

## UL TEST REPORT AND PROCEDURE

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| <b>Standard:</b>                   | ANSI/AAMI ES60601-1 (2005/(R) 2012 +A1:2012, C1: 2009/(R) 2012 + A2:2010/(R) 2012) Amendment 1 – Revision Date 2012/08/21.CAN/CSA – C22.2 No. 60601-1:14 – Edition 3 – Revision Date 2014/03.  |
| <b>Certification Type:</b>         | Component Recognition  |
| <b>CCN:</b>                        | QQHM2, QQHM8 (Power Supplies, Medical and Dental)  |
| <b>Product:</b>                    | Switching Power Supply   |
| <b>Model:</b>                      | NPT42-M, NPT43-M, NPT44-M  |
| <b>Rating:</b>                     | Input: 100 - 240Vac, 1.8A, 50/60Hz<br>Input Power must be less than 74Watts.<br><br>Model NPT42-M Output DC rating:<br>+5Vdc, 8.0A MAX<br>+12Vdc, 3.0A MAX<br>-12Vdc, 0.7A MAX<br><br>Model NPT43-M Output DC rating:<br>+5Vdc, 8.0A MAX<br>+15Vdc, 2.4A MAX<br>-15Vdc, 0.7A MAX<br><br>Model NPT44-M Output DC rating:<br>+5Vdc, 8.0A MAX<br>+24Vdc, 1.5A MAX<br>+12Vdc, 0.7A MAX<br><br>Maximum Output Power:<br>45W Convection Cooling<br>55W Forced Air Cooling<br>Output derates 2.5% per degree from 50 deg C to 80 deg C. |
| <b>Applicant Name and Address:</b> | ASTEC INTERNATIONAL LTD - PHILIPPINE<br>BRANCH<br>16TH FL<br>LU PLAZA<br>2 WING YIP ST<br>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.

Issue Date: 2015-09-29

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Report Reference #

E182560-V4-S20

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.

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Reviewed by: Sammi Liang

**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**

Models NPT42-M, NPT43-M and NPT44-M are an AC/DC switch mode power supply designed to deliver 45W rated output power during natural convection cooling and 55 W on forced air cooling.

This equipment has been evaluated for use in Class I or Class II application. 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.

MOPP insulation was provided.

**Model Differences**

Models NPT43-M and NPT44-M are identical to model NPT42-M except secondary winding of Transformer T1 and secondary components for output rating. See Enclosure ILL 7-03 for details.

Model NPT42-M:

Loading Condition 1: (45W load with natural convection cooling) at 50 degC

V1: +5V, 5A

V2: +12V, 1.17A

V3: -12V, 0.5A

Loading Condition 2: (45W load with natural convection cooling) at 50 degC

V1: +5V, 1.8A

V2: +12V, 2.5A

V3: -12V, 0.5A

Loading Condition 2 tested at 75% load with natural convection cooling at 60 degC

Loading Condition 2 tested at 50% load with natural convection cooling at 70 degC

Loading Condition 2 tested at 25% load with natural convection cooling at 80 degC

Loading Condition 3 : (55W load with 30CFM forced air cooling) at 50 degC; Set-up Condition B

V1: +5V, 8A

V2: +12V, 0.55A

V3: -12V, 0.7A

Loading Condition 4 : (55W load with 30CFM forced air cooling) at 50 degC; Set-up Condition B

V1: +5V, 2.12A

V2: +12V, 3A

V3: -12V, 0.7A

Loading Condition 3 (55W load with 30CFM forced air cooling) at 50 degC; tested using Set-up Condition D

Loading Condition 3 (55W load with 30CFM forced air cooling) at 50 degC; tested using Set-up Condition A

Loading Condition 3 (55W load with 30CFM forced air cooling) at 50 degC; tested using Set-up Condition C

NPT43-M:

Loading Condition 1: (45W load with natural convection cooling) at 50degC

V1: +5V, 5A

V2: +15V, 0.84A

V3: -15V, 0.5A

Loading Condition 2: (45W load with natural convection cooling) at 50degC

V1: +5V, 1.5A

V2: +15V, 2.0A

V3: -15V, 0.5A

Loading Condition 2 tested at 75% load with natural convection cooling at 60degC

Loading Condition 2 tested at 50% load with natural convection cooling at 70degC

Loading Condition 2 tested at 25% load with natural convection cooling at 80degC

Loading Condition 3 : (55W load with 30CFM forced air cooling) at 50degC; Set-up Condition B

V1: +5V, 8A

V2: +15V, 0.3A

V3: -15V, 0.7A

Loading Condition 4 : (55W load with 30CFM forced air cooling) at 50degC; Set-up Condition B

V1: +5V, 1.7A

V2: +15V, 2.4A

V3: -15V, 0.7A

Loading Condition 3 (55W load with 30CFM forced air cooling) at 50degC; tested using Set-up Condition D

Loading Condition 3 (55W load with 30CFM forced air cooling) at 50degC; tested using Set-up Condition A

Loading Condition 3 (55W load with 30CFM forced air cooling) at 50degC; tested using Set-up Condition C

NPT44-M:

Loading Condition 1: (45W load with natural convection cooling) at 50degC

V1: +5V, 5A

V2: +24V, 0.59A

V3: +12V, 0.5A

Loading Condition 2: (45W load with natural convection cooling) at 50degC

V1: +5V, 3A

V2: +24V, 1A

V3: +12V, 0.5A

Loading Condition 2 tested at 75% load with natural convection cooling at 60degC

Loading Condition 2 tested at 50% load with natural convection cooling at 70degC

Loading Condition 2 tested at 25% load with natural convection cooling at 80degC

Loading Condition 3 : (55W load with 30CFM forced air cooling) at 50degC; Set-up Condition B

V1: +5V, 8A

V2: +24V, 0.28A

V3: +12V, 0.7A

Loading Condition 4 : (55W load with 30CFM forced air cooling) at 50degC; Set-up Condition B

V1: +5V, 2.12A

V2: +24V, 1.5A

V3: +12V, 0.7A

Loading Condition 3 (55W load with 30CFM forced air cooling) at 50degC; tested using Set-up Condition D

Loading Condition 3 (55W load with 30CFM forced air cooling) at 50degC; tested using Set-up Condition A

Loading Condition 3 (55W load with 30CFM forced air cooling) at 50degC; tested using Set-up Condition C

Note: Loading conditions are the output settings of the power supply during test. Loading conditions at the end-system may vary. However, it should not exceed the output ratings given (see "ratings" for details).

#### 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:: AAMI ES60601-1 AMD 1 MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE, AMENDMENTS - Edition 1 - Issue Date 2012/08/20CSA C22.2 NO. 60601-1:14 MEDICAL ELECTRICAL EQUIPMENT. PT. 1, GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - Edition 3 - Issue Date 2014/01/01
- 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 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.
- This power supply is a built-in device as part of medical equipment. The date of manufacture need to be evaluated in the end-product.
- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment.
- Maximum rated operating temperature Tma (°C) is between 50 deg. C to 80 deg. C. Output derates 2.5% per degree from 50 deg C to 80 deg C.
- The transformers 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 max working voltage measured between transformer T1 of model NPT42-M Primary to Secondary: 266 V rms, 634 Vpk; between transformer T1 of model NPT43-M Primary to Secondary: 262.4 V rms, 557 Vpk; between transformer T1 of model NPT44-M Primary to Secondary: 274.7 V rms, 557 Vpk.
- The power supplies have not been evaluated for patient connected applications.
- Fuses F1 and F2 are not intended to be accessible by user. Final application to be determined in the

end-product investigation (e.g., Fuse rating/markings are to be provided in the end use application.)

- Earthing test need to be conducted in end-product investigation.
- Leakage current test, Temperature test, marking test, and earth impedance test need to be repeated / considered in end-product investigation.
- Suitability for the PE tab to be used with quick-connect connector needs to be evaluated in end-product.
- 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 disconnection from the line must be in the end system.
- The insulation between accessible parts and live part must be re-evaluated in end product.
- The equipment has rated output of 45W when used with convection cooling, and rated output of 55W when used with 30CFM forced air cooling. Additional temperature test shall be further considered in end application. The necessity to add detailed information of force air cooling on the rating label according to Clause 7.2.15 shall also be considered in end application.”
- 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 and Fire enclosure shall be provided in end product.
- This equipment has been evaluated for use in Class I or Class II application. 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.