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:	AC-DC Power Supply
Model:	mHNSP4-1000P. and mHPCSA-1000P. (where "." minimum 5 characters, maximum 50 characters, any alphanumeric character, hyphen or blank, which denotes control number)
Rating:	AC INPUT: 100-240 V, 9.6 A-4.0 A, 50/60 Hz DC OUTPUT: CH1: 3.3 Vdc. 10 A (maximum 25 A, peak 30 A) CH2: 5 Vdc, 10 A (maximum 25 A, peak 30 A) CH3: 12 Vdc, 15 A (maximum 18 A, peak 25 A) CH4: 12 Vdc, 15 A (maximum 18 A, peak 25 A) CH5: 12 Vdc, 15 A (maximum 18 A, peak 25 A) CH6: 12 Vdc, 15 A (maximum 18 A, peak 25 A) CH7: -12 Vdc, 0.3 A (maximum 1.2 A, peak 1.2 A) CH8: 5 Vdc, 3 A (maximum 3 A, peak 4 A) Peak: maximum 5 seconds Interval: 45 seconds Total Wattage: 822 W maximum (CH1+CH2: 207.5 W maximum, CH3+CH4+CH5+CH6: 792 W maximum, CH7: 14.4 W maximum, CH8: 15 W maximum) Total Peak Wattage: 1000 W maximum (CH1+CH2: 249 W maximum, CH3+CH4+CH5+CH6: 1000 W maximum, CH7: 14.4 W maximum, CH8: 20 W maximum)
Applicant Name and Address:	NIPRON CO LTD 2-57 OHAMA-CHO AMAGASAKI-SHI HYOGO-KEN 660-0095 JAPAN

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.

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: Toshinori Mori Reviewed by: Tsutomu Abe

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 equipment is component type power supply for medical equipment.

Model Differences

Model mHNSP4-1000P. is identical to Model mHPCSA-1000P. except for model designation, battery pack unit and connector CN11.

Model mHNSP4-1000P. has battery pack unit and CN11 to connect battery pack unit.
Model mHPCSA-1000P. does not have battery pack unit and CN11.

Model HNSP4-1000. is supplied from Battery Pack Unit to prevent momentary stop when disconnect from supply mains.

Technical Considerations

- Classification of installation and use : Built-in
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : To supply regulated power, no patient connection
- Mode of operation : Continuous
- Supply connection : N/A (to be considered in end-use 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) (includes National Differences for Canada), ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States)
- The product was not investigated to the following standards or clauses:: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)
- 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:

- The equipment has been evaluated for use at altitudes up to 3,000m.
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra): 40 °C for 100% load / 60°C for 60% load.
- This power supply has been judged on the basis of the required creepage and clearances in the Standard for Medical Electrical Equipment, AAMI ES / CSA / IEC / EN 60601-1, Sub clause 8.9.
- This unit is a power supply intended for building in. Final installation should comply with the enclosure, mounting, marking, spacing and separation requirements. In addition, Temperature, Leakage Current, Dielectric Voltage Withstand and Interruption of the Power Supply tests should be

considered as part of the end product evaluation.

- The output circuit has not evaluated for connecting to Applied Parts. For end products intended to connect the output circuit to Applied Parts, suitable evaluation of the separation, leakage current, dielectric voltage withstand and related requirements should be conducted.
- The unit provides the following MOOP (means of operator protection): 2 MOOP based upon a working voltage 335 Vrms, 625 Vpk between input circuit of isolation transformer (T101) and transformer output circuit. And the core of the transformer is treated as floating.
- Isolation transformer T201 and T12 employ a Class B (130 degree C) insulation system.
- 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.
- Secondary outputs are SELV for all models.
- Considerations to applied parts requirements must be made for the end-product to which this component is used in.
- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment. The end-use product shall ensure that the power supply is used within its ratings.
- The output terminals are not intended for field connections, they are only intended for factory wiring inside the end-use product.
- The functional enclosure provided on some sub-models has not been evaluated as a fire enclosure.
- 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 to be classified as contrary to the above.
- Connection, separation and isolation from the mains supply shall be determined and evaluated as part of the end-product, including provision for appropriate fusing of the mains input to the device.
- The risk management requirements of the standard were not addressed and must be considered in the end product investigation.

Additional Information

Load conditions were as follows (CH1, CH2, CH3, CH4, CH5, CH6, CH7, CH8)
Condition A (100% of rated resistive load)
3.3V/10A, 5V/10A, 12V/15A, 12V/15A, 12V/15A, 12V/15A, -12V/0.3A, 5V/3A

Condition B (90% of rated resistive load)
3.3V/9A, 5V/9A, 12V/13.5A, 12V/13.5A, 12V/13.5A, 12V/13.5A, -12V/0.27A, 5V/2.7A

Condition C (100% of rated resistive load (Maximum current CH1 and CH2))
3.3V/25A, 5V/25A, 12V/12.5A, 12V/12.5A, 12V/12.5A, 12V/12.06A, -12V/0.4A, 5V/3A

Condition D (100% of rated resistive load (Maximum current CH3, CH4, CH5 and CH6))
3.3V/0A, 5V/2.04A, 12V/18A, 12V/16.5A, 12V/16.5A, 12V/15A, -12V/0.4A, 5V/3A

Condition E (100% of rated resistive load (Peak current CH1 and CH2))
Repeats 5 seconds peak output current and 45 seconds rated output current.
3.3V/30A, 5V/30A, 12V/15A, 12V/15A, 12V/15A, 12V/15A, -12V/12A, 5V/4A

Condition F (100% of rated resistive load (Peak currenrtCH3, CH4, CH5 and CH6))
Repeats 5 seconds peak output current and 45 seconds rated output current.

3.3V/0A, 5V/0A, 12V/22A, 12V/22A, 12V/22A, 12V/15.7A, -12V/0A, 5V/4A

Condition G (60% load of resistive load)
3.3V/6A, 5V/6A 12V/9A, 12V/9A, 12V/9A, 12V/9A, -12V/0.18A, 5V/1.8A

Condition H (73% of rated resistive load (600W)), Supplied from Battery Pack Unit.
3.3V/7.3A, 5V/7.3A, 12V/10.95A, 12V/10.95A, 12V/10.95A, 12V/10.95A, -12V/0.219A, 5V/2.19A

Installation condition:
Condition A: Point A (Signal Connector) is upper side
Condition B: Point B (AC Inlet) is upper side
Condition C: Point C (Power Switch) is upper side
Condition D: Point D (Fan) is upper side

This equipment is provided a variable Fan that changes the rotating speed from low to high at ambient temperature more than approx. 28°C.
Heating test for low speed condition was performed in chamber at 27.5°C.
(Operating condition E with installation condition D, which is the worst condition at high speed condition.)

AC Inlet side of Enclosure for Main Unit is evaluated to be outside surface of the end product.
The other parts of Enclosure must be checked in the end product.

Three battery packs incorporated in Battery Pack Unit.
A battery pack is composed seven secondary Ni-MH battery cells. These battery cells are certified under IEC 62133 by Intertek.

Transformers T101, T201, T11 and T12 are produced by the following manufacturer according to the same specifications. The difference of manufacturer does not affect safety.

<T101, T11>
1) Nipron Co., Ltd.
2) East Corp.
3) Axis Corp.
4) Nippon Ceramic Co., Ltd.
5) Prisource Electronics Co., Ltd.
6) Toho Zinc Co., Ltd.
7) Todai Electric Ltd.
8) Smartcoil Electronical Industrial Co., Ltd.

<T201, T12>
1) Axis Corp.
2) Nippon Ceramic Co., Ltd.
3) Prisource Electronics Co., Ltd.
4) Todai Electric Ltd.
5) Smartcoil Electronical Industrial Co., Ltd.

Inductors LF101, LF103 and LF102 are produced by the following manufacturer according to the same specifications. The difference of manufacturer does not affect safety.

<LF101, LF103>
1) Nipron Co., Ltd.
2) Ueno corporation

<LF102>
1) Nipron Co., Ltd.
2) Toho Zinc Co., Ltd.

Additional Standards

The product fulfills the requirements of: N/A

Markings and instructions

Clause Title	Marking or Instruction Details
Model	Model number
Company identification	Classified or Recognized company's name, Trade name, Trademark or File

Special Instructions to UL Representative

N/A

Production-Line Testing Requirements

Test Exemptions - The following models are exempt from the indicated test

Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
All	N/A	N/A	N/A

Solid-State Component Test Exemptions - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:

Component
N/A

Sample and Test Specifics for Follow-Up Tests at UL

The following tests shall be conducted in accordance with the Generic Inspection Instructions

Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
N/A	N/A	N/A	N/A