

TEST REPORT IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for basic safety and essential performance	
Report Reference No.	08030601.s01
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Address	Smidshornerweg 18 9822 ZG Niekerk, The Netherlands
Address	--
Applicant's name	Medi Flowery ApS
Address	Kisumpakren 112, st.th. DK-2660, Demark
Test specification:	
Standard	EN 60601-1:2006
Test procedure	TSD's EVT, EVE, EVM
Non-standard test method.....	N/A
Test Report Form No.	IEC 601
TRF Originator.....	TR-EPS
Master TRF.....	Dated 08-11
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Test item description	Stimulation of the body
Trade Mark	Medikzap
Manufacturer	Medi-Flowery
Model/Type reference	TA
Ratings	3VDC

Copy of marking plate:



Photograph of EUT



Test item particulars			
Classification of installation and use		Internally powered by 2 alkaline LR6 AA batteries	
Possible test case verdicts:			
- test case does not apply to the test object : N/A			
- 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:	S.F.C.
- operational insulation:	OP	- basic insulation:	BI
- double insulation:	DI	- supplementary insulation:	SI
- basic insulation between parts of opposite polarity:	BOP	- reinforced insulation:	RI
General remarks:			
This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IEC 60601-1.			
The test 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 Issuing testing laboratory.			
"(see Enclosure #)" refers to additional information appended to the report.			
"(see appended table)" refers to a table appended to the report.			
Throughout this report, a point (coma) is used as the decimal separator.			
List of test equipment must be kept on file and available for review.			
This Test Report Form is intended for the investigation of medical electrical systems. It can only be used together with IEC 60601-1 Test Report.			
General product information:			
The Medikzap is a modern, electronic equipment generating a square wave current transferred to the body via two electrodes held in the hands. The generated wave has an amplitude of up to 9Volts peak-to-peak and has built-in protection against output short-circuit and reverse battery polarity.			

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Clause	Requirement + Test	Result - Remark	Verdict

4	GENERAL REQUIREMENTS		-
4.1	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.)	Appliance is battery operated at 3VDC	P

5	GENERAL REQUIREMENTS FOR TESTING		-
5.1	Tests described in this standard are type tests		P

6	CLASSIFICATION		-
6.1	General		-
6.2	Protection against electric shock		N/A
	Class I equipment		N/A
	Class II equipment		N/A
	Internally powered equipment	3VDC	P
6.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 60529	No IP classification given	N/A
6.4	Methods of sterilization or disinfection	No sterilization required	N/A
6.5	Equipment for use in an oxygen rich environment.		N/A
6.6	Mode of operation:		P
	-continuous operation		N/A
	-short-time operation, specified operation; period:		N/A
	-intermittent operation, specified operation; rest period :	4 times 7 minutes with 9 minutes rest in between per day	P
	-continuous operation with short-time, stated permissible loading time ::		N/A
	-continuous operation with intermittent, stated permissible loading/rest time :		N/A

7	IDENTIFICATION, MARKING AND DOCUMENTS		-
7.1	Usability of the identification, marking and documents		-
7.2	Marking on the outside of equipment or equipment parts		-
	b) Internally powered equipment		P
	c) Markings of the specific power supply affixed		N/A
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		N/A
	e) Name and/or trademark of the manufacturer or supplier:		P
	f) Model or type reference :		P
	g) Rated supply voltages or voltage range(s)		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Number of phases :		N/A
	Type of current :		N/A
	h) Rated frequency or rated frequency range(s) (Hz) :		N/A
	j) Rated power input (VA, W or A) :		N/A
	k) Power output of auxiliary mains socket-outlets		N/A
	l) Class II symbol		N/A
	Symbol for degree of protection against ingress of water provided :		N/A
	Symbol for protection against electric shock :		N/A
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets		N/A
	Symbol for protection of defibrillation-proof applied parts		N/A
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N/A
	m) Mode of operation (if no marking, suitable for continuous operation)	Electronics switches off after 7 minutes	P
	n) Types and rating of external accessible fuses :		N/A
	p) Ratings of external output :		N/A
	q) Symbol for physiological effect(s):		N/A
	- attention, consult accompanying documents		N/A
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N/A
	r) Anaesthetic-proof symbol: AP or APG :		N/A
	s) Dangerous voltage symbol		N/A
	t) Special cooling requirements		N/A
	u) Limited mechanical stability		N/A
	v) Protective packing requirement(s)		N/A
	- Marking(s) for unpacking safety hazard(s)		N/A
	- Equipment or accessories supplied sterile, marked as sterile		N/A
	y) Potential equalization terminal		N/A
	- Functional earth terminal		N/A
	z) Removable protective means		N/A
	Durability of marking test		P
7.3	Marking on the inside of equipment or equipment parts		P
	a) Nominal voltage of permanently installed equipment		N/A
	b) Maximum power loading for heating elements or holders for heating lamps		N/A
	c) Dangerous voltage symbol		N/A
	d) Type of battery and mode of insertion	Only polarization marked	P
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator		N/A
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram		N/A
	f) Protective earth terminal		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	g) Functional earth terminal		N/A
	h) Supply neutral conductor in permanently installed equipment (N)		N/A
	j) Markings required in 6.2 f), h), k) ,and l) remain visible after connection and are not affixed to parts which have to be removed		N/A
	- Markings comply with IEC 445		N/A
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)		N/A
	l) Statement for suitable wiring materials at temperatures over 75 °C		N/A
	n) Capacitors and/or circuit parts marked as required in Sub-clause 15c		N/A
7.4	Marking of controls and instruments		P
	a) Mains switch clearly identified	Internally powered equipment	N/A
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light	Symbol I used on MAX button	P
	b) Indication of different positions of control devices and switches	See above	P
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device		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		N/A
7.5	Safety signs selected from ISO7010		P
7.6	Symbols		P
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	See 6.3	P
7.7	Colors of the insulation of conductors		N/A
	a) Protective earth conductor has green/yellow insulation	Internally powered equipment	N/A
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		N/A
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow		N/A
	d) Color of neutral conductor :		N/A
	e) Colors of phase conductor(s) :		N/A
	- Compliance with IEC 227 and IEC 245		N/A
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N/A
7.8	Indicator lights and push-buttons		P
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action		N/A
	- Yellow used to indicate caution or attention required		P

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Color red used only for push-buttons by which a function is interrupted in case of emergency		N/A
7.9	Accompanying documents		P
7.9.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Document available	P
	Classifications specified in Clause 5 included in both the instructions for use and the technical description		P
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment		P
	Warning statements and the explanation of warning symbols provided in the accompanying documents		P
7.9.2	Instructions for use		P
	a) General information provided in instructions for use		P
	- state the function and intended application of the equipment		P
	- include an explanation of: the function of controls, displays and signals		P
	- the sequence of operation		P
	- the connection and disconnection of detachable parts and accessories		P
	- the replacement of material which is consumed during operation		N/A
	- 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		N/A
	- explanation of figures, symbols, warning statements and abbreviations on the equipment		P
	c) Signal output or signal input parts intended only for connection to specified equipment described		P
	d) Details about acceptable cleaning, disinfection or sterilization methods included		P
	e) Warning statement for mains operated equipment with additional power source		N/A
	f) A warning to remove primary batteries if equipment is not likely to be used for some time		P

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Clause	Requirement + Test	Result - Remark	Verdict
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries		N/A
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 60601-1		N/A
	j) Identification of any risks associated with the disposal of waste products, residues, etc.		N/A
	- Advice in minimizing these risks		N/A
7.9.3	Technical description		P
	a) All characteristics essential for safe operation provided		P
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment		P
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use		P
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided		P
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging		P

8	PROTECTION AGAINST ELECTRICAL HAZARDS		-
8.1	Fundamental rule of protection against electrical hazards		P
8.2	Requirements related to power sources		N/A
8.3	Classification of applied parts	Not specified in the accompanying documents	N/A
8.4	Limitation of voltage and/or energy		-
	Voltage measured one sec after disconnection of the mains plug does not exceed 60V		N/A
	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ		N/A
	Marking provided for manual discharging		N/A
8.5	Separation		-
	Separation method of the applied part from live parts:		-
	1) basic insulation: applied part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N/A
	4) by double or reinforced insulation		N/A
	5) by protective impedances limiting current to applied part		P
	- Additional leakage current test in single fault conditions	Battery powered	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		N/A
	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		N/A
	Separation method of accessible parts other than applied parts from live parts:		P
	1) basic insulation: accessible part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N/A
	4) by double or reinforced insulation		N/A
	5) by protective impedances limiting current to accessible part	Electrodes get max. 9V radio waves	P
	- Additional leakage current test in single fault conditions		N/A
	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N/A
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator		N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		N/A
8.6	Protective earthing, functional earthing and potential equalization		N/A
	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal		N/A
	Protective earth terminals suitable for connection to the protective earth conductor		N/A
	Potential equalization conductor		N/A
	- Readily accessible		N/A
	- Accidental disconnection prevented in normal use		N/A
	- Conductor detachable without the use of a tool		N/A
	- Power supply cord does not incorporate a potential equalization conductor		N/A
	- Connection means marked with Symbol 9, Table D1		N/A
	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1 \Omega$	(see appended table 18)	N/A
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $\leq 0.1 \Omega$	(see appended table 18)	N/A
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part $\leq 0.2 \Omega$	(see appended table 18)	N/A
	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	(see appended table 19)	N/A
	Functional earth terminal not used to provide protective earthing		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Class II equipment with isolated internal screens		N/A
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		N/A
	- functional earth terminal clearly marked		N/A
	- explanation of functional earth terminal provided in the accompanying documents		N/A
8.7	Leakage currents and patient auxiliary currents		N/A
	Leakage currents	Battery powered equipment	N/A
	- earth leakage current		N/A
	- enclosure leakage current		N/A
	- patient leakage current		N/A
	- patient auxiliary current		N/A
8.8	Insulation		-
	General		P
	Distance through insulation	Low voltages max. 9 VDC	P
	Dielectric strength	Battery powered equipment	N/A
8.9	Creepage distances and air clearances		-
	a) Values: compliance with at least the values of Table XVI in the standard		P
	Creepage distances for slot insulation of motors at least 50% of the specified values		N/A
	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	No mains parts in the EUT	N/A
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts	No defibrillation-proof applied parts in the EUT	N/A
8.10	Components and wiring assembly		-
	List of critical components		N/A
	Ratings of components not in conflict with the conditions of use in equipment		P
	Ratings of mains components are identified		P
	Components, movements of which could result in a safety hazard mounted securely		P
	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard		P
	Connectors provide separation		P
	Plugs for connection of patient circuit leads cannot be connected to other outlets on the same equipment		P
	Medical gas connections not interchangeable		N/A
	Accessible metal parts cannot become live when detachable interconnection cord between different parts of equipment is loosened or broken		P
	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Connections of capacitors		N/A
	Not connected between live parts and non-protectively earthed accessible parts		N/A
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14		N/A
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts		N/A
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs		N/A
	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment		N/A
	Temperature and overload control devices		N/A
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment		N/A
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits		N/A
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		N/A
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		NA
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times		N/A
	Non-self resetting over-current releases operated 10 times		N/A
	Thermostats with varying temperature settings clearly indicated		NA
	Operating temperature of thermal cut-outs indicated		N/A
	Batteries		P
	a) Battery compartments:		P
	- adequately ventilated		P
	- accidentally short-circuiting is prevented		P
	b) Incorrect polarity of connection prevented		P
	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used.		N/A
	- to indicate that equipment is energized		P
	- to indicate the operation of non-luminous heaters if a safety hazard could result		N/A
	- to indicate when output exists if a safety hazard could result		N/A
	- charging mode indicator provided		N/A
	Actuating parts of controls		P
	Actuating parts are adequately secured to prevent them from working loose during normal use		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Controls are secured to prevent the movement relative to scale marking (safety related only)		P
	Detachable indicating devices are prevented from incorrect connection without the use of tool		N/A
	Stops are provided on rotating controls:		N/A
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard		N/A
	- to prevent damage to wiring		N/A
	Cord-connected hand-held and foot-operated control devices		N/A
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g		N/A
	b) Hand-held control devices comply with the requirement and test of Sub-clause 21.5		N/A
	- Foot-operated control devices designed to support the weight of an adult human being	(see appended table 56.11b)	N/A
	c) Devices not change their setting when inadvertently placed		N/A
	d) Foot-operated control devices are at least IPX 1	(see appended table 44)	N/A
	- For surgical use, electrical switching parts are IPX 8		N/A
	e) Adequate strain relief at the cord entry provided	(see appended table 57.4)	N/A
8.11	Mains parts, components and layout		-
	Isolation from supply mains		N/A
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously		N/A
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents		N/A
	d) Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328		N/A
	f) Mains switches not incorporated in a power supply cord		N/A
	h) Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a		N/A
	m) Fuses and semiconductor devices not used as isolating devices		N/A
	Mains connectors and appliance inlets		N/A
	e) Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug		N/A
	g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment		N/A
	Power supply cords		N/A
	a) Not more than one connection to a particular supply mains		N/A
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	The mains plug has only one power supply cord		N/A
	Non-permanently connected equipment provided with power supply cord or appliance inlet		N/A
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53		N/A
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C		N/A
	c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV		N/A
	d) Stranded conductors not soldered if fixed by any clamping means		N/A
	Connection of power supply cords		N/A
	Cord anchorages		N/A
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting		N/A
	Tying the cord into a knot or tying the ends with string not used		N/A
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		N/A
	Cord anchorages made of metal provided with an insulating lining		NA
	Clamping screws do not bear directly on the cord insulation		N/A
	Screws associated with cable replacement are not used to secure other components		N//A
	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/A
	Power supply cord protected against excessive bending		N/A
	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		N/A
	Mains terminal devices and wiring of mains part		N/A
	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		N/A
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced		N/A
	Screws and nuts which clamp external conductors not serve to fix any other component		N/A
	b) Terminals closely grouped with any protective earth terminal		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Mains terminal devices accessible only with use of a tool		N/A
	Mains terminal devices located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact		N/A
	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		N/A
	Mains fuses and over-current releases		N/A
	Fuses or over-current releases provided accordingly for Class I and Class II		N/A
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current		N/A
	Protective earth conductor not fused		N/A
	Neutral conductor not fused for permanently installed equipment		N/A
	Wiring of the mains part		N/A
	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		N/A
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord		N/A
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard		P
	Mains supply transformers		N/A
	Overheating	No mains transformer used in the EUT	N/A
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		N/A
	Short-circuit of secondary windings not caused excessive temperature		N/A
	Overload of secondary windings not caused excessive temperature		N/A
	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests		N/A
	Construction		N/A
	a) Separation of primary and secondary windings		N/A
	- separate bobbins or formers		N/A
	- one bobbin with insulating partition		N/A
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm		N/A

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	- concentrically wound on one bobbin with windings separated by double insulation		N/A
	c) Means provided to prevent displacement of end turns		N/A
	d) Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn		N/A
	e) Insulation between the primary and secondary in transformers with double insulation		N/A
	- 1 insulation layer with thickness of at least 1 mm		N/A
	- at least 2 insulation layers with a total thickness of at least 0.3 mm		N/A
	- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation		N/A
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3 mm extending at least 20 mm outside the winding		N/A

9	PROTECTION AGAINST MECHANICAL HAZARDS		-
9.1	Mechanical hazards		P
9.2	Moving parts		N/A
	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment	No moving parts in the EUT	N/A
	Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation		N/A
	Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices		N/A
	Guides or safeguards are removable only with a tool		N/A
	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator		N/A
	Parts of equipment subject to mechanical wear are accessible for inspection		N/A
	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard		N/A
	Means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard		N/A
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents		N/A
	Means for stopping of movements operate as a result of one single action		N/A
9.3	Surfaces, corners and edges		-

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Clause	Requirement + Test	Result - Remark	Verdict
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered		P
9.4	Instability in normal use		-
	Equipment does not overbalance during normal use when tilted through an angle of 10°		P
	Equipment overbalances when tilted through an angle of 10°		N/A
	- does not overbalance when tilted through an angle of 5° in any position excluding transport		N/A
	- carry a warning notice stating that transport should only be undertaken in a certain position		N/A
	- in the position specified for transport does not overbalance when tilted to an angle of 10°		N/A
	Equipment or its parts with a mass of more than 20 kg is provided with:		N/A
	- suitable handling devices (grips etc.), or		N/A
	- instructions for lifting and handling during assembly		N/A
	b) On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons		N/A
9.5	Expelled parts		-
	Protective means are provided where expelled parts of the equipment could be a hazard		N/A
	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		N/A
9.6	Acoustic energy		NA
9.7	Pressure vessels and parts subject to pressure		-
	Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure	No pressure vessels to the EUT	N/A
	Maximum pressure does not exceed the maximum permissible working pressure for individual parts		N/A
	Unless excessive pressure cannot occur, pressure-relief device provided		N/A
	Pressure-relief device connected as close as possible to the pressure vessel		N/A
	Readily accessible for inspection		N/A
	Not capable of being adjusted or rendered inoperative without a tool		N/A
	Discharge opening located that the released material is not directed towards person		N/A
	Discharge opening located that operation will not deposit material which may cause a safety hazard		N/A
	Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure		N/A
	No shut-off valve between a pressure-relief device and the parts intended to be protected		N/A
	Minimum number of cycles of operation: 100.000		N/A
9.8	Hazards associated with support systems		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

10 PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS			
10.1	X-Radiation		N/A
	EQUIPMENT not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5 mR)		N/A
10.2	Alpha, beta, gamma, neutron or other radiation		N/A
10.3	Microwave radiation		N/A
10.4	Laser and LED's		N/A
10.5	Other visible electromagnetic radiation		N/A
10.6	Infrared radiation		N/A
10.7	Ultraviolet radiation		N/A

11 PROTECTION AGAINST EXCESSIVE TEMPERATURES			
11.1	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
	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient		P
	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C		N/A
	Guards to prevent contact with hot surfaces removable only with a tool		N/A
11.2	Fire prevention		-
	Strength and rigidity necessary to avoid a fire hazard		N/A
11.3	Constructional requirements for fire enclosures		N/A
11.4	Use with flammable anaesthetics		N/A
11.5	Use with flammable agents		N/A
11.6	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection		-
	Equipment contain a liquid reservoir:		N/A
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min	There are no liquid reservoirs to the EUT	N/A
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling)		N/A
	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)		P
	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		N/A
	Equipment sufficiently protected against the effects of humidity		P
	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529		P
	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions		P

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Clause	Requirement + Test	Result - Remark	Verdict

11.7	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		P
11.8	Interruption of the power supply		-
	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard		N/A
	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function		N/A
	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure		N/A

12	PROTECTION AGAINST HAZARDOUS OUTPUT		-
12.1	Accuracy of controls and instruments		N/A
12.2	Usability		P
12.3	Alarm systems		N/A
12.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally		N/A

13	HAZARDS AND FAULT CONDITIONS		-
	Equipment is so designed and manufactured that even in single fault condition no safety hazard exist.		P
	The safety of equipment incorporating programmable electronic systems is checked.		N/A
	Failure of thermostats presents no safety hazards		N/A
	Short-circuiting of either part of double insulation presents no safety hazard		N/A
	Impairment of cooling: temperatures not exceeding 1.7 times the values of minus 17.5°C		N/A
	Locking of moving parts presents no safety hazard		N/A
	Interruption and short-circuiting of motor capacitors presents no safety hazard		N/A
	Duration of motors locked rotor test		N/A
	Failure of one component at a time presents no safety hazard		P
	Overload of heating elements presents no safety hazard		N/A
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection		N/A
	h) Equipment with three-phase motors can safely operate with one phase disconnected		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS		-
14.1	General		N/A

15	CONSTRUCTION		-
15.1	Arrangements of controls and indicators		P
15.2	Serviceability		P
15.3	Mechanical strength		-
	Sufficient rigidity of an enclosure tested by: force of 45 N		P
	Sufficient strength of an enclosure tested by: impact hammer		P
	On portable equipment carrying handles or grips withstand the requirements of the loading test		N/A
	No damage to parts of patient support and/or immobilization system after the loading test		N/A
	Hand held equipment or equipment parts are safe after drop test		P
	Portable and mobile equipment is able to withstand rough handling		P
15.4	Terminals and connections		-
	Clamping means of the protective earth terminal		N/A
	Not be able to loosen without the aid of a tool		N/A
	Screws for internal earth connections are covered or protected against loosening from outside		N/A
	Earth pin of the appliance inlet regarded as the protective earth terminal		N/A
	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing		N/A
	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting		N/A
	Batteries		P
	Cord connected had-held devices		P
	Internal wiring		P
	a) Cables and wiring protected against contact with a moving part		N/A
	Wiring having basic insulation only protected by additional fixed sleeving		P
	Components are not likely to be damaged in the normal assembly or replacement of covers		P
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead		P
	c) Insulating sleeving adequately secured		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test		N/A
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material		N/A
	d) Aluminum wires of less than 16 mm ² cross-section not used		N/A
	Oil containers		N/A
15.5	Mains supply transformers		N/A
16	ME SYSTEMS	Such a system is not used	N/A
17	ELECTROMAGNETIC COMPATIBILITY		-
	Equipment complies with IEC 60601-1-2	(see EMC test report)	-

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Clause	Requirement + Test	Result - Remark	Verdict

7.2	TABLE: marking durability			P
Marking tested				Remarks
Rubbing				No problem found
Supplementary information:				

8.7	TABLE: power input					N/A
Operating condition	Voltage	Frequency	Current	Power	Remarks	
Supplementary information: Battery powered						

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Clause	Requirement + Test	Result - Remark	Verdict

8.11	TABLE: residual voltage in attachment plug										N/A
Voltage measured between:	Measurements [V]										Remarks
	1	2	3	4	5	6	7	8	9	10	

8.11	TABLE: residual voltage or energy in capacitors					N/A
Capacitor and its location	Residual voltage (V)	Time after disconnection (s)	Capacitance value (µF)	Residual energy (mJ)	Remarks	
Supplementary information:						

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Clause	Requirement + Test	Result - Remark	Verdict

153	TABLE: defibrillation-proof applied parts					N/A
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:						

153	TABLE: defibrillation-proof recovery time				N/A
Applied part with test voltage	Test voltage polarity	Recovery time from accompanying documents (s)	Measured recovery time (s)	Remarks	
Supplementary information:					

51	TABLE: protective earthing				N/A
Test location	Test current (A)	Measured voltage (V)	Resistance (ohms)	Remarks	
Supplementary information:					

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Clause	Requirement + Test	Result - Remark	Verdict

8.7	TABLE: leakage current			N/A
Type of leakage current and test condition (including single faults)	Supply voltage	Supply frequency	Measured max. value	Remarks

(Record at least maximum measured value for each test required by Clause 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 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

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Clause	Requirement + Test	Result - Remark	Verdict

8.8	TABLE: dielectric strength			N/A
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced)	Referenc e voltage (V)	Test voltage (V)	Remarks
Supplementary information: Battery powered				

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Clause	Requirement + Test	Result - Remark	Verdict

TABLE: mechanical strength			P
Part under test	Test (impact, drop, force, handle, rough handling, mobile)	Remarks	
Electrode	Impact, drop, rough handling	No problem	
Enclosure	Impact, drop, rough handling	No problem	
Supplementary information:			

TABLE: - stability			N/A
Part under test	Test condition	Remarks	
Supplementary information: Hand-held equipment			

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

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Clause	Requirement + Test	Result - Remark	Verdict

	TABLE: normal temperature		P
Supply voltage . :	Test Condition: :		
Ambient temperature . : 21 °C			
Measuring location	Measured temperature [°C]	Remarks	
Hot spot measurement	Δ t < 5 °C		
Supplementary information: COR - indicates measurements taken using change-of-resistance method			

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Clause	Requirement + Test	Result - Remark	Verdict

11.6	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		N/A
Test type and condition	Part under test	Remarks	
Supplementary information: Enclosure IP44			

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

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Clause	Requirement + Test	Result - Remark	Verdict

TABLE: abnormal operation			N/A
Test type, condition and clause reference	Observed results	Remarks	
Supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

TABLE: lists of critical component parts					N/A
Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity ¹⁾

¹⁾ an asterisk indicates a mark which assures the agreed level of surveillance

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Clause	Requirement + Test	Result - Remark	Verdict

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

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

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

TABLE: cord bending				N/A
Cord under test	Test mass	Measured curvature	Remarks	
Supplementary information:				

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Clause	Requirement + Test	Result - Remark	Verdict

TABLE: transformer short circuit						N/A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
Supplementary information:						

TABLE: overload							N/A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current or thermal cutout temp.	Remarks
		Primary	Secondary	Ambient			
Supplementary information:							

TABLE: transformer dielectric strength					N/A
Transformer under test	Test voltage applied to	Test voltage	Test frequency	Remarks	
Supplementary information:					

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Clause	Requirement + Test	Result - Remark	Verdict

SUMMARY OF CONTENTS:

The equipment has been tested according to standard EN 60601-1 (2006).

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 34 pages of CB Test Report and the following Attachments:

Attachment #	Description	Pages

Note:

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