

# 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 and 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

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

Report No.: E358786-D1013-1/A2/C0(M)

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

Base Standard(s): UL 60601-1, 1st Edition, 2006-04-26 , CSA CAN/CSA-C22.2 No. 601.1-M90 (R2005)

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>	UL 60601-1, 1st Edition, 2006-04-26 , CSA CAN/CSA-C22.2 No. 601.1-M90 (R2005)
<b>Certification Type:</b>	Component Recognition
<b>CCN:</b>	QQHM2 / QQHM8
<b>Complementary CCNs:</b>	
<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 and 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

+ModelDiffResults

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-A7-CB-2 issued at 2015-01-16 with Cert. No. US-24524-UL issued at 2015-01-16, Amendment 1 issued at 2015-09-07 with Cert. No. US-24524-A1-UL issued at 2015-09-08, Amendment 2 issued at 2016-11-07 with Cert. No. US-24524-A2-UL issued at 2016-11-07. 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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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.

The tests listed below were considered necessary on Model mOZP-350-15-JSE.

- Power Input (7.1)
- Dielectric Voltage Withstand (20.4)
- Temperature (42)
- Humidity Preconditioning Treatment (44.5)
- Working Voltage Measurement (20.3)
- Power Availability (52.4.1)

The following tests were conducted on model mOZP-350-48-JSE as representative models of except for model mOZP-350-15 series under CB Test Certificates No. US-19799-UL: issued date 2012-09-25, Test Report Ref No. E161936-A73-CB-1 evaluated to IEC 60601-1 2nd Edition.

- Voltage Limitation - Part 1 (15B)
- Earthing and Potential Equalization (18F)
- Leakage Current (19)
- Dielectric Voltage Withstand (20.4)
- Humidity Preconditioning Treatment (44.5)
- Working Voltage Measurement (20.3)

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

The following Test Records were derived from records of tests for a substantially similar models OZP-350-X-xyEnz series under CB Test Certificates No. JP-10110-UL: issued date 2012-06-11, JP-10110-M1-UL: issued date 2012-07-18, Test Report Ref No. E161936-A69-CB-1 evaluated to IEC 60950-1:2005 (2nd edition). These test records have been deemed appropriate for use in this Test Report because the Model mOZP-350-X-xyEnz series are identical to Model OZP-350-X-xyEnz series except for model designation. As applicable, technical equivalency or differences to requirements in IEC 60601-1 2nd Ed clauses are shown in ( ) following the respective IEC 60950-1. 2nd Ed Clause:

- Input: Single-Phase: IEC60950-1, Sub-Clause 1.6.2  
(Power Input Test: IEC 60601-1, Sub-Clause 7.1)
- Determination of Working Voltage: Working Voltage Measurement: IEC60950-1, Sub-Clause 2.10.2 Part 22  
(Working Voltage Measurement: IEC 60601-1, Sub-Clause 20.3)
- Ball Pressure: IEC60950-1, Sub-Clause 4.5.5, 4.5  
(Ball Pressure: IEC 60601-1, Sub-Clause 59.2)
- Heating: IEC60950-1, Sub-Clause 4.5.1, 1.4.12, 1.4.13  
(Temperature: IEC 60601-1, Sub-Clause 42)
- Component Failure: IEC60950-1, Sub-Clause 5.3.1, 5.3.4, 5.3.7  
(Abnormal Operation and Fault Condition: IEC 60601-1 Sub-Clause 52)
- Transformer Abnormal Operation: IEC60950-1, Sub-Clause 5.3.3, 5.3.7b, Annex C.1  
(Transformer Overload and Short-Circuit Tests: IEC60601-1, Sub-Clause 57.9.1)
- Evaluation of voltage limiting components in SELV circuits: IEC60950-1, Sub-Clause 2.2.2  
(Low Voltage Reliability: IEC 60601-1 Sub-clause 16e)
- Max. V, A, VA test: IEC60950-1, Sub-Clause 2.1.1.5  
(Power Availability: IEC 60601-1 Sub-clause 52.4.1)

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

[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.

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.

UL CBTL utilized currently published TRF from the IEC/IEEE TRF site to create this CBTR, which contains old MTL programs on Page 2 and we have informed the IEC/IEEE secretariat through our NCB Manager about this particular TRF that needs an update to the current template including new CTF program page.

#### Technical Considerations

- The product was investigated to the following additional standards: N/A
- The following additional investigations were conducted: UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA), CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada), EN 60601-1: 1990 + A1:1993 + A2:1995 (except EMC limitations, EN 60601-1-2, Biocompatibility, EN 10993-1, Programmable Electronic Systems, IEC 60601-1-4)
- The product was not investigated to the following standards or clauses: Clause 36, Electromagnetic Compatibility (IEC 601-1-2), Clause 48, Biocompatibility (ISO 10993-1), Clause 52.1, Programmable Electronic Systems (IEC 601-1-4)
- The following accessories were investigated for use with the product: Capacitor Pack, Type BS13\*-EC400/\*\*\*\*F (\* = 'A' to 'Z' or '0' to '9' or blank).
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No  
The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No

#### 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:

- Type BL100 and BL63 are low breaking type. These were evaluated in cl. 52. In the test, s-c of BOP before D1 were waived because BOP met the required cl./cr.  
Optical Isolators (PC1, 2, 4, 5) are certified under EN 60747-5-5:2011, and creepage and clearance distances at the outside surface are > 8.0 mm, and dielectric strength was conducted in component certification.

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).

The equipment (Built-in type Power Supply) covered by this report, are components, which are intended for use in end-product equipment used in a hospital or related health care facility, evaluated to standard for Medical Electrical Equipment.

The power supplies have been evaluated as Class I, continuous operation, ordinary equipment and have not been evaluated for use in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).

The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary - Earthed Dead Metal: 292 Vrms, 560 Vpk, 888 Vp-p, Primary - SELV: 352 Vrms, 672 Vpk, 1.30k Vp-p.

A suitable Electrical and Fire Enclosure shall be provided by the end product.

The power supply was evaluated as Double Insulation between Primary and Secondary and Basic Insulation between Primary and Chassis (optional). See enclosure for Insulation Diagram.

Leakage current tests should be repeated in the end-product application.

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 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): T1 (Class B); LF1, LF2 (120°C); L3 (130°C).

Optional metal chassis of the power supply shall be properly bonded to the main earthing termination in the end product.

The product was submitted and tested for use at maximum ambient temperature (Tma) permitted by the manufacturer's (See Enclosures-Miscellaneous-(008) for details of derating curve).

The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.

Reliability of Thermistors (TH2, TH3) have not been evaluated. Thermistors (TH2, TH3) were not provided for all tests.

For some tests, the power supply was 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 Enclosures-Miscellaneous-(009) for details.) (for mOZP-350 series)

If Optional Capacitor Pack is provided with the power supply unit, consideration for risk of electrical shock, fire and mechanical hazards shall be given in the end product investigation.

The power supply terminals and/or connectors are Suitable for factory wiring only.

