**DK-3350** 

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

Name and address of the applicant Nom et adresse du demandeur

Name and address of the manufacturer Nom et adresse du fabricant

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

Note: When more than one factory, please report on page 2 Note: Lorsque il y plus d'une usine, veuillez utiliser la 2<sub>eme</sub> page Ratings and principal characteristics Valeurs nominales et caractéristiques principales

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

Ref. De type

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

Additional information (if necessary may also be reported on page 2)

Les informations complémentaires (si nécessaire,, peuvent être indiqués sur la 2ème page

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

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

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

Jan-Erik Storgaard

Jan Buh Supunal

Medical Power Supply

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

**BRIDGEPOWER CORP** 964 GOSAEK-DONG GWONSEON-GU SUWON-SI GYEONGGI-DO 441-813 KOREA See Page 2

See Page 2

None

(a)ENB1040(b)(c)(d)(e)(f), BP(a)040(b)(c)(d)(e), See Page 2

Also investigated to EN 60601-1:2006

IEC 60601-1(ed.3)

E302267-20110526

Signature:

Date: 2011-06-09

considéré conforme à la



### **DK-3350**

### Model Details:

### BP(a)040(b)(c)(d)(e);

- (a) can be A to Z for family related designs.
- (b) can be S for single.
- (c) can be 05, 09, 12, 15, 18, 24 or 48 for output voltage.
- (d) can be F or N or Q for input plug type.
- (e) can be 00 thru 99 for customer options, not related safety concerns.

### (a)ENB1040(b)(c)(d)(e)(f)

- (a) can be A to Z for family related designs.(b) can be A to Z for design revision changes.
- (c) can be 05, 09, 12, 15, 18, 24 or 48 for output voltage.
- (d) can be 00 thru 99 for standard output cord options.
- (e) can be F or N or Q for input plug type.
- (f) can be 00 thru 99 for customer options, 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

# Ratings:

Rated Input; 100-240Vac, 50-60Hz, 1.2 A.

### Rated Output;

5Vdc, 5.0A or 9Vdc, 4.0A or 12Vdc, 3.4A or 15Vdc, 2.7A or 18Vdc, 2.2A or 24Vdc, 1.7A or 48Vdc, 0.83A. (Rated output voltage is designated in the model name designation system).

# Additional information (if necessary) Information complémentaire (si nécessaire)



Date: 2011-06-09

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



### 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.....:** E302267-20110526

Date of issue ...... 2011-05-26

Total number of pages.....: 233

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

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 .....: Medical Power Supply

Trade Mark .....: None

Manufacturer....: BRIDGEPOWER CORP

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

Model/Type reference:	BP(a)040(b)(c)(d)(e)
	(a) can be A to Z for family related designs.
	(b) can be S for single.
	(c) can be 05, 09, 12, 15, 18, 24 or 48 for output voltage.
	(d) can be F or N or Q for input plug type.
	(e) can be 00 thru 99 for customer options, not related safety concerns.
	(a)ENB1040(b)(c)(d)(e)(f)
	(a) can be A to Z for family related designs.
	(b) can be A to Z for design revision changes.
	(c) can be 05, 09, 12, 15, 18, 24 or 48 for output voltage.
	(d) can be 00 thru 99 for standard output cord options.
	(e) can be F or N or Q for input plug type.
	(f) can be 00 thru 99 for customer options, not related safety concerns.
Ratings::	Rated Input; 100-240Vac, 50-60Hz, 1.2 A.
	Rated Output;
	5Vdc, 5.0A or 9Vdc, 4.0A or 12Vdc, 3.4A or 15Vdc,
	2.7A or 18Vdc, 2.2A or 24Vdc, 1.7A or 48Vdc, 0.83A.
	(Rated output voltage is designated in the model name designation system).

Testing procedure and testing location:				
$\boxtimes$	CB Testing Laboratory:			
Testi	ng location/ address:	UL Korea, Ltd / #805, Manhatan Building, 36-2 Yeouido-Dong, Yeongdeungpo-Gu, Seoul 150-749, Korea		
	Associated CB Test Laboratory:			
Testi	ng location/ address::			
	Tested by (name + signature):	KiSoo Ahn	Ki soo Am	
	Approved by (+ signature):	ChanYo Won	hi soo Am	
	Testing procedure: TMP			
	Tested by (name + signature):			
	Approved by (+ signature):			
Testing location/ address::				
	Testing procedure: WMT			
	Tested by (name + signature):			
	Witnessed by (+ signature):			
	Approved by (+ signature):			
Testing location/ address::				
	Testing procedure: SMT			
	Tested by (name + signature):			
	Approved by (+ signature):			
	Supervised by (+ signature):			
Testi	ng location/ address:			
	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)
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- Photographs (7 pages)
- Schematics + PWB (20 pages)
- Miscellaneous (6 pages)
- Marking Plate (4 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)::	2011-02-07(E300305-A57-CB-1),			
	2011-02-09(E302267-A33-CB-1)			
Dates tests performed:	2011-02-07 to 2011-02-11			
	(E300305-A57-CB-1),			
	2011-02-09 to 2011-02-14			
	(E302267-A33-CB-1)			
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 $\square$ comma / $\boxtimes$ point is used as the decimal separator.				

Manufacturer's Declaration per sub-clause 6.2.5 of IECEE 02:				
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the	<ul><li>☑ Yes</li><li>☑ Not applicable</li></ul>			
sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided:				
When differences exist; they shall be identified in the	e 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 provide MOOP isolation from Primary to Secondary and/or MOOP isolation from Primary to Earth. 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. In addition, some series of power supply are the direct plug-in units. See "Model Differences" for details.

### **Model Differences**

- The BPM040 series is the basic model. Model (a)ENB1040 series is identical to the basic model series except for the model type designations.
- The marked models as 05, 09, 12, 15, 18, 24 and 48 on nomenclature are similar, except for Main transformer (T1) windings, output rating and minor secondary circuit options not affecting safety.

-For each plug-type configuration

F-Class I appliance inlet type: IEC60320-C14, Q-Class II appliance inlet type: IEC60320-C18, N-Class II appliance inlet type: IEC60320-C8.

### **Additional Information**

Testing was not considered necessary based upon previous evaluation under CB Scheme. The CB Scheme Test Certificate and Report Ref. No. (E302267-A33-CB-1 under CB Certificate No. DK-22050) and (E300305-A57-CB-1 under CB Certificate No. DK-2371).

Max. Normal Load Condition: Rated output current

## **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, 15.4.3Hand 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