Test Report issued under the responsibility of:

| IEC 60601-1<br>Medical electrical equipment<br>Part 1: General requirements for basic safety and essential performance | |
|---|---|
| Report Reference No. ..... : | E349607-D1011-1/A0/C0-UL |
| Date of issue ..... : | 2019-10-10 |
| Total number of pages ..... : | 160 |
| Testing Laboratory ..... : | UL Brea |
| Address ..... : | 2929 E. Imperial Hwy, Suite 100, Brea, CA, 92821, USA |
| Applicant's name ..... : | TDK-LAMBDA UK LTD |
| Address ..... : | Kingsley Avenue<br>Ilfracombe, Devon, EX34 8ES UNITED KINGDOM |
| Test specification: | |
| Standard ..... : | IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012<br>(or IEC 60601-1: 2012 reprint) |
| Test procedure ..... : | UL Certification |
| Non-standard test method…….: | N/A |
| Test Report Form No..... : | IEC60601_1K |

**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 UL testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting UL.

| | |
|---|---|
| Test item description: | Switch Mode Power Supply |
| Trade Mark: | N/A |
| Manufacturer: | Same as Applicant |
| 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<br><br>Output:<br>CUS400M-12 output: 12-13.2Vdc 33.5A<br>CUS400M-24 output: 24-26.4Vdc 16.7A<br><br>Each output has a range shown in the table above which is factory configurable only. |

| | | |
|---|---|---|
| Testing procedure and testing location: | | |
| [X] UL/DAP Testing Laboratory: | | |
| Testing location/ address: | UL Brea<br>2929 E. Imperial Hwy, Suite 100, Brea, CA, 92821, USA | |
| Tested by (name, function, signature): | Ahmad Daoudi, Project Handler |  |
| Approved by (name, function, signature): | Mitchell McGarry, Project 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 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) .....: | 2019-08-04 to 2019-10-04 |
| Dates tests performed .....: | 2019-09-23 to 2019-10-07 |
| 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**

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.

The CUS400M is a power supply for building-in to end product equipment. It is available as open frame, baseplate, U chassis, and U chassis and lid.
The power supply can be used as either a Class I or a Class II construction.
- For Class I construction, the power supply will need to be reliably earthed, professionally installed and fixed with suitable, metal screws.
-For Class II construction no earthing connection is required. The power supply needs to be fixed so that it is insulated from any unearthed accessible conductive part by reinforced insulation.
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. Due to the fact that air flow for cooling depends on end product use, only convection cooling were considered during temperature measurement.

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

**Model Differences**

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, or non-safety related model differences:
Blank = Open frame with potted baseplate; B = Unit provided with metal baseplate;
C = Unit provided with M3 threaded inserts for underside mounting; U = Unit provided with U chassis;
A = Unit provided with U chassis and cover;

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 1.0A 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 1.0A 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

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

| Model | Vout Range (V) | Max Iout (A) | Pout (W) |
|---|---|---|---|
| 12 | 12 – 13.2 | 33.5 | 400 |
| 24 | 24 – 26.4 | 16.7 | 400 |

Options

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

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. Temperatures should 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 should be run until all temperatures have stabilised.

| 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):

  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:

- 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, 448 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).

• Proper bonding to the end-product main protective earthing termination is required for Class 1 implementation.

• 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 32°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