

## UL TEST REPORT AND PROCEDURE

|                            |   |
|----------------------------|---|
| <b>Standard:</b>           | AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021<br>CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1)<br>and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14   |
| <b>Certification Type:</b> | Component Recognition   |
| <b>CCN:</b>                | QQHM2, QQHM8 (Power Supplies, Medical and Dental - Component)   |
| <b>Complementary CCN:</b>  | N/A   |
| <b>Product:</b>            | Power Supply  |
| <b>Model:</b>              | mUZP-120-12xxx-yx-x, mUZP-120-24xxx-yx-x, mUZPT-120-12xxx-yx-x, mUZPT-120-15xxx-yx-x, and mUZPT-120-24xxx-yx-x (where x may be maximum 10 numbers, any alphanumeric character, hyphen or blank; where y is J0L or JB0 or JBH)   |
| <b>Rating:</b>             | <p>&lt;mUZP-120-12 (J0L or JB0), mUZPT-120-12 (J0L or JB0)&gt;<br/>Input: AC100-240V, maximum 1.87A, 50-60Hz<br/>Output: 12Vdc, 8.4A (maximum 13.5A with forced airflow, peak 16.7A)</p> <p>Peak DC Output Wattage: 200.4W (See Enclosure Id. 07-10 for details.)<br/>Total DC Output Wattage without forced airflow: 100.8W<br/>Total DC Output Wattage with forced airflow: 162W</p> <p>&lt;mUZP-120-12 (JBH), mUZPT-120-12 (JBH)&gt;<br/>Input: AC100-240V, maximum 1.83A, 50-60Hz<br/>Output: 12Vdc, 10A (maximum 13.5A with forced airflow, peak 16.7A)</p> <p>Peak DC Output Wattage: 200.4W (See Enclosure Id. 07-10 for details.)<br/>Total DC Output Wattage without forced airflow: 120W<br/>Total DC Output Wattage with forced airflow: 162W</p> <p>&lt;mUZP-120-24 (J0L or JB0), mUZPT-120-24 (J0L or JB0)&gt;<br/>Input: AC100-240V, maximum 1.82A, 50-60Hz<br/>Output: 24Vdc, 5.0A (maximum 6.75A with forced airflow, peak 8.4A)</p> <p>Peak DC Output Wattage: 201.6W (See Enclosure Id. 07-10 for details.)<br/>Total DC Output Wattage without forced airflow: 120.0W<br/>Total DC Output Wattage with forced airflow: 162W</p> <p>&lt;mUZP-120-24 (JBH), mUZPT-120-24 (JBH)&gt;</p> |

|                                    |  |
|------------------------------------|--|
|                                    | <p>Input: AC100-240V, maximum 1.78A, 50-60Hz<br/>Output: 24Vdc, 5.0A (maximum 6.75A with forced airflow, peak 8.4A)</p> <p>Peak DC Output Wattage: 201.6W (See Enclosure Id. 07-10 for details.)<br/>Total DC Output Wattage without forced airflow: 120.0W<br/>Total DC Output Wattage with forced airflow: 162W</p> <p>&lt;mUZPT-120-15 (J0L or JB0)&gt;<br/>Input: AC100-240V, maximum 1.87A, 50-60Hz<br/>Output: 15Vdc, maximum 6.7A (maximum 10.8A with forced airflow, peak 13.4A)</p> <p>Peak DC Output Wattage: 201.0W (See Enclosure Id. 07-10 for details.)<br/>Total DC Output Wattage without forced airflow: 100.5W<br/>Total DC Output Wattage with forced airflow: 162W</p> <p>&lt;mUZPT-120-15 (JBH)&gt;<br/>Input: AC100-240V, maximum 1.83A, 50-60Hz<br/>Output: 15Vdc, maximum 8.0A (maximum 10.8A with forced airflow, peak 13.4A)</p> <p>Peak DC Output Wattage: 201.0W (See Enclosure Id. 07-10 for details.)<br/>Total DC Output Wattage without forced airflow: 120.0W<br/>Total DC Output Wattage with forced airflow: 162W</p> |
| <b>Applicant Name and Address:</b> | <p>NIPRON CO LTD<br/>2-57 OHAMA-CHO<br/>AMAGASAKI-SHI<br/>HYOGO 660-0095 JAPAN</p>   |

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: Zhuo Guoping / Project 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.

This power supply has two component layouts, 3431P1 and 3507P1. (See Enclosure Ids. 05-01 and 05-02 for difference details.)

(Fuse type 215 and ZNR2 may be provided for 3507P1 only.)

**Model Differences**

Model mUZP-120-12 is the basic model in this Test Report.

Model mUZP-120-24 is identical to Model mUZP-120-12 except for electrical rating, and Transformer (T1).

Models mUZPT-120-12 and mUZPT-120-24 are identical to Models mUZP-120-12 and mUZP-120-24 except for Transformer (T1).

Model mUZPT-120-15 is identical to Models mUZPT-120-12 except for electrical rating and Transformer (T1).

Suffix x denotes control numbers which do not affect safety. (Where x may be maximum 10 numbers, any alphanumeric character, hyphen or blank)

Suffix y denotes rectifier of secondary circuit as follows.

J0L, JB0: Diode

JBH: FET

**Test Item Particulars**

|  |  |
|--|--|
| Classification of installation and use .....                         | Building-in                                      |
| Supply Connection .....  | N/A (to be considered in end-use product)        |
| 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 .....                     | : Chassis, Cover |

**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 : N/A
- 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 5,000m and pollution degree 2.
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (T<sub>mra</sub>). 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): mUZP-120-12 and mUZP-120-24: MOOP/mUZPT-120-12, mUZPT-120-15 and mUZPT-120-24: MOOP and MOPP; These are based upon a working voltage (V<sub>rms</sub>/V<sub>pk</sub>); mUZP-120-12: Primary-GND (1MOOP): 248/418, Primary-Secondary (2MOOP): 232/430; mUZP-120-24: Primary-GND (1MOOP): 247/418, Primary-Secondary (2MOOP): 242/446; mUZPT-120-12: Primary-GND (1MOOP and 1MOPP): 246/414, Primary-Secondary (2MOOP and 2MOPP): 232/434; mUZPT-120-15: Primary-GND (1MOOP and 1MOPP): 248/422, Primary-Secondary (2MOOP and 2MOPP): 236/442; mUZPT-120-24: Primary-GND (1MOOP and 1MOPP): 247/414, Primary-Secondary (2MOOP and 2MOPP): 243/458 between input circuit of isolation transformer (T1) and transformer output circuit. And the core of the transformer is treated as floating.
- Isolation transformer T1 employs 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 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.
- Limitation of Voltage, Current or Power (8.4.2 c) for SIP/SOP connectors or separate power supply output connectors should be evaluated in end-product.

**Additional Information**

Maximum Normal Load Condition (Test Condition): See Enclosure Id. 07-10 for details.

Unless otherwise stated, all tests were conducted employing Model mUZP-120-12 (3507P1) as a representative model.

(For CB only)

This is an original test report based on CB Test Certificate No. US-26750-UL issued 2016-01-27, CB Test Report Ref. No. E358786-D1000-1/A0/C0-CB issued 2016-01-25, for upgrading IEC 60601-1:2005 + A1:2012 to IEC 60601-1:2005 + A1:2012 + A2:2020.

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

- Change factory address as below.

From: 3249 OIZU INDUSTRIAL PARK IN OYODO KOGYO DANCHI OAZA-YAMAOIZU AZA-NAKAJIMA  
MEIWA-CHO TAKI-GUN MIE-KEN 515-0303 JAPAN

To: 282-17 Nishiyama Taki-cho Taki-gun Mie 519-2171 JAPAN

- Addition of alternate Y-Capacitors (C18, C20), Types RA and SA.

- Correction of type of Plastic Body of Diode Bridge (D1), from CV3300 to CV4100.

- Addition of alternate Optical Isolators (PC1, PC2, PC5), Types TLP385 and LTV-10XX.

- Minor correction of table 8.10 not affecting safety.

No additional tests were considered necessary for this modification, because this modification do not affect to previous test results.

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                 |

#### 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 |
| No  | Grounding Continuity                         | N/A                         | N/A                |
| 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             |