

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^{ème} page

Ratings and principal characteristics
Valeurs nominales et caractéristiques principales

Rated Input: 100-240 Vac, 50-60Hz, 2.0 A.
Rated Output: +12V/7.5A, +13V/6.92A, +15V/6.4A, +16V/6.0A,
+18V/5.6A, +19V/5.2A or +24V/4.2A.
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

J(1)W1100(2)(3)(4)(5)F(6), (1)ENB1100(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^{ème} 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)

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

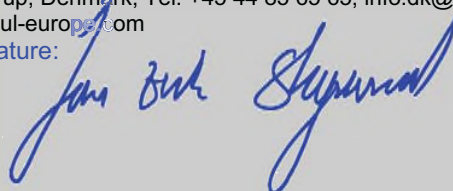
E302267-20110919 issued on 2011-09-19

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, Borupvang 5A, DK-2750
Ballerup, Denmark, Tel. +45 44 85 65 65, info.dk@dk.ul.com
www.ul-europe.com

Signature:



Date: 2011-09-19

Jan-Erik Storgaard

Model Details:

J(1)W1100(2)(3)(4)(5)F(6), (1)ENB1100(3)(4)(5)F(6);

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

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

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

(4) may be 12, 13, 15, 16, 18, 19 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. Not related safety concerns

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: 2011-09-19

UL International Demko A/S, Borupvang 5A, DK-2750
Ballerup, Denmark, Tel. +45 44 85 65 65, info.dk@dk.ul.com
www.ul-europe.com

Signature:



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.....: E302267-20110919

Date of issue: 2011-09-19

Total number of pages.....: 271

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

Address: #805, Manhattan 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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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


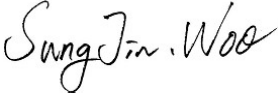
Trade Mark : None

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

Model/Type reference..... : J(1)W1100(2)(3)(4)(5)F(6) and (1)ENB1100(3)(4)(5)F(6)
(1) can be C, M or P for family related designs.

- (2) may be A to Z for customer option.
- (3) may be A to Z according to design revision.
- (4) may be 12, 13, 15, 16, 18, 19 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. Not related safety concerns

Ratings..... : Rated Input: 100-240 Vac, 50-60Hz, 2.0 A.
Rated Output: +12V/7.5A, +13V/6.92A, +15V/6.4A, +16V/6.0A,
+18V/5.6A, +19V/5.2A or +24V/4.2A.

Testing procedure and testing location:	
<input checked="" type="checkbox"/> CB Testing Laboratory: Testing location/ address..... : UL Korea, Ltd / #805, Manhattan Building, 36-2 Yeouido-Dong, Yeongdeungpo-Gu, Seoul 150-749, Korea <input type="checkbox"/> Associated CB Test Laboratory: Testing location/ address..... : Tested by (name + signature) .. : DongGug Cho Approved by (+ signature) : SungJin Woo	 <hr style="width: 50%; margin: 0 auto;"/> 
<input type="checkbox"/> Testing procedure: TMP Tested by (name + signature) .. : Approved by (+ signature) : Testing location/ address..... :	
<input type="checkbox"/> Testing procedure: WMT Tested by (name + signature) .. : Witnessed by (+ signature) : Approved by (+ signature) : Testing location/ address..... :	
<input type="checkbox"/> Testing procedure: SMT Tested by (name + signature) .. : Approved by (+ signature) : Supervised by (+ signature)..... : Testing location/ address..... :	
<input type="checkbox"/> Testing procedure: RMT 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 (8 pages)
- Diagrams (11 Pages)
- Schematics + PWB (8 pages)
- Miscellaneous (47 pages)
- Marking Plate (6 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

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use	Hand-held or Portable
Device type (component/sub-assembly/ equipment/ system)	Component power supply
Intended use (Including type of patient, application location)	To supply regulated power.
Mode of operation	Continuous
Supply connection	Appliance inlet
Accessories and detachable parts included	None
Other options include	None
Testing	
Date of receipt of test item(s)	N/A
Dates tests performed	N/A
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.
- means of Operator protection	MOOP
- single fault condition.....	S.F.C.
- 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 <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	

Manufacturer's Declaration per sub-clause 6.2.5 of IEC60060-1:

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 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)ENB1100(3)(4)(5)F(6) is identical to model J(1)W1100(2)(3)(4)(5)F(6), except for model designation.

The minor differences of main transformer (T1) and of a few secondary resistors existed according to the respective dc output voltage.

Following models are derived and specified from original model nomenclature due to have different primary component and transformer. Change concern is listed in table 56.1.

- J(1)W1100(2)B12(5)F(6), J(1)W1100(2)B13(5)F(6), J(1)W1100(2)B15(5)F(6), J(1)W1100(2)B16(5)F(6), J(1)W1100(2)B18(5)F(6), J(1)W1100(2)B19(5)F(6), J(1)W1100(2)B24(5)F(6), (1)ENB1100A12(5)F(6), (1)ENB1100A13(5)F(6), (1)ENB1100A15(5)F(6), (1)ENB1100A16(5)F(6), (1)ENB1100A18(5)F(6), (1)ENB1100A19(5)F(6), (1)ENB1100A24(5)F(6).

The below information is nomenclature detail for J(1)W1100(2)(3)(4)(5)F(6) and (1)ENB1100(3)(4)(5)F(6).

- (1) can be C, M or P for family related designs.
- (2) may be A to Z for customer option.
- (3) may be A to Z according to design revision.
- (4) may be 12, 13, 15, 16, 18, 19 or 24 according to output voltage.
- (5) may be 00 to 99 according to the shape of output connector.
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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 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