UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(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)
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Product:	DC-DC Converter
Model:	JHM03XXYZZ and JHM06XXYZZ Series (where XX can be 12 or 24, Y can be S or D, ZZ can be 05, 12, 15)
Rating:	Input: JHM0312YZZ and JHM0612YZZ Series: 10-17 VDC JHM0324YZZ and JHM0624YZZ Series: 20-30 VDC Output: See Model Differences for details.
Applicant Name and Address:	XP POWER LTD 401 COMMONWEALTH DR HAW PAR TECHNOCENTRE LOBBY B, #02-02 SINGAPORE 149598 SINGAPORE

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: Melissa DeGuia Reviewed by: Bernadette Matsuoka

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

Model JHM03 and JHM06 Series units are DC/DC Converters to be used as part of Medical Electrical Equipment, and are intended to provide Two MOPP between DC input circuits to DC output circuit. They have two input ranges: 10-17 VDC (12 VDC nominal) and 20-30 (24 VDC nominal).

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

Model Differences

Model JHM03XXYZZ Series:
The number "03" represents a maximum output of 3 W, while "XX" is the Nominal Input Voltage, 12 VDC or 24 VDC; and Y represents either S for single output or D for a dual output unit and where ZZ represents the output voltage: 05 = 5 VDC, 12 = 12 VDC, 15 = 15 VDC.

Model JHM06XXYZZ Series:
The number "06" represents a maximum output of 6 W, while "XX" is the Nominal Input Voltage, 12 VDC or 24 VDC; and Y represents either S for single output or D for a dual output unit and where ZZ represents the output voltage: 05 = 5 VDC, 12 = 12 VDC, 15 = 15 VDC.

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

See below for Model Output Ratings @ 60°C.

Output: Single Output Units:
JHM0312S05: 5 VDC, 600 mA
JHM0312S12: 12 VDC, 250 mA
JHM0312S15: 15 VDC, 200 mA
JHM0324S05: 5 VDC, 600 mA
JHM0324S12: 12 VDC, 250 mA
JHM0324S15: 15 VDC, 200 mA
JHM0612S05: 5 VDC, 1200 mA
JHM0612S12: 12 VDC, 500 mA
JHM0612S15: 15 VDC, 400 mA
JHM0624S05: 5 VDC, 1200 mA
JHM0624S12: 12 VDC, 500 mA
JHM0624S15: 15 VDC, 400 mA

Output: Dual Output Units:
JHM0312D12: +/-12 VDC, 125 mA
JHM0312D15: +/-15 VDC, 100 mA
JHM0324D12: +/-12 VDC, 125 mA
JHM0324D15: +/-15 VDC, 100 mA
JHM0612D12: +/-12 VDC, 250 mA
JHM0612D15: +/-15 VDC, 200 mA
JHM0624D12: +/-12 VDC, 250 mA
JHM0624D15: +/-15 VDC, 200 mA

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:: 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 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance)
- 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 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).
- 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:

- The unit is a DC/DC converter intended to be powered by an isolated regulated secondary DC source and has not been evaluated for connection 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 (Tmra) of 60°C at Full Load.
- The output circuit has not been evaluated for connecting to Applied Parts.
- 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-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 using a DC source connected to a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- § The units were evaluated for 2 MOPP from Input to Enclosure and 2 MOPP from Input to Output based on a maximum input voltage of 30Vdc. Additionally evaluated for 1 MOPP for 250 Vrms.
- § Abnormal tests were conducted with the input provided with an external UL Listed fuses of the following values: 1.5 A for the 10-17 VDC (Nominal 12 VDC) Input units and 1.0 A for the 20-30 VDC (Nominal 24 VDC) Input units. Testing conducted with an isolated regulated secondary DC source.
- § The need for Marking durability and label legibility to be determined as part of the end product evaluation.
- § End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
- § Overcurrent protection is not provided; the end-product evaluatoin shall consider compliance to Clause 8.11.5.

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: 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 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance)

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.
Special Instructions to UL Representative 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
All Models	Exempt	Test	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