Test Report issued under the responsibility of:

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

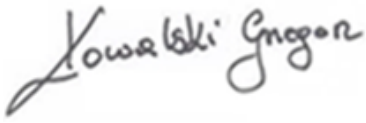
Report Reference No.....:	E349607-D1011-2/A2/C0-CB
Date of issue .....:	2020-07-31; A1:2020-08-25;A2:2020-11-27
Total number of pages.....:	195
CB Testing Laboratory.....:	UL International Sp.z.o.o.
Address .....:	ul.Równoległa 4 02-235 Warszawa, Poland
Applicant's name.....:	TDK-LAMBDA UK LTD
Address .....:	Kingsley Avenue Ilfracombe, 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 .....:	CB Scheme
Non-standard test method……..:	N/A
Test Report Form No.....:	IEC60601_1P
Test Report Form Originator.....:	UL(US)
Master TRF.....:	2019-10-11

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.

General disclaimer:

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 CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description.....:	Switch Mode Power Supply
Trade Mark.....:	Trademark image(s): TDK·Lambda
Original Product/Equipment Manufacturer.....:	Same as Applicant
Branding Manufacturer(s).....:	
Model/Type reference.....:	CUS400M, (may be prefixed and followed by alphanumeric characters - See model differences section for details of nomenclature)
Ratings.....:	100-240 Vac, 47-63Hz, 5.75A Max Output: When provided with Fan Cover: CUS400M-12 Output: 12 Vdc 33.33A CUS400M-15 Output: 15 Vdc 26.67A CUS400M-19 Output: 19 Vdc 21.05A CUS400M-24 Output: 24 Vdc 16.67A CUS400M-28 Output: 28 Vdc 14.29A CUS400M-36 Output: 36 Vdc 11.11A CUS400M-48 Output: 48 Vdc 8.33A For other output loading options, see Model Differences.

Testing procedure and testing location:			
[X]	**CB Testing Laboratory:**		
Testing location/ address ..... :		UL International Sp.z.o.o. ul.Równoległa 4 02-235 Warszawa, Poland	
Tested by (name, function, signature) ..... :		Grzegorz Kowalski	
Approved by (name, function, signature) .. :		Mona Nielsen, Reviewer	
[ ]	**Testing procedure: CTF Stage 1:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Approved by (name, function, signature) .. :			

[ ]	**Testing procedure: CTF Stage 2:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Witnessed by (name, function, signature) . :			
Approved by (name, function, signature) .. :			
[ ]	**Testing procedure: CTF Stage 3:**		
[ ]	**Testing procedure: CTF Stage 4:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Witnessed by (name, function, signature) . :			
Approved by (name, function, signature) .. :			
Supervised 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 B of this report if testing was performed as part of this evaluation.*
Summary of compliance with National Differences
List of countries addressed: Austria, Republic of Korea, USA, Canada, United Kingdom, Sweden, Japan, Israel [X] The product fulfils the requirements of IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint).

Statement concerning the uncertainty of the measurement systems used for the tests

(may be required by the product standard or client)

[ ] **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

Procedure number, issue date and title:

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

[ ] **Statement not required by the standard used for type testing**

(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

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 NCBs that own 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 supply regulated power
Mode of Operation:	Continuous
Supply Connection:	To be determined in the end-product
Accessories and detachable parts included:	None
Other Options Include:	None

Testing

Date of receipt of test item(s) .....:	2020-05-05
Dates tests performed .....:	2020-06-30 to 2020-07-31

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 (collateral standards only)
- 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.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012

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

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies)..... :	Same as Applicant Panyu Trio Microtronic Co. Ltd Shiji Industrial Estate Dongyong, Nansha, Guangzhou, Guangdong CHINA TDK Lambda Malaysia SDN BHD Lot 2 & 3 Kawasan Perindustrian Bandar Baru Jaya Gading 26070 Kuantan Pahang Darul Makmur MALAYSIA TRIO-TRONICS (THAILAND) LTD. 7/295 MU. 6 MAP YANG PHON SUB-DISTRICT PLUAK DAENG DISTRICT RAYONG PROVINCE THAILAND

General product information:

Report Summary

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

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

Product Description

Products are component power supplies intended to be used as part of Medical Electrical Equipment.

This component power supply is a Class I or Class II – see conditions of acceptability for details.

The power supply provides two fuses for input protection. One in the Live line and one in the Neutral line. Option E uses one fuse only. This is fitted in the live line only.

The power supply is convection cooled.

The component temperatures listed in the additional information shall not be exceeded.

Model Differences

The Marking label is representative of the entire series.

CUS400M models as described below:
Units may be marked with a Product Code: CUS400M-xxVx/yyyy where x may be any number of numbers of left blank to indicate output voltage. V represents a decimal place when required or can be left blank. Y can be any number of letters (excluding B, C, U, A, F) when indicating non-safety related model differences. y can be B, C, U, A, F when indicating the standard options as listed below. Unit nomenclature may be prefixed by K, SP# and/or NS# followed by / or – (where # may be any number of characters indicating non-safety related model differences)

Unit Nomenclature

CUS400M-xxVx/yyyy

Where:

xxVx = Channel 1 output voltage from within the output voltage adjustment range from the Output Parameters Tables below
yyyy = Unit options from list of standard unit options below,
Blank = open frame with potted baseplate;
B = Potted with metal baseplate;
C = Potted baseplate with M3 treaded inserts;
U = Potted baseplate installed into U chassis;
A = Potted baseplate installed into U chassis with cover
F = Potted baseplate installed into U chassis with fan cover and lid.

CONNECTOR OPTIONS:
Blank = JST Connector fitted;
M = Molex Connector fitted.

FUSE OPTIONS:
Blank = Unit is dual fused for each supply line (L and N);
E = Unit is single fused in one supply line (L).

SIGNAL, STANDBY OPTIONS:
X2 = option board 2: 5V 2.0A standby supply, remote on/off (enable), dc good, ac fail, remote sense;
X3 = option board 3: 12V 0.83A standby supply, remote on/off (enable), dc good, ac fail, remote sense;
X5 = option board 5: 5V 2.0A standby supply, remote on/off (inhibit), dc good, ac fail, remote sense;
X6 = option board 6: 12V 0.83A standby supply, remote on/off (inhibit), dc good, ac fail, remote sense;

LEAKAGE CURRENT OPTIONS:

Blank for standard leakage <250µA
R = Reduced Leakage <150µA
T = Tiny Leakage <50uA;

FOR UNITS WITH NON-SAFETY RELATED CHANGES (Reduced OVP, current limit, etc.), the unit nomenclature is followed by "-NNNNL", where N is a string of numbers which identifies the unique requirement, and L is an optional letter starting with "A", which is incremented for any customer revision. Example: CUS400M-24/FE-0001A

FOR NON-STANDARD UNITS WHICH REQUIRE A SAFETY FILE UPDATE, the unit nomenclature is prefixed with “NS-”, and appended with “-NNNNL”, where N is a string of numbers which identifies the non-standard requirement. L is an optional letter starting with “A”, which is incremented for any customer revision. Example: NS-CUS400M-12/FE-0002A

POWER RATINGS

Input Parameters
Nominal input voltage: 100-240Vac
Input Voltage Range: 85-264Vac
Input Frequency Range: 47 – 63Hz
Maximum input current: 5.75Arms

All ratings apply for ambient temperatures up to 50°C (see variations and limitations below)Output power is reduced linearly by 10% for input voltages from 90 to 85Vac

Output Parameters
Maximum power output when provided with fan cover option (50 °C):

Model	Vout Range (V)	Max Iout (A)	Pout (W)	
12	12 – 13.2	33.33	400	
15	15-16.5	26.67		400
19	19-20.9	21.05		400
24	24 – 26.4	16.67	400	

28	28-30.8	14.29	400
36	36-39.6	11.11	400
48	48-52.8	8.33	400

Standby Options:

5	4.9 – 5.1	2	10
12	11.8 – 12.2	0.83	10

Power output for other configurations vary by chassis options and input voltages. See report enclosure Miscellaneous – (003) for derating based on chassis, input voltage and ambient temperatures.

Variations and limitations
Convection and conduction cooling, max ambient 70°C (Note 1)

Note 1. Maximum output power and current ratings are dependent on the ambient used in the end equipment.

Additional Information

The following method must be used for determining the safe operation of PSUs.
The components listed in the following table must not exceed the temperatures given. To determine the component temperatures the heating tests must be conducted in accordance with the requirements of the standard in question. Consideration should also be given to the requirements of other safety standards.
Test requirements include: PSU 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. To determine the most adverse conditions consideration should be given to the end use equipment maximum operating ambient, the PSU loading and input voltage, ventilation, end use equipment orientation, the position of doors & covers, etc.

Circuit Ref.	Description	Max. Temperature (°C)
L1	Choke	105
L2	Boost choke	105
L6, L7	Common Mode Choke	105
C1, C9, C13, C14, C15	Electrolytic Capacitors	105
C6, C7	X Capacitor	100
C5, C8, C10, C11, C12	Y Capacitors	105
C2 (option board, if fitted)	Y Capacitor	105
TX1	Transformer Winding	130
TX3 (option board, if fitted)	Transformer Winding	130
XU203, XU204	Opto-Coupler	110
XQ3	FET	130
J1	Input Connector	105

Technical Considerations

- The product was investigated to the following standards:

  Main Standard(s):

  IEC 60601-1 Edition 3.1 (2012)

  From Country Differences:

  - Austria: EN 60601-1:2006/A1:2013
  - Republic of Korea: KS C IEC 60601-1
  - USA: ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)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))
- Israel: SI 60601 Part 1 (2018-06)

Additional Standards:

EN 60601-1:2006/A1:2013, KS C IEC 60601-1, ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, BS EN 60601:2006 A1, SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014

- The following additional investigations were conducted: N/A
- The product was not investigated to the following standards or clauses: 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 (ME Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems), Clause 17 (Electromagnetic Compatibility).

  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
  Annex Z of EN standards for compliance with the MDD
- The following accessories were investigated for use with the product: None.
- • 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
  • Manufacturer's Recommended Ambient: 50°C
  • Options included: See model differences.

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:
For use only in or with complete equipment where the acceptability of the combination is determined by

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

• Considerations to the applied parts requirement, to be conducted as end-product

•. The need for airflow across units not provided with a fan shall be determined as part of the end-product evaluation.

• Attention to the temperature limit or the components below and shall be considered in the end-use application when determining the appropriate level of airflow across the unit.

Circuit Ref.	Description	Max. Temperature (°C)
L1	Choke	105
L2	Boost choke	105
L6, L7	Common Mode Choke	105
C1, C9, C13, C14, C15	Electrolytic Capacitors	105
C6, C7	X Capacitor	100
C5, C8, C10, C11, C12	Y Capacitors	105
C2 (option board, if fitted)	Y Capacitor	105
TX1	Transformer Winding	130
TX3 (option board, if fitted)	Transformer Winding	130
XU203, XU204	Opto-Coupler	110
XQ3	FET	130
J1	Input Connector	105

• The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).

• The input/output connectors are not acceptable for field connections, they are only intended for factory wiring inside the end-use product.

• 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 patient protection)/MOOP (means of operator protection):
2 MOPP based upon a working voltage 240 Vrms, 620 Vpk between Primary to Secondary,
1 MOPP based upon a working voltage 240 Vrms, 571 Vpk between Primary and Earth, and
1 MOPP based upon a working voltage 240 Vrms between Secondary and Earth (or Secondary side mounting holes).

• Class I Implementation - the power supply shall be reliably earthed (bonded) to the end-product main protective earthing system

• Class II implementation - no earthing connection is required. The power supply shall be fixed so that it is insulated from any unearthed accessible conductive part by reinforced insulation.

• The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 50°C at Full Load and 70°C at Half Load.

• Magnetic devices TX1 (12V & 24V Models) and TX3 (12V & 24V Models) employ a Class F (155°C) or higher insulation system. See Critical component list for details.

• The PWB is rated 130°C.

• The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.

• Additional fusing may be required in the end product to meet the requirement of Cl. 8.11.5, Mains fuses and Over Current Release. The product is tested and provided with dual fuses. Single fuse model is

provided with a model designation identifier “E” – See Model differences for details.

• 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 t to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1, F2)

• 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.

• Exposure Condition outside of Humidity Range: Power Supply tested in 30°C, 93%RH. End product Risk Management Process to determine risk acceptability criteria.

• Insulating Materials: 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.

• Not tested with Test Corner: 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.

• Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.

• End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.

• Units with Enclosures: End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted 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.

• End product to determine the acceptability of risk in conjunction to the use of Thermal Cut-off and Overcurrent releases as part of the power supply

• The following end-product enclosures are required: Mechanical, Fire, Electrical

• 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.

• All models require component temperatures to be monitored as detailed in the additional information.

• All models were evaluated with the largest capacitors installed. Models with suffix “R” or “T” designating lower leakage currents were not investigated. The capacitance values for the low leakage models are not described in this report. If lower leakage values are required in the end product, consideration shall be given to identifying the capacitors installed in the power supply.

• Impairment of cooling test in accordance with Cl 13.2.7 was not conducted. The end product employing the fan model (with suffix "F") shall consider conducting this test.

Report Modifications

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2019-10-29	The manufacturer submitted representative production sample(s) of CUS400M-12 and the CUS400M-24. Only limited testing was considered based upon previous evaluation under the CB Scheme. The CB Scheme Test Certificate: CB-DK-88353-UL and Report Ref. No. E135494-A6007-CB-1, Issue Date: 2019-10-04, was prepared by UL (Demko), Borupvang 5A DK-2750 Ballerup, DENMARK. The following test(s) we’re waived based on the CB report referenced above - tested to IEC 62368-1:2014 - and considered representative of the following IEC 60601-1:2005+A1:2012 test(s) : Cl 8.5.4 – Working Voltage Measurements (IEC 62368-1, Clause 5.4.1.8) Cl 8.6.4 – Impedance and Current-Carrying Capability Test (IEC 62368-1, Cl 5.6.6.2) Cl 11 – Temperature Tests (IEC 62368-1, Cl 6.3) 13 – Single Fault Conditions (IEC 62368-1, Annex B.4) The following Tests were conducted at UL Brea, 2929 E. Imperial Highway, Suite 100 Brea CA 92821 USA during this investigation and stored in Test Reference Supplements - (003) & (004) : Cl 4.11 – Input Test Cl 5.7 – Humidity Conditioning Cl 8.4.3 – Voltage Limitation Cl 8.7 – Leakage Current Tests Cl 8.7.4.5 – Earth Leakage Cl 8.7.3 e) – Non-Frequency-Weighted Leakage Current Cl 8.8.3 – Dielectric Voltage Withstand Test Cl 13 – Abnormal Operation Testing Cl 15.5.1.2 – Transformer Short Circuit Test Cl 15.5.1.3 – Transformer Overload The results of this investigation, including construction review and testing, indicate that the products evaluated comply with the applicable requirements in the standard(s) referenced in the first page of this report and, therefore, such products are judged eligible to bear UL's Mark as described on the Conclusion Page of this Report.	Ahmad Daoudi
2020-07-31	Reissue 1: This report is a reissue of CBTR Ref. No. E348673-D1011-1/A0/C0, CB Test Certificate Ref. No. US-34728-UL. based on previously conducted testing and the review of product construction, only following tests were deemed necessary: Power Input, Humidity Conditioning, Leakage Current Test , Dielectric Strength Test, Temperature Test, Abnormal	Maciej Kostalkowski

	Operation Test , Transformer Short and Overload Test. Report is issued to include 15V, 19V, 28V, 36V, 48V output options, new pcb, new thermistor. NCB has changed due to location of CBTL performing testing.	
2020-08-25	Technical Amendment 1: This is a technical amendment of CBTR Ref. No. E348673-D1011-2/A0/C0, CB Test Certificate Ref. No. DK-101446-UL. The report is issued to include correct current ratings of 12VDC and 24VDC model. Based on the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, has been determined that the product continues to comply with the standard. No tests conducted under this investigation. All required tests were carried out under the original investigation.	Maciej Kostalkowski
2020-11-27	Technical Amendment 2: This is a technical amendment of CBTR Ref. No. E349607-D1011-2/A1/C0, CB Test Certificate Ref. No. DK-101446-M1-UL. The report is issued to include additional supplier Axis Corporation to transformer components: - TX1 Transformer 12V - TX1 Transfomer 15V - TX1 Transfomer 19V - TX1 Transformer 24V - TX1 Transformer 28V - TX1 Transformer 36V - TX1 Transformer 48V - TX3 Transformer 5V, 2A - TX3 Transformer 12V, 1A Addition of new Manufacturing Facility Trio-Tronics, (Thailand) Based on the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, has been determined that the product continues to comply with the standard. No tests conducted under this investigation. All required tests were carried out under the original investigation.	Grzegorz Kowalski