Certificate of Compliance

Council Directive 93/42/EEC

Certification Number : **L070411-02**

Application : **Aaeon Technology Inc.**

Product : **Medical Station**

Electronic Rating : **AC 100-240V~, 50-60Hz, 1-0.5A, Class I**

Model/Type : **xxxxxONYX-175HTy-xx-xxxx (for 17" LCD Panel)**
xxxxxONYX-195HTy-xx-xxxx (for 19" LCD Panel)

Other Specification :

Standards applied : **EN 60601-1:1990+A1+A2+A13**
Also comply with IEC 60601-1:1988+ A1+A2 excluding National Deviation

This tested samples of the above products are in conformity with the technical provisions of the Following European Directive-

Council Directive 93/42/EEC

DATA Issued : **May 30, 2007**

Approve & Authorized Signer: _____

Prodigy Technology Consultant Co.Ltd.
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Total Page: 01 of 51	**TEST REPORT**	
	EN 60601-1	
	Medical electric equipment **Part 1: General requirements for safety**	

Report

Reference No. ..... : L070411-02

Compiled by (+ signature) ..... : Danny Lin .....

Approved by (+ signature) ..... : Angus Hsu .....

Date of issue ..... : 30 May, 2007

Contents ..... : 51 Pages

Testing laboratory

Name ..... : Prodigy Technology Consultant Co., Ltd.

Address ..... : 1F, No. 30, Sec. 1, Wunhua 1st Rd., Linkou, Taipei Country, Taiwan

Testing location ..... : Same as above

Client

Name ..... : Aaeon Technology Inc.

Address ..... : 5F, No. 135, Lane 235, Pao Chiao Rd., Hsin-Tien City, Taipei, Taiwan

Test specification

Standard ..... : EN 60601-1:1990+A1+A2+A13

Also comply with IEC 60601-1:1988+A1+A2 excluding National Deviation

Non-standard test method ..... : N/A

Test item

Description ..... : Medical Station

Trademark ..... : AAEON

Model and/or type reference..... : xxxxxONYX-175HTy-xx-xxxx (for 17" LCD Panel),

xxxxxONYX-195HTy-xx-xxxx (for 19" LCD Panel)

(where x =0-9, A-Z, "-" or blank; y=T or blank)

Manufacturer ..... : Aaeon Technology Inc.

Address ..... : 5F, No. 135, Lane 235, Pao Chiao Rd., Hsin-Tien City, Taipei, Taiwan

Rating(s)..... : 100-240Vac, 50-60Hz, 1-0.5A, Class I

Particulars: test item vs. test requirements	
Classification of installation and use ..... :	Portable equipment
Supply connection..... :	Appliance coupler
Test case verdicts	
Test case does not apply to the test object..... :	N(.A.)
Test item does meet the requirement ..... :	P(ass)
Test item does not meet the requirement ..... :	F(ail)
..... :	
Testing	
Date of receipt of test item ..... :	May 7, 2007
Date(s) of performance of test..... :	May 25, 2007
..... :	

General remarks

This test report shall not be reproduced except in full without the written approval of the testing laboratory.
The test results presented in this report relate only to the item tested.
"(see remark #)" refers to a remark appended to the report.
"(see appended table)" refers to a table appended to the report.

Brief description of the test sample:

- This Medical Station is supplied by an internal certified power supply, and having no patient applied part.
- The Medical Station also employs the: a). Rotatable Medical Panel; b). DC/AC inverter inside the equipment.
- Model: xxxxxONYX-175HTy-xx-xxxx is similar to Model: xxxxxONYX-195HTy-xx-xxxx except for model designation and LCD panel size.
- The AC/DC switching power supply (FSP180-50MP) of this equipment was tested by Nemko and passed the requirements of IEC 60601-1.
- Maximum specified ambient temperature is 40 °C.
- USB ports and PS/2 ports are according to the LPS (Limited Power Source) requirement of IEC 60950-1.
- DC/AC Inverter is according to the LCC (Limited Current Circuit) requirement of IEC 60950-1.

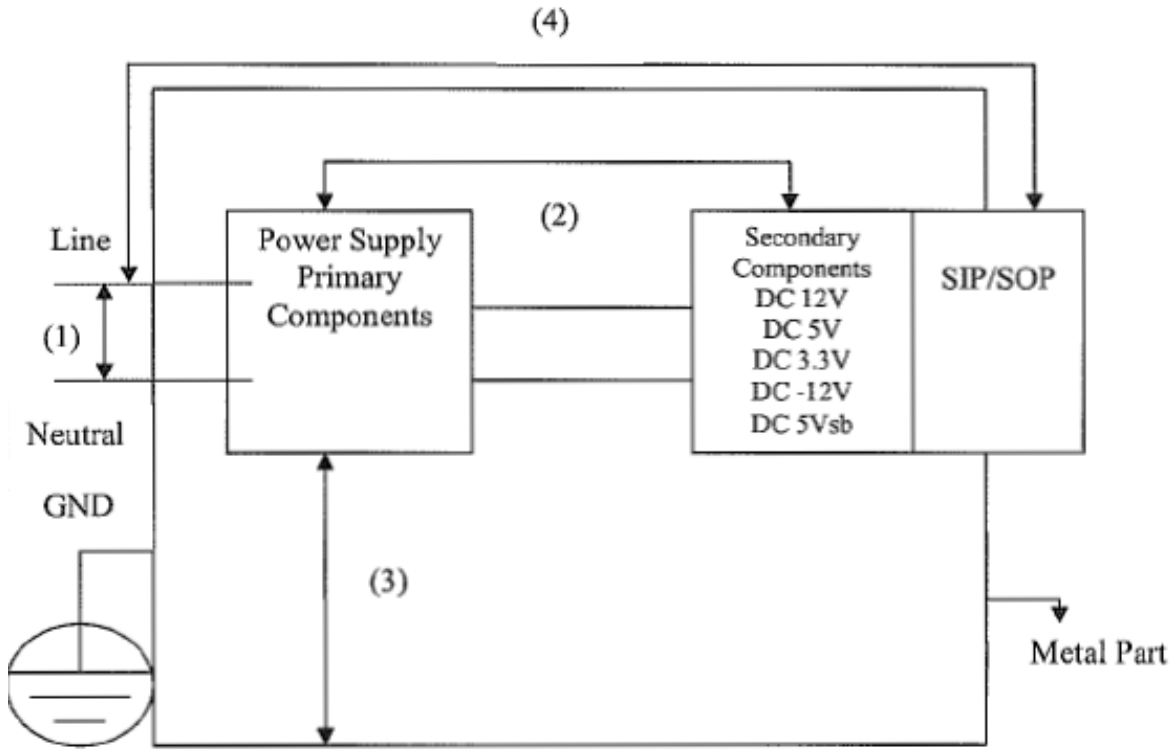
Copy of the marking plate :

EN 60601-1			
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.)	The equipment causes no hazards when used according to the manufacturers instructions.	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	All alternate constructions were evaluated in the report.	N
5.	CLASSIFICATION		P
5.1	Type of protection against electric shock		P
	Class I equipment	Class I equipment.	P
	Class II equipment	Class I equipment.	N
	Internally powered equipment	Class I equipment.	N
	Degree of protection against electric shock		N
5.2	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	As the equipment is not intended to be connected to the patient and does not have any patient applied parts, it is should not be marked with the type B applied part symbol. Nevertheless, the product complies with the requirements for type B applied part concerning protection against electric shock.	P
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 equipment, IPX0.	N
5.4	Methods of sterilization or disinfection	Not applicable.	N
5.5	Equipment not suitable for use in the presence of flammable mixtures	The equipment is not AP or APG category equipment.	N
	Category AP equipment		N

EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
	Category APG equipment		N
5.6	Mode of operation:		P
	continuous operation	The equipment is designed for continuous operation.	P
	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 ..... :		

EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
	Table: insulation diagram		P
	Protection against electric shock - Block diagram of system		P

INSULATION DIAGRAM



(1) A-f, BOP, U=250V, E.S = 1500Vac
(2) A-e, Double Insulation, U = 383V, E.S = 4528Vac
(3) A-a1, Basic Insulation, U = 250V, E.S = 1500Vac
(4) A-e, Double Insulation, U = 383V, E.S = 4528Vac

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Clause	Requirement Test	Result – Remark	Verdict

	Table: to insulation diagram						P
area	insulation type: operational/basic/ supplementary/ double/reinforced	reference voltage (V)	required creepage (mm)	Required clearance (mm)	measured creepage (mm)	Measured clearance (mm)	Remarks
(1)	A-f	250	3.0	1.6	3.2	3.2	Evaluated in the certified power supply
(2)	A-e	383	12.0	7.0	17.2	17.2	Evaluated in the certified power supply
(3)	A-a1	250	4.0	2.5	5.2	5.2	Evaluated in the certified power supply
(4)	A-e	383	12.0	7.0	> 20.0	> 20.0	Evaluated in the certified power supply

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 requirements of Clause 17, 20 and 57.

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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 are affixed	No applicable. No specific power supply affixed.	N
	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 ..... :	AAEON TECHNOLOGY INC or AAEON	P
	f) Model or type reference ..... :	xxxxxONYX-175HTy-xx-xxxx (for 17" LCD Panel), xxxxxONYX-195HTy-xx-xxxx (for 19" LCD Panel) (where x =0-9, A-Z, "-" or blank; y=T or blank)	P
	g) Rated supply voltages or voltage range(s)	AC 100-240 V~	P
	Number of phases ..... :	Single phase.	N
	Type of current ..... :	AC	P
	h) Rated frequency or rated frequency range(s) (Hz) ..... :	50-60 Hz	P
	j) Rated power input (VA, W or A) ..... :	1-0.5 A	P
	k) Power output of auxiliary mains socket-outlets	No socket-outlet.	N
	l) Class II symbol	Class I equipment.	N
	Symbol for degree of protection against ingress of water provided ..... :	Ordinary equipment. IP X0.	N
	Symbol for protection against electric shock ..... :	No applied parts.	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
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		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):		P

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Clause	Requirement Test	Result – Remark	Verdict
	attention, consult accompanying documents	Symbol 14 of Table DI was used in the User Manual.	P
	non-ionizing radiation, or symbols as adopted by ISO or IEC 60417	Not applicable.	N
	r) Anaesthetic-proof symbol: AP or APG ..... :	Not of category AP or APG.	N
	s) Dangerous voltage symbol	Not used.	N
	t) Special cooling requirements	Not applicable.	N
	u) Limited mechanical stability	The equipment did no overbalance.	P
	v) Protective packing requirement(s)	Transportation or storage temperature: -20°C to 60°C Transportation or storage 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	Not applicable.	N
	Functional earth terminal	No functional earth.	N
	z) Removable protective means	No removable protective means.	N
	Durability of marking test		P
6.2	Marking on the inside of equipment or equipment parts		P
	a) Nominal voltage of permanently installed equipment	Not permanently connected equipment.	N
	b) Maximum power loading for heating elements or holders for heating lamps	No heating elements or lamps inside the equipment.	N
	c) Dangerous voltage symbol	High voltage exist in the DC/AC inverter of Medical Station. Enclosure and user touchable ports comply with the leakage current limitations in normal and single fault conditions. Furthermore the o/p had been tested according to the Limit Current Circuit (LCC) requirement of IEC 60950. Therefore the voltages are not considered to be dangerous. No marking required.	P
	d) Type of battery and mode of insertion	See appended table 56.1.	P

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Clause	Requirement Test	Result – Remark	Verdict
	Marking referring to accompanying documents used for battery not intended to be changed by the operator		P
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram	Fuses were not accessible.	N
	f) Protective earth terminal	Appliance inlet used.	P
	g) Functional earth terminal	No functional earth terminal.	N
	h) Supply neutral conductor in permanently installed equipment (N)	Not permanently installed equipment.	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 60445	See below.	P
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)	Not permanently connected equipment.	N
	l) Statement for suitable wiring materials at temperatures over 75 °C	Not permanently connected equipment.	N
	n) Capacitors and/or circuit parts are marked as required in Cl. 15. c)	Not applicable.	N
6.3	Marking of controls and instruments		P
	a) Mains switch clearly identified	No mains switch provided.	N
	ON and OFF positions marked according to Symbols 15 and 16 of Table D1 or indicated by an adjacent indicator light	Ditto.	N
	b) Indications of different positions of control devices and switches	Indication of control devices were provided on the equipment.	P
	c) Indication of the direction in which the magnitude of the function changes, or an indicting device	No setting device could cause a safety hazard.	N
	f) The functions of operator controls and indicators are identified	Provided in the user manual.	P
	g) Numeric indications of parameters are in SI units except for units listed in A2	Provided in SI units.	P
6.4	Symbols		P
	Symbols used comply with Appendix D or IEC 60417 and/or IEC 60878 or ISO publications (if applicable)	Mark ⏻ used.	P
6.5	Colours of insulation of conductors		P

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Clause	Requirement Test	Result – Remark	Verdict
	a) Protective earth conductor has green/yellow insulation	The protective earth conduct is green/yellow color insulation.	P
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		P
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow		P
	d) Colour of neutral conductor ..... :	Not provided with the power supply cord.	N
	e) Colours of phase conductors ..... :	Ditto.	N
	Compliance with IEC 60227 and IEC 60245	Ditto.	N
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors	Multi-conductor cord not used.	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	No red indicator lights used.	N
	Yellow used to indicate caution or attention required		N
	Green used to indicate ready for action	Green indicator lights used to indicate “Normal condition of Medical Station”.	P
	b) Colour red used only for push-buttons by which a function is interrupted in case of emergency	No red indicator lights used.	N
6.8	Accompanying documents		P
6.8.1	Equipment is accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Stated in operations manual.	P
	Classifications specified in Cl. 5. are included in both the instructions for use and the technical description	Stated in operations manual.	P
	Markings specified in 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	Marking permanently affixed enclosure of equipment.	N

EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
	Warning statements and the explanation of warning symbols provided in the accompanying documents		P
6.8.2	Instructions for use		P
	a) General information provided in instructions for use:		P
	- state the function and intended application of the equipment	Provided in the user manual.	P
	- include an explanation of: the function of controls, displays and signals	Provided in the user manual.	P
	- the sequence of operation	Provided in the user manual.	P
	- the connection and disconnection of detachable parts and accessories	Provided in the user manual.	P
	- the replacement of material which is consumed during operation	No replacement material.	N
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	Provided in the user manual.	P
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety		N
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	Provided in the user manual.	P
	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	Provided in the user manual.	P
	c) Signal output or signal input parts intended only for connection to specified equipment described	The marking: “The unit is for exclusive interconnection with IEC 60xxx certified equipment outside of patient environment and IEC 60601-1 certified equipment inside the patient environment.” was provided in the user manual.	P
	d) Details about acceptable cleaning, disinfection or sterilization methods included	No direct contact to the patient.	N

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Clause	Requirement Test	Result – Remark	Verdict
	e) Warning statement for mains operated equipment with additional power source	No additional power source.	N
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	No batteries in primary.	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 60601-1	No such device.	N
	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
	a) All characteristics essential for safe operation provided	Provided in the user manual.	P
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	Not permanently connected equipment.	N
	Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	No such device.	N
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	No user repairable parts.	N
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Temperature: -20 °C to +60 °C Humidity: 10% to 95% RH Air Pressure: 500 to 1060 hPa	P
7.	POWER INPUT		P
	Power input measurements	(See appended table)	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 operations manual for transportation and storage: Temp.: -20 ~+60°C. R.H.: 10%~95%.	P
10.2.2	a) Rated voltage not exceeding 250 V for hand-held equipment	Not hand-held.	N

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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 4 kVA	AC 100-240 V~.	P
	Rated voltage not exceeding 500 V for all other equipment		N
	Rated input frequency not more than 1 kHz	50-60 Hz	P
	b) Internal replaceable electric power source specified	No internal replaceable electric power.	N

14.	REQUIREMENTS RELATED TO CLASSIFICATION		P
14.4	a) Class I and Class II equipment in addition to basic insulation provided with an additional protection	The EUT was supplied by the internal certified power supply, which had been investigated to provide with the double or reinforced insulation.	P
	b) Equipment supplied from external d.c. source of reverse polarity results in no safety hazard	No hazards.	N
14.5	b) 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
14.6	c) Applied parts intended for direct cardiac application are of type CF	No applied parts provided.	N

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Clause	Requirement Test	Result – Remark	Verdict
15.	LIMITATION OF VOLTAGE AND/OR ENERGY		P
	b) Voltage measured one sec after disconnection of the mains plug does not exceed 60 V	Evaluated in the certified power supply.	P
	c) For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceeds 2 mJ	No such capacitor.	N
	Marking provided for manual discharging		N
16.	ENCLOSURES AND PROTECTIVE COVERS		P
	a) 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 and user touchable ports comply with the leakage current limitations in normal and single fault conditions. Furthermore the o/p had been tested according to the Limit Current Circuit (LCC) requirement of IEC 60950. Therefore the voltages are not considered to be dangerous. No marking required.	P
	Insertion or removal of lamps: protection against contact with live parts provided	No lamps inside the equipment.	N
	b) Opening in a top cover so positioned that accessibility of live parts by a test rod is prevented	Components enclosed in the EUT cannot be touched by the test rod.	P
	c) Conductive parts accessible after the removal of handles, knobs, levers:		N
	- have a resistance of not more than 0,2	No such components.	N
	- separated from live parts by one of the means described in Cl. 17. g)	Ditto.	N
	d) Parts with voltage exceeding 25 V a.c. or 60 V d.c. which cannot be disconnected by external mains switch or plug protected against contact	No mains connection.	N
	e) Removable enclosures protecting against contact with live parts	No live parts in this equipment. However the enclosure is secured by screws.	P
	Removal possible only with the aid of a tool	The removal of the enclosure needs the aid of tool.	P
	Use of automatic device making parts not live when the enclosure is opened or removed		N

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Clause	Requirement Test	Result – Remark	Verdict
	Exception 16 e) applied to the following parts ..... :		N
	f) Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	No pre-set control which may be adjusted during normal used.	N
17.	SEPARATION		N
	a) 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
	Additional leakage current test in single fault conditions	Ditto.	N
	c) There is no conductive connection between applied parts and accessible conductive parts, which are not protectively earthed	Ditto.	N
	d) Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)	No motor provided.	N
	g) Separation method of accessible parts other than applied parts from live parts: *No live parts inside LCD monitor / Adaptor is approved component*		P
	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	Evaluated in the certified power supply, which had provided with double or reinforced insulation.	P
	5) by protective impedances limiting current to accessible part		P
	Additional leakage current test in single fault conditions	(see appended table 19)	P

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Clause	Requirement Test	Result – Remark	Verdict
	h) 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		P
	a) Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal		P
	b) Protective earth terminals suitable for connection to the protective earth conductor	Appliance inlet used.	P
	e) Potential equalization conductor:		N
	- readily accessible	No potential equalization conductor.	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
	f) For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1\ \Omega$	No live parts, no protective earth required. Not applicable.	N
	For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $\leq 0.1\ \Omega$	(See appended table18)	P
	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
	g) If the impedance of protective earth connections other than in Cl. 18. f) exceeds 0,1 , the allowable value of the enclosure leakage current is not exceeded in single fault condition		N
	k) Functional earth terminal not used to provide protective earthing	Functional earthing terminal not used.	N
	l) Class II equipment with isolated internal screens		N

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Clause	Requirement Test	Result – Remark	Verdict
	- 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
19.1	b) Leakage currents	(see appended table 19)	P
	Earth leakage current		P
	Enclosure leakage current		P
	Patient leakage current	No patient leakage current.	N
	Patient auxiliary current	No patient auxiliary current.	N
20.	DIELECTRIC STRENGTH AT OPERATING TEMPERATURE		P
	Overall compliance with Cl. 20.	(see appended table 20)	P
21.	MECHANICAL STRENGTH		P
	a) Sufficient rigidity of enclosure tested by: force of 45 N	(see appended table 21)	P
	b) Sufficient strength of an enclosure tested by: impact hammer	No damage after the test.	P
	c) Portable equipment carrying handles or grips withstand the requirements of the loading test	No handle and grip on the enclosure.	N
21.3	No damage to parts of patient support and/or immobilization system after the loading test	No such parts.	N
21.5	Hand-held equipment or equipment parts are safe after drop test	No hand held equipment.	N
21.6	Portable and mobile equipment is able to withstand rough handling	(see appended table 21)	P
22.	MOVING PARTS		N
22.2	a) Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment	No moving parts inside the equipment.	N

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Clause	Requirement Test	Result – Remark	Verdict
	b) 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 of the control 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, taken 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	The edges are well rounded.	P

EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
24.	STABILITY IN NORMAL USE		P
24.1	Equipment does not overbalance during normal use when tilted trough an angle of 10	The EUT did not overbalance at 10º.	P
24.3	Equipment overbalances when tilted through an angle of 10 :		N
	- 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
24.6	a) Equipment or its parts with a mass of more than 20 kg is provided with:		N
	- suitable handling devices (grips etc.), or	The weight of the equipment is 13.77 kg max. (< 20 kg)	N
	- instructions for lifting and handling during assembly		N
	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		N
25.1	Protective means are provided where expelled parts of the equipment could be a hazard	No expelled part.	N
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion	No such device used.	N
28.	SUSPENDED MASSES		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 28.4	No suspended masses.	N
	Safety device has safety factors complying with 28.4.2		N
	Clear indication to the operator that the safety device has been activated after failure of suspension means		N

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Clause	Requirement Test	Result – Remark	Verdict
28.4	Suspension systems of metal without safety devices:		N
	1) the 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, bandwheels and guides so constructed that the safety factors shall be 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)	No X-radiation inside the equipment.	N
36.	ELECTROMAGNETIC COMPATIBILITY		P
	Equipment complies wit IEC 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 not belongs 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 specified in 10.2.1	(see appended table 42)	P
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25 C ambient	(see appended table 42)	P
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41 C		N
42.5	Guards to prevent contact with hot surfaces removable only with a tool	No such surface.	N

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Clause	Requirement Test	Result – Remark	Verdict
43.	FIRE PREVENTION		P
	Strength and rigidity necessary to avoid a fire hazard	Rated V-1 plastic enclosure provided.	P
44.	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION, DISINFECTION		P
44.2	If equipment contains a liquid reservoir:		N
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min	No liquid reservoir inside the equipment.	N
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15 in the least favourable 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)	No use of liquid inside the equipment.	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	32ºC, 48 hours, 95% RH. (See appended table)	P
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 60529	Not rated, IPX0.	N
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	Testing performed according to method described in the user manual.	P
45.	PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE *No 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	No pressure vessels and parts inside the equipment.	N
45.3	The maximum pressure does not exceed the maximum permissible working pressure for individual parts		N
45.7	Unless excessive pressure cannot occur, pressure-relief device provided		N
	a) Pressure-relief device connected as close as possible to the pressure vessel		N

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Clause	Requirement Test	Result – Remark	Verdict
	b) Readily accessible for inspection		N
	c) Not capable of being adjusted or rendered inoperative without a tool		N
	d) Discharge opening so located that the released material is not directed towards any person		N
	e) Discharge opening so located that operation will not deposit material which may cause a safety hazard		N
	f) Adequate discharge capacity to ensure that pressure does not exceed the maximum permissible working pressure		N
	g) No shut-off valve between the pressure-relief device and the parts intended to be protected		N
	h) Minimum number of cycles of operation is 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		N
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may give a safety hazard	No automatic resetting device inside the equipment.	N
49.2	Interruption and restoration of the power supply shall not result in a safety hazard other than interruption of its intended function		P
49.3	Means are provided for removal of mechanical constraints on a patient in case of a supply mains failure		N
51.	PROTECTION AGAINST HAZARDOUS OUTPUT		N
51.4	Equipment providing both low-intensity and high-intensity outputs provided with means minimizing the possibility of a high-intensity output being selected accidentally	Not applicable.	N

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Clause	Requirement Test	Result – Remark	Verdict
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)	P
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	No software incorporated.	N
52.5.2	Failure of thermostat presents no safety hazard	No thermostat used.	N
52.5.3	Short-circuiting of either constituent part of double insulation presents no safety hazard		N
52.5.5	Impairment of cooling: temperatures not exceeding 1,7 times the values of Cl. 42. minus 17,5 C		P
52.5.6	Locking of moving parts presents no safety hazard	No moving part inside the equipment.	N
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	Certified fan used.	N
52.5.8	Duration of motors locked rotor test in compliance with 52.5.8	Ditto.	N
52.5.9	Failure of one component at a time presents no safety hazard	(see appended table 52)	P
52.5.10	Overload of heating elements presents no safety hazard	No heating elements.	N
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	Certified fan used.	N
	h) Equipment with three-phase motors can safely operate with one phase disconnected	Certified fan used.	N
56.	COMPONENTS AND GENERAL ASSEMBLY		P
	List of critical components	(see appended table 56)	P
56.1	b) Ratings of components not in conflict with the conditions of use in equipment	The components are used according to their rating.	P
	Ratings of mains components are identified	The critical components were used within the intended rating.	P
	d) Components, movements of which could result in a safety hazard mounted securely	The movement of components is prevented.	P

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Clause	Requirement Test	Result – Remark	Verdict
	f) Conductors and connectors are secured and/or insulated to prevent accidental detachment resulting in a safety hazard	No connection was likely to be detached.	P
56.3	a) Connectors provide separation required by Cl. 17. g)	Double or reinforce insulation provided.	P
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	No connection to the patient.	N
	Medical gas connections not interchangeable		N
	b) Accessible metal parts cannot become live when detachable interconnection cord between different parts of equipment is loosened or broken	Interconnection cord only connected to Safety Extra Low Voltage.	P
	c) 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 patient connection.	N
56.4	Connections of capacitors		P
	Not connected between live parts and non-protectively earthed accessible parts		P
	If connected between mains part and protectively earthed metal parts, comply with IEC 60384-14	Evaluated in the certified power supply.	P
	Enclosure of capacitors connected to mains part and providing only basic insulation is not secured to non-protectively earthed metal parts	No such device.	N
	Capacitors or other spark-suppression devices are not connected between the contacts of thermal cut-outs	No thermal cut-off used.	N
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	No such device.	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 inside the equipment.	N
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits	No thermal safety devices inside the equipment.	N
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard	No such device.	N
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		N

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Clause	Requirement Test	Result – Remark	Verdict
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times	No such device.	N
	Non-self-resetting over-current releases operated 10 times		N
	b) Thermostats with varying temperature settings clearly indicated	No thermostat inside the equipment.	N
	Operating temperature of cut-outs is clearly indicated		N
56.7	Batteries		P
	a) Battery compartments are:		P
	- adequately ventilated		P
	- accidentally short-circuiting is prevented		P
	b) Incorrect polarity of connection prevented		P
56.8	Indicators, unless indication is provided by other means (from the normal operation position), indicator lights are used (colour see 6.7)		P
	- to indicate that equipment is energized		N
	- to indicate the operation of non-luminous heaters if a safety hazard could result	No heaters inside the equipment.	N
	- to indicate when output exists if a safety hazard could result		N
	- charging mode indicator is provided	No charging mode.	N
56.10	Actuating parts of controls	No actuating parts of controls used.	N
	b) Actuating parts are adequately secured to prevent them from working loose during normal use		N
	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 a tool		N
	c) 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		N
56.11	Cord-connected hand-held and foot-operated control devices		N
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17. g)	No cord-connected hand-held or foot-operated control device.	N

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Clause	Requirement – Test	Result – Remark	Verdict
	b) Hand-held devices comply with the requirement and test of 21.5		N
	Foot-operated control devices designed to support the weight of an adult human being		N
	c) Devices shall not change their setting when inadvertently placed		N
	d) Foot-operated control devices are at least IPX1		N
	For surgical use, electrical switching parts are IPX8		N
	e) Adequate strain relief at the cord entry provided		N
57.	MAINS PARTS, COMPONENTS AND LAYOUT		P
57.1	Isolation from supply mains		P
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	Provided with appliance coupler serving as the disconnect device.	P
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents	Appliance coupler serving as the disconnect device, which was indicated in the user manual.	P
	d) Switches used to comply with 57.1 a) comply with the creepage distances and air clearances as specified in IEC 328		N
	f) Mains switches not incorporated in a power supply cord	No such device.	N
	h) Appliance couplers and flexible cords with mains plugs provide compliance with 57.1 a)	Certified appliance coupler serving as the disconnect device.	P
	m) Fuses and semiconductor devices are not used as isolating devices		P
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	Not provided with power supply cord.	N

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Clause	Requirement Test	Result – Remark	Verdict
	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 60227, designation 53 and IEC 60245, 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		N
	d) Stranded conductors not soldered if fixed by any clamping means		N
57.4	Connection of power supply cords		N
	a) Cord anchorages:		
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting	Appliance coupler used.	N
	Tying the cord into a knot or tying the ends with string not used		N
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		N
	Cord anchorages made of metal provided with an insulating lining		N
	Clamping screws do not bear directly on the cord insulation		N
	Screws associated with cable replacement are not used to secure other components		N
	Conductors of the power supply cord so arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals		N
	b) Power supply cord protected against excessive bending		N
	c) Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		N

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Clause	Requirement Test	Result – Remark	Verdict
57.5	Mains terminal devices and wiring of mains part		N
	a) Mains connected equipment other than those with a detachable supply cord is provided with mains terminals, where connections are made with screws, nuts or equally effective methods	Appliance coupler used.	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 shall 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 so 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
	d) Cord terminals shall not require special preparation of the conductor		N
57.6	Mains fuses and over-current releases		P
	Fuses or over-current releases provided accordingly for Class I and Class II	Two fuses (EF1, EF2) are provided in the certified power supply.	P
	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 mains part		P
	a) Individual conductors in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC 60227 or IEC 60245, treated as bare conductor ..... :		P
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply		P

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Clause	Requirement Test	Result – Remark	Verdict
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits are sufficient to prevent any fire hazard		P
57.9	Mains supply transformers		P
57.9.1	Overheating		P
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative	Evaluated in the certified power supply.	P
	a) Short-circuit of secondary windings not caused excessive temperature		P
	b) Overload of secondary windings not caused excessive temperature		P
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests		P
57.9.4	Construction		P
	a) Separation of primary and secondary windings:		N
	- separate bobbins or formers	Evaluated in the certified power supply.	P
	- 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	Evaluated in the certified power supply.	P
	d) Insulated overlap of not less than 3 mm if a protective earth screen has only one turn	Fixed with tape.	P
	e) Insulation between the primary and secondary winding in transformers with double insulation:		P
	- 1 insulation layer having a thickness of at least 1 mm		N
	- at least 2 insulation layers with a total thickness of at least 0,3 mm		N
	- 3 layers provided that each combination of 2 layers can withstand the dielectric strength test for reinforced insulation		P

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Clause	Requirement Test	Result – Remark	Verdict
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having a total thickness at least 0,3 mm extending at least 20 mm outside the winding		N
57.10	Creepage distances and air clearances		P
	a) Values: compliance with at least the values of Table XVI	(see table for insulation diagram)	P
	Creepage distances for slot insulation of motors are at least 50% of the specified values	Certified fan used.	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	(see appended table 52)	N
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts	No defibrillation-proof applied parts in the equipment.	N
58.	PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS		P
58.1	Clamping means of the protective earth terminal	Tool required.	P
	Not be able to loosen without the aid of a tool	No access from outside.	P
	Screws for internal earth connections are covered or protected against loosening from outside		P
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal		P
58.8	The protective earth terminal is not used for the mechanical connection or the fixing of any component not related to earthing	Appliance coupler used.	P
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	Tool required.	P
59.	CONSTRUCTION AND LAYOUT		P
59.1	Internal wiring		P
	a) Cables and wiring protected against contact with a moving part	No moving part inside the equipment.	N
	Wiring having basic insulation only protected by additional fixed sleeving		N
	Components are not likely to be damaged in the normal assembly or replacement of covers	No cover or inspection door provided.	N

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Clause	Requirement Test	Result – Remark	Verdict
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead	No movable leads inside the equipment.	N
	c) Insulating sleeving adequately secured	No insulating sleeving used as critical insulation.	N
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 60227 and IEC 60245 and dielectric strength test		N
	Conductors subjected to temperatures exceeding 70 C, have an insulation of heat-resistant material		N
	d) Aluminium wires of less than 16 mm² cross-section not used	No aluminum wiring used.	N
	f) Connecting cords between equipment parts considered as belonging to the equipment		N
59.2	Insulation		P
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation	(see appended table 59.2b)	P
	c) Insulation not likely to be impaired by deposition of dirt or dust resulting from wear of parts		P
	Parts of rubber resistant to ageing		N
59.3	Excessive current and voltage protection		N
	Internal electrical power source provided with device for protection against fire hazard	No internal power 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.	No such device.	N
59.4	Oil containers		N
	Oil containers adequately sealed	No oil container used.	N
	Container design shall 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

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.

7.	TABLE: power input				P
operating condition	Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks
For Model: xxxxxONYX-175HTy-xx-xxxx					
Max. normal load	90	50	1.10	98.0	Rated input current: 1 - 0.5A
Ditto	90	60	1.10	98.0	Ditto
Ditto	100	50	0.98	98.3	Ditto
Ditto	100	60	0.98	98.3	Ditto
Ditto	240	50	0.41	95.2	Ditto
Ditto	240	60	0.42	95.1	Ditto
Ditto	254	50	0.43	95.1	Ditto
Ditto	254	60	0.44	95.1	Ditto
Ditto	264	50	0.44	94.8	Ditto
Ditto	264	60	0.44	94.8	Ditto
For Model: xxxxxONYX-195HTy-xx-xxxx					
Max. normal load	90	50	1.14	101.0	Rated input current: 1 - 0.5A
Ditto	90	60	1.14	101.0	Ditto
Ditto	100	50	1.02	100.1	Ditto
Ditto	100	60	1.02	100.1	Ditto
Ditto	240	50	0.45	97.1	Ditto
Ditto	240	60	0.46	97.1	Ditto
Ditto	254	50	0.44	97.1	Ditto
Ditto	254	60	0.45	97.1	Ditto
Ditto	264	50	0.43	97.0	Ditto

Ditto	264	60	0.44	97.0	Ditto
Note: Measured under worst case in normal condition is defined as max. brightness/contrast , unit crossed reading and writing data between HDD and CD-ROM drive, each USB loaded 2.5W and working continuously.					

15. b)	TABLE: residual voltage in attachment plugs										N
voltage measured between:	measurements (V)										Remarks
	1	2	3	4	5	6	7	8	9	10	
Evaluated in the certified power supply, which had been found complied with this Standard.											

15. c)	TABLE: residual voltage or energy in capacitors				N
capacitor and its location	residual voltage (V)	time after disconnection (s)	capacitance value (F)	residual energy (mJ)	Remarks

17. h1)	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					

17. h2)	TABLE: defibrillation-proof recovery time				N
applied part with test voltage	Test voltage polarity	recovery time from accompanying document(s)	measured recovery time (s)	remarks	
No defibrillation approved applied parts					

18.	TABLE: protective earthing				P
test location		test current (A)	measured voltage (V)	resistance (mΩ)	remarks
AC inlet Earth Pin to Enclosure		40	0.2	5 mΩ	2 min
Supplementary information:					

19.	TABLE: leakage current				P
type of leakage current and test condition (including single faults)		supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
For Model: xxxxxONYX-195HTy-xx-xxxx					
Figure 16, Earth Leakage					
Before humidity conditioning					
ER; NC	(Limited 500µA)	264	50	249.7	S1=1; S5 = 1
ER; NC	(Limited 500µA)	264	50	244.1	S1=1; S5 = 0
ER; SFC	(Limited 1mA)	264	50	492.2	S1=0; S5 = 1
ER; SFC	(Limited 1mA)	264	50	489.7	S1=0; S5 = 0
After humidity conditioning (48 hours)					
ER; NC	(Limited 500µA)	264	50	250.1	S1=1; S5 = 1
ER; NC	(Limited 500µA)	264	50	245.9	S1=1; S5 = 0
ER; SFC	(Limited 1mA)	264	50	494.1	S1=0; S5 = 1
ER; SFC	(Limited 1mA)	264	50	492.0	S1=0; S5 = 0
Figure 18, Enclosure Leakage					
Before humidity conditioning					
EN, NC	(Limited 100µA)	264	50	1.3	S1 = 1, S5 = 1, S7 = 1 (MD1)
EN, NC	(Limited 100µA)	264	50	1.8	S1 = 1, S5 = 0, S7 = 1 (MD1)
EN, SFC	(Limited 500µA)	264	50	1.5	S1 = 0, S5 = 1, S7 = 1 (MD1)
EN, SFC	(Limited 500µA)	264	50	2.0	S1 = 0, S5 = 0, S7 = 1 (MD1)
EN, SFC	(Limited 500µA)	264	50	250.1	S1 = 1, S5 = 1, S7 = 0 (MD1)
EN, SFC	(Limited 500µA)	264	50	244.1	S1 = 1, S5 = 0, S7 = 0 (MD1)
EN, NC	(Limited 100µA)	264	50	1.2	S1 = 1, S5 = 1, S7 = 1 (MD2)
EN, NC	(Limited 100µA)	264	50	1.4	S1 = 1, S5 = 0, S7 = 1 (MD2)
EN, SFC	(Limited 500µA)	264	50	1.2	S1 = 0, S5 = 1, S7 = 1 (MD2)
EN, SFC	(Limited 500µA)	264	50	1.6	S1 = 0, S5 = 0, S7 = 1 (MD2)
EN, SFC	(Limited 500µA)	264	50	14.1	S1 = 1, S5 = 1, S7 = 0 (MD2)
EN, SFC	(Limited 500µA)	264	50	13.9	S1 = 1, S5 = 0, S7 = 0 (MD2)

After humidity conditioning (48 hours)					
EN, NC	(Limited 100μA)	264	50	1.5	S1 = 1, S5 = 1, S7 = 1 (MD1)
EN, NC	(Limited 100μA)	264	50	1.9	S1 = 1, S5 = 0, S7 = 1 (MD1)
EN, SFC	(Limited 500μA)	264	50	1.6	S1 = 0, S5 = 1, S7 = 1 (MD1)
EN, SFC	(Limited 500μA)	264	50	2.1	S1 = 0, S5 = 0, S7 = 1 (MD1)
EN, SFC	(Limited 500μA)	264	50	253.6	S1 = 1, S5 = 1, S7 = 0 (MD1)
EN, SFC	(Limited 500μA)	264	50	247.2	S1 = 1, S5 = 0, S7 = 0 (MD1)
EN, NC	(Limited 100μA)	264	50	1.4	S1 = 1, S5 = 1, S7 = 1 (MD2)
EN, NC	(Limited 100μA)	264	50	1.6	S1 = 1, S5 = 0, S7 = 1 (MD2)
EN, SFC	(Limited 500μA)	264	50	1.4	S1 = 0, S5 = 1, S7 = 1 (MD2)
EN, SFC	(Limited 500μA)	264	50	1.7	S1 = 0, S5 = 0, S7 = 1 (MD2)
EN, SFC	(Limited 500μA)	264	50	14.3	S1 = 1, S5 = 1, S7 = 0 (MD2)
EN, SFC	(Limited 500μA)	264	50	14.0	S1 = 1, S5 = 0, S7 = 0 (MD2)
Before humidity conditioning					
EN, SFC	(Limited 500μA)	264	50	1.5	S1 = 1, S5 = 1, S7 = 1 (MD1) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500μA)	264	50	1.9	S1 = 1, S5 = 0, S7 = 1 (MD1) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500μA)	264	50	1.7	S1 = 0, S5 = 1, S7 = 1 (MD1) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500μA)	264	50	2.0	S1 = 0, S5 = 0, S7 = 1 (MD1) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500μA)	264	50	250.3	S1 = 1, S5 = 1, S7 = 0 (MD1) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500μA)	264	50	244.3	S1 = 1, S5 = 0, S7 = 0 (MD1) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500μA)	264	50	1.1	S1 = 1, S5 = 1, S7 = 1 (MD2) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500μA)	264	50	1.1	S1 = 1, S5 = 0, S7 = 1 (MD2) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500μA)	264	50	1.1	S1 = 0, S5 = 1, S7 = 1 (MD2) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500μA)	264	50	1.3	S1 = 0, S5 = 0, S7 = 1 (MD2) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500μA)	264	50	14.3	S1 = 1, S5 = 1, S7 = 0 (MD2) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500μA)	264	50	14.1	S1 = 1, S5 = 0, S7 = 0 (MD2) (D/A Inverter HV-Metal chassis

					short)
<u>After humidity conditioning (48 hours)</u>					
EN, SFC	(Limited 500µA)	264	50	1.6	S1 = 1, S5 = 1, S7 = 1 (MD1) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500µA)	264	50	2.0	S1 = 1, S5 = 0, S7 = 1 (MD1) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500µA)	264	50	1.8	S1 = 0, S5 = 1, S7 = 1 (MD1) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500µA)	264	50	2.1	S1 = 0, S5 = 0, S7 = 1 (MD1) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500µA)	264	50	251.7	S1 = 1, S5 = 1, S7 = 0 (MD1) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500µA)	264	50	246.1	S1 = 1, S5 = 0, S7 = 0 (MD1) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500µA)	264	50	1.2	S1 = 1, S5 = 1, S7 = 1 (MD2) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500µA)	264	50	1.2	S1 = 1, S5 = 0, S7 = 1 (MD2) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500µA)	264	50	1.2	S1 = 0, S5 = 1, S7 = 1 (MD2) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500µA)	264	50	1.4	S1 = 0, S5 = 0, S7 = 1 (MD2) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500µA)	264	50	14.3	S1 = 1, S5 = 1, S7 = 0 (MD2) (D/A Inverter HV-Metal chassis short)
EN, SFC	(Limited 500µA)	264	50	14.3	S1 = 1, S5 = 0, S7 = 0 (MD2) (D/A Inverter HV-Metal chassis short)
(Record at least maximum measured value for each test required by Cl._19. and the specific conditions of the test circuit and equipment).					

<u>Abbreviations used:</u> 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 IEC 60601-1	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

20.	TABLE: dielectric strength			P
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
Primary - Earth	BI	250	1500Vac	Pass
Primary – SIP / SOP	DI	383	4528Vac	Pass
Primary – Enclosure (with Foil)	BI	250	1500Vac	Pass
Supplementary information:				

21.	TABLE: mechanical strength	P
part under test	test (impact, drop, force, handle, rough handling, mobile)	Remarks
Plastic enclosure top/ side/ rear	Force Test: 45N	Pass
Plastic enclosure top/ side/ rear	Impact Test by the impact hammer 0.5 J	Pass
Medical Station with base	Drop Test at height: 3 cm	Pass
Supplementary information:		

24.	TABLE: stability	P
part under test	test condition	Remarks
Medical Station	10° tilt conducted on front, rear and sides	Pass, not overbalance
Supplementary information:		

29.	TABLE: X-radiation		P
part under test	test condition	measured radiation (mR)	remarks
Supplementary information:			

42.	TABLE: normal temperature		P
	Supply voltage ……:	AC 100V-10% / 240V+10%	—
	ambient temperature °C ……...:	See below	—
	test condition ……...:	See below	—

measuring location	measured temperature (°C)		Remarks (Allowed Tmax, °C)
For Model: xxxxxONYX-195HTy-xx-xxxx			
AC inlet	48.5 / 63.0	49.0 / 63.3	65
CX1 body	59.4 / 73.7	56.3 / 70.6	105
EL1 coil	63.2 / 77.5	61.1 / 75.4	105
EL2 coil	61.4 / 75.7	60.3 / 74.6	105
PWB under BD1	67.2 / 81.5	65.2 / 79.5	105
L1 coil	63.8 / 78.1	60.7 / 75.0	105
C1 body	62.2 / 76.5	61.6 / 75.9	105
T1 coil	59.5 / 73.8	59.0 / 73.3	130
T1 core	64.1 / 78.4	63.6 / 77.9	130
T2 coil	58.5 / 72.8	58.1 / 72.4	130
T2 core	58.7 / 73.0	58.4 / 72.7	130
IC3 body	58.3 / 72.6	58.3 / 72.6	100
EU5 body	55.6 / 69.9	55.6 / 69.9	100
EU6 body	55.2 / 69.5	55.1 / 69.4	100
L8 coil	68.6 / 82.9	68.3 / 82.6	105
C32 body	57.3 / 71.6	57.2 / 71.5	105
Main board P/N: COM-945	--	--	--
PWB under CPU	81.7 / 96.0	81.7 / 96.0	105
PWB under U4	70.6 / 84.9	70.7 / 85.0	105
L26 Coil	85.0 / 99.3	85.0 / 99.3	105
Main board P/N: 1907T07002	--	--	--
PWB under U8	56.9 / 71.2	57.0 / 71.3	105
EC14 body	56.1 / 70.4	56.1 / 70.4	105
RTC body	56.2 / 70.5	56.0 / 70.3	--
DC/AC Inverter P/N: QF132V1	--	--	--
T2 coil	62.1 / 76.4	62.4 / 76.7	105
T2 core	60.9 / 75.2	62.1 / 75.5	105

L2 coil	62.1 / 76.4	62.7 / 77.0	105
C1 body	62.4 / 76.7	62.9 / 77.2	105
Panel body	54.4 / 68.7	54.6 / 68.9	--
HDD body	43.3 / 57.6	43.9 / 58.2	--
CD-ROM body	49.2 / 63.5	49.9 / 64.2	--
Enclosure inside near top	45.5 / 59.8	45.3 / 59.6	60
Enclosure outside near top	37.5 / 51.8	36.9 / 51.2	85
Ambient (°C)	25.7 / 40.0	25.7 / 40.0	--

The maximum specified ambient temperature is 40 °C

The temperatures were measured under worst case in normal condition is defined as max. brightness/contrast , unit crossed reading and writing data between HDD and CD-ROM drive, each USB loaded 2.5W and working continuously.Note:

44.	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection	P

test type and condition	part under test	Remarks
Humidity (48hrs, 95%, 32°C)	PCB, electric components	Result see table 19

Supplementary information:

45.	TABLE: hydrostatic pressure and pressure-relief device cycling test	N

test type and condition	part under test	test pressure	Remarks

Supplementary information:

52.	TABLE: abnormal operation		P
test type, condition and clause reference		observed results	Remarks (test time)
Component	Fault		
For Model: xxxxxONYX-195HTy-xx-xxxx			
Ventilation Openings	Blocked	T1 coil: 113.6 °C T1 core: 111.1 °C T2 coil: 97.1 °C T2 core: 94.6 °C At ambient: 26.0 °C, no hazards.	6.4 hrs
CPU Fan	Stalled	T1 coil: 62.4 °C T1 core: 64.1 °C T2 coil: 57.7 °C T2 core: 56.2 °C At ambient: 25.0 °C, no hazards.	4.9 hrs
Power Fan	Stalled	T1 coil: 117.3 °C T1 core: 111.1 °C T2 coil: 102.7 °C T2 core: 102.1 °C At ambient: 25.0 °C, no hazards.	7.5 hrs
RTC Battery (CR2032)	Normal	Reverse Charging Current: 0 mA	--
RTC Battery (CR2032)	D11 Pin 1-2 short	Reverse Charging Current: 3.0 mA	--
Supplementary information:			

56.1	TABLE: lists of critical component parts				P
object/part No.	manufacturer/ trademark	type/model	technical data	standard	mark(s) of conformity[1])
Power Supply	FSP Group Inc.	FSP180-50MP	I/P: 100-240Vac, 50-60Hz, 4A; O/P: +3.3V/16.8A, +5V/12A, +12V/12A, -12V/0.8A, +5Vsb/2A	IEC 60601-1	Nemko CB (Certificate No: NO 27244)
Hard Disk Drive (Optional)	--	--	5Vdc, 2.0A max.	EN 60950-1	TUV
DVD-ROM Drive (Optional)	--	--	5Vdc, 2.0A max.	EN 60950-1	TUV
Speaker (two provided)	--	--	4Ω, 2W max.	--	--
RTC Battery	Matsushita Electric Industrial Co., Ltd. PanasonicCorp Of North America	CR2032	3V, 225mAh, maximum abnormal charging current 10mA. Battery is protected against charging current by multiple components (Diode D11 and 1k ohm Resistor R98).	UL 1642	UL

CPU Fan	Sunonwealth Electric Machine Industry Co., Ltd.	KDE1207PHV1	12Vdc, 0.16A, 27 CFM	EN 60950-1	TUV
LCD Panel for Model xxxxxONYX-175HTy-xx-xxxx	Chunghwa Picture Tubes, Ltd.	CLAA170EA	17 inch TFT type, 5.5Vdc max., 950mA max.	--	--
LCD Panel for Model xxxxxONYX-195HTy-xx-xxxx	AU Optronics Corporation	M190EN04	19 inch TFT type, 5.5Vdc max., 1900mA max.	--	--
DC/AC Inverter	Hwa Youn Co., Ltd.	QF132V1	I/P: 13.2Vdc max., 2050mA max. O/P: 760Vrms, 6.7mA max.	--	--
- Transformer (T1, T2)	Hwa Youn Co., Ltd.	EFD15-TF505	Class 105 degree C	--	--
Enclosure	Teijin Chemicals Plastic Compounds Shanghai Ltd.	TN-7000	V-1, 1.2 mm thickness minimum, overall 460 by 385 by 98 mm	UL 94 UL 746C	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:		

56.11 b)	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:					

57.4 b)	TABLE: cord bending			N
cord under test	test mass	measured curvature	Remarks	
Supplementary information: Evaluated in the certified power supply, which had been found complied with this Standard.				

57.9.1 a)	TABLE: transformers short-circuit					N
winding under test	Protection	measured temperatures (°C)			test duration	remarks
		primary	secondary	ambient		
Supplementary information: Evaluated in the certified power supply, which had been found complied with this Standard.						

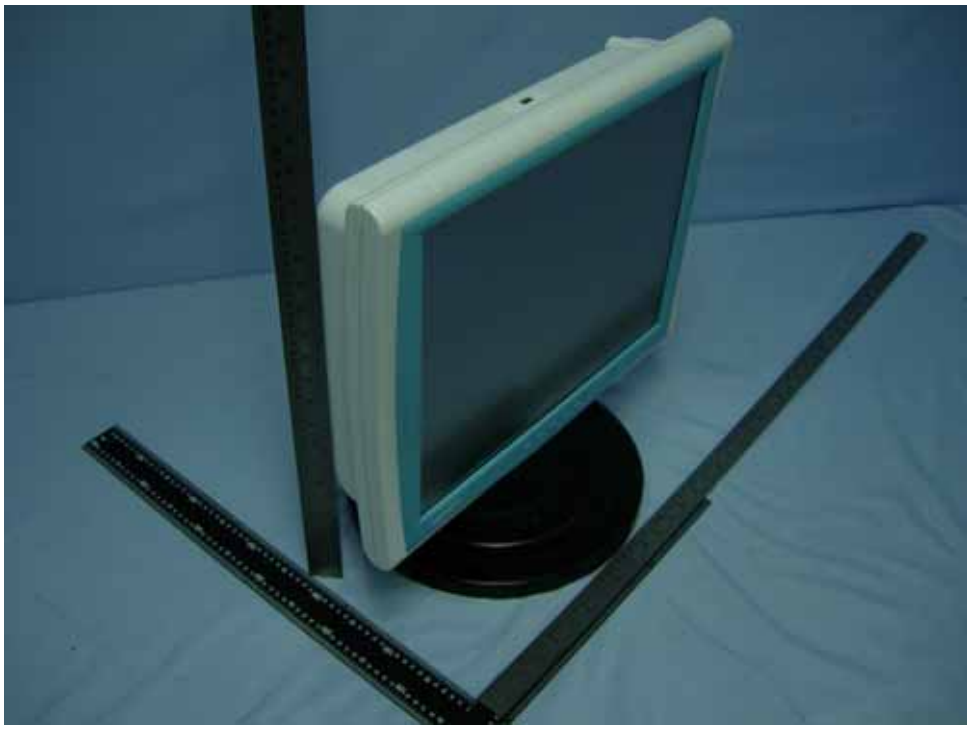
57.9.1 b)	TABLE: transformer overload						N
winding under test	Protection	measured temperatures (°C)			test duration	test current or thermal cut-out temp.	Remarks
		primary	secondary	ambient			
Supplementary information: Evaluated in the certified power supply, which had been found complied with this Standard.							

57.9.2	TABLE: transformer dielectric strength				N
transformer under test	test voltage applied to	test voltage	test frequency	Remarks	
Supplementary information: Evaluated in the certified power supply, which had been found complied with this Standard.					

59.2	TABLE: ball pressure tests		P
part/material	Temperature rise of this part (°C)	Test temperature (°C)	Impression diameter(mm)
Plastic enclosure	19.8 °C	75 °C at 1 hr	0.8 mm
Supplementary information:			

Photos of Model: xxxxxONYX-175HTy-xx-xxxx

Photos of Model: xxxxxONYX-195HTy-xx-xxxx



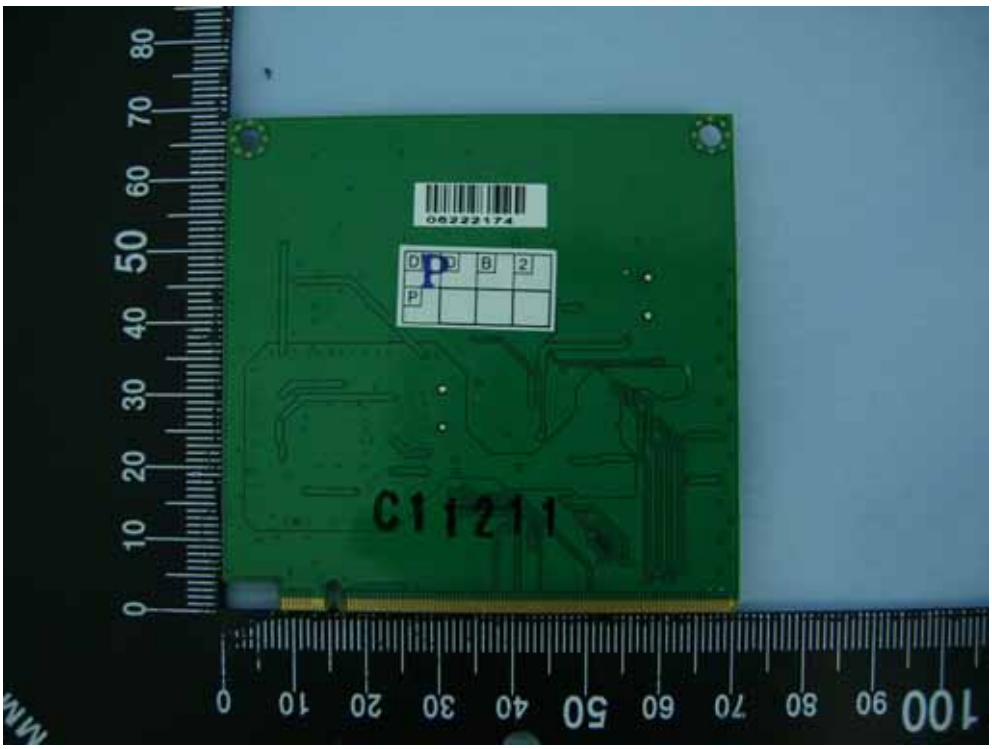
Photos of Models: xxxxxONYX-175HTy-xx-xxxx and xxxxxONYX-195HTy-xx-xxxx

Photos of Models: xxxxxONYX-175HTy-xx-xxxx and xxxxxONYX-195HTy-xx-xxxx

Photos of Models: xxxxxONYX-175HTy-xx-xxxx and xxxxxONYX-195HTy-xx-xxxx

Photos of Models: xxxxxONYX-175HTy-xx-xxxx and xxxxxONYX-195HTy-xx-xxxx

Photos of Models: xxxxxONYX-175HTy-xx-xxxx and xxxxxONYX-195HTy-xx-xxxx



Photos of Models: xxxxxONYX-175HTy-xx-xxxx and xxxxxONYX-195HTy-xx-xxxx