

## UL TEST REPORT AND PROCEDURE

<b>Standard:</b>	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)
<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>	73-690-0001i and iMP1-abbc-abbc-abbc-abbc-abbc-abbc-xx
<b>Rating:</b>	<p>Note:"abbc" is any alphanumeric character or blank for specific model designation. Please refer to illustration.</p> <p>Input: AC 100V-240V/200-240V, 50/60Hz, 20A/12A or DC 120Vmin-300Vmax/254Vmin-300Vmax, 20A/12A. Output: DC (for 73-690-0001i): +375V to + 395V, 1800Wmax +5Vsb, 1A +18M1Vcc, 0.1Amax +18M2Vcc, 0.1Amax +18M3Vcc, 0.1Amax +18M4Vcc, 0.1Amax +18M5Vcc, 0.1Amax +18M6Vcc, 0.1Amax +18M7Vcc, 0.1Amax</p> <p>(for iMP1 series): Depends on DC-DC modules used. (Refer to general product information for details) Maximum output power: 1500W (for 200-240Vac or 254-300Vdc) 1200W (for 100-240Vac or 120-300Vdc)</p>
<b>Applicant Name and Address:</b>	ASTECH INTERNATIONAL LTD - PHILIPPINE BRANCH 16TH FL LU PLAZA 2 WING YIP ST KWUN TONG KOWLOON HONG KONG

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Report Reference #

E182560-A57-UL

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.

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### **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

Switching Power Supply, Model iMP1-abbc-abbc-abbc-abbc-abbc-abbc-xx for use in Medical Equipment applications, where "abbc" is any alphanumeric character or blank for specific model designation. See report for details.

iMP1 series are Class I power supplies for building-in, for use in Medical Equipment applications. It consists of the Front-end module 73-690-0001i case and DC/DC converter modules inserted on the slots provided. Each iMP1 configured model has a total of 7 slots for the DC/DC converter modules.

There are single, dual and triple output DC/DC converter modules some of which occupy more than 1 slot. The iMP1 series can be configured with various combination of the following DC/DC modules:

Single output 210W module, (width=1 slot) : 73-551-xxxxi series  
Single output 360W module, (width=2 slots) : 73-552-xxxxi series  
Single output 750W module, (width=3 slots) : 73-553-xxxxi series  
Single output 1500W module, (width=4 slots) :73-558-xxxxi series  
Dual output 144W module, (width=1 slot) : 73-554-xxxxi series  
Triple output 36W module, (width=1 slot) : 73-550-xxxxi series

Switching mode power supply for building-in, 73-690-0001i, Class I equipment, manufactured by Astec International Limited - Philippine Branch, for use in Medical Equipment applications. This power supply requires Modules (DC/DC converters) before using in actual application in the end-system. A separate qualification is needed when the Modules are incorporated for proper configuration and use

### Model Differences

Model 73-690-0001i is a sub-assembly of model iMP1 series.

### 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:: 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:: 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 30A 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 transformer (T501) 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 with Normal MD, Non-frequency MD and Fuse Short Circuit Test.
- For Model 73-690-0001i, the maximum working voltage for T501 is 444 Vrms; 568Vpk. The electric strength tests in the end-product shall be based on this value.
- 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.
- This power supply has two fuse(F201,F202) rated 25A, 250V connected in Live and Neutral .
- The power supply shall be properly bonded to the main earthing termination in end-use.
- During the evaluation, an external forced air-cooling ( Fan with rating 0.45A ,12Vdc) from input terminal to output terminal is required when installing into the end system.
- For 73-690-0001i, excluding the +5Vsb, maximum continuous output power for +390V output is 1800W at input 200-240Vac/254-300Vdc, and 1200W at input of 100-240Vac/120-300Vdc. The maximum operating temperature is 50°C, and for operating temperature over 50°C and up to 70°C, the primary DC output (+390) should be decreased by 2.5% per 1 degree rise.
- For iMP1 series, excluding the +5Vsb output, the maximum continuous total output power on DC-DC modules is 1500W at AC200-240V or DC245Vmin-300Vmax. input voltage, and 1200W at AC100V-240V or DC120Vmin.-300Vmax. input voltage using normal airflow direction at 50°C ambient temperature. Normal airflow direction is fan blowing towards the components. Output power decreases at 2.5% per °C from 50°C to 70°C ambient temperature. Fan is reversible up to 40°C at 100% rated load. An end system ventilation setup was utilized for ventilation during testing.
- For iMP1 series using either 73-558-0005i or 73-558-0006i modules only, excluding the +5Vsb output, the maximum continuous total output power on DC-DC modules is 1500W at AC200-240V or DC245Vmin-300Vmax. input voltage using normal airflow direction at 40°C ambient temperature. The maximum continuous output power is 1200W at AC100V-240V or DC120Vmin.-300Vmax. input voltage using normal airflow direction at 50°C ambient temperature. Normal airflow direction is fan blowing towards the components. Output power decreases at 1.67% per °C from 40°C to 70°C ambient temperature. Fan is reversible up to 40°C at 100% rated load. An end system ventilation setup was utilized for ventilation during testing.