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:	NPS42-M, NPS43-M, NPS44-M, NPS45-M and NPS48-M
Rating:	Input: AC 100-250 V, 50/60 Hz, 2.5 A DC 140-300 V, 2.5 A Output for model NPS42-M: +5V, 11.0 A max; Output for model NPS43-M: +12V, 5.0 A max; Output for model NPS44-M: +15V, 4.0 A max; Output for model NPS45-M: +24V, 2.5 A max; Output for model NPS48-M: +48V, 1.25 A max; Maximum Output Power: (For models NPS43-M, NPS44-M, NPS45-M, NPS48-M) 45 W Convection Cooling at 50degC maximum ambient 60 W Forced Air Cooling at 50degC maximum ambient 50 W Convection Cooling at 40degC maximum ambient (For model NPS42-M) 40 W Convection Cooling at 50degC maximum ambient 55 W Forced Air Cooling at 50degC maximum ambient 45 W Convection Cooling at 40degC maximum ambient Output derates 2.5% per degree from 50degC to 80degC ambient temperature
Applicant Name and Address:	ASTEC INTERNATIONAL LTD - PHILIPPINE BRANCH 16TH FL LU PLAZA 2 WING YIP ST KWUN TONG KOWLOON HONG KONG

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: Jeffery Chan Reviewed by: Calvin Tang

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

1. The equipment is a switch mode power supply for building-in which has been evaluated for use in Class I and Class II medical application.

2. Refer to Illustration ID7-02 for Maximum allowed rating for convection forced - Air Cooling for models NPS42-M, NPS43-M, NPS44-M, NPS45-M and NPS48-M.

MOPP insulation was provided.

Model Differences

Models NPS42-M, NPS44-M, NPS45-M, NPS48-M and NPS43-M are identical except Transformer T1 secondary winding, output rating and some non-critical secondary components.

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) : Component - to be evaluated in end product
- 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:: CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) Edition 2 - Revision Date 2011/06/01., ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 1 - Revision Date 2012/01/01,
- 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
- The product is Recognized only to the following hazards: Fire, Shock.

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:

- The power supplies have been judged on the basis of the required creepage and clearances in the Standard for Medical Electrical Equipment, ANSI/AAMI ES 60601-1, Sub clause 8.9.
- This power supply has not been evaluated for patient connected applications.
- Total continuous output power for models NPS43-M, NPS44-M, NPS45-M, NPS48-M shall not exceed 60W with 30CFM forced-air cooling. Total continuous output power at natural convection cooling is 45W. Output derates 2.5% per degree from 50degC to 80degC ambient temp. For model NPS42-M shall not exceed 55W with 30CFM forced-air cooling. Total continuous output power at

natural convection cooling is 40W. Output derates 2.5% per degree from 50degC to 80degC ambient temp.

- Consideration should be given to measuring the temperatures on power electronic components and transformer windings when the power supply is installed in the enduse equipment. The primary transformer (T1) incorporates a Class 155 (F) insulation system.
- The power supply was evaluated as 2 MOPP Insulation between Primary and Secondary, and as 1 MOPP Insulation between Primary and Earth. See insulation diagram for details.
- The maximum measured working voltage is 344.7 V rms and 689 Vpk (337.1 V rms, 645 Vpk for Model NPS42-M, 340.6 V rms, 566 Vpk for Model NPS43-M and 342.7 V rms, 539 Vpk for Model NPS44-M, 344.7 Vrms, 539 Vpk for Model NPS45-M, 341.5 Vrms, 689 Vpk for Model NPS48-M; The electric strength tests in the end-product shall be based on this value.)
- Additional UL Recognized DC Fuse must be provided in end-system for DC input.
- Leakage current test need to be repeated in end-product investigation.
- 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.
- Instructions and equipment marking shall be provided in a language, which is acceptable in the country in which the equipment is to be installed.
- This power supply was tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary. The fuse employed didn't fractured and remained intact during the single fault condition testing and short circuit testing performed in client's facility.
- Input terminal/connector shall be connected to the supply neutral in the end use for simultaneous disconnection of all supply poles.
- The insulation between accessible parts and live part must be re-evaluated in end product.
- This power supply has been evaluated for use in 40degC ambient at 50 W load for models NPS43-M, NPS44-M, NPS45-M, NPS48-M and 40degC at 45 W load for model NPS42-M.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- 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 the movement of components 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 Risk Management Process to consider the need for simultaneous fault condition testing.
- 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.
- A suitable Electrical, Mechanical and Fire Enclosure shall be provided by end use equipment.
- This unit is not intented to used for permanent connection.
- This power supply has been evaluated for use in Class I or Class II, continuous operation equipment and oridinary Equipment. An additional evaluation shall be made if the power supply is intended for use in other than Class I equipment. When the power supply is used as Class II equipment, all PE

traces and components connected to PE on the primary side will be treated as primary part for spacing and insulation considerations. If unit to be considered as Class I in end use, Earthing Test should be considered.

- The secondary output circuits of Transformer (T1) are complied with Low Voltage Reliability. (Subclause 16e Requirement)
- The output connectors are not acceptable for field connection and are only intended for connections to mating connectors of internal wiring inside the end use product. The acceptability of these and the mating connectors relative to secureness, insulating materials, and temperatures shall be considered in the end , use product.
- Depending on the end product application, additional markings and documentation may be required. This is to be evaluated in the end product.
- The clearance and creepage distance have additionally been assessed for suitaility up to 4000m elevation.
- This power supply shall be installed in compliance with the enclosure, mounting, spacing, casualty, markings and , segregation requirements of the end use application.