

UL TEST REPORT AND PROCEDURE

Standard:	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)
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Product:	Switching Power Supply
Model:	Models: 73-956-0001,73-956-0001-G2; uMP16X-XXX-XXX-XXX-XXX-XXX-XX, 73-951-0001-G2, uMP10X-XXX-XXX-XXX-XXX-XXX-XX where "X" may be "T" or "C" or "S", which indicates the input type; where "XXX" may be "S2A", "S2B", "S2C", "S2D", "S2E", "S2F", "S2G", "S2H", "S2I", "S2J", "S2K", "S2L", "S2M", "S2N", "S2O", "S2P", "S2Q", "S2R", "S2S", "S2T", "S2U", "S2V", "S2W", "S2X", "S2Y", "SKT", "SKU", "SKV", "SKW", "SKX", "SKY", "IQQ" and "D(E-R)(E-R)" which indicates different output loading condition; where "XX" may be "10", "20", "30", "40", "50", "60", "70", "80", "90", "A0", "B0", "C0", "D0", "E0", "F0", "G0", "H0", "J0", "K0", "11", "21", "31", "41", "51", "61", "71", "81", "91", "A1", "B1", "C1", "D1", "E1", "F1", "G1", "H1", "J1", "K1", "13", "23", "33", "43", "53", "63", "73", "83", "93", "A3", "B3", "C3", "D3", "E3", "F3", "G3", "H3", "J3", "K3", "14", "24", "34", "44", "54", "64", "74", "84", "94", "A4", "B4", "C4", "D4", "E4", "F4", "G4", "H4", "J4", "K4", "15", "25", "35", "45", "55", "65", "75", "85", "95", "A5", "B5", "C5", "D5", "E5", "F5", "G5", "H5", "J5", "K5", "00", "01", "03", "04" and "05" which indicates application state.
*Rating:	For 73-956-0001, AC Input: 100 - 240V 13A max 50/60Hz AC Output: 380V +10/-20V RMS Square Wave, 1000W Max AC Input: 200 - 240V 10A max 50/60Hz AC Output: 380V +10/-20V RMS Square wave, 1600W Max For 73-956-0001-G2: AC Input: 100 - 240V, 13A max, 50/60Hz AC Output Voltage: 380V, +10/-20V RMS Square Wave, 1000W Max. AC Input: 200 - 240V, 10A max, 50/60Hz AC Output Voltage: 380V, +10/-20V RMS Square Wave, 1600W Max.

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AC Input: 110 - 240V, 13A max, 50/60Hz
AC Output Voltage: 380V, +10/-20V RMS Square Wave, 1200W Max.

AC Input: 220 - 240V, 13A max, 50/60Hz
AC Output Voltage: 380V, +10/-20V RMS Square Wave, 1800W Max.

uMP16X-XXX-XXX-XXX-XXX-XXX-XXX-XX:
AC Input: 100 - 240V, 13A max, 50/60Hz
Output: 1000W Max., Refer details in report

AC Input: 200 - 240V, 10A max, 50/60Hz
Output: 1600W Max., Refer details in report

AC Input: 110 - 240V, 13A max, 50/60Hz
Output: 1200W Max., Refer details in report

AC Input: 220 - 240V, 13A max, 50/60Hz
Output: 1800W Max., Refer details in report

For 73-951-0001-G2:
AC Input: 100 - 240V, 13A max, 50/60Hz
AC Output Voltage: 380V, +10/-20V RMS Square Wave, 1000W Max.

AC Input: 200 - 240V, 10A max, 50/60Hz
AC Output Voltage: 380V, +10/-20V RMS Square Wave, 1200W Max.

For uMP10X-XXX-XXX-XXX-XXX-XXX-XXX-XX:
AC Input: 100 - 240V, 13A max, 50/60Hz
Output: 1000W Max., Refer details in report

AC Input: 200 - 240V, 10A max, 50/60Hz
Output: 1200W Max., Refer details in report

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.

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Prepared by: Eileen Hu/Cary Hu

Reviewed by: **Hashan Dias / Friis Sven**

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 switching mode power supply, employs an appliance inlet/input terminal for plugging in power supply cord (Not provided) or input cable (Not Provided). Isolation transformers are used and all electronic components are mounted on PWB that rated V-0 and housed in a metal enclosure.

73-956-0001 and 73-956-0001-G2 (uMP16 case model) and 73-951-0001-G2 (uMP10 case model) AC output waveform is specially configured as square wave format to fit with end system special usage.

uMP16X-XXX-XXX-XXX-XXX-XXX-XXX-XX (uMP16 configured series model) and uMP10X-XXX-XXX-XXX-XXX-XXX-XXX-XX (uMP10 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, 73-962-0002 under file **E182560-A120**, model 73-963-0048 under file E182560-A108 **and 73-963-0024 under file E182560-V4-S71**, installed to the recognized Case model 73-956-0001 and 73-956-0001-G2 and 73-951-0001-G2 under E182560-A116 respectively. Each uMP16 and uMP10 series model have 6 slots for AC-DC modules.

Model Differences

Model 73-956-0001 and 73-956-0001-G2 are subassemblies of uMP16 configured series model.

Model 73-951-0001-G2 is a subassembly of uMP10 configured series model.

Models 73-956-0001 and 73-956-0001-G2 are identical except for model designations, input and output ratings, and EMI section PWB layout. There's no difference on the electrical circuit, Just EMI(section) PCB layout have changed.

Models 73-956-0001-G2 and 73-951-0001-G2 are identical to each other except for model designation and power ratings (input & output). There's no electrical circuit difference.

Model uMP16X-XXX-XXX-XXX-XXX-XXX-XXX-XX is a configured model of 73-956-0001 or 73-956-0001-G2 while uMP10X-XXX-XXX-XXX-XXX-XXX-XXX-XX is a configured model of 73-951-0001-G2. These models are identical to each other except for model designation 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 : Appliance coupler or inlet terminal, 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: AAMI ES60601-1 AMD 1 MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE, AMENDMENTS - Edition 1 - Issue Date 2012/08/20. CSA 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/)
- 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.
- 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 transformers (T801& T301) incorporates 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 382.7 Vrms, 681 Vpk for Primary - Secondary and 382.8 Vrms, 681 Vpk for Primary - Earth Dead Metal for model 73-956-0001. The maximum working voltage is 394.7 Vrms, 698 Vpk for Primary - Secondary and 395.2 Vrms, 707 Vpk for Primary - Earth Dead Metal for model 73-956-0001-G2 and 73-951-0001-G2. The electric strength tests in the end-product shall be based on these values.
- This power supply shall be installed in compliance with the enclosure, mounting, spacing, casualty, markings and segregation requirements of the end use application.
- 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 and the suitability of Fuse.
- The input and output connectors are not suitable for field connection.
- 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.
 - The power supply shall be properly bonded to the main earthing termination in end-use.
 - Maximum ambient temperature around the power supply must not exceed 50 deg C for forward airflow condition. Each output derates 2.5% per degree from 50 deg C to 70 deg C ambient temperature.
 - 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 – Limitation of voltage, current or energy.
 - The power supply can operate in reverse airflow direction at 40°C.
 - The power supply was tested in inhibit mode (fan off condition) up to maximum 50°C ambient

temperature.

- **Fro build-in switch power supply, there is no need to control model label.**