

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:	73-540-0001i / 73-540-0001i-E and iMP4-abbc-abbc-abbc-abbc-abbc-XX / iMP4E-abbc-abbc-abbc-abbc-abbc-XX
Rating:	<p>Note:"abbc" is any alphanumeric character or blank for specific model designation. Please refer to illustration.</p> <p>For iMP4-abbc-abbc-abbc-abbc-abbc-XX Input: AC Input: 100-240/200-240V, 50/60Hz, 12/9A; or DC Input: 120-300/254-300V, 12/9A</p> <p>For iMP4E-abbc-abbc-abbc-abbc-abbc-XX: AC Input: 100-240/200-240V, 50/60Hz, 12/9A;</p> <p>Output: See General product information.Maximum output power: 1158W</p> <p>For 73-540-0001i AC Input: 100-240/200-240VAC, 50/60Hz, 12/9A or DC Input: 120-300/254-300VDC, 12/9A</p> <p>For 73-540-0001i-E AC Input: 100-240/200-240VAC, 50/60Hz, 12/9A</p> <p>Output: +375VDC to +395VDC,1300W (For input voltage of 200-240 Vac or 254-300Vdc) +5Vsb; 1.0A +18M1Vcc, 0.1A; +18M2Vcc, 0.1A; +18M3Vcc, 0.1A; +18M4Vcc, 0.1A; +18M5Vcc, 0.1A;</p> <p>+375VDC to +395VDC,900W (For input voltage of 100-240 Vac or 120-300Vdc) +5Vsb; 1.0A +18M1Vcc, 0.1A; +18M2Vcc, 0.1A; +18M3Vcc, 0.1A; +18M4Vcc, 0.1A; +18M5Vcc, 0.1A;</p>
Applicant Name and Address:	ASTECH INTERNATIONAL LTD - PHILIPPINE BRANCH 16TH FL LU PLAZA

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2015-06-19

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Report Reference #

E182560-A56-UL

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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: Clare He

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

For iMP4 / iMP4E

-Models iMP4-abbc-abbc-abbc-abbc-xx and iMP4E-abbc-abbc-abbc-abbc-xx may be named iMP4 series and iMP4E series in this report correspondingly.

-iMP4 series and iMP4E series consist of the front-end case model 73-540-0001i (for iMP4 series) or 73-540-0001i-E (for iMP4E series) and any combination of separately approved DC-DC converter module series as output. Each iMP4 or iMP4E series model has 5 slots for DC-DC Converter modules used as output. There are single, dual and triple output DC-DC converter modules some of which occupy more than 1 slot.

The iMP4 or iMP4E series can be configured with various combinations of the following DC-DC converter modules:

73-558-xxxxi series: single output, 1500W(width: 4slots)

73-553-xxxxi series: single output, 750W(width: 3slots)

73-552-xxxxi series: single output, 360W(width: 2slots)

73-551-xxxxi series: single output, 210W(width: 1slot)

73-554-xxxxi series: dual output, 144W(width: 1 slot)

73-550-xxxxi series: triple output, 36W(width: 1slot)

For 73-540-0001i and 73-540-0001i-E :

Class I equipment for building-in. This power supply requires modules (DC-DC converter before using in actual application in the end system. A separate qualification is needed when modules are incorporated for proper configuration and use.

73-540-0001i is a sub-assembly of model iMP4 series.

73-540-0001-E is a sub-assembly of model iMP4E series.

For Model 73-540-0001i:

for input voltage rating AC200-240V or DC254-300V;

Output: +375V to +395V ,1300W;

+5Vsb, 1A;

+18M1Vcc, 0.1A;

+18M2Vcc, 0.1A;

+18M3Vcc, 0.1A;

+18M4Vcc, 0.1A;

+18M5Vcc, 0.1A;

For input voltage rating AC100-240V or DC120-300V;

Output: +375V to +395V, 900W;

+5Vsb, 1A;

+18M1Vcc, 0.1A;

+18M2Vcc, 0.1A;

+18M3Vcc, 0.1A;

+18M4Vcc, 0.1A;

+18M5Vcc, 0.1A;

For Model 73-540-0001i-E:

for input voltage of AC100-240V;

Output: +375V to +395V, 900W;

+5Vsb, 1A;

+18M1Vcc, 0.1A;

+18M2Vcc, 0.1A;

+18M3Vcc, 0.1A;

+18M4Vcc, 0.1A;

+18M5Vcc, 0.1A;

for input voltage of AC200-240V;
Output: +375V to +395V, 1300W;

+5Vsb, 1A;
+18M1Vcc, 0.1A;
+18M2Vcc, 0.1A;
+18M3Vcc, 0.1A;
+18M4Vcc, 0.1A;
+18M5Vcc, 0.1A;

Model Differences

Model 73-540-0001i is identical to 73-540-0001i-E except for the AC inlet is used on model 73-540-0001i-E instead of input connector is used for 73-540-0001i. Also model 73-540-0001i-E has no DC input voltage.

Model iMP4 series is identical to iMP4E series except for the front-end case module used. iMP4 series uses 73-540-0001i case while the iMP4E series uses 73-540-0001i-E case module.

Model 73-540-0001i is a sub assembly of model iMP4 series while 73-540-0001i-E is a sub assembly of model iMP4E 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 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 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 73-540-0001i / 73-540-0001i-E, the maximum working voltage for T501 is 442 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 16A, 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 0.47A ,12Vdc) from input terminal to output terminal is required when installing into the end system.
- For 73-540-0001i/73-540-0001i-E, excluding the +5Vsb, maximum continuous output power for +375Vdc to +395V max output is 1300W at input high line 200-240Vac/254-300Vdc, and 900W at input of low line 100-240Vac/120-300Vdc. Direction at 50°C ambient temperature and reverse airflow direction,At 40°C ambient temperature. Output power decreases 2.5% per °C, From 50°C to 70°C ambient temperature for normal airflow and 40°C to 70°C ambient temperature for reverse airflow.
- For iMP4-abbc-abbc-abbc-abbc-abbc-XX and iMP4E-abbc-abbc-abbc-abbc-abbc-XX, excluding +5Vsb output, maximum continuous total output power on DC/DC modules is 1158W at 200-240Vac / 254-300Vdc in put voltage, and 750W at 100-240Vac / 120-300Vdc input voltage using normal airflow direction at 50degC max. ambient temperature and 600W at 100-240Vac / 120-300Vdc input voltage using reverse airflow direction at 40degC max ambient temperature. Output power decreases 2.5% per degC from 50degC to 70degC ambient temperature for normal airflow, and 40degC to 60degC ambient temperature for reverse airflow.
- Overcurrent releases of adequate breaking capacity must be employed in the end product.