



Ref. Certif. No.

DE 2-009975

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST  
CERTIFICATES FOR ELECTRICAL EQUIPMENT  
(IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE  
CERTIFICATS D'ESSAIS DES EQUIPEMENTS  
ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE  
CERTIFICAT D'ESSAI OC

Product  
Produit

Panel PC

Name and address of the applicant  
Nom et adresse du demandeur

Advantech Co., Ltd.  
No.1, Alley 20, Lane 26  
Rueiguang Road, 114 Neihu, Taipei, Taiwan

Name and address of the manufacturer  
Nom et adresse du fabricant

Advantech Co., Ltd.  
No.1, Alley 20, Lane 26  
Rueiguang Road, 114 Neihu, Taipei, Taiwan

Name and address of the factory  
Nom et adresse de l'usine

☒ Additional Information page 2

Note: When more than one factory, please report on page 2  
Note: Lorsque il y plus d'une usine, veuillez utiliser la 2<sup>ème</sup> page

Ratings and principal characteristics  
Valeurs nominales et caractéristiques principales

AC 100-240V; 50-60Hz; 4-2A Max.; Class I

Trade mark (if any)  
Marque de fabrique (si elle existe)

ADVANTECH

Model/type Ref.  
Ref. de type

POC-154xxxxxxxxxx; POC-174xxxxxxxxxx;  
POC-155xxxxxxxxxx; POC-175xxxxxxxxxx  
(x = any alphanumeric character or blank for marketing purpose)

Additional information (if necessary may also be reported on page 2)  
Les Information complémentaire (si nécessaire, peuvent être indiqués sur la 2<sup>ème</sup> page)

Models differ in model name, the use of different DC/AC inverter and LCD panel, and source of motherboard.

A sample of the product was tested and found to be in conformity with  
Un échantillon de ce produit a été essayé et a été considéré conforme à la

**PUBLICATION** **EDITION**  
IEC 60601-1:1988+A1+A2  
for national deviations see test report

As shown in the Test Report Ref. No. which forms part of this Certificate  
Comme indiqué dans le Rapport d'essais numéro de référence qui constitue une partie de ce Certificat

21125273 001

This CB Test Certificate is issued by the National Certification Body  
Ce Certificat d'essai OC est établi par l'Organisme National de Certification



TÜV Rheinland Group

TÜV Rheinland Product Safety GmbH  
Am Grauen Stein · D-51105 Köln  
Phone + 49 221 806-1400  
Fax + 49 221 806-2095  
Mail: cert-validity@de.tuv.com  
Web: www.tuv.com



Date: 15.11.2006

Signature:

Dipl.-Ing. H.-J. Beck



Ref. Certif. No.

DE 2-009975

1. Advantech Co., Ltd. Fl.5, No.1, Lane 169, Kang-Ning St., Xi Zhi, Taipei Hsien 221, Taiwan	2. Beijing Yan Hua Xing Ye Elec. Science & Technology Co., Ltd. 7, 6th Street, Shang Di Zone  Haidian District, Beijing, China
3. Superior Co., Ltd. Tiensong Area, Qingxing Town  Dongguan, Guangdong China	4. Advantech Co., Ltd. No. 600 Han-Pu Road, Yu-Shan  Kun-Shan, Jiangsu China
5. Advantech Co., Ltd. 3F, No. 10, Lane 130 Ming Chuan Rd., Hsin-Tien City 231 Taipei Hsien, Taiwan	

Additional information (if necessary)  
Information complémentaire (si nécessaire)

Date: 15.11.2006

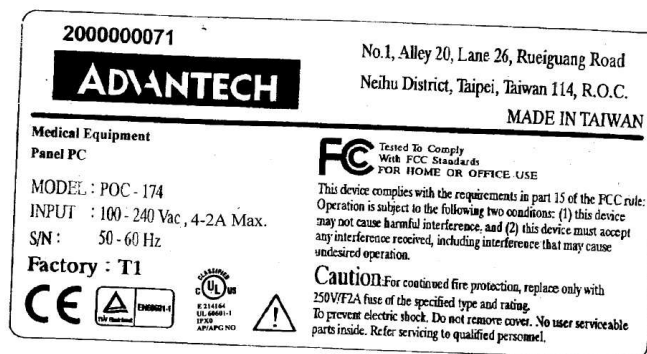
Signature:

Dipl.-Ing. H.-J. Beck



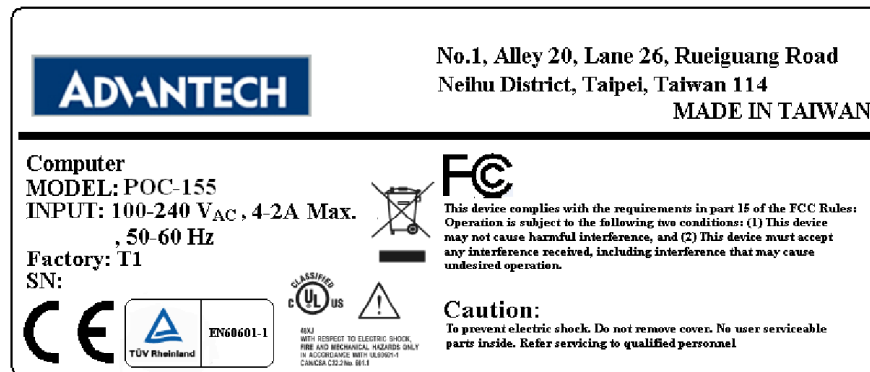
TEST REPORT	
IEC 601 -1	
Medical electrical equipment	
Part 1: General requirements for safety	
Report reference No. ....	21125273 001
Compiled by (+ signature).....	Thomas Illing
Reviewed by (+ signature) .....	C. Rüther
Approved by (+ signature).....	T. Stoelzel
Date of issue .....	October 27 <sup>th</sup> , 2006
Testing laboratory .....	TÜV Rheinland Product Safety GmbH
Address .....	Am Grauen Stein, Konstantin Wille-Str. 1, Cologne, Germany
Testing location .....	TÜV Rheinland Product Safety GmbH, Cologne, Germany
Applicant .....	Advantech Co., Ltd.
Address .....	No. 1, Alley 20, Lane 26, Rueiguang Road, 114 Neihsu, Taipei, Taiwan.
Standard .....	IEC 60601-1: 1988 + A1:1991 + A2:1995 EN 60601-1 : 1990 + A1:1993 + A2:1995 +A13:1996
Test Report Form No. ....	I601-1_C/97-04
TRF Originator .....	Underwriters Laboratories Inc.
Master TRF .....	dated 97-04
Copyright blank test report.....	the bodies participating in the Committee of Certification Bodies (CCB). This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator.
Test procedure.....	CB Scheme
Procedure deviation .....	N/A
Non-standard test method .....	N/A
Type of test object.....	Panel PC
Trademark .....	<b>ADVANTECH</b>
Model/type reference .....	POC-154xxxxxxxxxx, POC-174xxxxxxxxxx, POC-155xxxxxxxxxx, POC-175xxxxxxxxxx (x = any alphanumeric character or blank)
Manufacturer.....	Same as applicant
Address .....	Same as applicant
Rating.....	AC 100-240V, 50-60Hz, 4-2A

Copy of the marking plate:





Copy of the marking plate:



## GENERAL INFORMATION

Test item particulars (see also clause 5):

Classification of installation and use..... : Fixed equipment

Supply connection ..... : AC mains / Appliance inlet

Accessories and detachable parts included in the evaluation .. : None

Options included ..... : None

Possible test case verdicts:

- test case does not apply to the test object .....:N/A

- test object does meet the requirement.....:Pass

- test object does not meet the requirement.....:Fail

Abbreviations used in the report:

- normal condition .....:N.C. - single fault condition .....:S.F.C.

- operational insulation .....:OP - basic insulation .....:BI

- basic insulation between parts of opposite polarity .....:BOP - supplementary insulation.....:SI

- double insulation .....:DI - reinforced insulation .....:RI

General remarks:

**"This report is not valid as a CB Test Report unless appended to a CB Test Certificate issued by a NCB, in accordance with IEC 60335-1-2".**

"(see Attachment #)" refers to additional information appended to the report.

"(see appended table)" refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

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.

Summary of compliance with National Differences (for explanation of codes see below):

AT, AU, BE, BR, CA, CH, CS, CZ, DE, DK, FI, FR, GB, GR, HU, IE, IL, IN, IT, KE, KR, NL, NO, PL, PT, RU, SE, SI, SK, TR, US

AT = Austria, AU = Australia, BE = Belgium, BR = Brazil, CA = Canada, CH = Switzerland, CS = Serbia and Montenegro, CZ = The Czech Republic, DE = Germany, DK = Denmark, FI = Finland, FR = France, GB = United Kingdom, GR = Greece, HU = Hungary, IE = Ireland, IL = Israel, IN = India, IT = Italy, KE = Kenya, KR = Korea, NL = The Netherlands, NO = Norway, PL = Poland, PT = Portugal, RU = Russian Federation, SG = Singapore, SE = Sweden, SI = Slovenia, SK = Slovakia, TR = Turkey, US = United States

*Factories:*

1. Advantech Co., Ltd.  
5F, No. 1, Lane 169, Kang-Ning Street, Xi-Zhi, Taipei Hsien 221, Taiwan
2. Advantech Co., Ltd.  
3F, No. 10, Lane 130, Ming Chuan Rd., Hsin Tien City, Taipei Hsien 231, Taiwan

3. Superior Co., Ltd.  
Tiansong Area, Qingxing Town, Dongguan, Guangdong, P.R. China
4. Advantech Co., Ltd.  
No. 600, Han-Pu Road, Yu-Shan, Kun-shan, Jiangsu, P.R. China
5. Beijing Yan Hua Xing Ye Elec. Science & Technology Co., Ltd.  
7, 6th Street, Shang Di Zone, Haidian District, Beijing, P.R. China

#### General product information and considerations:

The equipment models POC-174xxxxxxxxx is a 17 inch panel PC intended for use with medical electrical equipment.

The model POC-154xxxxxxxxx is similar to model POC-174xxxxxxxxx except the model designation and the use of different DC/AC inverter and LCD panel (15 inch).

The models POC-175xxxxxxxxx and POC-155xxxxxxxxx are similar to models POC-174xxxxxxxxx and POC-154xxxxxxxxx respectively and differ from them in the model names and source of motherboard (type PCM-9682 for models POC-174xxxxxxxxx and POC-154xxxxxxxxx, type PCM-9690 for models POC-175xxxxxxxxx and POC-155xxxxxxxxx). The new motherboard supports alternative types of CPU and memory modules, has 3 IEEE1394 ports (one on the back side of the enclosure) and 8 USB ports of which only 6 are used where 4 are bonded to the back-side of the chassis.

For all models "x" can be any alphanumeric character or blank and is used for marketing purposes only.

The maximum specified operational ambient temperature is +40°C.

The equipment employs built-in type power supply, that was CB-scheme approved by Nemko according to IEC 60601-1:1988+A1+A2. The certificate number is NO 27244 and CB-scheme report No. is 14871.

General overview on the system:

- Panel PC incorporating the LCD panel and computer in one enclosure. The front panel is provided with four buttons and power indicator. All connectors such as serial ports, parallel port, USB ports, PS2 port, joystick port, audio connectors, LAN port and controls for brightness and contrast are located at the back-bottom side of the enclosure.
- There is a single-pole power switch is provided adjacent to the AC inlet. The AC inlet is considered as disconnect device. The power supply remains energized in either positions of the switch.
- The mounting means (optional) of the panel PC are located on its back enclosure.
- The inside of the equipment is considered as operator accessible area for exchanging built-in components as CPU, HDD, FDD, DVD-ROM, memory module, RTC battery
- The DC/AC inverter is provided with a plastic cover covering it completely.
- The built-in speakers are located at both sides of the bottom enclosure.
- The equipment can be connected to VESA mounting kit.
- The weight of the equipment is 12kg.

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Clause	Requirement + Test	Result - Remark	Verdict

<b>3</b>	<b>GENERAL REQUIREMENTS</b>		Pass
3.1	Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.)		Pass
3.4	An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained	Alternative means of construction not used.	N/A

<b>5</b>	<b>CLASSIFICATION</b>		Pass
5.1	Type of protection against electric shock		Pass
	Class I equipment	Basic insulation to protectively earthed parts or double/reinforced insulation is used.	Pass
	Class II equipment		N/A
	Internally powered equipment		N/A
5.2	Degree of protection against electric shock		Pass
	Type B applied part		N/A
	Type BF applied part		N/A
	Type CF applied part		N/A
	Not classified – no applied parts		Pass
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1) .....	Ordinary apparatus	N/A
5.4	Methods of sterilization or disinfection	No sterile parts.	N/A
5.5	Equipment not suitable for use in the presence of flammable mixtures	Apparatus not intended for use in the presence of flammable liquids with air.	Pass
	Category AP equipment		N/A
	Category APG equipment		N/A
5.6	Mode of operation:		Pass
	- continuous operation	Continuous operation considered.	Pass
	- short-time operation, specified operation; period:		N/A
	- intermittent operation, specified operation; rest		N/A



IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	period.....:		
	- continuous operation with short-time, stated permissible loading time .....		N/A
	- continuous operation with intermittent, stated permissible loading/rest time .....		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

### INSULATION DIAGRAM

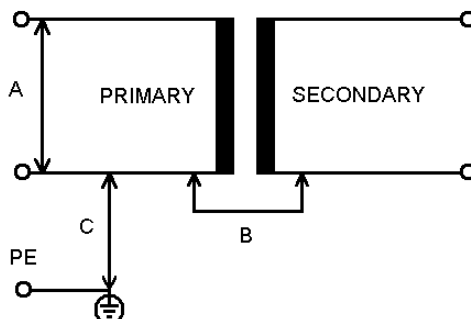


Table: to insulation diagram							Pass
Area	Insulation type: operational / basic / supplementary / double / reinforced	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
C	Basic insulation	250	4.0	2.5	4.0	4.0	See the note below

Notes:

The separation from the mains supply (items A and B and also partly item C on the insulation diagram above) has been evaluated during the approval of the switching power supply. Screws for fixing of the power supply do not impair the distance between primary and metal chassis (earth).

### INSULATION DIAGRAM CONVENTIONS

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optical isolators, wire insulation, creepage and clearance distances.
2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.
5. Blocks containing the letter "Z" indicate protective impedance.
6. Operational Insulation (OP) - indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with the requirements of clauses 17, 20 and 57.

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

<b>6</b>	<b>IDENTIFICATION, MARKING AND DOCUMENTS</b>		Pass
6.1	Marking on the outside of equipment or equipment parts		Pass
	c) Markings of the specific power supply affixed		N/A
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		N/A
	e) Name and/or trademark of the manufacturer or supplier .....	ADVANTECH	Pass
	f) Model or type reference .....	POC-154xxxxxxxxxx, POC-174xxxxxxxxxx, POC-155xxxxxxxxxx, POC-175xxxxxxxxxx (x = any alphanumeric character or blank)	Pass
	g) Rated supply voltages or voltage range(s)	100-240Vac	Pass
	Number of phases .....	Single phase	Pass
	Type of current .....	AC	Pass
	h) Rated frequency or rated frequency range(s) (Hz) .....	50-60Hz	Pass
	j) Rated power input (VA, W or A) .....	4-2A	Pass
	k) Power output of auxiliary mains socket-outlets	No such outputs	N/A
	l) Class II symbol	Class I apparatus	N/A
	Symbol for degree of protection against ingress of water provided .....	Ordinary apparatus	N/A
	Symbol for protection against electric shock .....		N/A
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets	No applied parts.	N/A
	Symbol for protection of defibrillation-proof applied parts		N/A
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N/A
	m) Mode of operation (if no marking, suitable for continuous operation)	Continuous operation	N/A
	n) Types and rating of external accessible fuses ...	No such fuses.	N/A
	p) Ratings of external output.....		N/A
	q) Symbol for physiological effect(s):		N/A
	- attention, consult accompanying documents		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N/A
	r) Anaesthetic-proof symbol: AP or APG .....	Refer to clause 5.5	N/A
	s) Dangerous voltage symbol		N/A
	t) Special cooling requirements	None.	N/A
	u) Limited mechanical stability	To be evaluated for the final system assembly.	N/A
	v) Protective packing requirement(s)	No specific requirements.	N/A
	- Marking(s) for unpacking safety hazard(s)		N/A
	- Equipment or accessories supplied sterile, marked as sterile		N/A
	y) Potential equalization terminal	Not provided.	N/A
	- Functional earth terminal		N/A
	z) Removable protective means		N/A
	Durability of marking test	Refer to appended table 6.1	Pass
6.2	Marking on the inside of equipment or equipment parts		Pass
	a) Nominal voltage of permanently installed equipment	No such equipment.	N/A
	b) Maximum power loading for heating elements or holders for heating lamps	No heating elements.	N/A
	c) Dangerous voltage symbol		N/A
	d) Type of battery and mode of insertion	There is a Li-Ion battery (CR2032) located on the built-in motherboard. It is accessible only with a tool and it is placed in a battery holder, which allows only one way of inserting. Warning statement provided in the accompanying documents.	Pass
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator	Not operator replaceable.	N/A
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram	In approved power unit.	Pass
	f) Protective earth terminal	Appliance inlet is used.	N/A
	g) Functional earth terminal		N/A
	h) Supply neutral conductor in permanently installed equipment (N)		N/A



IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	j) Markings required in 6.2 f), h), k), and l) remain visible after connection and are not affixed to parts which have to be removed		N/A
	- Markings comply with IEC 445		N/A
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)		N/A
	l) Statement for suitable wiring materials at temperatures over 75 °C		N/A
	n) Capacitors and/or circuit parts marked as required in Sub-clause 15c		N/A
6.3	Marking of controls and instruments		Pass
	a) Mains switch clearly identified	Located on the back side of the enclosure adjacent to the appliance inlet.	Pass
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light	On the switch knob.	Pass
	b) Indication of different positions of control devices and switches		N/A
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device		N/A
	f) The functions of operator controls and indicators are identified	Identified in the accompanying documents.	Pass
	g) Numeric indications of parameters are in SI units except for units listed in Am. 2		N/A
6.4	Symbols		Pass
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	In accordance with appendix D	Pass
6.5	Colors of the insulation of conductors		Pass
	a) Protective earth conductor has green/yellow insulation	In approved power unit.	Pass
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations	Same as above.	Pass
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow	Same as above.	Pass
	d) Color of neutral conductor.....:		N/A
	e) Colors of phase conductor(s) .....		N/A
	- Compliance with IEC 227 and IEC 245		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N/A
6.6	Medical gas cylinders and connections		N/A
	a) In accordance with ISO ISO/R 32		N/A
	b) Identification of connection point		N/A
6.7	Indicator lights and push-buttons		Pass
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action	Not used.	N/A
	- Yellow used to indicate caution or attention required	Not used.	N/A
	- Green used to indicate ready for action	Green LED provided for indicating operational condition, amber LED indicated stand-by mode.	Pass
	b) Color red used only for push-buttons by which a function is interrupted in case of emergency		N/A
6.8	ACCOMPANYING DOCUMENTS		Pass
6.8.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Provided in the accompanying documents.	Pass
	Classifications specified in Clause 5 included in both the instructions for use and the technical description	Provided in the accompanying documents section "Specifications".	Pass
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment		N/A
	Warning statements and the explanation of warning symbols provided in the accompanying documents	Provided throughout the accompanying documents.	Pass
6.8.2	Instructions for use		Pass
	a) General information provided in instructions for use	Provided in the accompanying documents. See below.	Pass
	- state the function and intended application of the equipment	Provided in section "Introduction"	Pass
	- include an explanation of: the function of controls, displays and signals	Provided in section "A Quick Tour of the POC-174/154/175/155xxxxxxxxxx".	Pass
	- the sequence of operation	Provided throughout the accompanying documents.	Pass

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- the connection and disconnection of detachable parts and accessories	Provided in section "Installation Procedures"	Pass
	- the replacement of material which is consumed during operation	There is Li-Ion battery that may need to be replaced during the expected lifetime of the equipment. Proper instructions are provided in section "Safety Instructions".	Pass
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	Provided in the accompanying documents under section "Warnings and Cautions".	Pass
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	None. Suitable information regarding the choice of proper power supply cord is provided in section "Additional Information and Assistance".	Pass
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	Same as above.	Pass
	General information provided in instructions:		Pass
	- information for the safe performance or routine maintenance	Provided in the accompanying documents.	Pass
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	No such parts.	N/A
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	All necessary information is provided throughout the accompanying documents.	Pass
	c) Signal output or signal input parts intended only for connection to specified equipment described	Statement "This equipment shall be interconnected only to IEC60601-1 approved equipment" provided in section "Specifications"	Pass
	d) Details about acceptable cleaning, disinfection or sterilization methods included	Ditto.	Pass
	e) Warning statement for mains operated equipment with additional power source	No additional power source.	N/A
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	No primary batteries.	N/A
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	No rechargeable batteries.	N/A
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	j) Identification of any risks associated with the disposal of waste products, residues, etc.	No operator accessible parts inside.	N/A
	- Advice in minimizing these risks		N/A
6.8.3	Technical description		Pass
	a) All characteristics essential for safe operation provided	Provided.	Pass
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	No such fuses.	N/A
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	No such parts.	N/A
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	There are not particular parts designated as repairable. However, contact information for customer support is provided in section "Additional Information and Assistance" in the accompanying documents.	N/A
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Provided in section "Environment" in the accompanying documents.	Pass
<b>7</b>	<b>POWER INPUT</b>		Pass
	Power Input Measurements	Refer to appended table 7	Pass
<b>10</b>	<b>ENVIRONMENTAL CONDITIONS</b>		Pass
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer	Transportation and storage: Temp. range: -20°C - +50°C R.H.: 10% to 95%  Altitude up to 40000ft (12192m)  Operating conditions: Temp. range: +10°C - +40°C R.H.: 20% to 90%  Altitude up to 6000ft (1829m)	Pass
10.2.2a	Rated voltage not exceeding 250 V for hand-held equipment	Not a hand-held equipment.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA	Equipment rated 100-240VAC	Pass
	Rated voltage not exceeding 500 V for all other equipment		N/A
	Rated input frequency not more than 1kHz	Equipment rated 50-60Hz.	Pass
10.2.2b	Internal replaceable electrical power source specified	No internal power source (except CR2032 type battery for the BIOS).	N/A

<b>14</b>	<b>REQUIREMENTS RELATED TO CLASSIFICATION</b>		Pass
14.4a	Class I and Class II equipment in addition to basic insulation provided with an additional protection	The equipment is classified as class I and employs basic insulated earthed parts and parts separated from primary by double or reinforced insulation.	Pass
14.4b	Equipment supplied from external dc source of reverse polarity results in no safety hazard		N/A
14.5b	Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected		N/A
14.6c	Applied parts intended for direct cardiac application are of type CF	No applied parts.	N/A

<b>15</b>	<b>LIMITATION OF VOLTAGE AND/OR ENERGY</b>		Pass
15b	Voltage measured one sec after disconnection of the mains plug does not exceed 60V	Evaluated for the approved power supply unit.	Pass
15c	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ		N/A
	Marking provided for manual discharging		N/A

<b>16</b>	<b>ENCLOSURES AND PROTECTIVE COVERS</b>		Pass
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	The inner compartment of the equipment is considered as operator accessible area and the operator is instructed to install certain parts as CPU, FDD, HDD, DVD-ROM, memory module, RTC battery.	Pass



IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
		The test finger and pin can touch only earthed parts (inner metal chassis), which is connected to protective earth. There are not areas on the equipment where the test hook can be inserted besides around the output connectors. However, no live parts become accessible after applying pull force of 20N for 10 seconds.	
	Insertion or removal of lamps - protection against contact with live parts provided		N/A
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented	The equipment does not have top or side openings. There are numerous openings on the upper-back and bottom side of the equipment having diameter of $\varnothing 3.6\text{mm}$ . No live parts become accessible when the metal rod is applied. Additionally the output wires of SPS are provided with bushing, which prevents access to live parts in the SPS.	Pass
16c	Conductive parts accessible after the removal of handles, knobs, levers		Pass
	- have a resistance of not more than $0.2\ \Omega$	All metal parts are connected to protective earth with resistance to earth below $0.1\ \Omega$	Pass
	- separated from live parts by one of the means described in Sub-clause 17g	All non-earthed parts are separated from live parts as required in 17g.	Pass
	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact		N/A
16e	Removable enclosures protecting against contact with live parts		Pass
	- Removal possible only with the aid of a tool	The earth connection is provided in the approved SPS. Earth connection can be removed only with the aid of a tool.	Pass
	- Use of automatic device making parts not live when the enclosure is opened or removed		N/A
	- Exception 16e applied to the following parts .....		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	No such controls.	N/A

<b>17</b>	<b>SEPARATION</b>		Pass
17a	Separation method of the applied part from live parts:		N/A
	1) basic insulation: applied part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N/A
	4) by double or reinforced insulation		N/A
	5) by protective impedances limiting current to applied part		N/A
	- Additional leakage current test in single fault conditions		N/A
17c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		N/A
17d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		N/A
17g	Separation method of accessible parts other than applied parts from live parts:		Pass
	1) basic insulation: accessible part earthed	In the approved power supply unit.	Pass
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N/A
	4) by double or reinforced insulation	In the approved power supply unit.	Pass
	5) by protective impedances limiting current to accessible part		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

	- Additional leakage current test in single fault conditions	The output of the built-in DC/AC inverter was evaluation if, hazardous live. Compliance of the requirements with the standard is evaluated by measurement of the leakage current from the output of the DC/AC inverter to earth other parts of the enclosure. For test results refer to appended table 19.	Pass
17h	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N/A
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator		N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		N/A

<b>18</b>	<b>PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION</b>		Pass
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal	The approved power supply unit is provided with metal enclosure. Evaluation of the requirements of this sub-clause has therefore evaluated during its approval. The inner metal chassis of the equipment is reliably connected to metal chassis of the power supply unit.	Pass
18b	Protective earth terminals suitable for connection to the protective earth conductor	Approved source of appliance inlet is provided on the built-in power supply unit.	Pass
18e	Potential equalization conductor		N/A
	- Readily accessible		N/A
	- Accidental disconnection prevented in normal use		N/A
	- Conductor detachable without the use of a tool		N/A
	- Power supply cord does not incorporate a potential equalization conductor		N/A
	- Connection means marked with Symbol 9, Table DI		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

18f	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1 \Omega$		N/A
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $\leq 0.1 \Omega$		N/A
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part $\leq 0.2 \Omega$		N/A
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds $0.1 \Omega$ , the allowable value of the enclosure leakage current is not exceeded in single fault condition		N/A
18k	Functional earth terminal not used to provide protective earthing		N/A
18l	Class II equipment with isolated internal screens		N/A
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		N/A
	- functional earth terminal clearly marked		N/A
	- explanation of functional earth terminal provided in the accompanying documents		N/A

<b>19</b>	<b>CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS</b>		Pass
19.1b	Leakage currents	See below.	Pass
	- earth leakage current	Refer to appended table 19.	Pass
	- enclosure leakage current	Same as above.	Pass
	- patient leakage current	No patient circuits.	N/A
	- patient auxiliary current	Same as above.	N/A

<b>20</b>	<b>DIELECTRIC STRENGTH</b>		Pass
	Overall compliance with Clause 20	Refer to appended table 20.	Pass

<b>21</b>	<b>MECHANICAL STRENGTH</b>		Pass
21a	Sufficient rigidity of an enclosure tested by: force of 45 N	Applied and passed. Only one enclosure material is used.	Pass
21b	Sufficient strength of an enclosure tested by: impact hammer	Same as above.	Pass

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test		N/A
21.3	No damage to parts of patient support and/or immobilization system after the loading test		N/A
21.5	Hand held equipment or equipment parts are safe after drop test	Not a hand-held equipment.	N/A
21.6	Portable and mobile equipment is able to withstand rough handling		N/A

<b>22</b>	<b>MOVING PARTS</b>		Pass
22.2a	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment		N/A
22.2b	Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation	There are DC fans provided in the approved power supply unit and for cooling the CPU. However, the DC fans are not considered as hazardous moving part due to their size.	Pass
22.3	Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices		N/A
	Guides or other safeguards are removable only with a tool		N/A
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator		N/A
22.6	Parts of equipment subject to mechanical wear are accessible for inspection		N/A
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard		N/A
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard		N/A
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents		N/A
	Means for stopping of movements operate as a result of one single action		N/A

<b>23</b>	<b>SURFACES, CORNERS AND EDGES</b>		Pass
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IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	The enclosure edges are smooth and cannot cause an injury.	Pass
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<b>24</b>	<b>STABILITY IN NORMAL USE</b> (see appended table 24)		N/A
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°	Fixed equipment. To be evaluated for the final assembly position.	N/A
24.3	Equipment overbalances when tilted through an angle of 10°		N/A
	- does not overbalance when tilted through an angle of 5° in any position excluding transport		N/A
	- carry a warning notice stating that transport should only be undertaken in a certain position		N/A
	- in the position specified for transport does not overbalance when tilted to an angle of 10°		N/A
24.6a	Equipment or its parts with a mass of more than 20 kg is provided with:		N/A
	- suitable handling devices (grips etc.), or		N/A
	- instructions for lifting and handling during assembly		N/A
24.6b	b) On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons		N/A

<b>25</b>	<b>EXPELLED PARTS</b>		N/A
25.1	Protective means are provided where expelled parts of the equipment could be a hazard		N/A
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		N/A

<b>28</b>	<b>SUSPENDED MASSES</b>		N/A
28.3	Suspension system with safety device		N/A
	Safety device provided where the integrity of a suspension depends on parts which may have hidden defects, or on parts having safety factors not complying with Sub-clause 28.4		N/A
	Safety device has safety factors complying with Sub-clause 28.4.2		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Clear indication to the operator that the safety device has been activated after failure of suspension means		N/A
28.4	Suspension systems of metal without safety devices		N/A
	1) Total load does not exceed the safe working load		N/A
	2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired		N/A
	3) Safety factors not less than 8 where impairment is expected		N/A
	4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%		N/A
	5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement		N/A
<b>29</b>	<b>X-RADIATION</b>		N/A
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure $\leq 130$ nC/kg (0.5 mR)		N/A
<b>36</b>	<b>ELECTROMAGNETIC COMPATIBILITY</b>		Pass
	Equipment complies with IEC 601-1-2	Compliance with the requirements of IEC/EN 60601-1-2 is evaluated. Test report number 0606100 (Neutron Engineering, Inc.)	Pass
<b>37</b>	<b>COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT</b>		N/A
	Requirements for category AP and APG equipment (Cl. 37 - 41)		N/A
<b>42</b>	<b>EXCESSIVE TEMPERATURES</b>		Pass
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures per Clause 10.2.1	Refer to appended table 42.	Pass
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient	Same as above.	Pass

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C		N/A
42.5	Guards to prevent contact with hot surfaces removable only with a tool		N/A

<b>43</b>	<b>FIRE PREVENTION</b>		Pass
	Strength and rigidity necessary to avoid a fire hazard	Refer to sub-clause 21 and table 56.1 for enclosure material.	Pass

<b>44</b>	<b>OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION</b>		Pass
44.2	Equipment contain a liquid reservoir:		N/A
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min		N/A
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling)		N/A
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)		N/A
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		N/A
44.5	Equipment sufficiently protected against the effects of humidity	Refer to appended table 44.	Pass
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529		N/A
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions		N/A

<b>45</b>	<b>PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE</b>		N/A
45.2	Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure		N/A
45.3	Maximum pressure does not exceed the maximum permissible working pressure for individual parts		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
45.7	Unless excessive pressure can not occur, pressure-relief device provided		N/A
45.7a	Pressure-relief device connected as close as possible to the pressure vessel		N/A
45.7b	Readily accessible for inspection		N/A
45.7c	Not capable of being adjusted or rendered inoperative without a tool		N/A
45.7d	Discharge opening located that the released material is not directed towards person		N/A
45.7e	Discharge opening located that operation will not deposit material which may cause a safety hazard		N/A
45.7f	Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure		N/A
45.7g	No shut-off valve between a pressure-relief device and the parts intended to be protected		N/A
45.7h	Minimum number of cycles of operation: 100.000		N/A
<b>48</b>	<b>BIOCOMPATIBILITY</b>		N/A
	Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1		N/A
<b>49</b>	<b>INTERRUPTION OF THE POWER SUPPLY</b>		Pass
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard	Not such components provided.	N/A
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function	The equipment is a computer system (point-of-care) not intended for use with live supporting equipment.	Pass
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure		N/A
<b>51</b>	<b>PROTECTION AGAINST HAZARDOUS OUTPUT</b>		N/A
51.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

<b>52</b>	<b>ABNORMAL OPERATION AND FAULT CONDITIONS</b>		Pass
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13)	See below.	Pass
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	The equipment is computer incorporating monitoring device. The safety aspect of the software used shall be evaluated for the final system assembly based upon its intended use.	N/A
52.5.2	Failure of thermostats presents no safety hazards	No thermostat used.	N/A
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard	Tested accordingly during the approval of the built-in power supply unit.	Pass
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C	Refer to appended table 52.	Pass
52.5.6	Locking of moving parts presents no safety hazard	The built-in sources of DC fan are approved components.	Pass
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	No such components used.	N/A
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8		N/A
52.5.9	Failure of one component at a time presents no safety hazard	Tested accordingly for the approved power supply unit. For the outputs of the DC/AC inverter, refer to appended table 19.	Pass
52.5.10	Overload of heating elements presents no safety hazard	No heating elements.	N/A
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	No motors incorporated.	N/A
	h) Equipment with three-phase motors can safely operate with one phase disconnected		N/A

<b>56</b>	<b>COMPONENTS AND GENERAL ASSEMBLY</b>		Pass
	List of critical components	Refer to appended table 56.1	Pass
56.1b	Ratings of components not in conflict with the conditions of use in equipment	All components rated accordingly.	Pass

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Ratings of mains components are identified	Refer to appended table 56.1	Pass
56.1d	Components, movements of which could result in a safety hazard mounted securely	Evaluated during the approval of the built-in power supply unit.	N/A
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard	Same as above.	N/A
56.3a	Connectors provide separation required by Sub-clause 17g		N/A
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment		N/A
	Medical gas connections not interchangeable	No such connections.	N/A
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken	No such cord.	N/A
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.		N/A
56.4	Connections of capacitors		Pass
	Not connected between live parts and non-protectively earthed accessible parts	In approved power supply unit.	Pass
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14	Same as above.	Pass
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts	Same as above.	Pass
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs		N/A
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment		N/A
56.6	Temperature and overload control devices		N/A
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment		N/A
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		N/A
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		N/A
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times		N/A
	Non-self resetting over-current releases operated 10 times		N/A
56.6b	Thermostats with varying temperature settings clearly indicated		N/A
	Operating temperature of thermal cut-outs indicated		N/A
56.7	Batteries		Pass
	a) Battery compartments:		Pass
	- adequately ventilated	The battery provided is coin-type non-rechargeable Li-Ion battery.	N/A
	- accidentally short-circuiting is prevented	Prevented by the design of the battery holder.	Pass
	b) Incorrect polarity of connection prevented	Same as above.	Pass
56.8	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):		Pass
	- to indicate that equipment is energized	Provided on the front enclosure of the equipment (green LED).	Pass
	- to indicate the operation of non-luminous heaters if a safety hazard could result		N/A
	- to indicate when output exists if a safety hazard could result		N/A
	- charging mode indicator provided		N/A
56.10	Actuating parts of controls	See below.	Pass
56.10b	Actuating parts are adequately secured to prevent them from working loose during normal use	No actuating parts the movement of which may cause hazards.	Pass
	Controls are secured to prevent the movement relative to scale marking (safety related only)		N/A
	Detachable indicating devices are prevented from incorrect connection without the use of tool		N/A
56.10c	Stops are provided on rotating controls:		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard		N/A
	- to prevent damage to wiring		N/A
56.11	Cord-connected hand-held and foot-operated control devices		N/A
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g		N/A
	b) Hand-held control devices comply with the requirement and test of Sub-clause 21.5		N/A
	- Foot-operated control devices designed to support the weight of an adult human being		N/A
	c) Devices not change their setting when inadvertently placed		N/A
	d) Foot-operated control devices are at least IPX 1		N/A
	- For surgical use, electrical switching parts are IPX 8		N/A
	e) Adequate strain relief at the cord entry provided		N/A

<b>57</b>	<b>MAINS PARTS, COMPONENTS AND LAYOUT</b>		Pass
57.1	Isolation from supply mains		Pass
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	Approved appliance inlet used.	Pass
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents	Same as above.	Pass
	d) Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328	Same as above.	N/A
	f) Mains switches not incorporated in a power supply cord		Pass
	h) Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a	See 57.1 a)	Pass
	m) Fuses and semiconductor devices not used as isolating devices	Not used.	Pass
57.2	Mains connectors and appliance inlets		Pass
	e) Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug	No socket outlets.	N/A



IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment	Class I equipment.	Pass
57.3	Power supply cords		Pass
	a) Not more than one connection to a particular supply mains	Approved power supply cord set is to be used.	Pass
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously		N/A
	The mains plug has only one power supply cord		N/A
	Non-permanently connected equipment provided with power supply cord or appliance inlet		N/A
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53		N/A
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C		N/A
	c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV	Suitable information for choosing appropriate power cord is provided in the accompanying documents.	Pass
	d) Stranded conductors not soldered if fixed by any clamping means		N/A
57.4	Connection of power supply cords		N/A
57.4a	Cord anchorages		N/A
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting		N/A
	Tying the cord into a knot or tying the ends with string not used		N/A
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		N/A
	Cord anchorages made of metal provided with an insulating lining		N/A
	Clamping screws do not bear directly on the cord insulation		N/A
	Screws associated with cable replacement are not used to secure other components		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Conductors of the power supply cord arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals		N/A
57.4b	Power supply cord protected against excessive bending		N/A
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		N/A
57.5	Mains terminal devices and wiring of mains part		N/A
	Mains connected equipment other than those with a detachable supply cord provided with mains terminals, where connections are made with screws, nuts or equally effective methods		N/A
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced		N/A
	Screws and nuts which clamp external conductors not serve to fix any other component		N/A
	b) Terminals closely grouped with any protective earth terminal		N/A
	Mains terminal devices accessible only with use of a tool		N/A
	Mains terminal devices located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact		N/A
	c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened		N/A
	d) Cord terminals not require special preparation of the conductor		N/A
57.6	Mains fuses and overcurrent releases		Pass
	Fuses or over-current releases provided accordingly for Class I and Class II	Provided in the approved power supply unit.	Pass
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current	Same as above.	Pass
	Protective earth conductor not fused		Pass
	Neutral conductor not fused for permanently installed equipment	Not a permanently installed equipment.	N/A
57.8	Wiring of the mains part		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Individual conductor in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC 227 or 245, treated as bare conductor		N/A
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord		N/A
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard		N/A
57.9	Mains supply transformers		Pass
57.9.1	Overheating	Evaluated during the approval of the power supply unit and the current assessment.	Pass
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative	Same as above.	Pass
57.9.1a	Short-circuit of secondary windings not caused excessive temperature	Evaluated during the approval of the power supply unit.	Pass
57.9.1b	Overload of secondary windings not caused excessive temperature	Same as above.	Pass
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests	Same as above.	Pass
57.9.4	Construction		Pass
	a) Separation of primary and secondary windings	Evaluated during the approval of the power supply unit.	Pass
	- separate bobbins or formers		N/A
	- one bobbin with insulating partition		N/A
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm		N/A
	- concentrically wound on one bobbin with windings separated by double insulation	Evaluated during the approval of the power supply unit.	Pass
	c) Means provided to prevent displacement of end turns	Same as above.	Pass
	d) Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn		N/A
	e) Insulation between the primary and secondary in transformers with double insulation		Pass

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- 1 insulation layer with thickness of at least 1 mm		N/A
	- at least 2 insulation layers with a total thickness of at least 0.3 mm		N/A
	- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation	Evaluated during the approval of the power supply unit.	Pass
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3 mm extending at least 20 mm outside the winding		N/A
57.10	Creepage distances and air clearances		Pass
	a) Values: compliance with at least the values of Table XVI	Evaluated during the approval of the power supply unit and the current assessment.	Pass
	Creepage distances for slot insulation of motors at least 50% of the specified values		N/A
	b) Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuiting does not produce a safety hazard		N/A
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts	No such parts.	N/A
<b>58</b>	<b>PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS</b>		Pass
58.1	Clamping means of the protective earth terminal		Pass
	Not be able to loosen without the aid of a tool	A tool is needed to access connections of the protective earthing loop.	Pass
	Screws for internal earth connections are covered or protected against loosening from outside	Same as above.	Pass
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal		Pass
58.8	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing	Not used.	Pass
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting	Approved source of appliance inlet is used.	Pass

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
<b>59</b>	<b>CONSTRUCTION AND LAYOUT</b>		Pass
59.1	Internal wiring		Pass
	a) Cables and wiring protected against contact with a moving part	The internal wiring routed away from the rotating blades of internal fans. Additionally where appropriate metal guards are provided to prevent internal wires from contact with the rotating parts.	Pass
	Wiring having basic insulation only protected by additional fixed sleeving	Internal wiring with basic insulation in contact only with earthed metal parts.	Pass
	Components are not likely to be damaged in the normal assembly or replacement of covers		Pass
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead		N/A
	c) Insulating sleeving adequately secured		N/A
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test		N/A
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material	All internal wiring is suitable rated.	Pass
	d) Aluminum wires of less than 16 mm <sup>2</sup> cross-section not used	Not used.	Pass
	f) Connecting cords between equipment parts considered as belonging to the equipment		N/A
59.2	Insulation		Pass
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation	Evaluated during the approval of the built-in switching power supply.	Pass
	c) Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts	No such parts.	N/A
	Parts of rubber resistant to ageing		N/A
59.3	Excessive current and voltage protection		N/A
	Internal electrical power source provided with device for protection against fire hazard		N/A
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder		N/A
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
59.4	Oil containers		N/A
	Oil containers adequately sealed		N/A
	Container allow for the expansion of the oil		N/A
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		N/A
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N/A

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

6.1	TABLE: marking durability		Pass
Marking tested		Remarks	
Product rating label		Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit at ambient temperature and then for 15 s with a cloth rag soaked with isopropyl alcohol.	
Supplementary information:			

7	TABLE: power input					Pass
Operating condition		Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks
Tested for model POC-174xxxxxxxxxx supplied by power adaptor type FSP180-50MP, motherboard PCM-9682						
Maximum normal load		90	50	2.1	186	Load of the built-in power unit $\approx$ 70% of its maximum rated load.
Same as above		100	50	1.9	185	Rated current = 4A
Same as above		240	50	0.8	178	Rated current = 2A
Same as above		264	50	0.7	177	
Same as above		90	60	2.1	186	
Same as above		100	60	1.9	184	Rated current = 4A
Same as above		240	60	0.8	178	Rated current = 2A
Same as above		264	60	0.7	177	
Tested for model POC-175xxxxxxxxxx supplied by power adaptor type FSP180-50MP, motherboard PCM-9690						
Maximum normal load		90	50	1.7	149	
Same as above		100	50	1.5	148	Rated current = 4A
Same as above		240	50	0.6	142	Rated current = 2A
Same as above		264	50	0.6	142	
Same as above		90	60	1.7	149	
Same as above		100	60	1.5	148	Rated current = 4A
Same as above		240	60	0.6	144	Rated current = 2A
Same as above		264	60	0.6	142	

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

CPU 2GHz, DDRAM 2GB/533MHz, HDD Fujitsu, type MHT2020AT, Speaker 2 x 8Ω, 1W, system fan 10.8CFM (outwards), panel M170EN07, DC/AC inverter LV-170LC-A, IEEE 1394 loaded 12W each (12V/1A), USB ports loaded 2.5W each (5V/0.5A), HDD and CD-ROM seeking, pink noise supplied to the audio input (according to EN 60065)

15b	TABLE: residual voltage in attachment plug										N/A	
Voltage measured		Measurements [ V ]									Remarks	
between:		1	2	3	4	5	6	7	8	9	10	
Supplementary information: Evaluated during the approval of the built-in power supply unit.												

15c	TABLE: residual voltage or energy in capacitors					N/A
Capacitor and its location		Residual voltage (V)	Time after disconnection (s)	Capacitance value (μF)	Residual energy (mJ)	Remarks
Supplementary information:						

17h1	TABLE: defibrillation-proof applied parts					N/A
Test Condition: Fig. 50 or 51	Accessible part of measurement:	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks	

Supplementary information:

17h2	TABLE: defibrillation-proof recovery time				N/A
Applied part with test voltage	Test voltage	Recovery time from accompanying	Measured recovery	Remarks	



IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

	polarity	documents (s)	time (s)	

Supplementary information:

18	TABLE: protective earthing				Pass
Test location		Test current (A)	Measured voltage (V)	Resistance (mΩ)	Remarks
Earth pin of the AC inlet to inner metal chassis around power supply unit.		25	0.85	34	
Same as above		40	1.25	31	
Supplementary information:					

19	TABLE: leakage current				Pass
Type of leakage current and test condition (including single faults)		Supply voltage (V)	Supply frequency (Hz)	Measured max. value (mA)	Remarks
<u>Before humidity conditioning</u>					
EN; NC (limit = 0.1mA)		264	60	0.02	S1=1 or 0; S5 = 0 or 1; S7=1
EN; SFC (limit = 0.1mA)		264	60	0.02	S1=1 or 0; S5 = 0 or 1; S7=1
EN, SFC (limit = 0.5mA)		264	60	0.17	S1=1 or 0; S5 = 0 or 1; S7=0
<u>After humidity conditioning</u>					
EN; NC (limit = 0.1mA)		264	60	0.02	S1=1 or 0; S5 = 0 or 1; S7=1
EN; SFC (limit = 0.1mA)		264	60	0.02	S1=1 or 0; S5 = 0 or 1; S7=1
EN, SFC (limit = 0.5mA)		264	60	0.17	S1=1 or 0; S5 = 0 or 1; S7=0
(Record at least maximum measured value for each test required by Clause 19 and the specific conditions of the test circuit and equipment).					

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

#### Supplementary information:

The test was performed for the DC/AC inverter under normal and single fault condition for evaluation of compliance according to sub-clause 17g) (See below). In the data "s-c" stands for short circuit and "o-c" stands for open circuit.

- For DC/AC Inverter type LV-1701LC-A:  
The following locations have been tested: CN2 (2 – 4), CN2 (2 – earth), CN2 (4 – earth), T1 (10 – earth). In all cases the DC/AC inverter shutdown (leakage current below 0.1mA was measured). The following single faults were evaluated: D1 s-c, R9 s-c, R2 s-c, R5 s-c, L1 s-c, R17 s-c, C2 s-c, Q9 s-c.
- For DC/AC Inverter type LV-1201-D:  
Following locations have been tested: CN3 (1 – 2), CN3 (1 – earth), CN3 (2 – earth). In all cases, the DC/AC inverter shutdown (leakage current below 0.1mA was measured). The following single faults were evaluated: D7 s-c, Q5 (C-E) s-c, Q9 (C-E), L1 s-c, R9 s-c, R5 s-c, R41 s-c, M1 (1-3) s-c, D1 (2-3) s-c and R13 o-c, R19 o-c.
- For DC/AC Inverter type LV-1702LC-AB:  
Following locations have been tested: CN3 (2 – 4), CN3 (2 – earth), CN3 (4 – earth).  
In all cases, the DC/AC inverter shutdown (leakage current below 0.1mA was measured). The following single faults were evaluated: D1 (pin 2 to pin3) s-c, R9 s-c, R1 s-c, R5 s-c, R19 s-c, L1 s-c, R41 s-c, Q5 (C-E) s-c, D7 s-c and R13 o-c, R19 o-c.

The earth leakage currents have been evaluated for all appropriate positions of S1, S5 and S7 during the approval of the power supply unit and were found in compliance with IEC 60601-1+A1+A2.

#### Abbreviations used:

ER - Earth leakage current	A - After humidity conditioning
EN - Enclosure leakage current	B - Before humidity conditioning
P - Patient leakage current	1 - Switch closed or set to normal polarity
PM - Patient leakage current with mains on the applied parts	0 - Switch open or set to reversed polarity
PA - Patient auxiliary current	N.C. - Normal condition
Fig. 15 - refers to Fig. 15 in IEC601-1	S.F.C. - Single fault condition
MD - Measuring device	

20	TABLE: dielectric strength				Pass
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational/ BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (Va.c.)	Test voltage (Vd.c.)	Remarks	
Before humidity conditioning					
A – b	BI	250	1500	No breakdown	
A – a2	RI	533 <sup>1)</sup>	5132	No breakdown	
After humidity conditioning					
A – b	BI	250	1500	No breakdown	
A – a2	RI	533 <sup>1)</sup>	5132	No breakdown	

#### Supplementary information:

1) Tested with working voltages as measured during the approval of the power supply unit (full rated load). The

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

working voltages measured in the power supply unit at loads as used in the EUT do not exceed this value.

21	TABLE: mechanical strength		Pass
Part under test		Test (impact, drop, force, handle, rough handling, mobile)	Remarks
Plastic enclosure		Force of 45N applied over surface of 625mm <sup>2</sup>	No damages
Ditto.		Impact with 0.5J	No damages.
Supplementary information:			

24	TABLE: - stability		N/A
Part under test		Test condition	Remarks
Supplementary information: Refer to the relevant sub-clause.			

29	TABLE: X - radiation			N/A
Part under test		Test condition	Measured radiation (mR)	Remarks
Supplementary information:				

42	TABLE: normal temperature			Pass	
Supply voltage .....:		A. 100V-10%/60Hz B. 240V+10%/50Hz	Test Condition: (see appended table 7.1)		
Ambient temperature..... : 27°C					
Measuring location			Measured temperature [°C]		Remarks (allowed Tmax [°C])
			A.	B.	
Model POC-174xxxxxxxxxxx, DC/AC inverter type LV-1701LC-A					
Components in the built-in SPS					

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
EL1 coil	71	58	117
EL2 coil	61	57	117
T1 coil	71	71	107
T2 coil	57	57	107
L1 coil	72	65	117
Components in the built-in DC/AC inverter			
L2 coil	80	77	92
T2 coil	84	82	92
Components other than SPS and DC/AC inverter			
PCB near CPU	42	42	117
PCB near U29	43	43	117
HDD body	36	36	47
FDD body	36	36	47
DVD-ROM body	38	38	47
Enclosure inside	36	36	72
Enclosure outside	33	33	72
LCD panel	41	42	72
Model POC-174xxxxxxxxxx, DC/AC inverter type LV-1701-D, components in the built-in DC/AC inverter			
T1 coil	63	63	92
L1 coil	68	67	92
LCD panel (Chunghwa Picture Tubes, type CLAA150XE01)	33	33	72
F Model POC-174xxxxxxxxxx, DC/AC inverter type LV-1702LC-AB, components in the built-in DC/AC inverter			
T1 coil	54	55	92
L1 coil	61	61	92
LCD panel (Chunghwa Picture Tubes, type CLAA150XE01)	34	34	72

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

Model POC-175xxxxxxxxxx, DC/AC inverter type LV-1701LC-A			
Components in the built-in DC/AC inverter			
L2 coil (DC/AC inverter)	86	76	92
T2 coil (DC/AC inverter)	86	87	92
LCD panel	53	53	72
Components other than SPS and DC/AC inverter			
PCB near U41	90	92	107
PCB near U38	94	95	107
PCB near U40	87	89	107
PCB near U70	76	78	107
HDD body	69	68	--
CD-ROM body	65	68	--
Enclosure inside near power supply	58	59	--
Enclosure outside near power supply	49	49	72
Supplementary information:			
The maximum specified ambient temperature is 40°C.			
The lowest ambient temperature during the test is 27°C.			
The maximum absolute temperatures Tmax (in °C) are calculated as follows:			
Winding components (with safety insulation):			
<ul style="list-style-type: none"> <li>Class B → Tmax = 130 – 10* - (40-27) = 107</li> </ul>			
Capacitors or components having:			
<ul style="list-style-type: none"> <li>maximum temperature of 105°C → Tmax = 105 – (40-27) = 92</li> <li>maximum temperature of 130°C → Tmax = 130 – (40-27) = 117</li> </ul>			
Accessible parts which are held by the operator short period:			
<ul style="list-style-type: none"> <li>maximum temperature of 60°C → Tmax = 60 – (40-27) = 47</li> <li>maximum temperature of 85°C → Tmax = 85 – (40-27) = 72</li> </ul>			
Notes:			
1) An asterisk indicates that for temperature rises of windings determined by thermocouple method, these figure are reduced by 10 K except in case of motors.			
2) The output load of the built-in SPS as used within the EUT is approximately 70% of its maximum normal load evaluated during its approval. Only some components were therefore measured in order to evaluate the heating of the power supply with its current load.			

44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning,	Pass
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IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

	sterilization, disinfection		
Test type and condition		Part under test	Remarks
Humidity treatment at 40°C, 93% R.H. for 120 hours		Entire equipment.	No hazards.
Supplementary information:			

45	TABLE: hydrostatic pressure and pressure-relief device cycling test			N/A
Test type and condition		Part under test	Test pressure	Remarks
Supplementary information:				

52	TABLE: abnormal operation		Pass
Test type, condition and clause reference	Observed results	Remarks	
Model POC-174xxxxxxxxxxx, DC/AC inverter type LV-1701LC-A			
Ventilation openings covered	Normal operation. The temperatures on the components do not significantly differ from those measured under normal condition.	No safety hazards.	
CPU fan locked	Same as above	No safety hazards.	
D7 short circuit	Li-Ion battery abnormal charge. Charge current = 3mA.	No safety hazards.	
R421 short circuit	Li-Ion battery abnormal charge. Charge current = 0mA.	No safety hazards.	
Model POC-175xxxxxxxxxxx, DC/AC inverter type LV-1701LC-A			
Enclosure openings covered	Test time 5 hours. Temperatures stabilized at:  L2 coil (DC/AC inverter) = 105°C, T2 coil (DC/AC inverter) = 106°C, Enclosure – outside = 63°C, Ambient = 40°C	No safety hazards.	
Supplementary information: Thermocouple method used. Test voltage for all tests 264V/60Hz			
Based upon the construction of the motherboard models, a system fan failure testing (CPU) was not considered necessary.			

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

56.1	TABLE: lists of critical component parts					Pass
Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity <sup>1)</sup>	
PCB	Various	Various	V-1 or better, 105°C min.	UL94	UL	
Enclosure material	Chi Mei	PA-765A	V-1 or better, 80°C min.	UL 94	UL	
HDD Drive (Optional)	Fujitsu	MHT2020AT	DC 5V, 0.55A max.	EN 60950-1:2001	TÜV, UL	
FDD Drive (Optional)	NEC	FD3238T	DC 5V, 1.5A max.	EN 60950-1:2001	TÜV, UL	
CD / DVD-ROM / CD-RW Drive (Optional)	Quanta Storage Inc.	SCR-242	DC 5V, 1.5A, Class 1 Laser Product	EN 60950-1:2001	TÜV, UL	
	Toshiba Corp	XM-7004Bxx, XM-1902Bxx	DC 5V, 1.5A, Class 1 Laser Product	EN 60950-1:2001	TÜV, UL	
	Quanta Storage Inc	SDR-XXXX	DC 5V, 1.8A max., Class 1 Laser Product	EN 60950-1:2001	TÜV, UL	
	Matsushita	SR-8175-C, SR-8176-C	DC 5V, 1.8A max., Class 1 Laser Product	EN 60950-1:2001	TÜV, UL	
	Quanta Storage Inc.	SBW-243	DC 5V, 1.5A max., Class 1 Laser Product	EN 60950-1:2001	TÜV	
	Quanta Storage Inc.	SDW-082S	DC 5V, 1.5A max., Class 1 Laser Product	EN 60950-1:2001	TÜV	
	TEAC	CD-224E	DC 5V, 1.5A max., Class 1 Laser Product	EN 60950-1:2001	TÜV	
Lithium Battery	Toshiba	CR2032	DC 3V, maximum abnormal charging current 10mA	UL 1642	UL	
	Rayovac	BR2032	DC 3V, maximum abnormal	UL 1642	UL	

IEC 601+ Am. 1 & 2					
Clause	Requirement + Test		Result - Remark		Verdict
			charging current 10mA		
	Sony	CR2032	DC 3V, maximum abnormal charging current 10mA	UL 1642	UL
	Vic-Dawn Enterprise Co Ltd	CR2032	DC 3V, maximum abnormal charging current 10mA	UL 1642	UL
	Mitsubishi Electric Corp	CR2032	DC 3V, maximum abnormal charging current 10mA	UL 1642	UL
	Matsushita	CR2032	DC 3V, maximum abnormal charging current 5mA	UL 1642	UL
System Fan	ADDA	AD0612MB- G76	DC 12V, 0.13A, 12.0CFM	EN 60950-1	TÜV, UL
	ADDA	AD0612LB-G76	DC 12V, 0.11A, 11.7CFM	EN 60950-1	TÜV, UL
LCD Panel	AU Optronics Couporation	M170EN07	TFT type, SVGA 17 inch	--	--
	AU Optronics Corporation	M170EG01	TFT type, SXGA 17 inch		
DC/AC Inverter for 17 inch panel	Lecerf Technology Co., Ltd	LV-1701LC-A	Input: DC 12V, 1.8A, Output: 680Vrms, 13mA	--	--
- Transformer (T1, T2)	Lecerf Technology Co., Ltd	X08-C-1	105°C	--	--
LCD Panel	Chunghwa Picture Tubes, Ltd.	CLAA150XE01	TFT type, SVGA, 15 inch	--	--
	AU Optronics Corporation	G150XG01	TFT type, SVGA, 15 inch		
	AU Optronics Corporation	M150XN07	TFT type, SVGA, 15 inch		
	AU Optronics	M170EG01 V.5	TFT type, SXGA		



IEC 601+ Am. 1 & 2					
Clause	Requirement + Test		Result - Remark		Verdict
	Corporation		17 inch		
	AU Optronics Corporation	M170EG01 V.8	TFT type, SXGA 17 inch		
DC/AC Inverter (for both 15 and 17 inch)	Lecerf Technology Co., Ltd.	LV-1702LC-AB	Input: DC 13V, 1.4A, Output: 750Vrms, 16mA	--	--
- transformer (T1, T2)	Lecerf Technology Co., Ltd.	X08	105°C	--	--
DC/AC Inverter (for 15 inch)	Lecerf Technology Co., Ltd.	LV-1201-D	Input: DC 13V, 1.4A, Output: 750Vrms, 8mA	--	--
- transformer (T1, T2)	Lecerf Technology Co., Ltd.	X03	105°C	--	--
PTC device (L6)(for VGA connector)	Polytronics	SMD0805P020 T(+)	DC 9V, 0.2A, (Ih), 0.5A (It)	IEC/EN 60730-1	UL, TUV
PTC device (FS5) (for PS2 connector)	Tyco Corp. (Raychem)	miniSMDC110	DC 8V, 1.1A	IEC/EN 60730-1	UL, TUV
PCB (Motherboard)	Various	Various	130°C	UL 94	UL
- PTC device (FS2, FS3, FS5) (for COM connector)	Tyco Corp. (Raychem)	miniSMDC110	DC 8V, 1.1A	EN 60730-1, UL 1434	TÜV, UL
- PTC device (FS6) (for PS2 KB+MS connector)	Tyco Corp. (Raychem)	miniSMDC110	DC 8V, 1.1A	EN 60730-1, UL 1434	TÜV, UL
- PTC device (F1) (for VGA connector)	Tyco Corp. (Raychem)	miniSMDC110	DC 8V, 1.1A	EN 60730-1, UL 1434	TÜV, UL
- PTC device (F2, F3, F4, F5, F6, F7) (for USB connector)	Tyco Corp. (Raychem)	miniSMDC110	DC 8V, 1.1A	EN 60730-1, UL 1434	TÜV, UL
- PTC device (FS9) (for IEEE 1394 connector)	Polytronics Technology Corp.	SMD2920P150 TS	DC 12V, 3A	EN 60730-1, UL 1434	TÜV, UL

IEC 601+ Am. 1 & 2					
Clause	Requirement + Test		Result - Remark		Verdict
Power Supply Unit	FSP Group Inc	FSP180-50MP	Input: 100-240Vac, 4A, 50-60Hz; DC Output: +3.3V/16.8A, +5V/12A, +12V/12A, +5Vsb/2.0A, -12V/0.8A	IEC 60601-1+A1+A2	CB-scheme approval
1. Enclosure	Various	Various	Metal, thick 0.6 mm	--	--
2. PCB	Various	Various	Min. V-0, 130°C min.	UL 94	UL
3. Appliance Inlet	Hua Feng	HF-301	10A, 250VAC	IEC/EN 60320-1, UL498	VDE, UL (E164798)
	Rong Feng	SS-7B, SS-120	10A, 250VAC	IEC/EN 60320-1, UL498	VDE, UL (E102641)
	Supercom	SC-9	10A, 250VAC	IEC/EN 60320-1, UL498	VDE, UL (E152973)
	Inalways	0711, 0707-1, 0707	10A, 250VAC	IEC/EN 60320-1, UL498	VDE, UL (E94191) VDE
	Singatron	AC-008A	10A, 250VAC	IEC/EN 60320-1, UL498	VDE, UL (E67635)
	Rich Bay	R-301SN, R-301	10A, 250VAC	IEC/EN 60320-1, UL498	VDE, UL (E128780)
	Kautt & Bux KG	SFF330	10A, 250VAC	IEC/EN 60320-1	VDE
	Solteam	ST-01	10A, 250VAC	IEC/EN 60320-1, UL498	VDE, UL (E200241)
4. Y-capacitors (CY1, CY2, EC2, EC3) (Optional)	Matsushita	NS-A, RS, TS, ECQ-UV	Max. 220pF, 250VAC min.	IEC 60384-14 2ed. / UL1414	VDE, UL (E62674)
(CY1, CY2: secured on inlet) (EC2, EC3: loc. on E-board)	Murata	KC, KH	Max. 220pF, 250VAC min.	IEC 60384-14: 1993, UL1414	VDE, UL (E37921)
	Pan Overseas	AC, AH	Max. 220pF, 250VAC min.	IEC 60384-14: 1993, UL1414	VDE, UL (E146544)
	Sam Hwa	SC	Max. 220pF, 250VAC min.	IEC 60384-14: 1993,	VDE, UL (E97754)

IEC 601+ Am. 1 & 2					
Clause	Requirement + Test			Result - Remark	Verdict
				UL1414	
	Welson	KL	Max. 220pF, 250VAC min.	IEC 60384-14: 1993, UL1414	VDE, UL (E104572)
	TDK	CS, CD	Max. 220pF, 250VAC min.	IEC 60384-14: 1993, UL1414	VDE, UL (E37861)
	Rifa	PHE 289M, PHE 271Y	Max. 220pF, 250VAC min.	IEC 60384-14: 1993, UL1414	VDE, UL (E100117)
	Samsung [Netron]	AD, AA	Max. 220pF, Min. 400Vac	IEC 60384-14: 1993, UL1414	VDE, [UL (E87113)]
	Iskra	KNB2520	Max. 220pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E103619)
	Siemens [Epcos]	B81122 series	Max. 220pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E97863)
	Success	SE, SF, SB	Max. 220pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E114280)
5. X-capacitors (CX) (Optional) (Secured on inlet)	Pilkor	PCX2 335M	Max. 0.68μF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E165646)
	Taishing	MPX	Max. 0.68μF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E64032)
	Matsushita	ECQ-UL	Max. 0.68μF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E62674)
	Iskra	KNB1530, KNB1560, KNB1520	Max. 0.68μF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E145156)
	Roederstein (ERO)	F1772	Max. 0.68μF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E76297)
	Okaya	RE, LE, PA series	Max. 0.68μF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E78644)
	UTX [Dong Guan Qi Shi Sin Yu]	HQX	Max. 0.68μF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E2241300)

IEC 601+ Am. 1 & 2					
Clause	Requirement + Test		Result - Remark		Verdict
	Nitsuko	CFKC	Max. 0.68 $\mu$ F, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E84015)
	Teapo	XG-VP, XG-VS	Max. 0.68 $\mu$ F, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E81959)
	Thomson	QX	Max. 0.68 $\mu$ F, Min. 250V	IEC 60384-14: 1993	VDE
	Chiefcon	CKX	Max. 0.68 $\mu$ F, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E209251)
	Rifa	PHE 830M, PHE 840M	Max. 0.68 $\mu$ F, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E73869)
	Siemens [Epcos]	B81130	Max. 0.68 $\mu$ F, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E97863)]
	Farad	FXK	Max. 0.68 $\mu$ F, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E178496)
	Hua Jung	MKP	Max. 0.68 $\mu$ F, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E149075)
	Philips	PCX2 335	Max. 0.68 $\mu$ F, Min. 250V	IEC 60384-14: 1993	VDE
	Cheng Tung	CTX	Max. 0.68 $\mu$ F, Min. 250V		VDE, UL (E193049)
6. Fuse (EF1, EF2)	Conquer	MST	T4A, 250V	IEC 60127-3 / UL248	VDE, UL (E82636)
	Wickmann- Werke	392	T4A, 250V	IEC 60127-3 / UL248	VDE, UL(E67006)
7. X-capacitor (EC1) (Optional) (Loc. on E- board)	Pilkor	PCX2 335M	Max. 0.1 $\mu$ F, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E165646)
	Taishing	MPX	Max. 0.1 $\mu$ F, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E64032)
	Matsushita	ECQ-UL	Max. 0.1 $\mu$ F, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E62674)
	Iskra	KNB1530, KNB1560,	Max. 0.1 $\mu$ F, Min. 250V	IEC 60384-14: 1993,	VDE, UL (E145156)

IEC 601+ Am. 1 & 2					
Clause	Requirement + Test		Result - Remark		Verdict
		KNB1520		UL1414	VDE
	Roederstein (ERO)	F1772	Max. 0.1µF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E76297)
	Okaya	RE, LE, PA series	Max. 0.1µF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E78644)
	UTX [Dong Guan Qi Shi Sin Yu]	HQX	Max. 0.1µF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E2241300)
	Nitsuko	CFKC	Max. 0.1µF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E84015)
	Teapo	XG-VP, XG-VS	Max. 0.1µF, Min. 250V	IEC 60384-14 2ed. / UL1414	VDE, UL (E81959)
	Thomson	QX	Max. 0.1µF, Min. 250V	IEC 60384-14: 1993	VDE
	Chiefcon	CKX	Max. 0.1µF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E209251)
	Rifa	PHE 830M, PHE 840M	Max. 0.1µF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E73869)
	Siemens [Epcos]	B81130	Max. 0.1µF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E97863)
	Farad	FXK	Max. 0.1µF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E178496)
	Hua Jung	MKP	Max. 0.1µF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E149075)
	Philips	PCX2 335	Max. 0.1µF, Min. 250V	IEC 60384-14: 1993	VDE
	Cheng Tung	CTX	Max. 0.1µF, Min. 250V	IEC 60384-14: 1993, UL1414	VDE, UL (E193049)
8. Bleeder Resistor (ER10) (Loc. on E-board)	Various	Various	560 kΩ, 1/4W Loc. after fuse	--	--
9. Bleeder Resistor (RX) (Secured on	Tai	RD	560kΩ, 1/4W	IEC 60065	Nemko

IEC 601+ Am. 1 & 2					
Clause	Requirement + Test		Result - Remark		Verdict
inlet)					
10. Y-capacitors (C3, C4) (Optional)	Matsushita	NS-A, RS, TS, ECQ-UV	Max. 470pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E62674)
	Murata	KC, KH	Max. 470pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E37921)
	Pan Overseas	AC, AH	Max. 470pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E146544)
	Sam Hwa	SC	Max. 470pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E97754)
	Welson	KL	Max. 470pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E104572)
	TDK	CS, CD	Max. 470pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E37861)
	Rifa	PHE 289M, PHE 271Y	Max. 470pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E100117)
	Samsung [Netron]	AD, AA	Max. 470pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E87113)
	Iskra	KNB2520	Max. 470pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E103619)
	Siemens [Epcos]	B81122 series	Max. 470pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E97863)
	Success	SE, SF, SB	Max. 470pF, Min. 250Vac	IEC 60384-14: 1993, UL1414	VDE, UL (E114280)
11. Storage capacitor (C7)	Various	Various	120µF, 450V, min. 105°C	--	--
12. Photo coupler (IC3, EU5, EU6)	Toshiba	TLP732	dti= 0.4mm ext. dcr = 8.0mm	EN 60747-5-2, IEC 60950-1	VDE
(EU5, EU6: on C-board)	Vishay	CNR 21	dti= 0.4mm ext. dcr = 8.0mm	EN 60747-5-2, IEC 60950-1, UL1577	VDE, UL(E76222)

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

	Fairchild	H11....	dti= 0.4mm ext. dcr = 8.0mm	EN 60747-5-2, IEC 60950-1, UL1577	VDE, UL(E90700)
13. Choke (EL1, EL2) (Optional) (Loc. on E- board)	SPI	8LM00376	130°C	--	--
14. Choke (L1) (Optional)	SPI	8LM00258	130°C	--	--
15. Choke (L6) (Optional)	SPI	8LM00257	130°C	--	--
16. Choke (L8) (Optional)	SPI	8LM00375	130°C	--	--
17. Choke (L12) (Optional)	SPI	8LA00057	130°C	--	--
18. Transformer (T1)	SPI	8TG00107	Class B	Applicable part according IEC 60601-1 and IEC 60085	Accepted by TÜV
19. Transformer (T2)	SPI	8TC00164	Class B	Applicable part according IEC 60601-1 and IEC 60085	Accepted by TÜV
20. Varistor (M1) (Optional)	Centra	CNR-07D471K	300VAC, 385VDC	UL1449	UL (E150709)
	Song Long	07D471K, SAS-471KD07	300VAC, 385VDC	UL1449	UL (E171541)
	Matsushita	V7241U	300VAC, 385VDC	UL1449	UL (E86821)
	Thinking	TVR07471	300VAC, 385VDC	UL1449	UL (E173642)
	Joyin	JVR07N471K	300VAC, 385VDC	UL1449	UL (E153360)
	Ceramate	GNR07D471K	300VAC, 385VDC	UL1449	UL (E166389)
	Uppermost	V07K300	300VAC, 385VDC	UL1449	UL (E105157)
	Epcos	S07K150	300VAC, 385VDC	UL1449	UL (E97877)
	Maida	Z151-03	300VAC,	UL1449	UL (E86730)

IEC 601+ Am. 1 & 2					
Clause	Requirement + Test			Result - Remark	Verdict
			385VDC		
	AVX	VF07M10241K	300VAC, 385VDC	UL1449	UL (E84108)
21. DC fan	Sunonwealth	KDE1204PKBX	DC 12V, 0.13A, 10.8CFM	IEC 60950-1, UL507	TÜV, UL (E77551)
	Protechnic / Rotechnic	MGA4012ZB- A20	DC 12V, 0.22A, 11.09CFM	IEC 60950-1, UL507	TÜV, UL (E187236)
<sup>1)</sup> an asterisk indicates a mark which assures the agreed level of surveillance					

56.10	TABLE: actuating parts and controls		N/A
Part under test		Torque applied	Remarks
Supplementary information:			

56.11b	TABLE: foot operated control devices-loading		N/A
Part under test		Observed results	Remarks
Supplementary information:			

57.4	TABLE: cord anchorages					N/A
Cord under test		Mass of equipment	Pull	Torque	Remarks	Verdict
Supplementary information:						

57.4b	TABLE: cord bending				N/A
Cord under test		Test mass	Measured curvature	Remarks	



IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:			

57.9.1a	TABLE: transformer short circuit					N/A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
Supplementary information: Evaluated during the approval of the power supply unit.						

57.9.1b	TABLE: overload						N/A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current or thermal cut-out temp.	Remarks
		Primary	Secondary	Ambient			
Supplementary information: Evaluated during the approval of the power supply unit.							

57.9.2	TABLE: transformer dielectric strength				N/A
Transformer under test	Test voltage applied to	Test voltage (V)	Test frequency (Hz)	Remarks	
Supplementary information:					

	TABLE: additional tests		Pass
Clause	Test type and condition	Remarks and observed results	Verdict
2.5 of IEC 60950-1:2001	Limited power source measurement according to the requirements of IEC 60950-1:2001. The test is performed for	U <sub>OC</sub> =5.05V (for PS2); U <sub>OC</sub> =5.15V (for USB); U <sub>OC</sub> =5.04V (for VGA);	Pass

IEC 601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	<p>the PS2, USB and VGA ports (motherboard type PCM-9682).</p> <p>Compliance with the requirements is ensured by the usage of PTC devices provided in the power lines of those ports.</p>	$I_{SC} = 1.65A$ (for PS2); $I_{SC} = 0.88A$ (for USB); $I_{SC} = 0.97A$ (for VGA); Max. VA = 6.14, limit = 25.25VA (for PS2); Max. VA = 3.95, limit = 25.75VA (for USB); Max. VA = 4.03, limit = 25.20VA (for VGA);	
2.5 of IEC 60950-1:2001	Limited Power Source Measurement for ports with PTC type miniSMD C110 (motherboard type PCM-9690)	$U_{OC} = 5.05V$ , $I_{SC} = 1.6A$ , Max power = 6.4W	Pass
2.5 of IEC 60950-1:2001	Limited Power Source Measurement for ports with PTC type SMD2920P150TS (motherboard type PCM-9690)	$U_{OC} = 12.1V$ , $I_{SC} = 3.0A$ , Max power = 30.2W	Pass
Supplementary information:			

**SUMMARY OF CONTENTS:**

The equipment has been tested according to standards IEC 60601-1 (1998) and amendments A1 and A2, and EN 60601-1 (1990) and amendments A1, A2 and A13.

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

These tests fulfill the requirements of standard EN ISO 17025 (replaced the obsolete EN45001).

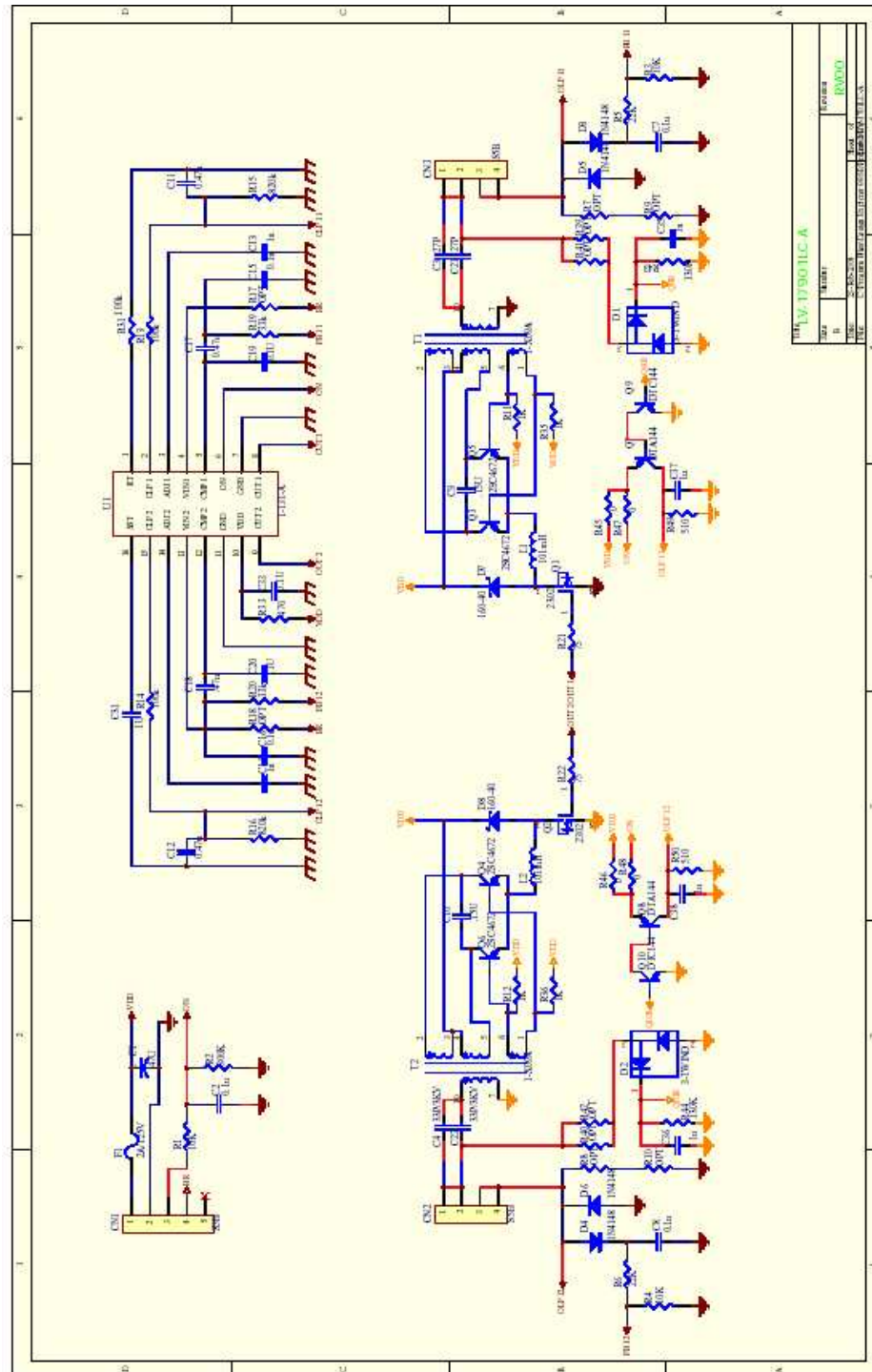
This test report comprises 56 including this page, 11 pages of national differences and the following Attachments:

Attachment #	Description	Pages
1	Circuit diagrams (all there sources of DC/AC inverter)	57 – 59

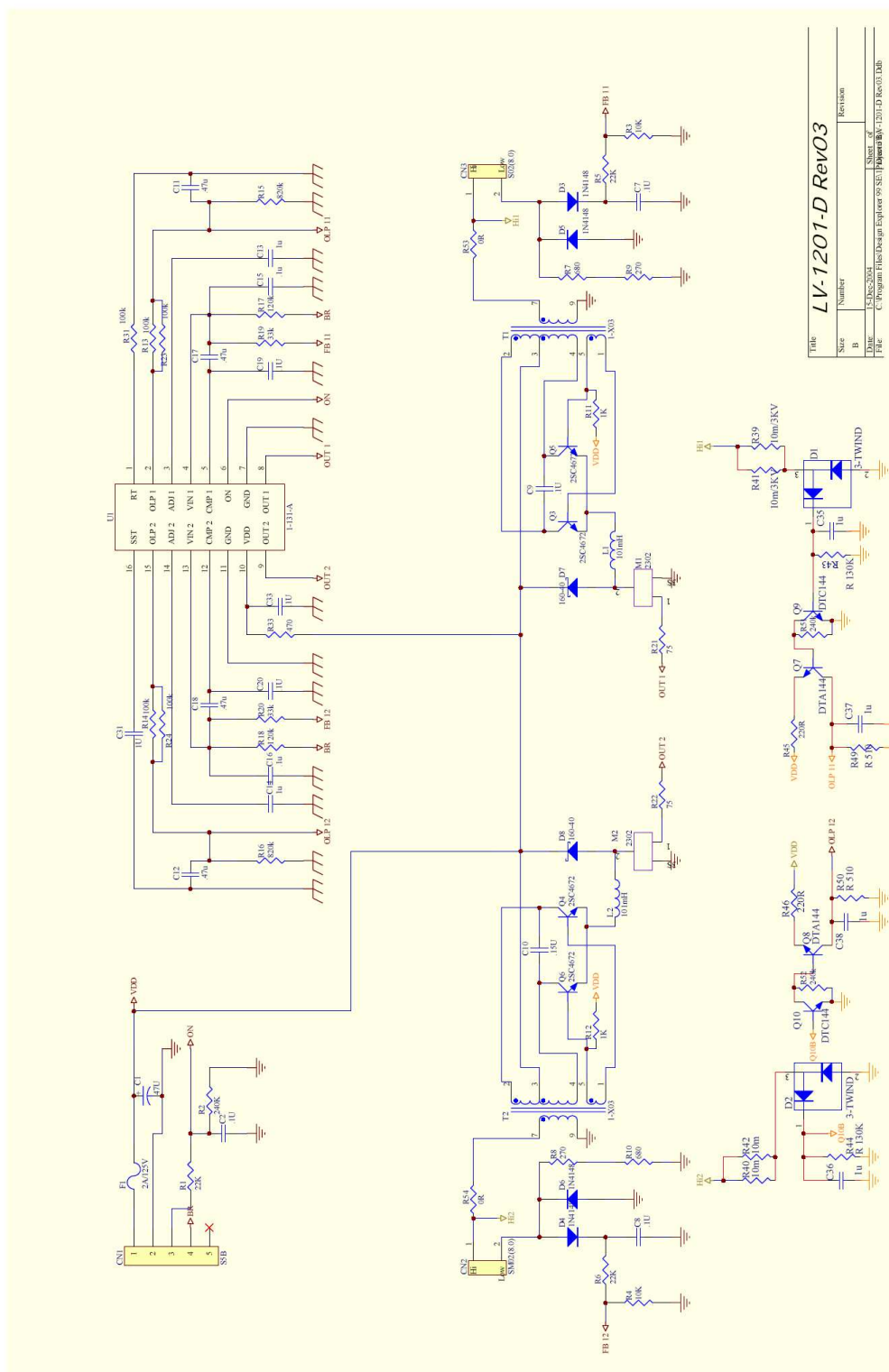
**Note:**

Attachments may include Schematics, Components information, Component test Reports, Particular Standard test Reports, Standard test Reports, Information from accompanying documents and similar.

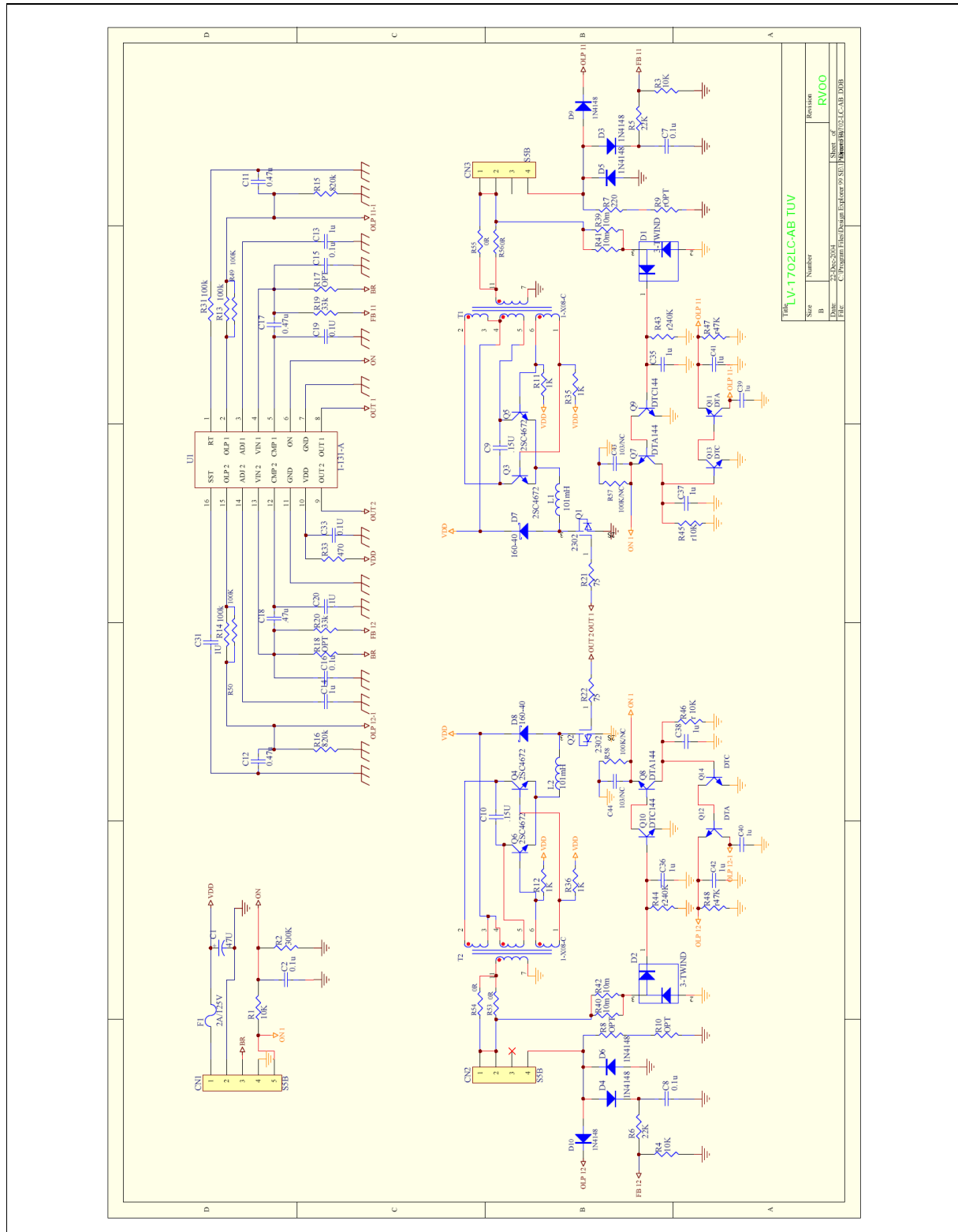
## Attachment 1



## Attachment 1



## Attachment 1



National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Australian National Differences according to CB Bulletin No. 109A, December 2005 (AS/NZS 3200-1-0:1998) (IEC Publication 60601-1:1988+A1:1991+A2:1995)		Pass
6.1 g)	Insert the following sub-clause between the first and second dashes:	Inserted.	Pass
	For low voltage equipment rated at 200V or more, voltage marking (which may be part of a voltage range) of not less than 230V. Supply frequency ratings which include 60Hz must also include 50Hz.	Rated 100-240VAC, 50-60Hz	Pass
6.6	Replace the existing text of item a) with the following:  a) Identification of the contents of gas cylinders used in medical practice as part of electrical EQUIPMENT shall be in accordance with AS 1944, (see also Sub-clause 56.3a).	No medical gas cylinders.	N/A
28.2	Replace the existing text with the following:	Replaced.	N/A
	Support (a) Ceiling-supported EQUIPMENT EQUIPMENT shall comply with the following requirements:  (i) EQUIPMENT shall be fitted with an anticrash device or have suspension cables duplicated and independently anchored.  (ii) Motorized drives shall be designed to prevent the driven part from becoming hazardous in the event of a power failure.  (iii) Carriages, brakes and supports shall be design such that any single failure will not constitute a hazard to the PATIENT.  (iv) Effective means shall be incorporated to prevent carriages running off supporting rails.  (v) Effective means shall be incorporated to facilitate adequate inspection of cables an anchorages  (vi) Proximity or pressure switches may be used to minimize hazards.  (vii) Ceiling-supported EQUIPMENT or parts thereof connected by electrical supply cables shall be provided with stops (e.g. for limitation of rotation or linear movement) to restrict movement in a manner which avoids any undue strain on the wiring termination or	Not such equipment.	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
	<p>damage to the wiring.</p> <p>(b) Floor and floor-to-ceiling supported (including mobile) EQUIPMENT</p> <p>Equipment shall comply with the following requirements:</p> <p>(i) Anticrash devices shall be fitted to cable, chains, etc.</p> <p>(ii) Means shall be incorporated to facilities adequate inspection of cables and anchorages.</p> <p>(iii) Cross-arms or pivots shall be fitted with adequate stops, locknuts, grub screws or similar devices to prevent supported masses being dislodged.</p>		
42.3	<p>Item 2) Add the following prior to the first dash:</p> <p>For this clause only, low voltage equipment rated at greater than 200V is regarded as having a maximum rated voltage of 230V.</p>	No applied parts.	N/A
Table XII	In second row, first dash, after 'if impedance protected' add 'maximum value'.	Added.	Pass
51.2 a)	<p>Replace "not used" with:</p> <p>Supply plugs – Provision for inspection</p> <p>Where a supply flexible cord is fitted with a rewirable plug of a type complying with the requirements of AS 3112 for 3-pin plugs, the plug shall be clear-backed to facilitate inspection of the core colours and the condition the terminations.</p>	Replaced. To be evaluated during the national approval.	N/A
56.3 a)	<p>Replace the text in the 3<sup>rd</sup> dash by the following:</p> <p>Medical gas connections on EQUIPMENT shall, if operating at positive pressures greater than 50 kPa in NORMAL USE comply with AS 2472, AS 2473, or AS 2896, as appropriate.</p>	No medical gas connections.	N/A



National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Canadian National Differences according to CB Bulletin No. 109A, December 2005 (CAN/CSA 22.2 No. 601.1-M90) (IEC Publication 60601-1:1988+A1:1991+A2:1995)		Pass
6	Where written safety warnings appears as equipment markings, they should appear in French and English.	Equipment marking in English.	Pass
6.61	The point connection of gas cylinders to equipment is gas specific. The point of connection of gas cylinders to equipment is non-interchangeable. The point of connection of gas cylinders to equipment is identified.	No gas cylinders.	N/A
56.3 a	Medical gas inlet connectors on equipment are specific Medical gas inlet connectors on equipment are non-interchangeable. Medical gas inlet connectors on equipment are DISS type complying with CGA V-5 Medical gas inlet connectors on equipment are configured to permit the supply from assemblies complying with CAN/CSA – Z305.2.	No gas connections.	N/A
56.6 a	Where consequential loss of function caused by operation of a thermal cut-out presents a safety hazard, both visible and audible warnings provided.	No thermal cut-out used.	N/A
57.2 g	Mains plug of non-permanents installed equipment: - if molded on type – hospital grade complying with CSA C22.2, No. 21 Mains plug of non-permanent installed equipment: - hospital grade disassembly type complying with CSA C22.2, No. 42 Mains plug of non-permanent installed equipment: - if Class II equipment – polarized hospital grade CSA configuration 1-15P	No plug provided.	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
57.3 b	<p>Detachable power supply cord is unlikely to be detached accidentally.</p> <p>Detachable power supply cord impedance of earth contracts presents no safety hazard.</p> <p>Detachable power supply cord: possibility of replacement by a cord which could make equipment hazards minimized.</p> <p>Detachable power supply cord complies with CSA C 22.2 No.21.</p> <p>Detachable power supply cord not smaller than No. 18 AWG</p> <p>Detachable power supply cord minimum serviceability of type SJ for mobile equipment of Type SV for other.</p>	No power supply cord provided.	N/A
57.9	Switching power supplies conform to CSA Electrical Bulletin 1402C.	To be evaluated when submitted for national approval.	N/A
58.2	Protective earth connections comply with CSA C 22.2 No.04	To be evaluated when submitted for national approval.	N/A
59.1	Connecting cables comply with Canadian Electrical Code, Part I.	To be evaluated when submitted for national approval.	N/A
60	Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts.	No such parts.	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Danish National Differences according to CB Bulletin No. 109A, December 2005 (IEC Publication 60601-1:1988+A1:1991+A2:1995)		Pass
	For plugs and socket outlets the National Standard SB 107-2-D1 3 <sup>rd</sup> ed. Applies.	Not provided for this evaluation.	N/A
	For Class I equipment: Plugs: DK 2-1a, DK 2-1a with flat phasepin or DK 2-5a Socket outlets: DK 1-3a		N/A
	For Class II equipment: Plugs: DKA 2-1a, DKA 2-1b Clb, C5, C6 or according to EN 50075		N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Israeli National Differences according to CB Bulletin No. 109A, December 2005 (SI 1011) IEC Publication 60601-1:1988+A1:1991+A2:1995)		Pass
	Clause 4.7 – Supply and mains voltages:	See below.	Pass
A.	Equipment that is to be connected to the mains, shall be intended for one of the following voltages and frequencies:  Nominal frequency of 50Hz.  Nominal voltage of 230V for portable and hand-held equipment.  Nominal voltage 230V, for one phase equipment with input power not exceeding 4kVA.  Nominal voltage 400V, for multiphase equipment.	Equipment rated 100-240VAC, 50-60Hz	Pass
B.	It is allowed to connect to the mains other equipment, with the following ratings:  One phase equipment, for the range of 220 to 240 Volts.  Multiphase equipment, for the range of 380 to 440 Volts.  The equipment shall comply with all the requirements of the standard, while being connected to the above mentioned mains frequencies and voltages, as if it was marked for 50Hz and 230 or 400 Volts.	To be evaluated for the final system.	N/A
36.	Change clause 36. – EMC – to:  The equipment shall comply with the equipments of SI 1011 part 1.2 (IEC 60601-1-2).	To be evaluated during the national approval.	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Korean National Differences according to CB Bulletin No. 109A, December 2005 (IEC Publication 60601-1:1988+A1:1991+A2:1995)		Pass
	LIMITATIONS	See below.	Pass
	<Supply voltage rating> National supply voltages are 110, 220V and 380V	Equipment rated 100-240VAC	Pass
	<Frequency> Only appliances having supply frequency of 60Hz or a frequency range including 60Hz are accepted.	Supply voltage 100-240VAC, 50-60Hz	Pass
	<Instruction> Instruction manuals and appliance markings related safety, including nameplate shall be in Korean or graphical symbols in accordance with IEC Publication 417.  Plugs for connection of the equipment to the supply mains shall comply with the Korean Standard (KSC 8305 and 8300)  More details are available from KTL (c/o KTL) on request.	To be evaluated when submitted for national approval.	N/A
	DEVIATIONS	Marked as voltage and frequency range (see above).	Pass
6.1 j)	Insert the following sub-clause between the second and third sub-clauses:  Equipment for one or several RATED voltage or frequency ranges, the RATED input for 220V, 60Hz or if applicable for 110V, 60Hz shall be separately marked.	No high voltage terminal devices.	N/A
6.1 s)	HIGH VOLTAGE TERMINAL DEVICES on the outside of EQUIPMENT which are accessible without the use of a TOOL shall be marked with the symbol "dangerous voltage" (see Appendix D, Table DII, Symbol 6) and with the Korean language, "고압주의",	See above.	N/A
6.2 c)	Replace the existing sub-clause with the following:  The presence of HIGH VOLTAGE PARTS shall be marked with the symbol "dangerous voltage" (see Appendix D, Table DII, Symbol 6) and with the Korean language, "고압주의",	Same as above	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
6.8.1	Insert the following sub-clause after the last paragraph: Language of accompanying documents shall be included Korean.	To be evaluated when submitted for national approval.	N/A

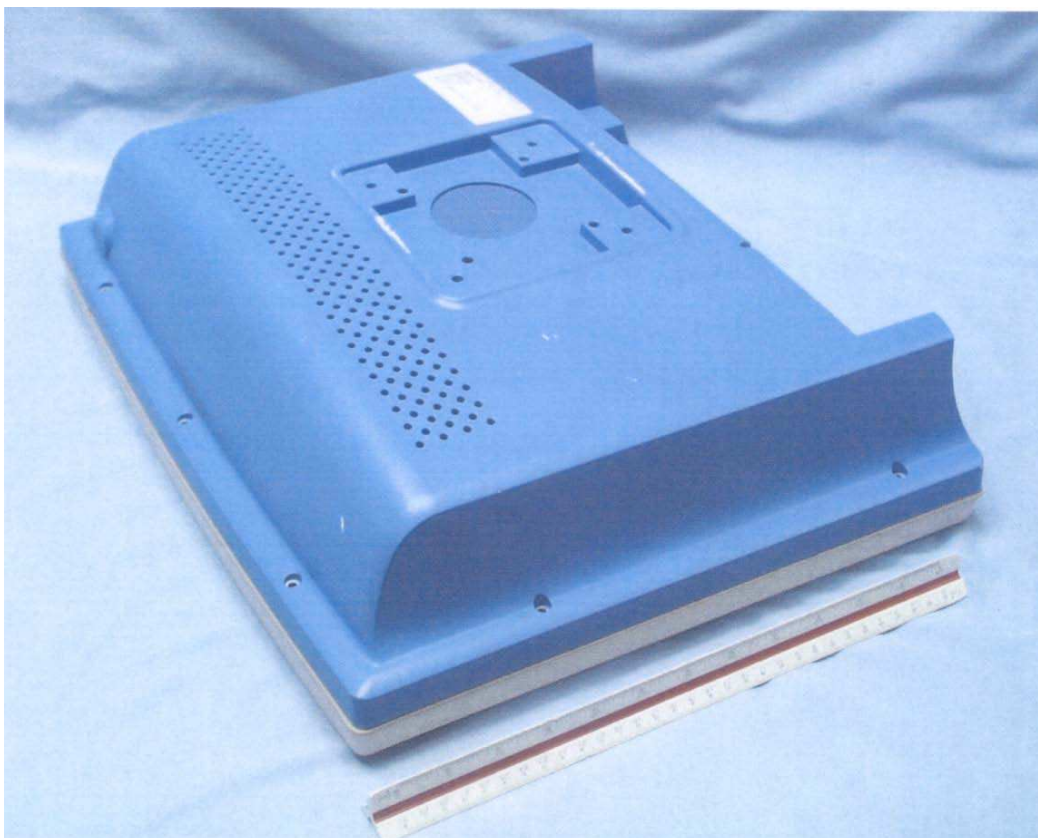
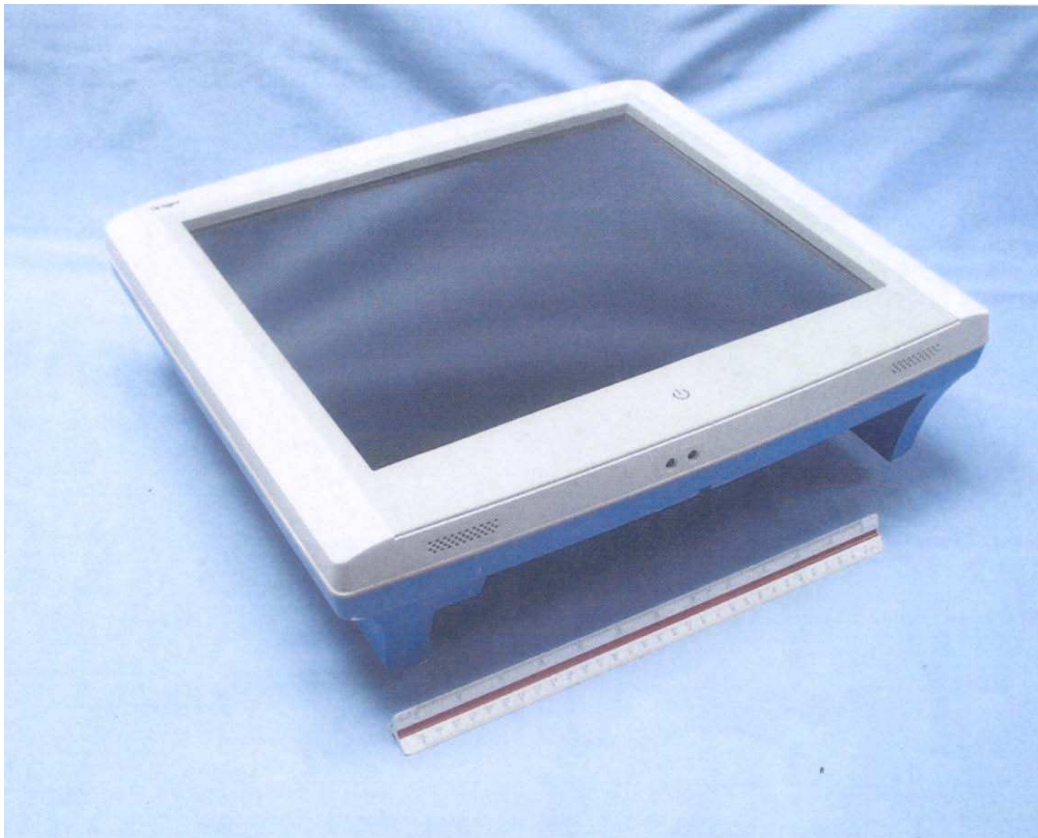
National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	US National Differences according to CB Bulletin No. 109A, December 2005 (UL 2601-1/IEC 60601-1-1) (IEC Publication 60601-1:1988+A1:1991+A2:1995)		Pass
The following US National differences are based on requirements in the US National Electrical Code (NEC), ANSI/NFPA 70-1993.			
2.4.1, 2.10.100 (new), 2.10.101 (new) c) 10.2.2	High voltage X-ray installations Long Time and Momentary ratings definitions Clause 6, 6.2 and product markings shall agree with the NEC.	No X-ray source.	N/A
6.21	Replace 70°C with 60°C	Replaced.	N/A
Clause 14, clause 18	The class of high voltage parts of equipment shall be in accordance with the provisions of NEC.	No high voltage parts.	N/A
57	All equipment installations are required to be in accordance with NEC.	To be evaluated when submitted for national approval.	N/A
57.2	“Hospital Grade” or “Hospital Only” mains plugs required on cord connected equipment marking/instructions regarding grounding reliability is to be provided. Radiographic control disconnect mains plugs shall be acceptable for a current not less than 50 per cent of the maximum input current measured. Except for X-Ray equipment mains plugs shall be rated no less than 125 percent of the rated current of the equipment. Where polarized mains plugs are used in edison base lampholders and any single pole protective device shall be connected in the ungrounded side of the line, except if it is in addition to the one in the ungrounded side.	Not provided.	N/A
57.3, 59.1	Power supply cords and internal wiring including interconnection cords between equipment shall meet the requirements of NEC. A detachable power supply cord for non-permanently installed equipment shall be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety hazard.	Same as above.	N/A

National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
The following US National deviations are based on requirements other than the US National Electrical Code (NEC)			
1.1, Section 5	Safety hazards resulting from intended physiological function of and ionizing radiation resulting from equipment covered by this standard are not considered. Such equipment is subject to US FDA requirements and US Federal Radiation Standards (21CFR Part 1020) promulgated under the Radiation Control for Health and Safety Act of 1968.		N/A
2.12.100 (new) 2.12. 101 new, 19	In addition to the requirements in the base standard, equipment shall comply with ANSI/AAMI Safety Current Limits (SCL) and ANSI/NFPA 99 Health Care Facilities Standards. X-Ray equipment need only comply with the Clause 19 requirements in UL 2601-1.	No X-ray source.	N/A
3 (new sub-clause 3.100, 3.100.1, 3.101, 3.101.1, 3.101.2, 3.102) and 57.5	In addition to compliance with this standard, primary connected components, printed wiring boards, lithium batteries, optical isolators, wiring and tubing, and cathode ray tubes exceeding 5 inches maximum dimensions shall meet US nationally recognized standards, such as ANSI/UL standards or internationally harmonized component standards. Components shall be used in accordance with their intended use and in consideration of their inherent limitations.	Considered. See appended table 56.1.	Pass
6	“CAUTION”, “WARNING” or “DANGER” markings shall be in contrasting color to the background. The signal word letters shall be minimum 2.8 mm high, all others minimum 1.6 mm high. A “WARNING” statement is required for ionizing radiation producing equipment.	No such marking provided.	N/A
22 and 28	In addition to the requirements and basic standard, equipment shall be found to be in compliance with the Standard for X-Ray equipment, ANSI/UL 187, 5 <sup>th</sup> edition, Sections 31 and 34 with respect to the movement control and supported masses.		N/A
42	In addition, to the basic requirements in this standard, insulating systems operating at greater than Class 105°C limits during normal use and normal condition shall comply with the requirements of the Standard for Systems of Insulating Materials - General (UL 1446).		N/A



National Differences			
Clause	Requirement – Test	Result – Remark	Verdict
55	The flaking or peeling of a conductive coating is not to contribute to safety hazard. External combustible materials having a surface area of more than 4.74 square meters shall have controlled flame spread characteristics. Polymetric enclosures and covers shall be considered for flammability characteristics and be resistant to mold stress relief and impact/drop safety hazards consistent with their use.		N/A
56.3	The likelihood of a patient connected lead or part being misused so as to introduce a safety hazard shall be investigated.	No patient circuit.	N/A
58.2	Connections shall be made mechanically secure as well as being soldered.	Complies.	Pass
400 (new)	For equipment which uses oxygen or recommends use with oxygen, special safety hazards associated with use of oxygen should be addressed in accordance with Clause 400. These requirements are based on oxygen-related requirements from IEC 601-2-19, particular requirements for the safety of baby incubators.	This equipment does not generate or use oxygen.	N/A
600 (new)	A separate power unit employing a separable connector for supplying the equipment shall be packaged with the equipment or be referenced to by the marking on the equipment. Direct plug-in units shall comply with the mechanical assembly, enclosure, input connections, accessibility of live parts, grounding, marking and performance requirements in the Standard for Class 2 Power Units, UL 1310.		N/A

Product: **Panel PC**  
Type Designation: **POC-154xxxxxxxxxx, POC-174xxxxxxxxxx,  
POC-155xxxxxxxxxx, POC-175xxxxxxxxxx**  
(x = any alphanumeric character or blank)  
Report Number: **21125273 001**



Model POC-174xxxxxxxxxx

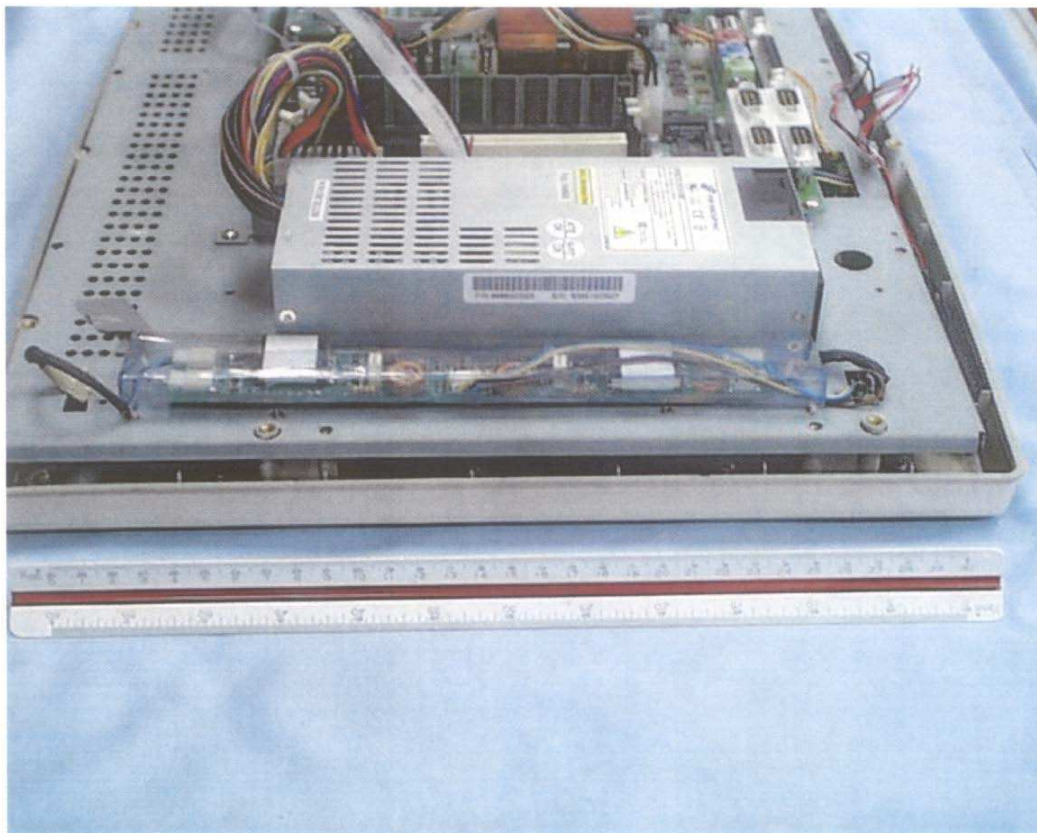
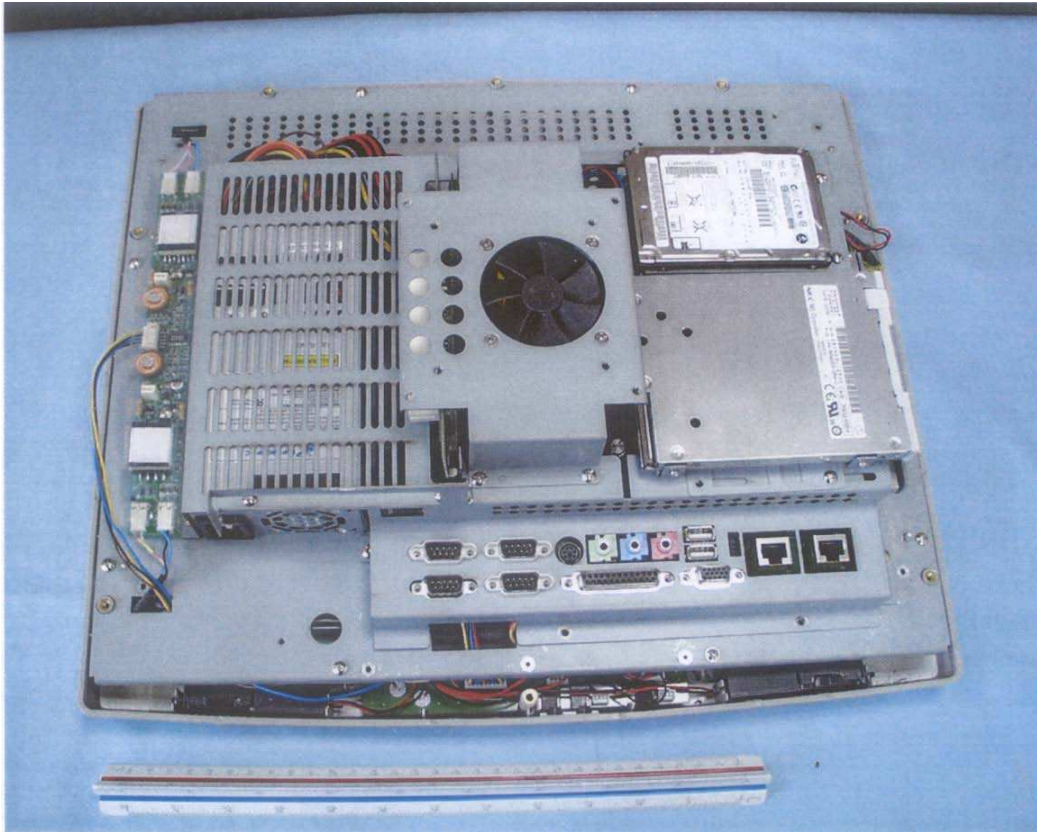
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 (x = any alphanumeric character or blank)  
 Report Number: **21125273 001**



Model POC-174xxxxxxxxxx

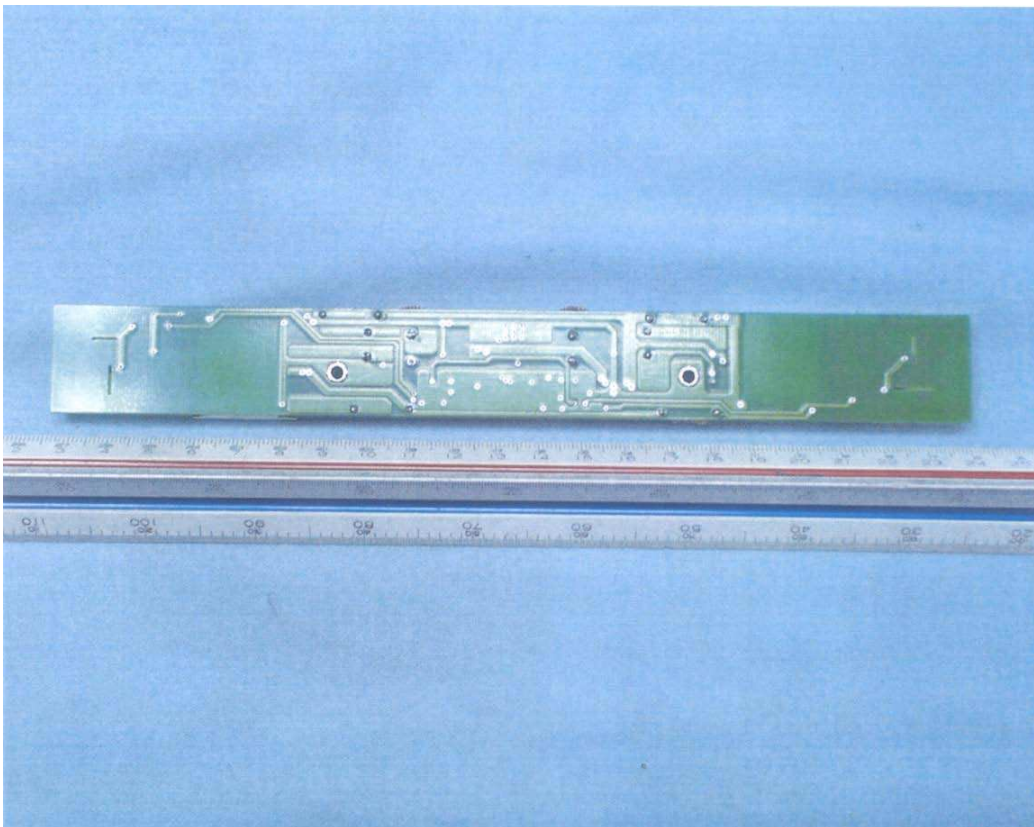
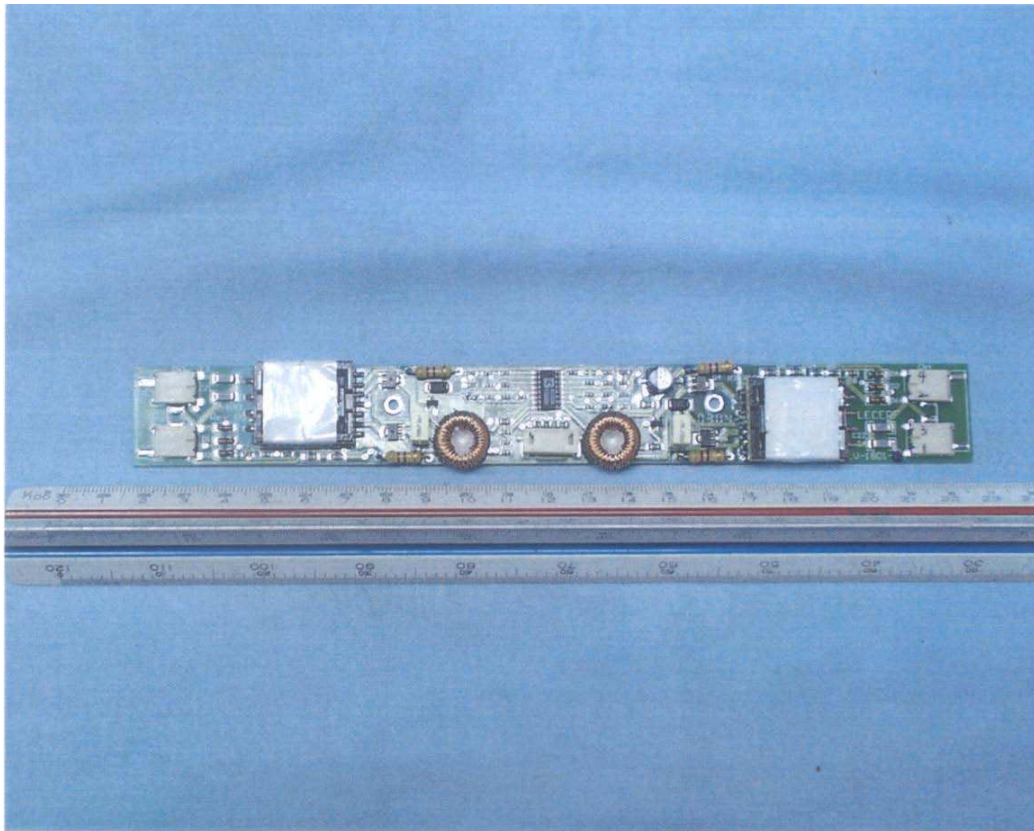


Product: **Panel PC**  
 Type Designation: **POC-154xxxxxxxxxx, POC-174xxxxxxxxxx,  
 POC-155xxxxxxxxxx, POC-175xxxxxxxxxx**  
 (x = any alphanumeric character or blank)  
 Report Number: **21125273 001**



Model POC-174xxxxxxxxxx

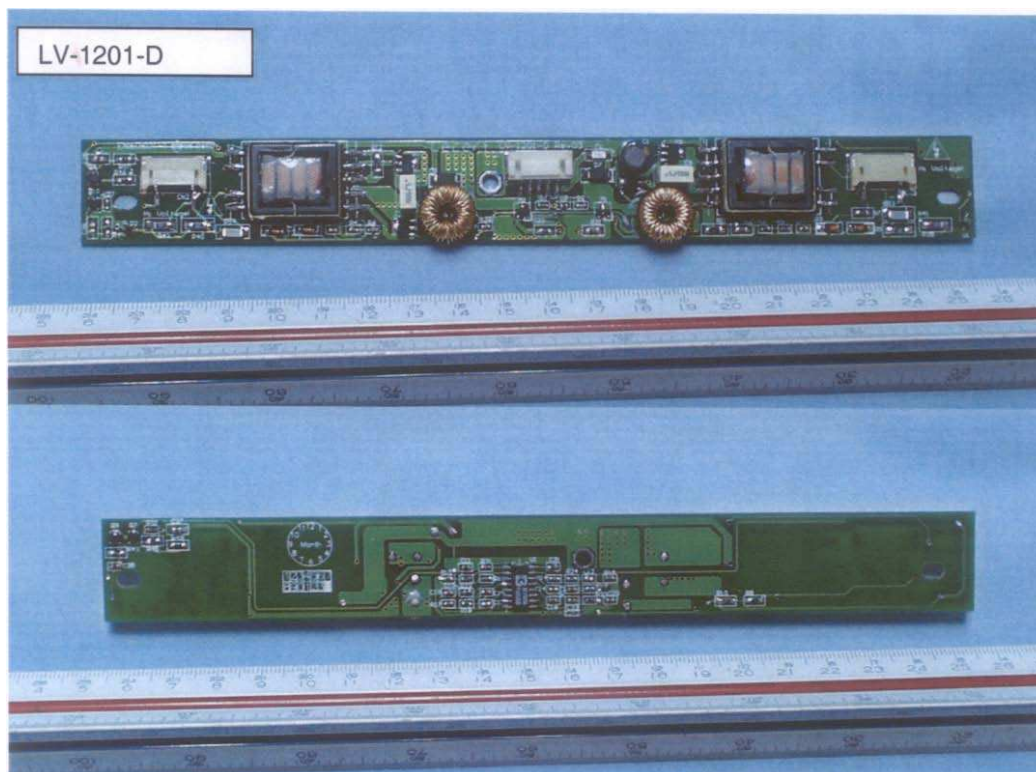
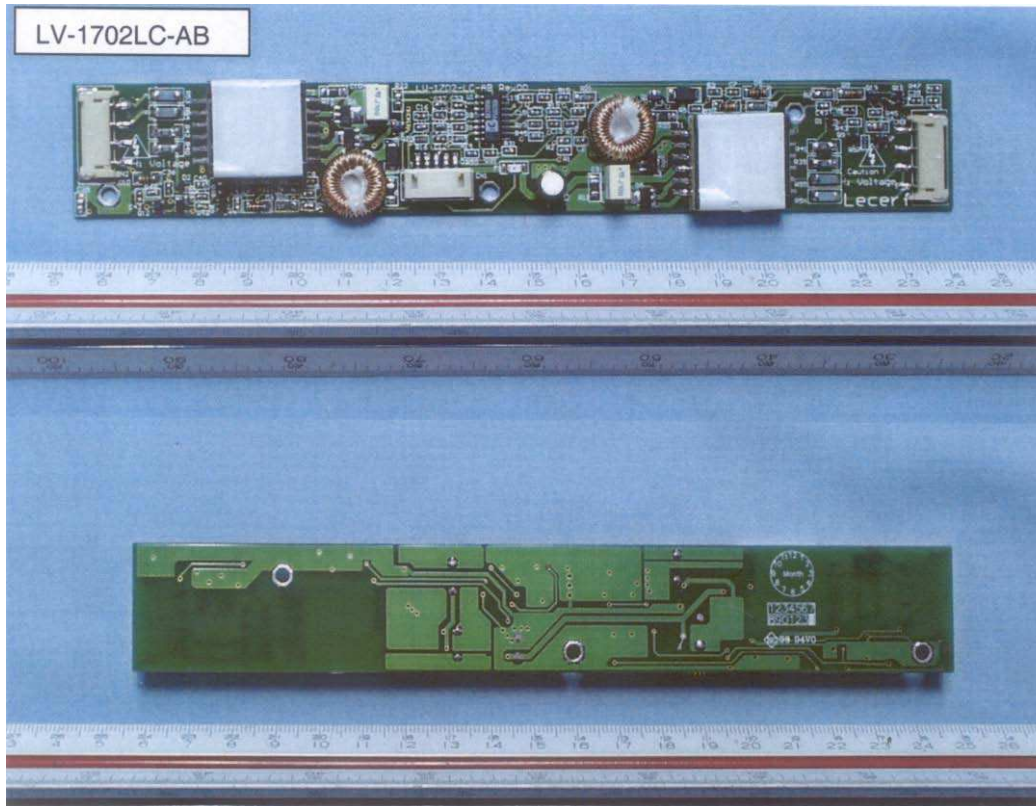
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 (x = any alphanumeric character or blank)  
 Report Number: **21125273 001**



Model POC-174xxxxxxxxxx

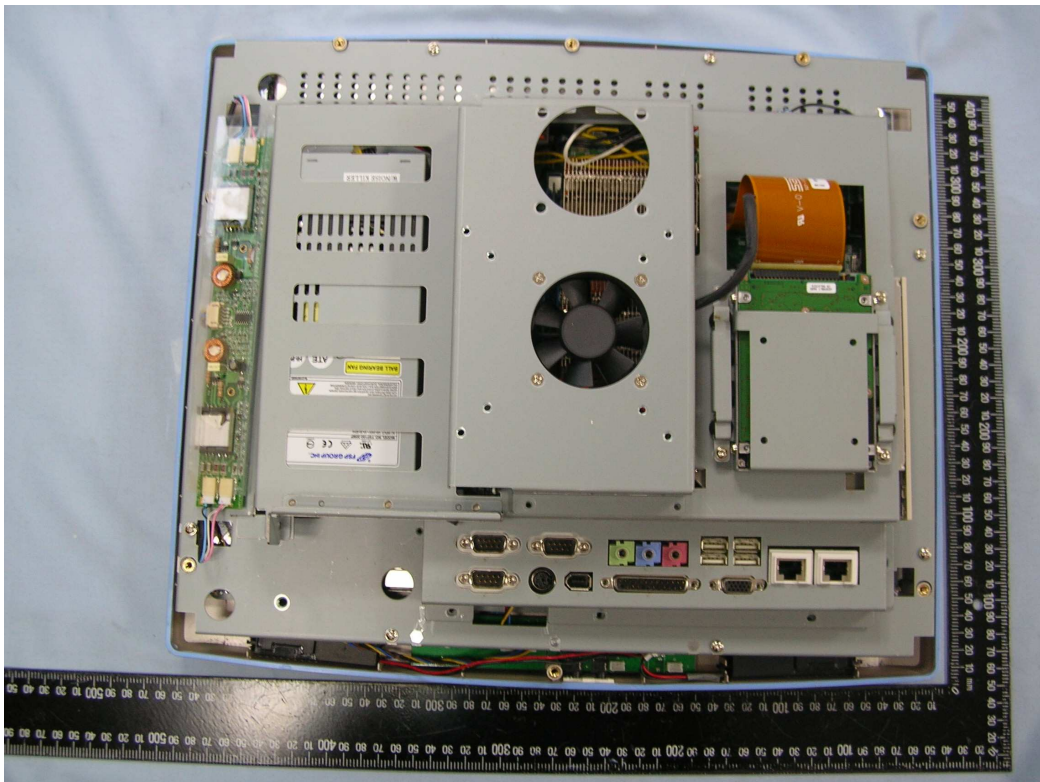


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Type Designation: **POC-154xxxxxxxxxx, POC-174xxxxxxxxxx,  
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(x = any alphanumeric character or blank)  
Report Number: **21125273 001**



Model POC-174xxxxxxxxxx

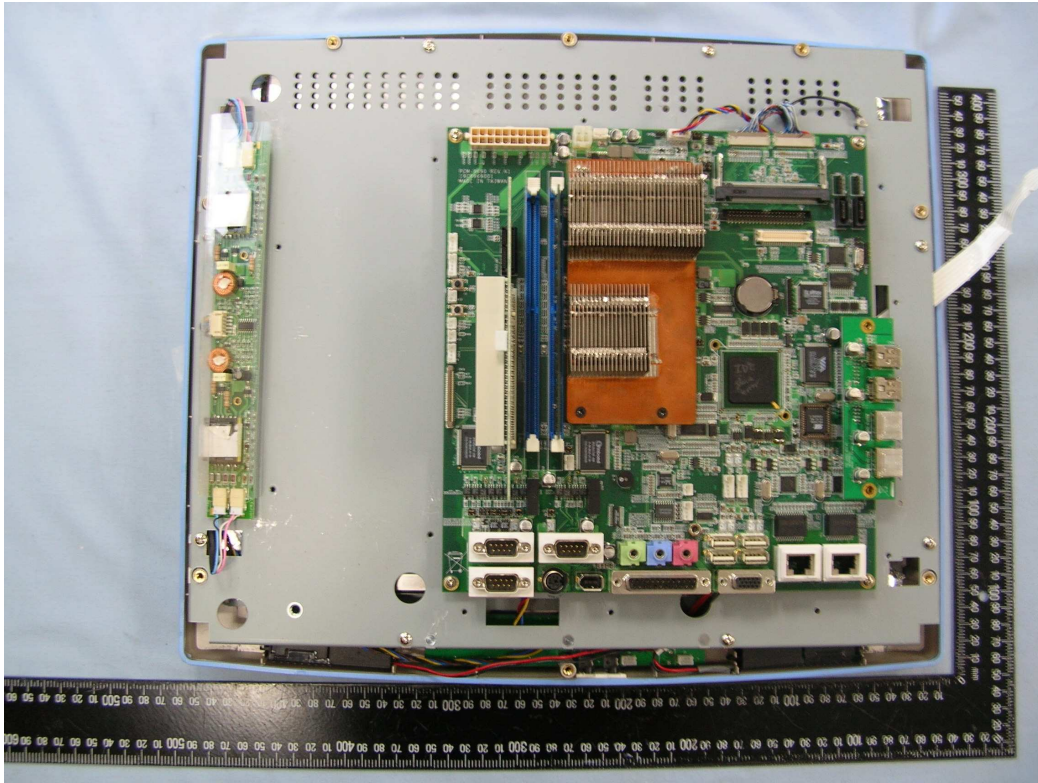
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Type Designation: **POC-154xxxxxxxxxx, POC-174xxxxxxxxxx,  
POC-155xxxxxxxxxx, POC-175xxxxxxxxxx**  
(x = any alphanumeric character or blank)  
Report Number: **21125273 001**



Model POC-175xxxxxxxxxx



Product: **Panel PC**  
Type Designation: **POC-154xxxxxxxxxx, POC-174xxxxxxxxxx,  
POC-155xxxxxxxxxx, POC-175xxxxxxxxxx**  
(x = any alphanumeric character or blank)  
Report Number: **21125273 001**



Model POC-175xxxxxxxxxx