

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:	DA12-050US-M, DA12-050MP-M
Rating:	Input: 100-240 Vac, 0.3A max., 50/60Hz Output: 5Vdc, 2.0A max., 10W max.
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.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Michael Wetherington/ Jeffery Chan Reviewed by: Calvin Tang

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

The equipment under test is Class II AC/DC Switch Mode Power Supply, with electronic components mounted on PWB covered by polymeric enclosure, which is intended for use in medical electrical equipment. A step down isolation transformer is used and all electronic components are mounted on PWB which rated V-0 and housed in plastic enclosure which rated V-0.

2 MOPP insulations were provided between primary and secondary/external enclosure.

Model Differences

Models DA12-050US-M and DA12-050MP-M are exactly the same in terms of its electrical construction. They only differ in model designation and bottom plug part configuration.

DA12-050US-M has polarized fixed plug.

DA12-050MP-M has input connection of detachable polarized plug and detachable non-polarized appliance inlet.

Technical Considerations

- Classification of installation and use : Transportable - Direct Plug-in Power Adapter
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : Component - to be evaluated in end product
- Mode of operation : Continuous
- Supply connection : Direct Plug-in Power Adapter
- 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 II, 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 II 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 provided between Primary and Secondary, and 2 MOPP provided between Primary and External Enclosure; see insulation diagram for details.
- Consideration shall be given to measuring the temperatures on power electronic components and transformer windings when the power supply is installed in/with the end-use equipment. Transformer T1, employs a Class F (155) insulation system.
- The secondary output circuit is SELV and is not at hazardous energy level.
- The maximum ambient temperature of the product is 40°C.
- 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.
- The maximum working voltage for T1 present is 240 Vrms; 504 Vpk. 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.
- "Voltage or charge limitation" may need to reconsider if additional EMC filter is provided between appliance inlet/ power cord to the product.
- This power supply is operated up to 3000m above sea level as declared by manufacturer.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply and the suitability of Fuse.
- 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.
- A suitable fuse shall be considered in end product investigation. F1 and F2 fuse shall be used in

accordance with the critical component list, and additional consideration should be given when alternate other fuse sources. For fuse without minimum Interrupting rating 100A, such as models 20T and 5ET by Hollyland, Overcurrent releases of adequate breaking capacity (Minimum Interrupting rating is 100A for current rating of fuse 1.0A) must be employed in the end product

- This power supply has not been evaluated for patient connected applications.
- The end-use product shall ensure that the power supply is used within its ratings.
- The reliability of the silkscreen printing should be evaluated in end system.
- This power supply complied with ES60601-1, Table 23, the requirement for allowable maximum temperatures for ME Equipment parts that are likely to be touched. The external surfaces for this power supply that are likely to be touched for a time "t" is $t < 1$ second.
- The acceptability of the output connectors, insulating materials, and temperatures shall be considered in the end use product.