

## 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>	Component Type Power Supply
<b>Model:</b>	73-580-0001i and iMP8-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 Ratings: 100-240/200-240VAC, 50/60Hz, 20A/12A or 120-300/254-300VDC, 20A/12A</p> <p>Output Ratings: (for 73-580-0001i using AC200-240V or DC254Vmin-300Vmax Input Voltage) +375V to +395V, 1500W; +5Vsb, 1.0A; +18M1Vcc, 0.1A; +18M2Vcc, 0.1A; +18M3Vcc, 0.1A; +18M4Vcc, 0.1A; +18M5Vcc, 0.1A; +18M6Vcc, 0.1A; Total Output Power: 1515.8W</p> <p>(for 73-580-0001i using AC100-240V or DC120Vmin-300Vmax Input Voltage) +375V to +395V, 1200W; +5Vsb, 1.0A; +18M1Vcc, 0.1A; +18M2Vcc, 0.1A; +18M3Vcc, 0.1A; +18M4Vcc, 0.1A; +18M5Vcc, 0.1A; +18M6vcc, 0.1A; Total Output Power: 1215.8W</p> <p>(For iMP8 series) 2-60VDC, 1200W max. (for 200-240VAC or 254-300VDC Input Voltage)</p> <p>2-60VDC, 1000W max. (for 100-240VAC or 120-300VDC Input Voltage)</p>

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2015-05-18

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Report Reference #

E182560-A51-UL

<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.

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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

(For 73-580-0001i):

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 the modules are incorporated for proper configuration and use. Model 73-580-0001i is a sub-assembly of model iMP8 series.

For input voltage of AC200-240V or DC254Vmin-300Vmax at 50degC:

Output : +375V to +395V, 1500W;

+5Vsb, 1.0A;  
+18M1Vcc, 0.1A;  
+18M2Vcc, 0.1A;  
+18M3Vcc, 0.1A;  
+18M4Vcc, 0.1A;  
+18M5Vcc, 0.1A;  
+18M6Vcc, 0.1A;

Total Output Power: 1515.8Watts

For input voltage of AC100-240V or DC120Vmin-300Vmax at 50degC:

Output : +375V to +395V, 1200W;

+5Vsb, 1.0A;  
+18M1Vcc, 0.1A;  
+18M2Vcc, 0.1A;  
+18M3Vcc, 0.1A;  
+18M4Vcc, 0.1A;  
+18M5Vcc, 0.1A;  
+18M6Vcc, 0.1A;

Total Output Power: 1215.8 Watts

1. Maximum continuous output power for +375Vdc to +395Vdc output is 1500W at 200-240Vac / 254-300Vdc input voltage, and 1200W at 100-240Vac / 120-300Vdc input voltage using normal airflow direction or 30CFM external fan set-up condition at 50degC maximum ambient temperature and reverse airflow direction at 40degC maximum ambient temperature.

2. Output power decreases 2.55 per deg C from 50degC to 70degC ambient temperature for normal airflow or 30CFM external fan set-up, 40degC to 60 degC ambient temperature for reverse airflow direction.

For iMP8 Series:

Input ratings: 100-240Vac / 200-240Vac, 50/60Hz, 20A/12A or  
DC 120Vmin-300Vmax / DC 254Vmin- 300Vmax; 20A/12A;

Output ratings:

Excluding +5Vsb at 200-240Vac or 254-300Vdc input voltage:

-1200W at maximum 50degC, normal airflow.

-Output rating derates 2.55 per deg C from 50degC to 70degC for normal airflow.

Excluding +5Vsb at 100-240Vac or 120-300Vdc input voltage:

-1000W at maximum 50degC, normal airflow.

-Output ratings derates 2.55 per deg C from 50degC to 70degC for normal airflow.

Notes:

1. Output classification level may be 1,3,5 or 6 depending on model configuration. "Level 1" is a CSA designation which denotes that outputs are either not suitable for, or have not been investigated for SELV.

"Level 3" is a CSA designation which denotes that outputs are SELV and non-hazardous energy 240VA hazardous energy level. "Level 5" is a CSA designation which denotes that outputs are SELV and exceed 240VA hazardous energy level. "Level 6" is a CSA designation which denotes a multiple output power supply with outputs in any combination of Levels 1, 3 and 5.

2. The subject power supplies consist of a front-end, AC-DC converter, and chassis and modules, DC-DC converter modules, which are individually approved and listed under CB scheme.

Each iMP8 series model has 6 slots for DC-DC converter modules. There are single, dual and triple output DC-DC converter modules, some of which occupy more than 1 slot. The iMP8 series may be configured with various combinations of the following modules:

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

Remark:

1. Clearance evaluated for operating altitude up to 10000 feet (3048 meters) above sea level.
2. All outputs are energy hazard (exceeding 240VA), when installing into end system, care must be taken that the output and associated wire(s) may not be touched.

#### **Model Differences**

Model 73-580-0001i is a sub-assembly of model iMP8 series.

#### **Technical Considerations**

- Classification of installation and use : Component for building-in.
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : Power supply to medical device.
- Mode of operation : Continuous
- Supply connection : Switching mode power supply for building-in. To be considered in end use.
- Accessories and detachable parts included : N/A
- Other options include : N/A
- The product was investigated to the following additional standards:: 1. 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;; 2. 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 degree of protection against harmful ingress of water is:: IPX0
- The mode of operation is:: Continuous
- For 73-580-0001i, the maximum continuous power for +375Vdc to +395Vdc output power is 1500W at 200-240Vac / 254-300Vdc input voltage, and 1200W at 100-240Vac / 120-300Vdc input voltage using normal airflow direction at 50degC ambient temperature and 40degC ambient temperature at reverse airflow direction. Output power decreases 2.5% per deg C from 50degC to 70degC ambient temperature for normal airflow. For iMP8 series , excluding +5Vsb output, the maximum continuous total power on DC-DC modules is 1200W at AC200-240V / DC254Vmin-300Vmax input voltage, and 1000W at AC100-240V / DC120Vmin-300Vmax input voltage using normal airflow direction at 50degC ambient temperature and reverse airflow direction at 40degC ambient temperature. Output

power decreases 2.5% per deg C from 50degC to 70degC ambient temperature for normal airflow.

### **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:

- A suitable electrical, mechanical and fire enclosure shall be provided by the end use equipment.
- The terminals and connectors have not been evaluated for field wiring.
- Refer to installation and operation instructions for details of operating temperature and loading condition.
- Clearance distance was evaluated for operating altitude up to 3048m above sea level.
- These power supplies are considered Class I product. The power supply shall be properly bonded to the main earthing termination in end-use.
- These power supplies are not evaluated for end system mounting. When installed in the end system, proper evaluation should be considered.
- 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 has two fuse(F201,F202) connected in Live and Neutral .
- When installing this equipment, all requirements of the mentioned standard must be fulfilled.
- The output was not evaluated as patient connected circuits.
- Compliance with the requirements for EMC shall be evaluated for the end use product.
- This product has been investigated only as a component part for use in equipment where the suitability of the combination is subject to end product investigation.
- This power supply must be installed with accordance to with the instruction manual.
- The leakage current test shall be checked in the end product.
- Clearance/creepage distance and dielectric strength were evaluated and fulfill the requirements for MOPP.
- Additional evaluation using an external forced air-cooling from input terminal to output terminal with air flow 30 CFM was conducted. This should be considered when installing into the end system.
- Output power decreases 2.5 per deg C from 50degC to 70degC ambient temperature for normal airflow or 30CFM external fan set-up, 40degC to 60 degC ambient temperature for reverse airflow direction.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component.
- 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.
- 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 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.
- End product to determine the acceptability of risk in conjunction to the use of Thermal Cut-off and Overcurrent releases as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the use of Pre-set controls as part of the power supply.