MINT1065DX75KZ Series (Class I type), and MINT1065DX75CZ Series (Class II type) are open-frame AC/DC power supplies, designed for building-in to an end-product.

The MINT1065CX75KZ Series (Class I type) are AC/DC power supplies, provided with a top cover and bottom chassis, and are designed for building-in to an end-product.

Model Differences

The power supplies in the MINT1065WX75YZ 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 voltage and amps. The MINT1065WX75YZ Series are Class I or Class II type, and are available with different types of input and output connectors.

MINT1065 Class II Series is identical to MINT1065 Class I Series except the following components have been removed: CYP1, CYP2, CYP3, CYS1, the ground terminal (quick connect tab on PWB adjacent to input connector "CON1"), and jumper wire W1. Class II Models are not provided with a chassis.

MINT1065CX75KZ Series is identical to MINT1065DX75KZ Series, except it is provided with a Top Cover and Bottom Chassis.

All models have one dc output.

The following are additional differences between Model MINT1065WX75YZ, where W is C or D; where X is any number 12 through 48; where Y is C or K; where Z is any number 01 through 99.

MINT1065DX75KZ Series: D + K designates Class I type; X suffix designates output voltages from 12 to 48 Vdc; Z suffix designates additional configurations indicating non-safety related options.

MINT1065DX75CZ Series: D + C designates Class II type; X suffix designates output voltages from 12 to 48 Vdc; Z suffix designates additional configurations indicating non-safety related options.

MINT1065CX75KZ Series: C + K designates Class I type with a top and bottom chassis; X suffix designates output voltages from 12 to 48 Vdc; Z suffix designates additional configurations indicating non-safety related options.

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) : None
- Mode of operation : Continuous
- Supply connection : For building-in
- Accessories and detachable parts included : None

- Other options include : None
- The product was investigated to the following additional standards:: 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), 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)
- 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)
- The degree of protection against harmful ingress of water is:: Ordinary
- 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

Engineering Conditions of Acceptability

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:

- This component has been judged on the basis of the required spacing in the 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) 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), which covers the end use product for which the component is designed.
- The component shall be installed in compliance with the enclosure, mounting, spacing, casualty markings and segregation 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 input/output connectors are not acceptable for field connection, they are only intended for connection to mating connectors of internal wiring inside the end-use machine. the output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- Models MINT1065DX75KZ, and MINT1065CX75KZ Series (Class I) are to be properly bonded to Earth in the end-use equipment.
- The temperature test was performed at room ambient of 25 °C and calculated for an ambient of 40

°C.

- Leakage Current testing should be repeated in the end-product application.
- The Power Transformer (T1) comply with Class B (130°C) limits.
- This power supply was evaluated with Two MOOP between primary and secondary (Class I and Class II); One MOOP between primary and Earth.
- The need for Marking Durability and Marking Legibility Testing to be considered as part of the end product installation.
- 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.
- End product to determine the acceptability of risk in conjunction to insulation's resistance to heat, moisture, and dielectric strength.
- Humidity testing was conducted, however the end product Risk Management Process to determine risk acceptability criteria.
- Components were secured to prevent movement, however end product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
- Wiring was secured to prevent movement of wire where conductor could be damaged or contact unwanted voltages, however end product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply
- Power Supply was considered for Pollution Degree 2.
- Power Supply was considered Overvoltage Category II (OVCI).
- Power Supply rated for operation at a maximum altitude of 4000 m. The applicable multiplication factor from Table 8 for MOOP was applied for Clearances.
- Power Supply complies with the limits of 8.4.2.c) and 8.7.3.c).

Additional Information





The models covered under this Report are currently Recognized to UL 60601-1, Second edition and CSA C22.2 No. 60601-1, Second edition. The purpose of the submission of the CBTC No. DE 3-4551 and CBTR No. 095-1101815101-100 was to upgrade the Report to CAN/CSA-C22.2 No. 60601-1 (2008) and ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10).


This power supply was evaluated for Functional insulation between secondary and Earth (Class I).

Additional Standards

The product fulfills the requirements of: 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); 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)

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
Class II equipment	
Direct current	
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.
Fuses	Ratings (current and voltage) and type. (located adjacent to fuse OR as a diagram inside enclosure)
Protective earth ground	

Warning: dangerous voltage	
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
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			