UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(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:	Switching Power Supply
Model:	CPS253-M, CPS255-M, CPS258-M
Rating:	For model CPS253-M: AC Input : 100-240Vac, 50/60Hz,3A DC Output: +12V, 20.83A Max +12VFan, 0.5A Max For model CPS255-M: AC Input:100-240Vac, 50/60Hz,3A DC Output: +24V, 10.42A MAX +12V FAN, 0.5 A MAX For Model CPS258-M AC Input: 100-240Vac, 3A, 50/60Hz DC Output: +48V, 5.21A MAX +12V FAN, 0.5 A MAX For all above models: Maximum Output Power: 155W Convection Cooling 250W Forced Air Cooling Total output power for natural convection cooling is 155W at 50 degree C. Above 50 degree C, the power shall be de-rated at 2.9% / degree C up to 70 degree C maximum ambient temperature for input line voltage of 90-100Vac and it shall be de-rated at 2.5% / degree C for input line voltage 100- 264Vac. Below 100 Vac, and up to 50 degree C, de-rate at 1% / Vac. The total output power for forced air cooling minimum of 10CFM shall be 250W at 50 degree C. At ambient above 50 degree C the power shall be de-rated at 1.9% / degree C up to 70 degree C maximum ambient temperature. Below 100Vac, and up to 50 degree C, de-rate at 1% / Vac.
Applicant Name and Address:	ASTEC INTERNATIONAL LTD - PHILIPPINE BRANCH 16TH FL LU PLAZA

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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 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: Cary Hu Reviewed by: Elisabeth Gingelmaier

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 equipment is an AC/DC switching power supply designed to deliver 155W rated output power during natural convection cooling and forced air cooling designed to deliver 250W at minimum 10CFM.

This equipment is intended for use in Class I or Class II application.

2MOPP is provided between primary and secondary circuits and 1MOPP is provided between primary circuits and Earth as well as secondary circuit and earth. When the equipment is used as Class II, earth trace is considered dead metal.

Risk management is not addressed in this report.

Model Differences

Model CPS253-M is identical to Model CPS255-M except for the following safety controlled parameters:
1) Model name and Ratings of DC output;
2) Power Transformer secondary(T501) and Resonant Choke (L4).

Model CPS258-M is identical to Model CPS253-M and CPS255-M except for the following safety controlled parameters:
1) Model name and Ratings of DC output
2) Power Transformer (T501).

Technical Considerations

- Classification of installation and use : Component to be installed in end product
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : Recognized power supply for medical equipment usage
- Mode of operation : Continuous
- Supply connection : Input Connector
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1 (2005/(R)2012 + C1:2009/(R)2012 + A2:2010/(R)2012) - Revision Date 2012/01/17 , CAN/CSA-C22.2 No. 60601-1:08 - Edition 2 (Incorporates Corrigendum 2) - Revision Date 2011/06
- The product was not investigated to the following standards or clauses:: Biocompatibility (ISO 10993-1), Clause 14, Programmable Electronic Systems, Electromagnetic Compatibility (IEC 60601-1-2)
- The degree of protection against harmful ingress of water is:: Ordinary
- 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 UL LLC. When installed in an end-product, consideration must be given to the following:

- This power supply has been judged on the basis of the required creepage and clearances in the First Edition of the Standard for Medical Electrical Equipment, ANSI/AAMI ES 60601-1, Sub Clause 8.9.
- This power supply is component level power supply intended for use in Class I or Class II application. Additional evaluation to be considered in end product for different classification use.

- Two MOPP is provided between primary circuit to secondary circuit and one MOPP is provided between primary circuit to earth and secondary circuit to earth. When this equipment is used as Class II, earth trace is considered dead metal wherein basic insulation is maintained between primary circuits and PE trace and between secondary circuits and PE trace. Must be checked and evaluated in end system.If used as Class I, Impedance and Current Carrying Capability and 200A fault current test on the PE trace should be evaluated in the end product.
- Consideration should be given to measuring the temperatures on power electronic components and transformer windings when the power supply is installed in the end use equipment. Transformers (T501) and (TX601) incorporates Class 155 (F) insulation system.
- The secondary circuit of this power supply has not been evaluated for patient connected applications.
- Total output power for natural convection cooling is 155W at 50 degree C. Above 50 degree C the power shall be de-rated at 2.9% / degree C up to 70 degree C maximum ambient temp for input line voltage of 90-100Vac and it shall be de-rated at 2.5% / degree C for input line voltage 100-264Vac.Below 100 Vac, and up to 50oC, derate at 1% / Vac.
- The total output power for forced air cooling of minimum 10 CFM shall be 250W at 50 degree C. At ambient above 50 degree C the power shall be de-rated at 1.9% / degree C up to 70 degree C maximum ambient temp. Below 100 Vac, and up to 50oC, derate at 1% / Vac.
- A suitable Electrical, Mechanical and Fire Enclosure shall be provided by end use equipment.
- This power supply is operated up to 3000m above sea level as declared by manufacturer.
- Earthing terminal at input connector is not considered protective earthing terminal, but is considered bonding terminal. Power supply chassis is to be reliably bonded earthing in end use equipment before energized.
- This secondary circuit of this power supply has not been evaluated for patient connected applications.
- This power supply shall be installed in compliance with the enclosure, mounting, spacing, casualty, markings and segregation requirements of the end use application.
- Fuse of Littelfuse, type 392 does not have an adequate breaking capacity 200A; Overcurrent releases of adequate breaking capacity must be employed in the end product.
- The following tests shall be performed in the end-product evaluation: Earthing and Potential Equalization Test, Temperature Test, Dielectric Voltage Withstand Tests, Leakage Current Test with Normal MD, Non-frequency-weighted MD.
- This power supply was tested on a 20A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply and the suitability of Fuse.
- 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 to resistance to heat, moisture, and dielectric strength.
- End product to determine the acceptability of risk in conjunction to the movement of components and 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.
- 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.

- End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.
- 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.
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- A suitable fuse shall be considered in end product investigation.
- Built-in switching power supply. Applicability of the following is to be determined in End Product Evaluation: 8.4.2 - Accessible Parts Including Applied Parts.
- The maximum working voltage measured between primary and secondary: For model CPS253-M, the maximum working voltage for T501 is 248.7 Vrms;546Vpk, for TX601 is 245.5Vrms, 624 Vpk. for model CPS 255-M, T501 is 254.1 Vrms, 495Vpk, for TX601 is 155.7Vrms, -575 Vpk, and for model CPS258-M, T501 is 268.8Vrms,-578Vpk ,TX601 is 160.8Vrms, -578Vpk. The electric withstand test in the end-product shall be based on this value.
- The 12V, 24V, and 48V output voltage can be adjustable to 0%/+10%. The Fan Output may move according to set point. Output load setting beyond nominal output voltage shall cause the power supply to be de-rated to 140W maximum power for Natural convection conditions and Forced Air conditions.