

Test Report issued under the responsibility of:



TEST REPORT IEC 60601-1

Part 1: General requirements for basic safety and essential performance

Report Number.....: E349607-D10

Date of issue.....: 2018-07-27

Total number of pages 182

Name of Testing Laboratory UL International Polska Sp. z o.o.

preparing the Report Aleja Krakowska 81, 05-090 Sekocin Nowy, Poland

Applicant's name: TDK-LAMBDA UK LTD

Address..... : KINGSLEY AVE, ILFRACOMBE,

DEVON, EX34 8ES UNITED KINGDOM

Test specification:

Standard: IEC 60601-1:2005 (Third Edition) + CORR. 1 (2006) + CORR. 2

(2007) + AM1 (2012) or IEC 60601-1 (2012 reprint)

Test procedure: CB Scheme

Non-standard test method: N/A

Test Report Form No.: IEC60601_1J_PS

Test Report Form(s) Originator....: UL(US) **Master TRF** 2014-09

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Test item description:	Switch Mode Power Supply				
Trade Mark	TDK-Lambda				
Manufacturer:	TDK-Lambda TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE				
	DEVON				
	EX34 8ES UNITED KINGDOM				
Model/Type reference: Ratings:	Vega 450, Vega 650, Vega 900, Vega Lite 550 and Vega Lite 750 models (see model differences for details of models and nomenclature) Vega 450 and Vega Lite 550. PSUs with cooling option F and without xEW and xFW options: Input voltage: 94.5-240 V ac nom., 85-264V ac max., 47-63 Hz, 8.5 Arms max. All other PSUs: Input voltage: 100-240 V ac nom., 90-264V ac max., 47-63 Hz, 8.5 Arms max. Vega 650, Vega Lite 750 and Vega 900. PSUs with cooling option F and without xEW and xFW options: Input voltage: 94.5-240 V ac nom., 85-264V ac max., 47-63 Hz, 12 Arms max. All other PSUs: Input voltage: 100-240 V ac nom., 90-264V ac max., 47-63 Hz, 11 Arms max.				
Testing procedure and testing location	on:				
☐ CB Testing Laboratory:					
Testing location/ address	:				
Associated CB Testing Laborate					
Testing location/ address	:				
Tested by (name + signature)	:				
Approved by (name + signature)	:				
	. 1				
Testing procedure: TMP/CTF Sta					
Testing location/ address	·······::				
Tested by (name + signature)	:				
Approved by (name + signature)	:				

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	Testing procedure: WMT/CTF Stage 2:			
Test	ing location/ address:			
Test	ed by (name + signature):			
Witn	essed by (name + signature):			
App	roved by (name + signature):			
\boxtimes	Testing procedure: SMT/CTF Stage 3 or 4:			
Test	ing location/ address:	TDK-LAMBDA UK LTD KINGSLEY AVE, ILFRA DEVON, EX34 8ES UNITED KINGDOM	COMBE	
Test	ed by (name + signature):	S. Hirstwood (Tester)	Sisturo	-1
Witn	essed by (name + signature):			
App	roved by (name + signature):	Krzysztof Wasilewski (Reviewer)	Knystof	Wasilewski
Sup	ervised by (name + signature):	Hima Chetty (Handler)	#	

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List of Attachments (including a total number of pages in each attachment):

Enclosure (22)

Summary of testing

Tests performed (name of test and test clause): Testing location:

Clause 11 Temperature TDK-Lambda UK

Clause 13 Abnormal Operation Testing Kingsley Avenue, Ilfracombe, Devon, EX34 8ES. UK

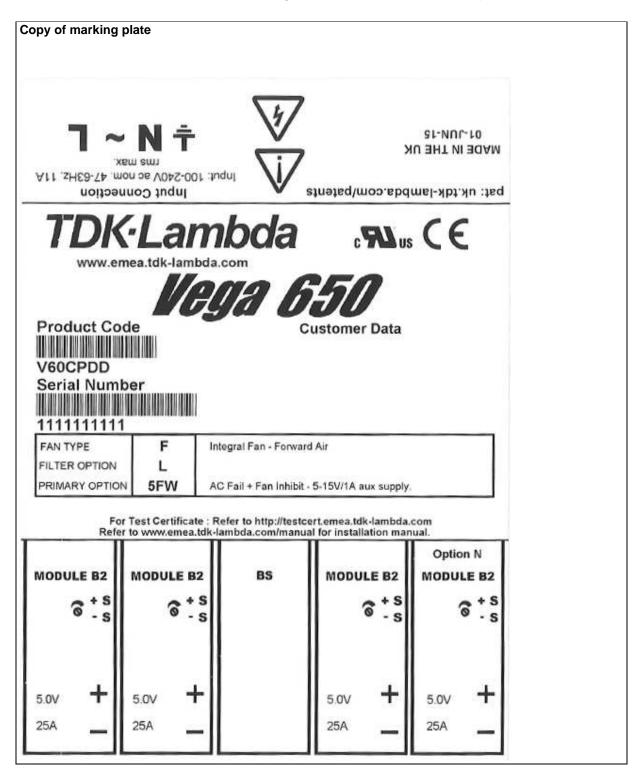
Summary of compliance with National Differences

List of countries addressed: AT, CA, GB, KR, SE, US

☐ The product fulfils the requirements of IEC60601-1:2005 + A1:2013, ANSI/AAMI ES60601-1:2005/C1:2009 and A2 2010, Canada - Differences to IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + A1 (2011); EN60601-1:2006/A12:2014.

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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 Intended use (Including type of patient, application location): To supply regulated power Mode of operation: Continuous Supply connection For building into host equipment Accessories and detachable parts included.....: None Other options include: None Testina 2018-06-05 Date of receipt of test item(s) 2018-06-06 to 2018-06-07 Dates tests performed: 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: - single fault condition.....: S.F.C. - normal condition: N.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 \square comma / \boxtimes point is used as the decimal separator. This Test Report Form is intended for the investigation of power supplies in accordance with IEC 60601-1:2005, 3rd edition + AM1. The Risk Management was excluded from the investigation; this shall be clearly identified in this report and on the accompanying CB Test Certificate. Additional test data and/or information may be provided in the attachments to this report.

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Manufacturer's Declaration per sub-clause 4.2.5 of I 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 □ Not applicable							
When differences exist; they shall be identified in the General product information section.								
Name and address of factory (ies):	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM PANYU TRIO MICROTRONIC CO., LTD,							
Concept was direct information.	SHIJI INDUSTRIAL ESTATE, DONGYONG, NANSHA, GUANGZHOU GUANGDONG CHINA							

General product information:

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Report Summary

The Original Test Report E349607-D10-CB-1 was modified on 2017-12-14 to include the following changes/additions:

- added alternate fan YEN SUN TECHNOLOGY CORP type FD126025HB rated 12V, 24.5cfm.
- CBTL changed to UL International Polska

After review no test deemed necessary.

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Product Description

 Vega 450, Vega 650, Vega 900, Vega Lite 550 and Vega Lite 750 are switch mode power supply units for building into host equipment.

Model Differences:

Vega 450, Vega 650, Vega 900, Vega Lite 550 and Vega Lite 750 are switch mode power supply units for building into host equipment. There are essentially 2 converters (450 and 650) and all units use the same modules. The Vega 450 and 550 use the 450 converter whilst the Vega 650, 750 and 900 use the 650 converter.

PRODUCTS COVERED

Vega models as described below:

Units may be marked with a Product Code: Ky*, KVy* or Vy* where y may be 4, 5, 6, 7 or 9 and * may be any series of numbers from 0 to 9 and/or any letters from A to Z.

 V4, V5, V6, V7, V9, Vega 450, Vega 650, Vega 900, Vega Lite 550, Vega Lite 750, Vega Smart or Vega Smart Plus

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Where V4 = Vega 450 range

> V5 = Vega Lite 550 range V6 = Vega 650 range V7 = Vega Lite 750 range V9 = Vega 900 range

Vega Smart = Vega 450 or 650 PSU with primary digital option fitted

Vega Smart Plus = Vega 450 or 650 PSU with primary and secondary digital options fitted

(may be prefixed by NS - # / or - where # may be up to any four letters and may be followed by -\$ where \$ may be any number between 000 to 999, indicating non-safety related model differences.

b) Followed by: A, C, D, E, F, R, Q or P

> Where F = Standard fan, forward airflow

> > R = Standard fan, reverse air Q = Quiet fan, forward airflow P = Quiet fan, reverse air C = Customer air

A = Custom models only

D* = Ruggedised fan, forward airflow E* = Ruggedised fan, reverse air

Optionally followed by: F, I or S c)

> Where F = Fast-on or quick connect input terminals

S = Screw input terminals

I = IEC input

d) Followed by: L, R, or T

> L = Low Leakage Where

> > R = Reduced Leakage

T = Tiny Leakage

e) Optionally followed by: E, F, EV, FV, EY, FY, xEW, xFW or D

Where E = AC fail with PSU & fan enable and 5V aux supply

F = AC fail with PSU & fan inhibit and 5V aux supply

EV = AC fail with PSU & fan enable and 5V/300mA aux supply FV = AC fail with PSU & fan inhibit and 5V/300mA aux supply

EY = AC fail with PSU & fan enable, 5V/300mA aux supply and fan fail signal

FY = AC fail with PSU & fan inhibit, 5V/300mA aux supply and fan fail signal

xEW = AC fail with PSU & fan enable and 5-15V/1A aux supply, where x = voltage setting xFW = AC fail with PSU & fan inhibit and 5-15V/1A aux supply, where x = voltage setting

D = Primary digital option. Provides PSU inhibit and enable, fan monitor, standby supply, hours of operation, serial numbers, mains fail, over temperature warning. When secondary digital options fitted also provides status bytes, unit and module IDs, grouping, digital voltage and current limit programming, secondary inhibit and enable, secondary turn on delay, global and secondary module good, module monitoring.

Modules

B@, C@, C1Y, D@, E@, F1, F2, H@/@ or @_@, L@, W2, W5, W8 & W9.

Where the letter represents a module and @ is a number between 1 and 5, which represents the number of turns on the transformer secondary. By reference to the following table, this in turn defines the permitted

^{*} These fans must not be used for user accessible applications.

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voltage range of the module.

@ may optionally be followed by the letter L or H, where L and H indicate the low or high output voltage variants of the module.

For W2, W5, W8 & W9 modules only: @ is followed by F, T, E or S

where F = Fixed OVP

T = Tracking OVP

E = Fixed OVP, high current output

S = Tracking OVP, high current output

Followed by F or S, where F indicates fast-on output terminals and S indicates screw output terminals.

or Z#

Where # is a number between 1 and 99. This code represents any two of the above modules that have had their outputs paralleled together. The number # is a module reference number and does not represent the number of turns. May optionally followed by F or S, where F indicates fast-on output terminals and S indicates screw output terminals.

or BB@, CC@, DD@, EE@, HH@/@ or @ @, JJ@/@ or @ @, LL@, C5B4 or B5B4

where @ is a number between 1 and 5, which represents the number of turns on the transformer secondary. For HH@/@ or @_@ the code represents one H module that has had its two outputs connected in series. For all other variants this code represents two modules, selected from those listed above, that have had their outputs connected in series. May optionally followed by F or S, where F indicates fast-on output terminals and S indicates screw output terminals.

Note: Seriated outputs may make all outputs hazardous, see Electrical & Thermal Ratings section for details. JJ@/@ or @_@ modules are HH@/@ or @_@ modules with reduced OVP and/or current ratings.

or X1, X2, X4, X8, XR1, XR2, XR4 & XR8

Where the number relates to the maximum voltage capability of the X or XR module (voltage rating is 10 multiplied by the number). The X or XR modules are connected to the output terminals of B, D, E or W modules, which may be connected in series or parallel. The X and XR modules contains diodes in series with their output (for paralleling use). The X module also has additional circuitry for remote sense, paralleling with other X modules and module inhibit. A maximum of two X or XR modules may be fitted in a PSU.

or B/S where B/S indicates that a blanking plate is fitted in place of a module.

Any of the above modules (except the X and XR modules) may have the module letter preceded with # or #/# where # is represents the module output voltage.

Module Options:

N, E, P, R, T, L, K, D, V‡ or R‡

Where N = Inhibit, module good and remote sense.

E = Enable, module good and remote sense

P = Parallel with current share

R = Remote sense (twin output modules only)

T = Remote sense (one output of twin output modules only)

L = Module good using LED indication

K = Allows for Vega products to be paralleled with Omega products

D = Secondary digital option (may only be fitted to single output modules). Provides analogue

voltage and resistive programming, current limit modes, inhibit output, enable output, turn on delay, module good, N+1 paralleling.

V‡ = Voltage programmable output voltage
R‡ = Resistance programmable output voltage

Where ‡ represents a number between 1 and 99. Each number indicates an option variant which does not affect safety, of these the following are standard variants:

- 1 = Inhibit, fixed current limit
- 2 = Inhibit, programmable current limit
- 3 = Enable, fixed current limit
- 4 = Enable, programmable current limit

May additionally be marked with K4x, K5x, K6x, or V4x, V5x, V6x, V7x, V9x where x can be up to 5 digits of any letter or number between 0 and 9 indicating non-safety related model differences.

ELECTRICAL & THERMAL RATINGS:

Output modules:

Module	O/P V	Rated I	Р	Slots	Turns	A/T
B1L	1 - 3.8V	20A	76W	1	1	20
B1H	2 - 5.5V	20A	110W	1	1	20
B2	3 - 9V	25A	225W	1	2	50
B3	9.1 - 16.2V	12A	195W	1	3	36
B4	16.3 - 21.5V	10A	215W	1	4	40
B5	21.6 - 31V	6A	186W	1	5	30
C1	1 - 4.1V	35A	144W	1	1	35
C1Y	1 - 4.1V	40A	164W	1	1	40
C3	9.1 - 16.2V	18A	292W	1	3	54
C4	16.3 - 21.5V	14A	301W	1	4	56
C5	21.6 - 31V	10A	310W	1	5	50
D1L	1 - 3.8V	50A	190W	1.5	1	50
D1H	3.9 - 5.5V	50A	275W	1.5	1	50
D2	3.8 - 9V	45A	405W	1.5	2	90
D3	8 - 16.5V	24A	396W	1.5	3	72
D4	14 - 21.5V	18A	387W	1.5	4	72
D5	21 - 28V	15A	420W	1.5	5	75
E1	1 - 3.8V	60A	228W	2	1	60
E2	3.8 - 8V	60A	480W	2	2	120
E3L	8 - 13.9V	40A	556W	2	3	120
E3H	14 - 15V	36A	540W	2	3	108
E4	14 - 19.9V	30A	597W	2	4	120
E5L	20 - 24V	27A	648W	2	5	135
E5H	24 - 28V	25A	650W	2	5	125
F1	1 - 3.8V	80A	640W	2	1	80
F2	3.8 - 8V	80A	640W	2	2	160
H1L/1L	1-3.8/1-3.8V	12A/8A	46W/31W	1	1/1	12/8
H1L/1H	1-3.8/3.9-5.5V	12A/8A	46W/44W	1	1/1	12/8
H1H/1L	3.9-5.5 /1-3.8V	12A/8A	66W/31W	1	1/1	12/8
H1H/1H	3.9-5.5 /3.9-5.5V	12A/8A	66W/44W	1	1/1	12/8

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H1L/2	1-3.8/5-9V	12A/6A	46W/54W	1	1/2	12/12
H1H/2	3.9-5.5/5-9V	12A/6A	66W/54W	1	1/2	12/12
H1L/3	1-3.8/9.1-16.2V	12A/6A	46W/98W	1	1/3	12/18
H1H/3	3.9-5.5/9.1-16.2V	12A/6A	66W/98W	1	1/3	12/18
H1L/4	1-3.8/16.3-25V	12A/4.5A	46W/113W	1	1/4	12/18
H1H/4	3.9-5.5/16.3-25V	12A/4.5A	66W/113W	1	1/4	12/18
H2/1L	5.6-9/1-3.8V	10A/8A	90W/31W	1	2/1	20/8
H2/1H	5.6-9/3.9-5.5V	10A/8A	90W/44W	1	2/1	20/8
H2/2	5.6-9/5.6-9V	10A/6A	90W/54W	1	2/2	20/12
H2/3	5.6-9/9.1-16.2V	10A/6A	90W/98W	1	2/3	20/18
H2/4	5.6-9/16.3-25V	10A/4.5A	90W/113W	1	2/4	20/18
H3/1L	9.1-16.2/1-3.8V	10A/8A	162W/31W	1	3/1	30/8
H3/1H	9.1-16.2/3.9-5.5V	10A/8A	162W/44W	1	3/1	30/8
H3/2	9.1-16.2/5.6-9V	10A/6A	162W/54W	1	3/2	30/12
H3/3	9.1-16.2/9.1-16.2V	10A/6A	162W/98W	1	3/3	30/18
H3/4	9.1-16.2/16.3-25V	10A/4.5A	162W/113W	1	3/4	30/18
H5/1L	16.2-31/1-3.8V	5A/8A	155W/31W	1	5/1	25/8
H5/1H	16.2-31/3.9-5.5V	5A/8A	155W/44W	1	5/1	25/8
H5/2	16.2-31/5.6-9V	5A/6A	155W/54W	1	5/2	25/12
H5/3	16.2-31/9.1-16.2V	5A/6A	155W/98W	1	5/3	25/18
H5/4	16.2-31/16.3-25V	5A/4.5A	155W/113W	1	5/4	25/18
L1	4.2 - 5.5V	35A	193W	1	1	35
W2	0.25 - 7.5V	30A	225W	1	2	60
W5 (Standard)	0.25 - 32V	8.5A	272W	1	5	50
W5	0.25 - 15V	10A	272W	1	5	50
(High current o/p)	15.01 - 32V	8.5A				
W8	1 - 48V	5A	240W	1	8	-
W9	1-30V	2A	60W	1	5	-
X1	10V (See Note 1)	90A	See Note 2	1	-	-
X2	20V (See Note 1)	64.5A	See Note 2	1	-	-
X4	40V (See Note 1)	32.4A	See Note 2	1	-	-
X8	80V (See Note 1)	16.2A	See Note 2	1		-

Note 1: Actual voltage and current output of X and XR modules is dependent, and limited by, the ratings of the modules from which it is fed. The ratings given above are additional rating limitations imposed by the X module itself.

Note 2: The maximum power output of PSUs fitted with X or XR modules is reduced from its normal rated value by the following power: 0.55 x (total X1 & XR1 current) + 0.7 x (total X2, X4, XR2 & XR4 current) + 0.9 x (total X8 & XR8 current)

Additional module limitations:

E2 module fitted in slots 4/5 is limited to 55A.

C1Y module can only be fitted in slot 1.

F2 module may only be fitted in slots 1/2 and is limited to 75A for ambient temperatures of greater than 45°C.

F1 module may only be fitted in slots 1/2.

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For PSUs with three D modules fitted:

D1L & D1H in slots 2/3 is limited to 42A and in slots 4/5 is limited to 47A

D2 in slots 2/3 is limited to 40A

For 900W PSUs:

W2 module not permitted.

F1 and F2 modules not permitted.

PSUs fitted with a W2 module are limited to a maximum ambient of 45°C.

All the above ratings and limitations apply to the individual modules from which a series or paralleled pair is made.

SELV and Outputs Connected In Series:

Outputs are SELV except as described below:

Non-earthed outputs that have secondary's with 2 or more turns are non-SELV as a single fault in the secondary may make them exceed the SELV limit between output and earth.

Non-earthed outputs that are connected in series are non-SELV unless all the seriated outputs use 1 turn secondary's and there are no more than 3 outputs connected in series.

Outputs connected in series are non-SELV if the total output voltage + 20% of the max. rated output voltage of the output with the highest rated voltage exceeds 60Vdc (the 20% addition allows for a single fault in any one individual channel).

The total voltage of a seriated output must not exceed 160V.

If any output or seriesed output is non-SELV then all the outputs in the PSU must be considered non-SELV. Note:

Non-SELV outputs must be guarded or a deflector fitted during installation to avoid a service engineer making inadvertent contact with the output terminals, or dropping a tool onto them.

All outputs have operational spacing's to earth, and due consideration must be given to this in the end product design.

When the IEC inlet option is fitted (option I) together with a plastic fan grill then the end face of the PSU with the fan grill may be operator accessible.

Ratings Specific to Vega 450 and Vega Lite 550 Ranges:

PSUs with cooling option F and without xEW and xFW options:

Input voltage: 94.5-240 V ac nom., 85-264V ac max., 47-63 Hz, 8.5 A rms max.

All other PSUs:

Input voltage: 100-240 V ac nom., 90-264V ac max., 47-63 Hz, 8.5 A rms max.

Permitted orientations: Horizontal with chassis lowest, on either side or vertical with the airflow upwards.

Cooling Option	Max. Amb (°C)	Dual Width Modules Fitted	P (W)	Max. AT (Total)	Max. AT in adj	Max Modules I Rating Regions (Note 1)
F	See table	No	See table	180	N/A	100%
	below	Yes	below	180	180	100%
D	50	No	450	180	N/A	100%
		Yes	450	180	180	100%
R, E	50	No	450	180	N/A	100%
		Yes	450	180	162	90%
Q	50	No	450	180	N/A	100%
		Yes	450	180	180	100%

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Р	50	No	450	180	N/A	100%	
		Yes	450	180	180	85%	
С	50	See custo	See customer air cooling section for ratings				

Note 1: The PSU main transformer has three regions for module secondary's separated by two primary windings. Starting nearest slot 1, region A, primary winding, region B, primary winding, region C. The total ampere turns (AT) in any two adjacent regions is limited to that in the table above column, "Max AT in adjacent regions (note 1)". See Mains transformer regions table for modules allowed in each region. The table uses module widths with a twin output module being single width. For PSUs fitted with F2 modules "Max AT in adjacent regions" does not apply.

n/a = not applicable

Ampere Turns (AT) is the sum of (output amps x secondary turns)

Power ratings for cooling option F:

		Max. Amb. 40°C	Max. Amb. 50°C
I/P V (Vrms)	O/P P (W)	xEW or xFW option fitted	xEW or xFW option fitted
85	425	Not permitted	425
90	470	450	450
100	520	450	500
110-149.9	570	450	550
150-264	630	450	560

Linear interpolation may be used to determine the permitted output power for input voltages between 85 and 110V.

Ratings Specific to Vega 650 and Vega 750 Lite Ranges:

PSUs with cooling option F and without xEW and xFW options:

Input voltage: 94.5-240 V ac nom., 85-264V ac max., 47-63 Hz, 12 A rms max.

All other PSUs:

Input voltage: 100-240 V ac nom., 90-264V ac max., 47-63 Hz, 11 A rms max.

Permitted orientations: Horizontal with chassis lowest, on either side or vertical with the airflow upwards.

Cooling Option	Max. Amb (°C)	Dual Width Modules Fitted	P (W)	Max. AT (Total)	Max AT in Adj I	Max Module Rating Regions (Note 1)
F	See table	No	See table	220	N/A	100%
	below	Yes	below	220	180	100%
D	50	No	650	220	N/A	100%
		Yes	650	220	180	100%
R, E	40	No	530	212	N/A	100%
		Yes	550	212	158	90%
	45	Yes	500	212	158	90%
	50	No	575	180	N/A	100%
		Yes	600	210	162	90%
		No	500	200	N/A	100%
Q	50	Yes	550	180	140	100%

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		No	650	220	N/A	100%	
		Yes	610	220	180	95%	
		Yes	650	145	115	95%	
Р	40	Yes	500	203	152	85%	
	45	Yes	420	203	152	85%	
	50	No	500	180	N/A	100%	
		Yes	450	190	162	85%	
С	50	See Customer	Air Cooling sec	tion for ratings			

Note 1: The PSU main transformer has three regions for module secondary's separated by two primary windings. Starting nearest slot 1, region A, primary winding, region B, primary winding, region C. The total ampere turns (AT) in any two adjacent regions is limited to that in the table above column, "Max AT in adjacent regions (note 1)". See Mains transformer regions table for modules allowed in each region. The table uses module widths with a twin output module being single width. For PSUs fitted with F2 modules "Max AT in adjacent regions" does not apply.

n/a = not applicable

Ampere Turns (AT) is the sum of (output amps x secondary turns)

Power ratings for cooling option F:

	Max. Amb. 40°C		Max. Amb. 50°C
	O/P Power	xEW or xFW option	xEW or xFW option
I/P V (Vrms)	(W)	fitted	fitted
85	650	Not permitted	615
90	720	650	650
100	830	650	720
110-149.9	900	650	770
150-264	900	900	900

Linear interpolation may be used to determine the permitted output power for input voltages between 85 and 110V.

Ratings Specific to Vega 900 Range:

PSUs with cooling option F and without xEW and xFW options:

Input voltage: 94.5-240 V ac nom., 85-264V ac max., 47-63 Hz, 12 A rms max.

All other PSUs:

Input voltage: 100-240 V ac nom., 90-264V ac max., 47-63 Hz, 11 A rms max.

Permitted orientations: Horizontal with chassis lowest, on either side or vertical with the airflow upwards.

For input voltages equal to or greater than 150V ac ratings are as follows:

Cooling Option	Max. Amb (°C)	Dual Width Modules	P (W)	Max AT (Total)	Max AT in Adj	Max Module I Rating	
F, D	50	No	900	220	180	100%	
		Yes	900	220	180	100%	
		No	650	220	N/A	100%	
Q	50	No	750	180	N/A	100%	

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		Yes	750	180	140	100%
С	50	See Customer	Air Cooling see	ction for rating:	S	
Con impost valte	agaa laga than 11	E01/ a a ratio da a	ra aa fallawa.			
For input voita	ages less than 15	ouv ac raungs a	re as follows.			
Cooling	Max. Amb	Dual Width	P (W)	Max AT	Max AT in	Max Module
Option	(°C)	Modules	,	(Total)	Adj	I Rating
F	See table	No	See table	220	N/A	100%
	below	Yes	below	220	180	100%
D	50	No	650	220	N/A	100%
		Yes	650	220	180	100%
R, E	40	No	530	212	N/A	100%
		Yes	550	212	158	90%
	45	Yes	500	212	158	90%
	50	No	575	180	N/A	100%
		Yes	600	210	162	90%
		No	500	200	N/A	100%
Q	50	Yes	550	180	140	100%
		No	650	220	N/A	100%
		Yes	610	220	180	95%
		Yes	650	145	115	95%
Р	40	Yes	500	203	152	85%
I						

420

500

450

See Customer Air Cooling section for ratings

203

180

190

152

N/A

162

85%

100%

85%

Power ratings for cooling option F:

С

45

50

50

		Max. Amb. 40°C	Max. Amb. 50°C		
	O/P Power	xEW or xFW option	xEW or xFW option		
I/P V (Vrms)	(W)	fitted	fitted		
85	650	Not permitted	615		
90	720	650	650		
100	830	650	720		
110-149.9	900	650	770		

Yes

No

Yes

Linear interpolation may be used to determine the permitted output power for input voltages between 85 and 110V.

Note 1: The PSU main transformer has three regions for module secondary's separated by two primary windings. Starting nearest slot 1, region A, primary winding, region B, primary winding, region C. The total ampere turns (AT) in any two adjacent regions is limited to that in the table above column, "Max AT in adjacent regions (note 1)". See Mains transformer regions table for modules allowed in each region. The table uses module widths with a twin output module being single width. For PSUs fitted with F2 modules "Max AT in adjacent regions" does not apply.

n/a = not applicable

Ampere Turns (AT) is the sum of (output amps x secondary turns)

Main transformer regions table:							
REGION C	SLOT 5 PRIMARY	REGION B		SLOT 1 PRIMARY REGION A			
Slot 1		Slot 5.5.	Slot 1	REGION A	Slot 5.5		
	Dogion P	Region C		Dogion P			
Region A	Region B D	D	Region A 1.5	Region B 1.5	Region C		
Blank	D		1.5 S		-		
		D		S, S	D		
S	D,S	S	1.5	1.5	D		
S	D	S	-	F, M, S	S, S		
S	D D	-	-	F, M, S	S		
-		-	-	F, M, S	-		
S	S, S, S	S	-	F, M	-		
S	S, S	S	-	F, M, S	D		
S	S	-	-	F, M	D		
	S	-	-	F, M, S	1.5		
1.5	D	1.5	-	F, M	1.5		
S	D	1.5	-	F, M 1.5	1.5		
-	D	1.5	-	F, M 1.5	S		
S	1.5, S	S	_				
S	1.5	S	Combined Modu				
S	1.5	-	S	D	D		
1.5	1.5	1.5	-	D	D		
S	1.5, 1.5	S	1.5	D	1.5		
S	1.5	1.5	S	D	1.5		
-	1.5	1.5	-	D	1.5		
-	1.5	-	S	1.5, 1.5	S		
-	S, S	D	S	1.5, 1.5	-		
-	1.5, S	S	-	1.5, 1.5	-		
1.5	1.5, S	S	1.5	1.5, D	1.5		
-	D, S	S	1.5	1.5	1.5		
1.5	D	S	1.5	1.5, S	S		

D = Dual. S = Single, M = Module

Custom Models:

All ratings as per standard models unless otherwise stated.

Model: Vega 450 AFT B/S 24D5S 21D5S (K40054, NS-CLE-010)

Input: 85-264Vac, 47-63Hz

Maximum outputs: 24V, 12.5A; 21V, 7.143A

Orientation: All except upside down and vertical with the airflow downwards

Cooling: Papst 612NML or 612NGML or 612NMLE fan fitted with up to 66 ohms total resistance in series.

Comments: Forward air.

Model: Vega 650 BFTF B/S 24.5E5HFN

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Input: 90-264Vac, 47-63Hz Maximum output: 24.5V, 18.37A Maximum output power: 450W

Orientation: All except upside down and vertical with the airflow downwards

Cooling: Papst 612NML or 612NGML fan fitted with up to 64 ohms total resistance in series.

Comments: Reverse air.

Model: Vega 450 AFT B/S 24E5HS (NS-CLE-011)

Input: 85-264Vac, 47-63Hz Maximum outputs: 24V, 14.59A Maximum output power: 350W

Orientation: All except upside down and vertical with the airflow downwards

Cooling: Papst 612NML or 612NGML fan fitted with up to 64 ohms total resistance in series.

Comments: Forward air.

Model: NS-TLC/V9QSLF 24C5SN 12Z20S (K90064*) where * may be A or B

Input: 100-240Vac nom. See table below for details Maximum output power: See table below for details

Orientation: As standard model

OP1	OP1 A	OP2	OP2 A	Amb.	Line V	STBY	STBY	Power W
V	max	V	max	Max.	min	V	mA	max
24	7	12	50	40	150	5	100	769
24	2.084	12	50	40	90	5	100	651
24	7	12	46.67	50	150	5	100	729
24	3.75	12	46.67	50	90	5	100	651
24	7	12	60	40	150	5	100	889
24	0	12	60	40	90	5	100	721

Model: NS-TLC/V9QSLF 24C5SN 12Z20S (K90064*) where * may be any number of letters and/or numbers except A or B, indicating non-safety related differences.

Fan: EBM-Papst 612NME

Input: 100-240Vac nom. See table below for details Maximum output power: See table below for details

Orientation: As standard model

OP1	OP1 A	OP2	OP2 A	Amb.	Line V	STBY	STBY	Power W
V	max	V	max	Max.	min	V	mA	max
24	7	12	50	40	150	5	100	769
24	2.084	12	50	40	90	5	100	651
24	3.75	12	46.67	40	90	5	100	651

Additional Information

Customer Air Cooling (option C):

The following method must be used for determining the safe operation of PSUs when C option (Customer Air) is fitted, i.e. fan not fitted to PSU.

For PSUs 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 must still be complied with, e.g. mains input voltage range, maximum output power, ampere turns, module voltage / current ratings and maximum ambient temperature. To determine the component temperatures the heating tests must be conducted in accordance with the requirements of the standards this report complies with. 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

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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. Temp (°C) -	
-	Power transformer	130	
T1, TX101, TX201	Module current transformer	127 (130)	
XQ1, XT	D, E, EV, F & FV Primary Option transformers	90	
XTR1	EY, FY, EV & FV Primary option transformers	90	
TX1	xEW & xFW Primary option transformer	130	
L1, L2, XT601	Choke winding	110 (130)	
L4, T2	Choke winding	117 (130)	
Various	All Choke & transformer windings	110	
RLY1	Relay	100	
Various	X capacitor	100	
C2, C3, C14	Electrolytic Capacitors 67	105	
Various	All other 10mm dia Electrolytic Capacitors	80 (105)	
Various	All other 12.5mm dia Electrolytic Capacitors	85 (105)	

- + The higher temperature limits in brackets may be used by product life may be reduced
- ++ When fitted

Amendment 1

The Original Test Report E349607-D10-CB-1 was modified on 2017-12-14 to include the following changes/additions:

- added alternate fan YEN SUN TECHNOLOGY CORP type FD126025HB rated 12V, 24.5cfm.
- CBTL changed to UL International Polska

After review no test deemed necessary.

Amendment 2

- -The original report was modified include the following changes/additions:
- E349607-D10 issued 2015-07-15 with CB Certificate No. (DK-47548-UL) issued 2015-08-05.

E349607-D10 issued 2017-12-14 with CB Certificate No. (DK-47548-M1-UL) issued 2018-01-17.

Technical Amendment to the report to make the following changes

- 1. Addition of alternate components having similar or better ratings to previous components detailed in the Critical Components Table
- 2. Addition of a non-standard model K90064x (where x may be any letter) employing a lower cfm rated fan
- 3. Deletion of the Avnet manufacturing location
- 4. Update to enclosures to include Vega 650, 750 & 900 manual
- 5. Updated the text in the Model Differences section
- 6. Updated the text in the of Additional Information section

Only limited testing was considered necessary to make this change. Based on the previously conducted testing and the review of product technical documentation it has been determined that product continues to comply with the Standard and only limited testing was required.

This report must be read in conjunction with the original CB test report and the Amendment 1 report ref. no. E349607-D10-CB-1.

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Technical Considerations:

 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 anaesthetics mixture with air or oxygen or with nitrous oxide:: No
- Risk Management has not been applied to these products.

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.
- 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 (EMC)
- 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
- The product is Classified only to the following hazards: Casualty, Fire, Shock
- The power supply is Class I.
- The product was submitted and tested for use at the maximum ambient temperature (Tma) permitted by the manufacturer's specification of: 50°C (full load); 70°C (output power decreasing linearly by 2.5%/°C above 50°C).
- The product was assessed for operation at an altitude of 5000m, excluding the IEC60320 inlet and cooling options D and E which are rated up to 3000m.
- The Printed Wiring Board Trace was evaluated for protective earthing/bonding

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.

Engineering Conditions of Acceptability

- When installed in an end-product, consideration must be given to the following:
- The following Production-Line tests are conducted for this product: Electric Strength, Earthing Continuity
- The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-SELV: 680 Vpk, Primary-Earthed Dead Metal: 616 Vpk, insulation (Separation) between secondary circuits earth: functional insulation 0 (zero) MOOP. See Insulation diagram and Table below for details.
- The following secondary output circuits are SELV: All outputs subject to restrictions described within the

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attached handbook.

- The following secondary output circuits are at hazardous energy levels: See additional information for modules with energy hazard.
- 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: 16A (20A For North America and Canada)
- Proper bonding to the end-product main protective earthing termination is: Required
- An investigation of the protective bonding terminals has: Been conducted
- 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.
- The equipment has been evaluated as a Class 1
- 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: Primary and Earth is one MOPP or MOOP: 616Vpeak
- Insulation separation between: Primary and secondary is 2 MOPP (2 MOOP for 1A primary option): 680Vpeak
- Altitude of operation: 5000m except for models which are fitted with an IEC60320 inlet or mains switch or a Papst 622HH can only be operated for an altitude of up to 3000m.