

UL TEST REPORT AND PROCEDURE

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| Standard: | UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1: General Requirements for Safety) CAN/CSA-C22.2 No. 601.1-M90, 2005 (Medical Electrical Equipment - Part 1: General Requirements for Safety) |
| Certification Type: | Power Supplies, Medical and Dental |
| CCN: | QQHM2, QQHM8 |
| Product: | Medical Grade Power Supply |
| Model: | HWS300-12/ME, HWS300-15/ME, HWS300-24/ME and HWS300-48/ME |
| Rating: | HWS300-12/MEL, HWS300-15/MEL, HWS300-24/MEL and HWS300-48/MEL HWS300-24/ME and HWS300-24/MEL: Input: 100-240VAC 50/60Hz 4.1A Output: 24V 14A DC Class I No Patient Applied Parts. HWS300-12/ME and HWS300-12/MEL- as above except: Output: 12V (9.6-14.4V) 27A DC HWS300-15/ME and HWS300-15/MEL - as above except: Output: 15V (12-18V) 22A DC HWS300-24/ME and HWS300-24/MEL - as above except: Output: 24V (19.2-28.8V) 14A DC HWS300-48/ME and HWS300-48/MEL- as above except: Output: 48V (38.4-52.8V) 7A DC |
| Applicant Name and Address: | TDK-LAMBDA CORP NAGAOKA TECHNICAL CENTER R&D DIV 2701 TOGAWA, SETTAYA NAGAOKA-SHI NIIGATA 940-1195 JAPAN |

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2010-09-29

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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

Component Power Supplies

Model Differences

N/A

Technical Considerations

- Classification of installation and use : Permanently installed
- Supply connection : Permanently installed
- Accessories and detachable parts included in the evaluation : None
- Options included : None
- The product was investigated to the following additional standards:: CAN/CSA C22.2 No. 601.1-M90 (R1997), CAN/CSA C22.2 No. 601.1S1-94, and CAN/CSA C22.2 No. 601.1B-98 (National Differences for Canada)
- The product was not investigated to the following standards or clauses:: Clause 52.1, Programmable Electronic Systems (IEC 601-1-4) , Clause 48, Biocompatibility (ISO 10993-1) , Clause 36, Electromagnetic Compatibility (IEC 601-1-2)
- The product is Classified only to the following hazards:: Shock , Fire , Casualty
- 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 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:

- The measurements recorded in this Report (other than results taken from the above TUV Reports) only relate to the tested items detailed above and demonstrate conformity with the stated specifications. The items tested were selected as the optimum representative of the product group in Annex 2 with , which they has design and constructional similarity and a communality of materials and , components. A combination of the test measurements reported and an evaluation of the ,



manufacturer's technical data were applied to establish these facts. , Consequently, if all the items in the group were to be tested they would in all probability , confirm with the specifications stated on the front cover of this Report. ,

- It should be noted that the power supplies have been assessed as a component part. It is the installer's responsibility to ensure that the final installation is in accordance with the Densei Lambda HWS 300o600/ME Series Instruction Manual, the relevant specifications sheets and that it is in compliance with UL60601-1.
- The Power Supplies detailed in this Report were rated, by the Client, for Basic insulation requirements between the mains input and DC outputs, with respect to , IEC 60601-1/EN 60601-1/UL60601-1 applications. ,
- Although the equipment was not marked with the following a label drawing was provided to , show: , 1. The symbol. , 2. The word 'max' adjacent to the current consumption. , 6. The suffix ME is used to identify the medical versions of these power supplies and is , shown on the rating label, the instruction manual (Version Dwg no: A231-04-80/ME) and , on the specifications page. ,
- With the exception of the HWS300-24/MEL PSU: The leakage current test results as per section 19 were accepted incorporating 19.5DV.1. The power supplies MUST be enclosed within a nonconductive material. HWS300-24/MEL is a low leakage current version meeting US leakage current deviations.
- The equipment has been classified by the manufacturer for installation into a plastic enclosure to meet the leakage requirements of 19.5DV.1
- Only equipment incorporating all of the above modifications can be considered to comply.
- The PSU is fitted with single pole fusing only. As per installation instructions, the need for double pole fusing shall be considered in the end-installation.

Additional Information

N/A

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 | 251658240  |
| Direct current | 251658240  |
| Supply Frequency | Rated frequency range in hertz |

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|--|---|
| Power Input | Amps, VA, or Watts |
| Output | Rated output voltage, power, frequency. |
| Special Instructions to UL Representative | |
| N/A | |