Description

UL TEST REPORT AND PROCEDURE

Standard: Certification Type:	ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601- 1:14, Component Recognition			
Product:	AC/DC Adaptor			
Model:	B(1)010(2)(3)(4), B(1)020(2)(3)(4), (1)E10(2)(3)(4)(5)(6) and (1)E20(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)			
Rating:	Rated Input: 100-240 Vac, 50-60Hz, 0.4A (0.4A - 0.2A) Rated Output: 5Vdc,2.0A/3.0A or 5.9Vdc,1.67A/2.5A or 7.5Vdc,1.33A or 2.0A or 9Vdc,1.33A/2.0A or 12Vdc,1.0A/1.5A or 15Vdc,0.8A/1.2A or 18Vdc,0.67A/1.0A or 24Vdc,0.5A/0.83A or 48Vdc,0.25A/0.42A or 5Vdc/3 - 48Vdc/0.42A			
Applicant Name and Address:	BRIDGEPOWER CORP (GOSAEK-DONG) 16 OMOKCHEN-RO 132BEON-GIL GWONSEON-GU SUWON-SI GYEONGGI 441-813 , KOREA			

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: SungJoo Lee

Reviewed by:

d by: DongGug Cho

Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

A. Authorization - The Authorization page may include additional Factory Identification Code markings.

B. Generic Inspection Instructions -

- i. **Part AC** details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.
- ii. **Part AE** details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.
- iii. **Part AF** details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

Product Description

Products are component power supplies intended to be used as part of Medical Electrical Equipment. This AC Input Power Supply provides 2MOPP isolation from Primary to Secondary/Enclosure (for 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. Refer to the Report Modifications page for any modifications made to this report.

Model Differences

B(1)010(2)(3)(4) is basic model. B(1)020(2)(3)(4) is identical to B(1)010(2)(3)(4), except output power rating. (1)E10(2)(3)(4)(5)(6) is identical to B(1)010(2)(3)(4), except model designation. (1)E20(2)(3)(4)(5)(6) is identical to B(1)020(2)(3)(4), except model designation.

The below information is nomenclature detail for B(1)010(2)(3)(4) and B(1)020(2)(3)(4) :

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

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

(3) Output Voltage : 05, 06, 07, 09, 12, 15, 18, 24, 48 or may any number 05 through 48

(4) Standard Input Cord Options

Can be F or Q or N or B or H or G or M or C for input plug type. Photographs for each plug-type configuration

F : (Class I = IEC320-C14)

Q : (Class II = IEC320-C18)

N : (Class II = IEC320-C8)

B: Class II North America, UK, Korea, Australia, European, China, Japan Changeable Direct-plug-in type C: Class II - direct-plug-in for North America, China, Japan

H- Class II direct-plug-in for Australia(AS/NZS 3112) & Argentina

G- Class II direct-plug-in for British(BS 1363) & Singapore

M- Class II direct-plug-in for European(CEE /16)] & Korea

The below information is nomenclature detail for (1)E10(2)(3)(4)(5)(6) and (1)E20(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, 06, 07, 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 Cord Options

Can be F or Q or N or B or H or G or M or C for input plug type. Photographs for each plug-type configuration

F: (Class I = IEC320-C14)

Q : (Class II = IEC320-C18)

N : (Class II = IEC320-C8)

B: Class II North America, UK, Korea, Australia, European, China, Japan Changeable Direct-plug-in type

- C: Class II direct-plug-in for North America, China, Japan
- H- Class II direct-plug-in for Australia(AS/NZS 3112) & Argentina
- G- Class II direct-plug-in for British(BS 1363) & Singapore

M- Class II direct-plug-in for European(CEE /16)] & Korea

(6) Model Configuration Number : 00 thru 99

Additional Information

The manufacturer submitted representative production samples for testing which are output voltages 5, 6, 7, 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 :

The manufacturer submitted BM020S48F, BM020S48B, BM020S48G, BM020S48M which are F, B, G and M type. IP22 test was conducted using those 4 samples.

Refer to IP test reports attached to the enclosure.

Technical Considerations

- The product was investigated to the following additional standards: 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

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. 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 246 Vrms and a working voltage 510Vpk 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.

Markings and instructions			
Clause Title	Marking or Instruction Details		
Company identification	Classified or Recognized company's name, Trade name, Trademark or File		
Model	Model number		
Serial number or lot or batch identifier	Serial number or lot or batch identifier		
Date of manufacture or use by date	Date of manufacture or use by date		
Supply Connection	Voltage range, ac/dc, phases if more than single phase		
Alternating current	\sim		
Direct current			
Supply Frequency	Rated frequency range in hertz		
Class II equipment			
Power Input	Amps, VA, or Watts		
Output	Rated output voltage, power, frequency.		
IP Rating	IP22		
Protective earth ground			

Special Instructions to UL Representative

Special marking provided on the enclosure with removable label "S-B(1)010(2)(3)(4)", "S-B(1)020(2)(3)(4)", "S-(1)E10(2)(3)(4)(5)(6)" and "S-(1)E20(2)(3)(4)(5)(6)" indicates that the assembly was manufactured by WENDENG JEIL ELECTRONICS CO LTD in accordance with the Report Reference No. E302267-D1005-1-UL, Volume D2

These special marking is applied to some of product manufactured by WENDENG JEIL ELECTRONICS CO LTD

In the case of applying special marking,

Korea Field Lab:

- Verify that the product applied special marking was sent from WENDENG JEIL ELECTRONICS CO LTD. - Inspect the product to comply with marking requirement.

China Field Lab:

- Inspection will be conducted in E302267-D1005-1-UL, Volume D2

Production-Line Testing Requirements						
Test Exemptions - The following models are exempt from the indicated test						
Test	Exemption Specifics	Details				

Grounding Continuity		Q, N, B, C, H, G and M type are Exempted			None	
Dielectric Voltage Withstand		All models are Not Exempted			None	
Patient Circuit Dielectric Voltage Withstand		All models are Exempted			None	
Solid-State Components		N/A			N/A	
Sample and Test Sp	ecifics for	Follow-Up	Tests at UL			
The following tests sh	all be cond	ducted in ac	cordance with the Ger	neric In	spection Instructions	
Plastic Enclosure or Part	Test		Sample(s)		Test Specifics	
None	N/A		N/A	N/A	N/A	