Description

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14
Certification Type:	Component Recognition
CCN:	QQHM2 / QQHM8
Complementary CCNs:	AAAU
Product:	Power Supply
Model:	mOZP-350-12-xyEnz, mOZP-350-15-xyEnz, mOZP-350-24-xyEnz, mOZP-350-30-xyEnz, mOZP-350-36-xyEnz, mOZP-350-48-xyEnz ("m": is suffix not affecting safety. The suffix does not affect basic safety or essential performance. x is "J", "T", or "W", y is "0" or "S", n is any number "0" to "9" or any letter "A" to "Z" except for "E" or blank and z is "-K" or "-C" or blank)
Rating:	mOZP-350-12-xyEnz Input: 100-240 Vac, 4.8 A, 50-60 Hz Output: 12 Vdc, 25 A (42 Apeak) mOZP-350-15-xyEnz Input: 100-240 Vac, 4.8 A, 50-60 Hz Output: 15 Vdc, 20 A (40 Apeak) mOZP-350-24-xyEnz except for mOZP-350-24-JSE3 and mOZP-350-24-WSE3 Input: 100-240 Vac, 5.5 A, 50-60 Hz Output: 24 Vdc, 14.6 A (25 Apeak) mOZP-350-24-JSE3, mOZP-350-24-WSE3 Input: 100-240 Vac, 3.1 A, 50-60 Hz Output: 24 Vdc, 11.67 A (25 Apeak) mOZP-350-30-xyEnz Input: 100-240 Vac, 5.5 A, 50-60 Hz Output: 30 Vdc, 11.7 A (20 Apeak) mOZP-350-36-xyEnz Input: 100-240 Vac, 5.5 A, 50-60 Hz Output: 36 Vdc, 9.8 A (16.7 Apeak) mOZP-350-48-xyEnz Input: 100-240 Vac, 5.5 A, 50-60 Hz Output: 48 Vdc, 7.3 A (12.5 Apeak)
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 as applicable.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Jun Orito, Project Handler Reviewed by: Tsutomu Abe, 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

mOZP-350 series are building-in type switching power supplies which are intended for used with Medical Electrical Equipment in hospital environment.
Refer to the Report Modifications page for any modifications made to this report.

Model Differences

Model mOZP-350-12-xyEnz is described as basic model in this report.

Model mOZP-350-15-xyEnz is identical to Model mOZP-350-12-xyEnz except for model designation, output rating, Transformer (T1), and secondary components.
Model mOZP-350-24-xyEnz (except for mOZP-350-24-JSE3 and mOZP-350-24-WSE3) is identical to Model mOZP-350-12-xyEnz except for model designation, output rating, Transformer (T1), and secondary components.
Models mOZP-350-24-JSE3 and mOZP-350-24-WSE3 are identical to Model mOZP-350-24-xyEnz except for Fuse (F1, F2), and electrical rating.
Model mOZP-350-30-xyEnz is identical to Model mOZP-350-12-xyEnz except for model designation, output rating, Transformer (T1), and secondary components.
Model mOZP-350-36-xyEnz is identical to Model mOZP-350-12-xyEnz except for model designation, output rating, Transformer (T1), and secondary components.
Model mOZP-350-48-xyEnz is identical to Model mOZP-350-12-xyEnz except for model designation, output rating, Transformer (T1), and secondary components.

Model designations: (Representative example)
[mOZP-350-12-xyEnz]
1) mOZ: Series name ("m": is suffix not affecting safety. The suffix does not affect basic safety or essential performance.)
2) P: Corresponding to peak
3) -350: 350 W
4) -12: Output Voltage 12 Vdc
5) -x: Input/Output Connection; "J": Nylon Connector, "T": Terminal Block, “W”: Nylon Connector and Terminal Block
6) y: Output Current Balance Function; "0": Not Provided, "S": Provided
7) E: Provided function of cutting down standby electricity
8) n: Any number "0" to "9", any letter "A" to "Z" or blank, which does not affected safety.
9) z: Chassis and Cover; "Blank": Not Provided, "-C": Chassis Provided, "-K": Chassis and Cover Provided

Capacitor Pack, 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.

Additional Information

EMC compliance has not been verified nor has it been taken into consideration. An accredited EMC Test

Report will be required in conjunction with the Certification of the end product.

The manufacturer submitted representative production sample of Switching Power Supply, Models mOZP-350-12/-15/-24/-30/-36/-48-JSE and mOZP-350-12/-15/-24/-30/-36/-48-JSE with Optional Capacitor Pack, Type BS13A-EC400/422F.

Unless otherwise stated, all tests were conducted on Model mOZP-350-48-JSE and OZP-350-48-JSE with Optional Capacitor Pack, Type BS13*-EC400/***F.
Tests conducted with manufacturer request output conditions. (See Enclosure Miscellaneous-(08), (09) and (10))

During the test, optional standby power supply, model PS-10WP-5VSB* designed to supply additional secondary output circuits of 5Vdc were connected to switching power supply, Model mOZP-350 series as load. The optional standby power supply, model PS-10WP-5VSB* is not covered in this investigation.

This was a test report to upgrade from 3.0 edition to 3.1 edition included adding following alternate components which would not give impact to the test results.
- Addition of Alternate Varistor (ZNR1) for mOZP-350-15 series only.
The product has been previously evaluated by UL according to CB scheme to IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007, CB Test Report Ref. No.E358786-A6-CB-2;2014-12-11 + A1;2015-09-07 + A2;2016-11-07 (Ref. Certification No.US-24398-UL +A1 +A2). Tests conducted per mentioned above edition of the standard were reviewed and considered representative of the corresponding tests required by IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 as follows.
- 4.11 Power Input
- 5.7 Humidity Preconditioning Treatment
- 8.4.2 Limitation of Voltage, Current or Energy
- 8.4.3 Voltage Or Charge Limitation
- 8.5.4 Working Voltage Measurements
- 8.6.4a Impedance and Current Carrying Capability
- 8.7 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

Following additional tests were conducted for verification, and to fill a gap between 3rd edition and 3rd edition with Amendment 1.
- 8.4.2 Limitation of Voltage, Current or Energy
- 8.5.4 Working Voltage Measurements
- 8.7 Leakage Current (Measuring by Non-frequency-weighted device)
- 8.8.3 Dielectric Voltage Withstand
- RISK Management File Review

Technical Considerations

- The product was investigated to the following additional standards:
- The following additional investigations were conducted: EN 60601-1:2006+A1:2013+A12:2014
- The product was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2), Biocompatibility (ISO 10993-1), Annex Z of EN standards for compliance with the MDD
- The following accessories were investigated for use with the product: None
- Scope of Power Supply evaluation defers the following clauses to the be determined as part of the end product: Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems) Power supply has been evaluated with a protective earth and could be used in Class I applications. To be further evaluated in the end product.
  For heating test conditions 1-38, 12V model was tested as the representative with all the combinations with input, w/ or w/o chassis and cover, Forced air or not, Orientation of EUT, output

load and Tma. Then, the following combination was considered as the worst case. Input: 90V/60Hz, with chassis and cover, Forced Air (yes)-continuous output rated load, Orientation of EUT: A, Output: continuous rated load, Tma from derating curve in Miscellaneous-(08).

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 output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
  - The output connectors are not acceptable for field connections, they are only intended for factory wiring inside the end-use product.
  - The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.
  - Power supply provides the following MOPP (means of patient protection)/MOOP (means of operator protection): For 2MOPP based upon a working voltage 293 Vrms, 624 Vpk (except for models mOZP-350-15 series), 352 Vrms, 672 Vpk (models mOZP-350-15 series) between Primary and Secondary. For 1MOPP based upon a working voltage 292 Vrms, 560 Vpk (except for models mOZP-350-15 series), 352 Vrms, 672 Vpk (models mOZP-350-15 series) between Primary and Earth/Metal flame.
  - The following secondary output circuits are SELV (42.4 Vpeak a.c. or 60 V d.c.): 12 Vdc Output, 15 Vdc Output, 24 Vdc Output, 30 Vdc Output, 36 Vdc Output, 48 Vdc Output.
  - The following secondary output circuits are at hazardous energy levels: 12 Vdc Output, 15 Vdc Output, 24 Vdc Output, 30 Vdc Output, 36 Vdc Output and 48 Vdc Output.
  - The maximum investigated branch circuit rating is: 20 A. If used on a branch circuit greater than this, additional testing may be necessary.
  - The following output terminals were referenced to earth during performance testing: Input Connector (CN1) (N), Input Connector (CN1) (FG), Output Connector (CN8) Output (-).
  - Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation.
  - End product Risk Management Process to include consideration of requirements specific to the Power Supply.
  - Humidity conditioning test was conducted on the power supply with 25 °C, 93 %RH, 48 hrs. End product Risk Management Process to determine risk acceptability criteria.
  - End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply.
  - Power supply has been evaluated with a protective earth and could be used in Class I applications. To be further evaluated in the end product.
  - Proper bonding to the end-product main protective earthing termination is required.
  - The power supply FG Terminal of Terminal Block/Connector (CN1) is connected to printed wiring board trace directly; the Limited Short-Circuit Test in CSA C22.2 No. 0.4, Bonding of Electrical Equipment not conducted due to building-in type component. The evaluation shall be considered in the end-product in case metal chassis of power supply unit is not connected to Protective Earth.
  - Fuse (F1, F2, F3) is intended to provide in non-operator access area.
  - 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) are provided.
  - Temperature and Abnormal operation test were tested in a cooling carton box, which was provided with nine DC Fans (UL Recognized Component (GPWV2), Melco Technorex Co., Ltd., Type MMF-08C12DS, rated 1.5 m/second) and Filter. See Enclosure - Miscellaneous - (08) and (09) for cooling carton box and installation condition.
  - The temperature test shall be conducted in the end product. Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end product.
  - The end-use product shall ensure that the power supply is used within its ratings.
  - All necessary tests were conducted on the power supply without optional thermistors (TH2, TH3). Therefore this product does not rely on these thermistor for safety.

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
Regarding TABLE: List of Critical Components, verify the information relating to UL and cUL or CSA only. Other Standard No. in critical components list is out of inspection.

Production-Line Testing Requirements			
Required	Test	Model/Part Exempt from Test	Additional Details
Yes	Grounding Continuity	None	Not exempt
Yes	Dielectric Voltage Withstand	None	Not exempt
No	Patient Circuit Dielectric Voltage Withstand	All models	--
Solid-State Components			
The following solid-state components that can be disconnect from the remainder of the circuitry during either Dielectric Voltage Withstand Test:		Parts to be disconnected for test:	Specific Test:
		None	NA

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
None	NA	NA	NA