

IEC SYSTEM FOR CONFORMITY TESTING AND
CERTIFICATION OF ELECTRICAL EQUIPMENT (IECEE)
CB SCHEME

SYSTEME CEI D'ESSAIS DE CONFORMITE ET DE CERTIFICATION
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

Rating and principal characteristics
Valeurs nominales et caractéristiques principales

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

Model / Type Ref.
Ref. de type

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

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

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

Power Supplies

Condor D C Power Supplies Inc.
2311 Statham Pky
Oxnard, CA 93033, USA

Condor D C Power Supplies Inc.
2311 Statham Pky
Oxnard, CA 93033, USA

1. Industrias S L S A de C V, Costa Rica #60, Col Cuahutemoc
Mexicali, Baja California N., Mexico
2. Flash Electronics Inc. (Shanghai) W E D Z
2 Gutang Rd, Wujiang City, Suzhou Jiangsu, China
3. Shanghai GES Information Technology Co Ltd, Zhangjiang, Hi Tech Park
668 Li Shi Zhen Rd., 201203 Shanghai, China

Input: 100-240 V ac, 2.3 A, 50/60 Hz
Output: 20 A or 115 W max., with a minimum 150 LFM, with or without optional cover.
12 A or 80 W max., with no airflow and no cover, 8.8 A or 50 W max., with no airflow
and suffix -E. Fan output is 12 Vdc, 0.1 A.

Condor

GPFM115-X, where X represents the output voltage, which may be any number
from 3.3 to 48. May be followed by suffix -C to indicate optional cover/fan or -E to
indicated optional slotted cover is provided.

This report comprises 5 enclosures. The CB Test Certificate was amended
on March 16, 2005 to add model suffix and add new factory.

PUBLICATION

EDITION

**IEC 60601-1 (1988) Second Edition,
with Amendment No. 1 (1991) and No. 2 (1995)** with the exception of:
Clause 36, Electromagnetic Compatibility, Clause 48, Biocompatibility, and
Clause 52.1 Programmable Electronic Systems.
See CB Test Report for National Differences.

E116994-A7-CB-1

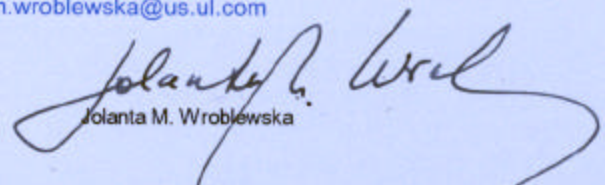
This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification



Underwriters Laboratories Inc. / Certification Programs Office
333 Pfingsten Road, Northbrook, IL 60062-2096
United States of America
TEL INT* 1-847-272-8800, Ext. 43008 FAX INT* 1-847-272-9562
email: jolanta.m.wroblewska@us.ul.com

Date: Issued: 2003 December 3
Amended: 2005 March 16 (Am. 1)

Signature:



Jolanta M. Wroblewska

COVER PAGE FOR TEST REPORT

Test Item Description:	Power Supplies
Model/Type Reference:	GPFM115-X, where X represents the output voltage, which may be any number from 3.3 to 48. May be followed by suffix -C to indicate optional cover/fan or -E to indicated optional slotted cover is provided.
Rating(s):	Input: 100-240 V ac, 2.3 A, 50/60 Hz Output: 20 A or 115 W maximum, with a minimum 150 LFM, with or without optional cover. 12 A or 80 W maximum, with no airflow and no cover. 8.8 A or 50 W maximum, with no airflow and suffix -E. Fan output is 12 Vdc, 0.1 A.
Standards:	IEC 60601-1:1988 + A1:1991 + A2:1995
Applicant Name and Address:	CONDOR D C POWER SUPPLIES INC 2311 STATHAM PKY OXNARD CA 93033
Factory Location(s):	INDUSTRIAS SL, S.A. DE C.V. COSTA RICA NO. 60, COL. CUAHUTEMOC MEXICALI, B.C. MEXICO FLASH ELECTRONICS INC. (SHANGHAI), NO. 2 GUTANG ROAD, W E D Z WUJIANG CITY, SUZHOU JIANGSU PROVINCE, CHINA SHANGHAI GES INFORMATION TECHNOLOGY CO LTD ZHANGJIANG, HI TECH PARK 668 LI SHI ZHEN RD. 201203 SHANGHAI, CHINA

This Report includes the following parts, in addition to this cover page:

1. Specific Technical Criteria
2. Clause Verdicts
3. Test Results
4. Enclosures
 - a. National Differences
 - b. Photographs
 - c. Manuals
 - d. Miscellaneous

The original report was modified on 2005-03-09 to include the following changes/additions:

Suffix -E, which indicates optional slotted cover was added to the model/type reference on the report cover page.

New factory location, Shanghai GES Information Technology Co., Ltd was added to the cover page.

Suffix -E was added to the model/type reference in the Test Report.

Output Rating was revised to include maximum output rating for model numbers with suffix -E with no airflow. General Information was revised to add slotted cover under "options included".

Engineering Considerations was revised to include optional slotted cover in the "accessories investigated for use with the product".

Sub-clause 6.1f was revised to include suffix -E for optional slotted cover.

Table 42 was revised to add temperature test data for Models GPFM115-5-E, GPFM115-12-E and GPFM115-28-107.

Enclosure, National Differences was revised to include National Differences for additional countries.

Enclosure, Photographs was revised to include photo of power supply with optional slotted cover.

Enclosure, Miscellaneous was revised to include list of test equipment.

Enclosure, Manuals was revised to include the latest version of Installation Instructions.

All applicable tests according to the above standard(s) have been carried out.

Test results are valid only for the tested equipment.

This Test Report can be reproduced only in whole.

Amendments and corrections can be reproduced only with the original CB Test Report.

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TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1: General requirements for safety

Report Reference No: E116994-A7-CB-1

Compiled by (+ signature): Ahmad Daoudi



Reviewed by (+ signature): Amanda Pack



Date of issue: 2003-12-01

CB Testing Laboratory: Underwriters Laboratories Inc.

Address: 1655 Scott Boulevard, Santa Clara, CA, 95050, USA

Testing location/procedure: CBTL [] SMT [x] TMP [] WMT []

Address: CONDOR D C POWER SUPPLIES INC., 2311 STATHAM PKY,
OXNARD CA 93033

Applicant's name: CONDOR D C POWER SUPPLIES INC

Address: 2311 STATHAM PKY
OXNARD CA 93033

Test specification:

Standard: IEC 60601-1:1988 + A1:1991 + A2:1995

Test procedure: CB Scheme

Non-standard test method: N/A

Test Report Form No.: IEC60601_1C/97-04

TRF originator: Underwriters Laboratories Inc.

Master TRF: dated 97-04

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Test item description: Power Supplies

Trade Mark: Condor

Model/Type reference: GPFM115-X, where X represents the output voltage, which may be any number from 3.3 to 48. May be followed by suffix -C to indicate optional cover/fan or -E to indicated optional slotted cover is provided.

Manufacturer: CONDOR D C POWER SUPPLIES INC
2311 STATHAM PKY

OXNARD CA 93033

Rating: Input: 100-240 V ac, 2.3 A, 50/60 Hz

Output: 20 A or 115 W maximum, with a minimum 150 LFM, with
or without optional cover.
12 A or 80 W maximum, with no airflow and no cover.
8.8 A or 50 W maximum, with no airflow and suffix -E.
Fan output is 12 Vdc, 0.1 A.

Marking Plate - Refer to Enclosure titled Miscellaneous for copy.

GENERAL INFORMATION		
Test item particulars (see also clause 5):		
Classification of installation and use	Permanently installed	
Supply connection.....	Header Connector	
Accessories and detachable parts included in the evaluation.....	None	
Options included	Optional cover/fan or slotted cover	
Possible test case verdicts:		
- test case does not apply to the test object	N / A	
- test object does meet the requirement	P(Pass)	
- test object does not meet the requirement	F(Fail)	
Abbreviations used in the report:		
- normal condition	N.C. - single fault condition	S.F.C.
- operational insulation	OP - basic insulation	BI
- basic insulation between parts of opposite polarity:	BOP - supplementary insulation	SI
- double insulation	DI - reinforced insulation	RI
General remarks:		
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 a NCB in accordance with IEC60084-2.		
The test 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 Issuing testing laboratory. List of test equipment must be kept on file and be available for review. "(see Enclosure #)" refers to additional information appended to the report. "(see appended table)" refers to a table appended to the report. Throughout this report a point is used as the decimal separator.		

General Product Information:
Report Summary
The original report was modified on 2005-03-09 to include the following changes/additions: Suffix -E, which indicates optional slotted cover was added to the model/type reference on the report cover page. New factory location, Shanghai GES Information Technology Co., Ltd was added to the cover page. Suffix -E was added to the model/type reference in the Test Report. Output Rating was revised to include maximum output rating for model numbers with suffix -E with no airflow. General Information was revised to add slotted cover under "options included". Engineering Considerations was revised to include optional slotted cover in the "accessories investigated for use with the product". Sub-clause 6.1f was revised to include suffix -E for optional slotted cover.

<p>Table 42 was revised to add temperature test data for Models GPFM115-5-E, GPFM115-12-E and GPFM115-28-107. Enclosure, National Differences was revised to include National Differences for additional countries. Enclosure, Photographs was revised to include photo of power supply with optional slotted cover. Enclosure, Miscellaneous was revised to include list of test equipment. Enclosure, Manuals was revised to include the latest version of Installation Instructions.</p>	
Product Description	
<p>The equipment (DC Power Supplies) covered by this report, are components, which are intended for use in end-product equipment used in a hospital or related health care facility, evaluated to standard for Medical Equipment.</p>	
Model Differences	
<p>GPFM115 Series models are similar to each other and differ only on secondary circuitry.</p>	
Additional Information	
<p>The schematics for these models are kept in file at the CB Testing Laboratory mentioned in the first page of this test report, and can be provided by the applicant upon request by CBTL's.</p>	
Technical Considerations	
<p>The product was investigated to the following additional standards:</p>	<p>EN 60601-1: 1990 + A1:1993 + A2:1995 + A13:1996 (except EMC limitations, EN 60601-1-2, Biocompatibility, EN 10993-1, Programmable Electronic Systems, IEC 60601-1-4)</p>
<p>The product was not investigated to the following standards or clauses:</p>	<p>Clause 52.1, Programmable Electronic Systems (IEC 601-1-4) Clause 48, Biocompatibility (ISO 10993-1) Clause 36, Electromagnetic Compatibility (IEC 601-1-2)</p>
<p>The product is Classified only to the following hazards:</p>	<p>Fire, Shock</p>
<p>The degree of protection against harmful ingress of water is:</p>	<p>Ordinary</p>
<p>The following accessories were investigated for use with the product:</p>	<p>Optional cover/fan and slotted cover.</p>
<p>The mode of operation is:</p>	<p>Continuous</p>
<p>Software is relied upon for meeting safety requirements related to mechanical, fire and shock:</p>	<p>No</p>
<p>The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:</p>	<p>No</p>

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

Note: No default COAs exist for 60601

1. This component has been judged on the basis of the required spacings in the First Edition of the Standards for Medical Electrical Equipment, Part 1: General Requirements for Safety, UL 60601-1 and CSA C22.2 No. 601-1, which covers the end use product for which the component is designed., 2. The component shall be installed in compliance with the enclosure, mounting, spacing, casualty markings and segregation requirements of the end-use application., 3. 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., 4. The input/output connectors are not acceptable for field connections, they are only intended for connection to mating connectors of internal wiring inside the end-use machine. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF)., 5. The component should be properly bonded to ground in the end-use equipment. , 6. The isolation transformer, T4 complies with Class 155 limits., 7. Leakage current testing should be repeated in the end product application., 8. Models were evaluated as double insulation between primary and secondary; basic insulation between primary to ground. , 9. The GPFM115 Series power supply has been evaluated as Class I, continuous operation, ordinary equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide., 10. This product provides fusing in the line input lead only. Need for fusing of the neutral lead should be considered in the end product., 11. This product series may be provided with a cooling fan as an option. The product, when manufactured with the fan option, is not provided with a guard as the product is intended to be built into an end-product. Therefore, acceptability of the fan guard is to be considered in the end-product evaluation.

File E116994
Project 00SC03769

2000-03-22

REPORT

ON

COMPONENT - POWER SUPPLIES, MEDICAL
AND
DENTAL EQUIPMENT

***SL Power Electronics, Inc.**
***Ventura, California**

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DESCRIPTION

PRODUCT COVERED:

USR, CNR - COMPONENT, Switching Power Supply, Medical and Dental, Model **GPFM115-X-YYY G** where **X** equals any number from 3.3 through 48, **Y** is numeric character 000-999 which represents value added options not related to safety. May be followed by suffix **-C** to indicate optional cover/fan or **-E** to indicate optional slotted cover is provided. May be followed by a suffix **"R"** which indicated compliance with RoHS. (RoHS compliance has not been evaluated by UL)

ELECTRICAL RATINGS:

Input: 100-240 V ac, 50/60 Hz, 2.3 A.
Output: Voltage Range = 3.3 through 48 V dc
Current Range = 12 through 1.7 A, convection cooled,
= 20 through 2.4 A, with cover/fan option
or minimum 150 LFM airflow.
8.8 A or 50 W maximum, with no airflow and
suffix -E.
+48 V dc/1.05 A (GPFM115-48-105)+48 V dc/1.8 A (GPFM115-28-107)
+15 V dc/4.7 A (GPFM115-15-106, **GPFM115-15-111G**)

ENGINEERING CONSIDERATIONS (NOT FOR FIELD REPRESENTATIVE'S USE):

USR - indicates investigation to the Standard for Medical Electrical Equipment, UL 60601-1, First Edition

CNR - indicates investigation to Canadian Standard CSA C22.2 No. 601.1

For use in product where the acceptability of the combination is determined by Underwriters Laboratories Inc.

ENGINEERING REFERENCES:

Following Illustrations are provided for engineering references:

- ILL. 1 - Isolation Diagram
- ILL. 2 - Installation Instruction Sheet
- ILL. 3 - PWB Trace Layout
- ILL. 4 - Transformer Construction Detail (T4)

Condition of Acceptability - When installed in the end-use equipment, the following are among the considerations to be made:

1. This component has been judged on the basis of the required spacings in the Second Edition of the Standards for Medical Electrical Equipment, Part 1: General Requirements for Safety, UL 2601-1, which covers the end use product for which the component is designed.
2. The component shall be installed in compliance with the enclosure, mounting, spacing, casualty markings and segregation requirements of the end-use application.
3. 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.
4. The input/output connectors are not acceptable for field connections, they are only intended for connection to mating connectors of internal wiring inside the end-use machine.
5. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
6. The component should be properly bonded to ground in the end-use equipment.
7. The Temperature Test was performed in a raised ambient of 50°C.
8. The main isolation transformer, T4, complies with Class F (155°C) limits, except for GPFM115-28-100, which complies with Class H (180°C) limits.
9. Leakage current testing should be repeated in the end product application.
10. The power supply was evaluated as Reinforced insulation between primary and secondary; basic insulation between primary to ground.
11. This power supply has been evaluated as Class I, continuous operation, ordinary equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
12. These power supplies have been evaluated for patient care equipment, but not patient connected.
13. Under normal and single fault conditions, the outputs do not exceed 25 V ac or 60 V dc.
14. Double fusing in the end-product should be considered since primary fusing of both sides on the mains supply lines was not provided.

CONSTRUCTION DETAILS:

See Section General, Construction Details.

Trace Layout - Field Representative to insure that the trace layout has not changed. See ILL. 3.

Model GPFM115-28-100 is a GPFM115-28 with the thermal switch RT2 glued to transformer core of T4.

Model GPFM115-48-105 is a GPFM115-48 with a slotted cover without fan. The output rating is derated to 50 W max with convection cooling.

Model GPFM115-15-106 is a GPFM115-15 with SEC shield added to the transformer construction to improve EMI. The transformer construction is similar to the GPFM115-48 transformer.

Model GPFM115-28-107 is a Model GPFM115-28-100 with a slotted enclosure added from Model GPFM115-48-105. Model GPFM115-X-E is a GPFM115 with an optional slotted cover.

Model GPFM115-15-106 is changed with a new EMI Inductor T1 and its location on the PWB swapped with T2. Capacitors C3 and C4 changed from 1000 pF to 470 pF. The PWB layout is changed, and the chassis is modified to include mounting tabs and a solid cover is added. The output rating is derated to +15 V/4.7 A or 70 W with convection cooling.

Model GPFM115-15-106 is further changed to improve EMI by changing Inductor T2 to part used as T1 (P/N 34372-1) on the GPFM115 Series, the value of C2 increased to 0.47 μ F, and the PWB layout is changed slightly in the EMI section.

Model GPFM115-15-111G is electrically identical to the GPFM116-15-106. The only difference is purely mechanical. The Chassis and Cover has different mounting points.



Product Service

CERTIFICATE

No. B 07 12 59743 033

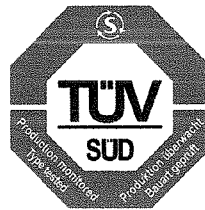
Holder of Certificate: SL Power Electronics, Corp.



6050 King Drive Bldg A
Ventura CA 93003
USA

Production Facility(ies): 16784, 52962

Certification Mark:



Product: Medical power supplies
(Power Supply for medical equipment)

Model(s): GPFM115-Series

Parameters:

Rated Input Voltage:	100 - 240 V AC
Rated Input Frequency:	50 / 60 Hz
Rated Input Current:	2.3 A
Rated DC Outputs:	See attachment
Protection Class:	I
Ta:	50°C

When installing the equipment, all requirements of the standard must be met.

See attachment for additional information.

Tested according to: EN 60601-1/A13:1996

The product was tested on a voluntary basis and complies with the essential requirements. The certification mark shown above can be affixed on the product. The certification mark must not be altered in any way. See also notes overleaf.

Test report no.: SI700003-108

Date, 2008-01-10

Page 1 of 2





Product Service

**ATTACHMENT TO CERTIFICATE NO. B 07 12 59743 033
FOR SL POWER ELECTRONICS, CORP.**

AC/DC SWITCHING POWER SUPPLIES

GENERAL PRODUCT INFORMATION:

GPFM115-X-YYY-C G series, GPFM115-28-100; GPFM115-48-105: GPFM115-15-106,
GPFM115-28-107: GPFM115-15-111G

Where X represents the output voltage, which may be any number from 3.3 through 48, -YYY is a numeric character 000-999 value added options not related to Safety.

May be followed by optional Suffixes: -C, when used, indicates optional cover/fan is provided.

May be followed by an optional "G" which indicates compliance to RoHS.

RATINGS:

Output:

GPFM115-X-YYY-C G

20 A or 115 W maximum, with a minimum of 150 LFM without cover,
12 A or 80 W maximum, with no airflow and no cover.
8.8A or 50W maximum, with no airflow and suffix -E

GPFM115-28-100

28V DC, 4.1A

GPFM115-48-105

48V DC, 1.05A

GPFM115-15-106, GPFM115-15-111G

15V DC, 4.7A

GPFM115-28-107

28V DC, 1.8A, with convection cooling

Fan Output : 12 V dc, 0.1 A (provided for connection of fan only)

CONDITIONS OF ACCEPTABILITY:

Notes:

1. Maximum ambient temperature for rated output power is 50°C
2. Maximum Operating Relative Humidity 96%, no condensation
3. Storage: -40°C to 85°C. Units should be allowed to warm up under non condensing conditions before application of power
4. Protection against electric shock = Class I
5. Degree of protection against electric shock = Not acceptable for applied part without additional isolation (contact factory for details)
6. Protection against harmful ingress of water = Ordinary (no protection)
7. Has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. This evaluation is to be made on the end equipment by the OEM
8. Mode of operation= Continuous
9. Do not exceed 5A per contact on J3

Report Number: SI700003-108

Page 2 of 2

2008-1-10