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REPORT

on

COMPONENT - POWER SUPPLY, MEDICAL AND DENTAL

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DESCRIPTION

PRODUCT COVERED:

USR/CNR - Power Supply, Model AN-327.xxx.xx or ML50.xxx/AN-322.xxx.xx or ML30.xxx intended for use in Medical and Dental applications.

ELECTRICAL RATING:

| Model | Input | | | Output, (dc) | |
|------------------------------|--------------|-------------|-------|--------------|----|
| | V | A | Hz | V | W |
| AN-327.xxx.xx or ML50.xxx | 100-240 V ac | 0.9 A-0.5 A | 47-63 | 24-28 | 50 |
| AN-322.xxx.xx or ML30.xxx | 100-240 V ac | 0.9 A-0.5 A | 47-63 | 24-28 | 30 |

x stands for customer specific versions

ENGINEERING CONSIDERATIONS (NOT FOR UL REPRESENTATIVE'S USE):

Use - For use only in (or with) complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc.

Special Considerations - The following items are the considerations that were used when evaluating this Product.

USR/CNR indicates investigation to the standard for Medical Electrical Equipment UL 2601 and CSA22.2-601.

The component was submitted and tested for a maximum ambient (Tmax) of 40°C.

The equipment is:

Protection Class I, IP 20, continuous mode.

Conditions of Acceptability - When installed in the end-product, consideration shall be given to the following:

1. The power supply shall be installed in compliance with the enclosure, mounting, spacing, casualty and segregation requirements of the ultimate application.
2. Consideration should be given to measuring the temperature on power electronic components and transformer winding when the power supply is installed in the end-use equipment. The transformers comply with UL Class F insulation.
3. This product has been judged on the basis of the required spacing in the Standard for Medical Equipment and Electrical Equipment CAN/CSA-C22.2 No. 601.1-M90 and Medical Electrical Equipment, Part 1: General Requirements for Safety, UL 2601-1, which cover the end-use product for which this component was designed.
4. The power supply complies with requirements for Basic Insulation between primary to secondary and Basic Insulation between primary and ground.
5. The input and output connectors are not acceptable for field connections and are only intended for connection to mating connectors of the internal wiring inside the end-use machine. The acceptability of these and the mating connectors relative to secureness, insulation materials, and temperature shall be considered.
6. The need to reconduct the Leakage Current Test shall be considered in the end-use application.
7. When build-in in the end-use product, the end-use product shall be equipped with two mains fuses.
8. When build-in in the end-use product, the end-use product shall be equipped with ON/OFF indicator when end-use product is connected to Mains.
9. When build-in in the end-use product, the end-use product shall be equipped with a mean to disconnect the end-use product from Mains.
10. When build-in in the end-use product, the end-use product shall provide a suitable fire-enclosure.
11. The power supply shall be properly bonded to the main protective earthing termination in the end product.
12. The maximum measured earth leakage current with European 240 V configuration according to Fig. 10 of UL 2601-1 was 380 μ A. This is in compliance with IEC 60601-1 but exceeds 300 μ A limit from US Deviations. When measured with Center-Tapped Power Supply according to Fig. 11 of UL 2601-1, the maximum measured earth leakage current was 293 μ A. The user manual of the end product shall state, that in North America the end product shall be connected only to a center tapped power supply.

CONSTRUCTION DETAILS:

See Section General for additional details.

Interconnecting Cables - Not provided unless specified, described.

Internal Wiring - See Section General.

Printing Wiring Board - See Section General for details.

General appearance of the trace layouts same as in Ill. 1.

MODEL DIFFERENCES:

x stands for customer specific versions.