

# Underwriters Laboratories (UL LLC) Safety Certification (Manufacturing Factory) Report



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 (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)

Device Description: Power Supply

Applicant: NIPRON CO LTD  
2-57 OHAMA-CHO AMAGASAKI-SHI  
HYOGO-KEN 660-0095 JAPAN

Manufacturer: Same as Applicant

Manufacturing Facility(ies): NIPRON CO LTD  
282-17 Nishiyama Taki-cho  
Taki-gun Mie 519-2171 JAPAN

Report No.: E358786-D1014-1/A2/C0(M)

Report (Re)Issue Date: 2021-10-11 (original), 2022-04-12 (A1), 2023-08-24 (A2)

Base Standard(s): ANSI/AAMI ES60601-1:2005 + C1:2009 + A2:2010, CSA CAN/CSA-C22.2 NO. 60601-1:08

Additional Standards: N/A

Report Types: This report consists of the following report types:  
[ Yes ] US Certification (UL Recognition)  
[ Yes ] CAN Certification (cUL Recognition)

This report covers the Safety evaluation of the referenced model(s) according to the standard(s) specified above.

This is the Manufacturing Factory report only, which is used as part of the factory FUS inspections.

**Description****UL TEST REPORT AND PROCEDURE**

<b>Standard:</b>	ANSI/AAMI ES60601-1:2005 + C1:2009 + A2:2010, CSA CAN/CSA-C22.2 NO. 60601-1:08
<b>Certification Type:</b>	Component Recognition
<b>CCN:</b>	QQHM2 / QQHM8
<b>Complementary CCNs:</b>	AAAU
<b>Product:</b>	Power Supply
<b>Model:</b>	mOZP-350-12-xyEnz, mOZP-350-15-xyEnz, mOZP-350-24-xyEnz, mOZP-350-30-xyEnz, mOZP-350-36-xyEnz, mOZP-350-48-xyEnz (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)
<b>Rating:</b>	<p>mOZP-350-12-xyEnz Input: 100-240 Vac, 4.8 A, 50-60 Hz Output: 12 Vdc, 25 A (42 Apeak)</p> <p>mOZP-350-15-xyEnz Input: 100-240 Vac, 4.8 A, 50-60 Hz Output: 15 Vdc, 20 A (40 Apeak)</p> <p>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)</p> <p>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)</p> <p>mOZP-350-30-xyEnz Input: 100-240 Vac, 5.5 A, 50-60 Hz Output: 30 Vdc, 11.7 A (20 Apeak)</p> <p>mOZP-350-36-xyEnz Input: 100-240 Vac, 5.5 A, 50-60 Hz Output: 36 Vdc, 9.8 A (16.7 Apeak)</p> <p>mOZP-350-48-xyEnz Input: 100-240 Vac, 5.5 A, 50-60 Hz Output: 48 Vdc, 7.3 A (12.5 Apeak)</p>
<b>Applicant Name and Address:</b>	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

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### 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
- 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

This report is a reissue of Test Report Ref. No. E358786-A6-CB-2 issued at 2014-12-11 with Cert. No. US-24398-UL issued at 2014-12-11, Amendment 1 issued at 2015-09-07 with Cert. No. US-24398-A1-UL issued

at 2015-09-07, Amendment 2 issued at 2016-11-07 with Cert. No. US-24398-A2-UL issued at 2016-11-08. Reissue involves the technical changes below.

- Change of type name for material of input connector (CN1), output connector (CN8, CN10) (for models with suffix "J".) and connector (CN3) (optional) from CM3004-V0(rg) to CM3004-V0(rr)
- Addition of alternate insulation tape of inductor (L3), Sumitomo Bakelite Co., Ltd., type PM-9823
- Addition of manufacturer for alternate transformer (T1) for all models, Chaoyue Precision Electronics Co., Ltd.
- Addition of alternate insulation system of transformer (T1) for all models, Chaoyue Precision Electronics Co., Ltd., types SBI4.2 and YS-130
- Addition of alternate bobbin of transformer (T1) for all models, Sumitomo Bakelite Co., Ltd., type PM-9823
- Addition of alternate optical isolators (PC1, PC2, PC4, PC5) (PC4 and PC5 are optional), Toshiba Electronic Devices & Storage Corporation, type TLP785F
- Addition of manufacturer for alternate transformer (T3), Chaoyue Precision Electronics Co., Ltd.
- Addition of alternate bobbin of transformer (T3), Sumitomo Bakelite Co., Ltd., type PM-9823

Based on the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, has been determined that the product continues to comply with the standard.

Testing was not considered necessary based upon the results of previous investigations. All required tests were carried out under the original investigation.

At the same time, critical components list was also updated for the following manufacturer's name, type, technical data and applicable standard of components due to only change of the descriptions. Licenses were removed from the report. No additional tests were considered necessary.

This amendment updates the following Enclosures in this report.

- Miscellaneous-(001) Specifications of Transformer (T1) for Model mOZP-350-12 (Type MT1615) was revised.
- Miscellaneous-(002) Specifications of Transformer (T1) for Model mOZP-350-24 (Type MT1616) was revised.
- Miscellaneous-(003) Specifications of Transformer (T1) for Model mOZP-350-30 (Type MT1630) was revised.
- Miscellaneous-(004) Specifications of Transformer (T1) for Model mOZP-350-36 (Type MT1617) was revised.
- Miscellaneous-(005) Specifications of Transformer (T1) for Model mOZP-350-48 (Type MT1618) was revised.
- Miscellaneous-(007) Specifications of Inductor (L3) (Type LT1429) was revised.
- Miscellaneous-(011) Specifications of Transformer (T1) for Model mOZP-350-15 (Type MT1690) was revised.
- Miscellaneous-(012) Manufacturers Declaration was revised.

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Several licenses/certificates enclosed may be over 3 years old and accepting NCBs may require updated documentation upon submitting the unit to obtain a national mark.

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.

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The manufacturer submitted representative production sample of Switching Power Supply, Models mOZP-350-15-JSE and mOZP-350-48-JSE with Optional Capacitor Pack, Type BS13\*-EC400/\*\*\*F.

Unless otherwise stated, all tests were conducted on Model mOZP-350-15-JSE and mOZP-350-48-JSE with Optional Capacitor Pack, Type BS13\*-EC400/\*\*\*F.

Based on applicant's request, all tests were conducted with Main Supply Tolerance +10% and -10%.

Tests conducted with following output conditions. (See Enclosures-Miscellaneous-(008), (009) and (010) for details.)

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.

[For Models mOZP-350-12 and mOZP-350-15 series]

12 Vdc (10.8-13.2 Vdc, maximum 432 W), 15 Vdc (12.9-16.5 Vdc, maximum 435 W)

Output Power 430 W with Forced Air (1.5 m/second)  
Without Chassis and Cover / With Chassis and Cover  
A position: Tma is 60°C / 45°C

Output Power 340 W with Forced Air (1.5 m/second)  
Without Chassis and Cover  
A position: Tma is 70°C

Output Power 290 W with Forced Air (1.5 m/second)  
With Chassis and Cover  
A position: Tma is 70°C

Output Power 300 W without Forced Air  
Without Chassis and Cover / With Chassis and Cover  
A position: Tma is 40°C / 30°C (\*1)  
B position: Tma is 30°C / 25°C  
C position: Tma is 40°C / 30°C  
D position: Tma is 30°C / 25°C  
E position: Tma is 25°C / 25°C  
F position: Tma is 25°C / 25°C  
(\*1) Tma is 25°C when used with Optional Capacitor Pack and Optional Standby power supply (Model PS-10WP-5VSB\*).

Output Power 210 W without Forced Air  
Without Chassis and Cover / With Chassis and Cover  
A position: Tma is 60°C / 55°C  
C position: Tma is 60°C / 55°C

Output Power 180 W without Forced Air  
Without Chassis and Cover / With Chassis and Cover  
B position: Tma is 60°C / 55°C  
D position: Tma is 60°C / --

Output Power 140 W without Forced Air  
Without Chassis and Cover / With Chassis and Cover  
D position: Tma is -- / 55°C  
E position: Tma is 60°C / 55°C  
F position: Tma is 60°C / 55°C

[Except for Models mOZP-350-12 and mOZP-350-15 series]

24 Vdc (21.6-26.4 Vdc, maximum 504 W), 30 Vdc (27.0-33.0 Vdc, maximum 504 W), 36 Vdc (32.4-39.6 Vdc, maximum 504 W), 48 Vdc (43.2-52.8 Vdc, maximum 504 W)

Output Power 500 W with Forced Air (1.5 m/second)  
Without Chassis and Cover / With Chassis and Cover  
A position: Tma is 60°C / 45°C

Output Power 400 W with Forced Air (1.5 m/second)  
Without Chassis and Cover  
A position: Tma is 70°C

Output Power 340 W with Forced Air (1.5 m/second)  
With Chassis and Cover  
A position: Tma is 70°C



Output Power 350 W without Forced Air  
Without Chassis and Cover / With Chassis and Cover

A position: Tma is 40°C / 30°C

B position: Tma is 30°C / 25°C

C position: Tma is 40°C / 30°C

D position: Tma is 30°C / 25°C

E position: Tma is 25°C / 25°C

F position: Tma is 25°C / 25°C

Output Power 230 W without Forced Air  
Without Chassis and Cover / With Chassis and Cover

A position: Tma is 60°C / 55°C

C position: Tma is 60°C / 55°C

Output Power 200 W without Forced Air  
Without Chassis and Cover / With Chassis and Cover

B position: Tma is 60°C / 55°C

D position: Tma is 60°C / --

Output Power 170 W without Forced Air  
Without Chassis and Cover / With Chassis and Cover

D position: Tma is -- / 55°C

E position: Tma is 60°C / 55°C

F position: Tma is 60°C / 55°C

Only limited tests were performed for Optional Capacitor Pack, Type BS13\*-EC400/\*\*\*F (\* = 'A' to 'Z' or '0' to '9' or blank), due to Optional Capacitor Pack was previously conducted on the similarity Power Supply under CB Test Certificates No. US-19282-UL: issued date 2012-06-29, Test Report Ref No. E161936-A66-CB-1.

#### Technical Considerations

- The product was investigated to the following additional standards: N/A
- The following additional investigations were conducted: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States), CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada), EN 60601-1: 2006 + CORR: 2010 + A11: 2011 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance)
- The product was not investigated to the following standards or clauses: Biocompatibility (ISO 10993-1), Clause 14, Programmable Electronic Systems, Electromagnetic Compatibility (IEC 60601-1-2)
- The following accessories were investigated for use with the product: None
- The degree of protection against harmful ingress of water is: Ordinary  
The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No  
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)  
The pollution degree is: 2  
The overvoltage category is: II (2500 V)  
The altitude is: < 3000 m (MOPP)  
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 Enclosures-Miscellaneous-(008).

**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 (-). 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. 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. End product Risk Management Process to consider the acceptability of risk for components which are identified as High-Integrity Component. End product Risk Management Process to consider the need for simultaneous fault condition testing. End product Risk Management Process to consider the need for different orientations of installation during testing. 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 results of Mechanical Testing conducted as part of the power supply. 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. End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength. End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges 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 ID 7-08 and 7-09 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.

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.

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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
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts

### Special Instructions to UL Representative

	N/A
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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			
<p>The following solid-state components that can be disconnect from the remainder of the circuitry during either Dielectric Voltage Withstand Test:</p>		Parts to be disconnected for test:	Specific Test:
		None	N/A

### Sample and Test Specifics for Follow-Up Tests at UL

The following tests shall be conducted in accordance with the Generic Inspection Instructions

[illegible]