

## UL TEST REPORT AND PROCEDURE

<b>Standard:</b>	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
<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-150-12x, mUZP-150-18x, mUZP-150-24x and mUZP-150-48x (where x maybe maximum 20 characters, any alphanumeric character, hyphen, slash or blank)
<b>Rating:</b>	<p>mUZP-150-12x Input: AC 100 -240 V, 50 - 60 Hz, 3.0 A Output: 12 V, 12.5 A (33.4 A Peak)</p> <p>mUZP-150-18x Input: AC 100 -240 V, 50 - 60 Hz, 2.9 A Output: 18 V, 8.4 A (22.3 A Peak)</p> <p>mUZP-150-24x Input: AC 100 -240 V, 50 - 60 Hz, 3.2 A Output: 24 V, 6.3 A (16.7 A Peak)</p> <p>mUZP-150-48x Input: AC 100 -240 V, 50 - 60 Hz, 3.1 A Output: 48 V, 3.2 A (8.4 A Peak)</p>
<b>Applicant Name and Address:</b>	NIPRON CO LTD 2-57 OHAMA-CHO AMAGASAKI-SHI HYOGO 660-0095 JAPAN

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Report Reference # E358786-D6001-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: Yoshifusa Koyanagi / Project  
Handler

Reviewed By: Deborah Jennings-Conner /  
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 model mUZP-150-12x, mUZP-150-18x, mUZP-150-24x and mUZP-150-48x of Power Supplies are intended for building into end-product installations.

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

Discharge resistor unit (Optional), Type ACC3416  
CN401 of this unit is connected to CN3 on mUZP-150 series.

Capacitor Board 1 (two capacitors) (Optional), Type ACC3430-01  
CN301 of this unit is connected to pattern CN7 (removed) on mUZP-150 series.  
And CN312 of this unit is connected to pattern CN103 (removed) on mUZP-150 series.

Capacitor Board 1 (three capacitors) (Optional), Type ACC3430-02  
CN301 of this unit is connected to pattern CN7 (not removed) on mUZP-150 series.  
And CN312 of this unit is connected to pattern CN103 (removed) on mUZP-150 series.  
When this unit is provided, cover is not provided.

Capacitor Board 2 (Optional), Type CB03  
CN1 of this unit is connected to CN3 on mUZP-150 series by internal harness.

Capacitor Pack (Optional), Type BS13\*-EC400/\*\*\*F (\* = 'A' to 'Z' or '0' to '9' or blank):  
An additional charging / discharging circuit for capacitor unit for back-up power. They activate to discharging mode when the supply source is disconnected.  
Connected to CN3 on mUZP-150 series by internal harness.

### Model Differences

Models mUZP-150-12x is similar to Model mUZP-150-18x, mUZP-150-24x and mUZP-150-48x except for items as follows.

- Electrical rating

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

Models mUZP-150-18x is similar to Model mUZP-150-24x and mUZP-150-48x except for items as follows.

- Electrical rating
- Model designation
- Transformer (T1)

Models mUZP-150-24x is similar to Model mUZP-150-48x except for items as follows.

- Electrical rating
- Model designation
- Transformer (T1)

#### Test Item Particulars

Classification of installation and use .....	Built-in
Supply Connection .....	Built-in
Device type (component/sub-assembly/ equipment/ system) .....	Component
Intended use (Including type of patient, application location) .....	To supply regulated power, Not intended to contact with patients
Mode of operation .....	Continuous
Accessories and detachable parts included .....	None
Other options include .....	Chassis, Cover, Discharge resistor unit, Capacitor Board 1 (two capacitors or three capacitors), Capacitor Board 2 and 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 : Biocompatibility, IEC60601-1-2, IEC60601-1-6
- The following accessories were investigated for use with the product : N/A
- No Other Considerations.

#### 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). See Enclosure "Miscellaneous 08" for additional details regarding out derating 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): 2 MOPP and 2 MOOP based upon a working voltage 264 Vrms, 640 Vpk 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 at hazardous energy level and at non-hazardous voltage level for all models except for SIP/SOP connectors and separate power supply output connectors.
- 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.
- 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.
- When the equipment uses Low breaking capacity fuse, additional testing may be required in the end product.
- 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 Board2, Type CB03) are provided.
- The risk management requirements of the standard were not addressed and must be considered in the end product investigation.
- 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**

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

(For CB only)

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This report is based on CB Test Certificate No. US-30092-UL and US-30092-M1-UL, CB Test Report Ref. No. E358786-D1004-1/A0/C0-CB and E358786-D1004-1/A1/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 modification was made:

- Addition of manufacturer of Inductor (LF1, LF2), Type ET24-662B, "Chaoyue Precision Electronics Co., Ltd." (No construction change)
- Addition of alternate Bobbin of Alternate Inductor (LF1, LF2), Type 1403G6.
- Addition of alternate Optical Isolators (PC1, PC2, PC5), Type LTV-816.

Only limited tests below were deemed necessary. Test of Type 1403G6 was conducted in Report Reference No. E161936-A89-CB-3 and transcribed.

- 8.8.4.1 - Ball Pressure

The other test data was cited from Report Reference No. E358786-D1004-1/A0/C0-CB. For details, see Appended Tables.

#### 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

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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	N/A	N/A
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	N/A	N/A	N/A