
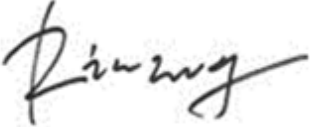



Test Report issued under the responsibility of:



IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No.....	E116994-D1021-1/A1/C0-UL
Date of issue.....	2018-10-19; (A1) 2019-04-29
Total number of pages.....	204
Testing Laboratory.....	2929 E. Imperial Hwy., Suite 100, Brea 92821, CA, United States of America
Applicant's name	SL POWER ELECTRONICS CORP
Address.....	6050 KING DRIVE, BLDG A VENTURA, CA 93003 UNITED STATES
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
Copyright © 2015 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. 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 UL testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting UL.	

<p>Test item description:</p> <p>Trade Mark:</p>	<p>Medical Power Supply</p> <p>Trademark image(s):</p> 
<p>Manufacturer:</p>	<p>Same as Applicant</p>
<p>Model/Type reference:</p>	<p>SE240AXXYZWW, where S can be M or T, XX represents the output voltage from 12V to 48V, Y represents any number from 0 to 9 or blank, Z represents F, N, Q, while F means class I construction and N or Q means Class II construction, W represents any number from 0 to 9 or blank, unless specified below.</p>
<p>Ratings:</p>	<p>Model ME240A24YYF02, ME240B2400F02, Input: 100-240V~, 50-60Hz, 2.8A Output: See Model Differences for the output ratings</p> <p>Model ME240A1251Z01: Input: 100-110Vac, 50-60Hz, 2.8A; Output: 12Vdc, 16.6A Input: 110-240Vac, 50-60Hz, 2.8A; Output: 12Vdc, 16.6A</p> <p>Model ME240A2451Z01: Input: 100-110Vac, 50-60Hz, 2.8A; Output: 24Vdc, 9.17A Input: 110-240Vac, 50-60Hz, 2.8A; Output: 24Vdc, 10.0A</p> <p>Model ME240A2851Z01: Input: 100-110Vac, 50-60Hz, 2.8A; Output: 28Vdc, 7.86A Input: 110-240Vac, 50-60Hz, 2.8A; Output: 28Vdc, 8.60A</p> <p>Model ME240A4851Z01: Input: 100-110Vac, 50-60Hz, 2.8A; Output: 48Vdc, 5.0A Input: 110-240Vac, 50-60Hz, 2.8A; Output: 48Vdc, 5.0A</p> <p>Model ME240A2451F02: Input: 100-110Vac, 50-60Hz, 2.8A; Output: 25Vdc, 8.80A Input: 110-240Vac, 50-60Hz, 2.8A; Output: 25Vdc, 9.60A</p> <p>Model ME240A1251Q02: Input: 100-240Vac, 50-60Hz, 2.8A; Output: 12Vdc, 16.6A</p> <p>Model ME240B2400F02: Input: 100-110Vac, 50-60Hz, 2.8A; Output: 24Vdc, 9.17A Input: 110-240Vac, 50-60Hz, 2.8A; Output: 24Vdc, 10.0A</p>
<p>Testing procedure and testing location:</p>	
<p><input checked="" type="checkbox"/> UL/DAP Testing Laboratory:</p>	
<p>Testing location/ address:</p>	<p>2929 E. Imperial Hwy., Suite 100, Brea 92821, CA, United States of America</p>

Tested by (name, function, signature):	Ricky Wang Project Handler	
Approved by (name, function, signature):	Angela Li Project Reviewer	
<hr/>		
<input type="checkbox"/> Testing procedure: WMT:		
Testing location/ address:		
Tested by (name, function, signature):		
Witnessed by (name, function, signature):		
Approved by (name, function, signature):		
<hr/>		

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, Power Supply
Intended use (Including type of patient, application location):	To supply regulated power to end products
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)	2018-02-22 to 2018-10-10
Dates tests performed	2018-03-11 to 2018-10-12; (A1)2019-04-18 to 2019-04-25
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:	
"(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	
Switching Power Supply housed within a thermoplastic enclosure.	
The equipment (Switching power supplies) covered by this report, are components, which are intended for use with end-product equipment used in a hospital or related health care facility, evaluated to Medical Equipment standard.	
Model Differences	
The models differ in output ratings which require different turns and gage in transformers T1 and T2, and secondary circuitry component values to accommodate the rated output.	
Model number nomenclature explains construction as follows:	
SE240AXXYZWW, where S can be M or T, XX represents the output voltage from 12V to 48V, Y	

represents any number from 0 to 9 or blank, Z represents F, N, Q, while F means class I construction and N or Q means Class II construction, W represents any number from 0 to 9 or blank, unless specified below.
Model ME240A24YYF02

ME240 and TE240 are the same except for the model designations.

The SE240 family power supply has two types of construction: Class I and Class II.

For each construction, all models are similar except for secondary winding of transformer, secondary components and output rating.

SE240AXXYF02 is Class I construction, all models are similar except for secondary winding of transformer, secondary components and output rating.

SE240AXXYN02 is Class II construction, N is for C8 AC inlet, all models are similar except for secondary winding of transformer, secondary components and output rating.

SE240AXXYQ02 is Class II construction, Q is for C18 AC inlet, all models are similar except for secondary winding of transformer, secondary components and output rating.

Models SE240AXXYF02 are identical to SE240AXXYN02, SE240AXXYQ02 and ME240B2400F02 except for class of equipment, designation, AC inlet, C53, C58, C59 and C60.

Model ME240A2400F02 is similar to Model ME240A2451F01 except for the following:

1. Adjust the output voltage from 24V to 24.8V~25V to compensate the voltage drop with loading due to cable length increasing. (R84 & D27)

Model ME240A1200Q02 is same as Model ME240A2451Q01 except for the following:

1. Change PCB hole size

Model ME240B2400F02 is identical to Model ME240A2400F01 except for the following:

1. Changes of removed component C58 and short circuit to earthing part.

Additional Information

The schematics for these models are kept in file at the CB Testing Laboratory mentioned in the first page of this test report, and can be provided by the manufacturer upon request by NCB's/CBTL's.

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 Electrical and Nameplate Labels are representative of all models in the series. The Marking Plate, Optional 240 W reference is not shown.

Amendment 1: Technical amended to add a Class I model ME240B2400F02 to the report, Addition model are identical to previous recognized model ME240A2400F01 in structure design & electrical insulations, Just minor changes to the secondary circuit and considered that was no affect previous structure. Throughout investigated to the changes that have not influence to the original test data, The previous test results are continues to comply with the standard. Only limited tests was deemed necessary.

1. Add new model ME240B2400F02 in the report, Refer to model difference information for details.
2. Alternate a Fuse 216SP in CCL, Rated is same with original.

Refer to Appendix B Table for details of tests carried out.

Technical Considerations

- The product was investigated to the following standards:

Main Standard(s):

ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012) -

Amendment 1 - Revision Date 2012/08/21; CAN/CSA-C22.2 No. 60601-1:14 - Edition 3 -
Revision Date 2014/03

From Country Differences:

- USA: AAMI/IEC 60601-1:2005 + AMD 1:2012
- Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14

Additional Standards:

EN 60601 1:2006/ A1:2013/ A12:2014;
EN 60601-1-6:2010 / A1:2015

- The following additional investigations were conducted: None
- 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 following accessories were investigated for use with the product: None
- The degree of protection against harmful ingress of water is: IPX2
- The degree of protection against harmful ingress of particular matter is: IP2X
- 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
- Manufacturer's Recommended Ambient: 40°C
- The product is Classified only to the following hazards: Shock, Fire, Heat, Mechanical, Energy
- Power Supply was considered Overvoltage Category II (OVCII)

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.

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.

Transformers (T1, T2) is provided with a Class B (130) insulation system.

Temperature of external enclosure was high, Since PSU was considered at maximum output conditions for test. Acceptable duration of operator contact with enclosure shall not exceed 1s. End product shall re-evaluate the temperature of external surface for PSU if longer touch time needed.

The compliance with cl. 7.9 shall be evaluated in end product.

Instability hazards according to cl. 9.4 need to be considered in end product.

End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.

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 Arrangement of Indicators as part of the power supply.

End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply.

This power supply has been evaluated as 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 available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions.

End product Risk Management Process to include consideration of requirements specific to the Power Supply.

Single fault testing was conducted without dielectric breakdown, however end product Risk Management Process to consider the need for simultaneous fault condition testing.

End product Risk Management Process to consider the need for different orientations of installation during testing.

Humidity testing was conducted, however the end product Risk Management Process to determine risk acceptability criteria.

Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk with respect to insulation's resistance to heat, moisture, and dielectric strength per 8.8.4.

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.

Leakage current testing (with the MD and non-frequency weighed device, cl. 8.7.3.e) should be considered in the end product application.

The expected service life of this product is 5 years.

Both Line and Neutral of the power supplies are fused.

For Class I configuration, Two MOPP is provided between primary and secondary, and between primary and plastic outer enclosure; One MOPP is provided between primary and earth. One MOPP is provided between output and earth (for all models except for ME240B2400F02). In addition, the power supply was evaluated with either the output (+) or (-) connected to ground

For Class II configuration, Two MOPP is provided between primary and secondary, and between primary and plastic outer enclosure;

Both Class I and Class II were evaluated for the leakage current test results for TYPE BP circuitry(Except for ME240B2400F02).

The end product will need to determine the appropriate air clearance required if rated operating altitude is greater than 5000 m. This air clearance for this component evaluation was based on operating altitude \leq 5000 m.

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