Ref. Certif. No.

DK-3180-A1-UL

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	Medical Power Supply
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 Note: *When more than one factory, please report on page 2* Note: *Lorsque il y plus d'une usine, veuillez utiliser la 2ème page*	BRIDGEPOWER CORP 964 GOSAEK-DONG GWONSEON-GUSUWON-SI GYEONGGI-DO 441-813 KOREA ☒ Additional Information on page 2
Ratings and principal characteristics Valeurs nominales et caractéristiques principales	See Page 2
Trademark (if any) Marque de fabrique (si elle existe)	None
Type of Manufacturer's Testing Laboratories used Type de programme du laboratoire d'essais constructeur	
Model / Type Ref. Ref. De type	(a)ENB1010(b)(c)(d)(e)(f), (a)ENB1011(b)(c)(d)(e) (f), BP(a)010(b)(c)(e)(f), BP(a)011(b)(c)(e)(f) See Page 2
Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire,, peuvent être indiqués sur la 2ème page	☒ Additional Information on page 2
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-D2-CB-1 issued on 2012-10-09

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 (US), 333 Pfingsten Rd IL 60062, Northbrook, USA
☒ UL (Demko), Borupvang 5A DK-2750 Ballerup, DENMARK
☐ UL (JP), Marunouchi Trust Tower Main Building 6F, 1-8-3 Marunouchi, Chiyoda-ku, Tokyo 100-0005, JAPAN
☐ UL (CA), 7 Underwriters Road, Toronto, M1R 3B4 Ontario, CANADA

For full legal entity names see www.ul.com/ncbnames

Date: 2012-10-15
Original Issue Date: 2011-05-26

Signature:

Jan-Erik Storgaard

Ref. Certif. No.

DK-3180-A1-UL

Model Details:
(a)ENB1010(b)(c)(d)(e)(f),(a)ENB1011(b)(c)(d)(e) (f),BP(a)010(b)(c)(e)(f),BP(a)011(b)(c)(e)(f)
(a) can be A to Z for family related designs.
(b) can be S for single output in model BP(a)010 series and (b) can be A to Z for design revision changes in model (a)ENB1010 series.
(c) can be 05 for 5Vdc, 06 for 6Vdc, 07 for 7.5Vdc, 09 for 9Vdc, 12 for 12Vdc, 15 for 15Vdc, 16 for 16Vdc, 18 for 18Vdc, 24 for 24Vdc and 48 for 48Vdc output voltage.
(d) can be can be 00 thru 99 for standards output cord options ("(d)" is not provided in model BP(a)010series).
(e) can be F or N or Q or B or H or G or M or C for appliance inlet or plug type.

F - Class I appliance inlet type (IEC60320-C14)
Q - Class II appliance inlet type (IEC60320-C18)
N - Class II appliance inlet type (IEC60320-C8)
B or C - Class I & Class II direct-plug-in type for North America, China, Japan and Argentina (Changeable Direct-plug-in type is only used for Class II)
H - Class I & Class II direct-plug-in type for Australia (AS/NZS 3112)
G - Class I & Class II direct-plug-in type for United Kingdom (BS 1364)
M - Class I & Class II direct-plug-in type for Europe (CEE 7/16) and Korea.

(f) can be 00 thru 99 for customer options. Not related with safety concerns

Factories:
WENDENG JEIL ELECTRONICS CO LTD
DONG SHOU GUANGZHOU LU KAIFA-QU WENDENG-SHI SHANDONG
CHINA

Ratings:
Rated Input; 100-240 Vac, 50-60 Hz, 0.3 A(0.3 A-0.1 A)
Rated Output;
5 Vdc, 2.0 A or 6 Vdc, 2.0 A or 7.5 Vdc, 1.6 A or 9 Vdc,1.1 A or 12 Vdc, 1.0 A or 15 Vdc, 0.8 A or 16 Vdc, 0.75 A or 18 Vdc, 0.67 A or 24 Vdc, 0.5 A or 48 Vdc, 0.25 A
(Rated output voltage is identified in the model designation.)

Additional Information:
Additionally evaluated to EN 60601-1:2006
National Difference specified in the CB Test Report

The original report was modified to include the following changes/additions:
- Change of Means Of Protection(MOP) from Means Of Operator Protection(MOOP) to Means Of Patient Protection(MOPP)
- Change of Altitude up to 4000m
- Change of Rated Input from "0.3 A" to "0.3 A(0.3 A-0.1 A)"
- Addition of National Differences

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

- ☐ UL (US), 333 Pfingsten Rd IL 60062, Northbrook, USA
- ☒ UL (Demko), Borupvang 5A DK-2750 Ballerup, DENMARK
- ☐ UL (JP), Marunouchi Trust Tower Main Building 6F, 1-8-3 Marunouchi, Chiyoda-ku, Tokyo 100-0005, JAPAN
- ☐ UL (CA), 7 Underwriters Road, Toronto, M1R 3B4 Ontario, CANADA

For full legal entity names see www.ul.com/ncbnames

Date: 2012-10-15
Original Issue Date: 2011-05-26

Signature:

Jan-Erik Storgaard

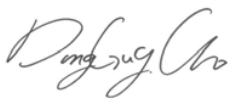
Test Report issued under the responsibility of:

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No.....:	E302267-D2-CB-1
Date of issue .....:	2012-10-09
Total number of pages.....:	144
CB Testing Laboratory.....:	UL Korea, Ltd.
Address .....:	#808, 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 2011-11**

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)010(b)(c)(e)(f), (a)ENB1010(b)(c)(d)(e)(f), BP(a)011(b)(c)(e)(f) and (a)ENB1011(b)(c)(d)(e) (f). (a) can be A to Z for family related designs. (b) can be S for single output in model BP(a)010 series and (b) can be A to Z for design revision changes in model (a)ENB1010 series. (c) can be 05 for 5Vdc, 06 for 6Vdc, 07 for 7.5Vdc, 09 for 9Vdc, 12 for 12Vdc, 15 for 15Vdc, 16 for 16Vdc, 18 for 18Vdc, 24 for 24Vdc and 48 for 48Vdc output voltage. (d) can be can be 00 thru 99 for standards output cord options ("(d)" is not provided in model BP(a)010series). (e) can be F or N or Q or B or H or G or M or C for appliance inlet or plug type. F - Class I appliance inlet type (IEC60320-C14) Q - Class II appliance inlet type (IEC60320-C18) N - Class II appliance inlet type (IEC60320-C8) B or C - Class I & Class II direct-plug-in type for North America, China, Japan and Argentina (Changeable Direct-plug-in type is only used for Class II) H - Class I & Class II direct-plug-in type for Australia (AS/NZS 3112) G - Class I & Class II direct-plug-in type for United Kingdom (BS 1364) M - Class I & Class II direct-plug-in type for Europe (CEE 7/16) and Korea. (f) can be 00 thru 99 for customer options. Not related with safety concerns
Ratings..... :	Rated Input; 100-240 Vac, 50-60 Hz, 0.3 A(0.3 A-0.1 A) Rated Output; 5 Vdc, 2.0 A or 6 Vdc, 2.0 A or 7.5 Vdc, 1.6 A or 9 Vdc,1.1 A or 12 Vdc, 1.0 A or 15 Vdc, 0.8 A or 16 Vdc, 0.75 A or 18 Vdc, 0.67 A or 24 Vdc, 0.5 A or 48 Vdc, 0.25 A (Rated output voltage is identified in the model designation.)

Testing procedure and testing location:	
☒ CB Testing Laboratory:	
Testing location/ address..... :	UL Korea, Ltd / #808, Manhatan Building, 36-2 Yeouido-Dong, Yeongdeungpo-Gu, Seoul 150-749, Korea
☐ Associated CB Test Laboratory:	
Testing location/ address..... :	
Tested by (name + signature).. :	DongGug Cho 
Approved by (+ signature) ..... :	DongYoul Kim 
☐ 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) .... :	
Testing 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):

- Photograph s (17 pages)
- Schematics + PWB (32 pages)
- Miscellaneous (5 pages)
- Marking Plate (24 pages)

Summary of testing

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

N/A N/A

Summary of compliance with National Differences

List of countries addressed: CA, CH, US

☒ 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 or Direct Plug-in type
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.**	- 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 ☐ comma / ☒ 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 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 2M OPP 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.

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.

Model Differences

The BP-series is the base model. Model ENB1010-series is identical to the base model BP-series except for the model type designations.

The below information is nomenclature detail for BP(a)010(b)(c)(e)(f) and (a)ENB1010(b)(c)(d)(e)(f):

(a) can be A to Z for family related designs.

(b) can be S for single output in model BP(a)010 series and (b) can be A to Z for design revision changes in model (a)ENB1010 series.

(c) can be 05, 06, 07, 09, 12, 15, 16, 18, 24 and 48 for output voltage.

(d) can be can be 00 thru 99 for standards output cord options ("(d)" is not provided in model BP(a)010series).

(e) can be F or N or Q or B or H or G or M or C for appliance inlet or plug type.

F - Class I appliance inlet type (IEC60320-C14)

Q - Class II appliance inlet type (IEC60320-C18)

N - Class II appliance inlet type (IEC60320-C8)

B or C - Class I & Class II direct-plug-in type for North America, China, Japan and Argentina (Changeable Direct-plug-in type is only used for Class II)

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

G - Class I & Class II direct-plug-in type for United Kingdom (BS 1364)

M - Class I & Class II direct-plug-in type for Europe (CEE 7/16) and Korea.

(f) can be 00 thru 99 for customer options.

Following model designations for only direct plug-in type.

BP(a)011(b)(c)(e)(f) series are identical with (a)ENB1011(b)(c)(d)(e)(f) series.

BP(a)011(b)(c)(e)(f) and (a)ENB1011(b)(c)(d)(e) (f).

(a) can be A to Z for family related designs.

(b) can be S for single output in model BP(a)010 series and

(b) can be A to Z for design revision changes in model (a)ENB1010 series.

(c) can be 05, 09 and 12 for output voltage.

(d) can be can be 00 thru 99 for standards output cord options ("(d)" is not provided in model BP(a)011series).

(e) can be B or M for input plug type See Enclosure-Photographs for each plug-type configuration

B- Class II direct-plug-in for North America, China , Japan and Argentina.

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

(f) can be 00 thru 99 for customer options, not related safety concern.

Additional Information

This test report shall be read in conjunction with the original report, number:

E302267-20110524 issue date 2011-05-24, With CB Certificate No. (DK-3180) issued on 2011-05-26.

This report has been amended, due to:

- Change of Means Of Protection(MOP) from Means Of Operator Protection(MOOP) to Means Of Patient Protection(MOPP)

- Change of Altitude up to 4000m

- Change of Rated Input from “0.3 A” to “0.3 A(0.3 A-0.1 A)”

- Addition of National Differences

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-A21 and Certificate No. DK-17778-A1, and also by UL to IEC 60950-1:2005 under CB Test Report No. E300305-A45 and Certificate No. DK-17600-A2. 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 equi pment where the acceptability of the comb ination is determined by Underwriters Laborato ries Inc. When installed in an end-p roduct, con sideration 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 MOPP (means of operator protection): 2 MOPP based upon a rated voltage 191 Vrms and a working voltage 590 Vpk between Primary and Secondary/Enclosure and 1 MOPP 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 power supply. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted.

INSULATION DIAGRAM

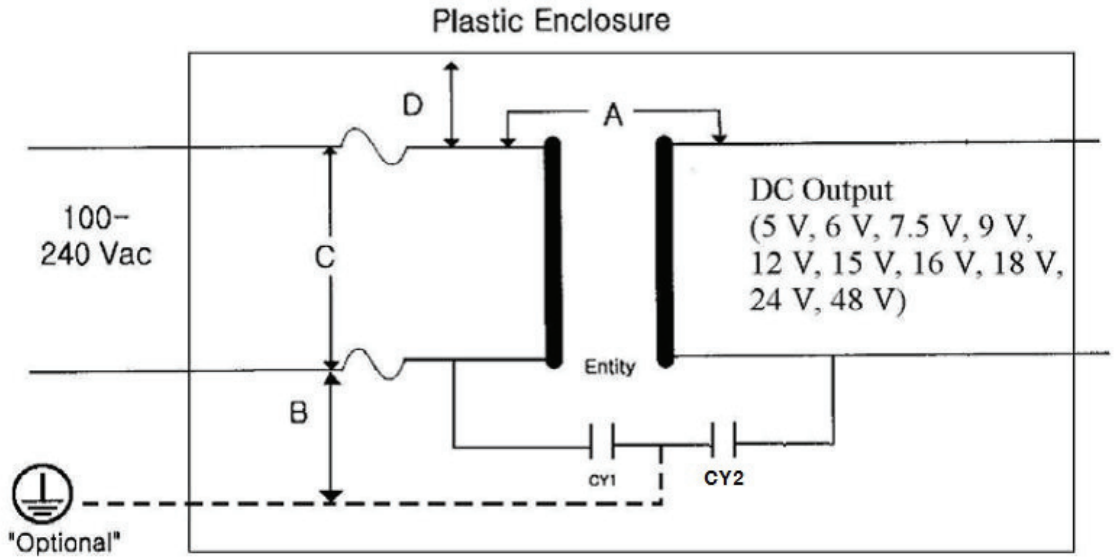


TABLE: To insulation diagram		Pass
Pollution degree ..... :	2	—
Overvoltage category..... :	II	—
Altitude..... :	Up to 4000 m	—
Additional details on parts considered as applied parts ..... :	☒ None ☐ Areas _____ (See Clause 4.6 for details)	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			Vrms	Vpk					
A	2 MOPP	IIIb	191	590	8.0	5.7	8.1	7.2	
B	1 MOPP	IIIb	240	N/A	4.0	2.9	5.7	3.7	
C	1 MOPP (BOP)	IIIb 240		N/A	3.0	1.8	>3.9	>2.4	
D	2 MOPP	IIIb	240	N/A	8.0	5.7	10	10	

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.