



TEST REPORT IEC 60601-1 Medical electrical equipment Part 1: General requirements for safety		
Report reference No.....:	9112349067	
Tested by (+ signature).....	David Khaykin	
Compiled by (+ signature)	Anatoly Tsukerman	
Reviewed by (+ signature).....:	Irina Antonov	
Date of issue	17.11.2011	
CB Testing laboratory.....:	SII	
Address	42 Chaim Levanon St. Tel Aviv, ISRAEL	
Testing location	as above	
Applicant.....:	MediTouch Ltd.	
Address	45 Hamelacha, Poleg industrial zone, Netanya, Israel. 42505, POB: 8306	
Standard.....:	IEC 601-1:1988 + A1:1991 + A2:1995, IEC60601-1-1:2000	
Test Report Form No.:	I601-1_C/97-04	
TRF Originator.....:	Underwriters Laboratories Inc.	
Master TRF	dated 97-04	
Copyright blank test report	The bodies participating in the Committee of Certification Bodies (CCB). This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator.	
Test procedure	CB Scheme	
Procedure deviation	CA, US	
Non-standard test method.....:	(other standard apart from the IEC 60601-1 series standards)	
Type of test object.....:	Motion capture devices for rehabilitation training	
Trademark.....:	3DTutor™, ArmTutor™, HandTutor™, LegTutor™	
Model/type reference.....:	3DT100(3DTutor™), AT100(ArmTutor™), HT100(HandTutor™), LT100(LegTutor™)	
Manufacturer	MediTouch Ltd.	
Address	45 Hamelacha, Poleg industrial zone, Netanya, Israel. 42505, POB: 8306	
Rating	AT100: 5Vdc, 100mA (USB); HT100: 5Vdc, 300mA (USB) LT100: 5Vdc, 100mA (USB) 3DT100: 5Vdc, 400mA (USB Charging); Internally powered; 3.7Vdc, 650mAh	



Copy of marking plate:

Manf.: MediTouch
 Model: AT100
 P/N: AS-20-52-01-A
 Input: 5V DC 100mA

SIDE L

Manf.: MediTouch
 Model: AT100
 P/N: AS-20-51-01-A
 Input: 5V DC 100mA

SIDE R

Manf.: MediTouch
 Model: LT100
 P/N: AS-20-50-01-A
 Input: 5V DC 100mA

SIDE L

Manf.: MediTouch
 Model: LT100
 P/N: AS-20-54-01-A
 Input: 5V DC 100mA

SIDE R

Manf.: MediTouch
 Model: HT100
 P/N: AS-10-17-00-A
 Input: 5V DC 300mA

Manf.: MediTouch Ltd.
 Model: 3DT100
 P/N: AS-21-50-01-A
 Charge: 5V 400mAh

CHARGE VIA S^B



SUMMARY OF TESTS

CSA / UL / IEC CLAUSE	CLAUSE INFORMATION	TEST VERDICT		
		P	F	N/A
6.1	Label Rub Test for External Labels	X		
7	Power Input	X		
15 b)	Limitation of Voltage and / or Energy			X
15 c)	Internal Capacitor Discharge Test			X
16 a)	Enclosure Test	X		
17h1	Defibrillation-proof applied parts			X
17h2	Defibrillation-proof recovery time			X
18	Protective Earthing (Ac Power supply)			X
19	Leakage Current	X		
20	Dielectric Strength	X		
21 a) b) c)	Rigidity, Impact, Handle Loading	X		
21.3	Weight Application to an Immobilization or Patient Support Unit			X
21.5	Hand Held Drop Test (Applied parts)	X		
21.6	Rough Handling of Portable and Mobile Equipment	X		
24.1-24.3	Stability Test (10 degree Tip or alternative under 24.3)			X
28	Suspended Masses			X
29	X-Radiation			X
42	Excessive Temperatures	X		
44.2	Overflow of Liquid Reservoir			X
44.3	Spillage, for Equipment Using or Handling Liquids			X
44.4	Leakage, for Equipment Using or Handling Liquids			X
44.5	Humidity	X		
44.6	Ingress of Liquids as per IEC 60529			X
44.7	Cleaning, Sterilization, Disinfection	X		
45.2	Pressure			X
45.7	Pressure Relief Device Test			X
49.1	Cut-Outs / Overprotection in Power Supply			X



CSA / UL / IEC CLAUSE	CLAUSE INFORMATION	TEST VERDICT		
		P	F	N/A
49.2	Safe Operation During Power Interruption	X		
52.5	Abnormal Operation	X		
52.5.1	Overloading of Mains transformer in Equipment			X
52.5.2	Failure of Thermostats			X
52.5.3	Short-Circuit of part of Double Insulation.			X
52.5.4	Interruption of Protective Earth Conductor (CI 19.4)			X
52.5.5	Impairment of Cooling			X
52.5.6	Locking of Moving Parts			X
52.5.7	Short-Circuiting of Motor capacitors			X
52.5.8	Additional Test for Motor Operated Equipment			X
52.5.9	Failure of Components	X		
52.5.10 a)	Overload - Having Heating Elements			X
52.5.10 b)	Overload - Motors			X
55	Enclosures: Conductive Coating			X
	Flammability Test			X
	Mold Stress Relief Distortion Test (UL 746C)	X		
	Impact and Drop (see also CI 21)	X		
56.6	Temperature & Overload Control Devices			X
56.10 b) c)	Prevention of Maladjustment of Controls and Knobs			X
56.11 a)	Hand-Held or Foot Operated Devices			X
56.11 b)	Foot-Controls withstand 1350N for 1 Min			X
57.4 a)	Strain Relief Test			X
57.4 b)	Bending Cord Test			X
57.9 a)	Transformer Short Circuit Tests			X
57.9 b)	Transformer Overload Tests			X
57.9.2	Induced Dielectric Strength Test for Transformer			X
57.9.4 e)	Dielectric Strength for Double or Reinforced Transformer			X
59.2 b) (1) or (2)	Enclosure Ball Pressure Test	X		
59.2 c)	Rubber Insulation Aging Test			X
60DV.1.2.3	Direct Plug-In Power Supply (UL 1310)			X



CSA / UL / IEC CLAUSE	CLAUSE INFORMATION	TEST VERDICT		
		P	F	N/A
Test Case Verdict : N / A (Not applicable) - Test case does not apply to the test object P (Pass) - Test item does meet the requirements F (Fail) - Test item does not meet the requirements				



GENERAL INFORMATION	
Test item particulars (see also clause 5):	
Classification of installation and use	portable
Supply connection	AT100, HT100,LT100, 3DT100 charging: USB cable 3DT100: Internally powered
Accessories and detachable parts included in the evaluation ..	
Options included	No options
Possible test case verdicts:	
- test case does not apply to the test object	N / A
- test object does meet the requirement.....	Pass
- test object does not meet the requirement.....	F
Abbreviations used in the report:	
- normal condition.....:N.C.	- single fault condition:S.F.C.
- operational insulation	- basic insulation
- basic insulation between parts of opposite polarity.....:BOP	- supplementary insulation.....:SI
- double insulation	- reinforced insulation
General remarks:	
<p>"This report is not valid as a CB Test Report unless appended to a CB Test Certificate issued by a NCB, in accordance with IEC 60384-2".</p> <p>"(See Attachment #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. Throughout this report a point is used as the decimal separator. The tests results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment shall be part of this document or can be kept on file and available for review. Summary of contents provided in the first pages of this report.</p>	



General product information and considerations:

The ArmTutor™ device, model AT100 is intended for functional rehabilitation of the upper extremity. The device consists of an ergonomic wearable arm brace and electronic card, measured the isolated and a combination of elbow and three directional shoulder motions. Powered from the USB port.

The LegTutor™ device, model LT100 is intended for functional rehabilitation of the lower extremity. The device consists of an ergonomic wearable leg brace and electronic card, measured the knee and three directional hip motions. Powered from the USB port.

HandTutor™ device, model HT100 is intended for functional and fine motor rehabilitation of the hand. The device consists of an ergonomic wearable glove and electronic card, measured isolated and a combination of finger/s and wrist motions. Powered from the USB port.

The 3DTutor™ device, model 3DT100 is intended for functional rehabilitation of the upper and lower extremities. The device consists of a wearable wireless motion feedback device and wireless adaptor, connected to PC USB port.

The VCSEL sensor is used for motion capture in the AT100, LT100, HT100 devices. The laser light (include the reflections) doesn't go out from the plastic enclosure.

All models are motion capture devices, used together with appropriate PC running SW, for rehabilitation training.

The PC used with the devices must be medical PC (approved according IEC60601-1) or laptop working from internal battery.

All models are housed in plastic enclosure, type BF applied part.

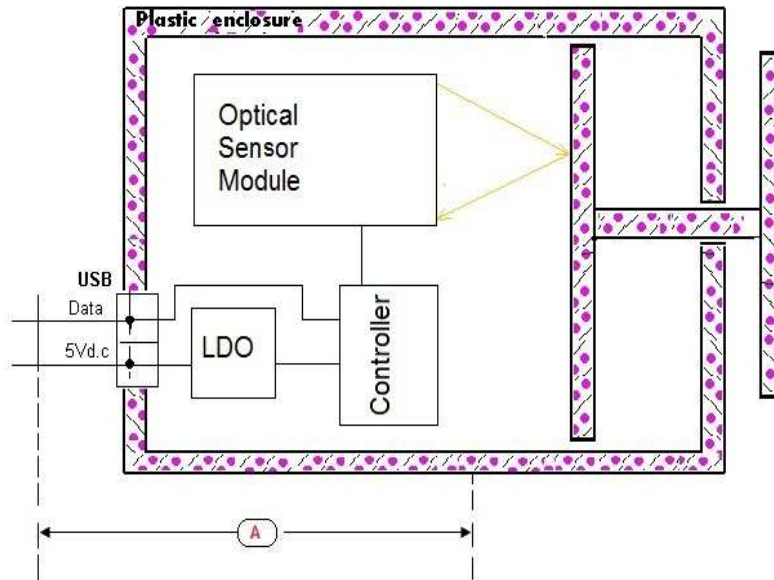


3	GENERAL REQUIREMENTS		
3.1	Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.)		Pass
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		N / A

5	CLASSIFICATION		
5.1	Type of protection against electric shock		
	Class I equipment		N / A
	Class II equipment		N / A
	Internally powered equipment	3DT100	Pass
5.2	Degree of protection against electric shock		
	Type B applied part		N / A
	Type BF applied part		Pass
	Type CF applied part		N / A
	Not classified - no applied parts		N / A
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1)	Ordinary equipment	Pass
5.4	Methods of sterilization or disinfection		N / A
5.5	Equipment not suitable for use in the presence of flammable mixtures	Not suitable	Pass
	Category AP equipment		N / A
	Category APG equipment		N / A
5.6	Mode of operation:		
	-continuous operation		Pass
	-short-time operation, specified operation; period ...:		N / A
	-intermittent operation, specified operation; rest period.....:		N / A
	-continuous operation with short-time, stated permissible loading time.....:		N / A
	-continuous operation with intermittent, stated permissible loading/rest time		N / A

INSULATION DIAGRAMS

AT100, LT100, HT100 models:



3DT100 model:

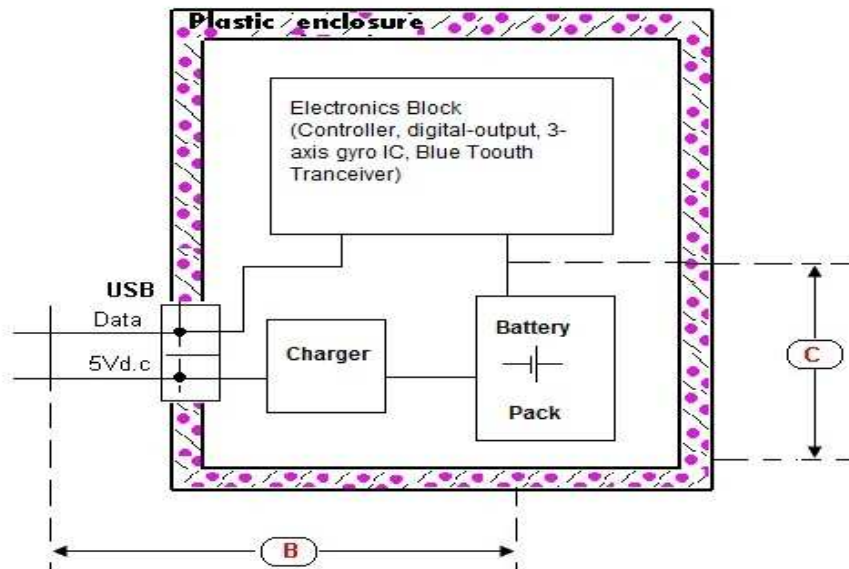




Table: to insulation diagram							Pass
Area	Insulation type: basic / supplementary / double / reinforced	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A (AT100)	BI	240	4.0	2.5	---	---	B-d, Solid insulation
A (LT100)	BI	240	4.0	2.5	---	---	B-d, Solid insulation
A (HT100)	BI	240	4.0	2.5	---	---	B-d, Solid insulation
B (3DT100)	BI	240	4.0	2.5	---	---	B-d, Solid insulation
C (3DT100)	RI	5 dc	3.4	1.6	---	---	B-a, Solid insulation

INSULATION DIAGRAM CONVENTIONS

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

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.
5. Blocks containing the letter "Z" indicate protective impedance.
6. Operational Insulation (OP) - indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with the requirements of clauses 17, 20 and 57.



6	IDENTIFICATION, MARKING AND DOCUMENTS		
6.1	Marking on the outside of equipment or equipment parts		
	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	MediTouch	Pass
	f) Model or type reference	AT100, HT100, LT100, 3DT100	Pass
	g) Rated supply voltages or voltage range(s)	5 Vdc	Pass
	Number of phases		N / A
	Type of current	dc	Pass
	h) Rated frequency or rated frequency range(s) (Hz)		N / A
	j) Rated power input (VA, W or A)	100mA for AT100, 300mA for HT100, 100mA for LT100; 400mA for 3DT100 in charge mode	Pass
	k) Power output of auxiliary mains socket-outlets	No socket outlets	N / A
	l) Class II symbol		N / A
	Symbol for degree of protection against ingress of water provided.....	Ordinary equipment	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)	Continuous operation, no marking is need	N / A
	n) Types and rating of external accessible fuses		N / A
	p) Ratings of external output		N / A
	q) Symbol for physiological effect(s):		
	- 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	(see appended table 6)	Pass
6.2	Marking on the inside of equipment or equipment parts		
	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		N / A
	- 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
	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		Pass
	- Markings comply with IEC 445		Pass
	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
6.3	Marking of controls and instruments		
	a) Mains switch clearly identified		N / A
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light		N / A
	b) Indication of different positions of control devices and switches		N / A
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device		N / A
	f) The functions of operator controls and indicators are identified		N / A
	g) Numeric indications of parameters are in SI units except for units listed in Am. 2		N / A
6.4	Symbols		
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)		Pass
6.5	Colors of the insulation of conductors		
	a) Protective earth conductor has green/yellow insulation		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
6.6	Medical gas cylinders and connections		
	a) In accordance with ISO ISO/R 32		N / A
	b) Identification of connection point		N / A
6.7	Indicator lights and push-buttons		



	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		N / A
	b) Color red used only for push-buttons by which a function is interrupted in case of emergency		N / A
6.8	ACCOMPANYING DOCUMENTS		
6.8.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Provided in Usage Guide	Pass
	Classifications specified in Clause 5 included in both the instructions for use and the technical description		Pass
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment		N / A
	Warning statements and the explanation of warning symbols provided in the accompanying documents		Pass
6.8.2	Instructions for use		
	a) General information provided in instructions for use		Pass
	- state the function and intended application of the equipment		Pass
	- include an explanation of: the function of controls, displays and signals		Pass
	- the sequence of operation		Pass
	- the connection and disconnection of detachable parts and accessories		Pass
	- the replacement of material which is consumed during operation		N / A
	- information regarding potential electromagnetic or other interference and advice regarding avoidance		N / A
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety		N / A
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance		Pass
	General information provided in instructions:		



	- information for the safe performance or routine maintenance		Pass
	- 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		Pass
	c) Signal output or signal input parts intended only for connection to specified equipment described		Pass
	d) Details about acceptable cleaning, disinfection or sterilization methods included		Pass
	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	The rechargeable battery used	N / A
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries		Pass
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1		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
6.8.3	Technical description		
	a) All characteristics essential for safe operation provided	Usage guide	Pass
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment		N / A
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use		Pass
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided		N / A
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Product Specification Temperature: -30°C to +70°C Relative humidity: 10 – 95% Atmospheric pressure: 500 – 1060 hPa	Pass



7	POWER INPUT		---
	Power Input Measurements	(see appended table 7)	Pass

10	ENVIRONMENTAL CONDITIONS		---
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer		Pass
10.2.2a	Rated voltage not exceeding 250 V for hand-held equipment		Pass
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA		Pass
	Rated voltage not exceeding 500 V for all other equipment		N / A
	Rated input frequency not more than 1kHz	DC supply	Pass
10.2.2b	Internal replaceable electrical power source specified		N / A

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



15	LIMITATION OF VOLTAGE AND/OR ENERGY		---
15b	Voltage measured one sec after disconnection of the mains plug does not exceed 60V	(see appended table 15b)	N / A
15c	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ	(see appended table 15c)	N / A
	Marking provided for manual discharging		N / A

16	ENCLOSURES AND PROTECTIVE COVERS		---
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)		Pass
	Insertion or removal of lamps - protection against contact with live parts provided		N / A
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented		N / A
16c	Conductive parts accessible after the removal of handles, knobs, levers		
	- have a resistance of not more than 0.2 Ω	(see appended table 18)	N / A
	- separated from live parts by one of the means described in Sub-clause 17g		Pass
16d	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact		N / A
16e	Removable enclosures protecting against contact with live parts		
	- Removal possible only with the aid of a tool		Pass
	- Use of automatic device making parts not live when the enclosure is opened or removed	No such device	N / A
	- Exception 16e applied to the following parts.....:		N / A
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts		N / A



17	SEPARATION		---
17a	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		Pass
	5) by protective impedances limiting current to applied part		N / A
	- Additional leakage current test in single fault conditions	(see appended table 19)	N / A
17c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		N / A
17d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		N / A
17g	Separation method of accessible parts other than applied parts from live parts:		
	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		Pass
	5) by protective impedances limiting current to accessible part		N / A
	- Additional leakage current test in single fault conditions	(see appended table 19)	N / A
17h	Arrangements used to isolate defibrillation-proof applied parts so designed that:		
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator	(see appended table 17h1)	Pass
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function	(see appended table 17h2)	Pass

18	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION		---
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18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal		N / A
18b	Protective earth terminals suitable for connection to the protective earth conductor		N / A
18e	Potential equalization conductor		
	- 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 DI		N / A
18f	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
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1Ω , the allowable value of the enclosure leakage current is not exceeded in single fault condition	(see appended table 18 and 19)	N / A
18k	Functional earth terminal not used to provide protective earthing		N / A
18l	Class II equipment with isolated internal screens		
	- 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

19	CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS		---
19.1b	Leakage currents	(see appended table 19)	
	- earth leakage current		N / A



	- enclosure leakage current		Pass
	- patient leakage current		Pass
	- patient auxiliary current		Pass

20	DIELECTRIC STRENGTH		---
	Overall compliance with Clause 20	(see appended table 20)	Pass

21	MECHANICAL STRENGTH		---
21a	Sufficient rigidity of an enclosure tested by: force of 45 N		Pass
21b	Sufficient strength of an enclosure tested by: impact hammer		Pass
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test		N / A
21.3	No damage to parts of patient support and/or immobilization system after the loading test		N / A
21.5	Hand held equipment or equipment parts are safe after drop test	(see appended table 21)	Pass
21.6	Portable and mobile equipment is able to withstand rough handling	(see appended table 21)	Pass

22	MOVING PARTS		---
22.2a	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment		N / A
22.2b	Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation		N / A
22.3	Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices		N / A
	Guides or other safeguards are removable only with a tool		N / A
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator		N / A



22.6	Parts of equipment subject to mechanical wear are accessible for inspection		N / A
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard		N / A
	The 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

23	SURFACES, CORNERS AND EDGES		---
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	No rough surfaces, sharp corners and edges which may cause an injury	Pass

24	STABILITY IN NORMAL USE (see appended table 24)		---
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°	Equipment is fixed on the patient during the use	N / A
24.3	Equipment overbalances when tilted through an angle of 10°		
	- 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
24.6a	Equipment or its parts with a mass of more than 20 kg is provided with:		
	- suitable handling devices (grips etc.), or		N / A
	- instructions for lifting and handling during assembly		N / A
24.6b	b) On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons		N / A



25	EXPELLED PARTS	---
25.1	Protective means are provided where expelled parts of the equipment could be a hazard	N / A
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion	N / A

28	SUSPENDED MASSES	---
28.3	Suspension system with safety device	
	Safety device provided where the integrity of a suspension depends on parts which may have hidden defects, or on parts having safety factors not complying with Sub-clause 28.4	N / A
	Safety device has safety factors complying with Sub-clause 28.4.2	N / A
	Clear indication to the operator that the safety device has been activated after failure of suspension means	N / A
28.4	Suspension systems of metal without safety devices	
	1) Total load does not exceed the safe working load	N / A
	2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired	N / A
	3) Safety factors not less than 8 where impairment is expected	N / A
	4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%	N / A
	5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement	N / A

29	X-RADIATION	---
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5 mR)	N / A



36	ELECTROMAGNETIC COMPATIBILITY		---
	Equipment complies with IEC 601-1-2	EMC Test report provided separately	N / A

37	COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT		---
	Requirements for category AP and APG equipment (Cl. 37 - 41)		N / A

42	EXCESSIVE TEMPERATURES		---
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures per Clause 10.2.1	(see appended table 42)	Pass
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient		Pass
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C		Pass
42.5	Guards to prevent contact with hot surfaces removable only with a tool		N / A

43	FIRE PREVENTION		---
	Strength and rigidity necessary to avoid a fire hazard		Pass

44	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION		---
44.2	Equipment contain a liquid reservoir:		
	- the equipment is electrically safe after 15% overflow steadily over a period of 1 min		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
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)		N / A



44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		N / A
44.5	Equipment sufficiently protected against the effects of humidity	(see appended table 44)	Pass
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529		N / A
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	(see appended table 44)	Pass

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		N / A
45.3	Maximum pressure does not exceed the maximum permissible working pressure for individual parts		N / A
45.7	Unless excessive pressure can not occur, pressure-relief device provided		N / A
45.7a	Pressure-relief device connected as close as possible to the pressure vessel		N / A
45.7b	Readily accessible for inspection		N / A
45.7c	Not capable of being adjusted or rendered inoperative without a tool		N / A
45.7d	Discharge opening located that the released material is not directed towards person		N / A
45.7e	Discharge opening located that operation will not deposit material which may cause a safety hazard		N / A
45.7f	Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure		N / A
45.7g	No shut-off valve between a pressure-relief device and the parts intended to be protected		N / A
45.7h	Minimum number of cycles of operation: 100.000	(see appended table 45)	N / A



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	Not evaluated in this test report	N / A

49	INTERRUPTION OF THE POWER SUPPLY		---
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard		N / A
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function		Pass
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure		N / A

51	PROTECTION AGAINST HAZARDOUS OUTPUT		---
51.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally		N / A



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)	(see appended table 52)	Pass
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	Not evaluated in this test report	N / A
52.5.2	Failure of thermostats presents no safety hazards	No thermostats	N / A
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard		N / A
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C		N / A
52.5.6	Locking of moving parts presents no safety hazard		N / A
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard		N / A
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8		N / A
52.5.9	Failure of one component at a time presents no safety hazard	(see appended table 52)	Pass
52.5.10	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



56	COMPONENTS AND GENERAL ASSEMBLY		---
	List of critical components	(see appended table 56)	
56.1b	Ratings of components not in conflict with the conditions of use in equipment	See appended table 56.1	Pass
	Ratings of mains components are identified		Pass
56.1d	Components, movements of which could result in a safety hazard mounted securely		N / A
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard		Pass
56.3a	Connectors provide separation required by Sub-clause 17g		N / A
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment		Pass
	Medical gas connections not interchangeable		N / A
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken		Pass
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.		Pass
56.4	Connections of capacitors		
	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
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment		N / A
56.6	Temperature and overload control devices		
	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		N / A
	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
56.6b	Thermostats with varying temperature settings clearly indicated		N / A
	Operating temperature of thermal cut-outs indicated		N / A
56.7	Batteries		
	a) Battery compartments:		
	- adequately ventilated		N / A
	- accidentally short-circuiting is prevented		Pass
	b) Incorrect polarity of connection prevented		Pass
56.8	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):		
	- to indicate that equipment is energized	By LEDs	Pass
	- 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
56.10	Actuating parts of controls		
56.10b	Actuating parts are adequately secured to prevent them from working loose during normal use		N / A
	Controls are secured to prevent the movement relative to scale marking (safety related only)		N / A
	Detachable indicating devices are prevented from incorrect connection without the use of tool		N / A



56.10c	Stops are provided on rotating controls:		
	- 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
56.11	Cord-connected hand-held and foot-operated control devices		
	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



57	MAINS PARTS, COMPONENTS AND LAYOUT		---
57.1	Isolation from supply mains		
	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
57.2	Mains connectors and appliance inlets		
	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
57.3	Power supply cords		
	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
	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
57.4	Connection of power supply cords		
57.4a	Cord anchorages		
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting	(see appended table 57.4)	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		N / A
	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
57.4b	Power supply cord protected against excessive bending	(see appended table 57.4b)	N / A
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		N / A
57.5	Mains terminal devices and wiring of mains part		
	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
	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		N / A
	d) Cord terminals not require special preparation of the conductor		N / A
57.6	Mains fuses and over-current releases		
	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
57.8	Wiring of the mains part		
	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		N / A
57.9	Mains supply transformers		
57.9.1	Overheating		
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		N / A
57.9.1a	Short-circuit of secondary windings not caused excessive temperature	(see appended table 57.9.1a)	N / A
57.9.1b	Overload of secondary windings not caused excessive temperature	(see appended table 57.9.1b)	N / A
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests	(see appended table 57.9.2)	N / A



57.9.4	Construction		
	a) Separation of primary and secondary windings		
	- 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
	- 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		
	- 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
57.10	Creepage distances and air clearances		
	a) Values: compliance with at least the values of Table XVI	(see table for insulation diagram)	Pass
	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	(see appended table 52)	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	N / A
58	PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS		---
58.1	Clamping means of the protective earth terminal		
	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
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal		N / A
58.8	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing		N / A
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		N / A

59	CONSTRUCTION AND LAYOUT		---
59.1	Internal wiring		
	a) Cables and wiring protected against contact with a moving part		N / A
	Wiring having basic insulation only protected by additional fixed sleeving		N / A
	Components are not likely to be damaged in the normal assembly or replacement of covers		Pass
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead		N / A
	c) Insulating sleeving adequately secured		N / A
	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) Aluminium wires of less than 16 mm ² cross-section not used		N / A
	f) Connecting cords between equipment parts considered as belonging to the equipment		Pass
59.2	Insulation		
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation		Pass
	c) Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		Pass
	Parts of rubber resistant to ageing		N / A
59.3	Excessive current and voltage protection		



	Internal electrical power source provided with device for protection against fire hazard		N / A
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuse-holder		N / A
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		N / A

59.4	Oil containers		
	Oil containers adequately sealed		N / A
	Container allow for the expansion of the oil		N / A
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		N / A
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N / A



6.1	TABLE: marking durability	Pass
Marking tested		Remarks
15s with a cloth rag soaked with distilled water		O.K.
15s with a cloth rag soaked with methylated spirit		O.K.
15s with a cloth rag soaked with isopropyl alcohol		O.K.
Supplementary information:		

7	TABLE: power input AMB.: 24°C HUMID.: 55% ATM PRESS.: 1006.6 hPa					Pass
Operating condition	Voltage (V)	Frequency (Hz)	Current (A)	Power (VA)	Remarks	
AT100						
Max normal load	5.0	DC	0.080	0.4		
LT100						
Max normal load	5.0	DC	0.082	0.41		
HT100						
Max normal load	5.0	DC	0.268	1.34		
3DT100						
Internally powered	4.2	DC	0.120	0.504		
Battery charging	5.0	DC	0.345	1.725		
Supplementary information: Input: AT100: 5Vdc, 100mA (USB) HT100: 5Vdc, 300mA (USB) LT100: 5Vdc, 100mA (USB) 3DT100: 5Vdc, 400mA (USB Charging); Internally powered; 3.7Vdc, 650mAh						



15b	TABLE: residual voltage in attachment plug										N / A
Voltage measured between:	Measurements [V]										Remarks
	1	2	3	4	5	6	7	8	9	10	
supply pins (pin 1 & pin 2)											
line pin 1 and enclosure											
line pin 2 and enclosure											
pin 1 and earth pin											
pin 2 and earth pin											
Supplementary information:											

15c	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:					

17h1	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:					



17h2	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:					

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



19	TABLE: leakage current AMB.: 24°C HUMID.: 55% ATM PRESS.: 1006.6 hPa				Pass
Type of leakage current and test condition (including single faults)	Supply voltage V	Supply frequency Hz	Measured max. value µA	Remarks	
Before humidity conditioning					
HT100 P	5.0	DC	0.2	NC	
HT100 PM	5.0	DC	6.8	SFC	
AT100 P	5.0	DC	0.2	NC	
AT100 PM	5.0	DC	9.0	SFC	
LT100 P	5.0	DC	0.2	NC	
LT100 PM	5.0	DC	14.0	SFC	
3DT100 P	5.0	DC	0.2	NC	
3DT100 PM	5.0	DC	5.0	SFC	
After humidity conditioning					
HT100 P	5.0	DC	0.2		
HT100 PM	5.0	DC	6.8		
AT100 P	5.0	DC	0.2		
AT100 PM	5.0	DC	9.1		
LT100 P	5.0	DC	0.2		
LT100 PM	5.0	DC	14.2		
3DT100 P	5.0	DC	0.2		
3DT100 PM	5.0	DC	5.3		
(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		



20	TABLE: dielectric strength AMB.: 24°C HUMID.: 55% ATM PRESS.: 1006.6 hPa				Pass
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (V)	Test voltage (Vac)	Remarks	
Before humidity conditioning					
HT100 Power + Data to Enclosure	BI	240ac	1500	No breakdown	
AT100 Power + Data to Enclosure	BI	240ac	1500	No breakdown	
LT100 Power + Data to Enclosure	BI	240ac	1500	No breakdown	
3DT100 Power + Data to Enclosure	BI	240ac	1500	No breakdown	
3DT100 Internal Battery output to Enclosure	RI	5.0dc	500	No breakdown	
After humidity conditioning					
HT100 Power + Data to Enclosure	BI	240ac	1500	No breakdown	
AT100 Power + Data to Enclosure	BI	240ac	1500	No breakdown	
LT100 Power + Data to Enclosure	BI	240ac	1500	No breakdown	
3DT100 Power + Data to Enclosure	BI	240ac	1500	No breakdown	
3DT100 Internal Battery output to Enclosure	RI	5.0dc	500	No breakdown	
Supplementary information:					



21	TABLE: mechanical strength AMB.: 23°C HUMID.: 51% ATM PRESS.: 1006.1 hPa		Pass
Part under test		Test (impact, drop, force, handle, rough handling, mobile)	Remarks
21a Rigidity of enclosure (AT100, LT100, HT100, 3DT100)		45N test force	No hazard
21b Strength of enclosure (AT100, LT100, HT100, 3DT100)		0.5J test blows	No hazard
21.5 AT100, LT100, HT100, 3DT100		Dropped from 1.22 m on a concrete surface, 3 times	No hazard
Supplementary information:			

24	TABLE: - stability		N / A
Part under test		Test condition	Remarks
Supplementary information:			



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

42	TABLE: normal temperature AMB.: 25°C HUMID.: 47% ATM PRESS.: 1006.6 hPa			Pass
Supply voltage: 5Vd.c		Test Condition: Max normal load		
Measuring location	Measured temperature [°C]	Compensated Temperature at 40 °C	Remarks	
AT100				
LDO U2	38.3	53.3		
PCB	34.5	49.5		
Patient contacted surface	25.6	40.6		
LT100				
LDO U2	37.4	52.4		
PCB	35.1	50.1		
Patient contacted surface	25.4	40.4		
HT100				
PCB	43.9	58.9		
Laser mouse sensor U5	44.0	59.0		
LDO U12	55.0	70.0		
Patient contacted surface	25.7	40.7		
3DT100				
PCB	51.1	66.1		
Battery pack	46.3	61.3		
Patient contacted surface	25.6	40.6		
Supplementary information:				



44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection AMB.: 25°C HUMID.: 47% ATM PRESS.: 1006.6 hPa		Pass
Test type and condition		Part under test	Remarks
44.5 Humidity for 48 hour (27°C, 93%)		Equipment	No hazard
44.7 Cleaning		Equipment	No hazard
Supplementary information:			

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

52.5.5	TABLE: abnormal temperature		N / A
Supply voltage: 103V, 60Hz		Test Condition:	
Measuring location	Measured temperature [°C]	Compensated Temperature at 40 °C	Remarks
Supplementary information:			



52	TABLE: abnormal operation AMB.: 25°C HUMID.: 47% ATM PRESS.: 1006.6 hPa	Pass
Test type, condition and clause reference		Observed results
52.5.9 Failure of components		Remarks
AT100/LT100		
C1 (5V USB input) shorted	PC USB over current protection operated immediately	No hazard
C4 (3.3V) shorted	U2 over current protection operated immediately	No hazard
C10 (1.8V) shorted	U3 over current protection operated immediately	No hazard
HT100		
C10 (5V USB input) shorted	PC USB over current protection operated immediately	No hazard
C8 (3.3V) shorted	U2 over current protection operated immediately	No hazard
3DT100		
C11 (5V USB input) shorted	PC USB over current protection operated immediately	No hazard
C10 (3.3V) shorted	IC2 over current protection operated immediately	No hazard
Battery pack output shorted during operation mode	Battery pack build in over current protection operated immediately	No hazard
Battery pack output shorted during charging mode	IC3 over current protection operated immediately	No hazard
Abnormal charging (IC3 p4-p5 shorted)	Battery pack build in over current protection operated immediately	No hazard
Supplementary information:		



Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity ¹⁾
56.1	TABLE: lists of critical component parts				Pass
LT100 and AT100					
Plastic enclosure (INT)	Bayer	PolyCarbonate 2805	130x53x25mm thickness 2mm V-2 for 1.5mm	UL94	UR E41613
Navigation Sensor	Avago Technologies	ADNS9500	3V or 5V 50mA max		Accepted
PCB ArmTutor Left (LegTutor Right) (INT)	INNOQUICK ELECTRONIC S LTD	PCB-20-01-01	84x51mm, 1.8mm thickness V-0, 105°C	UL94	UR E326340
PCB ArmTutor Right (LegTutor Left) (INT)	INNOQUICK ELECTRONIC S LTD	PCB-20-02-01	84x51mm, 1.8mm thickness V-0, 105°C	UL94	UR E326340
HT100					
Plastic enclosure (INT)	Bayer	PolyCarbonate 2805	134x85x37 thickness 2mm V-2 for 1.5mm	UL94	UR E41613
Navigation Sensor	Avago Technologies	ADNS6010	3Vdc, 53mA max		Accepted
PCB (INT)	INNOQUICK ELECTRONIC S LTD	MBRD-001-A	104x5mm 1.6mm thickness V-0, 105°C	UL94	UR E326340
3DT100					
Plastic enclosure (INT)	Bayer	PolyCarbonate 2805	54x42x16 thickness 1.5mm V-2 for 1.5mm	UL94	UR E41613
Lithium polymer battery pack (INT)	Advanced Electronics Energy	AE603040	3.7Vdc, 650mAh	UL1642	UR MH29257
PCB (INT)	INNOQUICK ELECTRONIC S LTD	PCB-21-01-01-B	48x36mm 1mm thickness, V-0, 105°C	UL94	UR E326340
¹⁾ an asterisk indicates a mark which assures the agreed level of surveillance					



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

56.11b	TABLE: foot operated control devices-loading			N / A
Part under test		Observed results	Remarks	
Supplementary information:				

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

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

57.9.1a	TABLE: transformer short circuit					N / A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
Supplementary information:						



57.9.1a	TABLE: transformer short circuit					N / A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
Supplementary information:						

57.9.1b	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:							

57.9.1b	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:							

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

	TABLE: additional tests			
Clause	Test type and condition	Remarks and observed results		Verdict
59.2	Ball Pressure test on the AT100, LT100, HT100, 3DT100 plastic enclosures	No adverse effect. Dielectric Test pass		Pass



SUMMARY OF CONTENTS:

The equipment has been tested according to standard IEC 60601-1 (1988) Second Edition + Am.1 + Am.2

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

These test fulfill the requirements of standard ISO/IEC 17025.

This test report comprises 48 pages of CB Test Report and the following Appendixes:

Appendix #	Description	Pages
Appendix 1	Photographs	9
Appendix 2	Test Instruments	2

Note:

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



Appendix 1

Photographs

(9 pages, including this one)

Arm Tutor AT100



Leg Tutor LT100t



AT100/LT100 Electronic Board



Hand Tutor HT100



Hand Tutor HT100 internal view



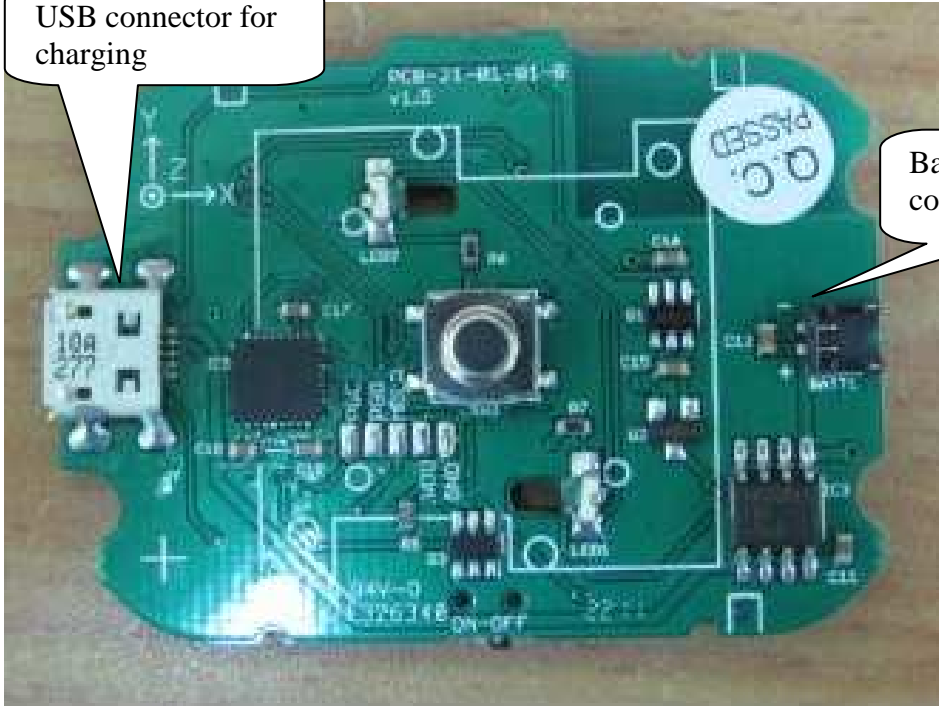


3D Tutor (without belt) and wireless USB adaptor



3D Tutor board

USB connector for charging



Battery connector





3D Tutor Lithium Polymer Battery Pack



**APPENDIX 2 - Test instruments**

	SII Ref.No.	Instrument Type	Manufacturer	Model	Calibration date	Calibration due	SII Location
	1462	Humidity Cabinet	Heraeus Votsch	HCZ-003L	08/11	08/12	Elec. Lab
x	252-478	Humidity Cabinet	Heraeus Votsch	4033	01/11	01/12	Telem. Lab
	142	Furnace	Heraeus Votsch	T5050E	11/10	11/11	Chem Lab
	2301	Multimeter	Fluke	77	03/11	03/12	Telem. Lab
x	4611	Leakage Current Measuring Device – IEC 60601	SII	--	07/11	07/12	Telem. Lab
x	5795	Data Acquisition/Switch Unit with Thermocouples Type J	Agilent	34970A, 34901A S/N MY44025242	11/10	11/11	Telem. Lab
	564453	Data Acquisition Unit	Measurement Computing	WLC-TC S/N 76772	11/10	11/11	Telem. Lab
	54580	Thermo-Hygrometer	TFA	Digital Max-Min	04/11	04/12	Telem. Lab
x	600120	Humidity & Temperature Recorder	Extech	CH13004	04/11	04/12	Telem. Lab
	51754	Rigid test finger	PTL	P10.38	01/11	01/12	Elec. Lab
	52885	Torque	Torqueleader	TT250	09/11	09/12	Elec. Lab
	52654	Jointed test finger	PTL	P10.04	01/11	01/14	Telem. Lab
x	52656	Steel ball for Impact test	SII	--	01/11	01/14	Telem. Lab
x	2374	Impact hammer	PTL	F22.50No.9106 151.2	12/09	12/12	Elec. Lab
	52746	Test gauge	PTL	L25.84	01/11	01/14	Telem. Lab
x	52839	Test probe 250N	PTL	P10.64	06/11	06/12	Telem. Lab
	560340	Digital Force Gauge	Lutron	FG-20KG	06/11	06/12	Telem. Lab
	4424	Set of grooved weights 0.2-10 kg	--	--	07/11	07/12	Calibration Lab
	560191	Set of grooved weights 0.5-10 kg	Troemmer	--	11/09	11/11	Calibration Lab
	4272	Set of weights 1-2000 gr	Mettler	--	11/10	11/11	Calibration Lab
	6008	Impulse Tester	Compliance West	MegaPulse	11/10	11/11	Telem. Lab
x	53820	Ball Pressure Test Instrument	PTL	P10.02	01/11	01/14	Telem. Lab
	53821	Test pin	SII	--	01/11	01/14	Telem. Lab
	54028	True RMS Multimeter	Fluke	187	07/11	07/12	Telem. Lab
x	605102	True RMS Multimeter	Fluke	289	05/11	05/12	Telem. Lab
	54039	Industrial Scopemeter	Fluke	123	04/11	04/12	Telem. Lab
x	54045	Dielectric Tester	Zentech	9072A	06/11	06/12	Telem. Lab
	6042	Dielectric Tester	Chroma	19052	04/11	04/12	Telem. Lab
	54046	Ground Continuity Tester	Zentech	9570	06/11	06/12	Telem. Lab
	6041	Ground Continuity Tester	Chroma	19572	04/11	04/12	Telem. Lab
	54075	Digital Power Meter	Zentech	2100	07/11	07/12	Telem. Lab
	6748	Power Analyzer	Voltech	PM1000	10/10	10/11	Telem. Lab
x	54227	Digital Caliper	Motoko	--	03/11	03/12	Telem. Lab
	605524	Digital Caliper	Venus	--	11/10	11/11	Telem. Lab



54228	Micrometer	Motoko	--	04/11	04/12	Telem. Lab
4050	Microscope/Comparator	ST Industries (Scherr-Tumico)	20-3600 (74-0426)	03/11	03/12	Calibration Lab
600153	High Voltage Probe	TES TEC	HVP-15HF	07/11	07/12	Telem. Lab
4650	Clamp Ampermeter	Appa	36	06/11	06/12	Telem. Lab
600049	Clamp Meter	Fluke	337	05/11	05/12	Telem. Lab
4498	Oscilloscope	Philips	PM3375	06/11	06/12	Telem. Lab
563019	Stopwatch / Timer	Extech Instruments	365528	11/10	11/11	Telem. Lab
5863	Dust Chamber	MAGNI	S/N 002261/07	02/11	02/12	Electrical Lab
1239	IP Water Test Set-up (pressure gauge)	WIKA	---	02/11	02/12	Electrical Lab
54249	IP Water Test Set-up (pressure gauge)	Eshel	---	04/11	04/12	Electrical Lab
6025	Function/Arbitrary/ Waveform Generator	Agilent	33220A	04/11	04/12	Telem. Lab
6486	Test circuit (IEC60601-2-27)	SII	2-23-2	08/11	08/12	Telem. Lab
6485	Test circuit (IEC60601-2-27)	SII	2-23-2	08/10	08/11 cal	Telem. Lab

× - Test Instrument used in the report