

UL TEST REPORT AND PROCEDURE

Standard:	AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021 CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental - Component)
Complementary CCN:	N/A
Product:	DC Power Supply
Model:	mHPCSF-400Px (where x maybe maximum 50 characters, any alphanumeric character, hyphen or blank, which denotes control number)
Rating:	Input: 100-240Vac, 50/60Hz, 3.8-1.6A Output: CH1: 3.3 Vdc, maximum 16 A (peak 20 A) CH2: 5 Vdc, maximum 16 A (peak 20 A) CH3: 12 Vdc, maximum 25 A (peak 30 A) CH4: -12 Vdc, maximum 0.5 A (peak 0.5 A) CH5: 5VSB, maximum 2 A, peak 3 A) Peak: maximum 5 seconds Interval: 45 seconds Total Wattage: 310 W maximum (CH1+CH2: 90 W maximum, CH3: 300 W maximum, CH4: 6 W maximum, CH5: 10 W maximum) Total Peak Wattage: 400 W maximum (CH1+CH2: 120 W maximum, CH3: 360 W maximum, CH4: 6 W maximum, CH5: 15 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.

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: Masaki Nunoya / Project Handler Reviewed By: Cynthia Xiao / Reviewer

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.

Model Differences

mHPCSF-400P**+x (where * any alphanumeric character, where + maybe any alphanumeric character except for "N", "Z", where x maybe maximum 47 characters, any alphanumeric character, hyphen or blank):

Optional switch (SW401) was provided; Suffixes denote control number which does not affect safety.

mHPCSF-400P**Nx and mHPCSF-400P**Zx (where * any alphanumeric character, where x maybe maximum 47 characters, any alphanumeric character, hyphen or blank):

Optional switch (SW401) was not provided; Suffixes * and x denote control number which does not affect safety.

Test Item Particulars

Classification of installation and use	Building-in
Supply Connection	Appliance Coupler
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
Accessories and detachable parts included	None
Other options include	Capacitor Pack

Technical Considerations

- The product was investigated to the following additional standards : EN 60601-1:2006 + A1:2013 + A12:2014 + A2:2021
- The following additional investigations were conducted : N/A
- The product was NOT investigated to the following standards or clauses : Clause 7.1.1: Usability, Clause 11.7: Biocompatibility, Clause 17: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1), Risk Management (ISO 14971), Usability (IEC 60601-1-6, 62366)
- The following accessories were investigated for use with the product : Chassis, Cover, Capacitor Pack
- Mains supply tolerance (%): +10% / -10% (-15% to -10% with output de-rating)

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 and pollution degree 2.
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tma). See Enclosure Id 07-10 for additional details regarding out de-rating depends on the product orientation.
- 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 MOP (means of protection): Primary-GND (1MOOP): 342 Vrms, 700 Vpeak and Primary-Secondary (2MOOP): 342 Vrms, 724 Vpeak, which is measured by using case 2 mentioned in figure 41
- 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.
- All secondary outputs are SELV. CH3 (12Vdc) is at hazardous energy levels, other outputs are at non-hazardous energy levels.
- 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 input/output terminals are not intended for field connections, they are only intended for factory wiring inside the end-use product.
- 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.
- Instruction Manual shall be evaluated in the end product application.
- Proper bonding to protective earthing terminal of end product shall be provided via chassis. Printed Wiring Board Trace of 6164P1, 6164P2 and 6206P4 Board or Trace of 6255P1, 6255P2 and 6257P4 Board were investigated as part of the protective earthing/bonding. (See Enclosure Id 5-01 and 05-02)
- Limitation of Voltage, Current or Power (8.4.2 c) for SIP/SOP connectors or separate power supply output connectors may be needed in end-product evaluation.
- The clearances and creepage distances between each optional units shall be evaluated in the end product.

Additional Information

This equipment is temperature dependent equipment.

When the temperature of transistor (Q202) changes, thermistor (TH201) detects it changing and controls fan speed. Fan speed is maximum when short circuit thermistor (TH201). When the room ambient is approximately 25°C and output is the rating condition, fan speed is maximum speed.

Fan has two types as follows.

- Nidec Corporation, Type a60R12MMAB

- Minebea Motor Manufacturing Corporation, Type 2406VL-04W-B4

Maximum air flow is the same, but is different in the characteristic of that Static Pressure versus Air Flow curves (see Enclosure Id 7-06). Therefore, Unless specified in particular, tests were conducted with Type a60R12MMAB.

Line Filter (LF101) has two types as follows.

- Nipron Co., Ltd. or Ueno Corporation, Type LT6119 X ("X" maybe maximum 50 characters, any alphanumeric number or blank, which denotes control number)

- JFE Ferrite Corporation, Type DR18a-0510-H

All tests were conducted at employing Type LT6119 due to Type DR18a-0510-H is same construction as Type LT6119 except for type name and manufacturer that do not affect the safety requirement.

Line Filter (LF102, LF103) has three types as follows.

- Nipron Co., Ltd., Type LT6118 X ("X" maybe maximum 50 characters, any alphanumeric number or blank, which denotes control number)

- JFE Ferrite Corporation, Type DR20AJ-0520-H

- Ueno Corporation, Type ADR20K-0520T

All tests were conducted at employing Type LT6118 due to Type DR20AJ-0520-H and Type ADR20K-0520T is same construction as Type LT6118 except for type name and manufacturer that do not affect the safety requirement.

Transformer (T101):

All tests were conducted at employing Nipron Co., Ltd., Type MT6105 due to difference was only manufacturer.

Transformer (T102):

All tests were conducted at employing Nipron Co., Ltd., Type MT6106 due to difference was only manufacturer.

Transformer (T103):

All tests were conducted at employing Nipron Co., Ltd., Type DT6027 due to difference was only manufacturer.

Inductor (L101):

All tests were conducted at employing Nipron Co., Ltd., Type LT6164 due to difference was only manufacturer.

6257P4, 6255P1, 6255P2, 6255P3, 6257P4, 6255P5, 6255P6 Boards are identical to 6206P4, 6164P1, 6164P2, 6164P3, 6206P4, 6164P5, 6164P6 Boards except for some components and/or pattern layout. Refer to Enclosure Id 05-01 to 05-06.

Insulation Sheet (between PWB (6164P1 Board or 6255P1 Board, 6164P2 Board or 6255P2 Board, 6164P3 Board or 6255P3 Board) and Chassis:

All tests were conducted at employing AGC Polycarbonate Co., Ltd., Type CARBOGLASS CFR(z)C. Type CARBOGLASS CFR(z)C was considered representative of the other Insulation Sheet because all Insulation Sheet were evaluated to Distance through insulation measurements tests by previous models.

Tests were conducted with following output load conditions (CH1, CH2, CH3, CH4, CH5).

Condition A (Standard load):

3.3 Vdc/ 8 A, 5 Vdc/ 8 A, 12 Vdc/ 19 A, -12 Vdc/ 0.5 A, 5VSB/ 2 A

Condition B (Maximum continuous load, Most unfavorable load for T101, total 310W):

3.3 Vdc/ 0 A, 5Vdc/ 0 A, 12 Vdc/ 24.5A, -12 Vdc/ 0.5A, 5VSB/ 2 A

Condition C (Maximum continuous load, Most unfavorable load for T102 and CH1, total 310W):

3.3 Vdc/ 16 A, 5 Vdc/ 7.5 A, 12 Vdc/ 17.5 A, -12 Vdc/ 0 A, 5VSB/ 2 A

Condition D (Maximum continuous load, Most unfavorable load for T102 and CH2, total 310W):

3.3 Vdc/ 3.1 A, 5 Vdc/ 16 A, 12 Vdc/ 17.5 A, -12 Vdc/ 0 A, 5VSB/ 2 A

Condition E (Pulse, Most unfavorable load for T101, total 400W)

3.3 Vdc/ 0 A, 5 Vdc/ 3.8 A, 12 Vdc/ 30 A, -12 Vdc/ 0.5 A, 5VSB/ 3 A

Condition F (Pulse, Most unfavorable load for T102 and CH1, total 400W)

3.3 Vdc/ 20 A, 5 Vdc/ 10.8 A, 12 Vdc/ 21.6 A, -12 Vdc/ 0.5 A, 5VSB/ 3 A
Condition G (Pulse, Most unfavorable load for T102 and CH2, total 400W)
3.3 Vdc/ 6.1 A, 5 Vdc/ 20 A, 12 Vdc/ 21.6 A, -12 Vdc/ 0.5 A, 5VSB/ 3 A
Condition H (No Load)
3.3 Vdc/ 0 A, 5 Vdc/ 0 A, 12 Vdc/ 0 A, -12 Vdc/ 0 A, 5VSB/ 0 A

This equipment may be provided with Back-Up Function with Capacitor Pack, if AC Mains stops, output is supplied from Capacitor Pack.

(For CB certification only)

This product has been previously evaluated by UL according to IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (including USA and Canada national differences) at CBTR Ref. No. 4786498951, CBTC Ref. No. US-24030-UL issued by UL Solutions (US), and IEC 62368-1:2018 (including USA and Canada national differences) at CBTR Ref. No. E161936-A6068-CB-1 (Original), CBTC Ref. No. JP-27254-UL issued by UL Solutions (JP).

Compliance with the following test requirements was determined upon the review of the previous test results where the test method and conditions are identical:

4.11 - Power Input
5.7 - Humidity Conditioning
8.4.2 - Limitation of Voltage, Current or Power
8.4.3 - Voltage or Charge Limitation
8.5.4 - Working Voltage Measurements
8.6.4 a - Impedance and Current Carrying Capability (for 6206P4 board, 6257P4 at test current 40 A)
8.7 - Leakage Current Tests
8.7.4.5 - Earth Leakage Current
8.7.4.6 - Touch Leakage Current
8.7.3 e) - Non-Frequency-Weighted Leakage Current
8.8.3 - Dielectric Voltage Withstand
8.8.4.1 - Ball Pressure
11 - Temperature
13 - Abnormal Operation Testing
15.5.1.2 - Transformer Short Circuit
15.5.1.3 - Transformer Overload

In addition to the above, following report modification was made:

- Change of maximum condenser capacity of line to ground capacitors for all models; (C103, C104): 4700pF to no mount, (C105, C106, C133): from 4700pF to 2200pF, (C116, C134): from 2200pF to 470pF

Only limited tests were deemed necessary.

8.6.4 a - Impedance and Current Carrying Capability (for 6257P4 at test current 25 A)

The marking plate label provided is representative of all series models because the required information except for model name is same as representative.



When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.

Additional Standards

The product fulfills the requirements of: AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021, CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14

EU Group Differences (No National or Group Differences declared).

Markings and Instructions

Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Alternating current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.
Fuses	Ratings (current and voltage) and type. (located adjacent to fuse OR as a diagram inside enclosure)
Protective earth ground	
Special Instructions to UL Representative N/A	

Product-Line Testing Requirements			
Required? (NOTE TO USER: A YES or NO verdict is required in this column.)	Test	Model/Part Exempt from Test	Additional Details
Yes	Grounding Continuity	None	None
Yes	Dielectric Strength	None	None
No	Patient Circuit Dielectric Voltage Withstand	N/A	N/A

Solid State Component Instructions		
Solid State Component	Parts to be disconnected for test	Specific Test
The following solid-state components that can be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:	N/A	N/A
	N/A	N/A
	N/A	N/A
	N/A	N/A
	N/A	N/A

Sample and Test Specifics for the Follow-Up Tests at UL			
Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
None	NA	NA	NA
None	NA	NA	NA