Description

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14
Certification Type:	Component Recognition
CCN:	QQHM2 / QQHM8
Complementary CCNs:	
Product:	AC-DC Power Module
Model:	TMF 20 series: TMF 20105; TMF 20112; TMF 20115; TMF 20124 / TMF 30 series: TMF 30105; TMF 30112; TMF 30115; TMF 30124
Rating:	Input: TMF 20 series: 100-240 Vac; 47-63 Hz; 0,45 A max TMF 30 series: 100-240 Vac; 47-63 Hz; 0,77 A max Output (TMF 20 series): TMF 20105: 3,75 to 5,25 Vdc / 3600 mA max. / 18 W max. TMF 20112: 9 to 12,6 Vdc / 1667 mA max. / 20 W max. TMF 20115: 11,25 to 15,75 Vdc / 1333 mA max. / 20 W max. TMF 20124: 18 to 25,2 Vdc / 833 mA max. / 20 W max. Output (TMF 30 series): TMF 30105: 3,75 to 5,25 Vdc / 5000 mA max. / 25 W max. TMF 30112: 9 to 12,6 Vdc / 2500 mA max. / 30 W max. TMF 30115: 11,25 to 15,75 Vdc / 2000 mA max. / 30 W max. TMF 30124: 18 to 25,2 Vdc / 1250 mA max. / 30 W max.
Applicant Name and Address:	TRACO ELECTRONIC AG Sihlbruggstrasse 111 CH-6340 Baar, Switzerland

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 as applicable.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Bruno F. Motta Reviewed by: Paola Galliani

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

EUT is power supply unit intended for building-in provided with a single power output and with universal input range 100-240 Vac.
Power supply unit is provided with plastic enclosure and additionally filled with non-conductive insulation compound to increase rigidity of the power supply unit. Clearance and creepage distances not rely on insulation compounds; therefore thermal cycling not performed.
Power supply unit is provided with input and output pins intended for soldering to the PCB within end medical product.
The power supply is rated as Class II construction (provided in fully plastic e+nclosure). The power supply is intended to be built-in within the end medical product. Power supply has primary and secondary pins and will be soldered on the printed circuit board within end medical product. Manufacturer of the end medical product need to ensure that the power supply will be soldered appropriately and that the reinforced insulation will be provided between primary and secondary pins on the bottom side of power supply unit.

The power supplies TMF 20 series are intended for operating at ambient temperature up to 50°C (without derating) or up to 70°C (with derating – 3% per K). Additional derating at input voltage below 100 Vac.
The power supplies TMF 30 series are intended for operating at ambient temperature up to 50°C (without derating) or up to 70°C (with derating – 3% per K). Additional derating at input voltage below 100 Vac.
Refer to the Report Modifications page for any modifications made to this report.

Model Differences

TMF 20 series: The models within this serie differ only in the electrical ratings. For details, refer to Ratings, in the beginning of this report.
TMF 30 series: The models within this serie differ only in the electrical ratings. For details, refer to Ratings, in the beginning of this report.

The TMF 20 series and TMF 30 series differs in the external dimensions, size of the PWB, internal components and ratings.

The same transformer is used in both series. For details, refer to List of Critical Components and Enclosures - Transformer Construction Details.

Additional Information

- Throughout this report a comma is used as the decimal separator.
- The unit is medical power supply unit intended for building-in and provided with plastic enclosure (filled with insulation compound to improve rigidity of the enclosure). Enclosure is considered as part that cannot be touched by the operator when installed within the end medical product.
- The unit provides internally one primary fuse. Primary fuse not accessible due the power supply unit is additionally filed with insulation compound;
- Power supply unit was evaluated only for Means of Patient Protection (MOPP): 2 x MOPP between primary and secondary circuit; Secondary output circuit is separated from mains by reinforced insulation and

rated SELV. The output does not provide hazard energy level.
- The power supply is rated as class II construction (provided in fully plastic enclosure);
- The transformers T1 provide reinforced insulation. These transformers are built up to fulfil the requirement of insulation class B;
- The equipment has been evaluated for use in a Pollution Degree 2 and overvoltage category II environment and a maximum altitude of 5000 m;
Multiplication factor 1,48 used for required clearance distance for parts of opposite polarity (2 x MOOP);
Multiplication factor 1,29 used for required clearance distance between primary and secondary (2 x MOPP).
- Power supply unit is provided with plastic enclosure made by non-flammable material V-0;
- The power supply is maintenance free.

Technical Considerations

- The product was investigated to the following additional standards: EN 60601-1:2006 + A1:2013 + A12:2014
- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: Biocompatibility, PESS, EMC, Annex Z of EN standards for compliance with the MDD
- The following accessories were investigated for use with the product: None
- No Other Considerations.

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:

- Essential performance shall be determined within the end medical equipment.
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- The unit is medical power supply unit intended for building-in and provided with plastic enclosure (filled with insulation compound to improve rigidity of the enclosure). Enclosure is considered as part that cannot be touched by the operator when installed within the end medical product.
- The device must be completely enclosed by a mechanical, fire and electrical enclosure in the end product.
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- The following clauses shall be evaluated by the end product investigation:
- - 7.5 - Safety Signs,
- - 7.9 - Accompanying Documents,
- - 8.11 - Mains Parts, components and layout,
- - 9 - Protection agains mechanical hazards of ME EQUIPMENT and ME SYSTEMS,
- - 11.3 - Constructional requirements for fire ENCLOSURE of ME EQUIPMENT,
- - Risk Management requirements.
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- For use only in or with complete equipment where the acceptability of the combination is determined by the Testing Laboratory, when installed in an end-product, consideration must be given to the following:
- For Power Supplies with No RM:
- - 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 Component: i.e. Fuse (F1).
- - 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.
- - with Exposure Condition outside of Humidity Range: Power Supply tested in 23,5°C, 94,0%RH. End product Risk Management Process to determine risk acceptability criteria.

- - and Insulating Materials: 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 as part of the power supply.
- - End product to determine the acceptability of risk in conjunction to the movement of 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.
- - and Not tested with Test Corner: 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.
- - or Units without Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
- - or Units with Liquids: End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.
- - or Units with Indicators: End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.
- - or Units with Enclosures: End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply
- - 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
- - and with Thermal Cut-off: End product to determine the acceptability of risk in conjunction to the use of Thermal Cut-off and Overcurrent releases as part of the power supply
- - with Pre-set components: End product to determine the acceptability of risk in conjunction to the use of Pre-set controls as part of the power supply.
- Reinforced insulation between primary and secondary pins on the bottom side of power supply unit shall be granted also after installation in the end product.