

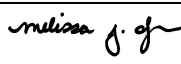




Test Report issued under the responsibility of:



IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No.....:	4786488107-20111217
Date of issue	2014-08-13; Correction 1: 2015-05-12
Total number of pages.....:	11
CB Testing Laboratory.....:	UL Camas
Address	2600 NW Lake Rd., Camas WA 98607, USA
Applicant's name.....:	XP Power LLC
Address	15641 Red Hill Ave., STE 100, Tustin, CA 927080 USA
Test specification:	
Standard	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure.....:	CB Scheme
Non-standard test method.....:	
Test Report Form No.....:	IEC60601_1J
Test Report Form Originator	UL(US)
Master TRF	2014-07
Copyright © 2014 Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE), Geneva, Switzerland. All rights reserved. This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context. If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed. This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.	
General disclaimer: The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.	

Test item description	Component Switching Power Supply	
Trade Mark		
Manufacturer	XP Power LLC, 15641 RED HILL AVE., STE 100, TUSTIN, CA 92780 USA	
Model/Type reference.....	EMH250PSXXYY-ZZ and EMH350PSXXYY-ZZ, where XX is 12-48, where YY is any number between 0-9, ZZ is "SF" or blank, may also be provided with additional suffixes "-TF", "-VF", "D" and "-S", where "-" considered optional; EMH350PS12-01 XB0188 and EMH350PS12-XA1007	
Ratings.....	<p>For Model EMH250PSXXYY-ZZ Series: Input: 100-240Vac, 50/60Hz, 3.8A, 250W Output: Refer to Model Differences for details.</p> <p>For Model EMH350PSXXYY-ZZ Series and Model EMH350PS12-01 XB0188: Input: 100-240Vac, 50/60Hz, 4.8A, 350W Output: Refer to Model Differences for details</p> <p>For EMH350PS12-XA1007: Input: 100-240Vac, 50/60Hz, 4.8A, 350W Output: 12.3Vdc, 28.5A</p>	
Testing procedure and testing location:		
<input checked="" type="checkbox"/>	CB Testing Laboratory:	
Testing location/ address		UL Camas 2600 NW Lake Road, Camas, WA 98607 USA
<input type="checkbox"/>	Associated CB Testing Laboratory:	
Testing location/ address		
Tested by (name + signature).....		Bernadette Matsuoka 
Approved by (name + signature)		Melissa DeGuia 
<input type="checkbox"/>	Testing procedure: TMP/CTF Stage 1:	
Testing location/ address		
Tested by (name + signature).....		
Approved by (name + signature)		
<input type="checkbox"/>	Testing procedure: WMT/CTF Stage 2:	

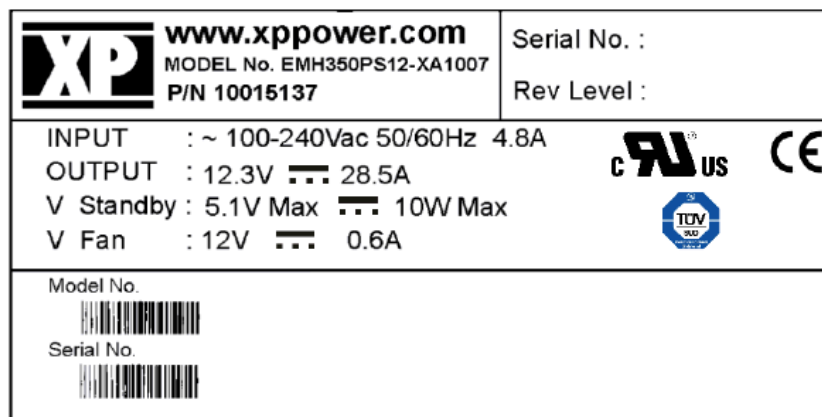
Testing location/ address		
Tested by (name + signature).....		
Witnessed by (name + signature)		
Approved by (name + signature)		
<input type="checkbox"/>	Testing procedure: SMT/CTF Stage 3 or 4:	
Testing location/ address		
Tested by (name + signature).....		
Witnessed by (name + signature)		
Approved by (name + signature)		
Supervised by (name + signature).....		

List of Attachments (including a total number of pages in each attachment): N/A	
Summary of testing N/A	
Tests performed (name of test and test clause): N/A	Testing location:
Summary of compliance with National Differences List of countries addressed: Austria, Canada, Republic of Korea, Sweden, United Kingdom and USA <input checked="" type="checkbox"/> The product fulfils the requirements of IEC 60601-1, Edition 3.1 (2012)	

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Marking plate below is considered representative of the entire series with the exception that "BETA" is not provided



GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use	For building-in
Device type (component/sub-assembly/ equipment/ system):	Component Power Supply
Intended use (Including type of patient, application location) :	To supply regulated power
Mode of operation	Continuous
Supply connection	For building-in
Accessories and detachable parts included	N/A
Other options include	N/A
Testing	
Date of receipt of test item(s)	N/A
Dates tests performed	N/A
Possible test case verdicts:	
- test case does not apply to the test object	N/A
- test object does meet the requirement.....	Pass (P)
- test object was not evaluated for the requirement	N/E (collateral standards only)
- test object does not meet the requirement.....	Fail (F)
Abbreviations used in the report:	
- normal condition	N.C.
- single fault condition.....	S.F.C.
- means of Operator protection	MOOP
- means of Patient protection	MOPP
General remarks:	
<p>"(See Attachment #)" refers to additional information appended to the report.</p> <p>"(See appended table)" refers to a table appended to the report.</p> <p>The tests results presented in this report relate only to the object tested.</p> <p>This report shall not be reproduced except in full without the written approval of the testing laboratory.</p> <p>List of test equipment must be kept on file and available for review.</p> <p>Additional test data and/or information provided in the attachments to this report.</p>	
Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC60601-1	
<p>The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided..... :</p> <p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> Not applicable</p>	
When differences exist; they shall be identified in the General product information section.	

Name and address of factory (ies)	XP POWER LLC., 990 BENECIA AVE., SUNNYVALE CA 94085, UNITED STATES XP POWER (KUNSHAN) LTD., 230 BIN JIANG NAN RD., ZHANGPU TOWN, KUNSHAN, JIANGSU 215321 CHINA
------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Test Report Summary:

The following corrections were made to the report on 2015-05-12:

Correct the Model No from ECS350PS12-XA1007 to EMH350PS12-XA1007 in the list of changes under Amendment 1 below

The following revisions were made to this Report on 2015-04-20:

Amendment 1:

- Revise the output ratings for Model EMH350PS12-XA1007 from 12Vdc, 29.2A to 12.3Vdc, 28.5A. In addition the Stand-by Output rating was revised from 5Vdc, 2A to 5.1Vdc, 10W.
- Update the CCL to make Transistor (TR3) optional for Model ECS350PS12-XA1007.
- Update the CCL to make all Y-capacitors "Optional" as well as add Type "Y2" to the Technical Description.
- Add alternate PWB layouts, Rev. F, to the Enclosures section.
- Update the Applicant and Manufacturing address from Santa Ana, CA USA to Tustin, CA USA. Includes updating the Letter of Assurance with the new address in the Enclosures section (Enclosure 7-01).

General product information:

Products are component power supplies intended to be used as part of Medical Electrical Equipment. It is an open frame power supply intended for building-in Class I or Class II end-products. Earthing symbol may only be provided for Class I power supplies.

Model Differences

Model EMH250PSXXYY-ZZ Series and Model EMH350PSXXYY-ZZ Series are identical with exception that the EMH250PSXXYY-ZZ Series is designed to be rated for a 250 W output power and the EMH350PSXXYY-ZZ Series designed to be rated for a 350 W output power.

All models within the each series are identical with exception to the output rating, mains transformer windings, and minor secondary components.

Model EMH350PS1201 B0188 is identical to Model EMH350PSXXYY-ZZ except standby output is 12V instead of 5V.

Models EMH250PSXXYY-ZZ and EMH350PSXXYY-ZZ have the following nomenclature:

XX = 12-48, denotes the rated output voltage.

YY= 0-9, denotes non-safety related functions

ZZ = SF or blank, denotes either single pole fusing (SF) or double fusing (blank)

Units provided with additional suffix "-TF" or "-VF" provided with Top Fan and Cover.

Units provided with additional suffix "-S" indicates models provided with input screw terminals.

Units provided with additional suffix "D" provided with integral O-ring diode located in the secondary

See below for the Output Rating for 50°C Ambient provided with 12CFM Forced Air Cooling, 3 inches Fan distance from Input side with inward air-flow direction .

Model EMH250PS12YY-ZZ: 10.1 Vdc to 13.5 Vdc, 21 A Max, (250 W Max)

Model EMH250PS15YY-ZZ: 13.6 Vdc to 17 Vdc, 16.7 A Max, (250 W Max)

Model EMH250PS18YY-ZZ: 17.1 Vdc to 21 Vdc, 14 A Max, (250 W Max)

Model EMH250PS24YY-ZZ: 21.1 Vdc to 26 Vdc, 10.5 A Max, (250 W Max)

Model EMH250PS28YY-ZZ: 26.1 Vdc to 31 Vdc, 9.0 A Max, (250 W Max)

Model EMH250PS33YY-ZZ: 31.1 Vdc to 33 Vdc, 7.6 A Max, (250 W Max)

Model EMH250PS36YY-ZZ: 33.1 Vdc to 42 Vdc, 6.9 A Max, (250 W Max)

Model EMH250PS48YY-ZZ: 42.1 Vdc to 54 Vdc, 5.2 A Max, (250 W Max)

Model EMH350PS12YY-ZZ: 10.1 Vdc to 13.5 Vdc, 29.2 A Max, (350 W Max)

Model EMH350PS15YY-ZZ: 13.6 Vdc to 17 Vdc, 23.3 A Max, (350 W Max)
 Model EMH350PS18YY-ZZ: 17.1 Vdc to 21 Vdc, 19.5 A Max, (350 W Max)
 Model EMH350PS24YY-ZZ: 21.1 Vdc to 26 Vdc, 14.6 A Max, (350 W Max)
 Model EMH350PS28YY-ZZ: 26.1 Vdc to 31 Vdc, 12.5 A Max (350 W Max)
 Model EMH350PS33YY-ZZ: 31.1 Vdc to 33 Vdc, 10.6 A Max, (350 W Max)
 Model EMH350PS36YY-ZZ: 33.1 Vdc to 42 Vdc, 9.8 A Max, (350 W Max)
 Model EMH350PS48YY-ZZ: 42.1 Vdc to 54 Vdc, 7.3 A Max (350 W Max)

Stand-by Output for all models: 5Vdc, 2 A or 12 Vdc, 0.8 A

Fan Output for all models (V2): 12 Vdc, 0.6 A (Optionally marked on nameplate)

See Enclosure 7-02 for de-rating curve. For Fan or external 12CFM cooling: 50°C at 100% of rated load; 70°C ambient at 50% of rated load.

Model EMH350PS12-XA1007 is the same as Model EHM350PS12YY-ZZ except Capacitor (C21, C55) are rated 220pF, Output is rated 12.3Vdc, 28.5A, and Stand-by Output is rated 5.1V, 10W.

Additional Information

The clearance distances have additionally been assessed for suitability up to 3000 m elevation. The creepage and clearance measurement in Table: To insulation diagram.

The schematics are kept in file at the CBTL and can be provided by the manufacturer upon request by NCB's/CBTL's.

These power supplies have been previously evaluated by UL to IEC60601-1: 2005 (3rd Edition); under CB Test Report 11ME05687 dated 2012-12-15 and amended on 2012-06-01 and 2013-3-25 and CB Certificate US-18274-A2-UL, dated 2011-12-21 and amended 2012-06-05 and 2013-03-25. All tests conducted per 3rd ed of IEC 60601-1 were considered representative of the corresponding tests required by 3rd ed of IEC 60601-1+AM1.

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.

The Marking Plate provided is representative of all models covered under this Report.

Technical Considerations

- The product was investigated to the following additional standards: ANSI/AAMI ES60601-1:2005 (R2012) (includes National Differences for USA); CAN/CSA-C22.2 No. 60601-1:14 (includes National Differences for Canada), EN 60601-1:2006+A1 (2013) + IEC 60601-1, Edition 3.1 (2012)
- 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)
- Scope of Power Supply 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

- The product is Classified only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: Ordinary
- The mode of operation is: Continuous
- 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 anaesthetics mixture with air or oxygen or with nitrous oxide: No
- Units provided with either a Cover or Chassis should be used only in a Class I application with earthing symbol applied. The cover and chassis shall be reliably earthed in the end-use application.

Risk Controls/ Engineering Condition of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc. When installed in an end-product, consideration must be given to the following:

- Considerations to the applied parts requirements shall be considered as part of the end-product evaluation.
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- 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 output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- The available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions.
- The input/output connectors are not acceptable for field connections, they are only intended for connection to mating connectors of internal wiring inside the end-use equipment.
- Primary Heatsink was considered floating live and should not be connected to earth in the end-product.
- The "floating" mounting hole shall be mounted on insulating post or properly earthed for Class I end-product.
- Units may be provided with one fuse in the Line side for models with SF suffix or one fuse in both the Line and Neutral sides. The need for additional fusing shall be determined as part of the end-product evaluation.
- Units provided with either a Cover or Chassis should be used only in a Class I application with earthing symbol applied. The cover and chassis shall be reliably earthed in the end-use application.
- When installed in a Class I end product, and if the Chassis and Cover are not provided, the power supply shall be mounted in a manner that provides, at a min. 2.8 mm Clearance between the primary side of the power supply and protectively earthed accessible conductive parts. In addition, when installed in a Class I end product, the protective bonding terminal of the power supply shall be reliably connected to the main protective earthing terminal of the end product.
- When installed in a Class II end product, the power supply shall be mounted, on insulating posts, in a manner that provides, at a min. 5.5 mm Clearance between the primary side of the power supply and any accessible conductive parts.
- Power supply provides the following MOPP (means of patient protection): two MOPP based upon a working voltage 250 Vrms, 680 Vpk between Primary to Secondary, one MOPP based upon a working voltage 250 Vrms, 354 Vpk between Primary and Earth/Enclosure, two MOPP based upon a working voltage 48Vdc between secondary to floated earth trace on PWB as Class II application for BF output consideration, one MOPP based upon a working voltage 48Vdc between secondary and earthing trace or chassis as Class I application for BF output consideration.
- Temperature, Leakage Current including when measured with a non-frequency-weighted device (Clause 8.7.3e), Protective Bonding, 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 evaluated for use at the maximum ambient temperature (Tmra) permitted by the manufacturer's specification of: 50°C at 100% rated output and 70°C at 50% rated output with external 12CFM forced air (See De-rating Curve, Enclosure 7-02 for details)
- Temperature test was conducted with 12CFM force air cooling as part of this evaluation. Suitability of convection cooling shall be fully determined as part of the end product evaluation and

Temperature Test.

- Magnetic devices T1, T2, L12, L13, and PFC employ a Class F (155°C insulation system).
- The PWB is rated 130°C.
- The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The need for Marking Durability and Legibility of Marking testing to be considered as part of the end product application.
- Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
- A single maximum current rating of 3.8A or 4.8A was provided for the entire 100-240Vac voltage range. The end product evaluation shall consider the acceptability of this component power supply rating as it relates to the requirements of Clause 7.2.7.