

# Underwriters Laboratories (UL LLC) Safety Report



**Model:** EFE400Mxy-a-b-cdef-gh-i-j-klm or EFE-400M-a-b-cdef-gh-i-j-klm  
Units may be marked with a Product Code: U6x or Y6x where x may be any number of characters.  
Unit Configuration Code (Description :) may be prefixed by NS # followed by / or - (where # may be any number of characters indicating non- safety related model differences).  
Unit Configuration Code (Description :) may be prefixed by SP followed by / or (SP represents a sales code)  
Where:  
x = blank or J  
y = blank, P or D  
a = Channel one output voltage and can be from 11.4 to 50  
b = Standby voltage 5 or 12  
c = BC, HN, HU, HC, EC, NN, NU, NC, HP, NP or TF  
d = M or S  
e = D, F, E or G  
f = L, R, T or Z  
g = Y or N  
h = T, E or N  
i = V or blank  
j = blank, xD, xPD  
klm = number from 0-9 or Blank

Non-standard models  
Y60001#

**Device Description:** Medical Switch Mode Power Supply  
**Applicant:** TDK-LAMBDA UK LTD  
KINGSLEY AVE, ILFRACOMBE DEVON  
EX34 8ES UNITED KINGDOM  
**Manufacturer:** Same as Applicant

**Manufacturing Facility(ies):** Same as Applicant

PANYU TRIO MICROTRONIC CO., LTD,  
SHIJI INDUSTRIAL ESTATE, DONGYONG, NANSHA  
GUANGZHOU, GUANGDONG CHINA

Trio-Tronics (Thailand) Ltd.  
7/295 Mu. 6, Map Yang Phon Sub-District  
Pluak Daeng District, Rayong Province Thailand

**Report No.:** E349607-D1040-1/A1/C0-ULCB  
**Report (Re)Issue Date:** 2024-11-06; 2025-10-22 A1

**Base Standard(s):** AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021, CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to

CAN/CSA-C22.2 No. 60601-1:14, IEC 60601-1:2005, AMD1:2012,  
AMD2:2020

Additional Standards: EN 60601-1:2006/A2:2021 (IEC60601-1, Edition 3.2)

Report Types: This report consists of the following report types:

- [ Yes ] US Certification (UL Recognition)
- [ Yes ] CAN Certification (cUL Recognition)
- [ Yes ] CB Report & Certificate
- [ No ] IEC/EN Informative Report

This report covers the Safety evaluation of the referenced model(s) according to the standard(s) specified above.

The **CB Certificate** is provided as a separate enclosure to this report and not provided in the body of this report.

**Table of Contents**

**REPORT CONTENTS:** ..... 1

  Test Report ..... 1

    TABLE: List of critical components ..... 178

**APPENDIX A: Enclosures** ..... 1

  Collateral/Particular Standard Enclosures ..... 1

  Other Enclosures ..... 2

**UL CERTIFICATION DOCUMENTATION:** ..... 1

**APPENDIX B: UL Certification Documentation** ..... 1

    Test Record ..... 2

    ML Correlation Sheet ..... 2

**APPENDIX C: Follow-Up Service Documentation (Page Section: C)** ..... 1

    Follow-Up Service Procedure ..... 1

    UL Appendix: ..... 5

      GENERIC INSPECTION INSTRUCTIONS ..... 5

      INSTRUCTIONS AND DUTIES FOR UL REPRESENTATIVE ..... 6

      INSTRUCTIONS FOR FOLLOW-UP TESTS AT UL ..... 12

      RESPONSIBILITIES AND REQUIREMENTS FOR MANUFACTURER ..... 13

      GENERAL TERMINOLOGY ..... 18

      GENERAL PRODUCT CONSTRUCTION REQUIREMENTS ..... 19

      UL CERTIFICATION MARK ..... 27

    Description ..... 28

      Markings and instructions ..... 35

      Special Instructions to UL Representative ..... 35

      Production-Line Testing Requirements ..... 35

      TABLE: List of Critical Components ..... 37

**TEST RESULTS:** ..... 1

**APPENDIX D: Test Datasheets Enclosures (Page Section: B)** ..... 1

## Report Modifications Summary

The following changes were made to this report. If none listed in the below table, this report is the originally issued report.

The following scheme is used throughout this report to reflect the **Report No.**:

(File No.) – (Report Ref. No.) – (x) / A(y) / C(z) – YYY, where:

(x) = Report (Re)Issue No.

(y) = Amendment No.

(z) = Correction No.

YYY = Report Type (UL/CB/IEC)

*NOTE: The **CB Certificate** may not be updated for report corrections that don't affect the CB Certificate contents; therefore if this report includes a correction number (z), it may not be reflected in the CB Certificate.*

Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By
2024-11-06	<p>This report is reissued based on -            -CBTR Ref. No. E349607-D1012-1/A0/C0-CB, issued 2019-10-06, CB Test Certificate Ref. No. DK-88676-UL, Issued 2019-10-06            -CBTR Ref. No. E349607-D1012-1/A1/C0-CB, issued 2020-03-31, CB Test Certificate Ref. No. DK-88676-M1-UL, Issued 2020-04-09,            -CBTR Ref. No. E349607-D1012-1/A2/C0-CB, issued 2022-08-18, CB Test Certificate Ref. No. DK-88676-M2-UL, Issued 2022-08-18, CB Test Certificate Ref. No. DK-88676-A1-UL, Issued 2022-08-25,            -CBTR Ref. No. E349607-D1012-1/A3/C0-CB, issued 2024-09-17, CB Test Certificate Ref. No. DK-88676-M3-UL, Issued 2024-09-20, CB Test Certificate Ref. No. DK-88676-A1-UL, Issued 2022-08-25, with the following changes:</p> <ol style="list-style-type: none"> <li>1. Upgrade standard to IEC 60601-1:2005, AMD1:2012, AMD2:2020 ; ANSI/AAMI ES60601-1:2005, AMD1:2012, AMD2:2021 CAN/CSA C22.2 No.60601-1:14 + AMD2:2022</li> <li>2. Add Japan ND</li> <li>3. Updated Letter to UL for factory locations and samples for EFE400M series in Report Enclosure - Miscellaneous</li> </ol> <p>Based on previously conducted testing and the review of product construction, no tests were considered necessary:</p>	Steve Chiu
2025-10-22	<p>Project 4791915350</p> <p>Technical Amendment 1</p> <p>The original report was modified on 2025-10-10 to include the following changes/additions:            This report has been amended (technical amendment), due to the LoCC list being updated as follows:            - Add alternate Fan source, Type YS Tech FD124020UB-H-NCB 12V, 0.22A DC Brushless Fan            - Add alternate Fan source, Type YS Tech FD124020UB-H-NAH 12V, 0.27A DC Brushless Fan            - Add prefix PSE to TX1 transformer in model description</p>	Kamil Janeczek



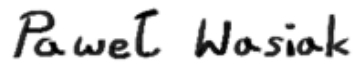
	<ul style="list-style-type: none"><li>- Add prefix PSE to TX2 transformer in model description and update overall dimensions in LoCC</li><li>- Add prefixes to TX3 transformer in model description</li></ul> <p>Based on previously conducted testing and the review of product construction, only the following tests were deemed necessary:</p> <ul style="list-style-type: none"><li>8.8.3 – Dielectric Voltage Withstand</li><li>11 – Temperature</li><li>13.2 - Locking of Moving Parts</li></ul> <p>Fixed errors resulting from the update of the report from version 3.1 Standard 60601:</p> <ul style="list-style-type: none"><li>- removed reference from Report E349607-D1012 on the basis of which the E349607-D1040 report was upgraded</li><li>- Test Tables updated due to the Report upgrade</li></ul>	

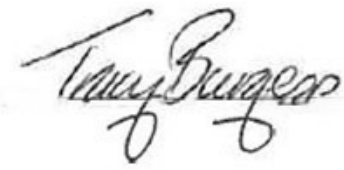


Test Report issued under the responsibility of:



<b>TEST REPORT</b> <b>IEC 60601-1</b> <b>Medical Electrical Equipment</b> <b>Part 1: General requirements for basic safety and essential performance</b>	
<b>Report Number</b> .....	E349607-D1040-1/A1/C0-ULCB
<b>Date of issue</b> .....	2024-11-06; 2025-10-22 A1
<b>Total number of pages</b> .....	191
<b>Name of Testing Laboratory preparing the Report</b> .....	UL VS Limited Unit 1 – 3 Horizon, Wade Road Kingsland Business Park Basingstoke RG24 8AH United Kingdom
<b>Applicant's name</b> .....	TDK-LAMBDA UK LTD
<b>Address</b> .....	KINGSLEY AVE, ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
<b>Test specification:</b>	
<b>Standard</b> .....	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
<b>Test procedure</b> .....	CB Scheme
<b>Non-standard test method</b> .....	N/A
<b>TRF template used</b> .....	IECEE OD-2020-F1:2020, Ed.1.3
<b>Test Report Form No.</b> .....	IEC60601_1U
<b>Test Report Form(s) Originator</b> .....	UL(US)
<b>Master TRF</b> .....	2023-08-24
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<b>General disclaimer:</b>	
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 NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.	

<b>Test item description</b> .....:	Medical Switch Mode Power Supply	
<b>Trade Mark(s)</b> .....	Trademark image(s):  	
<b>Manufacturer</b> .....	Same as Applicant	
<b>Model/Type reference</b> .....:	<p>EFE400Mxy-a-b-cdef-gh-i-j-klm or EFE-400M-a-b-cdef-gh-i-j-klm  Units may be marked with a Product Code: U6x or Y6x where x may be any number of characters.  Unit Configuration Code (Description :) may be prefixed by NS # followed by / or - (where # may be any number of characters indicating non- safety related model differences).  Unit Configuration Code (Description :) may be prefixed by SP followed by / or (SP represents a sales code)  Where:  x = blank or J  y = blank, P or D  a = Channel one output voltage and can be from 11.4 to 50  b = Standby voltage 5 or 12  c = BC, HN, HU, HC, EC, NN, NU, NC, HP, NP or TF  d = M or S  e = D, F, E or G  f = L, R, T or Z  g = Y or N  h = T, E or N  i = V or blank  j = blank, xD, xPD  klm = number from 0-9 or Blank</p> <p>Non-standard models  Y60001#</p>	
<b>Ratings</b> .....:	100-240Vac nom, 45-63Hz, 6.1A rms max. (See Model Differences for details of ratings)	
<b>Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):</b>		
<input checked="" type="checkbox"/>	<b>CB Testing Laboratory:</b>	
<b>Testing location/ address</b> .....	UL VS Limited Unit 1 – 3 Horizon, Wade Road Kingsland Business Park Basingstoke RG24 8AH United Kingdom	
<b>Tested by (name, function, signature)</b> .....	Kamil Janeczek, Project Handler	
<b>Approved by (name, function, signature)</b> .. :	Grzegorz Kowalski, Reviewer	
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 1:</b>	
<b>Testing location/ address</b> .....		

<b>Tested by (name, function, signature) .....</b> :		
<b>Approved by (name, function, signature) ..</b> :		
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 2:</b>	
<b>Testing location/ address .....</b> :		
<b>Tested by (name, function, signature) .....</b> :		
<b>Witnessed by (name, function, signature) ..</b> :		
<b>Approved by (name, function, signature) ..</b> :		
<input checked="" type="checkbox"/>	<b>Testing procedure: CTF Stage 3:</b>	
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 4:</b>	
<b>Testing location/ address .....</b> :		TDK-Lambda UK Limited Kingsley Avenue, Ilfracombe Devon, EX34 8ES United Kingdom
<b>Tested by (name, function, signature) .....</b> :		M.Gisbey, Tester 
<b>Witnessed by (name, function, signature) ..</b> :		Mark John De Sagun, Engineer See the original CBTR for signatures
<b>Approved by (name, function, signature) ..</b> :		Tracy Burges , Approver 
<b>Supervised by (name, function, signature) :</b>		Kamil Janeczek, Handler 

**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):**

*Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.*

**Testing location:**

*Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.*

**Summary of compliance with National Differences (List of countries addressed):**

List of countries addressed: United States of America, Canada

The product fulfils the requirements of AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021, CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14.

**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.*

<b>Test item particulars .....</b>	
<b>Classification of Installation and Use:</b>	For building in
<b>Supply Connection:</b>	For building into host equipment
<b>Device type (component/sub-assembly/ equipment/ system):</b>	Component
<b>Intended use (Including type of patient, application location):</b>	To supply regulated power
<b>Mode of Operation:</b>	Continuous
<b>Accessories and detachable parts included:</b>	None
<b>Other Options Include:</b>	None
<b>Supply Connection</b>	For building into host equipment
<b>Possible test case verdicts:</b>	
- test case does not apply to the test object .....	N/A
- test object does meet the requirement .....	P (Pass)
- test object was not evaluated for the requirement.....	N/E (collateral standards only)
- test object does not meet the requirement .....	F (Fail)
<b>Abbreviations used in the report:</b>	
- normal condition .....	N.C.
- means of Operator protection .....	MOOP
- single fault condition.....	S.F.C.
- means of Patient protection .....	MOPP
<b>Testing .....</b>	
<b>Date of receipt of test item .....</b>	2014-11-21 and 2019-06-03, 2021-11-25, 2019-06-03, 2021-11-25, 2022-01-10, 2023-04-05, 2023-10-16 to 2023-12-21, 2025-08-05
<b>Date(s) of performance of tests .....</b>	2014-12-01 to 2015-01-15 and 2019-06-11, 2021-12-13 to 2022-01-18, 2023-07-23, 2023-12-21 to 2024-06-04, 2025-08-05
<b>General remarks:</b>	
"(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 <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	
<b>Manufacturer's Declaration per sub-clause 4.2.5 of IEC60601-1:</b>	
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
<b>When differences exist; they shall be identified in the General product information section.</b>	
<b>Name and address of factory (ies).....</b>	Same as Applicant
PANYU TRIO MICROTRONIC CO., LTD,	

SHIJI INDUSTRIAL ESTATE, DONGYONG,  
NANSHA  
GUANGZHOU, GUANGDONG CHINA

Trio-Tronics (Thailand) Ltd.  
7/295 Mu. 6, Map Yang Phon Sub-District  
Pluak Daeng District, Rayong Province Thailand

### General product information and other remarks:

#### Report Summary

refer to Report modification

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

#### Product Description

Medical Switch Mode Power Supply (see Model Differences for details of models and nomenclature)

- 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.
- Options include a variable speed (temperature controlled) fan.
- Multilayer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report Enclosure 8-05 of this report.

1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:

- Clause 7.5 (Safety Signs),
- Clause 7.9 (Accompanying Documents),
- Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
- Clause 10 (Radiation),
- Clause 14 (PEMS),
- Clause 16 (ME Systems)
- Risk Management was excluded from this investigation.

2. Risk Controls/ Engineering Considerations for component power supply:

For use only in or with complete equipment where the acceptability of the combination is determined by the CB Testing Laboratory, when installed in an end-product, consideration must be given to the following:  
For Power Supplies with No RM: End product Risk Management Process to include consideration of requirements specific to the Power Supply.

#### Model Differences

EFE400Mxy-a-b-cdef-gh-i-j-klm or EFE-400M-a-b-cdef-gh-i-j-klm models as described below:

Units may be marked with a Product Code: U6x or Y6x where x may be any number of characters.

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

Unit Configuration Code (Description :) may be prefixed by SP followed by / or - (SP represents a sales code)

Unit Configuration Code: EFE400Mxy-a-b-cdef-gh-i-j-klm where:

TRF No. IEC60601\_1U

x = Nothing or J for Japanese models (may have non-safety differences).

y = Blank for Y2 capacitors from output to earth P for Y1 capacitors from output to earth  
D for Class II (with Y1 capacitors)

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

b = Standby voltage: see standby voltage in table below.

c = BC for cover and U chassis without fan grill, with fan fitted (temperature controlled). (Y60001x model only)

HN for Open frame, no fan, with 12V / 1A fan supply.

HU for U chassis (not EFE400MxD models), no fan, with 12V / 1A fan supply.

HC for Cover + chassis (not EFE400MxD models), no fan, with 12V / 1A fan supply.

EC for Cover + chassis (not EFE400MxD models), end fan (temp controlled).

NN for Open frame, no fan, no fan supply.

NU for U chassis (not EFE400MxD models), no fan, no fan supply.

NC for Cover + chassis (not EFE400MxD models), no fan, no fan supply.

HP for perforated cover, no fan, with 12V / 1A fan supply.

NP for perforated cover, no fan, no fan supply.

TF for Cover + chassis (not EFE400MxD models), top fan (fixed speed)

d = M for Molex KK type 41791 input connector or equivalent.

S for Molex Sabre type 43160 input connector or equivalent.

e = D for AC input with dual fusing.

F for AC/DC input with dual fusing.

E for single fuse input in the Live line.

G for single fuse input in the + line

f = L for low Leakage.

R for reduced Leakage.

T for tiny Leakage.

Z for EFE400MxD models (Class II).

where L < 300uA leakage, R < 150uA leakage and T < 75uA leakage.

g = Y for Oring FET included.

N for no Oring FET.

h = T for inhibit.

E for enable.

N for no remote signals

i = V for vertical output connector or nothing for horizontal output connector.

j = Nothing for standard channel 1 output voltage, xD or xPD where D is for units with programmed negative load regulation, PD is for units with programmed positive load regulation, x is the voltage of the regulation in 100mVolts and is within the Output Adjustment range (example, 7D = 0.7V of negative load regulation, 18PD = 1.8V of positive load regulation).

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

#### Input Parameters

Standard	60601-1
Nominal input voltage	100 - 240 Vac
Input voltage range	90 - 264Vac*
Input frequency range	45 - 63Hz
Maximum input current	6.1A rms

\* Input de-rated, see variations and limitations below.

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

#### Output Parameters

There are three EFE400M standard models and two non-standard models with various options and output parameters shown in the tables below.

#### Standard models:

	Vout Nom.	Adjustment Range (V)	Output Current (A)	Maximum Power (W)
Output Channel 1	12	11.4 - 13.2*	33.33	400 (530**)
	24	22.8 - 26.4*	16.67	400 (530**)
	48	47 - 50*	8.33	400 (470**)
Fan output (optional)	12	12	1	12
	5	5	2	10
	12	12 - 12.2*	1	12.2

#### Variations and limitations of use for Standard models:

1. Output power de-rated 1% per volt from 100V to 90V input (channel 1 power 360W at 90V input).
2. Output power further de-rated 2% per volt from 90V to 85V input (channel 1 power 320W at 85V input).
3. Maximum ambient 70°C (de-rating output power 2.5% per °C above 50°C).
4. \* Can be adjusted at the factory only.
5. Maximum continuous power output 400W (including fan output).
6. \*\* Peak power for 10 seconds maximum, maximum rms power of 400Wrms: Non-Standard Models: Non- Standard model: Y60001# (# can be any letter) (EFE400M-48-5-BCSDL-NT)

Output Channel	Vout Nom.	Adjustment Range (V)	Output Current (A)	Maximum Power (W)
Channel 1	48	47 to 50*	8.33	400
Standby output	5	fixed	2	10

#### Variations and limitations of use for Non- Standard model Y60001#:

1. Output power de-rated 1% per volt from 100V to 90V input. (e.g. channel 1 power 360W at 90V input)
2. Maximum ambient 50°C.
3. \* Can be adjusted at the factory only.

The limited testing of this report (see Report Modifications section) was conducted by TDKLAMBDA UK LTD in KINGSLEY AVE, ILFRACOMBE, EX34 8ES United Kingdom, under CTF Stage 3 Test Procedures for CB certification.

The following tests were selected as representative of the test program applicable to model covered by this CBTR:

- 8.8.3 Dielectric Voltage Withstand
- 11.1.1 Temperature Measurement
- 13 Abnormal Operation Testing (output short circuit)

These tests have been witnessed for models selected as representative of the standard covered by this report and the applicable test program.

#### Additional Information

Cooling for units with customer supplied air (all models except -BC and -EC) 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 give 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 stabilized.

Cooling for unit temperature table (see layout drawings below):

Circuit Ref.	Description	Max. Temperature (°C) †
J1	input connector	105 (75††)
C12, C8, C7	X cap	100
L1, L2	Common mode choke winding	130 (145)
L6	Series mode choke winding	130
TX1	Standby trx winding	130
U2, U3, U5, U6, U7	Opto-coupler	100
TX2	Primary, secondary windings and core	130
C5	Capacitor	85 (105)
C9	Boost capacitor	70 (105)
L3	Boost choke winding	130 (140)
L7	Channel 1 output choke	130
XQ225	Boost FET (ASY2 primary IMS)	125 (130)
Q2	Channel 1 output FET (ASY4 secondary IMS)	125 (130)
L8	Primary resonant choke (not 12V model)	130 (140)
J2	Output connector	105
XL701	fan output choke	110 (125)
C1, C11, C19, C20	Electrolytic capacitors	75 (105)

† The higher temperatures limits in brackets may be used but product life may be reduced. Cooling for units with customer supplied air (all models except -BC and -EC)

### Technical Considerations

- The product was investigated to the following standards:

#### Main Standard(s):

IEC 60601-1:2005, AMD1:2012, AMD2:2020

#### From Country Differences:

- United States of America: AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021

- Canada: CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14

#### Additional Standards:

EN 60601-1:2006/A2:2021 (IEC60601-1, Edition 3.2)

- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: Clause 4.2 RISK MANAGEMENT PROCESS, Clause 12.2 USABILITY, Clause 14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS, Clause 17 Electromagnetic Compatibility (IEC 60601-1-2) and Clause 11.7 Biocompatibility (ISO 10993-1)
- The following accessories were investigated for use with the product: None

- None

### Engineering Conditions of Acceptability

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

- 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: 396 Vrms, 922 Vpk, Primary-Earthed Dead Metal: 381 Vrms, 672 Vpk, Secondary outputs - Earthed Dead Metal: 240Vrms, 340Vpk.
  - The following secondary output circuits are SELV: All
  - 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, fan output
  - 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
  - Proper bonding to the end-product main protective earthing termination is: Required
  - An investigation of the protective bonding terminals has: Been conducted
  - The following magnetic devices (e.g. transformers or inductor) are provided with a Class F (155°C) insulation system: Transformer TX1 and TX2 - 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 the indicated maximum temperature measurements during component-level testing: Models without a fan require component temperatures monitored as detailed in the Additional Information.
- For open frame models H4 is the PWB fixing point connecting to J1 protective earth.
  - The equipment has been evaluated as a Class 1 unit (and Class II for EFE400MxD models), but is not intended to be used to terminate the end equipment to the incoming mains supply. Need for PE marking shall be determined in the end product investigation.
  - No essential performance has been considered
  - The risk management requirements of the standard were not addressed and must be considered in the end product investigation.
  - Output circuits have not been evaluated for direct patient connection (Type B, BF or CF)
  - The product was submitted and evaluated for use at the maximum ambient temperature (Tma) permitted by the manufacturer's specification of: 70°C (output de-rated 2.5% per °C above 50°C).
  - Insulation separation between: Secondary and Earth is one MOPP: 240Vrms, 340Vpeak
  - Insulation separation between: Primary and Earth is one MOPP: 381Vrms, 672Vpeak
  - Insulation separation between: Primary and secondary is 2 MOPP: 396Vrms, 922Vpeak
  - Altitude of operation: 3000m
  - The perforated cover when fitted to the EFE400MxD models (Class II) must be treated as a live part with 1 MOPP insulation to primary and 1 MOPP insulation to secondary.
- Clause 8.7 Leakage Currents and Patient Auxiliary Currents for EFE400MxD models requires assessment in the end equipment.

### Report Modifications

Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By
2024-11-06	This report is reissued based on - -CBTR Ref. No. E349607-D1012-1/A0/C0-CB, issued 2019-10-06, CB Test Certificate Ref. No. DK-88676-UL, Issued 2019-10-06 -CBTR Ref. No. E349607-D1012-1/A1/C0-CB, issued 2020-03-31, CB Test Certificate Ref. No. DK-88676-M1-UL, Issued 2020-04-09, -CBTR Ref. No. E349607-D1012-1/A2/C0-CB, issued 2022-	Steve Chiu

	<p>08-18, CB Test Certificate Ref. No. DK-88676-M2-UL, Issued 2022-08-18, CB Test Certificate Ref. No. DK-88676-A1-UL, Issued 2022-08-25,          -CBTR Ref. No. E349607-D1012-1/A3/C0-CB, issued 2024-09-17, CB Test Certificate Ref. No. DK-88676-M3-UL, Issued 2024-09-20, CB Test Certificate Ref. No. DK-88676-A1-UL, Issued 2022-08-25, with the following changes:</p> <ol style="list-style-type: none"> <li>1. Upgrade standard to IEC 60601-1:2005, AMD1:2012, AMD2:2020 ;              ANSI/AAMI ES60601-1:2005, AMD1:2012, AMD2:2021              CAN/CSA C22.2 No.60601-1:14 + AMD2:2022</li> <li>2. Add Japan ND</li> <li>3. Updated Letter to UL for factory locations and samples for EFE400M series in Report Enclosure - Miscellaneous</li> </ol> <p>Based on previously conducted testing and the review of product construction, no tests were considered necessary:</p>	
2025-10-22	<p>Project 4791915350</p> <p>Technical Amendment 1</p> <p>The original report was modified on 2025-10-10 to include the following changes/additions:          This report has been amended (technical amendment), due to the LoCC list being updated as follows:</p> <ul style="list-style-type: none"> <li>- Add alternate Fan source, Type YS Tech FD124020UB-H-NCB 12V, 0.22A DC Brushless Fan</li> <li>- Add alternate Fan source, Type YS Tech FD124020UB-H-NAH 12V, 0.27A DC Brushless Fan</li> <li>- Add prefix PSE to TX1 transformer in model description</li> <li>- Add prefix PSE to TX2 transformer in model description and update overall dimensions in LoCC</li> <li>- Add prefixes to TX3 transformer in model description</li> </ul> <p>Based on previously conducted testing and the review of product construction, only the following tests were deemed necessary:</p> <p>8.8.3 – Dielectric Voltage Withstand          11 – Temperature          13.2 - Locking of Moving Parts</p> <p>Fixed errors resulting from the update of the report from version 3.1 Standard 60601:</p> <ul style="list-style-type: none"> <li>- removed reference from Report E349607-D1012 on the basis of which the E349607-D1040 report was upgraded</li> <li>- Test Tables updated due to the Report upgrade</li> </ul>	Kamil Janeczek