

IEC**IECEE**
CB
SCHEME

Ref. Certif. No.

DE 2-006882

**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

LCD Monitor

Name and address of the applicant
Nom et adresse du demandeurAdvantech Co., Ltd. 4F, No. 108-3, Ming Chuan Road
Hsin Tien City
231 Taipei Hsien, TaiwanName and address of the manufacturer
Nom et adresse du fabricantAdvantech Co., Ltd. 4F, No. 108-3, Ming Chuan Road
Hsin Tien City
231 Taipei Hsien, TaiwanName and address of the factory
Nom et adresse de l'usine

(See appendix for factories information)

Rating and principal characteristics
Valeurs nominales et caractéristiques principales

DC 12V; 4A

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

ADVANTECH

Model/type Ref.
Ref. de typePDC-170xx-xx-xx
(x = any alphanumeric character or blank for marketing
purpose)Additional information (if necessary)
Information complémentaire (si nécessaire)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 laAs 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**PUBLICATION****EDITION**IEC 60601-1:1988 + A1 + A2
for national deviations see test report

21111174 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
Berlin Brandenburg**TÜV Rheinland Product Safety GmbH
Am Grauen Stein · D-51105 Köln
Phone + 49 221 806-1371
Fax + 49 221 806-3935
Mail: trps-certification@de.tuv.com
Web: www.tuv.com

Date: 10.03.2004

Signature:

Dipl.-Ing.

Appendix to CB Certificate DE 02006882

Report Number: 21111174 001

Name and address of the applicant

Advantech Co., Ltd.
4F, No. 108-3, Ming Chuan Road
Hsin Tien City
231 Taipei Hsien
Taiwan

Name and address of the factory(ies)

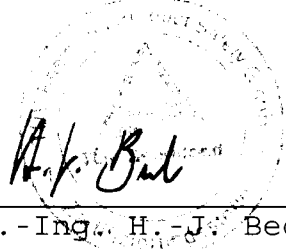
1. Advantech Co., Ltd.
Fl.5, No.1, Lane 169,
Kang-Ning St., Xi Zhi,
Taipei Hsien 221
Taiwan
2. Beijing Yan Hua Xing Ye Elec.
Science & Technology Co., Ltd.
7, 6th Street, Shang Di Zone

Haidian District, Beijing, China
3. Superior Co., Ltd.
Tiansong Area, Qingxing Town

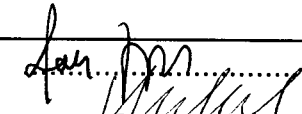
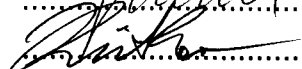
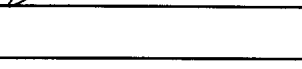
Dongguan, Guangdong
China
4. Advantech Co., Ltd.
No. 600 Han-Pu Road, Yu-Shan

Kun-Shan, Jiangsu
China
5. Advantech
Co., Ltd.
3F, No. 10, Lane 130
Ming Chuan Rd., Hsin-Tien City
231 Taipei Hsien, Taiwan

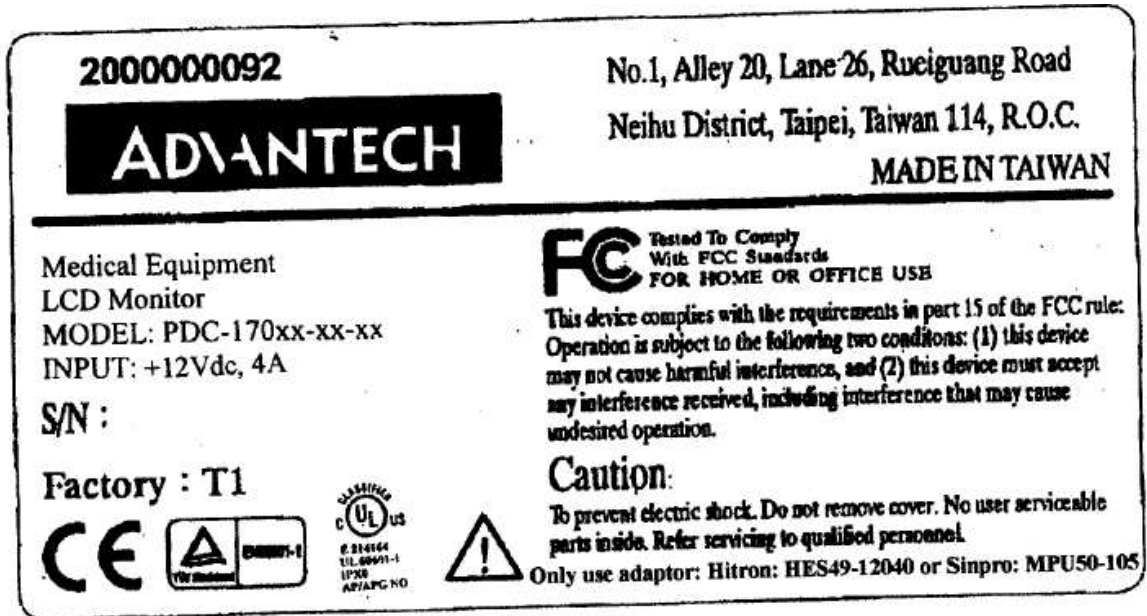
Date: 10.03.2004



Dipl.-Ing. H.-J. Beck

TEST REPORT IEC 601 -1 Medical electrical equipment Part 1: General requirements for safety	
Report reference No.	21111174 001
Compiled by (+ signature)	Ralf Vnagp 
Reviewed by (+ signature)	T. Stollzel 
Approved by (+ signature)	C. Rütger 
Date of issue.....	9-Mar-2004
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.....	4F, No. 108-3, Ming Chuan Rd., Hsin Tien City, Taipei Hsien 231, Taiwan
Standard	IEC 60601-1: 1988 + A1:1991 + A2:1995 EN 60601-1 : 1990 + A1:1993 + A2:1995 + A13:1996 AS3200.1/NZS 6150, CAN/CSA 22.2, SI 1011, UL 2601-1
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.....	Australia, Austria, Belgium, Brazil, Canada, The Czech Republic, Finland, France, Germany, Greece, Hungary, Ireland, India, Israel, Italy, Korea, Netherlands, Norway, Poland, Portugal, Russian Federation, Slovenia, Slovakia, Sweden, Switzerland, Turkey, United Kingdom, U.S.A.
Non-standard test method.....	N/A
Type of test object	LCD Monitor
Trademark	ADVANTECH
Model/type reference.....	PDC-170xx-xx-xx (where x represents any alphanumeric character or blank)
Manufacturer	Same as applicant
Address.....	Same as applicant
Rating	I/P: DC 12V, 4A

Copy of marking plate



GENERAL INFORMATION	
Test item particulars (see also clause 5):	
Classification of installation and use.....	: Stationary equipment
Supply connection	: Appliance coupler
Accessories and detachables 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.
- operational insulation	:OP
- basic insulation between parts of opposite polarity.:BOP	
- double insulation.....	:DI
- single fault condition.....	:S.F.C.
- basic insulation	:BI
- supplementary insulation	:SI
- reinforced insulation.....	:RI
General remarks:	
<p>"This report is not valid as a CB Test Report unless appended to a CB Test Certificate issued by a NCB, in accordance with IECEE 02".</p> <p>"(see Attachment #)" refers to additional information appended to the report.</p> <p>"(see appended table)" refers to a table appended to the report.</p> <p>Throughout this report a point is used as the decimal separator.</p> <p>The tests results presented in this report relate only to the object tested.</p> <p>This report shall not be reproduced except in full without the written approval of the testing laboratory.</p> <p>List of test equipment must be kept on file and available for review.</p> <p>Summary of contents provided on the page 51 of this report.</p>	
General product information and considerations:	
<ul style="list-style-type: none"> The equipment is a LCD monitor for general use in medical environment. The test samples were pre-production without serial number. In the model name, the variable "x" is used for marketing purpose only. Both AC/DC switching power adaptors (Sinpro, MPU50-105 and Hitron, HES 49-12040) are CB Scheme approved. Sinpro, MPU50-105 was tested by TUV and passed the requirements of EN/ IEC60601-1, Cert. No.:TA5002944 01. Hitron, HES 49-12040 was tested by Nemko according to IEC60601-1, Cert. No.: NO 8996. The LCD monitor powered by each above mentioned AC/DC switching power adaptor sources was tested and both sources were passed the requirements of EMI/EMC regulation according to EN60601-1-2. Maximum specified ambient temperature is 40°C. USB ports provided (1 x USB upstream, 2 x USB downstream), LPS (Limited power source) according to subclause 2.5 of IEC60950:1999 : <ul style="list-style-type: none"> - Uoc = 4.8V (measured under no load conditions for the USB port 1 Pin1-4). 	

with max. load conditions:

Measured current: $0.93A \leq 8A$.

Measured power = $4.5W (4.8V \times 0.93A) \leq 24VA(5 \times U_{oc})$.

- $U_{oc} = 3.4V$ (with U9 Pin4-5 s-c)

Measured current: $0.55A$.

Measured power = $1.87W (3.4V \times 0.55A) \leq 17VA(5 \times U_{oc})$.

- Max. loading of the LCD monitor = $38W^{1)}$ < $48W$ (Max. power output of adaptor).

¹⁾ : Condition which led to highest i/p current was described in table 7

- Attachment: Circuit Diagram: Page 62 to Page 67.

Factories :

1. Advantech Co., Ltd.
5th FL No 1, Lane 169 Kang-Ning Street, Xi-Zhi City, Taipei Hsien Taiwan.
2. Advantech Co., Ltd.
3rd Fl 10 Lane 130 Ming Chuan Rd Hsin-Tien Taipei Hsien 231 Taiwan.
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. Beijing Yan Hua Xing Ye Electronic Science & Technology Co., Ltd.
No.7, 6th Street, Shang Di Zone, Haidian District, Beijing, P.R. China.

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

3	GENERAL REQUIREMENTS		P
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.)		P
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		N

5	CLASSIFICATION		P
5.1	Type of protection against electric shock		P
	Class I equipment	EUT without direct mains connection. However external AC adaptor is Class I type.	N
	Class II equipment		N
	Internally powered equipment		N
5.2	Degree of protection against electric shock		N
	Type B applied part	No applied parts.	N
	Type BF applied part	Ditto	N
	Type CF applied part	Ditto	N
	Not classified - no applied parts	Ditto	N
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 protection: IPX0	P
5.4	Methods of sterilization or disinfection		N
5.5	Equipment not suitable for use in the presence of flammable mixtures	Device belongs not to category AP or APG.	P
	Category AP equipment		N
	Category APG equipment		N
5.6	Mode of operation:		P
	-continuous operation	The equipment is designed for	P

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

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

INSULATION DIAGRAM

Note: Inside LCD monitor : Voltages of the backlight circuit do not result in leakage currents in NC and SFC exceeding the limits of table IV nor are they accessible.

Table: to insulation diagram							N
Area	Insulation type: operational / basic / supplementary / double / reinforced	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A							
B							
C							

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, optocouplers, 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.
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

6	IDENTIFICATION, MARKING AND DOCUMENTS		P
6.1	Marking on the outside of equipment or equipment parts		P
	c) Markings of the specific power supply affixed	"Only use adaptor: Hitron: HES49-12040 or Sinpro:MPU50-105" is provided on the label.	P
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		N
	e) Name and/or trademark of the manufacturer or supplier	ADVANTECH	P
	f) Model or type reference	PDC-170xx-xx-xx	P
	g) Rated supply voltages or voltage range(s)	Not required. However, 12Vd.c. indicated.	N
	Number of phases		N
	Type of current	d.c.	N
	h) Rated frequency or rated frequency range(s) (Hz)	DC power supply source.	N
	j) Rated power input (VA, W or A)	Not required. However, 4A indicated.	N
	k) Power output of auxiliary mains socket-outlets	No mains socket-outlet used.	N
	l) Class II symbol	Approved adaptor is class I equipment.	N
	Symbol for degree of protection against ingress of water provided	Ordinary protection: IPX0 No symbol necessary.	N
	Symbol for protection against electric shock	The LCD monitor is not intended to be connected to the patient and does not have any patient applied parts, therefore no such symbol required.	N
	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
	Symbol for protection of defibrillation-proof applied parts	No defibrillation-proof applied parts.	N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable	Ditto	N
	m) Mode of operation (if no marking, suitable for continuous operation)	Continuous operation	P
	n) Types and rating of external accessible fuses :	No external accessible fuses	N
	p) Ratings of external output		N
	q) Symbol for physiological effect(s):	no applied parts	N
	- attention, consult accompanying documents		N
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N
	r) Anaesthetic-proof symbol: AP or APG..... :		N
	s) Dangerous voltage symbol		N
	t) Special cooling requirements		N
	u) Limited mechanical stability		N
	v) Protective packing requirement(s)	Transportation and storage: Temperature: -20°C to +60°C Humidity: 10% to 95%	P
	- Marking(s) for unpacking safety hazard(s)		N
	- Equipment or accessories supplied sterile, marked as sterile	No sterile equipment.	N
	y) Potential equalization terminal		N
	- Functional earth terminal	No functional earth.	N
	z) Removable protective means	No removable protective means.	N
	Durability of marking test	See appended table.	P
6.2	Marking on the inside of equipment or equipment parts		N
	a) Nominal voltage of permanently installed equipment		N
	b) Maximum power loading for heating elements or holders for heating lamps	No heating elements.	N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Dangerous voltage symbol	High voltage exists in the DC/AC inverter of LCD monitor. The unit complies with the leakage current limitations under normal and single fault conditions. Therefore the voltages are not considered to be dangerous. No marking required.	N
	d) Type of battery and mode of insertion	No batteries used.	N
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator	Ditto.	N
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram		N
	f) Protective earth terminal	Not class I equipment.	N
	g) Functional earth terminal		N
	h) Supply neutral conductor in permanently installed equipment (N)		N
	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
	- Markings comply with IEC 445		N
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)		N
	l) Statement for suitable wiring materials at temperatures over 75 °C	Temperature below 75 °C.	N
	n) Capacitors and/or circuit parts marked as required in Sub-clause 15c	Not applicable.	N
6.3	Marking of controls and instruments		P
	a) Mains switch clearly identified	Seesaw switch used to disconnect power from adaptor.	P
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light	"I" and "O" used.	P

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	b) Indication of different positions of control devices and switches	Stand by switch with symbol 	P
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device	The controls are identified in the accompanying documents.	P
	f) The functions of operator controls and indicators are identified	Ditto	P
	g) Numeric indications of parameters are in SI units except for units listed in Am. 2	No numeric indicators.	N
6.4	Symbols		P
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	Symbols 15 and 16 of table D1 and  used.	P
6.5	Colors of the insulation of conductors		N
	a) Protective earth conductor has green/yellow insulation	No green/yellow wire used inside the monitor.	N
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations	No internal PE wiring inside the monitor.	N
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow		N
	d) Color of neutral conductor		N
	e) Colors of phase conductor(s)		N
	- Compliance with IEC 227 and IEC 245		N
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N
6.6	Medical gas cylinders and connections		N
	a) In accordance with ISO/R 32	No medical gas cylinders and connections used.	N
	b) Identification of connection point	Ditto	N
6.7	Indicator lights and push-buttons		P
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action		N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- Yellow used to indicate caution or attention required		N
	Green used to indicate ready for action	LED indicator turns green when the power is switched ON and the power cord is properly attached.	P
	b) Color red used only for push-buttons by which a function is interrupted in case of emergency		N
6.8	ACCOMPANYING DOCUMENTS		P
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	Stated in user's manual.	P
	Classifications specified in Clause 5 included in both the instructions for use and the technical description	Stated in user's manual.	P
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	Marking permanently affixed on the enclosure of equipment.	N
	Warning statements and the explanation of warning symbols provided in the accompanying documents	 provided on label and the explanation in user guide.	P
6.8.2	Instructions for use		P
	a) General information provided in instructions for use	See below.	P
	- state the function and intended application of the equipment	Stated in the chapter 1 "General Information" of user's manual.	P
	- include an explanation of: the function of controls, displays and signals	State in the chapter2 and appendix of user's manual.	P
	- the sequence of operation	Continuous	N
	- the connection and disconnection of detachable parts and accessories	External power supply adaptor is considered as detachable part.	P
	- the replacement of material which is consumed during operation	Not applicable.	N
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	Stated in "FCC Class B" of user's manual.	P

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	External power supply adaptor is considered as detachable part. In user's manual mentioned that only the listed source can be used.	P
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	No contact with patient.	N
	General information provided in instructions:		P
	- information for the safe performance or routine maintenance	No routine maintenance required.	N
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	No need for preventive inspection.	N
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	State in the chapter "Safety Instruction", "Installation procedure" and "Appendix B" of user's manual.	P
	c) Signal output or signal input parts intended only for connection to specified equipment described	Stated in chapter "Connectors" of user's manual.	P
	d) Details about acceptable cleaning, disinfection or sterilization methods included	No patient contact.	N
	e) Warning statement for mains operated equipment with additional power source	LCD Monitor is powered by one external power adaptor.	N
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	No batteries.	N
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	Ditto	N
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	In user's manual mentioned that only the listed IEC60601-1 approved switching power adaptor can be used to supply the LCD monitor.	P
	j) Identification of any risks associated with the disposal of waste products, residues, etc.	Not applicable.	N
	- Advice in minimizing these risks	Ditto	N
6.8.3	Technical description		P

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

	a) All characteristics essential for safe operation provided	Stated in the chapter "Specifications" of user's manual.	P
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	Not applicable.	N
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	No detachable parts which are subject to deterioration during normal use.	N
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	Stated in the chapter "Additional Information and Assistance" of user's manual.	P
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Conditions stated in user's manual for transportation and storage: Temp.: -20 ~ +60°C. R.H.: 10% ~ 95% at 40 °C.	P

7	POWER INPUT		P
	Power Input Measurements	DC supply.	P

10	ENVIRONMENTAL CONDITIONS		P
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer	Conditions stated in user's manual for transportation and storage: Temp.: -20 ~ +60°C. R.H.: 10% ~ 95% at 40 °C..	P
10.2.2a	Rated voltage not exceeding 250 V for hand-held equipment	Not hand-held.	N
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA	Input voltage DC 12V.	P
	Rated voltage not exceeding 500 V for all other equipment		N
	Rated input frequency not more than 1kHz		N
10.2.2b	Internal replaceable electrical power source specified		N

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

14	REQUIREMENTS RELATED TO CLASSIFICATION		P
14.4a	Class I and Class II equipment in addition to basic insulation provided with an additional protection	The unit is supplied from an IEC60601-1 approved Class I type power adaptor that provides an o/p voltage on SELV level. The double or reinforced insulation is provided inside the approved power adaptor.	N
14.4b	Equipment supplied from external dc source of reverse polarity results in no safety hazard	The design of the connector prevent incorrect polarity of connection.	N
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	Equipment is not internally powered.	N
14.6c	Applied parts intended for direct cardiac application are of type CF	No applied parts provided.	N

15	LIMITATION OF VOLTAGE AND/OR ENERGY		N
15b	Voltage measured one sec after disconnection of the mains plug does not exceed 60V	No direct mains connection.	N
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	No such parts.	N
	Marking provided for manual discharging		N

16	ENCLOSURES AND PROTECTIVE COVERS		P
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	High voltage exist in the DC/AC inverter of LCD monitor. Enclosure, user touchable ports and o/p of the inverter comply with the leakage current limitations in normal and single fault conditions. Therefore the voltages are not considered to be dangerous. However, device is totally enclosed.	P

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

	Insertion or removal of lamps - protection against contact with live parts provided	No operator touchable lamps provided.	N
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented	The test rod cannot enter into the openings of the top and each side of the enclosure.	P
16c	Conductive parts accessible after the removal of handles, knobs, levers		N
	- have a resistance of not more than 0.2 Ω	No such components.	N
	- separated from live parts by one of the means described in Sub-clause 17g	Ditto	N
16d	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact	Disconnect device provided at external power adaptor.	N
16e	Removable enclosures protecting against contact with live parts		P
	- Removal possible only with the aid of a tool	The enclosure is secured by screws.	P
	- Use of automatic device making parts not live when the enclosure is opened or removed		N
	- Exception 16e applied to the following parts . :		N
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts		N

17	SEPARATION		N
17a	Separation method of the applied part from live parts:		N
	1) basic insulation: applied part earthed	No applied parts.	N
	2) by protectively earthed conductive part (e.g. screen)	Ditto	N
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure	Ditto	N
	4) by double or reinforced insulation	Ditto	N
	5) by protective impedances limiting current to applied part	Ditto	N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- Additional leakage current test in single fault conditions	Ditto	N
17c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed	Ditto	N
17d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)	No motor provided.	N
17g	Separation method of accessible parts other than applied parts from live parts: <i>No live parts inside LCD monitor / Adaptor is approved component.</i>		N
	1) basic insulation: accessible part earthed		N
	2) by protectively earthed conductive part (e.g. screen)		N
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N
	4) by double or reinforced insulation	Inside the power adaptor: Double/Reinforce insulation (transformer, photo coupler, PCB layout and enclosure)	N
	5) by protective impedances limiting current to accessible part		N
	- Additional leakage current test in single fault conditions		N
17h	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator		N
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		N
18	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION		N
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal	Approved SPS adapter used.	N
18b	Protective earth terminals suitable for connection to the protective earth conductor	Ditto	N
18e	Potential equalization conductor	no potential equalization	N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- Readily accessible	Ditto	N
	- Accidental disconnection prevented in normal use	Ditto	N
	- Conductor detachable without the use of a tool	Ditto	N
	- Power supply cord does not incorporate a potential equalization conductor	Ditto	N
	- Connection means marked with Symbol 9, Table DI	Ditto	N
18f	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1 \Omega$		N
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $\leq 0.1 \Omega$	Approved Class I adaptor.	N
	- 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
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1Ω , the allowable value of the enclosure leakage current is not exceeded in single fault condition		N
18k	Functional earth terminal not used to provide protective earthing		N
18l	Class II equipment with isolated internal screens		N
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		N
	- functional earth terminal clearly marked		N
	- explanation of functional earth terminal provided in the accompanying documents		N

19	CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS		P
19.1b	Leakage currents	See appended table.	P
	- earth leakage current	Ditto	P
	- enclosure leakage current	Ditto	P

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

	- patient leakage current		N
	- patient auxiliary current		N

20	DIELECTRIC STRENGTH		N
	Overall compliance with Clause 20	See appended table.	N

21	MECHANICAL STRENGTH		N
21a	Sufficient rigidity of an enclosure tested by: force of 45 N	High voltage exist in the DC/AC inverter of LCD monitor. Enclosure, user touchable ports and o/p of the inverter comply with the leakage current limitations in normal and single fault conditions. Therefore the voltages are not considered to be dangerous. No tests were considered necessary.	N
21b	Sufficient strength of an enclosure tested by: impact hammer		N
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test	No handles or grips.	N
21.3	No damage to parts of patient support and/or immobilization system after the loading test	No patient support or immobilization system.	N
21.5	Hand held equipment or equipment parts are safe after drop test	Not hand-held equipment.	N
21.6	Portable and mobile equipment is able to withstand rough handling		N

22	MOVING PARTS <i>No moving parts.</i>		N
22.2a	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment		N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
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		N
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
	Guides or other safeguards are removable only with a tool		N
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
22.6	Parts of equipment subject to mechanical wear are accessible for inspection		N
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard		N
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard		N
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents		N
	Means for stopping of movements operate as a result of one single action		N

23	SURFACES, CORNERS AND EDGES		P
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	Edges of monitor are rounded.	P

24	STABILITY IN NORMAL USE (see appended table 24) <i>To be evaluated during the final system approval.</i>		N
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°		N
24.3	Equipment overbalances when tilted through an angle of 10°		N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- does not overbalance when tilted through an angle of 5° in any position excluding transport		N
	- carry a warning notice stating that transport should only be undertaken in a certain position		N
	- in the position specified for transport does not overbalance when tilted to an angle of 10°		N
24.6a	Equipment or its parts with a mass of more than 20 kg is provided with:		N
	- suitable handling devices (grips etc.), or	Mass 14.5kg < 20kg	N
	- instructions for lifting and handling during assembly		N
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

25	EXPELLED PARTS <i>No expelled parts</i>		N
25.1	Protective means are provided where expelled parts of the equipment could be a hazard		N
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		N

28	SUSPENDED MASSES <i>No suspended masses</i>		N
28.3	Suspension system with safety device		N
	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
	Safety device has safety factors complying with Sub-clause 28.4.2		N
	Clear indication to the operator that the safety device has been activated after failure of suspension means		N
28.4	Suspension systems of metal without safety devices		N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	1) Total load does not exceed the safe working load		N
	2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired		N
	3) Safety factors not less than 8 where impairment is expected		N
	4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%		N
	5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement		N
29	X-RADIATION		N
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5 mR)		N
36	ELECTROMAGNETIC COMPATIBILITY		P
	Equipment complies with IEC 601-1-2	The LCD monitor powered by switching power adaptor passed the EMC testing according to the requirements of IEC/EN 60601-1-2.	P
37	COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT		N
	Requirements for category AP and APG equipment (Cl. 37 - 41)	Device belongs not to category AP or APG.	N
42	EXCESSIVE TEMPERATURES		P
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	See appended table.	P

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

42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient	See appended table.	P
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C	No applied part.	N
42.5	Guards to prevent contact with hot surfaces removable only with a tool	No hot surface.	N

43	FIRE PREVENTION		P
	Strength and rigidity necessary to avoid a fire hazard	Enclosure material is rated flammability Class V-1 or better.	P

44	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION		P
44.2	Equipment contain a liquid reservoir:		N
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min		N
	- 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
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)		N
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		N
44.5	Equipment sufficiently protected against the effects of humidity	Performed at 40°C, 95%(120hrs). For leakage current measurement, see appended table 19.	P
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529		N
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	No patient contact.	N

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

45	PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE		N
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
45.3	Maximum pressure does not exceed the maximum permissible working pressure for individual parts		N
45.7	Unless excessive pressure can not occur, pressure-relief device provided		N
45.7a	Pressure-relief device connected as close as possible to the pressure vessel		N
45.7b	Readily accessible for inspection		N
45.7c	Not capable of being adjusted or rendered inoperative without a tool		N
45.7d	Discharge opening located that the released material is not directed towards person		N
45.7e	Discharge opening located that operation will not deposit material which may cause a safety hazard		N
45.7f	Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure		N
45.7g	No shut-off valve between a pressure-relief device and the parts intended to be protected		N
45.7h	Minimum number of cycles of operation: 100.000		N

48	BIOCOMPATIBILITY		N
	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	No applied parts.	N

49	INTERRUPTION OF THE POWER SUPPLY		P
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IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard	No such automatic resetting device provided in adaptor nor in monitor.	N
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 LCD monitor not intended for use with live supporting equipment.	P
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure		N

51	PROTECTION AGAINST HAZARDOUS OUTPUT		N
51.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally	No such o/p provided.	N

52	ABNORMAL OPERATION AND FAULT CONDITIONS		P
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 appended table 52 and table 19. Power supply adaptor is approved component, the protections of the power supply ensure that there occur no hazards caused by the adapter if there are fault conditions in the circuit of the monitors.	P
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	Incorporated software not relevant for the safety concept of the EUT.	N
52.5.2	Failure of thermostats presents no safety hazards		N
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard	The double or reinforced insulation is provided inside the approved power adaptor.	N
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C	See appended table.	P

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
52.5.6	Locking of moving parts presents no safety hazard	No moving parts.	N
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	No motors.	N
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8	Ditto.	N
52.5.9	Failure of one component at a time presents no safety hazard	Tested accordingly for the approved adaptor. Abnormal testing of failure of component was not considered to be necessary except for described in table 19 or on page 4(LPS).	P
52.5.10	Overload of heating elements presents no safety hazard	Without heating elements.	N
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	Ditto.	N
	h) Equipment with three-phase motors can safely operate with one phase disconnected	Ditto.	N

56	COMPONENTS AND GENERAL ASSEMBLY		P
	List of critical components	See appended table.	P
56.1b	Ratings of components not in conflict with the conditions of use in equipment		P
	Ratings of mains components are identified		N
56.1d	Components, movements of which could result in a safety hazard mounted securely	No such component.	N
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard	No such conductors and connectors.	N
56.3a	Connectors provide separation required by Sub-clause 17g	No hazardous live parts in the LCD monitor, there fore there is no separation required.	N
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	No patient connection.	N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Medical gas connections not interchangeable	No medical gas connections.	N
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.	P
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.	No leads.	N
56.4	Connections of capacitors		N
	Not connected between live parts and non-protectively earthed accessible parts	No live or mains parts except in the approved adaptor.	N
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14	Ditto.	N
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts	Ditto.	N
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs	No thermal cut-out or similar device was used.	N
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	Only approved adaptor directly connected to the supply mains.	N
56.6	Temperature and overload control devices		N
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment	No thermal cut-out was used.	N
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits	Ditto.	N
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard	Ditto.	N
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard	Ditto.	N
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times	Ditto.	N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Non-self resetting over-current releases operated 10 times	Ditto.	N
56.6b	Thermostats with varying temperature settings clearly indicated	Ditto.	N
	Operating temperature of thermal cut-outs indicated	Ditto.	N
56.7	Batteries		N
	a) Battery compartments:		N
	- adequately ventilated		N
	- accidentally short-circuiting is prevented		N
	b) Incorrect polarity of connection prevented		N
56.8	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):		P
	- to indicate that equipment is energized	By green LED located on front side of LCD monitor.	P
	- to indicate the operation of non-luminous heaters if a safety hazard could result	No heaters.	N
	- to indicate when output exists if a safety hazard could result		N
	- charging mode indicator provided	No charging mode.	N
56.10	Actuating parts of controls	No actuating parts the movement of which may cause hazards.	P
56.10b	Actuating parts are adequately secured to prevent them from working loose during normal use		P
	Controls are secured to prevent the movement relative to scale marking (safety related only)		N
	Detachable indicating devices are prevented from incorrect connection without the use of tool		N
56.10c	Stops are provided on rotating controls:		N
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard		N
	- to prevent damage to wiring	Ditto.	N

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

56.11	Cord-connected hand-held and foot-operated control devices <i>No such devices.</i>		N
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g		N
	b) Hand-held control devices comply with the requirement and test of Sub-clause 21.5		N
	- Foot-operated control devices designed to support the weight of an adult human being		N
	c) Devices not change their setting when inadvertently placed		N
	d) Foot-operated control devices are at least IPX 1		N
	- For surgical use, electrical switching parts are IPX 8		N
	e) Adequate strain relief at the cord entry provided		N

57	MAINS PARTS, COMPONENTS AND LAYOUT <i>LCD monitor is powered by external adaptor which is an approved component.</i>		N
57.1	Isolation from supply mains		N
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously		N
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents		N
	d) Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328		N
	f) Mains switches not incorporated in a power supply cord		N
	h) Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a		N
	m) Fuses and semiconductor devices not used as isolating devices		N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
57.2	Mains connectors and appliance inlets		N
	e) Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug	No such outlets used.	N
	g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment		N
57.3	Power supply cords		N
	a) Not more than one connection to a particular supply mains	One appliance inlet on approved switching power adaptor. LCD monitor with only one jack for DC supply.	N
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously		N
	The mains plug has only one power supply cord		N
	Non-permanently connected equipment provided with power supply cord or appliance inlet		N
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53		N
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C		N
	c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV	No power cord provided. However the user's manual of adaptor states that the minima cross-sectional area of the conductor of a power cord should be 0.75mm ² .	N
	d) Stranded conductors not soldered if fixed by any clamping means	Not applicable due to inlet used for the adaptor.	N
57.4	Connection of power supply cords		N
57.4a	Cord anchorages		N
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting	Inlet provided for the adaptor.	N
	Tying the cord into a knot or tying the ends with string not used	Ditto.	N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation	Ditto.	N
	Cord anchorages made of metal provided with an insulating lining	Ditto.	N
	Clamping screws do not bear directly on the cord insulation	Ditto.	N
	Screws associated with cable replacement are not used to secure other components	Ditto.	N
	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	Ditto.	N
57.4b	Power supply cord protected against excessive bending	Ditto.	N
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected	Ditto.	N
57.5	Mains terminal devices and wiring of mains part		N
	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	No mains part within LCD monitor.	N
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced		N
	Screws and nuts which clamp external conductors not serve to fix any other component		N
	b) Terminals closely grouped with any protective earth terminal		N
	Mains terminal devices accessible only with use of a tool		N
	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
	c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened		N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	d) Cord terminals not require special preparation of the conductor		N
57.6	Mains fuses and overcurrent releases <i>Mains fuses are part of power adaptor (approved component).</i>		N
	Fuses or over-current releases provided accordingly for Class I and Class II		N
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current		N
	Protective earth conductor not fused		N
	Neutral conductor not fused for permanently installed equipment		N
57.8	Wiring of the mains part		N
	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	No mains part.	N
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord		N
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard		N
57.9	Mains supply transformers <i>Not incorporated in the LCD monitor.</i>		N
57.9.1	Overheating		N
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		N
57.9.1a	Short-circuit of secondary windings not caused excessive temperature		N
57.9.1b	Overload of secondary windings not caused excessive temperature		N
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests		N
57.9.4	Construction		N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Separation of primary and secondary windings		N
	- separate bobbins or formers		N
	- one bobbin with insulating partition		N
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm		N
	- concentrically wound on one bobbin with windings separated by double insulation		N
	c) Means provided to prevent displacement of end turns		N
	d) Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn		N
	e) Insulation between the primary and secondary in transformers with double insulation		N
	- 1 insulation layer with thickness of at least 1 mm		N
	- at least 2 insulation layers with a total thickness of at least 0.3 mm		N
	- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation		N
	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
57.10	Creepage distances and air clearances		N
	a) Values: compliance with at least the values of Table XVI		N
	Creepage distances for slot insulation of motors at least 50% of the specified values	No motors.	N
	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
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts	No applied part.	N

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
58	PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS <i>LCD Monitor is powered by approved adaptor. Protective earth is not within the LCD monitor. However the external adaptor is an approved component.</i>		N
58.1	Clamping means of the protective earth terminal		N
	Not be able to loosen without the aid of a tool		N
	Screws for internal earth connections are covered or protected against loosening from outside		N
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal		N
58.8	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing		N
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		N

59	CONSTRUCTION AND LAYOUT		P
59.1	Internal wiring		P
	a) Cables and wiring protected against contact with a moving part	No moving parts.	P
	Wiring having basic insulation only protected by additional fixed sleeving	No additional sleeving used for basic insulation.	N
	Components are not likely to be damaged in the normal assembly or replacement of covers		P
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead		N
	c) Insulating sleeving adequately secured	No additional sleeving used for basic insulation.	N
	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

IEC 601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material		N
	d) Aluminum wires of less than 16 mm ² cross-section not used	No aluminium wires.	N
	f) Connecting cords between equipment parts considered as belonging to the equipment		N
59.2	Insulation		N
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation	No Basic / Supplementary / Double / Reinforced insulation inside of the LCD monitor was required.	N
	c) Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts	Ditto.	N
	Parts of rubber resistant to ageing	No rubber used.	N
59.3	Excessive current and voltage protection		N
	Internal electrical power source provided with device for protection against fire hazard	No such source.	N
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder		N
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		N
59.4	Oil containers		N
	Oil containers adequately sealed	No oil container used.	N
	Container allow for the expansion of the oil		N
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		N
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N

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

6.1	TABLE: marking durability		P
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.	

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

7	TABLE: power input					P
Operating condition		Voltage	Frequency	Current	Power	Remarks
Power adaptor: Hitron, HES 49-12040						
Normal operation at Adaptor	90	50	0.71	37	Rated: 1.0A max.	
Normal operation at Adaptor	90	60	0.70	38		
Normal operation at Adaptor	100	50	0.65	37		
Normal operation at Adaptor	100	60	0.66	36		
Normal operation at Adaptor	240	50	0.33	37		
Normal operation at Adaptor	240	60	0.33	38		
Normal operation at Adaptor	264	50	0.31	37		
Normal operation at Adaptor	264	60	0.30	37		
Normal operation at LCD Monitor	12Vd.c.	—	2.80	34	Rated: 4.0A	
Power adaptor: Sinpro, MPU50-105						
Normal operation at Adaptor	90	50	0.71	37	Rated 1.35A max.	
Normal operation at Adaptor	90	60	0.71	37		
Normal operation at Adaptor	100	50	0.66	37		
Normal operation at Adaptor	100	60	0.65	37		
Normal operation at Adaptor	240	50	0.33	38		
Normal operation at Adaptor	240	60	0.33	38		
Normal operation at Adaptor	264	50	0.31	38		
Normal operation at Adaptor	264	60	0.30	38		
Normal operation at LCD Monitor	12Vd.c.	—	2.90	35	Rated: 4.0A	
Supplementary information: Max. load: Full raster, max. brightness, contrast and each USB port load 0.5A.						

15b	TABLE: residual voltage in attachment plug <i>Both switching power adaptors are approved components.</i>										N	
Voltage measured between:		Measurements [V]										Remarks
		1	2	3	4	5	6	7	8	9	10	

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

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15c	TABLE: residual voltage or energy in capacitors				N
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
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
No defibrillation approved applied parts					

17h2	TABLE: defibrillation-proof recovery time				N
Applied part with test voltage	Test voltage polarity	Recovery time from accompanying documents (s)	Measured recovery time (s)	Remarks	
No defibrillation approved applied parts					

18	TABLE: protective earthing <i>LCD monitor : 12Vd.c. powered, no earthing</i> <i>Switching Power Supply : approved component</i>				N
Test location		Test current (A)	Measured voltage (V)	Resistance (ohms)	Remarks
Supplementary information:					

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Clause	Requirement + Test	Result - Remark	Verdict

19	TABLE: leakage current				P
Type of leakage current and test condition (including single faults)		Supply voltage	Supply frequency	Measured max. value	Remarks
<u>Before humidity conditioning ⁽¹⁾</u>					
ER; NC	(Limit: 0.5mA)	264V	60 Hz	0.14	MD1, S1 = 1, S5 = 1 or 0
ER; SFC	(Limit: 1.0mA)	264V	60 Hz	0.25	MD1, S1 = 0, S5 = 1 or 0
ER; SFC	(Limit: 1.0mA)	264V	60 Hz	0.25	MD1, S1 = 1, S5 = 1 or 0, S2 or S3 = 0
EN; NC	(Limit: 0.1mA)	264V	60 Hz	0.01	MD1, S1 = S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.02	MD1, S1 = 0; S8 = 1, S5 = 0 or 1
EN; NC	(Limit: 0.1mA)	264V	60 Hz	0.08	MD3, S1 = S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.14	MD3, S1 = 0; S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.09	MD3, S1 = S8 = 1, S5 = 0 or 1, S2 or S3 = 0
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.08	MD3, S1 = 1; S8 = 0, S5 = 0 or 1
EN; NC	(Limit: 0.1mA)	264V	60 Hz	0.01	MD4, S1 = S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.02	MD4, S1 = 0; S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.01	MD4, S1 = S8 = 1, S5 = 0 or 1,

IEC 601 + Am. 1 & 2					
Clause	Requirement + Test	Result - Remark		Verdict	
				S2 or S3 =0	
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.01	MD4, S1 = 1; S8=0, S5 = 0 or 1
After humidity conditioning ⁽¹⁾					
ER; NC	(Limit: 0.5mA)	264V	60 Hz	0.14	MD1, S1 = 1, S5 = 1 or 0
ER; SFC	(Limit: 1.0mA)	264V	60 Hz	0.25	MD1, S1 =0, S5 = 1 or 0
ER; SFC	(Limit: 1.0mA)	264V	60 Hz	0.25	MD1, S1 = 1, S5 = 1 or 0, S2 or S3 =0
EN; NC	(Limit: 0.1mA)	264V	60 Hz	0.01	MD1, S1 =S8 =1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.02	MD1, S1 =0; S8 = 1, S5 = 0 or 1
EN; NC	(Limit: 0.1mA)	264V	60 Hz	0.09	MD3, S1 =S8 =1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.15	MD3, S1 =0; S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.09	MD3, S1 =S8 =1, S5 = 0 or 1, S2 or S3 =0
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.09	MD3, S1 = 1; S8=0, S5 = 0 or 1
EN; NC	(Limit: 0.1mA)	264V	60 Hz	0.01	MD4, S1 =S8 =1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.02	MD4, S1 =0; S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.01	MD4, S1 =S8 =1, S5 = 0 or 1, S2 or S3 =0

IEC 601 + Am. 1 & 2					
Clause	Requirement + Test	Result - Remark			Verdict
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.01	MD4, S1 = 1; S8 = 0, S5 = 0 or 1
<u>Before humidity conditioning</u> ⁽²⁾					
ER; NC	(Limit: 0.5mA)	264V	60 Hz	0.13	MD1, S1 = 1, S5 = 1 or 0
ER; SFC	(Limit: 1.0mA)	264V	60 Hz	0.21	MD1, S1 = 0, S5 = 1 or 0
ER; SFC	(Limit: 1.0mA)	264V	60 Hz	0.13	MD1, S1 = 1, S5 = 1 or 0, S2 or S3 = 0
EN; NC	(Limit: 0.1mA)	264V	60 Hz	0.01	MD1, S1 = S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.02	MD1, S1 = 0; S8 = 1, S5 = 0 or 1
EN; NC	(Limit: 0.1mA)	264V	60 Hz	0.08	MD3, S1 = S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.13	MD3, S1 = 0; S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.08	MD3, S1 = S8 = 1, S5 = 0 or 1, S2 or S3 = 0
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.08	MD3, S1 = 1; S8 = 0, S5 = 0 or 1
EN; NC	(Limit: 0.1mA)	264V	60 Hz	0.01	MD4, S1 = S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.02	MD4, S1 = 0; S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.01	MD4, S1 = S8 = 1, S5 = 0 or 1, S2 or S3 = 0
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.01	MD4,

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

				S1 = 1; S8=0, S5 = 0 or 1	
After humidity conditioning ⁽²⁾					
ER; NC	(Limit: 0.5mA)	264V	60 Hz	0.13	MD1, S1 = 1, S5 = 1 or 0
ER; SFC	(Limit: 1.0mA)	264V	60 Hz	0.21	MD1, S1 = 0, S5 = 1 or 0
ER; SFC	(Limit: 1.0mA)	264V	60 Hz	0.13	MD1, S1 = 1, S5 = 1 or 0, S2 or S3 = 0
EN; NC	(Limit: 0.1mA)	264V	60 Hz	0.01	MD1, S1 = S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.02	MD1, S1 = 0; S8 = 1, S5 = 0 or 1
EN; NC	(Limit: 0.1mA)	264V	60 Hz	0.08	MD3, S1 = S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.13	MD3, S1 = 0; S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.08	MD3, S1 = S8 = 1, S5 = 0 or 1, S2 or S3 = 0
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.08	MD3, S1 = 1; S8 = 0, S5 = 0 or 1
EN; NC	(Limit: 0.1mA)	264V	60 Hz	0.01	MD4, S1 = S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.02	MD4, S1 = 0; S8 = 1, S5 = 0 or 1
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.01	MD4, S1 = S8 = 1, S5 = 0 or 1, S2 or S3 = 0
EN; SFC	(Limit: 0.5mA)	264V	60 Hz	0.01	MD4, S1 = 1; S8 = 0.

IEC 601 + Am. 1 & 2					
Clause	Requirement + Test	Result - Remark			Verdict
					S5 = 0 or 1
EN; NC and SFC of DC/AC inverter of LCD monitor:					
EN; NC ⁽³⁾	(Limit: 0.1mA)	264V	60 Hz	0.01	MD4, S1 = S8 = 1, S5 = 0 or 1
EN; SFC ⁽⁴⁾	(Limit: 0.5mA)	264V	60 Hz	0.01	MD4, S1 = S8 = 1, S5 = 0 or 1
(Record at least maximum measured value for each test required by Clause 19 and the specific conditions of the test circuit and equipment).					
Abbreviations used:					
ER - Earth leakage current EN - Enclosure leakage current P - Patient leakage current PM - Patient leakage current with mains on the applied parts PA -Patient auxiliary current Fig. 15 - refers to Fig. 15 in IEC601-1 MD - Measuring device			A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition		
Note:					
(1) With power adaptor: Hitron, HES 49-12040.					
(2) With power adaptor: Sinpro, MPU50-105.					
(3) NC: CN3 pin1 to earth: (EN = 0.01mA)					
CN3 pin4 to earth: (EN = 0.01mA)					
CN3 pin1 to pin4: (EN = 0.01mA)					
(4) SFC: CN2 pin1 to earth:					
a. EN = 0.01mA, with R4 short.					
b. EN = 0.01mA, with C4 short.					
c. EN = 0.01mA, with R10 short.					
d. EN = 0.01mA, with R22 short.					
e. EN = 0.01mA, with L2 short.					
f. EN = 0.01mA, with Q2 short.					
SFC: CN2 pin4 to earth:					
a. EN = 0.01mA, with R4 short.					
b. EN = 0.01mA, with C4 short.					
c. EN = 0.01mA, with R10 short.					
d. EN = 0.01mA, with R22 short.					
e. EN = 0.01mA, with L2 short.					
f. EN = 0.01mA, with Q2 short.					
SFC: CN2 pin4 to earth:					
a. EN = 0.01mA, with R4 short.					

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

- b. EN=0.01mA, with C4 short.
- c. EN=0.01mA, with R10 short.
- d. EN=0.01mA, with R22 short.
- e. EN=0.01mA, with L2 short.
- f. EN=0.01mA, with Q2 short.

(5) Following information was provided in the user's manual:

"This equipment shall be interconnected only to IEC 60601-1 approved equipment."

Enclosure leakage current with 264V applied between earth and SIP/SOP was not considered.

20	TABLE: dielectric strength				N
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (V)	Test voltage (V)	Remarks	
The LCD monitor is powered by 12Vd.c. approved adaptor, and the DC/AC inverter of LCD monitor covered by metal chassis is not user accessible. No hazards. Under NC & SFC, the enclosure leakage current does not exceed the allowed values as the adaptor output is tested according the requirements of enclosure leakage current. No tests are considered necessary.					

21	TABLE: mechanical strength		N
Part under test		Test (impact, drop, force, handle, rough handling, mobile)	Remarks

24	TABLE: - stability		N
Part under test	Test condition	Remarks	

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

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

42.	TABLE: normal temperature			P
	Supply voltage:	a) 90V/60 Hz b) 264V/50 Hz		—
	ambient temperature °C:	See below		—
	test condition:	See below		—
measuring location		△ T (K)		Required △ T (K)
		a)	b)	
With power adaptor: HES49-12040				
For power adaptor				
Inlet pin		22	16	25
C4 body		30	28	45
C7 body		34	29	45
C9 body		36	35	45
IC2 body		34	38	60
L5 coil		26	22	65
L1 coil		37	32	65
L2 coil		39	34	65
PCB near DB1		38	30	65
PCB near Q1		37	38	65
PCB near D12		29	31	65
T1 coil		36	40	80
T1 core		36	40	80
Enclosure (inside)		34	40	--
Enclosure (outside)		19	19	45
C8 body		28	30	45

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

<u>For PDC-170</u>			
PCB near C72	24	24	65
T2 coil	43	43	65
L2 coil	37	37	65
Enclosure (inside)	17	16	40
Enclosure (outside)	10	9	40
Ambient	24°C	25°C	--
<i>With power adaptor: MPU50-105</i>			
<u>For power adaptor</u>			
L1 coil	39	32	65
L2 coil	42	38	65
T1 coil	42	49	80
Enclosure (outside)	16	18	45
<u>For PDC-170</u>			
PCB near C72	24	24	65
T2 coil (inverter)	44	43	65
L2 coil (inverter)	38	37	65
Enclosure (inside)	16	15	40
Enclosure (outside)	11	9	40
Ambient	24°C	25°C	--

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

The maximum specified ambient temperature is 40°C.

Maximum temperature rise calculated as:

Winding components:

- class B $\rightarrow \Delta T_{max} = 130^{\circ}\text{C} - 10^{\circ}\text{C} - 40^{\circ}\text{C} = 80^{\circ}\text{C}$

Electrolyte capacitor and component with:

- max. temp. of 65°C $\rightarrow \Delta T_{max} = (65 - 40)\text{K} = 25\text{K}$

- max. temp. of 80°C $\rightarrow \Delta T_{max} = (80 - 40)\text{K} = 40\text{K}$

- max. temp. of 85°C $\rightarrow \Delta T_{max} = (85 - 40)\text{K} = 45\text{K}$

- max. temp. of 105°C $\rightarrow \Delta T_{max} = (100 - 40)\text{K} = 60\text{K}$

- max. temp. of 120°C $\rightarrow \Delta T_{max} = (105 - 40)\text{K} = 65\text{K}$

Touchable surfaces: max. temp. of 85°C $\rightarrow \Delta T_{max} = (80 - 40)\text{K} = 45\text{K}$

The temperatures were measured under worst case in normal condition is defined as max.

brightness/contrast, the max. horizontal frequency of the monitor, max volume of speakers and full loading of USB ports.

Note:

An asterisk indicates where reference is made to IEC 60950: 1999 sub-clause 4.5.1 condition A "If temperature rises of windings are determined by thermocouples, these figure are reduced by 10 K except in case of motors."

44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		P
Test type and condition		Part under test	Remarks
Humidity (48hrs, 95%, 25°C)		PCB, electric components	Result see table 19

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

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

52	TABLE: abnormal operation		P
Test type, condition and clause reference		Observed results	Remarks
Ventilation openings blocked		On adaptor a. Inlet body: 40°C b. C4 body: 52°C c. C7 body: 53°C d. C9 body: 59°C e. IC2 body: 62°C f. L5 coil: 46°C g. L1 coil: 56°C h. L2 coil: 58°C i. PCB near DB1: 54°C j. PCB near Q1: 62°C k. PCB near D12: 55°C l. T1 coil: 65°C m. T1 core: 64 °C n. Enclosure (inside): 64°C o. Enclosure (outside): 44°C p. C8 body: 54°C On DC-AC inverter a. PCB near C72: 51°C b. T2 coil: 70°C c. Enclosure (inside): 35°C d. Enclosure (outside): 25°C At ambient: 25°C, no hazards.	1 hr.
Note: Test with power adaptor: HES49-12040			

56.1	TABLE: lists of critical component parts					P
Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity ¹⁾	
PCB	--	--	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	
LCD Panel	AU Optronics Corp.	M170EN05-1	TFT type, SVGA 17 inch	--	--	
Power Switch	Solteam	MR-21	6A, 250V	IEC 61058-1	VDE, S, UL	
Inverter	Lecerf Technology Co., Ltd.	LV-1702LC-AA	I/p: 13 V, 2500 mA, Max. O/P: 900 Vrms, 7.5 mA	--	--	
- Transformer (T1, T2)	Lecerf Technology Co., Ltd	X08-C-1	105°C	--	--	

IEC 601 + Am. 1 & 2					
Clause	Requirement + Test		Result - Remark		Verdict
Power Supply	Sinpro Electronics Co., Ltd.	MPU50-105	Input: 100-240Vac, 1.35A, 47-63Hz. DC Output: 11-13V/4.00-3.46A, 45W Max. temp. 40°C	EN 60601-1, IEC 60601-1	TUV, CB, UL
Power Supply	Hitron Electronics Corp.	HES 49-12040	Input: 100-240Vac, 1.0A max., 50-60Hz. DC Output: 12V/4A max. Max. temp. 40°C	IEC 60601-1	CB, UL
1) an asterisk indicates a mark which assures the agreed level of surveillance					

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

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

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

57.4b	TABLE: cord bending			N
Cord under test		Test mass	Measured curvature	Remarks
Supplementary information:				

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Clause	Requirement + Test	Result - Remark	Verdict

57.9.1a	TABLE: transformer short circuit <i>Mains Supply Transformer only inside power adaptor (approved component).</i>					N
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
Supplementary information:						

57.9.1b	TABLE: overload <i>Mains Supply Transformer only inside power adaptor (approved component).</i>						N
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current or thermal cutout temp.	Remarks
		Primary	Secondary	Ambient			
Supplementary information:							

57.9.2	TABLE: transformer dielectric strength <i>Mains Supply Transformer only inside power adaptor (approved component)</i>				N
Transformer under test	Test voltage applied to	Test voltage	Test frequency	Remarks	

59.2	TABLE: ball pressure tests			N
part/material		Temperature of this part from sub-clause 42 (°C)	Test temperature (°C)	Impression diameter(mm)
Enclosure/ Chi-Mei, type PA-765A		41 + 40 > 75	81	1.3mm
Note: Test was not required. However, performed and outer enclosure did not deform.				

SUMMARY OF CONTENTS:

These tests fulfill the requirements of standard EN45001.

This test report comprises 61 pages of CB Test Report (include this page and the national differences) and the following Attachments:

Attachment #	Description	Pages
1	Circuit Diagram of distribution power	62
2	Circuit Diagram of USB	63
3	Circuit Diagram of DC/AC inverter	64
4	Circuit Diagram of input data PCB	65
5	Circuit Diagram of input data PCB	66
6	PCB layout of DC/AC inverter	67

Note:

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

National Deviation			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Australian National Differences according to CB Bulletin No. 105A, May 2003 (AS/NZS 3200-1-0:1998) (IEC Publication 60601-1:1988 + A1:1991 + A2:1995)		P
EXPLANATION FOR ABBREVIATIONS P = Pass, F = Fail, N = Not applicable. Placed in the column to the right.			
6.1.g)	Insert the following sub-clause between the first and second dashes:	Inserted.	P
	For low voltage equipment rated at 200 V or more, voltage marking (which may be part of a voltage range) of not less than 230 V. Supply frequency ratings which include 60 Hz must also include 50 Hz.	Rating of adaptor are 100V-240Vac, 50-60 Hz and 100V-240Vac, 47-63 Hz	P
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
28.2	Replace the existing text with the following:	Replaced.	N
	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		N

National Deviation			
Clause	Requirement – Test	Result – Remark	Verdict
	<p>to minimize hazards.</p> <p>(vii) Ceiling-supported EQUIPMENT or parts there of 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 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 200 V is regarded as having a maximum rated voltage of 230 V.</p>	No applied parts.	N
Table XII	In second row, first dash, after 'if impedance protected' add 'maximum value'.	Added.	N
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. No supply flexible cord is provided.	N
56.3 a)	<p>Replace the text in the 3rd 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

National Deviation			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Canadian National Differences according to CB Bulletin No. 105A, May 2003 (CAN/CSA 22.2 No. 601.1-M90) (IEC Publication 60601-1:1988 + A1:1991 + A2:1995)		P
EXPLANATION FOR ABBREVIATIONS P = Pass, F = Fail, N = Not applicable. Placed in the column to the right.			
6	Where written warnings appears as equipment markings, they should appear in French and English.	Should be evaluated during national approval.	N
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 pint of connection of gas cylinders to equipment is identified.	No gas cylinders.	N
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
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


National Deviation			
Clause	Requirement – Test	Result – Remark	Verdict
57.2 g	<p>Mains plug of non-permanents installed equipment:</p> <ul style="list-style-type: none"> - if molded on type – hospital grade complying with CSA C22.2, No. 21 <p>Mains plug of non-permanent installed equipment</p> <ul style="list-style-type: none"> - hospital grade disassembly type complying with CSA C22.2, No. 42 <p>Mains plug of non-permanent installed equipment:</p> <ul style="list-style-type: none"> - if Class II equipment – polarized hospital grade CSA configuration 1-15P 	No power supply cord provided.	N
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:</p> <p>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
57.9	Switching power supplies conform to CSA Electrical Bulletin 1402C.	Should be evaluated during national approval.	N
58.2	Protective earth connections comply with CSA C 22.2 No.04	Should be evaluated during national approval.	N
59.1	Connecting cables comply with Canadian Electrical Code, Part I.	Should be evaluated during national approval.	N
60	Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts.	No such parts.	N

National Deviation			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Israeli National Differences according to CB Bulletin No. 105A, May 2003 (SI 1011) IEC Publication 60601-1:1988 + A1:1991 + A2:1995)		P
EXPLANATION FOR ABBREVIATIONS			
P = Pass, F = Fail, N = Not applicable. Placed in the column to the right.			
	Clause 4.7 – Supply and mains voltages :	Input voltage DC12V.	N
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.	Rating of adaptor are 100V-240Vac, 50-60 Hz, 48W Max. and 100V-240Vac, 47-63 Hz, 45W Max.	P
B.	It is equipment to connect to the mains other equipment, with the following ratings: One phase equipment, for the range of 220 to 40 Volts. Multiphase equipment, for the range of 380 to 440 Volts. The equipment shall comply with all the equipments 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. Change clause 36. – EMC – to: The equipment shall comply with the equipments of SI 1011 parts 1.2 (IEC 60601-1-2).		N

National Deviation			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	Korean National Differences according to CB Bulletin No. 105A, May 2003 (IEC Publication 60601-1:1988 + A1:1991 + A2:1995)		P
EXPLANATION FOR ABBREVIATIONS			
P = Pass, F = Fail, N = Not applicable. Placed in the column to the right.			
	LIMITATIONS	See below.	N
	< Supply voltage rating > National supply voltages are 110, 220V and 380V.	Rating of adaptor are 100V-240Vac, 50-60 Hz and 100V-240Vac, 47-63 Hz	P
	< Frequency > Only appliances having supply frequency of 60Hz or a frequency range including 60 Hz are accepted.	Ditto	P
	< 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
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.	DC power supply source.	N
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 D II, Symbol 6) and with the Korean language, "고압주의" (Gooap Jui).	No high voltage terminal devices.	N

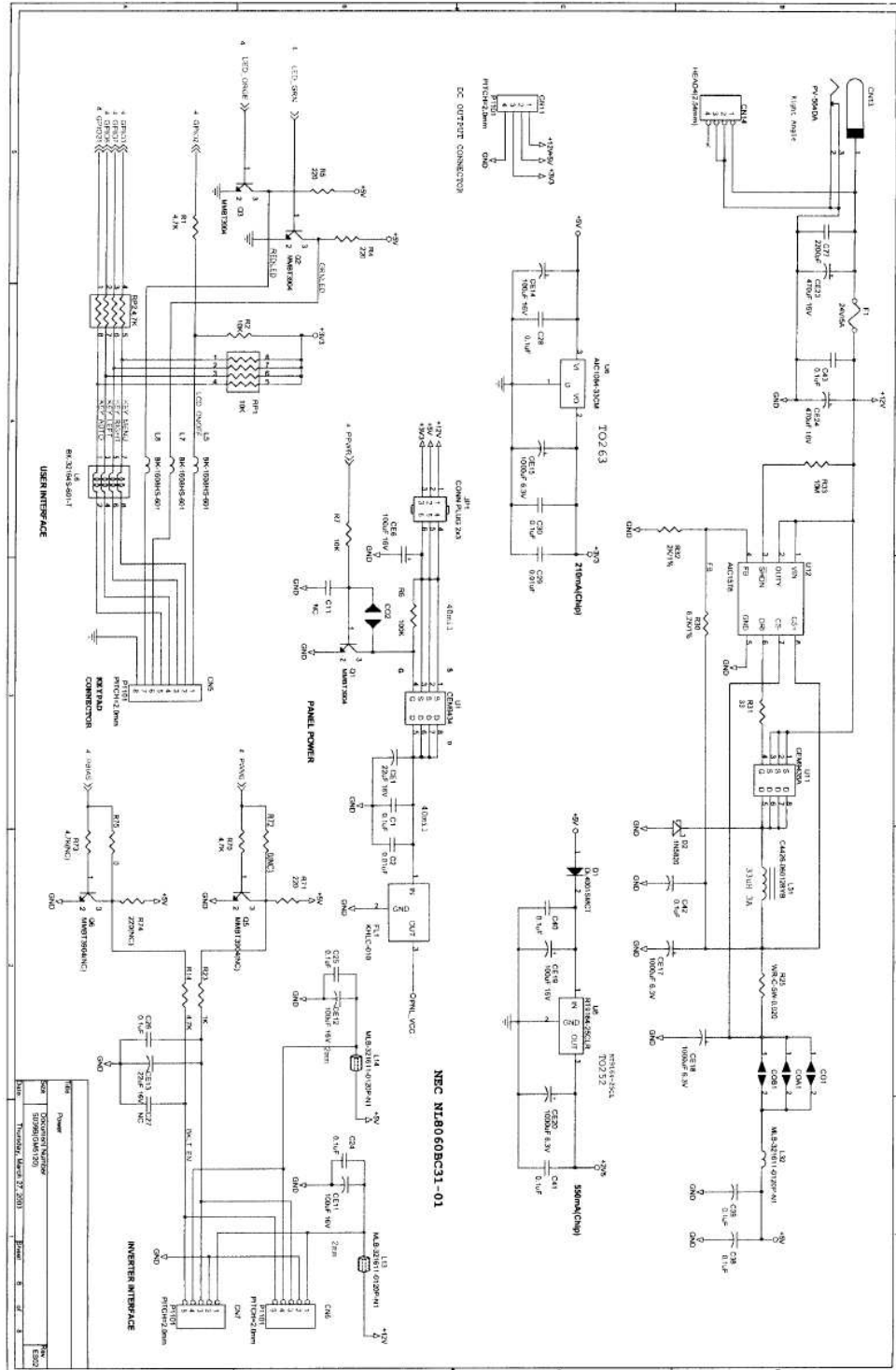
National Deviation			
Clause	Requirement – Test	Result – Remark	Verdict
6.2 c)	Replace the existing subclause wit the following: The presence of HIGH VOLTAGE PARTS shall be marked wit the symbol “dangerous voltage” (see Appendix D, Table DII, Symbol 6) and wit the Korean “ 고압주의 ”.	Ditto.	N
6.8.1	Insert 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

National Deviation			
Clause	Requirement – Test	Result – Remark	Verdict
APPENDIX	US National Differences according to CB Bulletin No. 105A, May 2003 (UL2601-1) (IEC Publication 60601-1:1988 + A1:1991 + A2:1995)		P
EXPLANATION FOR ABBREVIATIONS P = Pass, F = Fail, N = Not applicable. Placed in the column to the right.			
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 definition Clause 6, 6.2 and product markings shall agree with the NEC	No X-ray source.	N
6.21	Replace 70°C with 60°C		N
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
57	All equipment installations are required to be in accordance with NEC.	To be evaluated when submitted for national approval.	N
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
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.	Ditto.	N
The following US National deviations are based on requirements other than US National Electrical Code (NEC)			

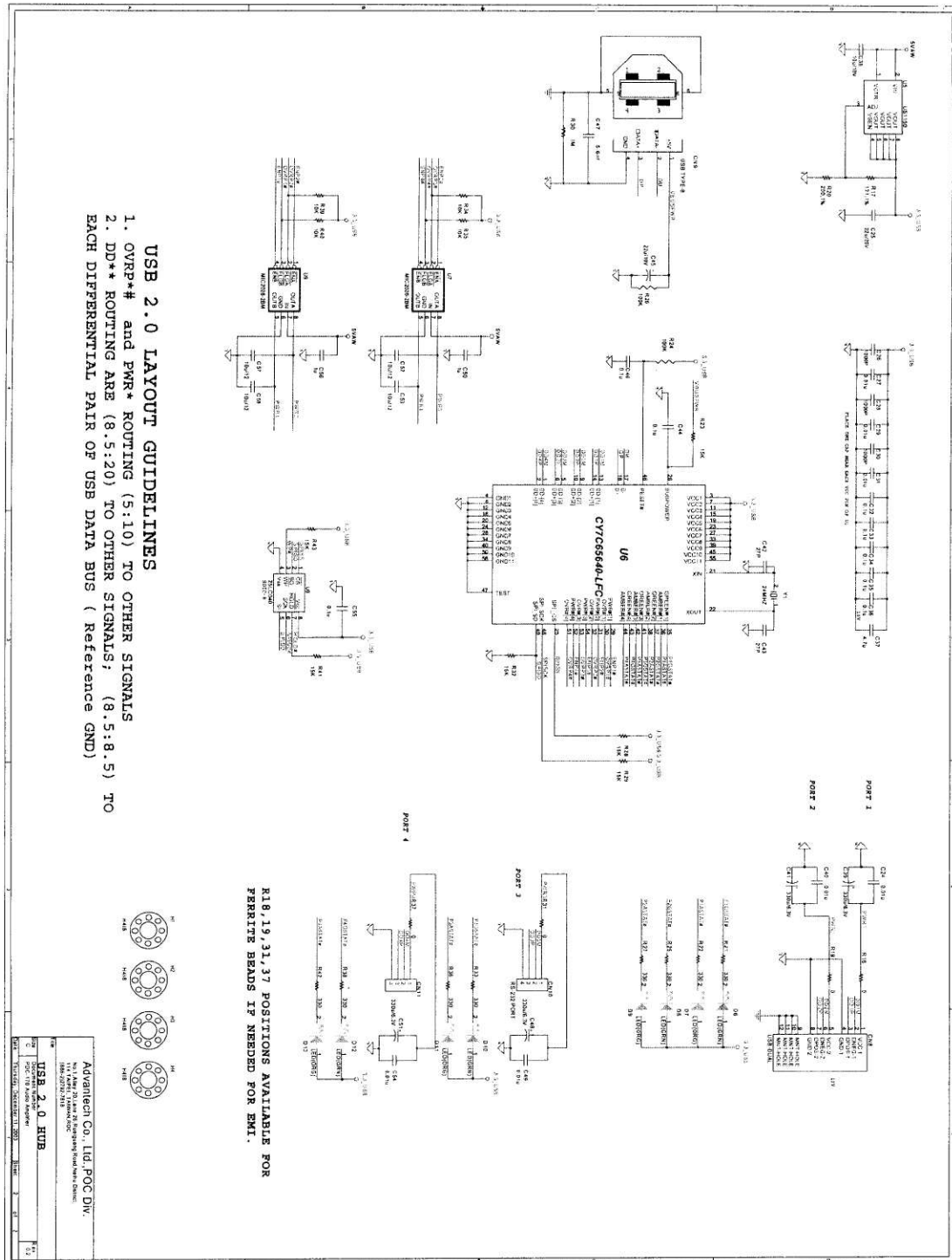
National Deviation			
Clause	Requirement – Test	Result – Remark	Verdict
1.1, Section 5	Safety hazards resulting from intended physiological function of and ionizing radiation resulting from equipment covered by this standard are not considered. Such equipment is subject to US FDA requirements and US Federal Radiation Standards (21CFR Part 1020) promulgated under the Radiation Control for Health and Safety Act of 1968.	Not applicable.	N
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
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.	Component which are approved according international harmonized standards or relevant national recognized standards have been used.	P
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.	 is used.	N
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 th edition, Sections 31 and 34 with respect to the movement control and supported masses.	Not applicable.	N
42	In addition, to the basic requirements in this standard, insulating systems operating at greater than Class 150°C limits during normal use and normal condition shall comply with the requirements of the Standard for Systems of Insulating Materials-General (UL 1446)	No insulation systems. (basic insulation or higher provided)	N

National Deviation			
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.	V-1 or better, 80°C min enclosure used.	P
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 circuits.	N
58.2	Connections shall be made mechanically secure as well as being soldered.	Complied.	P
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
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.	“Only use adaptor: Hitron: HES49-12040 or Sinpro:MPU50-105” is provided on the label.	P

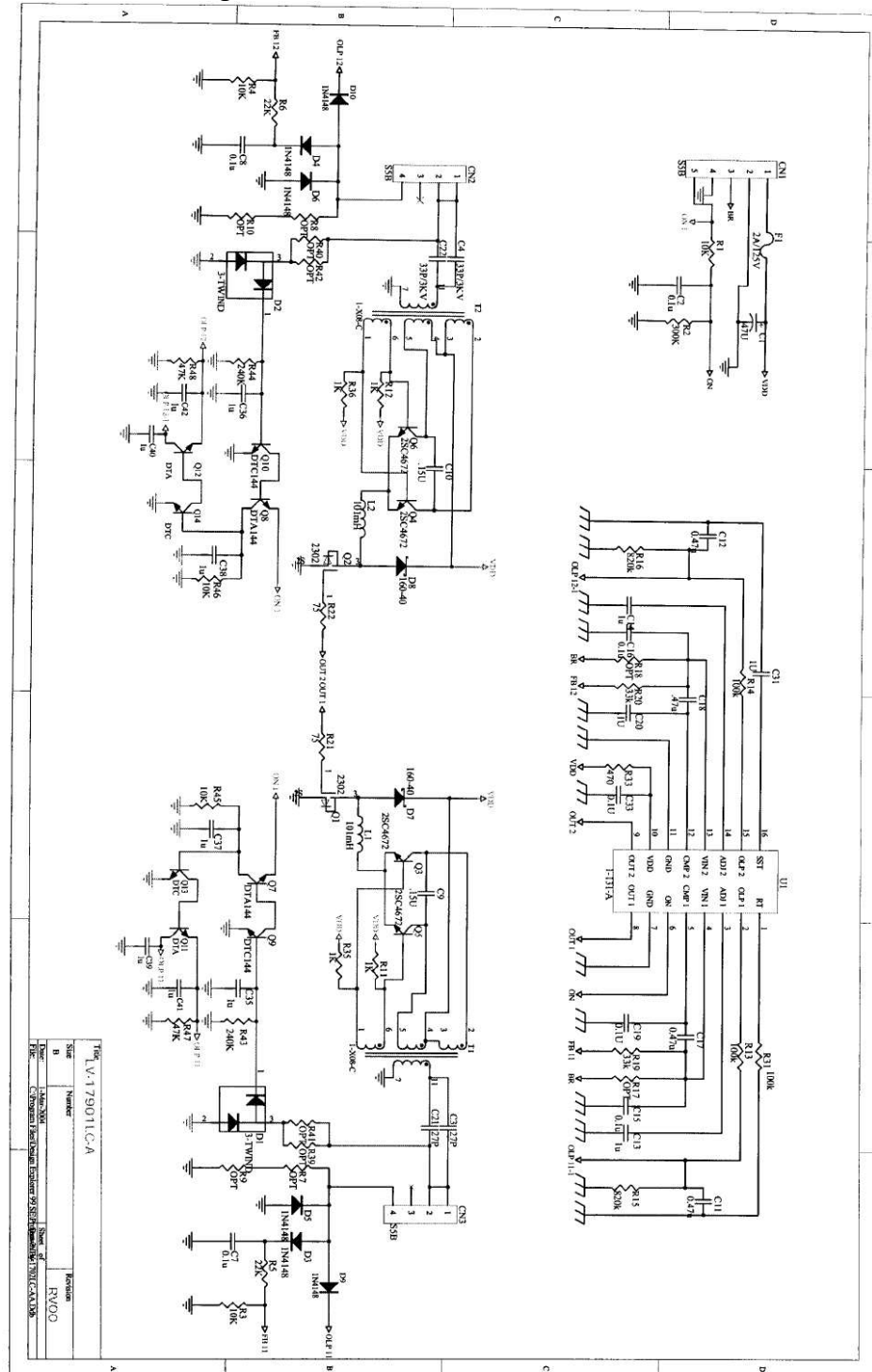
Attachment 1: Circuit Diagram of Distribution Power

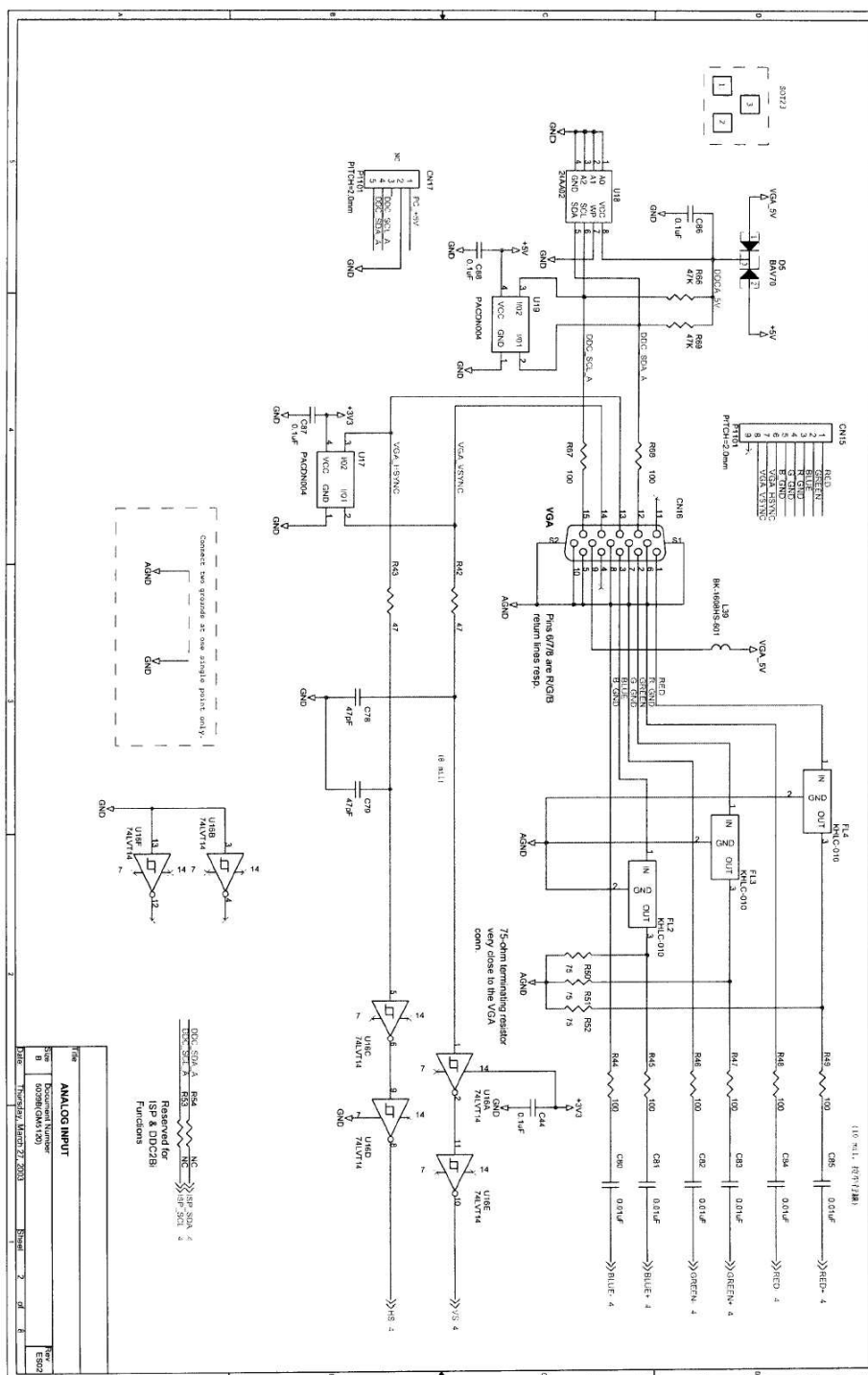


Attachment 2: Circuit Diagram of USB



Attachment 3: Circuit diagram of DC/AC Inverter





Attachment 6: PCB layout of DC/AC inverter

