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.....:	E302267-D1001-1-UL
Date of issue.....:	2015-04-28
Total number of pages.....:	166
CB Testing Laboratory.....:	
Address.....:	
Applicant's name .....:	BRIDGEPOWER CORP
Address.....:	(GOSAEK-DONG) 16 OMOKCHEN-RO 132BEON-GIL GWONSEON-GU SUWON-SI GYEONGGI 441-813 KOREA
Test specification:	
Standard .....:	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure.....:	UL Certification
Non-standard test method……..:	N/A
Test Report Form No.....:	IEC60601_1J
Test Report Form Originator.....:	UL(US)
Master TRF.....:	2014-07

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:	AC/DC Adaptor
Trade Mark:	None
Manufacturer:	Same as Applicant
Model/Type reference:	B(1)050(2)(3)(4), B(1)060(2)(3)(4), (1)E50(2)(3)(4)(5)(6) and (1)E60(2)(3)(4)(5)(6) (Where (1), (2), (4), (5), (6) may alphanumeric, "For marketing purpose and no impact safety related critical components and constructions", where (3) may any number 05 through 48)
Ratings:	Rated Input: 100-240 Vac, 50-60Hz, 1.5A (1.5A - 0.7A) Rated Output: 5Vdc,6.0A/7.0A or 9Vdc,5.0A/6.0A or 12Vdc,4.2A/5.0A or 15Vdc,3.36A/4.0A or 18Vdc,2.8A/3.4A or 24Vdc,2.1A/2.7A or 48Vdc,1.1A/1.3A or 5Vdc/7A - 48Vdc/1.3A

Testing procedure and testing location:		
[ ] CB Testing Laboratory:		
Testing location/ address:		
[ ] Associated CB Testing Laboratory:		
Testing location/ address:		
Tested by (name + signature):		
Approved by (name + signature):		
[ ] Testing procedure: TMP/CTF Stage 1:		
Testing location/ address:		
Tested by (name + signature):		
Approved by (name + signature):		
[ ] Testing procedure: WMT/CTF Stage 2:		
Testing location/ address:		
Tested by (name + signature):		
Witnessed by (name + signature):		
Approved by (name + signature):		
[ ] 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): 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.*
Summary of compliance with National Differences List of countries addressed: USA, Canada

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 Plate in the Enclosures section in Appendix A of this report for a copy.

GENERAL INFORMATION	
Test item particulars:	
Classification of Installation and Use:	Portable
Device Type:	Component
Intended Use Statement:	To supply regulated power
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) .....:	2015-02-15
Dates tests performed .....:	2015-02-21 to 2015-03-05, 2015-04-08
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. The Critical Component Table is located at the end of the Test Tables.	
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) .....:	Same as Applicant WENDENG JEIL ELECTRONICS CO LTD XIAMEN ROAD NO.2 WENDENG ECONOMIC DEVELOPMENT ZONE WEIHAI CITY SHANDONG PROVINCE CHINA

GENERAL PRODUCT INFORMATION:

Report Summary

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

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

Product Description

Products are component power supplies intended to be used as part of Medical Electrical Equipment. This AC-DC Adaptor provides 2MOPP isolation from Primary to Secondary/Enclosure(for Class I and Class II construction) and/or 1MOPP isolation from Primary to Earth (for Class I construction). It contains the mains transformer with UL Recognized Insulation System.

This product is the AC-DC Adaptor of the switching type power supply, which electronic components are mounted on PWB and housed in plastic enclosure and provided with appliance inlet.

Model Differences

B(1)050(2)(3)(4) is basic model.

B(1)060(2)(3)(4) is identical to B(1)050(2)(3)(4), except output power rating. (1)E50(2)(3)(4)(5)(6) is identical to B(1)050(2)(3)(4), except model designation. (1)E60(2)(3)(4)(5)(6) is identical to B(1)060(2)(3)(4), except model designation.

The below information is nomenclature detail for B(1)050(2)(3)(4) and B(1)060(2)(3)(4) :

(1) Family Related Designs: X is A-Z

(2) Output : X is S (S=Single)

(3) Output Voltage : 05, 09, 12, 15, 18, 24, 48 or may any number 05 through 48

(4) Standard Input Cord Options F : (Class I = IEC320-C14) Q : (Class II = IEC320-C18) N : (Class II = IEC320-C8),

The below information is nomenclature detail for (1)E50(2)(3)(4)(5)(6) and (1)E60(2)(3)(4)(5)(6)

(1) Family Related Designs: X is A-Z

(2) AC Ground Configuration : A to Z (Standard)

(3) Output Voltage : 05, 09, 12, 15, 18, 24, 48 or may any number 05 through 48

(4) Standards Output Cord Options Number : 00 thru 99

(5) Standard Input Connector Options F : (Class I = IEC320-C14) Q : (Class II = IEC320-C18) N : (Class II = IEC320-C8)

(6) Model Configuration Number : 00 thru 99

Additional Information

The manufacturer submitted representative production samples for testing which are output voltages 5, 9, 12, 15, 18, 24, 48V. If using out of these voltage could be need to construction review and additional testing.

Harmful Ingress of Liquids Test (11.6.5) IP22 :

Testing sample, BM050S48F was specified by manufacturer (F type is Class I type). This model have two alternate model which model types are Q and N - Class II type.

IP22 test was conducted using 1 sample which is F-type of appliance inlet. Refer to IP test reports attached to the enclosure.

Technical Considerations

- The product was investigated to the following additional standards:

  ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14

  Additional: IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC

60601-1: 2012, EN 60601-1:2006/A11:2011/A1:2013 /A12:2014

- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: 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 following accessories were investigated for use with the product: None
- The product is Classified only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: IP22.
- 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
- The product has been considered for Pollution Degree 2 and Overvoltage Category II.

Engineering Conditions of Acceptability

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

For use only in or with complete equipment where the acceptability of the combination is determined by the CB Testing Laboratory, when installed in an end-product, consideration must be given to the following:

For Power Supplies with No RM: End product Risk Management Process to include consideration of requirements specific to the Power Supply.

For Power Supplies with No RM: End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1).

For Power Supplies with No RM: End product Risk Management Process to consider the need for simultaneous fault condition testing.

For Power Supplies with No RM: End product Risk Management Process to consider the need for different orientations of installation during testing.

For Power Supplies with No RM with Exposure Condition outside of Humidity Range: Power Supply tested in 40°C, 95 %RH. End product Risk Management Process to determine risk acceptability criteria.

For Power Supplies with No RM and Insulating Materials: End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.

For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.

For Power Supplies with No RM: 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.

For Power Supplies with No RM and not tested with Test Corner: Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.

For Power Supplies with No RM or Units without Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.

For Power Supplies with No RM or Units with Liquids: End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.

For Power Supplies with No RM or Units with Enclosures: End product to determine the acceptability of risk

in conjunction to the results of Mechanical Testing conducted as part of the power supply

For Power Supplies with No RM: 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

For Power Supplies with Thermal Cut-off and No RM: End product to determine the acceptability of risk in conjunction to the use of Thermal Cut-off and Overcurrent releases as part of the power supply

Considerations to the applied parts requirement, to be conducted as end-product

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).

Power supply provides the following MOPP (means of patient protection): 2 MOPP based upon a rated voltage 241 Vrms and a working voltage 580Vpk between Primary and Secondary/Enclosure (For Class I) and 1 MOPP based on a rated voltage 240 Vrms between Primary and Earth (For Class I and Class II).

Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Marking Legibility tests should be considered as part of the end product evaluation.

Magnetic devices (T1) employ a Class B (130°C) insulation system.

The PWB is rated 105°C minimum.

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 end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.

Power Supply tested for 168 hours Humidity Preconditioning. End product Risk Management Process to determine risk acceptability criteria.