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:	Power Supply
Model:	mUZP-220-12x, mUZP-220-18x, mUZP-220-24x, mUZP-220-48x, mUZPS-220-12x, mUZPS-220-18x, mUZPS-220-24x, mUZPS-220-48x, mUZP-220/520P-24x (where x may be maximum 20 characters, any alphanumeric character, hyphen, slash or blank)
Rating:	-Model mUZP-220-12x: Input AC 100-240 V, 50-60 Hz, 3.0 A, Output 12 V, 15 A (33.4 A peak) -Model mUZP-220-12x with capacitor board1: Input AC 100-240 V, 50-60 Hz, 3.0 A, Output 12 V, 15 A (33.4 A peak) -Model mUZPS-220-12x: Input AC 100-240 V, 50-60 Hz, 3.0 A or 3.0 A – 1.3 A, Output OUT1 [12 V, 15 A (33.4 A peak)], OUT2 [5 V, 1.5 A (2.0 A peak)] or [12 V, 0.63 A (0.85 A peak)] (OUT2 is output of Stand-by power supply) -Model mUZP-220-18x: Input AC 100-240 V, 50-60 Hz, 2.9 A, Output 18 V, 10 A (22.3 A peak) -Model mUZP-220-18x with capacitor board1: Input AC 100-240 V, 50-60 Hz, 3.0 A, Output 18 V, 10 A (22.3 A peak) -Model mUZPS-220-18x: Input AC 100-240 V, 50-60 Hz, 3.0 A or 3.0 A – 1.3 A, Output OUT1 [18 V, 10 A (22.3 A peak)], OUT2 [5 V, 1.5 A (2.0 A peak)] or OUT2 [12 V, 0.63 A (0.85 A peak)], OUT2 is output of Stand-by power supply. -Model mUZP-220-24x: Input AC 100-240 V, 50-60 Hz, 3.8 A, Output 24 V, 9.2 A (16.7 A peak) -Model mUZP-220-24x with capacitor board1:

	Input AC 100-240 V, 50-60 Hz, 3.8 A, Output 24 V, 9.2 A (16.7 A peak) -Model mUZPS-220-24x: Input AC 100-240 V, 50-60 Hz, 3.8 A or 3.8 A – 1.7 A, Output OUT1 [24 V, 9.2 A (16.7 A peak)], OUT2 [5 V, 1.5 A (2.0 A peak)] or OUT2 [12 V, 0.63 A (0.85 A peak)], OUT2 is output of Stand-by power supply. -Model mUZP-220-48x: Input AC 100-240 V, 50-60 Hz, 3.7 A, Output 48 V, 4.6 A (8.4 A peak) -Model mUZP-220-48x with capacitor board1: Input AC 100-240 V, 50-60 Hz, 3.8 A, Output 48 V, 4.6 A (8.4 A peak) -Model mUZPS-220-48x: Input AC 100-240 V, 50-60 Hz, 3.8 A or 3.8 A – 1.7 A, Output OUT1 [48 V, 4.6 A (8.4 A peak)], OUT2 [5 V, 1.5 A (2.0 A peak)] or OUT2 [12 V, 0.63 A (0.85 A peak)], OUT2 is output of Stand-by power supply. -Model mUZP-220/520P-24x: Input AC 100-240 V, 50-60 Hz, 3.8 A or 3.8 A – 1.7 A, Output OUT1 [24 V, 9.2 A (21.7 A peak)], OUT2 [5 V, 1.5 A (2.0 A peak)] or OUT2 [12 V, 0.63 A (0.85 A peak)], OUT2 is output of optional Stand-by power supply.
Applicant Name and Address:	NIPRON CO LTD 2-57 OHAMA-CHO AMAGASAKI-SHI HYOGO 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: Reon Tsai / 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

The equipment under tests is power supply, model mUZP-220-12x, mUZP-220-18x, mUZP-220-24x, mUZP-220-48x, mUZPS-220-12x, mUZPS-220-18x, mUZPS-220-24x, mUZPS-220-48x and mUZP-220/520P-24x intended to be built into end-product installations.

Suffixes x denote control numbers which do not affect safety. (where x may be maximum 20 characters, any alphanumeric character, hyphen, slash or blank)

The equipment has the following options.

- Discharge resistor unit, type ACC3416 to make faster discharging of main unit. CN401 of this unit is connected to CN3 of main unit.

- Capacitor board 1 (two capacitors), type ACC3430-01 to expand hold-period in case of instantaneous power interruption. CN301 of this unit is connected to CN7 (not mounted) of main unit. CN312 of this unit is connected to CN103 (not mounted) of main unit.

- Capacitor board 1 (three capacitors), type ACC3430-02 to expand hold-period in case of instantaneous power interruption. CN301 of this unit is connected to CN7 (not mounted) of main unit. CN312 of this unit is connected to CN103 (not mounted) of main unit. When this unit is provided, cover is not provided.

- Capacitor board 2, type CB03. CN1 of this unit is connected to CN3 of main unit by harness.

- Capacitor pack, type BS13*-EC400/***F (* = 'A' to 'Z' or '0' to '9' or blank) for additional charging / discharging circuit for back-up power. The unit activates with discharging mode for back-up when the supply source of main unit is disconnected. CN1 of this unit is connected to CN3 of main unit by harness.

-Stand-by Power Supply (3234P2*, 5V, 12V output) provided with MOOP insulation is installed on the mUZPS-220 series only. It is connected to CN7 and CN103 of main unit that is same construction as mUZP-220 series. As long as there is an AC input, the Stand-by Power Supply continuously outputs the rated voltage regardless of the mUZPS-220 series output. The stand-by Power Supply can be used in combination with any of the above Capacitor Pack, Capacitor Board 2 and Discharge resistor unit that can be connected to CN3.

-Stand-by Power Supply (3730P1*, 5V, 12V output) provided with MOPP insulation is installed on the mUZP-220/520P-24x only. It is connected to CN7 and CN103 of main unit that is same construction as mUZP-220 series. As long as there is an AC input, the Stand-by Power Supply continuously outputs the rated voltage regardless of the mUZP-220/520P-24x output. The stand-by Power Supply can be used in combination with any of the above Capacitor Pack, Capacitor Board 1, 2 and Discharge resistor unit that can be connected to CN3.

- Discharge resistor for mUZP-220/520P-24x, this resistor is connected to using holes of CN3 (See CCL for details of discharge resistor). Therefore, in options of discharge resistor is selected case, options connected to CN3 such as Capacitor Pack cannot be selected.

- For the mUZP-220 series without option, the manufacturer is listed on the Rating label. But for the mUZP-220 series + option, mUZPS-220 series and mUZP-220/520P-24x, the manufacturer is listed on the serial label. See Enclosure ID 13-02. (for CB only)

Model Differences

Model mUZP-220-12x is similar to Model mUZP-220-18x and mUZP-220-24x except for below.

- Electrical rating
- Model designation
- Transformer (T1)
- Secondary circuit for output

Model mUZP-220-18x is similar to Model mUZP-220-24x except for below.

- Electrical rating
- Model designation
- Transformer (T1)

Model mUZP-220-48x is similar to Model mUZP-220-12x, mUZP-220-18x and mUZP-220-24x except for below.

- Electrical rating
- Model designation
- Transformer (T1)
- Secondary circuit for output

Model mUZPS-220 series are identical to mUZP-220 series except for the model name and providing Stand-by Power Supply. Model mUZPS-220 series intends MOOP design.

The configuration of Models mUZPS-220 series is physically same as Models mUZP-220 series with Stand-by Power Supply. When the Stand-by Power Supply is not provided, the models are mUZP-220 series. When provided, the models are mUZPS-220 series.

Stand-by Power Supply is installed only in the mUZPS-220 series. It is connected to CN7 and CN103 of main unit that is same construction as mUZP-220 series. Stand-by Power Supply continuously outputs the rated voltage regardless of the mUZP-220 series output ON and OFF. The stand-by Power Supply can be used in combination with any of the above Capacitor Pack, Capacitor Board 2 and Discharge resistor unit that can be connected to CN3.

There are two types of Stand-by Power Supply, 5V and 12V output. Output ratings are (5V, 1.5A) and (12V, 0.63A). Output voltage 5V and 12V are selectable in option.

Necessary markings for models mUZP-220 series except for with capacitor board1 are marked on single label, and the markings for Models mUZP-220 Series with capacitor board1 and mUZPS-220 series are marked on separate labels.

Model mUZP-220/520P-24x is identical to Model mUZP-220-24x except for model designation, peak output current, provided with or without Varistor (ZNR2), the primary pattern around the Varistor (ZNR2), capacitance of X-capacitor (C1) and Film capacitor (C6) and optional Stand-by Power Supply.

- Peak output current; 16.7 A for mUZP-220-24x, 21.7 A for mUZP-220/520P-24x.
- Varistor (ZNR2); Not provided for mUZP-220-24x, Provided for mUZP-220/520P-24x.
- Capacitances of X-capacitor (C1); 1uF for mUZP-220-24x, 1.5 uF for mUZP-220/520P-24x.
- Capacitances of Film capacitor (C6); 2.2uF for mUZP-220-24x, 3.3 uF for mUZP-220/520P-24x.

- Stand-by Power Supply; Existing Stand-by Power Supply (3234P2*) provided with MOOP insulation for mUZP-220-24x, New optional Stand-by Power Supply (3730P1*, 5V or 12 V output) provided with MOPP insulation for mUZP-220/520P-24x.

Stand-by power supply (3730P1*) for MOPP is installed only in mUZP-220 / 520P-24x.

The Stand-by Power Supply for MOPP (3730P1*) is a power supply that is compliant with MOPP by improving the insulation distance of the Stand-by Power Supply for MOOP (3234P2*). And Stand-by Power Supply for MOPP (3730P1*) has the same circuit and the same component constants as Stand-by Power Supply for MOOP (3234P2*).

Test Item Particulars	
Classification of installation and use ..... :	Built-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, discharge resistor unit (type ACC3416), capacitor board 1 (type ACC3430-01, ACC3430-02), capacitor board 2 (type CB03), and capacitor pack (BS13*-EC400/***F (* = 'A' to 'Z' or '0' to '9' or blank))

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 : Electromagnetic compatibility (IEC 60601-1-2), biocompatibility (ISO 10993-1), risk management (ISO 14971), PEMS (cl. 14)
- The following accessories were investigated for use with the product : (Models mUZP-220 series, mUZP-220/520P-24x), Chassis, cover, discharge resistor unit (type ACC3416), capacitor board 1 (type ACC3430-01, ACC3430-02), capacitor board 2 (type CB03), and capacitor pack (BS13*-EC400/***F (* = 'A' to 'Z' or '0' to '9' or blank)), (Models mUZPS-220 series), Chassis, cover, discharge resistor unit (type ACC3416), capacitor board 2 (type CB03), and capacitor pack (BS13*-EC400/***F (* = 'A' to 'Z' or '0' to '9' or blank))
- For some of critical components, EN standards were used to verify the compliance. The EN standards were harmonized to IEC standard, and technically equivalent.
  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.
  The product is not suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide.
  Input voltage deviation is -15 %, +10%.
  See Enclosure ID 07-01 for derating curve.

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 is not provided with disconnecting means in accordance with cl. 8.11.1. It shall be considered in the end product.
- The output circuit has not been evaluated for direct patient connection (type B, BF or CF). Additional requirements may be required if used for connection to applied parts.
- The following end product enclosures are required: Electrical, Fire, Mechanical.
- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the equipment is used with the end product. The end product shall ensure that the equipment is used within its ratings.
- Instructions for use shall be checked in the end product.
- The equipment has been evaluated for use under pollution degree 2, overvoltage category II, and at altitude up to 3000 m.
- Temperature Test was conducted without test corner. The acceptability of risk in conjunction to temperature testing with test corner shall be considered in the end product.
- Proper bonding to protective earthing terminal of end product shall be provided.
- Input and output connectors are not intended for field-wiring connection. They are only intended for factory-wiring inside the end product.
- Final installation of this equipment should comply with the enclosure, mounting, marking, spacing and separation requirements. In addition, temperature, leakage current, dielectric voltage withstand and interruption of this equipment tests should be considered as part of the end product evaluation.
- Risk management process in accordance with cl. 4.2 shall be evaluated in the end product.
- The equipment has been judged on the basis of the required creepage and clearance according to cl. 8.9 in IEC 60601-1 edition 3.2 (2020) that covers the end application for which the component was designed.
- The equipment has been evaluated as class I, continuous operation, and not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. Additional evaluations shall be considered if the equipment is intended for classifications other than these.
- The following magnetic devices (e.g. transformers or inductor) are provided with an OBJY2 insulation system with the indicated rating greater than Class A (105 °C): Power Supply mUZP-220 series, mUZPS-220 series and mUZP-220/520P-24x, Transformer (T1) (class B), Stand-by Power Supply (5V, 12V output) Transformer (T500) (class B).
- The equipment (mUZP-220 series) provides 1MOOP/1MOPP between primary and GND, and 2MOOP/2MOPP between primary and secondary circuits.
- The equipment (mUZPS-220 series) provides 1MOOP between primary and GND, and 2MOOP between primary and secondary circuits.
- The equipment (mUZP-220/520P-24x) provides 1MOOP/1MOPP between primary and GND, and 2MOPP between primary and secondary circuits.
- The maximum working voltages of mUZP-220 series and mUZPS-220 series to consider when conducting dielectric strength test are 261 Vrms, 508 Vpeak (mUZP-220 series and mUZPS-220 series), 352 Vrms, 552 Vpeak (Stand-by Power Supply 5V, 12V output)).
- The maximum working voltages of mUZP-220/520P-24x to consider when conducting dielectric strength test are 259 Vrms, 428 Vpeak (mUZP-220/520P-24x), 381 Vrms, 624 Vpeak (Stand-by Power Supply 5V, 12V output). Since the operating voltage of mUZP-220 / 520P-24x is smaller than that of mUZP-220 series, the insulation distance is not evaluated.
- The rated load 220W for natural convection air cooling of mUZPS-220 is the sum of main power supply mUZPS-220 and Stand-by power supply. (mUZPS-220: 212.5W + Stand-by power supply: 7.5W)
- Derating in the temperature test of mUZPS-220 was performed under the following conditions. At an ambient temperature of 70 °C condition, the load of mUZPS-220 was reduced to 40% (88W) of rated 220W based on the derating curve of Enclosure ID 07-01. The 40% reduced load on the mUZPS-220 and Stand-by power supply was 85W and 3W respectively.
- Derating in the temperature test of mUZP-220/520P-24x was performed under the following conditions. At an ambient temperature of 55 °C condition, the load of mUZPS-220/520P-24x was reduced to 65.91% (140.59W) of rated 220W based on the derating curve of Enclosure ID 07-06. The 65.91% reduced load on the mUZPS-220/520P-24x and Stand-by power supply was 140.59W and 4.95W respectively.

- Secondary output is non-hazardous voltage in accordance with cl. 8.4.2 c) except for SIP/SOP connectors and separate power supply output connectors.
- Secondary output except for Stand-by Power Supply has not been evaluated for non-hazardous energy level in accordance with cl. 8.4.2 c). The output of Stand-by Power Supply has been evaluated for non-hazardous energy level in accordance with cl. 8.4.2 c).
- The clearances and creepage distances between each unit shall be re-evaluated in the end product when the optional units (capacitor pack, type BS13*-EC400/***F or capacitor board 2, type CB03) are provided.
- Dielectric strength test may be considered on insulating tube for primary wiring in capacitor board 2 and capacitor pack in the end product if they touch any isolated component or circuit.
- Different polarity before F1, F2 shall be evaluated in the end product. Different polarity after F1, F2 was evaluated in abnormal test.
- 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

For chassis and cover of main unit, there are two types in each which differ in width as below.
- Chassis (original): 85 mm,
- Chassis (alternate): 83 mm,
- Cover (original): 84.8 mm,
- Cover (alternate): 82.8 mm

(For CB only)
This is an original test report based on CB Test Certificate No. US-41029-UL, CB Test Report Ref. Nos. E358786-D1006-2/A0/C0-CB for upgrading IEC 60601-1:2005 + A1:2012 to IEC 60601-1:2005 + A1:2012 + A2:2020.

In addition to the above, following report modifications were made from previous report:
- Addition of alternate Optical isolators (PC1, PC2, PC5, PC500), Type LTV-10XX.
- Addition of alternate Optical isolator (PC500), Type TLP385.
- Correction of Type of Insulation Tape of Transformer (T500), MT1624, from 630F2 #50 to 630F3 #50, and from 631S2 #50 to 631S3 #50.
- Addition of alternate Insulation Tape of Transformer (T500), MT1624, Types 632S3 #50 and 1318Y-1.
- Addition of alternate Pattern, silk trace layout for main unit (mUZP-220_520P-24x) (Enclosure Id. 05-11).
- Addition of Rating label for mUZP-220_520P-24x (Enclosure Id. 07-05).
- Minor correction of table 8.10 not affecting safety.

Only limited tests below were deemed necessary.
Test of Type 632S3 #50 was conducted in Report Reference No. OFF-11641263 (E161936-D1-CB-1) and transcribed. (Test of Type 632S2 #50 was conducted in Report Reference No. OFF-11641263, and Type 632S2 #50 and 632S3 #50 are identical except for type designation)
Test of Type 1318Y-1 was conducted in Report Reference No. E161936-A6061-CB-1 and transcribed.
8.8.3 - Dielectric Voltage Withstand

The other test data was cited from Report Reference No. E358786-D1006-2/A0/C0-CB. For details, see Appended Tables.

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

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

Additional country information: 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

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