UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical Electrical Equipment - Part 1 (IEC 60601-1:2005, Mod) CAN/CSA-C22.2 NO. 60601-1:14 - Medical electrical equipment - Part 1 (Adopted IEC 60601-1:2005, third edition, 2005-12, incl. Am1:2012, with Canadian deviations), Third Edition
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Product:	Switch mode power supply
Model:	CFE400M or CFE-400M series switch mode power supplies (see report Model Differences for details and nomenclature)
Rating:	100 - 240Vac nom, 47 - 63Hz, 6.1A rms max. (see report Model Differences for details)
Applicant Name and Address:	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

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Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Krzysztof Wasilewski Reviewed by:

Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

A. Authorization - The Authorization page may include additional Factory Identification Code markings.

B. Generic Inspection Instructions -

i. Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.

ii. Part AE details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.

iii. Part AF details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

Product Description

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

Model Differences

CFE400M or CFE-400M series as described below:

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).
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 2A.

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	60950-1
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*	2	11
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*	2	11
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*	2	11
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	Maximum Output	Maximum Power
		(V)	Current (A)	(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.
Seriesing of outputs is 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.

Technical Considerations

- Classification of installation and use : For building in
- Device type (component/sub-assembly/ equipment/ system) : Component Switched 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
- The product was investigated to the following additional standards:
  EN 60601-1:2006/A1:2013 (IEC60601-1, Edition 3.1),
  ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012,, C1:2009/(R)2012 and A2:2010/(R)2012 Medical Electrical Equipment - Part 1 (IEC 60601-1:2005, Mod),
  CAN/CSA-C22.2 NO. 60601-1:14 - Medical electrical equipment - Part 1 (Adopted IEC 60601-1:2005, third edition, 2005-12, incl. Am1:2012, with Canadian deviations), Third Edition
- The product was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)
- The degree of protection against harmful ingress of water is: Ordinary
- The mode of operation is: Continuous
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No
- Risk management has not been applied to these products.
- EMC compliance has not been verified nor has it been taken into consideration. An accredited EMC Test Report will be required in conjunction with the Certification of the end product.

Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. 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.

Additional Information
Additional Standards The product fulfills the requirements of: EN 60601-1: 2006 + CORR: 2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance). CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada). ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States).