Underwriters Laboratories (UL LLC)
Safety Certification Report

Model:	ALM85USXXYY-ZZ##V (where XX is any number between 12-24 designating output voltage and YY can be blank or "C2" designating Class II configuration, and -ZZ can be blank or "-A", "-6", "-6A", "-8", "-8A" designating AC inlet type, ## can be any alphanumeric character or blank designating marketing purposes only and V can be any alphanumeric or blank designating casing color. Model name can also include suffix identifier -SF to indicate a Single Fuse supplied for Class II configurations only)
Device Description:	Switching Brick Power Supply
Applicant:	XP Power LLC 15641 Red Hill Ave., Ste. 100 Tustin, CA 92780 USA
Manufacturer:	XP Power Ltd. 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598 Singapore
Manufacturing Facility(ies):	XP Power Inc. 990 Benecia Ave. Sunnyvale, CA 94085-2804 USA XP Power (Kunshan) Ltd 230 Bin Jiang Nan Rd Zhangpu Town, Kunshan, Jiangsu 215321 China XP Power (Vietnam) Co., Ltd. Lot D - 4Q-CN My Phuoc 3 Industrial Park Ben Cat District, Binh Duong Vietnam XP Power Horseshoe Park Pangbourne RG8 7JW United Kingdom
Report No.:	E146893-D1019-1/A0/C0-UL
Report (Re)Issue Date:	2018-04-19
Base Standard(s):	ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14
Additional Standards:	IEC 60601-1-6:2010 (Third Edition) + A1:2013
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.

Table of Contents

Report Modifications Summary

The following changes were made to this report. If none listed in the below table, this report is the originally issued report.

The following scheme is used throughout this report to reflect the **Report No.**:

(File No.) – (Report Ref. No.) – (x) / A(y) / C(z) – YYY, where:
(x) = Report (Re)Issue No.
(y) = Amendment No.
(z) = Correction No.
YYY = Report Type (UL/CB/IEC)

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By

Test Report issued under the responsibility of:

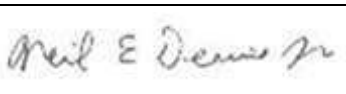
IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No. ..... :	E146893-D1019-1/A0/C0-UL
Date of issue..... :	2018-04-19
Total number of pages ..... :	143
Testing Laboratory..... :	UL Minneapolis
Address ..... :	2222 Woodale Drive, Suite 300 Mounds View, MN 55112 USA
Applicant's name ..... :	XP Power LLC
Address ..... :	15641 Red Hill Ave., Ste. 100 Tustin, CA 92780 USA
Test specification:	
Standard..... :	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure..... :	UL Certification
Non-standard test method……..:	N/A
Test Report Form No. ..... :	IEC60601_1K

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 UL testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting UL.

Test item description:	Switching Brick Power Supply
Trade Mark:	Trademark image(s): 
Manufacturer:	XP Power Ltd. 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02, Singapore 149598 Singapore
Model/Type reference:	ALM85USXXYY-ZZ##V (where XX is any number between 12-24 designating output voltage and YY can be blank or "C2" designating Class II configuration, and -ZZ can be blank or "-A", "-6", "-6A", "-8", "-8A" designating AC inlet type, ## can be any alphanumeric character or blank designating marketing purposes only and V can be any alphanumeric or blank designating casing color. Model name can also include suffix identifier -SF to indicate a Single Fuse supplied for Class II configurations only)
Ratings:	Input Rated: 100-240 Vac, 50/60 Hz, 1.7 A Output Rated: See Model Differences for details.

Testing procedure and testing location:		
[X] UL/DAP Testing Laboratory:		
Testing location/ address:	UL Minneapolis 2222 Woodale Drive, Suite 300 Mounds View, MN 55112 USA	
Tested by (name, function, signature):	Janice Pham / Project Handler	
Approved by (name, function, signature):	Ned Devine / Reviewer	
[ ] Testing procedure: WMT:		
Testing location/ address:		
Tested by (name, function, signature):		

Witnessed by (name, function, signature):		
Approved by (name, function, signature):		

List of Attachments (including a total number of pages in each attachment): Refer to Appendix A of this report. All attachments are included within this report.
Summary of testing
Tests performed (name of test and test clause): Testing location: *Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.*

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 owners of these marks.

Refer to the enclosure(s) titled Marking Label in the Enclosures section in Appendix A of this report for a copy.

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of Installation and Use:	Portable
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location):	Stand-alone power supply for use with Medical Electrical Equipment.
Mode of Operation:	Continuous
Supply Connection:	Appliance Coupler
Accessories and detachable parts included:	None
Other Options Include:	None
Testing	
Date of receipt of test item(s) .....:	2016-11-21, 2018-03-02
Dates tests performed.....:	2017-03-20 to 2017-03-31
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
- 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:
Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version “J” of TRF for IEC for 60601-1 3rd edition with Amendment 1.
"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests 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 testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a point is used as the decimal separator.

GENERAL PRODUCT INFORMATION:

Report Summary

All applicable tests according to the referenced standard(s) have been carried out.

Refer to the Report Modifications for any modifications made to this report.

Product Description

Stand-alone power supply for use with Medical Electrical Equipment.

Model Differences

All models within the series are identical with exception to power transformer (T1) winding and other minor changes to secondary circuit to accommodate different output voltages and current ratings.

Models may have an additional YY identifier which can be blank or "C2" to designate a Class II configuration.

Models may have an additional ZZ identifier which can be black or "A", "6", "6A", "8", "8A" to designate the type of input connector:
- blank designates a C14 input connector (Class I construction) or C18 input connector (Class II construction);
- "A" designates a C14 input connector with optional IEC cable retention;
- "6" designates a C6 input connector;
- "6A" designates a C6 input connector with optional IEC cable retention;
- "8" designates a C8 input connector;
- "8A" designates a C8 input connector with optional IEC cable retention.

Models may have an additional ## identifier which can be any alphanumeric or blank designating marketing purposes only.

Models may have an additional V identifier which can be any alphanumeric or blank to represent the color of
the casing.

Models may have an additional -SF identifier which indicates that the power supply is provided with a single fuse. This is applicable only for Class II configurations with the identifier C2.

Model ALM85US15-XA1185 is similar to Model ALM85US15 except that ALM85US15-XA1185 does not have
Y-Capacitor, C8.

Output voltage rating indicated in '( )' under "Ratings" represents voltage tolerance evaluated.
ALM85US12: 12 Vdc (10.1 - 13.5 Vdc), 6.67 A max., 80W max.;
ALM85US15: 15 Vdc (13.5 - 17.0 Vdc), 5.33 A max., 80W max.;
ALM85US19: 19 Vdc (17.1 - 21.0 Vdc), 4.47 A max., 85W max.;
ALM85US24: 24 Vdc (21.0 - 26.0 Vdc), 3.54 A max., 85W max.;

Additional Information

Marking label is representative of all models. The nameplate labels included in this report depict the draft artwork for the marking plate pending approval by National Certification Bodies and it will not be affixed to products prior to such approval.

Transformer Mfr: XP Power L L C, Type: 1002xxxx (x can be any number from 0 to 9) were designed to be used for the following Models (see Enclosure diagrams for each transformer construction):
- Type: 10020246 for Switching Brick Power Supply, Models ALM85US12 and ALM85US12C2
- Type: 10020247 for Switching Brick Power Supply, Models ALM85US15 and ALM85US15C2
- Type: 10020248 for Switching Brick Power Supply, Models ALM85US19 and ALM85US19C2
- Type: 10020249 for Switching Brick Power Supply, Models ALM85US24 and ALM85US24C2

Technical Considerations

- The product was investigated to the following standards:

  Main Standard(s):

  ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14

  From Country Differences:

- Austria: EN 60601-1:2006/A1:2013
- Korea, Republic of: KS C IEC 60601-1
- USA: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14
- United Kingdom: BS EN 60601:2006 A1
- Sweden: SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014

Additional Standards:

IEC 60601-1-6:2010 (Third Edition) + A1:2013

- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: Biocompatibility, PESS, EMC, Annex Z of EN standards for compliance with the MDD
- The following accessories were investigated for use with the product: None
- None

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

The component shall be installed in compliance with the Marking (clause 7) and Separation (clause 8) requirements of the end use application.

The product was submitted and evaluated for use at the maximum ambient temperature (Tmra) permitted by the manufacturer's specification of: 40°C output loaded to 100% rated, 60°C output loaded to 60% rated.

Repeating leakage current testing should be considered in the end product application.

This power supply was evaluated as having: One MOPP between Primary to Earth/Reference, Two MOPP between Primary and Secondary.

This power supply has been evaluated as a continuous operation, ordinary equipment and has not been evaluated for use in the presence of a 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 should ensure that the requirements related to accompanying documents, clause 7.9, are met.

The available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions

The output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of the end-use machine.

The Electric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal (Class I units): 346 Vpk, 244 Vrms; Primary-SEC: 512 Vpk, 345 Vrms.

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): L1 and L2 are Class B (130°C); T1 is Class F (155)

Accompanying documents to be provided as part of the end-product.

Cleaning test to be considered as part of end product evaluation.

Durability and Legibility of Markings Test conducted, however, the need for Marking Durability and Marking Legibility Testing to be considered as part of the end product installation.

Power cord suitable for the application to be provided as part of the end product evaluation.

It is anticipated that the requirements of IEC 60601-1-6 will be applied once again upon integration of power supply with the Medical Device.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Insulation Diagram - (01) Insulation Diagram

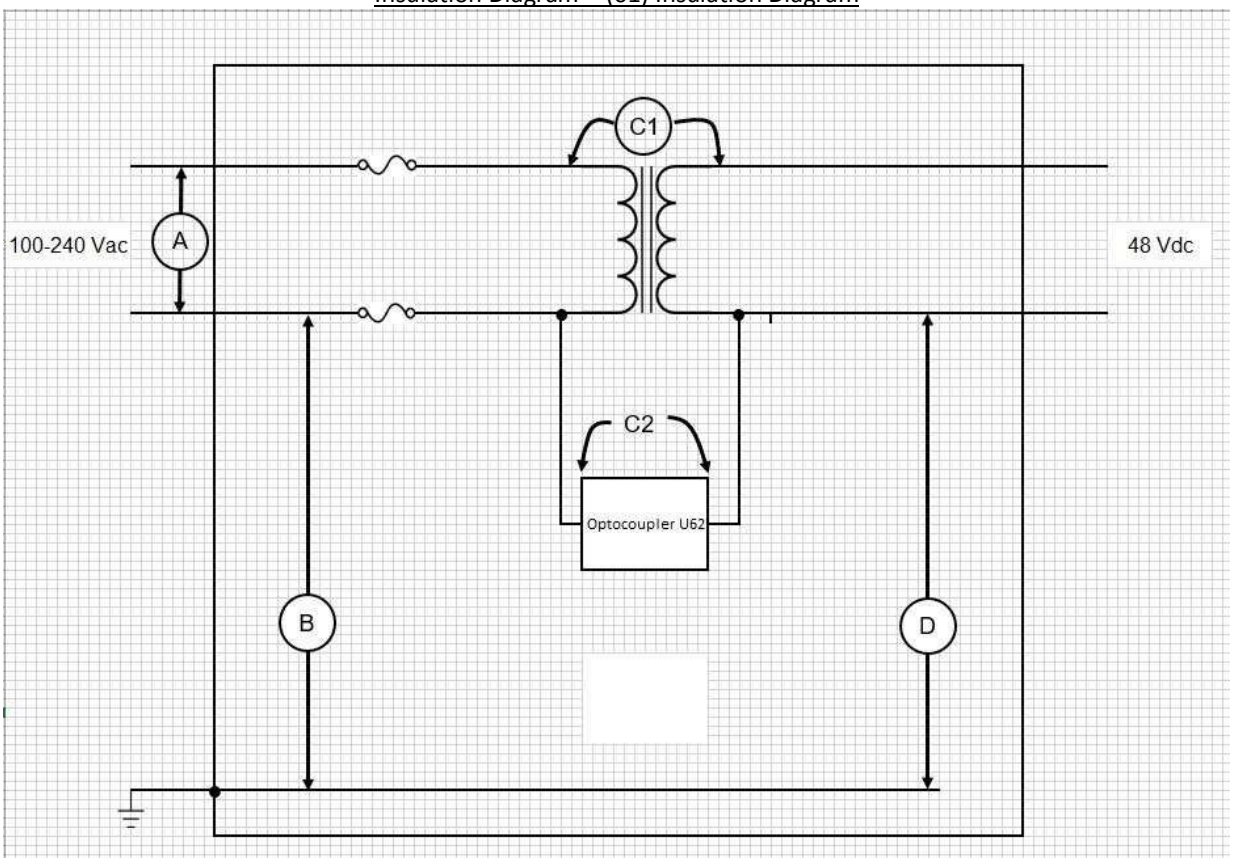


TABLE: INSULATION DIAGRAM									N/A
Pollution Degree:				**3**					-
Overvoltage category:				**II**					-
Altitude:				**5000 (m)**					-
Additional details on parts considered as applied parts:				**[X] None [ ] Areas: ___ (See Clause 4.6 for details)**					-
Area	**Number and type of Means of Protection: MOOP, MOPP**	**CTI**	**Working Voltage V_{rms}**	**Working Voltage V_{pk}**	**Required creepage (mm)**	**Required clearance (mm)**	**Measured creepage (mm)**	**Measured clearance (mm)**	**Remarks**
A	MOOP (1)	IIIb	244	346	3.91	2.96	4.2	4.2	
B	MOPP (1)	IIIb	242	344	4	3.225	4.2	4.2	
C1	MOPP (2)	IIIb	345	512	10.6	9.03	19	19	
C2	MOPP (2)	IIIb	210	388	7.4	6.45	19	19	
D	MOPP (0)	IIIb		48 Vpk, 48 Vdc	-	-	-	-	For Class I constructions
D	MOPP (1)	IIIb		48 Vpk,	2.3	1.548	4.1	4.1	For Class II

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

				48 Vdc					constructions

Supplementary Information:

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified. Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.

- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional

- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.

- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.