

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:	CNS653-M#-XXX, CNS655-MU-XXX, CNS658-MU-XXX (Where "#" can be E, F or U; and "-XXX" can be any alphanumeric character or blank which represents customer identity that do not affect safety)
Rating:	Input: 100-240Vac, 9.2A, 50/60Hz DC 127Vmin - 350Vmax, 9.2A Output: For CNS653-M#-XXX: +12V @ 54.2Amax +12V Fan @ 1.0Amax +5Vsb @ 2.0Amax For CNS655-MU-XXX: +24V @ 27.1Amax +12V Fan @ 1.0Amax +5Vsb @ 2.0Amax (For CNS658-MU-XXX) +48V, 13.55Amax +12V FAN, 1Amax +5Vsb, 2Amax Maximum Output Power: 410W Convection Cooling (for CNS653-MU-XXX, CNS653-MF-XXX, CNS655-MU-XXX and CNS658-MU-XXX only) 650W Forced Air Cooling
Applicant Name and Address:	ASTECH INTERNATIONAL LIMITED 16TH FLOOR, LU PLAZA 2 WING YIP STREET, KWUN TONG, KOWLOON, HONGKONG

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Report Reference #

E182560-A132-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.

Prepared by: Jelly Li / Clare He

Reviewed by: David Shih

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 medical switching mode power supply for building-in which has been evaluated for use in Class I medical application. Unit provided with insulation transformers and all components are mounted on 94V-0 PWB.

Model Differences

CNS653-MF-XXX, CNS653-ME-XXX and CNS653-MU-XXX are identical (same PCB, same electric circuitry, same transformers) except for mechanical construction.

CNS653-MF-XXX is an open frame power supply with heatsink on D1.

CNS653-MU-XXX is the same as CNS653-MF-XXX, but employs additional U-base chassis without heatsink on D1.

CNS653-ME-XXX is the same as CNS653-MU-XXX, but employs additional Fan Panel Chassis (with AC inlet connected to the input terminal block) and enclosure cover.

CNS655-MU-XXX are identical to CNS653-MU-XXX except for windings of power transformer (T1)-(refer to supplements of 4-01 for details), secondary circuit for 24 VDC output, and model name designation.

CNS658-MU-XXX is identical to CNS653-MU-XXX except for power transformer (T1), output ratings, and model name designation.

Technical Considerations

- Classification of installation and use : Component to be installed in end product
- 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 the end product
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1 (2005/(R)2012 + C1:2009/(R)2012 + A2:2010/(R)2012) - Revision Date 2012/01/17 , CAN/CSA-C22.2 No. 60601-1:08 - Edition 2 (Incorporates Corrigendum 2) - Revision Date 2011/0,
- 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 following accessories were investigated for use with the product:: None
- 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 not been evaluated for patient connected applications.
- 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 (T1, T900, T2 and T3) incorporate a Class 155 (F) insulation system.

- The power supply was evaluated as 2 MOPP between Primary to Secondary and 1 MOPP from Primary to Earth see insulation diagram for details.
- Maximum Operating Temperature Tmax (°C) is 50 deg. C for full load and 80 deg. C for 25% of the full load. Half load is at 70 deg C.
- Earthing terminal at input connector is not considered protective earthing terminal, but is considered bonding terminal. Power supply chassis is to be reliably bonded earthing in end use equipment before energized.
- The end-product Electric Strength Test is to be based upon a maximum working voltage of: T1 Pri-Sec: 230.9Vrms and 546Vpk; T2 Pri-Sec: 251.9Vrms and 472Vpk; T3 Pri-Sec: 251.9Vrms and 473Vpk; T900 Pri-Sec: 426.2Vrms and 650Vpk, for model CNS658-MU-XXX is: T1 Pri-Sec: 258.6Vrms and 514Vpk; T2 Pri-Sec: 253.1Vrms and 456Vpk; T3 Pri-Sec: 254.9Vrms and 460Vpk; T900 Pri-Sec: 428.7Vrms and 634Vpk.
- Leakage current and Earthing continuity test need to be repeated in end-product investigation.
- Instructions and equipment marking shall be provided in a language, which is acceptable in the country in which the equipment is to be installed.
- This power supply was tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary. The fuse employed didn't fracture and remained intact during the single fault condition testing and short circuit testing performed in client's facility.
- Input terminal/connector shall be connected to the supply neutral in the end use for simultaneous disconnection of all supply poles.
- The insulation between accessible parts and live part must be re-evaluated in end product.
- End product Risk Management Process to consider the need for simultaneous fault condition testing.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- 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 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 selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply.
- A suitable Electrical, Mechanical and Fire Enclosure shall be provided by end use equipment.
- This unit is not intended to be used for permanent connection.
- The output connectors are not acceptable for field connection and are only intended for connections to mating connectors of internal wiring inside the end use product. The acceptability of these and the mating connectors relative to secureness, insulating materials, and temperatures shall be considered in the end-use product.
- Depending on the end product application, additional markings and documentation may be required. This is to be evaluated in the end product.

- The clearance and creepage distance have additionally been assessed for suitability up to 3000m elevation.
- This power supply shall be installed in compliance with the enclosure, mounting, spacing, casualty, markings and segregation requirements of the end-use application.
- Built-in switching power supply. Applicability of the following is to be determined in End Product Evaluation: 8.4.2 - Accessible Parts Including Applied Parts.
- This power supply is component level power supply intended for use in Class I application.
- The suitable fuses shall be considered in end product investigation.
- For CNS653-M#-XXX: Additional evaluation has been considered on the +12V (-10% / +10%) output voltage adjustability limited to the following combined conditions: maximum 54.2A load current and 650W output power.
- Overcurrent releases of adequate breaking capacity must be employed in the end product.
- FAN and +5Vsb outputs should be considered part of the maximum output power (410W for convection cooling, 650W for forced air cooling).
- For CNS653-MU-XXX, CNS653-MF-XXX, CNS655-MU-XXX and CNS658-MU-XXX using convection cooling: The maximum continuous output power is 410W at AC180-264V or DC254-350V input; or 400W at AC110-179V or DC155-253V input; or 372.5W at AC100V or DC141V input; or 345W at AC90V or DC127V input at 50degC maximum ambient temperature. Output power derates at 2.5% per degC from 50degC to 80degC.
- For CNS653-MU-XXX, CNS653-MF-XXX, CNS655-MU-XXX and CNS658-MU-XXX using forced-air cooling: The maximum continuous output power is 650W AC90-264V or DC127-350V input at 50degC maximum ambient temperature with min. 400LFM fan airflow (for CNS653-MU-XXX, CNS653-MF-XXX, CNS655-MU-XXX and CNS658-MU-XXX using ventilation position 1 and 2) or min. 300LFM (for CNS653-MF-XXX using ventilation position 3 and 4). Output power derates at 2.5% per degC from 50degC to 80degC.
- For CNS653-ME-XXX: The maximum continuous output power is 650W AC90-264V or DC127-350V input at 50degC maximum ambient temperature. Output power derates at 2.5% per degC from 50degC to 80degC.
- Built-in switching power supply. Applicability of the following is to be determined in End Product Evaluation: 8.4.2 - Accessible Parts Including Applied Parts
- For CNS655-MU-XXX: Additional evaluation has been considered on the +24V (-10% / +10%) output voltage adjustability limited to the following combined conditions: maximum 27.1A load current and 650W output power.
- AC inlet is not considered as disconnect device for DC input application. This should be considered in End Product Application.
- For CNS658-MU-XXX: Additional evaluation has been considered on the +48V (-10% / +10%) output voltage adjustability limited to the following combined conditions: maximum 13.55A load current and 650W output power.
- Impairment of Cooling test should be consider in end product.