

## UL TEST REPORT AND PROCEDURE

<b>Standard:</b>	ANSI/AAMI ES60601-1:2005, 3rd ed. (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
<b>Certification Type:</b>	Component Recognition
<b>CCN:</b>	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
<b>Product:</b>	DC-DC Converter
<b>Model:</b>	JHM10XXSY and JHM10XXDY series (where 'XX' =05, 12, or 24; 'YY' = 05, 12, 15; and maybe provided optional suffix -SG01)
<b>Rating:</b>	Input: For Models JHM1005SY and JHM1005DY Series: 4.5-9Vdc, 2700mA;  For Models JHM1012SY and JHM1012DY Series: 9-18Vdc, 1300mA;  For Models JHM1024SY and JHM1024DY Series: 18-36Vdc, 650mA  Output: See Model Differences for details.
<b>Applicant Name and Address:</b>	XP POWER INC SUITE 150 1241 E DYER RD SANTA ANA CA 92705 UNITED STATES

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.

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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**

The unit is a DC/DC Converter to be used as part of Medical Electrical Equipment, and is intended to provide Two MOPP between DC input circuits to DC output circuit.

The unit is provided with top and bottom plastic enclosure. All components inside the unit are mounted on PWB.

**Model Differences**

Model JHMXXDYY Series is identical to Model JHMXXSYY Series with except it is provided with two output instead of one.

All models within a series are identical except for transformer windings, inductance and MOSFETs, and output ratings.

See below for Model Output Ratings @ 50°C.

JHM10XXS05: 5 Vdc, 2000mA

JHM10XXS12: 12Vdc, 833mA

JHM10XXS25: 15Vdc, 666mA

JHM10XXD05: 5Vdc, 1000mA; 5Vdc, 1000mA

JHM10XXD12: 12Vdc, 420mA; 12Vdc, 420mA

JHM10XXD15: 15Vdc, 333mA; 15Vdc, 333mA

Where XX can be 05, 12, 15 and denotes nominal input voltage ranges as follows:

05 = 4.5-9Vdc

12 = 9-18Vdc

24 = 18-36 Vdc

Additional suffix "-SG01" maybe provided but not related to safety.

**Technical Considerations**

- Classification of installation and use : Building In
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : Component DC-DC converter for use in medical power supplies
- Mode of operation : Continuous
- Supply connection : Isolated Secondary
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: 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), 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)

- The product was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)
- The degree of protection against harmful ingress of water is: Ordinary
- The following accessories were investigated for use with the product: None
- The mode of operation is: Continuous
- 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 this evaluation defers the following clauses to 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).
- Scope of this evaluation excludes the following: Patient applied parts clauses: 4.6, 7.2.10, 8.3, 8.5.2, 8.5.5, 8.7.4.7-8.7.4.9, 8.9.1.15; Battery related clauses: 7.3.3, 15.4.3; Hand Control related clauses: 8.10.4; Oxygen related clauses: 11.2.2; Fluids related clauses: 11.6.2 – 11.6.4; Sterilization clause: 11.6.7; Biocompatibility Clause: 11.7 (ISO 10993); Motor related clauses: 13.2.13.3, 13.4; Heating Elements related clause: 13.2; Flammable Anaesthetic Mixtures Protection: Annex G.

#### **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:

- This power supply has been judged on the basis of the required creepage and clearances in the Third Edition of the Standard for Medical Electrical Equipment, IEC 60601-1, Sub-clause 8.9, which covers the end-use product for which the component was designed.
- The unit is a DC/DC converter and not evaluated for the separation to SUPPLY MAINS; suitable MAINS separation shall be provided during final installation.
- 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.
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (T<sub>mra</sub>) of 70°C at Full Load.

- The output circuit has not been evaluated for connecting to Applied Parts. For end products intended to connect to Applied Parts, suitable evaluation should be considered.
- Considerations to the applied parts requirement, to be conducted as 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-use equipment. The end-use product shall ensure that the power supply is used within its ratings.
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- End product Risk Management Process to consider the need for simultaneous fault condition testing.
- 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 Leakage of Liquids 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.
- The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.

**Additional Information**

Marking label submitted is representative of all models in this Report.

CB Test certificates for components are included in Licenses Enclosure. In accordance with the current rules of CB Scheme, CB Test certificate is effective for 3 years. Recognizing NCB may challenge the CBTC when certificates are more than 3 years old.


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.

**Additional Standards**

The product fulfills the requirements of: 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), 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)

**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
Direct current	
Output	Rated output voltage, power, frequency.
<b>Special Instructions to UL Representative</b>	
N/A	

**Production-Line Testing Requirements**

**Test Exemptions** - The following models are exempt from the indicated test

Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
JHM10XXSY	Exempt	Not exempt	Exempt
JHM10XXDY	Exempt	Not exempt	Exempt

**Solid-State Component Test Exemptions** - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:

Component
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

Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
N/A	N/A	N/A	N/A