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. ..... :	E349607-D1014-1/A0/C0-UL
Date of issue ..... :	2020-06-26
Total number of pages ..... :	227
Testing Laboratory ..... :	UL International Polska Sp. z o.o.
Address ..... :	Aleja Krakowska 81 05-090 Sekocin Nowy Warszawy POLAND
Applicant's name ..... :	TDK-Lambda UK Ltd
Address ..... :	Kingsley Avenue, Ilfracombe North Devon, EX34 8ES UNITED KINGDOM
Test specification:	
Standard ..... :	IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint)
Test procedure ..... :	UL Certification
Non-standard test method…….. :	N/A
Test Report Form No..... :	IEC60601_1P

General disclaimer:

The test results presented in this report relate only to the object tested.

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Test item description:	Switch Mode Power Supply
Trade Mark:	Trademark image(s): TDK·Lambda
Manufacturer:	Same as Applicant
Model/Type reference:	CFE400M or CFE-400M series switch mode power supplies (see report Model Differences for details of nomenclature)
Ratings:	100-240Vac nom, 47-63Hz, 6.1A rms max (see report Model Differences for details)

Testing procedure and testing location:		
[X] UL/DAP Testing Laboratory:		
Testing location/ address:	UL International Polska Sp. z o.o. Aleja Krakowska 81 05-090 Sekocin Nowy Warszawy POLAND	
Tested by (name, function, signature):	Krzysztof Wasilewski (handler)	Krzysztof Wasilewski
Approved by (name, function, signature):	Dennis Butcher, Reviewer	
[ ] Testing procedure: WMT:		
Testing location/ address:		
Tested by (name, function, signature):		
Approved by (name, function, signature):		

List of Attachments (including a total number of pages in each attachment): Refer to Appendix A of this report. All attachments are included within this report.
Summary of testing
Tests performed (name of test and test clause): Testing location: *Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.*

Copy of marking plate
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective owners of these marks.

Refer to the enclosure(s) titled Marking Label in the Enclosures section in Appendix A of this report for a copy.

GENERAL INFORMATION	
Test item particulars(see also Clause 6):	
Classification of Installation and Use:	For building-in
Device type (component/sub-assembly/ equipment/ system):	Component Switch Mode Power Supply
Intended use (Including type of patient, application location):	To provide DC power for electronic circuit within medical equipment
Mode of Operation:	Continuous
Supply Connection:	Connection to mains via host equipment
Accessories and detachable parts included:	None
Other Options Include:	None
Testing	
Date of receipt of test item(s) .....:	2014-07-14 to 2014-11-28, 2020-05-15
Dates tests performed .....:	2014-07-28 to 2014-12-01, 2020-05-25
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 point is used as the decimal separator.

GENERAL PRODUCT INFORMATION:

Report Summary

This report is a reissue of CBTR Ref. No. E349607-D4, CB Test Certificate Ref. No.DK-44943-UL.
Following changes were done in the report:
- alternate discharge resistor were added
- user manual was updated (minor changes)
- licenses no longer needed were deleted,
- minor correction in the list of critical components were made

Based on previously conducted testing and the review of product construction, only VOLTAGE OR CHARGE LIMITATION: (IEC 60601-1, 3rd Edition, Clause 8.4.3) test was deemed necessary.

Refer to the Report Modifications for any modifications made to this report.

Product Description

CFE400M or CFE-400M series switch mode power supplies
(See Model Differences for details of nomenclature)

Model Differences

Units may be marked with a Product Code: U7x or Y7x where x may be any number of letters and/or numbers 0 to 9.

Unit Configuration (Description :) Code may be prefixed by NS # followed by / or - (where # may be any number of characters indicating non- safety related model differences) or by SP followed by / or – (SP represents a sales code)
Unit Configuration Code:

CFE400Mx-a-bc-defg-hi-j-k-lmn-o

Where:

x = Blank for Y2 capacitors from output to earth
P for Y1 capacitors from output to earth

a = Channel 1 output Voltage (see Ch1 in the table below, adjustment range column).

b = Standby voltage (see standby in the table below, adjustment range column).
N for no supply

c = N no for supply.
C for 0.1A.
H for 1A.

d = NN for no fan, no fan supply.
N1 for 12V nom / 0.25A fan supply. (V varies with Ch1 output voltage)
TF for chassis with fan fitted to cover.

e = U for chassis only.
C for chassis with perforated or top fan cover.
S for chassis with cover.

f = M for Molex KK type 41791 input connector or equivalent.
S for screw terminal input connector.

g = L for low Leakage,
R for reduced Leakage,
T for tiny Leakage*

h = Y for Oring FET included.
N for no Oring FET.

i = N for no inhibit or enable.
T for inhibit.
E for enable.

j = Omit for standard channel 1 output voltage with no droop.
Dx where D is for units with programmed negative load regulation,
x is the voltage of the regulation in 100mVolts and is within the Output Adjustment range
(example, D5 = 0.5V of negative load regulation).

k = Omit for no secondary comms.

lmn = Blank for standard output settings or three numbers from 0 to 9 which denotes various output voltage/current settings within the specified ranges of each output for a particular unit. (may define non-
safety related parameters/feature, e.g. reduced primary current limit, reduced OVP)

o = Blank for dual fuse input or -FL for single fuse input in the live line. FL version shall be used in

permanently installed end equipment only.

* L <300µA Leakage, R <150µA Leakage, T <75µA Leakage

Input Parameters

Standard	60601-1
Nominal input voltage	100 - 240 Vac
Input voltage range	85 - 264 Vac
Input frequency range	47 - 63 Hz
Maximum input current	6.1A rms (6.4A rms 450W peak)

All ratings apply for ambient temperatures up to 50°C. (see variations and limitations below)

Output Parameters

There are three CFE400M standard models with various options and output parameters shown in the tables below.

Standard models:

Standard models at 50°C maximum ambient in forced air and top fan models:

Output Channel	Vout Nom.	Adjustment Range (V)	Maximum Output Current (A)	Maximum Power (W)
Channel 1	12	9 - 14.4	33.33 (35.7†)	400 (450†)
	15	14.4 - 15.5	24.67	370
	24	18 - 28.8	16.67 (18.75†)	400 (450†)
	48	36 - 54	8.34 (9.38†)	400 (450†)
Fan output (optional)	12	9 - 12	0.25	3
Standby output (optional)	5	5 - 5.5*	1	5.5
Standby output (optional)	5	5	0.1	0.5

Variations and limitations of use for Standard models at 50°C maximum ambient in forced air and fan models:

1. * Can be adjusted at the factory only.
2. Maximum continuous power output 400W.
3. † Peak power of 450W for 10 seconds maximum, maximum rms power of 400W.
4. See Cooling for customer air below for forced air and convection cooled models.
5. Channel 1 output de-rated 10W/°C from 50°C - 70°C.

Standard model at 50°Cmaximum ambient convection cooled:

Output Channel	Vout Nom.	Adjustment Range (V)	Maximum Output Current (A)	Maximum Power (W)
Channel 1	12	9 - 14.4	20.83 (35.7†)	250 (450†)
	15	14.4 - 15.5	15.4	231
	24	18 - 28.8	10.41 (18.75†)	250 (450†)
	48	36 - 54	5.21 (9.38†)	250 (450†)
Fan output (optional)	12	9 - 12	0.25	3
Standby output (optional)	5	5 - 5.5*	1	5.5
Standby output (optional)	5	5	0.1	0.5

Variations and limitations of use for Standard models at 50°C maximum ambient convection cooled:

1. * Can be adjusted at the factory only.
2. Maximum continuous power output 250W.
3. † Peak power of 450W for 10 seconds maximum, maximum rms power of 250W.

4. See Cooling for customer air below for convection cooled models.
5. Channel 1 output de-rated 10W/°C from 50°C - 60°C.

Standard model at 40°Cmaximum ambient convection cooled:

Output Channel	Vout Nom.	Adjustment Range (V)	Maximum Output Current (A)	Maximum Power (W)
Channel 1	12	9 - 14.4	25 (35.7†)	300 (450†)
	15	14.4 - 15.5	18.46	277
	24	18 - 28.8	12.5 (18.75†)	300 (450†)
	48	36 - 54	6.25 (9.38†)	300 (450†)
Fan output (optional)	12	9 - 12	0.25	3
Standby output (optional)	5	5 - 5.5*	1	5.5
Standby output (optional)	5	5	0.1	0.5

Variations and limitations of use for Standard models at 40°C maximum ambient convection cooled:

1. * Can be adjusted at the factory only.
2. Maximum continuous power output 300W.
3. † Peak power of 450W for 10 seconds maximum, maximum rms power of 300W.
4. See Cooling for customer air below for convection cooled models.
5. Channel 1 output de-rated 5W/°C from 40°C - 50°C.

Variations and limitations of use for Standard models at 40°C maximum ambient convection cooled:

Output Channel	Vout Nom.	Adjustment Range (V)	Maximum Output Current (A)	Maximum Power (W)
Channel 1	40	38 - 42	6.25 (15†)	300 (630†)
Standby output (optional)	5	5	0.1	0.5

Variations and limitations of use for Standard models at 40°C maximum ambient convection cooled:

1. Maximum continuous power output 300W.
2. † Peak power of 630W with Ch1: 10ms sawtooth current waveform of 42V at 15A to 5A for 10s followed by 42V at 1A for 30s minimum. Standby at 5V, 0.1A continuous.
3. See Cooling for customer air below for convection cooled models.

Output Limitations

All outputs are SELV.
Series outputs are not allowed without further evaluation in end use product.
All outputs have basic spacings to earth rated for mains - 250Vac, and due consideration must be given to this in the end product design.

Environmental parameters

Description	Operation	Storage
Use	Indoor	-
Temperature	0°C - +70°C *	-40°C - +70°C
Humidity	5 - 95% RH, non-condensing	5 - 95% RH, non-condensing
Altitude	-200m - 5000m	-200m - 5000m
Pressure	54kPa - 106kPa	54kPa - 106kPa
Orientation	Sides, vertical with input lowest, horizontal (customer air versions: all)	All
Material Group	IIIb	
Pollution Degree	2	
Overvoltage Category	II	
Class	I	

* See variations and limitations of use for each model above.

Additional Information

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Technical Considerations

- The product was investigated to the following standards:

  Main Standard(s):

  ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14

  From Country Differences:

  - Austria: EN 60601-1:2006/A1:2013
  - Korea, Republic of: KS C IEC 60601-1
  - USA: AAMI/IEC 60601-1:2005 + AMD 1:2012
  - Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14
  - United Kingdom: BS EN 60601:2006 A1
  - Sweden: SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014
  - Japan: National standard JIS T 0601-1:2017 (IEC 60601-1:2005 + A1:2012(MOD))

  Additional Standards:

  EN 60601-1:2006/A1:2013 (IEC60601-1, Edition 3.1)

- The following additional investigations were conducted: Electromagnetic Compatibility (IEC 60601-1-2),
  Clause 14, Programmable Electronic Systems,
  Biocompatibility (ISO 10993-1)
- The product was not investigated to the following standards or clauses: -
- The following accessories were investigated for use with the product: -
- -

Engineering Conditions of Acceptability

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

• The following Production-Line tests are conducted for this product: Electric Strength, Earthing Continuity.
• The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-SELV: 384 Vrms, 614 Vpk, Primary-Earthed Dead Metal: 340 Vrms, 614 Vpk.
• The following secondary output circuits are at hazardous energy levels: Channel 1.
• The following secondary output circuits are at non-hazardous energy levels: Standby supply and fan supply.
• The following output terminals were referenced to earth during performance testing: All outputs and their return lines individually referenced to earth to obtain maximum working voltage.
• The power supply terminals and/or connectors are: Not investigated for field wiring.
• The maximum investigated branch circuit rating is: 20 A.
• The investigated Pollution Degree is: 2.
• Proper bonding to the end-product main protective earthing termination is: Required.
• The following magnetic devices (e.g. transformers or inductor) are provided with an OBJY3 insulation system with the indicated rating greater than Class A (105°C): Transformer TX1, TX3 andTX5 -

See table 8.10 for details of insulation systems used.
- The following end-product enclosures are required: Fire, Mechanical, Electrical.
- The following components require special consideration during end-product thermal (heating) tests due to their indicated maximum temperature measurements during component-level testing: All non-fan models require component temperatures monitored as detailed in the Additional Information section of this report.
- Consideration of spacings to the connections of the optional screw terminal input in the end equipment is required
- Insulation separation between: Primary and Secondary is two MOPPs: 384Vrms, 614Vpeak
- Insulation separation between: Primary and Earth is one MOPP: 340Vrms, 614Vpeak
- Insulation separation between: Secondary and Earth is one MOPP: 240Vrms, 340Vpeak
- The following secondary output circuits meet the limits of 8.4.2.: Standby outputs and Fan output.
- The clearance and creepage distances have been assessed for suitability up to 5000m elevation.
- Connecting output in series is not allowed without further evaluation in end product.
- Leakage current measurements with non-frequency weighted measuring device shall be performed during end product evaluation.
- Leakage current measurements shall be repeated during end product evaluation.
- FL option shall be used in permanently installed end equipment only
- 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 simultaneous fault condition testing.
- End product Risk Management Process to consider the need for different orientations of installation during testing.
- End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- Temperature Test was conducted without Test Corner. 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 selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply
- Customer Air Cooling:

The following method must be used for determining the safe operation of PSUs when NN, U or S options (Customer Air) are fitted, i.e. fan not fitted to PSU. The minimum permitted airflow for customer air cooling is 0.5m/s.

For PSUs and assemblies cooled by customer supplied airflow the components listed in the following table must not exceed the temperatures given. Additionally ratings specified for units with an internal fan shall still be complied with, eg. mains input voltage range, maximum output power, module voltage / current ratings and maximum ambient temperature. To determine the component temperatures the heating tests shall be conducted in accordance with the requirements of IEC60950-1. Consideration should also be given to the requirements of other safety standards.

Test requirements include: PSU/assembly to be fitted in its end-use equipment and operated under the most adverse conditions permitted in the end-use equipment handbook/specification and which will result in the highest temperatures in the PSU/assembly. To determine the most adverse conditions consideration shall be given to the end use equipment maximum operating ambient, the PSU/assembly loading and input voltage, ventilation, end use equipment orientation, the position of doors & covers, etc. Temperatures shall be monitored using type K fine wire thermocouples (secured with cyanoacrylate adhesive, or similar) placed on the hottest part of the component (out of any direct airflow) and the equipment shall be run until all temperatures have stabilised.

Circuit Ref.	Description	Max. Temperature (°C) †
J1	Input connector	105
C7, C8	X capacitor	100
L1, L2	Common mode choke winding	110
L9	Series mode choke winding	120 (130)
TX1††, TX3	Standby trx winding	110 (130)
U2, U7	Opto-coupler	100
ASY4-B	PFC FET	120
ASY4-C	Boost diode	120
L3, L5	Boost choke winding	110 (140)
C9	Boost capacitor	83 (105)
ASY5	Bridge	125 (130)
RLY1	Relay	100
L6 winding	Primary resonant choke winding	125 (145)
TX5-A	Primary wdg	110 (130)
TX5-B	Ch1 wdg	110 (130)
TX5-C	Sec aux wdg	110 (130)
XQ18	HS Ch1 synchronous rectifier	120 (130)
XL1	Channel 1 output choke	110 (130)
ASY7-C (††)	Stby switch	120
ASF4-F (††)	Oring FET	120
C1, C3, C5, C16, C17, C21 (††)	Electrolytic capacitors	82.5 (105)
C6, C18 (††)	Electrolytic capacitors	91 (105)

† The higher temperatures limits in brackets may be used but product life may be reduced.
†† When fitted.

Note the attached marking label is representative of all models in the series.