



TEST REPORT

EN 60601-1

**Medical electric equipment
Part 1: General requirements for safety**

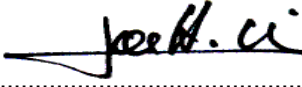
Report

Reference No. : STC-A09-095

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This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator (see below).

Testing laboratory

Name : KESCO Safety Test Center

Address : 338-1, Yeonghwa-Dong, Jangan-Gu, Suwon-City, Gyeonggi-Do,
440-819, Korea

Testing location : as above

Client

Name : HANMED Co., Ltd.

Address : #112 Gimhae Bio Medical Center, 155-1, Nogso-ri, Juchon-myeon,
Gimhae-si, Gyeongsangnam-do, Korea

Test specification

Standard : EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996

Test procedure : -

Procedure deviation : N.A.

Non-standard test method : N.A.

Test Report Form/blank test report

Test Report Form No. : I601-1_C/97-07

TRF originator. : UL

Master TRF : dated 97-04

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Test item

Description..... : Orthopedics appliance

Trademark..... : KINETRAC

Model and/or type reference : KNX-7000

Manufacturer : HANMED Co., Ltd.

Rating(s)..... : 220-240 V~, 50/60 Hz, 300 VA

Particulars: test item vs. test requirements

Classification of installation and use : Stationary equipment
 Supply connection : Appliance coupler

Test case verdicts

Test case does not apply to the test object : N(A.)
 Test item does meet the requirement..... : P(ass)
 Test item does not meet the requirement..... : F(ail)

Testing

Date of receipt of test item : 2009-07-17
 Date(s) of performance of test..... : 2009-08-17 to 2009-09-04

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.
 This investigation doesn't include requirements for Electromagnetic compatibility(Clause 36),
 Biocompatibility(Clause 48) and Programmable electronic systems(Clause 52.1).

Copy of marking plate:

Orthopedics appliance

KINETRAC

KNX-7000

Rating: 220~240 V~, 50/60 Hz, 300 VA
 Weight: 160kg

Serial Number

MGF Date

Please read the user's manual carefully before use.

1023

Manufacturer

Room112, Next Generation Medical Science life Center, 155-1
 Nong-so ri, Ju-chon myeon, Gimhae city, Gyeong nam, Korea
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Authorized EC representative

BERIMEXA Co.
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EN 60601-1:1990+A1+A2+A13			
Clause	Requirement – Test	Result - Remark	Verdict
3.	GENERAL REQUIREMENTS		
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.)	All the applicable standard clauses of this general standard (EN/IEC 60601-1) fulfilled	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 means of construction	N

5.	CLASSIFICATION		
5.1	Type of protection against electric shock		P
	Class I equipment	Complied	P
	Class II equipment		N
	Internally powered equipment		N
5.2	Degree of protection against electric shock		P
	Type B applied part	Complied	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)	Ordinary (IPX0)	N
5.4	Methods of sterilization or disinfection	No special sterilization or disinfection recommended	N
5.5	Equipment not suitable for use in the presence of flammable mixtures	No AP/APG proof	N
	Category AP equipment	No AP classified	N
	Category APG equipment	No APG classified	N
5.6	Mode of operation:		P
	continuous operation		P
	short-time operation, specified operation; period ... :		—
	intermittent operation, specified operation; rest period		—
	continuous operation with short-time, stated permissible loading time		—
	continuous operation with intermittent, stated permissible loading/rest time		—

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

INSULATION DIAGRAM

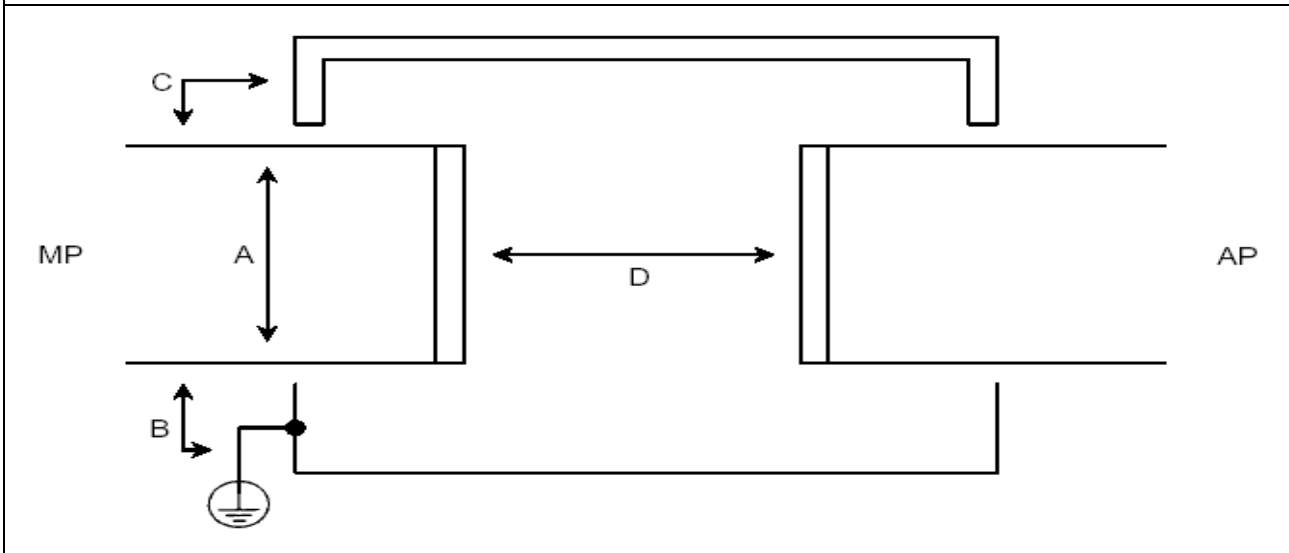


Table: to insulation diagram							P
area	insulation type: operational/basic/ supplementary/ double/reinforced	reference voltage (V)	required creepage (mm)	required clearance (mm)	measured creepage (mm)	measured clearance (mm)	remarks
A	BI (A-f)	230	3	1.6	> 4.0	> 2.0	See note 7
B	BI (A-a1)	230	4	2.5	> 4.0	> 4.0	See note 7
C	RI (A-a2)	230	8	5	> 10	> 10	See note 7
D	RI (B-a)	230	8	5	> 10	> 10	See note 7

See appended table 20 for dielectric strength test

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.
7. UL 60601-1 certified power supply used.

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Clause	Requirement – Test	Result - Remark	Verdict
6.	IDENTIFICATION, MARKING AND DOCUMENTS		
6.1	Marking on the outside of equipment or equipment parts		P
	c) Markings of the specific power supply are affixed	No specific power supply	N
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents	Suitable size and nature of enclosure	N
	e) Name and/or trademark of the manufacturer or supplier	HANMED Co., Ltd.	P
	f) Model or type reference	KNX-7000	P
	g) Rated supply voltages or voltage range(s)	220-240 V	P
	Number of phases	Single-phase supply	N
	Type of current	~	P
	h) Rated frequency or rated frequency range(s) (Hz)	50/60 Hz	P
	j) Rated power input (VA, W or A)	300 VA	P
	k) Power output of auxiliary mains socket-outlets		P
	l) Class II symbol	Class I equipment	N
	Symbol for degree of protection against ingress of water provided	IPX0	N
	Symbol for protection against electric shock	Type B applied part: symbol 1 of table DII	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	Same degrees of protection	N
	Symbol for protection of defibrillation-proof applied parts	No defibrillation proof applied parts	N
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N
	m) Mode of operation (if no marking, suitable for continuous operation	Continuous operation	N
	n) Types and rating of external accessible fuses :	No accessible fuses	N
	p) Ratings of external output	No external output	N
	q) Symbol for physiological effect(s):		N
	attention, consult accompanying documents	No physiological effect	N
	non-ionizing radiation, or symbols as adopted by ISO or IEC 417	No radiation hazards	N
	r) Anaesthetic-proof symbol: AP or APG	Not APG or AP rated	N
	s) Dangerous voltage symbol	No external high voltage connection	N

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Clause	Requirement – Test	Result - Remark	Verdict
	t) Special cooling requirements	No special cooling requirements	N
	u) Limited mechanical stability	Not limited	N
	v) Protective packing requirement(s)	No protective packing	N
	Marking(s) for unpacking safety hazard(s)		N
	Equipment or accessories supplied sterile, marked as sterile	Not sterile	N
	y) Potential equalization terminal	No potential equalization terminal	N
	Functional earth terminal	No functional earth terminal	N
	z) Removable protective means	No protective means to be removed by the operator for special function	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 or heating lamps	N
	c) Dangerous voltage symbol	No high voltage parts	N
	d) Type of battery and mode of insertion	No 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	UL 60601-1 certified power supply used	N
	f) Protective earth terminal	Symbol 6 of table DI marked near earth terminal	P
	g) Functional earth terminal	No functional earth terminal	N
	h) Supply neutral conductor in permanently installed equipment (N)	Not permanently installed equipment	N
	j) Markings required in 6.2 f), h), k), and l) remain visible after connection and are not affixed to parts which have to be removed	Complied	P
	Markings comply with IEC 445	Complied	P
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)	Not permanently installed equipment	N
	l) Statement for suitable wiring materials at temperatures over 75 °C	Not permanently connected equipment	N

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Clause	Requirement – Test	Result - Remark	Verdict
	n) Capacitors and/or circuit parts are marked as required in Cl. 15. c)	See clause 15. c)	N
6.3	Marking of controls and instruments		P
	a) Mains switch clearly identified	No mains switch	N
	ON and OFF positions marked according to Symbols 15 and 16 of Table D1 or indicated by an adjacent indicator light		N
	b) Indications of different positions of control devices and switches	All controls use clear symbol	P
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device	No safety hazard with change of controls	N
	f) The functions of operator controls and indicators are identified	Indicated by letters and figures	P
	g) Numeric indications of parameters are in SI units except for units listed in A2	No SI units	N
6.4	Symbols		P
	Symbols used comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	Appendix D and IEC 417 applied	P
6.5	Colours of insulation of conductors		P
	a) Protective earth conductor has green/yellow insulation	Green/yellow conductor used	P
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations	Green/yellow conductor used	P
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow	Protective earth conductor only	P
	d) Colour of neutral conductor	Approved power supply cord	P
	e) Colours of phase conductors	Approved power supply cord	P
	Compliance with IEC 227 and IEC 245	Complied with IEC 227	P
	f) Additional protective earthing in multi-conductor cords are marked green/yellow at the ends of the additional conductors	No multi-conductor cords	N
6.6	Medical gas cylinders and connections		N
	a) In accordance with ISO/R 32	No medical gas cylinders	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	Not used	N
	Yellow used to indicate caution or attention required	Not used	N

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Clause	Requirement – Test	Result - Remark	Verdict
	Green used to indicate ready for action	Not used	N
	b) Colour red used only for push-buttons by which a function is interrupted in case of emergency	Not used	N
6.8	Accompanying documents		P
6.8.1	Equipment is accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Provided in the User's manual	P
	Classifications specified in Cl. 5. are included in both the instructions for use and the technical description	Both the instructions for use and technical description are not separable	N
	Markings specified in 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	All applicable markings are provided on the equipment	P
	Warning statements and the explanation of warning symbols provided in the accompanying documents	Warning statement added to accompanying document	P
6.8.2	Instructions for use		P
	a) General information provided in instructions for use:		P
	- state the function and intended application of the equipment	Provided in the User's manual	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	No consumable material	P
	- 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		P
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance		P
	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

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Clause	Requirement – Test	Result - Remark	Verdict
	- 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	No signal output or signal input parts	N
	d) Details about acceptable cleaning, disinfection or sterilization methods included		P
	e) Warning statement for mains operated equipment with additional power source	No additional power source	N
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	No primary batteries	N
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	No rechargeable batteries	N
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	No specified power supply or battery charger	N
	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	Provided in the User's 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	No such parts	N
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	No repairable equipment parts	N
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging		P
7.	POWER INPUT		
	Power input measurements	(see appended table 7)	P
10.	ENVIRONMENTAL CONDITIONS		
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer	See 6.8.3 d)	N

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Clause	Requirement – Test	Result - Remark	Verdict
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 4 kVA	220-240 V~	P
	Rated voltage not exceeding 500 V for all other equipment		N
	Rated input frequency not more than 1 kHz	50/60 Hz	P
	b) Internal replaceable electric power source specified	No internal power source	N

14.	REQUIREMENTS RELATED TO CLASSIFICATION		
14.4	a) Class I and Class II equipment in addition to basic insulation provided with an additional protection	Metal enclosure is provide with protective earth conductor and plastic enclosure is separated from live part by reinforced insulation	P
	b) Equipment supplied from external d.c. source of reverse polarity results in no safety hazard	No external d.c. source	N
14.5	b) Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected	Not internally powered equipment	N
14.6	c) Applied parts intended for direct cardiac application are of type CF	No applied parts for direct cardiac application	N

15.	LIMITATION OF VOLTAGE AND/OR ENERGY		
	b) Voltage measured one sec after disconnection of the mains plug does not exceed 60 V	(See appended table 15)	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 manual discharging device	N

16.	ENCLOSURES AND PROTECTIVE COVERS		
	a) Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	No accessible live parts	P
	Insertion or removal of lamps: protection against contact with live parts provided	No such lamps	N
	b) Opening in a top cover so positioned that accessibility of live parts by a test rod is prevented	No accessible live parts	P
	c) 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	No such parts	N
	- separated from live parts by one of the means described in Cl. 17. g)		N
	d) Parts with voltage exceeding 25 V a.c. or 60 V d.c. which cannot be disconnected by external mains switch or plug protected against contact	No such parts	N
	e) Removable enclosures protecting against contact with live parts		P
	Removal possible only with the aid of a tool	No removable enclosure without tool	P
	Use of automatic device making parts not live when the enclosure is opened or removed	No automatic device	N
	Exception 16 e) applied to the following parts :	None	N
	f) Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	No opening for the pre-set controls	N

17.	SEPARATION		
	a) Separation method of the applied part from live parts:		P
	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		P
	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 such connection	P
	d) Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		N
	g) 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)		N
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N

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Clause	Requirement – Test	Result - Remark	Verdict
	4) by double or reinforced insulation		P
	5) by protective impedances limiting current to accessible part		N
	Additional leakage current test in single fault conditions		N
	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	No defibrillation-proof applied parts	N
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		N

18.	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION		
	a) Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal	(see appended table 18)	P
	b) Protective earth terminals suitable for connection to the protective earth conductor	Appliance inlet	P
	e) Potential equalization conductor:		N
	- readily accessible	No potential equalization conductor	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 $\leq 0,1 \Omega$	Appliance inlet used	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 $\leq 0,2 \Omega$		N
	g) If the impedance of protective earth connections other than in Cl. 18. f) exceeds $0,1 \Omega$, the allowable value of the enclosure leakage current is not exceeded in single fault condition		N
	k) Functional earth terminal not used to provide protective earthing	No functional earth terminal	N

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Clause	Requirement – Test	Result - Remark	Verdict
	I) 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		N
	- explanation of functional earth terminal provided in the accompanying documents		N

19.	CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS		
19.1	b) Leakage currents		P
	Earth leakage current	(see appended table 19)	P
	Enclosure leakage current	(see appended table 19)	P
	Patient leakage current	(see appended table 19)	P
	Patient auxiliary current		N

20.	DIELECTRIC STRENGTH AT OPERATING TEMPERATURE		
	Overall compliance with Cl. 20.	(see appended table 20)	P

21.	MECHANICAL STRENGTH		
	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	Not portable equipment	N
21.3	No damage to parts of patient support and/or immobilization system after the loading test	(see appended table 21)	P
21.5	Hand-held equipment or equipment parts are safe after drop test	No hand-held equipment	N
21.6	Portable and mobile equipment is able to withstand rough handling	Not portable or mobile equipment	N

22.	MOVING PARTS		
22.2	a) Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment	Not transportable 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	Guard provided	P

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Clause	Requirement – Test	Result - Remark	Verdict
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	No removable enclosure without tool	P
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	Only manually movable parts to be operated by operator	P
22.6	Parts of equipment subject to mechanical wear are accessible for inspection	No such parts	N
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard	No safety hazard	N
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard	No emergency switch	N
	Devices for emergency stopping able to break the full load current of the relevant circuit, taken into account possible stalled motor currents		N
	Means for stopping of movements operate as a result of one single action		N
23.	SURFACES, CORNERS AND EDGES		
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	No rough corners, no sharp edges; all rounded and smooth	P
24.	STABILITY IN NORMAL USE		
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°	Stationary equipment	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	See clause 24.1	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	Stationary equipment	N
	- instructions for lifting and handling during assembly		N

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Clause	Requirement – Test	Result - Remark	Verdict
	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	Not portable equipment	N
25.	EXPELLED PARTS		
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		
28.3	Suspension system with safety device:		N
	Safety device provided where the integrity of a suspension depends on parts which may have hidden defects, or on parts having safety factors not complying with 28.4	No suspension system	N
	Safety device has safety factors complying with 28.4.2		N
	Clear indication to the operator that the safety device has been activated after failure of suspension means		N
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		
29.2	Equipment not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0,5 mR)	No ionizing radiation	N
36.	ELECTROMAGNETIC COMPATIBILITY		
	Equipment complies with IEC 601-1-2	See page 2	N

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Clause	Requirement – Test	Result - Remark	Verdict
37.	COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT		
	Requirements for category AP and APG equipment (Cl. 37. - 41.)	Not AP or APG equipment	N
42.	EXCESSIVE TEMPERATURES		
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures specified in 10.2.1	(see appended table 42)	P
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25 °C ambient	(see appended table 42)	P
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41 °C	41 °C not exceeded	P
42.5	Guards to prevent contact with hot surfaces removable only with a tool	No hot surfaces	N
43.	FIRE PREVENTION		
	Strength and rigidity necessary to avoid a fire hazard	See clause 21	P
44.	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION, DISINFECTION		
44.2	If equipment contains a liquid reservoir:		N
	- the equipment is electrically safe after 15% overflow 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 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)	Not use of liquids	N
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard	No contain 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	IPX0	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		
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	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		
	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	See page 2	N
49.	INTERRUPTION OF THE POWER SUPPLY		
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	Interruption: Unit shut-downed Restoration: Unit start back-up	P
49.3	Means are provided for removal of mechanical constraints on a patient in case of a supply mains failure	No mechanical constraints on a patient	N

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Clause	Requirement – Test	Result - Remark	Verdict
51.	PROTECTION AGAINST HAZARDOUS OUTPUT		
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	No such multi-purpose unit	N
52.	ABNORMAL OPERATION AND FAULT CONDITIONS		
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.)	Approved power supply and components used	N
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	See page 2	N
52.5.2	Failure of thermostat presents no safety hazard	No thermostat	N
52.5.3	Short-circuiting of either constituent part of double insulation presents no safety hazard	Basic insulation or reinforced insulation	N
52.5.5	Impairment of cooling: temperatures not exceeding 1,7 times the values of Cl. 42. minus 17,5 °C	Natural cooling only	N
52.5.6	Locking of moving parts presents no safety hazard	Certified motors used	N
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	No motor capacitors	N
52.5.8	Duration of motors locked rotor test in compliance with 52.5.8		N
52.5.9	Failure of one component at a time presents no safety hazard		N
52.5.10	Overload of heating elements presents no safety hazard		N
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	No such motors	N
	h) Equipment with three-phase motors can safely operate with one phase disconnected	No three-phase motors	N
56.	COMPONENTS AND GENERAL ASSEMBLY		
	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	Components rated acc. to intended application	P
	Ratings of mains components are identified	Complied	P
	d) Components, movements of which could result in a safety hazard mounted securely	Components are mounted securely to prevent movement	P

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Clause	Requirement – Test	Result - Remark	Verdict
	f) Conductors and connectors are secured and/or insulated to prevent accidental detachment resulting in a safety hazard	Cable binders and tubing used	P
56.3	a) Connectors provide separation required by Cl. 17. g)	See clause 17 g)	P
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	No such plugs	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	Prevented	P
	c) Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages	No conductive patient connection	N
56.4	Connections of capacitors		P
	Not connected between live parts and non-protectively earthed accessible parts	No such connection of capacitors	P
	If connected between mains part and protectively earthed metal parts, comply with IEC 384-14	No such capacitor	N
	Enclosure of capacitors connected to mains part and providing only basic insulation is not secured to non-protectively earthed metal parts	No such capacitor	N
	Capacitors or other spark-suppression devices are not connected between the contacts of thermal cut-outs	No such connections	P
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	No such protective devices	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 thermal cut-outs	P
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits	No such thermal safety devices	N
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard	No safety hazard	N
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard	No such thermal cut-out	N
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times	No such components	N

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Clause	Requirement – Test	Result - Remark	Verdict
	Non-self-resetting over-current releases operated 10 times	No non-self-resetting over-current release	N
	b) Thermostats with varying temperature settings clearly indicated	No means for temperature setting of thermostat	N
	Operating temperature of cut-outs is clearly indicated		N
56.7	Batteries		N
	a) Battery compartments are:		N
	- adequately ventilated	No batteries	N
	- accidentally short-circuiting is prevented		N
	b) Incorrect polarity of connection prevented		N
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	Complied	P
	- to indicate the operation of non-luminous heaters if a safety hazard could result	No such heaters	N
	- to indicate when output exists if a safety hazard could result	No such output	N
	- charging mode indicator is provided	No charging mode	N
56.10	Actuating parts of controls		N
	b) Actuating parts are adequately secured to prevent them from working loose during normal use	No actuating parts	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	No detachable indicating devices	N
	c) Stops are provided on rotating controls:		N
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard		N
	- to prevent damage to wiring		N
56.11	Cord-connected hand-held and foot-operated control devices		N
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17. g)	No such control devices	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

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Clause	Requirement – Test	Result - Remark	Verdict
	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		
57.1	Isolation from supply mains		P
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	Mains plug provided	P
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents	Provided in the instruction manual	P
	d) Switches used to comply with 57.1 a) comply with the creepage distances and air clearances as specified in IEC 328		N
	f) Mains switches not incorporated in a power supply cord	No mains switch	N
	h) Appliance couplers and flexible cords with mains plugs provide compliance with 57.1 a)	See clause 57.1 a)	P
	m) Fuses and semiconductor devices are not used as isolating devices	Not used	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 equipment	N
57.3	Power supply cords		P
	a) Not more than one connection to a particular supply mains	Single connection	P
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously	No alternative connection	N
	The mains plug has only one power supply cord	Only one cord	P
	Non-permanently connected equipment provided with power supply cord or appliance inlet	Appliance inlet	P
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53	IEC 227, designation 53	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 external metal parts exceeding 75 °C	N
	c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV	Measured current: < 2 A Nominal cross-sectional area: 0.75 mm ²	P
	d) Stranded conductors not soldered if fixed by any clamping means	Detachable power cord set	N
57.4	Connection of power supply cords		N
	a) Cord anchorages:		N
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting	Appliance inlet provided	N
	Tying the cord into a knot or tying the ends with string not used		N
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		N
	Cord anchorages made of metal provided with an insulating lining		N
	Clamping screws do not bear directly on the cord insulation		N
	Screws associated with cable replacement are not used to secure other components		N
	Conductors of the power supply cord so arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals		N
	b) Power supply cord protected against excessive bending	Appliance inlet provided	N
	c) Adequate space inside equipment to allow the supply cable conductors to be introduced and connected	Appliance inlet provided	N
57.5	Mains terminal devices and wiring of mains part		N
	a) Mains connected equipment other than those with a detachable supply cord is provided with mains terminals, where connections are made with screws, nuts or equally effective methods	Detachable supply cord and appliance inlet provided	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

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Clause	Requirement – Test	Result - Remark	Verdict
	b) Terminals closely grouped with any protective earth terminal	Approved appliance inlet provided	N
	Mains terminal devices accessible only with use of a tool		N
	Mains terminal devices located or shielded so that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact		N
	c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened	Appliance inlet provided	N
	d) Cord terminals shall not require special preparation of the conductor	Approved appliance inlet provided	N
57.6	Mains fuses and over-current releases		P
	Fuses or over-current releases provided accordingly for Class I and Class II	Class I equipment; Circuit breaker used	P
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current	250 V, 15 A	P
	Protective earth conductor not fused	Not used	P
	Neutral conductor not fused for permanently installed equipment	Not permanently installed equipment	N
57.8	Wiring of mains part		P
	a) Individual conductors in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC 227 or IEC 245, treated as bare conductor	Complied with IEC 227	P
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply	0.75 mm ² Cu	P
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits are sufficient to prevent any fire hazard	Sufficient size according to rating of circuits	P
57.9	Mains supply transformers		N
57.9.1	Overheating		N
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative	UL 60601-1 certified power supply used	N
	a) Short-circuit of secondary windings not caused excessive temperature		N
	b) Overload of secondary windings not caused excessive temperature		N

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Clause	Requirement – Test	Result - Remark	Verdict
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests		N
57.9.4	Construction		N
	a) Separation of primary and secondary windings:		N
	- separate bobbins or formers		N
	- one bobbin with insulating partition		N
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0,13 mm		N
	- concentrically wound on one bobbin with windings separated by double insulation		N
	c) Means provided to prevent displacement of end turns		N
	d) Insulated overlap of not less than 3 mm if a protective earth screen has only one turn		N
	e) Insulation between the primary and secondary winding in transformers with double insulation:		N
	- 1 insulation layer having a thickness of at least 1 mm		N
	- at least 2 insulation layers with a total thickness of at least 0,3 mm		N
	- 3 layers provided that each combination of 2 layers can withstand the dielectric strength test for reinforced insulation		N
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having a total thickness at least 0,3 mm extending at least 20 mm outside the winding		N
57.10	Creepage distances and air clearances		P
	a) Values: compliance with at least the values of Table XVI	(see table for insulation diagram)	P
	Creepage distances for slot insulation of motors are at least 50% of the specified values	Not required	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	UL 60601-1 certified power supply used	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 parts	N

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Clause	Requirement – Test	Result - Remark	Verdict
58.	PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS		
58.1	Clamping means of the protective earth terminal	See clause 57.5 c)	N
	Not be able to loosen without the aid of a tool	Appliance inlet used	N
	Screws for internal earth connections are covered or protected against loosening from outside		N
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal	Approved appliance inlet used	P
58.8	The protective earth terminal is not used for the mechanical connection or the fixing of any component not related to earthing	Internal earth terminals are used only for earthing purposes	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	Approved appliance inlet used	P
59.	CONSTRUCTION AND LAYOUT		
59.1	Internal wiring		P
	a) Cables and wiring protected against contact with a moving part	Wiring is bundled and detoured to avoid rough edges and burrs	P
	Wiring having basic insulation only protected by additional fixed sleeving	Tubing used	P
	Components are not likely to be damaged in the normal assembly or replacement of covers	Service areas are supposed to be accessed by authorised, well trained personnel only	P
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead	No such leads	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 strength test	Complied with IEC 227	P
	Conductors subjected to temperatures exceeding 70 °C, have an insulation of heat-resistant material	No conductors touchable to excessive temperature part	N
	d) Aluminium wires of less than 16 mm ² cross-section not used	No aluminium wires used	N
	f) Connecting cords between equipment parts considered as belonging to the equipment	No such equipment parts	N
59.2	Insulation		P
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation	(see appended table: additional tests)	P

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Clause	Requirement – Test	Result - Remark	Verdict
	c) Insulation not likely to be impaired by deposition of dirt or dust resulting from wear of parts	Not likely to be impaired by deposition of dirt or by dust	P
	Parts of rubber resistant to ageing	Class I equipment	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	No such fuse	N
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.	No such protective devices	N
59.4	Oil containers		N
	Oil containers adequately sealed	No oil containers	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
6.1	TABLE: marking durability		P
marking tested		remarks	
Adhesive label on enclosure		Legible, not loosed and curled	

7.	TABLE: power input				P
operating condition	Voltage (V)	Frequency (Hz)	Current (A)	Power (VA)	remarks
Normal operation with maximum load	198	50	1.21	239.54	-
	198	60	1.12	221.08	-
	220	50	1.10	242.31	+15 %
	220	60	1.10	242.12	+15 %
	240	50	1.52	245.85	+15 %
	240	60	1.50	210.22	+15 %
	264	50	1.59	267.08	-
	264	60	1.58	243.49	-

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	
supply pins (pin 1 & pin 2)	0	0	0	0	0	0	0	0	0	0	60 V
line pin 1 and earth pin	0	0	0	0	0	0	0	0	0	0	60 V
line pin 2 and earth pin	0	0	0	0	0	0	0	0	0	0	60 V

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

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
-	-	-	-	-	-

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Clause	Requirement – Test	Result - Remark	Verdict
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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 (Ω)	remarks	
PE contact in appliance inlet – Accessible metal enclosure	25	1.0	0.04	0.1 Ω	

19.	TABLE: leakage current				P
type of leakage current and test condition (including single faults)	supply voltage (V)	supply frequency (Hz)	measured max. value (μ A)	remarks	
ER; Fig.16; MD; B/A; S1=1; S5=1; NC	264	50	1 / 1	500 μ A	
ER; Fig.16; MD; B/A; S1=1; S5=0; NC	264	50	1 / 1	500 μ A	
ER; Fig.16; MD; B/A; S1=0; S5=1; SFC	264	50	1 / 1	1 000 μ A	
ER; Fig.16; MD; B/A; S1=0; S5=0; SFC	264	50	1 / 1	1 000 μ A	
EN; Fig.18; MD1; B/A; S1=1; S5=1; S7=1; NC	264	50	1 / 1	100 μ A	
EN; Fig.18; MD1; B/A; S1=1; S5=0; S7=1; NC	264	50	1 / 1	100 μ A	
EN; Fig.18; MD1; B/A; S1=0; S5=1; S7=1; SFC	264	50	1 / 1	500 μ A	
EN; Fig.18; MD1; B/A; S1=0; S5=0; S7=1; SFC	264	50	1 / 1	500 μ A	
EN; Fig.18; MD1; B/A; S1=0; S5=0; S7=1; SFC	264	50	1 / 1	500 μ A	
EN; Fig.18; MD1; B/A; S1=1; S5=1; S7=0; SFC	264	50	1 / 1	500 μ A	
EN; Fig.18; MD2; B/A; S1=1; S5=1; S7=1; NC	264	50	1 / 1	100 μ A	
EN; Fig.18; MD2; B/A; S1=1; S5=0; S7=1; NC	264	50	1 / 1	100 μ A	
EN; Fig.18; MD2; B/A; S1=0; S5=1; S7=1; SFC	264	50	1 / 1	500 μ A	
EN; Fig.18; MD2; B/A; S1=0; S5=0; S7=1; SFC	264	50	1 / 1	500 μ A	
EN; Fig.18; MD2; B/A; S1=1; S5=1; S7=0; SFC	264	50	1 / 1	500 μ A	
EN; Fig.18; MD2; B/A; S1=1; S5=0; S7=0; SFC	264	50	1 / 1	500 μ A	
P; Fig.20; MD; B/A; S1=1; S5=1; S7=1; NC	264	50	1 / 1	100 μ A	
P; Fig.20; MD; B/A; S1=1; S5=0; S7=1; NC	264	50	1 / 1	100 μ A	
P; Fig.20; MD; B/A; S1=0; S5=1; S7=1; SFC	264	50	1 / 1	500 μ A	

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Clause	Requirement – Test	Result - Remark			Verdict
P; Fig.20; MD; B/A; S1=0; S5=0; S7=1; SFC	264	50	1 / 1	500 μ A	
P; Fig.20; MD; B/A; S1=1; S5=1; S7=0; SFC	264	50	1 / 1	500 μ A	
P; Fig.20; MD; B/A; S1=1; S5=0; S7=0; SFC	264	50	1 / 1	500 μ A	
(Record at least maximum measured value for each test required by Cl._19. and the specific conditions of the test circuit and equipment).					
<u>Abbreviations used:</u> ER - Earth leakage current EN - Enclosure leakage current P - Patient leakage current PM - Patient leakage current with mains on the applied parts PA - Patient auxiliary current Fig. 15 - refers to Fig. 15 in IEC 601-1 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	
A (A-f)	BI	240	1 500	No breakdown	
B (A-a1)	BI	240	1 500	No breakdown	
C (A-a2)	RI	240	4 000	No breakdown	
D (B-a)	RI	240	4 000	No breakdown	

21.	TABLE: mechanical strength		P
part under test	test (impact, drop, force, handle, rough handling, mobile)	remarks	
21.a) Enclosure	force (45 N)	No damage	
21.b) Enclosure	impact (0.5 J)	No damage	
21.3) Patient bed	test load (1.35 kN)	No damage	

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Clause	Requirement – Test	Result - Remark	Verdict
24.	TABLE: stability		N
part under test	test condition	remarks	
-	-	-	

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

42.	TABLE: normal temperature				P
	supply voltage	264 V, 50 Hz		—	
	ambient temperature °C	26.7		—	
	test condition	Maximum normal load		—	
measuring location	measured value at ambient	corrected value for 40 °C	corrected value for 25 °C	allowable value (°C)	
Appliance inlet	28.2	-	26.5	85	
Residual current operated circuit breakers with over current protection	30.2	-	28.5	85	
Noise filter	29.7	43.0	-	105	
Circuit breaker for over current	31.2	-	29.5	85	
Relay	41.5	54.8	-	105	
Power supply	29.4	-	-	-	
PC body	30.6	43.9	-	60	
Monitor	31.1	44.4	-	85	
Metal enclosure (Top part)	28.3	41.6	-	60	
Metal enclosure (Side part)	27.3	40.6	-	60	
DC Motor 1 (Ankle part)	25.8	39.1	-	105	
DC Motor 2 (Bed's top part)	26.3	39.6	-	105	
DC Motor 3 (Bed's top part)	25.9	39.2	-	105	
DC Motor 4 (Bed's middle part)	28.3	41.6	-	105	
DC Motor 5 (Bed's middle part)	26.2	39.5	-	105	
DC Motor 6 (Bed's side part)	26.9	40.2	-	105	
Applied part	26.4	-	-	41	

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Clause	Requirement – Test	Result - Remark	Verdict
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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
Humidity (93 %; 26 °C; 48 h)		Equipment	No hazards
Cleaning		Equipment	Tested according to instructions for use of the manufacturer. No deterioration and passed the dielectric strength test of clause 20.

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			N
test type, condition and clause reference		observed results	remarks	
-		-	-	

56.1	TABLE: lists of critical component parts					P
object/part No.	manufacturer /trademark	type/model	technical data	standard	mark(s) of conformity ¹⁾	
Power cord set	Hwajin KDK	KKP-4819R	250 V~, 16 A, H05VV-F, 3G0.75 mm ²	IEC 60884-1	VDE	
Appliance inlet	Rong Feng	SS-120	250 V~, 10 A	EN 60320-1, EN 60127-6	VDE	
Residual current operated circuit-breakers with integral over current protection	LS industrial system	32KGRa	In: 15 A, Vn: 220 V~, Icn: 15 mA, 2 protected poles	IEC 61009-1, IEC 61009-2-1	KEMA	
Circuit breaker for over current	LS industrial system	BS32a	In: 15 A, Vn: 220 V~, 2 protected poles	IEC 60898	KEMA	
Noisefilter	Fine Suntronix	SN-M3H-CM	250 V~, 3 A	EN 133200	TUV	
Relay	Honeywell	SZR-LY series	240 V, 24 V d.c.	EN 50081	TUV	

EN 60601-1:1990+A1+A2+A13					
Clause	Requirement – Test			Result - Remark	Verdict
Power supply	SYNQOR INC	AQ0300MU****	Input: 100-240 V~, 5 A Output: 24 V d.c.	UL 60601-1	UL
DC motor	SPG	S6D Series	24 V d.c., 15 W	EN 60601-1	CE
Linear Actuator	HIWIN	LAS3, LAS4	24 V d.c.	EN 60601-1	CE
Linear Actuator	LINAK	LA31	24 V d.c.	EN 60601-1	TUV
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	
-	-	-	-	-	-	

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

57.9.1 a)	TABLE: transformers short-circuit					N
winding under test	protection	measured temperatures (°C)			test duration	remarks
		primary	secondary	ambient		
-	-	-	-	-	-	-

EN 60601-1:1990+A1+A2+A13							
Clause	Requirement – Test				Result - Remark		Verdict
57.9.1 b)	TABLE: overload						N
winding under test	protection	measured temperatures (°C)			test duration	test current or thermal cut-out temp.	remarks
		primary	secondary	ambient			
57.9.2	TABLE: transformer dielectric strength						N
transformer under test	test voltage applied to	test voltage	test frequency	remarks			
-	-	-	-	-			
	TABLE: additional tests						P
Clause	test type and condition			remarks and observed results		verdict	
59.2 b)	Ball-pressure test; Terminal block; 125 °C			1.0 mm		< 2.0 mm	

Photograph

Fig. 1: Overall veiw



Fig. 2 : Overall view



Photograph

Fig. 3 : Inside view



Fig. 4 : Power supply



Photograph

Fig. 5 : Inside view (DC motors)

