Certificate of Compliance

with

European Low Voltage Directive

No. 10001 219 001

Type of equipment:	**Medical Station**
Certificate holder:	**AAEON Technology Inc.**
Type designation:	**ONYX-193HTx-yz (where x may be T or blank; y may be A-Z; z may be 1 or 2)**
Technical data:	**Rating (s) : 100-240Vac, 50-60Hz, 2-1A**

A sample of the equipment has been tested for CE-marking according to the EC Low Voltage Directive, 73/23/EEC, 93/68/EEC.

Standard(s) used for showing compliance with the essential requirements of the directive:

Standard(s):	*Test report(s):*	*Issued by:*	*Date(s):*
IEC 60601-1:1988 + A1:1991 + A2:1995 + corrigendum 1995, mod. EN 60601-1: 1990 + A1, A11, A12:1993 + A2:1995 + A13: 1996	10001 219 001	Cerpass	December 27, 2005

The referred test report(s) show that the product fulfills the requirements in the EC Low Voltage Directive for CE marking. On this basis, together with the manufacturer's own documented production control, the manufacturer (or his European authorized representative) can in his EC Declaration of Conformity verify compliance with the EC Low Voltage Directive.

Jackie Lin
Testing Department

Eric Chiu
Certification Department

TEST REPORT
IEC 60601-1
Medical electric equipment
Part 1: General requirements for safety

Report	
Reference No.	10001 219 001
Compiled by (+ signature)	Alan Tong
Approved by (+ signature)	Jackie Lin
Date of issue	December 27, 2005
Contents	44 pages
Testing laboratory	
Name	Cerpass Consultancy Corp.
Address	5F., No. 35, Lane 188, Ruiguang Rd., Neihu District, Taipei City 114, Taiwan
Testing location	Same as above
Client	
Name	AAEON Technology Inc.
Address	5F, No. 135, Lane 235, Pao Chiao Rd., Hsin-Tien City, Taipei Hsien, Taiwan, R.O.C.
Test specification	
Standard	IEC 60601-1:1988 + A1:1991 + A2:1995 + corrigendum 1995, mod. EN 60601-1: 1990 + A1, A11, A12:1993 + A2:1995+ A13: 1996
Test procedure	Test report
Procedure deviation	N.A.
Non-standard test method	N.A.

Test item	
Description	: Medical Station
Trademark	: AAEON
Model and/or type reference	: ONYX-193HTx-yz (where x may be T or blank; y may be A-Z; z may be 1 or 2)
Manufacturer	: Same as Client
Factory	: Same as Client
Rating(s)	: 100-240Vac, 50-60Hz, 2-1A

Particulars: test item vs. test requirements	
Classification of installation and use	: Portable
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	: December 16, 2005
Date(s) of performance of test	: December 25, 2005

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.

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

Brief description of device under test:

The subject product, Medical Station, consists of a LCD Panel, DVD/CD-R/RW drive, HDD, CPU and main board, enclosed in metal chassis and plastic enclosure, supplied by a built-in power supply, for use in the Medical System, intended to diagnose, treat or monitor the Patient.

The test samples were preproduction without serial number.

Attachment:

Copy of the marking plates:

IEC 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 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	No alternative construction.	N
5.	CLASSIFICATION		P
5.1	Type of protection against electric shock		P
	Class I equipment		P
	Class II equipment		N
	Internally powered equipment		N
5.2	Degree of protection against electric shock		P
	Type B applied part		N
	Type BF applied part		N
	Type CF applied part		N
	Not classified, no applied parts		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 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 is not tested according the requirements of 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 continuous operation.	P
	short-time operation, specified operation; period .. :		-

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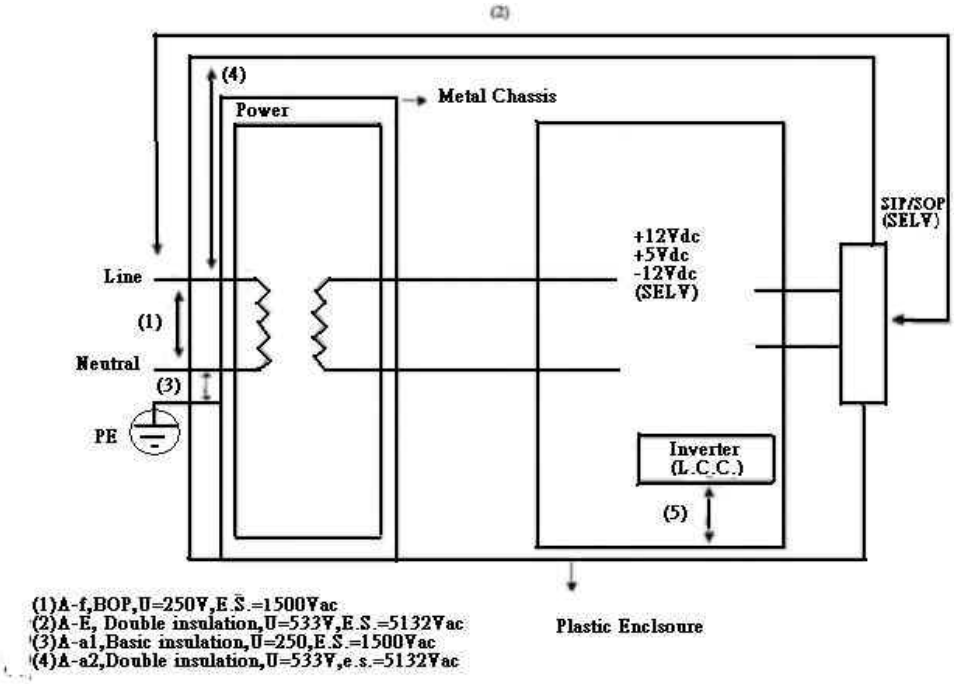
Clause	Requirement – Test	Result – Remark	Verdict
	intermittent operation, specified operation; rest period ..... :		-
	continuous operation with short-time, stated permissible loading time ..... :		-
	continuous operation with intermittent, stated permissible loading/rest time ..... :		-
	Table: insulation diagram		
	Protection against electric shock - Block diagram of system		

INSULATION DIAGRAM



(1)A-f,BOP,U=250V,E.S.=1500Vac
(2)A-E, Double insulation,U=533V,E.S.=5132Vac
(3)A-a1,Basic insulation,U=250,E.S.=1500Vac
(4)A-a2,Double insulation,U=533V,e.s.=5132Vac

IEC 60601-1			
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, BOP	250 V	3.0	1.6	3.2	3.2	Dielectric Voltage = 1500 Vac
(2)	A-e, DI/RI	250 V	21.0	12.0	56.6	56.5	Dielectric Voltage = 4000 Vac
(3)	A-a1, BI	250 V	4.0	2.5	4.2	4.2	Dielectric Voltage = 1500 Vac
(4)	A-a2, DI/RI	533 V	16.0	9.0	56.5	56.5	Dielectric Voltage = 5132 Vac
--	LCC + Basic Insulation + PE	389 V	6.0	3.5	7.2	7.2	Basic Insulation provided by Cl/Cr, and PE provided on metal enclosure.

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 Cl. 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		N
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		P
	e) Name and/or trademark of the manufacturer or supplier ..... :	Same as client	P
	f) Model or type reference ..... :	See Page 2	P
	g) Rated supply voltages or voltage range(s)	See Page 2	P
	Number of phases ..... :	Single	P
	Type of current ..... :	See Page 2	P
	h) Rated frequency or rated frequency range(s) (Hz) ..... :	See Page 2	P
	j) Rated power input (VA, W or A) ..... :	See Page 2	P
	k) Power output of auxiliary mains socket-outlets	No power output socket provided.	N
	l) Class II symbol	Class I Product	N
	Symbol for degree of protection against ingress of water provided ..... :	Optional, IPX0 or ordinary equipment.	P
	Symbol for protection against electric shock :	No applied part.	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		N
	Symbol for protection of defibrillation-proof applied parts ..... :	No applied part.	N
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable	No patient cable.	N
	m) Mode of operation (if no marking, suitable for continuous operation	Optional, continuous operation.	P
	n) Types and rating of external accessible fuses .. :	No external accessible fuses.	N
	p) Ratings of external output ..... :	No external output.	N
	q) Symbol for physiological effect(s):		N

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Clause	Requirement – Test	Result – Remark	Verdict
	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	No dangerous voltage.	N
	t) Special cooling requirements	No special cooling requirements.	N
	u) Limited mechanical stability		N
	v) Protective packing requirement(s)	No special measures have to be taken during transport or storage.	P
	Marking(s) for unpacking safety hazard(s)		N
	Equipment or accessories supplied sterile, marked as sterile		N
	y) Potential equalisation terminal	No such terminal provided.	N
	Functional earth terminal	No such terminal provided.	N
	z) Removable protective means	No such means.	N
	Durability of marking test	(see appended table 6.1)	P
6.2	Marking on the inside of equipment or equipment parts		P
	a) Nominal voltage of permanently installed equipment	Not permanently installed equipment.	N
	b) Maximum power loading for heating elements or holders for heating lamps	No heating elements and lamps.	N
	c) Dangerous voltage symbol	No dangerous voltage presents.	N
	d) Type of battery and mode of insertion	(see appended table 56.1)	P
	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		N
	f) Protective earth terminal	Marked according to Symbol 6 of table D1.	P
	g) Functional earth terminal		N
	h) Supply neutral conductor in permanently installed equipment (N)		N

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Clause	Requirement – Test	Result – Remark	Verdict
	j) Markings required in 6.2 f), h), k) ,and l) remain visible after connection and are not affixed to parts which have to be removed		P
	Markings comply with IEC 445		P
	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		N
	n) Capacitors and/or circuit parts are marked as required in Cl. 15. c)		N
6.3	Marking of controls and instruments		P
	a) Mains switch clearly identified		N
	ON and OFF positions marked according to Symbols 15 and 16 of Table D1 or indicated by an adjacent indicator light	Marked according to Symbols 15 and 16. The power supply cord is the mains disconnect indicated in accompanying documents.	P
	b) Indications of different positions of control devices and switches		N
	c) Indication of the direction in which the magnitude of the function changes, or an indicting device	No Safety Hazard caused during function changing.	P
	f) The functions of operator controls and indicators are identified		N
	g) Numeric indications of parameters are in SI units except for units listed in A2	No numeric indication used for control.	P
6.4	Symbols		P
	Symbols used comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)		P
6.5	Colours of insulation of conductors		P
	a) Protective earth conductor has green/yellow insulation	Protective earth conductor had been evaluated as part of the power supply.	P
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		N

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Clause	Requirement – Test	Result – Remark	Verdict
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow	Evaluated as part of the power supply.	P
	d) Colour of neutral conductor ..... :	Evaluated as part of the power supply.	P
	e) Colours of phase conductors ..... :		N
	Compliance with IEC 227 and IEC 245	Evaluated as part of the power supply.	P
	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		N
	b) Identification of connection point		N
6.7	Indicator lights and push-buttons		N
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action		N
	Yellow used to indicate caution or attention required		N
	Green used to indicate ready for action		N
	b) Colour 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 is accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	See user's manual.	P
	Classifications specified in Cl. 5. are included in both the instructions for use and the technical description	Ditto	P
	Markings specified in 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	Ditto	P
	Warning statements and the explanation of warning symbols provided in the accompanying documents	Ditto	P
6.8.2	Instructions for use		P
	a) General information provided in instructions for use:		P

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Clause	Requirement – Test	Result – Remark	Verdict
	- state the function and intended application of the equipment		P
	- include an explanation of: the function of controls, displays and signals		P
	- the sequence of operation		P
	- the connection and disconnection of detachable parts and accessories		P
	- the replacement of material which is consumed during operation		N
	- information regarding potential electromagnetic or other interference and advice regarding avoidance		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		N
	General information provided in instructions:		P
	- information for the safe performance or routine maintenance		P
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied		P
	- explanation of figures, symbols, warning statements and abbreviations on the equipment		P
	c) Signal output or signal input parts intended only for connection to specified equipment described		P
	d) Details about acceptable cleaning, disinfection or sterilization methods included		P
	e) Warning statement for mains operated equipment with additional power source		N
	f) A warning to remove primary batteries if equipment is not likely to be used for some time		N
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries		N
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1		N

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Clause	Requirement – Test	Result – Remark	Verdict
	j) Identification of any risks associated with the disposal of waste products, residues, etc.		P
	Advice in minimizing these risks		P
6.8.3	Technical description		P
	a) All characteristics essential for safe operation provided		P
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment		N
	Instructions for replacement of interchangeable and/or 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		P
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Storage and transportation: Temperature: -20 °C ~ 60 °C (-4 °F ~ 140 °F).	P
7.	POWER INPUT		P
	Power input measurements	See Table 7.	N
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	Storage and transportation: Temperature: -20 °C ~ 60 °C (-4 °F ~ 140 °F), Humidity: 5% ~ 90%	P
10.2.2	a) Rated voltage not exceeding 250 V for hand-held equipment	No hand-held equipment.	N
	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	100-240 Vac, single-phase	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		N

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Clause	Requirement – Test	Result – Remark	Verdict
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		P
	b) Equipment supplied from external d.c. source of reverse polarity results in no safety hazard		N
14.5	a) Dual classification for internally powered equipment with a means of connection to supply mains	Class I only.	N
	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	Class I only.	N
14.6	c) Applied parts intended for direct cardiac application are of type CF	No applied parts.	N
15.	LIMITATION OF VOLTAGE AND/OR ENERGY		P
	b) Voltage measured one sec after disconnection of the mains plug does not exceed 60 V	(see appended table 15b)	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 parts.	N
	Marking provided for manual discharging	No components 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)		N
	Insertion or removal of lamps: protection against contact with live parts provided		N
	b) Opening in a top cover so positioned that accessibility of live parts by a test rod is prevented	(see appended table 56.1)	P
	c) Conductive parts accessible after the removal of handles, knobs, levers:		N
	- have a resistance of not more than 0,2		N
	- separated from live parts by one of the means described in Cl. 17. g)		N

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Clause	Requirement – Test	Result – Remark	Verdict
	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		N
	e) Removable enclosures protecting against contact with live parts		P
	Removal possible only with the aid of a tool		P
	Use of automatic device making parts not live when the enclosure is opened or removed		N
	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		P
17.	SEPARATION		P
	a) Separation method of the applied part from live parts:		N
	1) basic insulation: applied part earthed		N
	2) by protectively earthed conductive part (e.g. screen)		N
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N
	4) by double or reinforced insulation		N
	5) by protective impedances limiting current to applied part		N
	Additional leakage current test in single fault conditions		N
	c) There is no conductive connection between applied parts and accessible conductive parts, which are not protectively earthed	No applied part.	N
	d) Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)	Not such parts.	N
	g) Separation method of accessible parts other than applied parts from live parts:		P
	1) basic insulation: accessible part earthed	The Accessible Part, protectived earthed metal Enclosure, is separated from Live parts by Basic Insulation.	P
	2) by protectively earthed conductive part (e.g. screen)		N

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Clause	Requirement Test	Result – Remark	Verdict
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N
	4) by double or reinforced insulation	Evaluated as part of the power supply.	P
	5) by protective impedances limiting current to accessible part		N
	Additional leakage current test in single fault conditions	Evaluated as part of the power supply.	P
	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	The Accessible Part, protectived earthed metal Enclosure, is separated from Live parts by Basic Insulation.	P
	b) Protective earth terminals suitable for connection to the protective earth conductor		P
	e) Potential equalization conductor:		N
	- readily accessible		N
	- accidental disconnection prevented in normal use		N
	- conductor detachable without the use of a tool		N
	- power supply cord does not incorporate a potential equalization conductor		N
	- connection means marked with Symbol 9, Table DI		N
	f) For equipment without power supply cord, impedance between protective earth terminal and accessible metal part 0,1		N
	For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part 0,1	(see appended table 18)	P

IEC 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
	For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part 0,2		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		N
	l) 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
19.1	b) Leakage currents	All combination of the conditions considered.	P
	Earth leakage current	(See appended table 19)	P
	Enclosure leakage current	(See appended table 19)	P
	Patient leakage current		N
	Patient auxiliary current	No applied part.	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	(see appended table 21)	P
	c) Portable equipment carrying handles or grips withstand the requirements of the loading test	No handles provided.	N

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Clause	Requirement – Test	Result – Remark	Verdict
21.3	No damage to parts of patient support and/or immobilization system after the loading test	No parts of patient support and/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		N
22.2	a) Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment		N
	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

IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
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
24.	STABILITY IN NORMAL USE		N
24.1	Equipment does not overbalance during normal use when tilted trough an angle of 10		N
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		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	Mass is less than 20 kg.	N
25.	EXPELLED PARTS		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		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		N

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Clause	Requirement – Test	Result – Remark	Verdict
	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
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)		N
36.	ELECTROMAGNETIC COMPATIBILITY		N
	Equipment complies wit IEC 601-1-2	Compliance documented by the manufacturer.	N
37.	COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT		N
	Requirements for category AP and APG equipment (Cl. 37. - 41.)	Not category AP or APG equipment.	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

IEC 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
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 accessible surface.	N
43.	FIRE PREVENTION		P
	Strength and rigidity necessary to avoid a fire hazard	The equipment is well constructed with regard to avoid fire hazard.	P
44.	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION, DISINFECTION AND COMPATLBILITY		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		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)		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	(see appended table 44)	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		P
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

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Clause	Requirement – Test	Result – Remark	Verdict
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
	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		N
49.	INTERRUPTION OF THE POWER SUPPLY		P
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may give a safety hazard	No such devices.	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

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Clause	Requirement – Test	Result – Remark	Verdict
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		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.)	Both normal and single fault condition considered.	P
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4		N
52.5.2	Failure of thermostat presents no safety hazard	No thermostats provided.	N
52.5.3	Short-circuiting of either constituent part of double insulation presents no safety hazard	Evaluated as part of the power supply.	P
52.5.5	Impairment of cooling: temperatures not exceeding 1,7 times the values of Cl. 42. minus 17,5 °C	See table 52 for details.	P
52.5.6	Locking of moving parts presents no safety hazard	(see appended table 52)	P
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	No motor provided.	N
52.5.8	Duration of motors locked rotor test in compliance with 52.5.8	No motor provided.	N
52.5.9	Failure of one component at a time presents no safety hazard		P
52.5.10	Overload of heating elements presents no safety hazard	Evaluated as part of the power supply.	P
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	No motor provided.	N
	h) Equipment with three-phase motors can safely operate with one phase disconnected	No motor provided.	N
56.	COMPONENTS AND GENERAL ASSEMBLY		P
	List of critical components	(See appended table 56.1)	P
56.1	b) Ratings of components not in conflict with the conditions of use in equipment		P

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Clause	Requirement – Test	Result – Remark	Verdict
	Ratings of mains components are identified	Evaluated as part of the power supply.	P
	d) Components, movements of which could result in a safety hazard mounted securely	The movement of components is prevented.	P
	f) Conductors and connectors are secured and/or insulated to prevent accidental detachment resulting in a safety hazard		P
56.3	a) Connectors provide separation required by Cl. 17. g)		P
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	No patient circuit.	N
	Medical gas connections not interchangeable	No medical gas connections.	N
	b) Accessible metal parts cannot become live when detachable interconnection cord between different parts of equipment is loosened or broken		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		N
56.4	Connections of capacitors		P
	Not connected between live parts and non-protectively earthed accessible parts	Evaluated as part of the power supply.	P
	If connected between mains part and protectively earthed metal parts, comply with IEC 384-14	Evaluated as part of the power supply.	P
	Enclosure of capacitors connected to mains part and providing only basic insulation is not secured to non-protectively earthed metal parts	Evaluated as part of the power supply.	P
	Capacitors or other spark-suppression devices are not connected between the contacts of thermal cut-outs	Evaluated as part of the power supply.	P
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment		P
56.6	Temperature and overload control devices		P
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment		N
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits	Thermal safety devices not provided.	N

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Clause	Requirement – Test	Result – Remark	Verdict
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		N
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard	No audible warning provided.	N
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times		N
	Non-self-resetting over-current releases operated 10 times	No such device provided.	N
	b) Thermostats with varying temperature settings clearly indicated	No thermostats provided.	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	See Table Additional Test for details.	P
	b) Incorrect polarity of connection prevented	See Table Additional Test for details.	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	See Sub-clause 6.3a and 6.7.	P
	- to indicate the operation of non-luminous heaters if a safety hazard could result		N
	- to indicate when output exists if a safety hazard could result		N
	- charging mode indicator is provided		N
56.10	Actuating parts of controls		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

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Clause	Requirement – Test	Result – Remark	Verdict
	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)		N
	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	Evaluated as part of the power supply.	P
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents		P
	d) Switches used to comply with 57.1 a) comply with the creepage distances and air clearances as specified in IEC 328		P
	f) Mains switches not incorporated in a power supply cord		P
	h) Appliance couplers and flexible cords with mains plugs provide compliance with 57.1 a)		P
	m) Fuses and semiconductor devices are not used as isolating devices	Evaluated as part of the power supply.	P

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Clause	Requirement – Test	Result – Remark	Verdict
57.2	Mains connectors and appliance inlets		P
	e) Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug		N
	g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment	Class I equipment with Class I appliance inlet.	N
57.3	Power supply cords		P
	a) Not more than one connection to a particular supply mains	Only one connection to a particular supply mains.	P
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously	No alternative supply allowed.	N
	The mains plug has only one power supply cord		P
	Non-permanently connected equipment provided with power supply cord or appliance inlet	Appliance Inlet provided.	P
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53		P
	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		P
	d) Stranded conductors not soldered if fixed by any clamping means		P
57.4	Connection of power supply cords		P
	a) Cord anchorages:		N
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting		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

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Clause	Requirement – Test	Result – Remark	Verdict
	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		P
	c) Adequate space inside equipment to allow the supply cable conductors to be introduced and connected	Evaluated as part of the power supply.	P
57.5	Mains terminal devices and wiring of mains part		P
	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	Detachable supply cord 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		P
	Mains terminal devices accessible only with use of a tool		P
	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		P
	c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened		P
	d) Cord terminals shall not require special preparation of the conductor		N
57.6	Mains fuses and over-current releases		P

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Clause	Requirement – Test	Result – Remark	Verdict
	Fuses or over-current releases provided accordingly for Class I and Class II	Class I, fuses were provided in each supply leads and evaluated as part of the power supply.	P
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current		P
	Protective earth conductor not fused	Evaluated as part of the power supply and no additional fuses employed in end Product.	P
	Neutral conductor not fused for permanently installed equipment	Portable 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 227 or IEC 245, 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
	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 as part of the power supply.	P
	a) Short-circuit of secondary windings not caused excessive temperature	Evaluated as part of the power supply.	P
	b) Overload of secondary windings not caused excessive temperature	Evaluated as part of the power supply.	P
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests	Evaluated as part of the power supply.	N
57.9.4	Construction		P
	a) Separation of primary and secondary windings:		P

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Clause	Requirement – Test	Result – Remark	Verdict
	- 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	Evaluated as part of the power supply.	P
	c) Means provided to prevent displacement of end turns	Evaluated as part of the power supply.	P
	d) Insulated overlap of not less than 3 mm if a protective earth screen has only one turn	Evaluated as part of the power supply.	N
	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	Evaluated as part of the power supply.	P
	- 3 layers provided that each combination of 2 layers can withstand the dielectric strength test for reinforced insulation	Evaluated as part of the power supply.	P
	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	Biult-in SPS had been evaluated as part of the power supply. The clearance and creepage of Panel PC comply with at least the values of Table XVI.	P
	Creepage distances for slot insulation of motors are at least 50% of the specified values	No motor provided.	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	Built-in SPS had been evaluated as part of the power supply. The clearance and creapage of Panel PC comply with at least the values of Table XVI.	P

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Clause	Requirement – Test	Result – Remark	Verdict
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts	No applied parts.	N
58.	PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS		P
58.1	Clamping means of the protective earth terminal		P
	Not be able to loosen without the aid of a tool	Evaluated as part of the power supply. The PE terminal is not able to loosen without the aid of a tool.	P
	Screws for internal earth connections are covered or protected against loosening from outside	Screws for internal protective earthing connections are completely covered or protected against inadvertent loosening from the outside of Equipment.	P
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal	Evaluated as part of the power supply.	P
58.8	The protective earth terminal is not used for the mechanical connection or the fixing of any component not related to earthing	Evaluated as part of the power supply.	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	Evaluated as part of the power supply.	P
59.	CONSTRUCTION AND LAYOUT		P
59.1	Internal wiring		P
	a) Cables and wiring protected against contact with a moving part		P
	Wiring having basic insulation only protected by additional fixed sleeving		P
	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		P
	c) Insulating sleeving adequately secured		P

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Clause	Requirement – Test	Result – Remark	Verdict
	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 strength test	Evaluated as part of the power supply.	P
	Conductors subjected to temperatures exceeding 70 °C, have an insulation of heat-resistant material	Evaluated as part of the power supply.	P
	d) Aluminium wires of less than 16 mm² cross-section not used		N
	f) Connecting cords between equipment parts considered as belonging to the equipment		P
59.2	Insulation		P
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation		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	No rubber provided.	N
59.3	Excessive current and voltage protection		P
	Internal electrical power source provided with device for protection against fire hazard	Fuse was provided by built-in recognized power supply.	P
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder		P
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.	No applied part.	N
59.4	Oil containers		N
	Oil containers adequately sealed		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

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Clause	Requirement Test	Result – Remark	Verdict
	ANNEX I, NATIONAL DIFFERENCES		N
	AUSTRALIA: see CB Bulletin 89A I, December 1996		N
	CANADA: see CB Bulletin 89A I, December 1996		N
	UNITED STATES: see CB Bulletin 89A I, December 1996		N
2.4.1	UNITED STATES: see CB Bulletin 89A I, December 1996		N
2.10.100	UNITED STATES: see CB Bulletin 89A I, December 1996		N
2.10.101	UNITED STATES: see CB Bulletin 89A I, December 1996		N
10.2.2	UNITED STATES: see CB Bulletin 89A I, December 1996		N
6.21	UNITED STATES: see CB Bulletin 89A I, December 1996		N
14.	UNITED STATES: see CB Bulletin 89A I, December 1996		N
18.	UNITED STATES: see CB Bulletin 89A I, December 1996		N
57.	UNITED STATES: see CB Bulletin 89A I, December 1996		N
57.2	UNITED STATES: see CB Bulletin 89A I, December 1996		N
57.3	UNITED STATES: see CB Bulletin 89A I, December 1996		N
59.1	UNITED STATES: see CB Bulletin 89A I, December 1996		N
	UNITED STATES: see CB Bulletin 89A I, December 1996		N
1.1	UNITED STATES: see CB Bulletin 89A I, December 1996		N
2.12.100	UNITED STATES: see CB Bulletin 89A I, December 1996		N
2.12.101	UNITED STATES: see CB Bulletin 89A I, December 1996		N
19.	UNITED STATES: see CB Bulletin 89A I, December 1996		N

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Clause	Requirement – Test	Result – Remark	Verdict
3.	UNITED STATES: see CB Bulletin 89A I, December 1996		N
3.100	UNITED STATES: see CB Bulletin 89A I, December 1996		N
3.100.1	UNITED STATES: see CB Bulletin 89A I, December 1996		N
3.101	UNITED STATES: see CB Bulletin 89A I, December 1996		N
3.101.1	UNITED STATES: see CB Bulletin 89A I, December 1996		N
3.101.2	UNITED STATES: see CB Bulletin 89A I, December 1996		N
3.102	UNITED STATES: see CB Bulletin 89A I, December 1996		N
57.5	UNITED STATES: see CB Bulletin 89A I, December 1996		N
6.	UNITED STATES: see CB Bulletin 89A I, December 1996		N
22.	UNITED STATES: see CB Bulletin 89A I, December 1996		N
28.	UNITED STATES: see CB Bulletin 89A I, December 1996		N
42.	UNITED STATES: see CB Bulletin 89A I, December 1996		N
55.	UNITED STATES: see CB Bulletin 89A I, December 1996		N
56.3	UNITED STATES: see CB Bulletin 89A I, December 1996		N
58.2	UNITED STATES: see CB Bulletin 89A I, December 1996		N
400	UNITED STATES: see CB Bulletin 89A I, December 1996		N
600	UNITED STATES: see CB Bulletin 89A I, December 1996		N

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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.

7.	TABLE: power input					N
operating condition	voltage	frequency	current	power	remarks	
--	Unit: V	Unit: Hz	Unit: A	Unit: W	Rating Current	
Maximum Normal Load/--	90	50	1.1	100	*	
Maximum Normal Load/--	90	60	1.1	100	*	
Maximum Normal Load/2.0A	100	50	0.98	97	*	
Maximum Normal Load/2.0A	100	60	0.98	97	*	
Maximum Normal Load/1.0A	240	50	0.44	95	*	
Maximum Normal Load/1.0A	240	60	0.44	95	*	
Maximum Normal Load/--	264	50	0.42	95	*	
Maximum Normal Load/--	264	60	0.42	95	*	
supplementary information:						
Maximum normal load was defined as follows: Cross reading and writing data between HDD, and CD-ROM in maximum speed, LCD with maximum brightness and contract, connect with 7 USB ports with dummy load 0.5 A.						

15. b)	TABLE: residual voltage in attachment plugs									P
voltage measured between:	measurements (V)									remarks
	1	2	3	4	5	6	7	8	9	10	
--	--	--	--	--	--	--	--	--	--	--	--
supplementary information:											
Evaluated as part of the power supply.											

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Clause	Requirement Test	Result – Remark	Verdict

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	

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

18.	TABLE: protective earthing				P
test location		test current (A)	measured voltage (V)	resistance ( )	remarks
AC Inlet earth pin to metal enclosure near power supply.		40	0.6	0.015	Pass, 2 minutes, Limitation 0.1 ohm

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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 (V)	supply frequency (Hz)	measured max. value (µA)	remarks
Earth Leakage Current (Fig. 16):		Vac	Hz	B/A (uA)	--
ER, NC S1=1, S5=1, MD		275	60	316/352	--
ER, NC S1=1, S5=0, MD		275	60	303/341	--
ER, SFC: S1=0, S5=1, MD		275	60	610/682	--
ER, SFC: S1=0, S5=0, MD		275	60	610/682	--
Enclosure Leakage Current (Fig. 18):		--	--	--	--
EN, NC (S1, S7=1), S5=1, MD1		275	60	1.8/2.0	--
EN, NC (S1, S7=1), S5=0, MD1		275	60	1.9/2.1	--
EN, SFC: S1=0, S7=1, S5=1, MD1		275	60	2.4/2.6	--
EN, SFC: S1=0, S7=1, S5=0, MD1		275	60	2.3/2.6	--
EN, SFC: S1=1, S7=0, S5=1, MD1		275	60	1.8/1.9	--
EN, SFC: S1=1, S7=0, S5=0, MD1		275	60	1.9/2.0	--
EN, NC (S1, S7=1), S5=1, MD2		275	60	0.1/1.0	--
EN, NC (S1, S7=1), S5=0, MD2		275	60	0.1/1.1	--
EN, SFC: S1= 0, S7=1, S5=1, MD2		275	60	0.8/1.2	--
EN, SFC: S1= 0, S7=1, S5=0, MD2		275	60	0.8/1.8	--
EN, SFC: S7= 0, S1=1, S5=1, MD2		275	60	0.4/1.1	--
EN, SFC: S7= 0, S1=1, S5=0, MD2		275	60	0.4/0.9	--
--		--	--	--	--
(Record at least maximum measured value for each test required by Cl._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 the applied parts PA - Patient auxiliary current Fig. 15 - refers to Fig. 15 in IEC 601-1	MD - Measuring device A - After humidity conditioning B - Before humidity condtioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition

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Clause	Requirement Test	Result – Remark	Verdict

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
Area (2), Primary to SIP/SOP	DI	533 Vac	5132 Vac	Pass
Area (3), Primary to GND/PE	BI	250 Vac	2121 Vdc	Pass
Area (4), Primary to plastic enclosure with foil	DI	250 Vac	4000 Vac	Pass

21.	TABLE: mechanical strength	P
part under test	test (impact, drop, force, handle, rough handling, mobile)	Remarks
Enclosure outside near power supply	Foece Test (21a)	Pass, 45 N
Enclosure outside near power supply	Impact Test (21b)	Pass, 0.5 J

24.	TABLE: stability	N
part under test	test condition	Remarks

29.	TABLE: X-radiation		N
part under test	test condition	measured radiation (mR)	Remarks

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Clause	Requirement Test	Result – Remark	Verdict

42.	TABLE: normal temperature		P
	supply voltage ..... :	See below	
	ambient temperature °C ..... :	See below	
	test condition ..... :	See below	

measuring location	Measured temperature (°C)	Reemarks
Power supply:	90 V/264 V, 60 Hz	Calculated, limitation
1. T1 coil	42.9/43.2	61.7/61.9, 130
2. EL2 coil	46.6/45.2	65.4/63.9, 130
3. C7 body	47.4/46.8	66.2/65.5, 105
4. T2 coil	37.9/38.1	56.7/56.8, 130
5. PCB near T1	62.5/62.5	81.3/81.2, 130
Inverter:	--	--
6. T1 coil	65.6/65.3	84.4/84.0, 105
7. L1 coil	68.3/68.5	87.1/87.2, 105
8. C1 body	70.9/71.3	89.7/90.0, 105
9. PCB near T1	63.3/63.5	82.1/82.2, 105
Main board:	--	--
10. U13 body	61.7/61.7	80.5/80.4, 105
11. L3 coil	58.0/58.1	76.8/76.8, 105
12. L4 coil	57.4/57.5	76.2/76.2, 105
13. L6 coil	60.2/60.1	79.0/78.8, 105
14. L7 coil	65.7/65.8	84.5/84.5, 105
15. L9 coil	59.2/59.2	78.0/77.9, 105
16. Heatsink of U10	56.5/56.5	75.3/75.2, 105
17. PCB near U10	59.3/59.2	78.1/77.9, 105
18. PCB of RAM	58.3/58.3	77.1/77.0, 105
19. HDD body	34.6/34.5	53.4/53.2, --
20. Enclosure of inside near power	27.9/28.0	46.7/46.7, 60
21. Enclosure of out side near power	26.6/26.7	45.4/45.4, 60
22. Ambient	21.2/21.3	40.0/40.0, --

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Clause	Requirement Test	Result – Remark	Verdict

supplementary information:
Maximum normal load was defined as follows: Cross reading and writing data between HDD, and CD-ROM in maximum speed, LCD with maximum brightness and contract, connect with 2 USB ports.

44.	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		P
test type and condition		part under test	remarks
Humidity, 25 °C, 95%, 48 hrs		The unit	No Breakdown, Pass, See Table 20 for test conditions.
Cleaning		The unit	No Breakdown, Pass, See Table 20 for test conditions.

45.	TABLE: hydrostatic pressure and pressure-relief device cycling test			N
test type and condition		part under test	test pressure	remarks

52.	TABLE: abnormal operation		P
test type, condition and clause reference		observed results	Remarks
Ventilation Openings blocked / 240Vac, 60 Hz, 2 hrs / Clause 52.5.5		Temperature Stabled, unit operated normally.	T1 coil: 74.6°C, T2 coil: 68.1°C, EL2 coil: 71.8°C. Inverter: T1 coil: 78.2°C, L1 coil: 81°C. No hazard, no damaged. No Breakdown, Pass, See Table 20 for test conditions.

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Clause	Requirement Test	Result – Remark	Verdict

CPU Fan Lock / 240Vac, 60 Hz, 3.5 hrs / Clause 52.5.5	Temperature Stabled, unit operated normally.	T1 coil: 52.2°C, T2 coil: 52.3°C, EL2 coil: 42.5°C. Inverter: T1 coil: 57.6°C, L1 coil: 58.7°C. No hazard, no damaged. No Breakdown, Pass, See Table 20 for test conditions.
Power Supply Fan Lock / 240Vac, 60 Hz, 5 hrs / Clause 52.5.5	Temperature Stabled, unit operated normally.	T1 coil: 135.2°C, T2 coil: 113.3°C, EL2 coil: 103.5°C. Inverter: T1 coil: 92.1°C, L1 coil: 94.3°C. No hazard, no damaged. No Breakdown, Pass, See Table 20 for test conditions.
Battery operated EUT		

56.1	TABLE: lists of critical component parts				P
object/part No.	manufac-turer/trademark	type/model	Technical data	standard	Mark(s) of conformity[1])
Enclosure	Teijin	TN-7000	V-0, 60°C, 1.5 mm thick min.	UL94	UL
PCB	--	--	V-1 min., 105°C	UL94	UL
Building-in switching power supply	FSP	FSP180-50MP	Input: AC 100-240V, 4A, 50-60 Hz Output: DC +3.3V, 16.8A; +5V, 12A; +12V, 12A; +5Vsb, 2A; -12V, 0.8A	DIN EN 60601-1 (VDE0750 Teil 1):1996-03; EN 60601-1: 1990 + A1:1993 + A2:1995	VDE

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DC-AC Inverter	ATBEL	QF132V1.16	I/P: DC 12V, 1900mA O/P: AC 760V, 6.2mA	--	--
- Transformers (T1, T2)	Fine	TF505C	105°C	--	--
RTC Battery	Sony	CR2032	3Vdc, max. abnormal charge current 10mA	UL1642	UL
DC Fan	Young Lin	DFC601005L	5Vdc, 0.2A, 14.35CFM	EN 60950	TUV
H. D. D. (Optional)	--	--	5Vdc, 0.55A max.	EN 60950	TUV
DVD-ROM (Optional)	--	--	5 Vdc, 1.5 A max.	EN 60950	TUV
LCD Panel	AU Optronics	M190EN04 V.1	19", TFT type	--	--
Speaker	--	--	Two provided, each 2W, 4Ω	--	--
[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

56.11 b)	TABLE: foot-operated control devices loading		N
part under test		observed results	remarks

57.4	TABLE: cord anchorages				N
cord under test	mass of equipment	pull	torque	remarks	verdict

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Clause	Requirement Test	Result – Remark	Verdict

57.4 b)	TABLE: cord bending			N
cord under test		test mass	measured curvature	remarks

57.9.1 a)	TABLE: transformers short-circuit					P
winding under test	protection	measured temperatures (C)			test duration	remarks
		primary	secondary	ambient		
--	--	--	--	--	--	--
supplementary information: Evaluated in separate report of power supply.						

57.9.1 b)	TABLE: overload						P
winding under test	protection	measured temperatures (C)			test duration	test current or thermal cut-out temp.	remarks
		primary	secondary	ambient			
--	--	--	--	--	--	--	--
supplementary information: Evaluated in separate report of power supply.							

57.9.2	TABLE: transformer dielectric strength				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 5.1 (°C)	Test temperature (°C)	Impression diameter(mm)	

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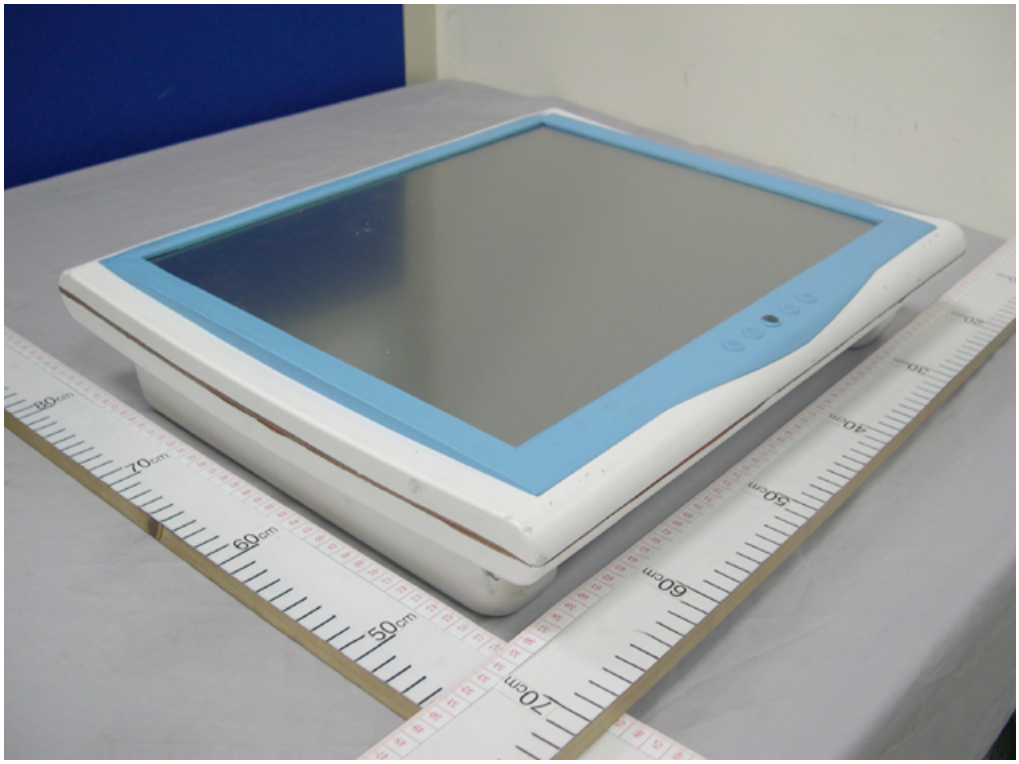
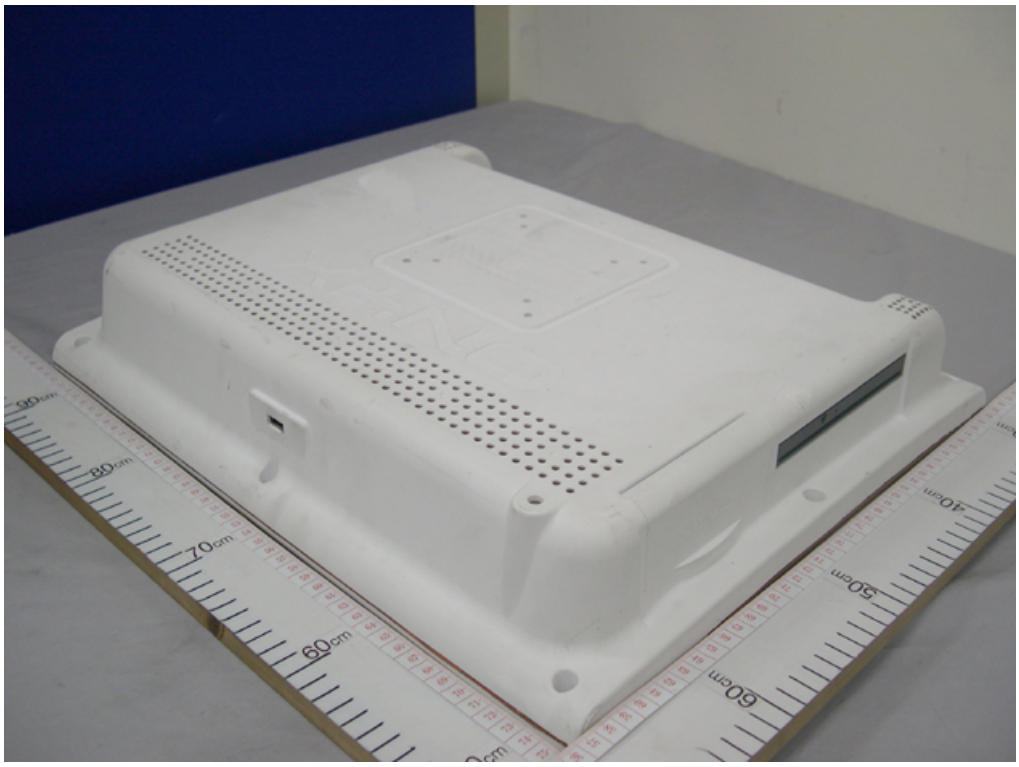
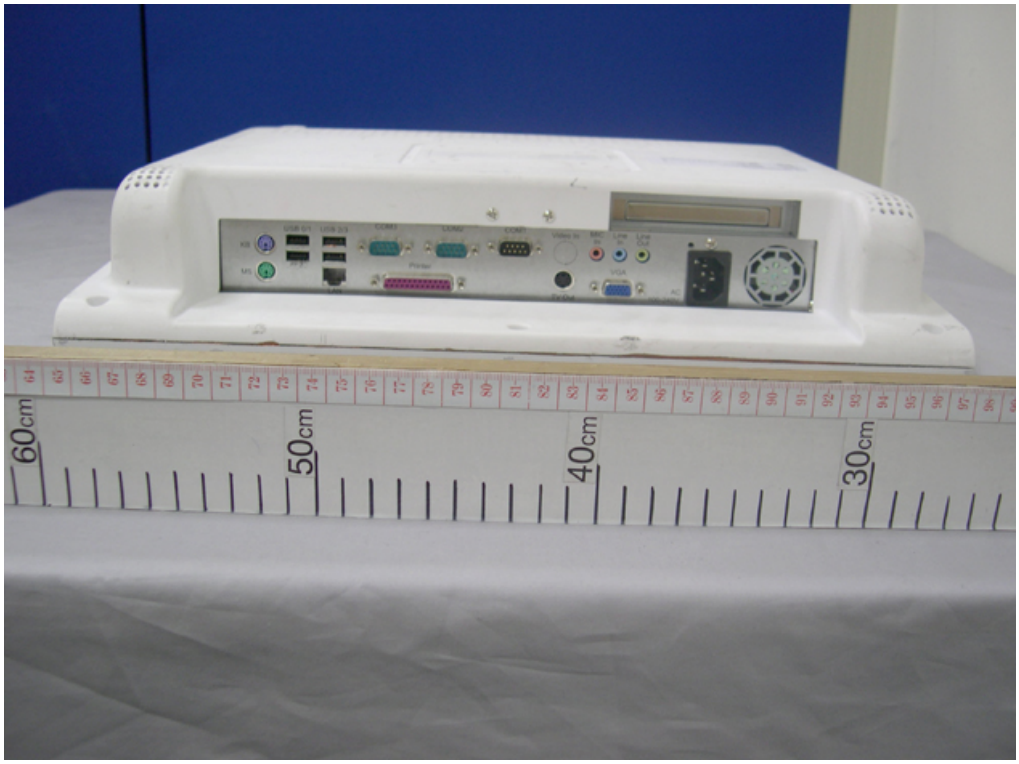
	TABLE: additional tests		Pass
Clause	Test type and condition	Remarks and observed results	Verdict
56.7	Reversed Battery Connection	Lithium Battery,Sony Energytec Inc., Model: CR2032, ,Max Abnormal Charging Current 10mA.	--
--	CR2032, normal	0mA	Pass
--	CR2032, R104 short	0.1mA	Pass
--	CR2032, D32 short	2.99mA	Pass



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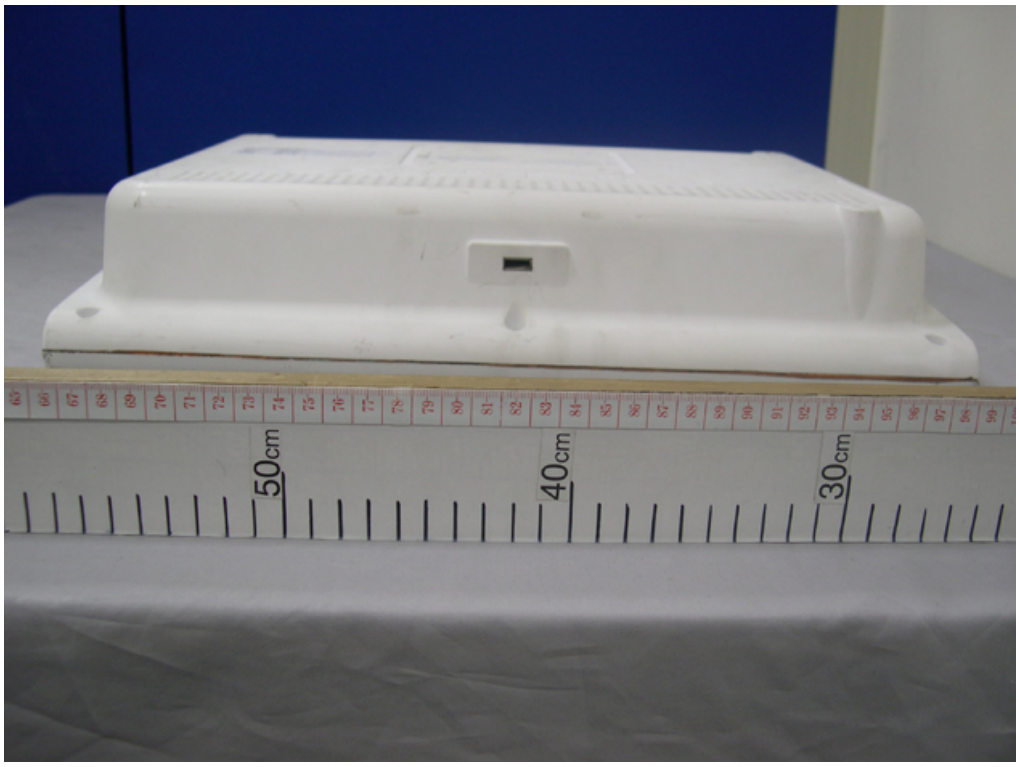
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