



TEST REPORT EN 60601 -1 Medical electrical equipment Part 1: General requirements for safety	
Report reference No.....:	TRS10080067
Compiled by (+ signature).....:	Ivy Chen 
Reviewed by (+ signature).....:	Bonnie Nie 
Approved by (+ signature).....:	Tiger Jiang 
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Testing laboratory.....:	SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION Co., Ltd.
Address	Keji Nan No.12 Road, Hi-tech Park, Shenzhen ,China
Testing location	Shenzhen City ,China
Applicant.....:	OTO BODYCARE PTE LTD
Address	625, ALJUNIED ROAD, #04-01, ALJUNIED INDUSTRIAL COMPLEX, SINGAPORE 389836
Standard	EN 60601-1 :1990+ A1:1993+ A2:1995
Test Report Form No.:	I601-1_C/97-04
TRF Originator.....:	Underwriters Laboratories Inc.
Master TRF	dated 97-04
Copyright blank test report.....:	the bodies participating in the Committee of Certification Bodies (CCB). This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator.
Test procedure	Test report only
Procedure deviation	N/A
Non-standard test method.....:	N/A
Type of test object.....:	Whole Body Vibration Machine
Trademark	
Model/type reference	WBV-3000
Manufacturer	Dong Guan Treasure-Tree Art & Crafts Co., Ltd.
Address	Datang Village, Dalingshan Town, Dongguan City, Guangdong, China.
Rating	Input: 220-240Vac 50/60Hz , 500VA

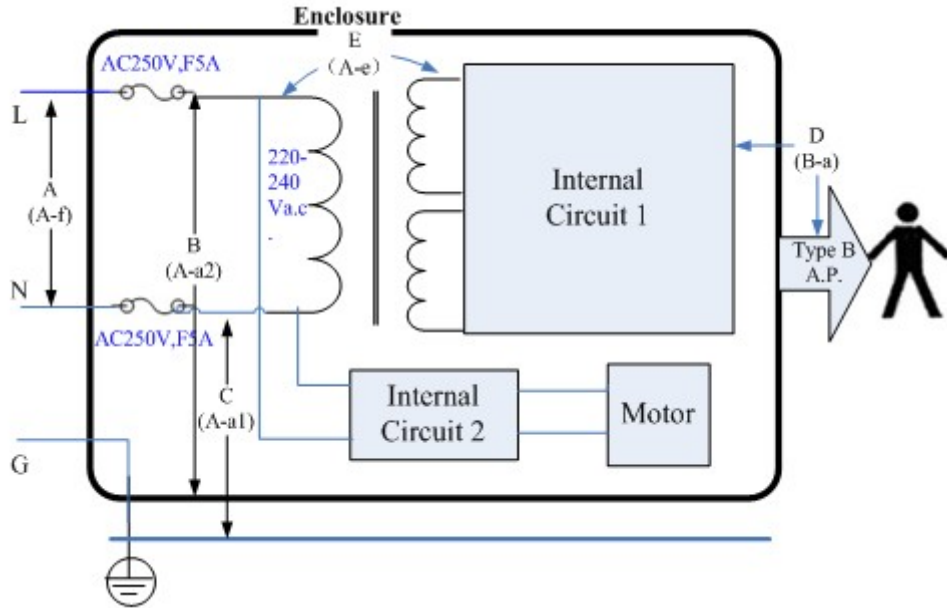
GENERAL INFORMATION	
Test item particulars (see also clause 5):	
Classification of installation and use	: Mobile
Supply connection	: appliance coupler
Accessories and detachables parts included in the evaluation	/
Options included	/
Possible test case verdicts:	
- test case does not apply to the test object	:N / A N
- test object does meet the requirement	:Pass P
- test object does not meet the requirement	:Fail F
Abbreviations used in the report:	
- normal condition	:N.C. - single fault condition
- operational insulation	:OP - basic insulation
- basic insulation between parts of opposite polarity	:BOP - supplementary insulation
- double insulation	:DI - reinforced insulation
General remarks:	
"This report is not valid as a CB Test Report unless appended to a CB Test Certificate issued by a NCB, in accordance with IEC 60335-1-2".	
"(see Attachment #)" refers to additional information appended to the report.	
"(see appended table)" refers to a table appended to the report.	
Throughout this report a point is used as the decimal separator.	
The tests results presented in this report relate only to the object tested.	
This report shall not be reproduced except in full without the written approval of the testing laboratory.	
List of test equipment must be kept on file and available for review.	
Summary of contents provided on the last page of this report.	
General product information and considerations:	
The test object is Body Vibration Machine, which is class I device without internally Power supply.	
The applied parts (handle grip and support panel) of the machine are type B.	

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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.)	No safety hazard	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 such construction	N

5	CLASSIFICATION		P
5.1	Type of protection against electric shock		P
	Class I equipment	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	The handle bar and vibration platform are type B applied part.	P
	Type BF applied part		N
	Type CF applied part		N
	Not classified - no applied parts		N
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1)..... :	Just Normal device: IPX0 device.	N
5.4	Methods of sterilization or disinfection		P
5.5	Equipment not suitable for use in the presence of flammable mixtures	Not suitable for use in the presence of flammable mixtures.	P
	Category AP equipment		N
	Category APG equipment		N
5.6	Mode of operation:		P
	-continuous operation		P
	-short-time operation, specified operation; period:		N
	-intermittent operation, specified operation; rest period..... :		N
	-continuous operation with short-time, stated permissible loading time..... :		N
	-continuous operation with intermittent, stated permissible loading/rest time..... :		N

INSULATION DIAGRAM



Note: Class I equipment, Type B applied part.

Table: 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
A	BOP (A-f)	240	3.0	1.6	>6	>6	line to neutral, inlet measure
B	DI/RI(A-a2)	240	8	5	>10	>10	Mains to plastic enclosure
C	BI (A-a1)	240	4	2.5	>5	>3	Live part to protective earthing.
D	DI/RI (B-a)	240	8	5	>10	>10	Applied part to live part
E	DI/RI((A-e))	240	8	5	9	6	Transformer primary to secondary
Note:							




INSULATION DIAGRAM CONVENTIONS

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

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.

2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.
5. Blocks containing the letter "Z" indicate protective impedance.
6. Operational Insulation (OP) – indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with the requirements of clauses 17, 20 and 57.

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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 affixed	Not use specific power supply	N
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents	Markings are all on the equipment	P
	e) Name and/or trademark of the manufacturer or supplier		P
	f) Model or type reference	Refer to the nameplate.	P
	g) Rated supply voltages or voltage range(s)	220-240V	P
	Number of phases	Single phases	P
	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)	500VA	P
	k) Power output of auxiliary mains socket-outlets	No auxiliary mains socket-outlets.	N
	l) Class II symbol	Class I	N
	Symbol for degree of protection against ingress of water provided	IPX0 device, not need to mark.	P
	Symbol for protection against electric shock.....:		P
	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	Only type B applied part.	N
	Symbol for protection of 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 :	AC250V, F5A	P
	p) Ratings of external output	No external output	N
	q) Symbol for physiological effect(s):		P
	- attention, consult accompanying documents		P
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417	Not non-ionizing radiation	N
	r) Anaesthetic-proof symbol: AP or APG.....:	No AP or APG equipment	N
	s) Dangerous voltage symbol	No dangerous voltage	N

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Clause	Requirement + Test	Result - Remark	Verdict
	t) Special cooling requirements		N
	u) Limited mechanical stability		N
	v) Protective packing requirement(s)		P
	- Marking(s) for unpacking safety hazard(s)	No unpacking safety hazard	N
	- Equipment or accessories supplied sterile, marked as sterile	No equipment supplied sterile	N
	y) Potential equalization terminal	No Potential equalization terminal	N
	- Functional earth terminal	No functional earth terminal	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	No permanently installed equipment	N
	b) Maximum power loading for heating elements or holders for heating lamps	No heating elements or holders for heating lamps	N
	c) Dangerous voltage symbol	No used dangerous voltage.	N
	d) Type of battery and mode of insertion	No used battery.	N
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator		N
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram		P
	f) Protective earth terminal		P
	g) Functional earth terminal	No functional earth terminal	N
	h) Supply neutral conductor in permanently installed equipment (N)	No 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		P
	- Markings comply with IEC 445	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)	No permanently connected devices	N
	l) Statement for suitable wiring materials at temperatures over 75 °C	Not permanently installed device.	N
	n) Capacitors and/or circuit parts marked as required in Sub-clause 15c		P
6.3	Marking of controls and instruments		P
	a) Mains switch clearly identified		P
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light		P

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Indication of different positions of control devices and switches	All indications are clearly marked.	P
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device	Refer to the LCD display on the control plane.	P
	f) The functions of operator controls and indicators are identified		P
	g) Numeric indications of parameters are in SI units except for units listed in Am. 2	Comply with the requirement	P
6.4	Symbols		P
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	Comply with Appendix D	P
6.5	Colors of the insulation of conductors		P
	a) Protective earth conductor has green/yellow 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) Color of neutral conductor	Blue neutral conductor	P
	e) Colors of phase conductor(s)	Comply with the requirement	P
	- Compliance with IEC 227 and IEC 245	Comply with the requirement	P
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors	Not use multi-conductor	N
6.6	Medical gas cylinders and connections		N
	a) In accordance with ISO ISO/R 32	No medical gas cylinders and connections.	N
	b) Identification of connection point	No medical gas cylinders and connections.	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	Not use red indicator light.	P
	- Yellow used to indicate caution or attention required		N
	b) Color red used only for push-buttons by which a function is interrupted in case of emergency	No red push-buttons	N
6.8	ACCOMPANYING DOCUMENTS		P
6.8.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Refer to the User Manual.	P
	Classifications specified in Clause 5 included in both the instructions for use and the technical description		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	All marking permanently affixed to equipment	P
	Warning statements and the explanation of warning symbols provided in the accompanying documents	Refer to the details in the user manual, Chapter 1.2 "Safety Information" and Chapter 1.3 "Explanation of Symbols".	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	Refer to the details in the user manual, Chapter 2	P
	- include an explanation of: the function of controls, displays and signals	Refer to the section 2.7.1 and section 2.7.2 in the user manual.	P
	- the sequence of operation	Refer to the Chapter 3 and Chapter 4 in the user manual.	P
	- the connection and disconnection of detachable parts and accessories	Refer to the section 3.2 in the user manual.	P
	- the replacement of material which is consumed during operation	No material which is consumed during operation.	N
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	Refer to the details in the user manual, Chapter 1 "safety information" and Appendix I	P
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	Only use with detachable supply cord, but no use other accessories, detachable parts or materials	P
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	Refer to the section 2.6 and Chapter 5 "maintenance" in the user manual.	P
	General information provided in instructions:		P
	- information for the safe performance or routine maintenance	Refer to the section 2.6 and Chapter 5 "maintenance" in the user manual.	P
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	Refer to the section 2.6 and Chapter 5 "maintenance" in the user manual.	P
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	Refer to the section 1.3 "Explanation of Symbols" in the user manual.	P
	c) Signal output or signal input parts intended only for connection to specified equipment described	No Signal output or signal input parts.	N
	d) Details about acceptable cleaning, disinfection or sterilization methods included	Refer to the Chapter 5 "maintenance" in the user manual.	P
	e) Warning statement for mains operated equipment with additional power source	No used additional power source.	N

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Clause	Requirement + Test	Result - Remark	Verdict
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	Not used primary batteries.	N
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	No use battery.	N
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	Not used specified external power supplies or battery chargers.	N
	j) Identification of any risks associated with the disposal of waste products, residues, etc.	Refer to the details in the Chapter 2 "Overview of product."	P
	- Advice in minimizing these risks		P
6.8.3	Technical description		P
	a) All characteristics essential for safe operation provided	Refer to the section 2.8 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 installed equipment.	N
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	Refer to the chapter 2 in the user manual.	P
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	Refer to the chapter 2 in the user manual.	P
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Refer to the section 2.8 in the user manual, and the packaging.	P
7	POWER INPUT		P
	Power Input Measurements	See appended table 7	P

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Clause	Requirement + Test	Result - Remark	Verdict

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	Comply with this requirement	P
10.2.2 a	Rated voltage not exceeding 250 V for hand-held equipment	Not 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 4kVA	220-240V a.c., and much less than 4kVA.	P
	Rated voltage not exceeding 500 V for all other equipment		N
	Rated input frequency not more than 1kHz	50/60 Hz	P
10.2.2b	Internal replaceable electrical power source specified	No use Internal replaceable electrical power source.	N

14	REQUIREMENTS RELATED TO CLASSIFICATION		P
14.4a	Class I and Class II equipment in addition to basic insulation provided with an additional protection	Comply with the requirement of Class I	P
14.4b	Equipment supplied from external dc source of reverse polarity results in no safety hazard	Not use external dc source	N
14.5b	Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected		N
14.6c	Applied parts intended for direct cardiac application are of type CF	No type CF applied part.	N

15	LIMITATION OF VOLTAGE AND/OR ENERGY		P
15b	Voltage measured one sec after disconnection of the mains plug does not exceed 60V	see appended table 15b	P
15c	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ	No such parts	N
	Marking provided for manual discharging	No such device	N

16	ENCLOSURES AND PROTECTIVE COVERS		P
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	Comply with the requirement	P
	Insertion or removal of lamps – protection against contact with live parts provided	No mentioned lamps	N
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented	No opening in a top	N
16c	Conductive parts accessible after the removal of handles, knobs, levers		N

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Clause	Requirement + Test	Result - Remark	Verdict
	- have a resistance of not more than 0.2 Ω		N
	- separated from live parts by one of the means described in Sub-clause 17g		N
16d	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact	Can be disconnected with external mains plug	N
16e	Removable enclosures protecting against contact with live parts		P
	- Removal possible only with the aid of a tool	Remove need a tool	P
	- Use of automatic device making parts not live when the enclosure is opened or removed	No such parts	N
	- Exception 16e applied to the following parts....:		P
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	No such controls	N

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

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Clause	Requirement + Test	Result - Remark	Verdict
	- Additional leakage current test in single fault conditions		N
17h	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator	No defibrillation-proof applied part.	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
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal		P
18b	Protective earth terminals suitable for connection to the protective earth conductor		P
18e	Potential equalization conductor		N
	- Readily accessible	No Potential equalization.	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
18f	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1 \Omega$	The equipment has power supply cord.	N
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $\leq 0.1 \Omega$	see appended table 18	P
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part $\leq 0.2 \Omega$	Detachable power supply cord	N
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1Ω , the allowable value of the enclosure leakage current is not exceeded in single fault condition	Not exceeds 0.1Ω	N
18k	Functional earth terminal not used to provide protective earthing	No functional earth terminal	N
18l	Class II equipment with isolated internal screens		N
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation	Class I equipment	N
	- functional earth terminal clearly marked	Class I equipment	N
	- explanation of functional earth terminal provided in the accompanying documents	Class I equipment	N

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Clause	Requirement + Test	Result - Remark	Verdict

19	Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		P
19.1b	Leakage currents	see appended table 19	P
	- earth leakage current		P
	- enclosure leakage current		P
	- patient leakage current		P
	- patient auxiliary current		P

20	Dielectric strength		P
	Overall compliance with Clause 20	see appended table 20	P

21	Mechanical strength		P
21a	Sufficient rigidity of an enclosure tested by: force of 45 N	see appended table 21	P
21b	Sufficient strength of an enclosure tested by: impact hammer	see appended table 21	P
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test	No portable equipment.	N
21.3	No damage to parts of patient support and/or immobilization system after the loading test	No damage to parts of patient support after the loading test.	P
21.5	Hand held equipment or equipment parts are safe after drop test	Not Hand held equipment, and no Hand held equipment part.	N
21.6	Portable and mobile equipment is able to withstand rough handling	see appended table 21	P

22	Moving parts		P
22.2a	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment		P
22.2b	Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation	Not stationary equipment.	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		P
	Guides or other safeguards are removable only with a tool		P
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator	Not possible cause physical injury to the patient the operator.	N
22.6	Parts of equipment subject to mechanical wear are accessible for inspection	No such part.	N

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Clause	Requirement + Test	Result - Remark	Verdict
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard	It has a STOP button.	P
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard		P
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents		P
	Means for stopping of movements operate as a result of one single action		P
23	SURFACES, CORNERS AND EDGES		P
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	No rough surface, sharp corners, flange or frame edges and burrs	P
24	Stability in NORMAL USE		P
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°	see appended table 24	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	Not overbalance when tilted through an angle of 10°.	N
	- carry a warning notice stating that transport should only be undertaken in a certain position		N
	- in the position specified for transport does not overbalance when tilted to an angle of 10°		N
24.6a	Equipment or its parts with a mass of more than 20 kg is provided with:		P
	- suitable handling devices (grips etc.), or	No need to mobile the equipment when using normally.	N
	- instructions for lifting and handling during assembly	Refer to the use manual.	P
24.6b	b) On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons	No portable equipment.	N
25	Expelled parts		N
25.1	Protective means are provided where expelled parts of the equipment could be a hazard	No expelled parts	N
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion	No display vacuum tubes	N
28	Suspended masses		N
28.3	Suspension system with safety device		N

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Clause	Requirement + Test	Result - Remark	Verdict
	Safety device provided where the integrity of a suspension depends on parts which may have hidden defects, or on parts having safety factors not complying with Sub-clause 28.4	No suspended masses	N
	Safety device has safety factors complying with Sub-clause 28.4.2	No suspended masses	N
	Clear indication to the operator that the safety device has been activated after failure of suspension means	No suspended masses	N
28.4	Suspension systems of metal without safety devices		N
	1) Total load does not exceed the safe working load	No suspended masses	N
	2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired	No suspended masses	N
	3) Safety factors not less than 8 where impairment is expected	No suspended masses	N
	4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%	No suspended masses	N
	5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement	No suspended masses	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 with IEC 60601-1-2	See EMC Test Report.	N
37	COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT		N
	Requirements for category AP and APG equipment (Cl. 37 – 41)	No AP or APG equipment	N

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Clause	Requirement + Test	Result - Remark	Verdict
42	EXCESSIVE TEMPERATURES		P
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures per Clause 10.2.1	see appended table 42	P
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient		P
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C		P
42.5	Guards to prevent contact with hot surfaces removable only with a tool		P
43	FIRE PREVENTION		P
	Strength and rigidity necessary to avoid a fire hazard	Enclosure can avoid fire hazard. Refer to 21.	P
44	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION		P
44.2	Equipment contain a liquid reservoir:		N
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min	No liquid reservoir	N
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling)	No liquid reservoir	N
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)	The equipment is not waterproof; refer to the section 1.2 safety information in the user manual.	N
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard	No liquid	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	The equipment is not waterproof.	N
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	see appended table 44	P

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Clause	Requirement + Test	Result - Remark	Verdict
45	PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE		P
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 vessel	N
45.3	Maximum pressure does not exceed the maximum permissible working pressure for individual parts	It will stop running automatically if the pressure exceeds the maximum permissible working pressure.	P
45.7	Unless excessive pressure can not occur, pressure-relief device provided	No Pressure-product device, no need pressure-relief device.	N
45.7a	Pressure-relief device connected as close as possible to the pressure vessel		N
45.7b	Readily accessible for inspection		N
45.7c	Not capable of being adjusted or rendered inoperative without a tool		N
45.7d	Discharge opening located that the released material is not directed towards person		N
45.7e	Discharge opening located that operation will not deposit material which may cause a safety hazard		N
45.7f	Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure		N
45.7g	No shut-off valve between a pressure-relief device and the parts intended to be protected		N
45.7h	Minimum number of cycles of operation: 100.000		N
48	BIOCOMPATIBILITY		N
	Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1	Evaluated by applicant	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 cause a safety hazard	Not use over-current release with automatic resetting	N
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function		P
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure	No mechanical constraints	N

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Clause	Requirement + Test	Result - Remark	Verdict
51	PROTECTION AGAINST HAZARDOUS OUTPUT		P
51.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally		P
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 60601-1-4	Evaluated by the manufacture.	N
52.5.2	Failure of thermostats presents no safety hazards	No thermostats	N
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard		P
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C	According to the structure, It's impossible to happen such risk.	N
52.5.6	Locking of moving parts presents no safety hazard	According to the structure, It's impossible to happen such risk.	N
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	see appended table 52	P
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8	see appended table 52	P
52.5.9	Failure of one component at a time presents no safety hazard	No safety hazard	P
52.5.10	Overload of heating elements presents no safety hazard	see appended table 52	P
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	The motor is not intended to remotely controlled, automatically controlled, or liable to be operated continuously.	N
	h) Equipment with three-phase motors can safely operate with one phase disconnected	Not three-phase Motors	N

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Clause	Requirement + Test	Result - Remark	Verdict
56	COMPONENTS AND GENERAL ASSEMBLY		P
	List of critical components	see appended table 56	P
56.1b	Ratings of components not in conflict with the conditions of use in equipment	Not conflict between ratings and condition	P
	Ratings of mains components are identified	All mentioned identified	P
56.1d	Components, movements of which could result in a safety hazard mounted securely	All components in equipment mounted securely	P
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard	Accidental detachment is prevented	P
56.3a	Connectors provide separation required by Sub-clause 17g	According with 17g	P
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	Can not be connected to other outlets on the same equipment	P
	Medical gas connections not interchangeable	No medical gas connections	N
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken	No accessible metal parts.	N
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.	No such connection to a patient.	N
56.4	Connections of capacitors		P
	Not connected between live parts and non-protectively earthed accessible parts	No capacitor connected like this.	P
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14	No capacitor connected like this.	N
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts	No capacitor connected like this.	P
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs	No such connected	P
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	Not provided such device	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	No such device	P
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits	The temperature did not exceed the limit value.	N
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard	No such device	N

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Clause	Requirement + Test	Result - Remark	Verdict
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard	No safety hazard caused by operation of a thermal cut-out.	N
	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		P
56.6b	Thermostats with varying temperature settings clearly indicated	No thermostat	N
	Operating temperature of thermal cut-outs indicated		N
56.7	Batteries		N
	a) Battery compartments:		N
	- adequately ventilated	No battery.	N
	- accidentally short-circuiting is prevented		N
	b) Incorrect polarity of connection prevented		N
56.8	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):		P
	- to indicate that equipment is energized	Refer to the LCD display.	P
	- to indicate the operation of non-luminous heaters if a safety hazard could result	No heaters	N
	- to indicate when output exists if a safety hazard could result	Refer to the LCD display.	P
	- charging mode indicator provided	No charging battery.	N
56.10	Actuating parts of controls		P
56.10 b	Actuating parts are adequately secured to prevent them from working loose during normal use	All actuating parts are secured	P
	Controls are secured to prevent the movement relative to scale marking (safety related only)	No such controls	N
	Detachable indicating devices are prevented from incorrect connection without the use of tool	No detachable indicating devices	N
56.10 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	No rotating control.	N
	- to prevent damage to wiring	No rotating control.	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. 17g	Not such device	N
	b) Hand-held control devices comply with the requirement and test of Sub-clause 21.5	Not such device	N
	- Foot-operated control devices designed to support the weight of an adult human being	Not such device	N

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Clause	Requirement + Test	Result - Remark	Verdict

	c) Devices not change their setting when inadvertently placed	Not such device	N
	d) Foot-operated control devices are at least IPX 1	Not such device	N
	- For surgical use, electrical switching parts are IPX 8	Not such device	N
	e) Adequate strain relief at the cord entry provided	Not such device	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	Use AC power cord	P
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents	It has mains switch.	P
	d) Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328		P
	f) Mains switches not incorporated in a power supply cord	Not incorporated in the power supply cord.	P
	h) Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a	Such mains plugs provided Refer to Table 56.1 "lists of critical component parts".	P
	m) Fuses and semiconductor devices not used as isolating devices	Not use such device 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 auxiliary mains socket-outlets	N
	g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment	Class I appliance	N
57.3	Power supply cords		P
	a) Not more than one connection to a particular supply mains	Only one connection	P
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously	No such alternative connections	N
	The mains plug has only one power supply cord	Mains plug has only one power supply cord	P
	Non-permanently connected equipment provided with power supply cord or appliance inlet	Provided with a power supply cord and an appliance inlet	P
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53	Comply with IEC227 designation53, approved cord set to be provided Refer to Table 56.1.	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C	No such metal parts	N
	c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV	Approved cord set to be provided (> 0.75mm ²)	P
	d) Stranded conductors not soldered if fixed by any clamping means	Not use soldered for fix	P
57.4	Connection of power supply cords		P
57.4a	Cord anchorages		P
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting		P
	Tying the cord into a knot or tying the ends with string not used	Detachable power supply cords	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 arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals		N
57.4b	Power supply cord protected against excessive bending	Detachable power supply cords	N
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		P
57.5	Mains terminal devices and wiring of mains part		P
	Mains connected equipment other than those with a detachable supply cord provided with mains terminals, where connections are made with screws, nuts or equally effective methods	Used detachable power supply cord.	N
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced	Used detachable power supply cord.	N
	Screws and nuts which clamp external conductors not serve to fix any other component	Used detachable power supply cord.	N
	b) Terminals closely grouped with any protective earth terminal		P
	Mains terminal devices accessible only with use of a tool		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Mains terminal devices located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact		P
	c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened		P
	d) Cord terminals not require special preparation of the conductor		P
57.6	Mains fuses and overcurrent releases		P
	Fuses or over-current releases provided accordingly for Class I and Class II	Class I device.	P
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current	Reliable in normal condition	P
	Protective earth conductor not fused	Not use fuse on earth conductors	P
	Neutral conductor not fused for permanently installed equipment	No permanently installed equipment	N
57.8	Wiring of the mains part		P
	a) Individual conductor in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC 227 or 245, treated as bare conductor	Insulation complying with IEC Publications 227	P
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord	No less than 0.75mm ²	P
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard	Size 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		P
57.9.1 a	Short-circuit of secondary windings not caused excessive temperature	See the appended table 57.9.1a	P
57.9.1 b	Overload of secondary windings not caused excessive temperature	See the appended table 57.9.1b	P
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it Pes tests	See the appended table 57.9.2	P
57.9.4	Construction		P
	a) Separation of primary and secondary windings		P
	- separate bobbins or formers		P

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Clause	Requirement + Test	Result - Remark	Verdict
	- 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		P
	d) Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn		N
	e) Insulation between the primary and secondary in transformers with double insulation		P
	- 1 insulation layer with thickness of at least 1 mm		P
	- at least 2 insulation layers with a total thickness of at least 0.3 mm		N
	- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation		N
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3 mm extending at least 20 mm outside the winding	No toroidal transformer	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 at least 50% of the specified values		P
	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	Adequate creepage distance and air clearance provided before input fuse.	P
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts	No defibrillation-proof applied part.	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		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 not used for the mechanical connection or the fixing of any component not related to earthing	Not connected other components	P

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Clause	Requirement + Test	Result - Remark	Verdict
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	the earth pin is longer than other pins	P

59	CONSTRUCTION AND LAYOUT		P
59.1	Internal wiring		P
	a) Cables and wiring protected against contact with a moving part	No such moving part.	N
	Wiring having basic insulation only protected by additional fixed sleeving	No such movement	N
	Components are not likely to be damaged in the normal assembly or replacement of covers		N
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead	No Movable leads around the guiding rollers	N
	c) Insulating sleeving adequately secured	Adequately secured	P
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test	Refer to table 56.1.	P
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material	No insulated conductor's temperature greater than 70°C	N
	d) Aluminum wires of less than 16 mm ² cross-section not used	Not use aluminum wires	N
	f) Connecting cords between equipment parts considered as belonging to the equipment	Consider cords as equipment's part	P
59.2	Insulation		P
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation	Not change all insulation. Refer to the additional test table 59.2.	P
	c) Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts	Insulation won't be impaired	P
	Parts of rubber resistant to ageing	Not use rubber	N
59.3	Excessive current and voltage protection		P
	Internal electrical power source provided with device for protection against fire hazard	No internal electrical power source.	N
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder	Fuse fully enclosed in a fuseholder	P
	Protective devices between a F -type applied part and the body of the equipment do not operate below 500 V r.m.s.	No F-type applied part.	N
59.4	Oil containers		N
	Oil containers adequately sealed	No oil containers	N
	Container allow for the expansion of the oil	No oil containers	N

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Clause	Requirement + Test	Result - Remark	Verdict
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport	No oil containers	N
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level	No oil containers	N

6.1	TABLE: marking durability		P
Marking tested		Remarks	
Label		T-w = 15s ,T-m = 15s, T-i = 15s	
Device Marks		T-w = 15s ,T-m = 15s, T-i = 15s	
Supplementary information: T-w = Time with distilled water T-m =Time with methylated spirit T-i = Time with isopropyl alcohol			

7	TABLE: power input				P
Operating condition	Voltage (V)	Frequency (Hz)	Current (A)	Power (VA)	Remarks
Normal Condition: 220-240Vac 50/60Hz 500 VA	198	50	1.75	347.0	The measured input power did not exceed 110 percent of the unit's ratings.
	220	50	1.70	374.0	
	240	50	1.75	420.0	
	264	50	1.78	469.9	
	198	60	1.69	335.1	
	220	60	1.70	373.8	
	240	60	1.75	420.1	
	264	60	1.78	469.7	

15b	TABLE: residual voltage in attachment plug										N
Voltage measured between:	Measurements [V]										Remarks
	1	2	3	4	5	6	7	8	9	10	
supply pins (pin 1 & pin 2)											
line pin 1 and enclosure											
line pin 2 and enclosure											
pin 1 and earth pin	--	--	--	--	--	--	--	--	--	--	--
pin 2 and earth pin	--	--	--	--	--	--	--	--	--	--	--
Supplementary Information: L-N C: <u>157pF</u> L-GND C: <u>198pF</u> N-GND C: <u>193 pF</u>											

15c	TABLE: residual voltage or energy in capacitors				N
Capacitor and its location	Residual voltage (V)	Time after disconnection (s)	Capacitance value (μ F)	Residual energy (mJ)	Remarks
Supplementary information: No need to test.					

17h1	TABLE: defibrillation-proof applied parts				N
Test Condition: Fig. 50 or 51	Accessible part of measurement:	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
Supplementary information: no defibrillation-proof applied parts.					

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

18	TABLE: protective earthing				P
Test location	Test current (A)	Measured voltage (V)	Resistance (ohms)	Remarks	
AC inlet Ground pin to Protect earthed screw	25A	---	0.03	5 sec	
AC inlet Ground pin to Protect earthed enclosure	25A	---	0.03	5 sec	
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 (uA)		Remarks Limited (uA)
			B	A	
Earth leakage current					
ER, S1=1, S5=1, S12=0, NC	264	60	482	482	500
ER, S1=1, S5=0, S12=0, NC	264	60	480	482	500
ER, S1=1, S5=1, S12=1, NC	264	60	479	481	500
ER, S1=1, S5=0, S12=1, NC	264	60	481	481	500
ER, S1=0, S5=1, S12=0, SFC	264	60	881	879	1000
ER, S1=0, S5=0, S12=0, SFC	264	60	877	878	1000
ER, S1=0, S5=1, S12=1, SFC	264	60	883	884	1000
ER, S1=0, S5=0, S12=1, SFC	264	60	885	883	1000
Enclosure leakage current					
EN, S1=1, S5=1, S7=1, S12=0, NC	264	60	0	0	100(MD1)
EN, S1=1, S5=0, S7=1, S12=0, NC	264	60	0	0	100(MD1)
EN, S1=1, S5=1, S7=1, S12=1, NC	264	60	0	0	100(MD1)
EN, S1=1, S5=0, S7=1, S12=1, NC	264	60	0	0	100(MD1)
EN, S1=1, S5=0, S7=0, S12=0, SFC	264	60	1	1	500(MD1)
EN, S1=1, S5=1, S7=0, S12=0, SFC	264	60	1	1	500(MD1)
EN, S1=1, S5=0, S7=0, S12=1, SFC	264	60	1	1	500(MD1)
EN, S1=1, S5=1, S7=0, S12=1, SFC	264	60	1	1	500(MD1)
EN, S1=0, S5=0, S7=1, S12=0, SFC	264	60	1	1	500(MD1)
EN, S1=0, S5=1, S7=1, S12=0, SFC	264	60	1	1	500(MD1)
EN, S1=0, S5=0, S7=1, S12=1, SFC	264	60	1	1	500(MD1)
EN, S1=0, S5=1, S7=1, S12=1, SFC	264	60	1	1	500(MD1)
EN, S1=1, S5=1, S7=1, S12=0, NC	264	60	0	0	100(MD2)
EN, S1=1, S5=0, S7=1, S12=0, NC	264	60	0	0	100(MD2)
EN, S1=1, S5=1, S7=1, S12=1, NC	264	60	0	0	100(MD2)
EN, S1=1, S5=0, S7=1, S12=1, NC	264	60	0	0	100(MD2)
EN, S1=1, S5=0, S7=0, S12=0, SFC	264	60	1	1	500(MD2)
EN, S1=1, S5=1, S7=0, S12=0, SFC	264	60	1	1	500(MD2)
EN, S1=1, S5=0, S7=0, S12=1, SFC	264	60	1	1	500(MD2)
EN, S1=1, S5=1, S7=0, S12=1, SFC	264	60	1	1	500(MD2)
EN, S1=0, S5=0, S7=1, S12=0, SFC	264	60	0	0	500(MD2)
EN, S1=0, S5=1, S7=1, S12=0, SFC	264	60	0	0	500(MD2)
EN, S1=0, S5=0, S7=1, S12=1, SFC	264	60	0	0	500(MD2)
EN, S1=0, S5=1, S7=1, S12=1, SFC	264	60	0	0	500(MD2)
Patient Leakage Current					
(The test record here was the maximum Patient leakage current of each patient connection combination during measuring at each test condition (S1, S5, S7 at different positions).)					
P, S1=1, S5=1, S7=1, NC	264	60	AC: 0	AC: 0	100
			DC: 0	DC: 0	10
P, S1=1, S5=0, S7=1, NC	264	60	AC: 0	AC: 0	100
			DC: 0	DC: 0	10
P, S1=0, S5=1, S7=1, SFC	264	60	AC: 0	AC: 0	500
			DC: 0	DC: 0	50
P, S1=0, S5=0, S7=1, SFC	264	60	AC: 0	AC: 0	500

			DC: 0	DC: 0	50
P,S1=1, S5=1, S7=0, SFC	264	60	AC: 24	AC: 23	500
			DC: 0	DC: 0	50
P,S1=1, S5=0, S7=0, SFC	264	60	AC: 24	AC: 24	500
			DC: 0	DC: 0	50
patient auxiliary current					
PA, NC, S1 = 1, S5 = N, S7 = 1	264	60	AC: 0	AC: 0	100
			DC: 0	DC: 0	10
PA, NC, S1 = 1, S5 = R, S7 = 1	264	60	AC: 0	AC: 0	100
			DC: 0	DC: 0	10
PA, SFC, S1 = 0, S5 = N, S7 = 1	264	60	AC: 0	AC: 0	500
			DC: 0	DC: 0	50
PA, SFC, S1 = 0, S5 = R, S7 = 1	264	60	AC: 0	AC: 0	500
			DC: 0	DC: 0	50
PA, SFC, S1 = 1, S5 = N, S7 = 0	264	60	AC: 0	AC: 0	500
			DC: 0	DC: 0	50
PA, SFC, S1 = 1, S5 = R, S7 = 0	264	60	AC: 0	AC: 0	500
			DC: 0	DC: 0	50
Supplementary information: The equipment has only type B applied part. The handle grip and the support panel are the applied parts.					
<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 IEC601-1 MD - Measuring device			A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition		

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	
Before humidity Processing					
B (A-a2)	DI/RI	240	4000	No breakdown	
C (A-a1)	BI	240	1500	No breakdown	
D (B-a)	DI/RI	240	4000	No breakdown	
E(A-e)	DI/RI	240	4000	No breakdown	
After humidity Processing					
B (A-a2)	DI/RI	240	4000	No breakdown	
C (A-a1)	BI	240	1500	No breakdown	
D (B-a)	DI/RI	240	4000	No breakdown	
E(A-e)	DI/RI	240	4000	No breakdown	
Supplementary information:					

21	TABLE: mechanical strength		P
Part under test	Test (impact, drop, force, handle, rough handling, mobile)	Remarks	
Top of control panel	Force Test (21a)	No damage	
Side of control panel	Force Test (21a)	No damage	
Bottom of control panel	Force Test (21a)	No damage	
Supper panel	Force Test (21a)	No damage	
Top of control panel	Impact Test (21b)	No damage	
Side of control panel	Impact Test (21b)	No damage	
Bottom of control panel	Impact Test (21b)	No damage	
Support panel	Impact Test (21b)	No damage	
Completed Unit	Rough Handling-Drop (21.6)	No damage	
Supplementary information:			

24	TABLE: - stability		P
Part under test	Test condition	Remarks	
Completed Unit	The equipment was placed in a position of normal use on a plane inclined 10° from the horizontal.	Not overbalance	
Supplementary information:			

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

42	TABLE: Normal working condition		P
Supply voltage: 264V/50Hz		Test Condition: Under maximum load	
Ambient temperature: see below			
Measuring location	Measured temperature		Remarks (Limit)
	Reading value [°C]	adjust o 40 °C [°C]	
Primary winding of Transformer	48.6	60.9	130°C
Secondary winding of Transformer	46.3	58.6	130°C
Core of Transformer	49.6	61.9	130°C
MOS transistors on the cooling fin	52.2	64.5	130°C
C9 (near Secondary of Transformer)	36.6	48.9	60°C
Motor	41.3	53.6	130°C
PCB 2	45.6	57.9	130°C
C7 (near Secondary of Transformer)	40.5	52.8	60°C
External Power supply cord	32.3	44.6	105°C
PCB of Power board	43	55.3	130°C
The biggest storage capacitance of power board	42.1	54.4	90°C
Internal Power supply cord	32.3	44.6	105°C
Enclosure	29.3	41.6	50°C
Button	29.4	41.7	50°C
Handle grip	28.6	40.9	41°C
LCD display	31	43.3	50°C
Ambient	27.7	40.0	--
Supplementary information: The enclosure, button, and LCD display can be touched to the patient for a short time. COR - indicates measurements taken using change-of-resistance method			

42	TABLE: Abnormal working condition		P
Supply voltage: 264V/50Hz		Test Condition: motor overload test, lock the motor moving for 10 min.	
Ambient temperature: see below			
Measuring location	Measured temperature		Remarks (Limit)
	Reading value [°C]	adjust o 40 °C [°C]	
Primary winding of Transformer	44.1	56.2	130°C
Secondary winding of Transformer	40.7	52.8	130°C
Core of Transformer	44.4	56.5	130°C
MOS transistors on the cooling fin	95.8	107.9	130°C
C9 (near Secondary of Transformer)	34.3	46.5	60°C
Motor	91.3	103.4	130°C
PCB 2	51.5	63.6	130°C
C7 (near Secondary of Transformer)	39.0	51.1	60°C
PCB of Power board	47.9	60.0	130°C
The biggest storage capacitance of power board	49.3	61.4	90°C
Internal Power supply cord	29.5	41.6	105°C
Ambient	27.9	40.0	--
Supplementary information: COR - indicates measurements taken using change-of-resistance method			

44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		P
Test type and condition		Part under test	Remarks
44.5 Humidity, 25°C, 90%, 48 HRS		Completed Unit	After this test, Dielectric strength and leakage current met requirements of this standard.
44.7 Cleaning		Completed Unit	No damage
Supplementary information:			

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

52	TABLE: abnormal operation		P
Test type, condition and clause reference		Observed results	Remarks
Short R1		The fuse blew out, and there was no safety hazard.	No damage
Short R2		The fuse blew out, and there was no safety hazard.	No damage
Short Q1 or Q2		The motor can not work at normal	No damage
Short secondary of the transformer (7V)		See table 57.9.1a	No damage
Short IC3		No safety hazard.	No damage
Short R17 or R18		No safety hazard	No damage
Short R14 or R12		No safety hazard	No damage
Supplementary information:			

56.1	TABLE: lists of critical component parts				P
Object/part No	Manufacturer/ trademark	Type/mode I	Technical data	Standard	Mark(s) of conformity1)
Plug	Ningbo Ousheng Electric Appliance Co., Ltd.	S03	16A, 250V~	DIN VDE 0620-1 IEC 60884-1	VDE 40023763
Alt.	Shenzhen Dongju Wire & Cable Co., Ltd.	DJ-012	16A, 250V~	DIN VDE 0620-1 IEC 60884-1	VDE 40011580
Alt.	New Square Company Ltd.	NS-13	16A, 250V~	DIN VDE 0620-1 IEC 60884-1	VDE 40015168
Alt.	Ningbo Qiaopu Electric Co., Ltd.	D03	16A, 250V~	DIN VDE 0620-1	VDE 40002872

				IEC 60884-1	
Supply cord	Ningbo Ousheng Electric Appliance Co., Ltd.	H05VV-F	3G0,75mm ²	DIN VDE 0281-5 HD 21.5 S3 60227 IEC 53	VDE 40021137
Alt.	Shenzhen Dongju Wire & Cable Co., Ltd	H05VV-F	3G0,75mm ²	DIN VDE 0281-5 HD 21.5 S3 60227 IEC 53	VDE 129988
Alt.	New Square Company Ltd.	H05VV-F	3G0,75mm ²	IN VDE 0281-5 HD 21.5 S3 60227 IEC 53	VDE 116006
Alt.	Ningbo Qiaopu Electric Co., Ltd.	H05VV-F	3G0,75mm ²	DIN VDE 0281-5 HD 21.5 S3 60227 IEC 53	VDE 136970
Connector	Ningbo Ousheng Electric Appliance Co., Ltd.	ST3	250V~ 10A	DIN EN 60320-1	VDE 40022825
Alt.	Shenzhen Dongju Wire & Cable Co., Ltd	DJ-022	250V~ 10A	DIN EN 60320-1	VDE 40032464
Alt.	New Square Company Ltd.	NS-15	250V~ 10A	DIN EN 60320-1	VDE 40031519
Alt.	Ningbo Qiaopu Electric Co., Ltd.	QT3	250V~ 10A	DIN EN 60320-1	VDE 40005934
Inlet	Jackson Electronic Ind. Corp.	JR-101-1FRS	AC250V, 10A		VDE4001234
Switch	Yinxian Lihe	RL3-4	10A 6A(2)A, AC250V, T125		VDE 40028540
Switch	Zhe Jiang Bei Er Jia Electronics Industrial Corp.	PS8A	Rated 250Vac, 8A. 6A 4AT105,		VDE 400285405
Fuse link	XC	5F	AC250V, F5A		VDE 40009609
Fuse link	Sunny East Enterprise Co.ltd	GFL	AC250V, F5AL		VDE 40001480
Fuse link	SHENZHEN LAN SON Electronics	F***L250V	AC250V, 5A		VDE40009306
Fuse link	SHENZHEN LAN SON Electronics	3JF***L250V	AC250V, 5A		VDE40009301
Internal wiring connect Switch	Dongguan Cheng Xing Electronic Co., Ltd	1015	600V 16AWG T105	UL 758	Testing in appliance UL E249743
Internal wiring Connect PCB	Dongguan Cheng Xing Electronic Co., Ltd	1015	600V 16AWG T105	UL 758	Testing in appliance UL E249743
Internal wiring Connect motor	Dongguan Cheng Xing Electronic Co., Ltd	1015	600V 16AWG T105	UL 758	Testing in appliance UL E249743
X2 capacitance	Tenta ELeCtric Co., Ltd	MEX	275V~ 0,47uF T100	DIN EN 132400 IEC 60384-14	VDE 119119
Y capacitance	JYA-NAY Co., Ltd.	JN	AC400V 3300PF T125	DIN EN123400 IEC 60384-14	VDE 40001831
Y capacitance	JYA-NAY Co., Ltd.	JN	AC400V 1000PF T125	DIN EN123400 IEC 60384-14	VDE 40001831

Inductance connect motor	HUI JIN Electronic Factory	L901	T25*12*15		Technique datasheet.
Transformer	Guangzhou Huadu Guang ErZhong Electronic Factory	EI 25	Primary:230V 50Hz/60HZ N1 1.07 N2 0.32 N3 0.03 N4 0.15		Testing in appliance
Varistor	Lien Shun Electronics Co., Ltd.	14D471K	AC 50-680V 25A T85	CECC 42000 CECC 42200 CECC 42201 IEC 61051-1 IEC 61051-2 IEC 61051-2-2	VDE 40005858
Optocoupler	Sharp Corporation	PC817	Input: IR-LED	DIN EN 60747-5-2	VDE 40008087
PCB	KIMGBOARD LAMINATES LTD	KB6150C	FR4/1.6mm	UL 94	Testing in appliance UL E123995
Motor	TE WEI INGINES CO.,LTD	C8S	1HP 4600RPM 180V	EN 60601-1	Testing in appliance
Plastic enclosure	CHI MEI	PA-765A(+)	ABS ,V-0	UL 94	Testing in appliance UL E56070
Handrail Grip	DONG GUAN CITY FA YUNG INOUSTRIAL.CO.,LTD		38*3MM		PAHS
1) an asterisk indicates a mark which assures the agreed level of surveillance					

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

56.11b	TABLE: foot operated control devices-loading			N
Part under test		Observed results	Remarks	
Supplementary information: No foot operated control.				

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

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

57.9.1a	TABLE: transformer short circuit					P
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
Secondary (7V)	---	58.5	144	26.7	No more than 8 minutes	The transformer was broken and no output, but there was no safety hazard.
Supplementary information: The Measured temperatures of Primary and Secondary winding were both less than 150 °C, according to the Table 19 of this standard, the transformer met the requirements of the standard.						

57.9.1b	TABLE: overload						N
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current Or thermal cutout temp.	Remarks
		Primary	Secondary	Ambient			
Supplementary information: Refer to table 57.9.1a; the input current of the circuit was no more than 2A (the fuse limit value was 5A) when shorting the output of the transformer.							

57.9..2	TABLE: transformer dielectric strength				P
Transformer under test	Test voltage applied to	Test voltage	Test frequency	Remarks	
Primary and Secondary of Transformer	1200 V	1200V	300Hz	The transformer was not broken after the test.	
Supplementary information:					

	TABLE: additional tests		P
Clause	Test type and condition	Remarks and observed results	
59.2	Ball Pressure Test 1hr (125 degree C) on the cover above the power supply PCBA.	The diameter of the impression is 1.2 mm	P

SUMMARY OF CONTENTS:

The equipment has been tested according to standard EN 60601-1:1990+ A1:1993+ A2:1995

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

These tests fulfill the requirements of standard EN45001.

This test report comprises 42 pages of Test Report and the following Attachments:

Attachment #	Description	Pages
1	Photo for DUT	4

Note:

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