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-D1027-1/A0/C0-CB
Date of issue .....:	2019-09-24
Total number of pages.....:	262
CB Testing Laboratory.....:	UL Brea
Address .....:	2929 E. Imperial Hwy., Suite 100, Brea 92821, CA, United States of America
Applicant's name.....:	SL POWER ELECTRONICS CORP
Address .....:	BLDG A 6050 KING DR VENTURA CA 93003 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 .....:	CB Scheme
Non-standard test method……..:	None
Test Report Form No.....:	IEC60601_1K
Test Report Form Originator.....:	UL(US)
Master TRF.....:	2015-11

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General disclaimer:

The test results presented in this report relate only to the object tested.
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Test item description.....:	Power supply
Trade Mark.....:	
Manufacturer.....:	Same as Applicant
Model/Type reference.....:	GU300SXXKZZ Where XX represents the output voltage which may be any number from 12 to 56. ZZ can be any number between 00-99, or any letter from AA to ZZ, or blank, only for market purpose, not affect safety performance
Ratings.....:	Input: 100-240V~, 50-60Hz, 3.5A Output: Model GU300S12K: For convection: max. output power: 180W and total max. 12W for V2 and V3 V1: 12Vdc/14.0A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. For conduction: max. output power: 246W and total max. 12W for V2 and V3 V1: 12Vdc/19.5A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. For 300LFM: max. output power: 278.4W and total max. 12W for V2 and V3 V1: 12Vdc/22.2A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. Model GU300S15K: For convection: max. output power: 180W and total max. 12W for V2 and V3 V1: 15Vdc/11.2A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. For conduction: max. output power: 246W and total max. 12W for V2 and V3 V1: 15Vdc/15.6A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. For 300LFM: max. output power: 279W and total max. 12W for V2 and V3

	V1: 15Vdc/17.8A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. Model GU300S24K: For convection: max. output power: 196.8W and total max. 12W for V2 and V3 V1: 24Vdc/7.7A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. For conduction: max. output power: 266.4W and total max. 12W for V2 and V3 V1: 24Vdc/10.6A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. For 300LFM: max. output power: 297.6W and total max. 12W for V2 and V3 V1: 24Vdc/11.9A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. Model GU300S48K: For convection: max. output power: 199.2W and total max. 12W for V2 and V3 V1: 48Vdc/3.9A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. For conduction: max. output power: 266.4W and total max. 12W for V2 and V3 V1: 48Vdc/5.3A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. For 300LFM: max. output power: 295.2W and total max. 12W for V2 and V3 V1: 48Vdc/5.9A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. Model GU300S56K: For convection: max. output power: 196.8W and total max. 12W for V2 and V3 V1: 56Vdc/3.3A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. For conduction: max. output power: 264W and total max. 12W for V2 and V3 V1: 56Vdc/4.5A Max. V2: 5Vdc/2.0A Max. V3: 12Vdc/0.5A Max. For 300LFM: max. output power: 297.6W and total max. 12W for V2 and V3 V1: 56Vdc/5.1A Max. V2: 5Vdc/2.0A Max.

	V3: 12Vdc/0.5A Max.	
Testing procedure and testing location:		
[ ] **CB Testing Laboratory:**		
Testing location/ address .....:	UL Brea 2929 E. Imperial Hwy., Suite 100, Brea 92821, CA, United States of America	
[ ] **Associated CB Testing Laboratory:**		
Testing location/ address .....:		
Tested by (name, function, signature) .....:		
Approved by (name, function, signature) ....:		
[ ] **Testing procedure: CTF Stage 1:**		
Testing location/ address .....:		
Tested by (name, function, signature) .....:		
Approved by (name, function, signature) ....:		
[ ] **Testing procedure: CTF Stage 2:**		
Testing location/ address .....:		
Tested by (name, function, signature) .....:		
Witnessed by (name, function, signature) ...:		
Approved by (name, function, signature) ....:		
[X] **Testing procedure: CTF Stage 3:**		
[ ] **Testing procedure: CTF Stage 4:**		
Testing location/ address .....:	SL Shanghai Power Electronics Corp / 4th Floor, Bldg 53, 1089 Qinzhou North Road, Shanghai, 200233, China	
Tested by (name, function, signature) .....:	Richard Yue / Tester	
Witnessed by (name, function, signature) ...:	Paul Zhang / LTR (project handler)	

Approved by (name, function, signature) .... :	Jay Lu / Reviewer	
Supervised by (name, function, signature) .. :	Paul Zhang / LTR (project handler)	

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 B of this report if testing was performed as part of this evaluation.*
Summary of compliance with National Differences
List of countries addressed: USA, Canada [X] The product fulfils the requirements of IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) .

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. *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:	Built-in
Device type (component/sub-assembly/ equipment/ system):	Component, power supply
Intended use (Including type of patient, application location):	The GU300SXXKZZ are open frame AC/DC power supplies designed for built-in to an end-product used in a hospital or related health care facility environment.
Mode of Operation:	Continuous
Supply Connection:	Built-in, to be determined in end product
Accessories and detachable parts included:	None
Other Options Include:	None
Testing	
Date of receipt of test item(s) .....:	2019-05-28 to 2019-07-30
Dates tests performed .....:	2019-05-30 to 2019-09-05
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:	
"(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.	
Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012	
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 .....: Yes	
When differences exist; they shall be identified in the General product information section.	

Name and address of factory (ies)..... :	SL XIANGHE POWER ELECTRONICS CORP No.B-02-03, North side of Landscape Ave, Qibu Distr Environmental Industrial Park Xianghe, Hebei 065400 China INDUSTRIAS S L S A DE C V CIRCUITO SIGLO XXI 2055 COL PARQUE INDUSTRIAL EX-XXI 21254 MEXICALI BC Mexico

General product information:

Report Summary

The results of this investigation indicate that the products evaluated comply with the applicable requirements in the standard for Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance, ANSI/AAMI ES60601-1:2005/(R)2012 + A1:2012 + C1:2009/(R)2012 + A2:2010/(R)2012) - Revision Date 2012/08/21, and Canadian Standard for Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance, CSA CAN/CSA-C22.2 NO.60601-1:14 - Revision Date 2014/03.

For testing items and sub-clause number, ANSI/AAMI ES60601-1:2005/(R)2012 + A1:2012 + C1:2009/(R)2012 + A2:2010/(R)2012) - Revision Date 2012/08/21; CSA/CAN/CSA-C22.2 NO.60601-1:14 - Revision Date 2014/03 can be representative for CSA/CAN/CSA-C22.2 NO. 60601-1:14 since there's no difference between these 2 standards.

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

Product Description

The GU300SXXKZZ are open frame AC/DC power supplies designed for built-in to an end-product used in a hospital or related health care facility environment.

Model Differences

Power supply GU300SXXKZZ series are similar in primary circuit, except for T100. In secondary circuit, some different components are used to serve for different output. Power supply GU300SXXKZZ series contain five kinds of transformers T100 as below: 5-36582-7012 (for GU300S12K), 5-36582-7015(for GU300S15K), 5-36582-7024(for GU300S24K), 5-36582-7048(for GU300S48K) and 5-36582-7056(for GU300S56K), described in enclosed Transformer specifications. The five transformers have similar construction, refer to Enclosure - Diagrams (04) to (08) for details.

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 following test were selected as representing of the test program applicable to model covered by this CBTR: 8.4.3 – Voltage or Charge Limitation and 8.8.3 – Dielectric Withstand These tests have been witnessed for models selected as representative of the standard covered by this report and of the applicable test program.

Technical Considerations

- The product was investigated to the following standards:

  Main Standard(s):

  IEC 60601 1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012

  From Country Differences:

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

  Additional Standards:

  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;
  IEC 60601 1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012;
  EN 60601 1:2006/ A1:2013/ A12:2014;

- 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
- Scope of Power Supply evaluation defers the following clauses to the be determined as part of the end product: Clause 4.2 (Risk Management), Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems)

  The degree of protection against harmful ingress of water is:: IPX0

  The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:: No

  Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No

  The product is evaluated only to the following hazards: Casualty, Fire, Shock

  Manufacturer’s Recommended Ambient: 50°C

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 relevant testing for label (Clause 7.1.2 Clause 7.1.3) shall be considered in the end application.
- Transformers and choke are provided with a Class F (155°C) insulation system: T100, T200, L100 and L104.
- The end product should ensure that the requirements related to accompanying documents, clause 7.9, are met.
- 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 were evaluated for Type BF leakage current per client's request, the test results were for reference only. The need for earth and enclosure leakage current tests shall be considered in the end product application.
- The available voltage for the main outputs (V1) does not exceed 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.
- The testing for PE impedance and current carrying capability (Clause 8.6.4) shall be tested in the end application. Proper bonding to the end-product main protective earthing termination is required.
- 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.
- 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.
- Two MOPPs are provided between primary and secondary; For T100, two MOPPs are provided between primary and core / primary and secondary, operational insulation provided between secondary and core; For T200, two MOPPs are provided between secondary and core / primary and secondary, operational insulation provided between primary and core; One MOPP is provided between primary and earth, one MOPP is provided between secondary and earth.
- 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 product.
- End product Dielectric Voltage Withstand Test shall be based on the following working voltages of the power supply: 1 MOPP = 354Vpk, 240Vrms and 2 MOPP = 644Vpk, 364Vrms.
- The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- Under conduction mode, the metal plate (dimension 215mm x 165mm x 2mm thick) was fixed on chassis through four screws.
- Units were tested with 300LFM forced air fan. Additional considerations shall be taken into consideration when installed in an end product with different airflow conditions.
- End product Risk Management Process to consider the need for different orientations of installation during testing.
- Power Supply tested in a max. ambient of 50°C. End product Risk Management Process to determine risk acceptability criteria.
- 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 movement of components as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- 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.
- This product was evaluated based on operating altitude up to 5000 m.

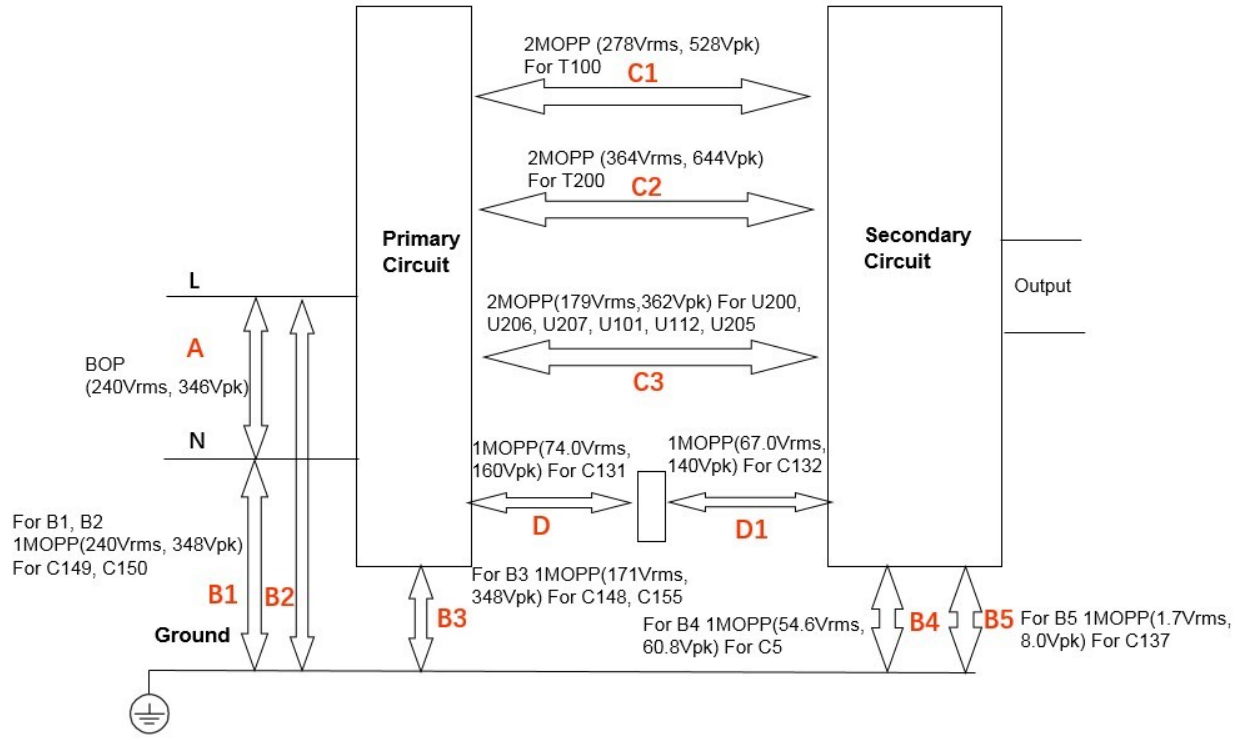
Report Modifications

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2019-09-24	E116994-D1027-1/A0/C0: Original report	Paul Zhang

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

Insulation Diagram - (001) Insulation diagram

Insulation Diagram - (001) Insulation diagram



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

TABLE: INSULATION DIAGRAM									Pass
Pollution Degree:			**2**						-
Overvoltage category:			**II**						-
Altitude:			**5000 (m)**						-
Additional details on parts considered as applied parts:			**[X] None [ ] Areas: SE Cable and back side of SE unit (aluminum surface)** **(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	1 MOOP	IIIb	240	346	3	3	5.3	5.3	L-N
B1	1 MOPP	IIIb	1.8	5.5	4	3.3	5	5	C149, L to chassis
B2	1 MOPP	IIIb	240	348	4	3.3	4.9	4.9	C150, N to chassis
B3	1 MOPP	IIIb	171	348	4	3.3	4.3	4.3	C148, C155
B4	1 MOPP	IIIb	54.6	60.8	4	3.3	4.3	4.3	C5, secondary to chassis
B5	1 MOPP	IIIb	1.7	8	4	3.3	5.7	5.7	C137
C1	2 MOPP	IIIb	278	528	9.1	9.1	9.9	9.9	T100
C2	2 MOPP	IIIb	364	644	11.1	9.1	11.6	10.3	T200
C3	2 MOPP	IIIb	179	362	8	6.5	8.6	8.6	U200, U206, U207, U101, U112, U205
D	1 MOPP	IIIb	74	160	4	3.3	5.4	5.4	C131
D1	1 MOPP	IIIb	67	140	4	3.3	5.6	5.6	C132

Supplementary Information: Vpk values were mathematically calculated based on IEC 60601-1, 2nd ed Vrms values recorded.
Refer to Appendix A for the Insulation Diagram.
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.