

## UL TEST REPORT AND PROCEDURE

<b>Standard:</b>	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10 + A1:12)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) CAN/CSA-C22.2 No. 60601-1 (2014) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
<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>	73-954-0001-G2, uMP04X-XXX-XXX-XXX-XXX-XX <b>(Please refer to Enclosure ILL.7-01, for model name configuration details of uMP04X)</b>  73-949-0001-G2, uMP09X-XXX-XXX-XXX-XXX-XX <b>(Please refer to Enclosure ILL.7-05, for model name configuration details of uMP09X)</b> *
<b>Rating:</b>	For 73-954-0001-G2: AC Input: 100 - 240V 8A max 50/60Hz DC Input: 120V min - 350V max 6.5A max (DC Input only for IT equipment) AC Output Voltage: 380V +10/-20V RMS Square Wave, 500W Max.  AC Input: 200 - 240V 8A max 50/60Hz DC Input: 254V min - 350V max 6.5A max (DC Input only for IT equipment) AC Output Voltage: 380V +10/-20V RMS Square Wave, 700W Max.  For uMP04X-XXX-XXX-XXX-XXX-XX: AC Input: 100 - 240V 8A max 50/60Hz DC Input: 120V min - 350V max 6.5A max (DC Input only for IT equipment) Output: 400W, Refer details in report  AC Input: 200 - 240V 8A max 50/60Hz DC Input: 254V min - 350V max 6.5A max (DC Input only for IT equipment) Output: 600W, Refer details in report  <b>For 73-949-0001-G2:</b> <b>AC Input: 100 - 240V 9A max 50/60Hz</b> <b>DC Input: 120V min - 350V max 6.5A max</b> <b>AC Output Voltage: 380V +10/-20V RMS Square Wave,700W Max.</b>  <b>AC Input: 200 - 240V 9A max 50/60Hz</b> <b>DC Input: 254V min - 350V max 6.5A max</b> <b>AC Output Voltage: 380V +10/-20V RMS Square Wave, 1300W Max.</b>

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Report Reference #

E182560-V4-S11

**For uMP09X-XXX-XXX-XXX-XXX-XX:**  
**AC Input: 100 - 240V 9A max 50/60Hz**  
**DC Input: 120V min - 350V max 6.5A max**  
**Output: 550W, Refer details in report**

**AC Input: 200 - 240V 9A max 50/60Hz**  
**DC Input: 254V min - 350V max 6.5A max**  
**Output: 1100W, Refer details in report**

<b>Applicant Name and Address:</b>	ASTEC INTERNATIONAL LTD - PHILIPPINE BRANCH 16TH FL LU PLAZA 2 WING YIP ST KWUN TONG KOWLOON HONG KONG
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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: Eileen Hu/Cary Hu

Reviewed by:

### **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

This unit is a medical switching mode power supply for building-in which has been evaluated for use in Class I medical application. Unit provided with an insulation transformer and all components are mounted on 94V-0 PWB.

73-954-0001-G2 and **73-949-0001-G2** (Case models) AC output waveform is specially configured as square wave format to fit with end system special usage.

uMP04X-XXX-XXX-XXX-XXX-XX and **uMP09X-XXX-XXX-XXX-XXX-XX** (Configured series model) were combined with a recognized AC-DC modules, model 73-961-0003, 73-961-0005, 73-961-0012, 73-961-0024, 73-961-0048, 73-962-0001 and 73-962-0002 under file E182560-A120 and **73-963-0048 (for uMP09X only) under file E182560-A108** installed to a case model 73-954-0001-G2 and **73-949-0001-G2** respectively. Each uMP series model has 4 slots for AC-DC modules.

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**Refer to Conditions of acceptability for operating ambient temperatures.**

### Model Differences

Model 73-954-0001-G2 is a subassembly of uMP04 configured series model **while 73-949-0001-G2 is a subassembly of uMP09 configured series model.**

**73-949-0001-G2 is identical to 73-954-0001-G2 except for model designation, AC input current ratings, and output power ratings.**

**uMP09X-XXX-XXX-XXX-XXX-XX is identical to uMP04X-XXX-XXX-XXX-XXX-XX except for model designation, AC input current ratings, and output power ratings.**

### Technical Considerations

- Classification of installation and use : For built-in
- 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 : To be evaluated in end product.
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards: N/A,
- 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 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

### 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.
- **The power supply is a built-in device as parts of medical equipment. The date of manufacture & S/N marked needs to be evaluated in the end-product.**
- This power supply has been evaluated as a Class I, continuous operation, ordinary Equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. An additional evaluation shall be made if the power supply is intended for use in other than Class I equipment.
- This power supply was tested on a 20A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The power supply was evaluated as 2 MOPP between Primary to Secondary and 1 MOPP from Primary to Earth see insulation diagram for details.
- 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. The primary transformers (T501 and T101) on 73-954-0001-G2 **and 73-949-0001-G2** incorporate a Class 155 (F) insulation system.
- The secondary circuit of this power supply has not been evaluated for patient connected applications.
- 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 and Fuse Short Circuit Test.
- The maximum working voltage is 364.1 Vrms, 751 Vpk for Primary - Secondary and 364.4 Vrms, 751 Vpk for Primary - Earth Dead Metal. The electric strength tests in the end-product shall be based on these value.
- For the purpose of spacing and insulation considerations, the input of these power supplies shall be derived from the end system mains of maximum 240Vac mains supply.
- This power supply shall be installed in compliance with the enclosure, mounting, spacing, casualty, markings and segregation requirements of the end use application.
- "Voltage or charge limitation" may need to be reconsidered if additional EMC filter is provided between appliance inlet/ power cord to the product.
- A suitable Mechanical, Electrical and Fire enclosure shall be provided in the end-use product.
- This power supply is operated up to 3000m above sea level as declared by manufacturer.
- Separation from secondary to earth need to evaluated in end product.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- The input and output connectors are not suitable for field connection.
- Proper bonding to the end-product main protective earthing termination is required.
- 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.
- These power supplies are not evaluated for end system mounting. When installed in the end system, proper evaluation should be considered.
- This power supply has two fuse (F1,F2) connected in Live and Neutral.
- Overcurrent releases of adequate breaking capacity must be employed in the end product.
- The touch time for external enclosure isn't determined by the client, end product shall consider it according to client's definition.
- Maximum Operating Temperature Tma (°C) must not exceed 50degC for full load and 70degC for half of the full load for forward airflow direction.
- Overcurrent releases of adequate breaking capacity must be employed in the end product.
- 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 power supply can operate in reverse airflow direction at 40 degree C ambient temperature.
- The power supply was tested in inhibit mode (fan off condition) up to maximum 50 degree C ambient temperature.