



Ref. Certif. No.

DK-3636

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE

CERTIFICAT D'ESSAI OC

Product  
Produit

AC-DC Adaptor

Name and address of the applicant  
Nom et adresse du demandeur

BRIDGEPOWER CORP  
964 GOSAEK-DONG GWONSEON-GU  
SUWON-SI GYEONGGI-DO 441-813 KOREA

Name and address of the manufacturer  
Nom et adresse du fabricant

BRIDGEPOWER CORP  
964 GOSAEK-DONG GWONSEON-GU  
SUWON-SI GYEONGGI-DO 441-813 KOREA

Name and address of the factory  
Nom et adresse de l'usine

See Page 2

Note: When more than one factory, please report on page 2  
Note: Lorsque il y plus d'une usine, veuillez utiliser la 2<sup>ème</sup> page

Ratings and principal characteristics  
Valeurs nominales et caractéristiques principales

Rated Input: 100-240 Vac, 50-60Hz, 1.5A.  
Rated Output: +12V/6.5A, +15V/5.2A, +18V/4.33A or  
+24V/3.25A.  
None

Trademark (if any)  
Marque de fabrique (si elle existe)

Type of Manufacturer's Testing Laboratories used  
Type de programme du laboratoire d'essais constructeur  
Model / Type Ref.  
Ref. De type

(1)ENB1080(3)(4)(5)F(6), J(1)W180(2)(3)(4)(5)F(6), See Page 2

Additional information (if necessary may also be reported on page 2)  
Les informations complémentaires (si nécessaire,, peuvent être indiqués sur la 2<sup>ème</sup> page

Also investigated to EN 60601-1:2006.

A sample of the product was tested and found to be in conformity with  
Un échantillon de ce produit a été essayé et a été considéré conforme à la

IEC 60601-1(ed.3), IEC 60601-1(ed.3);Corr.:1, IEC 60601-1(ed.3);Corr.:2

As shown in the Test Report Ref. No. which forms part of this Certificate  
Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat

E302267-20110630 issued on 2011-06-30

This CB Test Certificate is issued by the National Certification Body  
Ce Certificat d'essai OC est établi par l'Organisme National de Certification



UL International Demko A/S, Lyskaer 8, P.O. Box 514, DK-2730 Herlev, Denmark, Tel. +45 44 85 65 65, info.dk@dk.ul.com  
www.ul-europe.com

Signature:

Jan-Erik Storgaard

Date: 2011-07-07

## Model Details:

(1)ENB1080(3)(4)(5)F(6), J(1)W180(2)(3)(4)(5)F(6);

(1) can be C, M or P for family related designs.

(2) can be A to Z for customer option.

(3) may be A to Z according to design revision.

(4) may be 12, 15, 18 or 24 according to output voltage.

(5) may be 00 to 99 according to the shape of output connector.

(6) may be 00 to 99 or AA to ZZ according to customer's option.

## Factories:

BRIDGEPOWER CORP

964 GOSAEK-DONG GWONSEON-GU

SUWON-SI GYEONGGI-DO 441-813 KOREA

WENDENG JEIL ELECTRONICS CO LTD

DONG SHOU GUANGZHOU LU KAIFA-QU

WENDENG-SHI SHANDONG CHINA

## Additional information (if necessary)

## Information complémentaire (si nécessaire)



Date: 2011-07-07

UL International Demko A/S, Lyskaer 8, P.O. Box 514, DK-2730  
Herlev, Denmark, Tel. +45 44 85 65 65, info.dk@dk.ul.com  
www.ul-europe.com

Signature:

A handwritten signature in blue ink, appearing to read 'Jan Erik Storgaard', written over a light blue horizontal line.

Jan-Erik Storgaard



Test Report issued under the responsibility of:



**Underwriters  
Laboratories**

**IEC 60601-1  
Medical electrical equipment**

**Part 1: General requirements for basic safety and essential performance**

**Report Reference No**.....: E302267-20110630

**Date of issue** .....: 2011-06-30

**Total number of pages**.....: 215

**CB Testing Laboratory**.....: UL Korea, Ltd.

**Address** .....: #805, Manhatan Building, 36-2 Yeouido-Dong,  
Yeongdeungpo-Gu, Seoul 150-749, Korea

**Applicant's name**.....: BRIDGEPOWER CORP

**Address** .....: 964 GOSAEK-DONG GWONSEON-GU  
SUWON-SI GYEONGGI-DO 441-813 KOREA

**Test specification:**

**Standard** .....: **IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)**

**Test procedure**.....: **CB Scheme**

**Non-standard test method**.....: N/A

**Test Report Form No**.....: **IEC60601\_1G**

**Test Report Form Originator** .....: **Underwriters Laboratories Inc.**

**Master TRF** .....: **Dated 2010-11**

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If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo shall be removed

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.

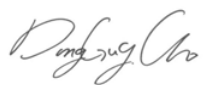
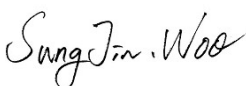
**Test item description** ..... : AC-DC Adaptor

**Trade Mark** ..... : None

**Manufacturer**.....: BRIDGEPOWER CORP

964 GOSAEK-DONG GWONSEON-GU  
SUWON-SI GYEONGGI-DO 441-813 KOREA

<b>Model/Type reference</b> ..... :	J(1)W180(2)(3)(4)(5)F(6) and (1)ENB1080(3)(4)(5)F(6) (1) can be C, M or P for family related designs. (2) can be A to Z for customer option. (3) may be A to Z according to design revision. (4) may be 12, 15, 18 or 24 according to output voltage. (5) may be 00 to 99 according to the shape of output connector. (6) may be 00 to 99 or AA to ZZ according to customer's option.
<b>Ratings</b> ..... :	Rated Input: 100-240 Vac, 50-60Hz, 1.5A. Rated Output: +12V/6.5A, +15V/5.2A, +18V/4.33A or +24V/3.25A.

<b>Testing procedure and testing location:</b>	
<input checked="" type="checkbox"/> <b>CB Testing Laboratory:</b>	
Testing location/ address .....	UL Korea, Ltd / #805, Manhattan Building, 36-2 Yeouido-Dong, Yeongdeungpo-Gu, Seoul 150-749, Korea
<input type="checkbox"/> <b>Associated CB Test Laboratory:</b>	
Testing location/ address .....	
Tested by (name + signature) ..:	
	DongGug Cho 
Approved by (+ signature).....:	SungJin Woo 
<input type="checkbox"/> <b>Testing procedure: TMP</b>	
Tested by (name + signature) ..:	
Approved by (+ signature).....:	
Testing location/ address .....	
<input type="checkbox"/> <b>Testing procedure: WMT</b>	
Tested by (name + signature) ..:	
Witnessed by (+ signature) .....	
Approved by (+ signature).....:	
Testing location/ address .....	
<input type="checkbox"/> <b>Testing procedure: SMT</b>	
Tested by (name + signature) ..:	
Approved by (+ signature).....:	
Supervised by (+ signature).....:	
Testing location/ address .....	
<input type="checkbox"/> <b>Testing procedure: RMT</b>	
Tested by (name + signature) ..:	
Approved by (+ signature).....:	
Supervised by (+ signature).....:	
Testing location/ address .....	

**List of Attachments (including a total number of pages in each attachment):**

- Photographs (4 pages)
- Schematics + PWB (9 pages)
- Miscellaneous (8 pages)
- Marking Plate (8 pages)

**Summary of testing****Tests performed (name of test and test clause):****Testing location:**

Testing of this AC-DC Adaptor was not considered necessary based on the results of previous investigations to IEC 60601-1 Second Edition and IEC 60950-1 Second Edition.

N/A

**Summary of compliance with National Differences**

List of countries addressed: See Technical Consideration for details.

The product fulfils the requirements of IEC 60601-1 Third Edition.

**Copy of marking plate -**

Refer to Attachment titled Marking Plate for copy

<b>GENERAL INFORMATION</b>	
<b>Test item particulars (see also Clause 6):</b>	
<b>Classification of installation and use</b> .....	Hand-held or Portable
<b>Device type (component/sub-assembly/ equipment/ system)</b> .....	Component power supply
<b>Intended use (Including type of patient, application location)</b> .....	To supply regulated power.
<b>Mode of operation</b> .....	Continuous
<b>Supply connection</b> .....	Appliance inlet or Direct Plug-in type
<b>Accessories and detachable parts included</b> .....	None
<b>Other options include</b> .....	None
<b>Testing</b>	
<b>Date of receipt of test item(s)</b> .....	N/A
<b>Dates tests performed</b> .....	N/A
<b>Possible test case verdicts:</b>	
- 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)
<b>Abbreviations used in the report:</b>	
- normal condition .....	<b>N.C.</b>
- single fault condition.....	S.F.C.
- means of Operator protection .....	<b>MOOP</b>
- means of Patient protection .....	MOPP
<b>General remarks:</b>	
"(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 <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	
<b>Manufacturer's Declaration per sub-clause 6.2.5 of IEC60601-1:</b>	
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..... :	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Not applicable

**When differences exist; they shall be identified in the General product information section.**

**Name and address of factory (ies)..... :**

BRIDGEPOWER CORP  
964 GOSAEK-DONG GWONSEON-GU  
SUWON-SI GYEONGGI-DO 441-813 KOREA  
WENDENG JEIL ELECTRONICS CO LTD  
DONG SHOU GUANGZHOU LU KAIFA-QU  
WENDENG-SHI SHANDONG CHINA



**General product information:**

Products are component power supplies intended to be used as part of Medical Electrical Equipment. This AC Input Power Supply provides 2MOOP isolation from Primary to Secondary/Enclosure(for Class II construction) and/or 1MOOP 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**

Model (1)ENB1080(3)(4)(5)F(6) is identical to model J(1)W180(2)(3)(4)(5)F(6), except for model designation.

The model for 15 Vdc output is identical to the model of 12Vdc output, except for a few minor resistors in SELV part and the rated output voltage and current, but same in output watt.

The model for 24 Vdc output is identical to the model of 18Vdc output, except for a few minor resistors in SELV part and the rated output voltage and current, but same in output watt.

The below information is nomenclature detail for J(1)W180(2)(3)(4)(5)F(6) and (1)ENB1080(3)(4)(5)F(6):

- (1) can be C, M or P for family related designs.
- (2) can be A to Z for customer option.
- (3) may be A to Z according to design revision.
- (4) may be 12, 15, 18 or 24 according to output voltage.
- (5) may be 00 to 99 according to the shape of output connector.
- (6) may be 00 to 99 or AA to ZZ according to customer's option.

**Technical Considerations**

- The product was investigated to the following additional standards: ANSI/AAMI ES60601-1:2005/C1:2009 (includes National Differences for USA); CAN/CSA-C22.2 No. 60601-1:08 (includes National Differences for Canada), EN 60601-1:2006
- Scope of Power Supply evaluation defers the following clauses to the be determined as part of the end product: Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (Mechanical Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems)
- Scope of Power Supply evaluation excludes the following:
  - 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
- These power supplies have been previously evaluated by UL to IEC 60601-1:1988+ A1:1991+ A2:1995 (2nd ed.), UL 60601-1: 1st ed., 2006-04-26 (includes National Differences for USA), CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada), and EN

60601-1:1990+A1:1993+A2:1995 under CB Test Report No. E302267-A16 and Certificate No. DK-14754, and also by UL to IEC 60950-1:2005 under CB Test Report No. E300305-A31 and Certificate No. DK-21192. All tests conducted per 2nd ed. of IEC 60601-1 and IEC 60950-1 were considered representative of the corresponding tests required by 3rd ed. of IEC 60601-1 as stated under Summary of Testing above.

- The product is Classified only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: Ordinary
- 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.

#### **Risk Controls/Engineering Conditions of Acceptability**

For use only in or with complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc. When installed in an end-product, consideration must be given to the following:

- 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).
- The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.
- Power supply provides the following MOOP (means of operator protection): 2 MOOP based upon a rated voltage 240 Vrms and a working voltage 510 Vpk between Primary and Secondary/Enclosure and 1 MOOP based on a rated voltage 240 Vrms between Primary and Earth.
- Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Marking Legibility tests should be considered as part of the end product evaluation.
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 40 °C at Full Load.
- Magnetic devices (T1) employ a Class B (130°C) insulation system.
- The PWB is rated 105°C minimum.
- The products were tested on a 15 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.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- End product Risk Management Process to consider the need for different orientations of installation during testing.
- Power Supply tested for 48 hours Humidity Preconditioning. 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.
- Temperature Test was conducted without Test Corner due to no heating elements incorporated in this