Description

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1:2005, CSA CAN/CSA-C22.2 NO. 60601-1:08
Certification Type:	Component Recognition
CCN:	QQHM2 / QQHM8
Product:	AC/DC Adaptor
Model:	B(1)040(2)(3)(4), B(1)030(2)(3)(4), (1)E40(2)(3)(4)(5)(6) and (1)E30(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: 100-240Vac, 50-60Hz, 1.2A (1.2A - 0.5A) Rated Output: B(1)040(2)(3)(4) and (1)E40(2)(3)(4)(5)(6) : 5Vdc,5.0A or 9Vdc,4.0A or 12Vdc,3.4A or 15Vdc,2.7A or 18Vdc,2.22A or 24Vdc,1.7A or 48Vdc,0.83A or 5Vdc/5.0A - 48Vdc/0.83A B(1)030(2)(3)(4) and (1)E30(2)(3)(4)(5)(6) : 5Vdc,4.0A or 9Vdc,3.0A or 12Vdc,2.5A or 15Vdc,2.0A or 18Vdc,1.67A or 24Vdc,1.33A or 48Vdc,0.63A or 5Vdc/4.0A - 48Vdc/0.63A
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.

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability as applicable.

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

Model Differences

B(1)040(2)(3)(4) is basic model.
B(1)030(2)(3)(4) is identical to B(1)040(2)(3)(4), except output power rating.
(1)E40(2)(3)(4)(5)(6) is identical to B(1)040(2)(3)(4), except model designation.
(1)E30(2)(3)(4)(5)(6) is identical to B(1)030(2)(3)(4), except model designation.

The below information is nomenclature detail for B(1)040(2)(3)(4) and B(1)030(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
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)E40(2)(3)(4)(5)(6) and (1)E30(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 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

* Accessible Parts : AC/DC Adaptor enclosure
* Applied parts: There are no physical contact parts incorporating the electrical circuitry.
* Possible contacting duration (Accessible Parts)
- AC/DC Adaptor (Contact Duration: Less than 10 sec)
* Working Conditions:
- Continuously operated with normal operation mode.
- Altitude: 4000 meters
- Operation Environmental condition: 0-40 deg, 0-95 %
- Storage Environmental condition: -30 to 85 deg, 5-95 %
- Material Group: IIIb
- Pollution Degree: 2
- Overvoltage category: II
- The least favourable working conditions are: maximum normal load and placed in ambient temperature/humidity: 40 °C, 95% RH.

* The following documents are provided by manufacturer as risk management files (Not attached in Report) and considered during test.
- Risk Management Report (Document No.BPM-QA-BX040 rev.0)

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 :
The manufacturer submitted BM040S48F, BM040S48B, BM040S48G, BM040S48M 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), EN 60601-1:2006/A11:2011/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, Biocompatibility (ISO 10993-1), Sub-clause 7.1.1, Sub-clause 11.7, Sub-clause 12.2, Sub-clause 15.1, Clause 17
- The following accessories were investigated for use with the product: None
- No Other Considerations.

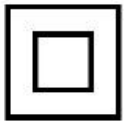
Engineering Conditions of Acceptability

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:
- 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 254Vrms and a working voltage 620Vpk between Primary and Secondary/Enclosure (For Class I and Class II) and 1 MOPP based on a rated voltage 240 Vrms between Primary and Earth (For Class I).
- Temperature, Leakage Current, Protective Earthing and Dielectric Voltage Withstand 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 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.
- This power adapter no any functions are defined as ESSENTIAL PERFORMANCE.
- The equipment has not been evaluated for use in or likely to be used in the patient vicinity.
- End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- The products have Lower breaking capacity type fuse and if the fuse fails under SFC testing violently, it would be considered unacceptable at the voltage rating.

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
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Alternating current	
Direct current	
Supply Frequency	Rated frequency range in hertz
Class II equipment	 Except F-type
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.
IP Rating	IP22
Protective earth ground	 F-type only

Special Instructions to UL Representative

Special marking provided on the enclosure with removable label “S-B(1)040(2)(3)(4)”, “S-B(1)030(2)(3)(4)”, “S-(1)E40(2)(3)(4)(5)(6)” and “S-(1)E30(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-D1012-1-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-D1012-1-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	None

	Exempted	
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 Specifics for Follow-Up Tests at UL

The following tests shall be conducted in accordance with the Generic Inspection Instructions

Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
None	NA	NA	NA