APPLICATION FOR TEST REPORT

On Behalf of

Prepared For	:	Longnan Renzhong Medical Equipment Co., Ltd Information Industry Technology City, Longnan Economic Development Zone, Longnan, Ganzhou, Jiangxi province, China
Product Name	:	INFRARED BODY THERMOMETER
Model	:	YK001, YK002, YK003, YK004
Prepared By	:	SHENZHEN CTO TECHNOLOGY CO., LTD 9/F, block B, SME incubation center, Tangtou Avenue, Shiyan Town, Bao'an District, Shenzhen City, Guangdong Province, China
Test Date	:	Feb. 06, 2020 –Mar. 12, 2020
Date of Report	:	Mar. 12, 2020
Report No.	:	CTO200312040DRS

TEST REPORT
60601-1
Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

Report Reference No.....:	CTO200312040DRS
Compiled by (+ signature).....:	Laurent Wu
Approved by (+ signature).....:	Mike Wang
Date of issue.....:	Mar. 11, 2020
Testing Laboratory.....:	SHENZHEN CTO TECHNOLOGY CO., LTD
Address.....:	9/F, block B, SME incubation center, Tangtou Avenue, Shiyan Town, Bao'an District, Shenzhen City, Guangdong Province, China
Applicant's name.....:	Longnan Renzhong Medical Equipment Co., Ltd
Address.....:	Information Industry Technology City, Longnan Economic Development Zone, Longnan, Ganzhou, Jiangxi province, China
Test specification:	
Standard.....:	EN60601-1:2006+A1:2013+A12:2014 EN 60601-1-11:2015
Non-standard test method.....:	N/A
Test item description.....:	INFRARED BODY THERMOMETER
Trade Mark.....:	*AFK*
Manufacturer.....:	Longnan Renzhong Medical Equipment Co., Ltd
Address.....:	Information Industry Technology City, Longnan Economic Development Zone, Longnan, Ganzhou, Jiangxi province, China
Model/Type reference.....:	YK001, YK002, YK003, YK004
Ratings.....:	3.0Vd.c. (AAAx2)

Possible test case verdicts:	
- test case does not apply to the test object....	N (Not apply)
- test object does meet the requirement.....	P (Pass)
- test object does not meet the requirement....	F (Fail)
test object was not evaluated for the requirement	N/E (collateral standards only)
Testing.....	
Date of receipt of test item.....	Feb. 06, 2020
Date(s) of performance of tests.....	Feb. 06, 2020 –Mar. 12, 2020
Test item particulars (see also Clause 6):	
Classification of installation and use.....	Classification of installation and use
Device type (component/sub-assembly/ equipment/ system)	Equipment
Intended use (Including type of patient, application location).....	Refer to user manual
Mode of operation.....	Continuous
Supply connection.....	internally powered
Abbreviations used in the report:	
- normal condition ..... : N.C.	- single fault condition ..... : S.F.C.
- means of Operator protection ... : MOOP	- means of Patient protection ..... : MOPP
General remarks: 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.	

General product information:

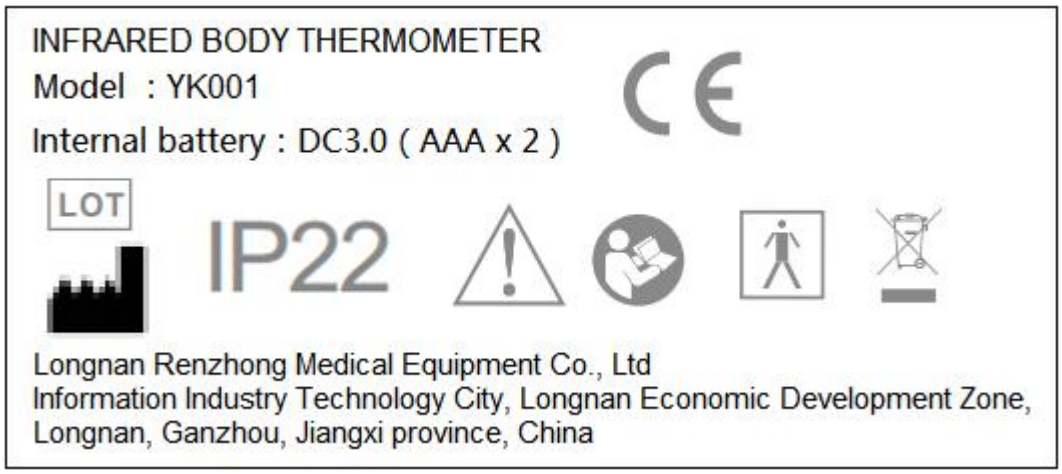
1, The equipment is used for measuring the temperature parameters of adults, pediatrics and neonates in healthcare and home environments.

2, It is supplied by 2x1.5Vd.c. AAA battery which can be replace by operator.

3, Max operating temperature is 40 degree C declared by the manufacture.

4, All models are only different in color，All tests are performed on YK001

Copy of marking plate:



INSULATION DIAGRAM

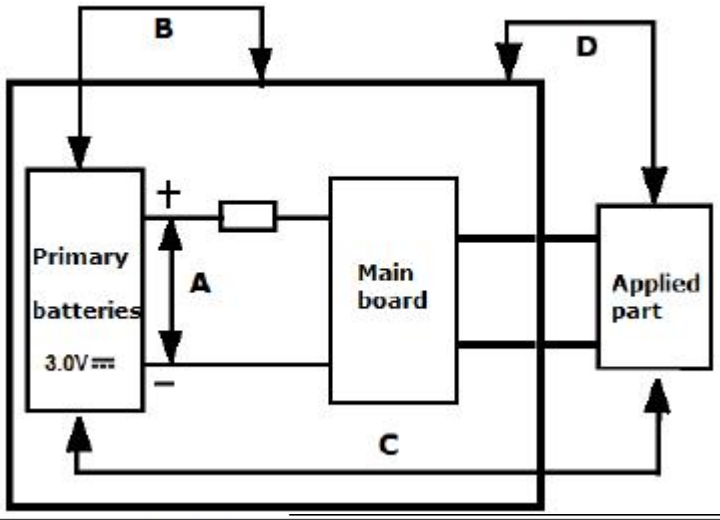


TABLE: To insulation diagram		P
Pollution degree ..... :	2	—
Overvoltage category ..... :	N/A	—
Altitude ..... :	≤2000m	—
Additional details on parts considered as applied parts ..... :	☒ None ☐ Areas _____ (See Clause 4.6 for details)	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			Vrms	Vpk					
A	RI (2MOOP)	IIIb	3.0Vd.c.	--	1.0	0.8	1.2	1.2	Opposite polarity of battery
B	RI (2MOPP)	IIIb	3.0Vd.c.	--	3.4	1.6	4.2	4.2	Battery to accessible enclosure of main unit
C	RI (2MOPP)	IIIb	3.0Vd.c.	--	3.4	1.6	4.5	4.5	Battery to applied part
D	BI (1MOPP)	IIIb	250	354	4.0	2.5	--1)	--1)	Applied part to enclosure

Supplementary information:

1) Applied part is connect with the enclosure of main part.

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:
A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.
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:
- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

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Clause	Requirement – Test	Result - Remark	Verdict
4	**GENERAL REQUIREMENTS**		**P**
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		P
4.2	Risk management process for ME equipment or ME systems		P
4.2.2	General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007)	See Appended RM Results Table 4.2.2.	P
4.2.3	Evaluating RISK		P
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level		P
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN		P
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		P
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		P
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.		P
4.3	Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.		P
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION		P
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		P
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE		P
	- RISK CONTROL measures implemented		P
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		P
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE	5 years	P
4.5	Alternative means of addressing particular RISKS considered acceptable based on MANUFACTURER'S justification that RESIDUAL RISKS resulting from application of alternative means equal to or less than RESIDUAL RISKS resulting from requirements of this standard	No equivalent safety for ME System	N
4.6	R ISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS , subjected to the requirements for APPLIED PARTS , except for Clause 7.2.10	No such part	N
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2.	Considered	P
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically :		P

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Clause	Requirement – Test	Result - Remark	Verdict
	RISK associated with failure of component during EXPECTED SERVICE LIFE of ME EQUIPMENT taken into account to evaluate if a component should be subjected to failure simulation		P
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, except as specified		P
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS		P
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following:		P
	a) Applicable safety requirements of a relevant IEC or ISO standard	See appended table 8.10	P
	b) where there is no relevant IEC/ISO standard, the relevant ANSI standard shall be applied; if no relevant ANSI standard exists, the requirements of this standard shall be applied	See appended table 8.10	P
4.9	A COMPONENT WITH HIGH -INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK		N/A
4.10	Power supply		P
4.10.1	ME EQUIPMENT is suitable for connection to a SUPPLY MAINS, specified to be connected to a separate power supply, can be powered by an INTERNAL ELECTRICAL POWER SOURCE, or a combination of the three	Main unit is supplied by Internal batteries	P
4.10.2	SUPPLYMAINS for ME EQUIPMENT and ME SYSTEMS		P
	— 250 V for HAND -HELD ME EQUIPMENT ;	Not hand-held equipment	N
	— 250 V d.c. or single-phase a.c. or 600 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input < 4 kVA; or	Rated: 3.0Vd.c.	P
	— 500 V for all other ME EQUIPMENT and ME SYSTEMS.		N
4.11	Power input		N
	- Measurements on ME EQUIPMENT or a ME SYSTEM marked with one or more RATED voltage ranges made at both upper and lower limits of the range	See appended Table 4.11	N
	Measurements on ME EQUIPMENT or a ME SYSTEM marked with one or more RATED voltage ranges made at both upper and lower limits of the range :		N
	Power input, expressed in volt-amperes, measured with a volt-ampere meter or calculated as the product of steady state current (measured as described above) and supply voltage	Not expressed in volt-amperes	N
5	**GENERAL REQUIREMENTS FOR TEST ME EQUIPMENT**		**P**
5.1	TYPE TESTS determined in consideration of Clause 4, in particular 4.2		P

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Clause	Requirement – Test	Result - Remark	Verdict
	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods	All the test have been performed.	N
5.2	TYPE TESTS conducted on one representative sample under investigation; multiple samples used simultaneously when validity of results was not significantly affected	Only one sample used	N
5.3	a) Tests conducted within the environmental conditions specified in technical description	Working condition see below:	P
	Temperature (ºC), Relative Humidity (%) .....:	Temperature:10 ºC up to 40 ºC Humidity: 30%RH up to 75%RH, no condensation	-
	Atmospheric Pressure (kPa).....:	70kPa~106kPa	-
	b) ME EQUIPMENT shielded from other influences that might affect the validity of tests	Testing lab environment under controlled	P
	c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained:		P
5.4	a) ME EQUIPMENT tested under least favourable working conditions specified in instructions for use and identified during RISK ANALYSIS, except as noted	All test under least favourable working conditions	P
	b) ME EQUIPMENT with adjustable or controlled operating values by anyone other than SERVICE PERSONNEL adjusted to values least favourable for the relevant test per instructions for use		P
	c) When test results influenced by inlet pressure and flow or chemical composition of a cooling liquid, tests performed within the limits in technical description	No such influenced	N
	d) Potable water used for cooling	No water cooling system	N
5.5	Supply voltage during tests was the least favourable of the voltages specified in 4.10 or voltages marked on ME EQUIPMENT (V)	3.0Vd.c.	P
	a) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)		P
	b) ME EQUIPMENT with more than one RATED voltage, or both a.c./ d.c. tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current	Internally powered equipment	N
	c) ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions		N
	d) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	Not connected to separate power supply	N
	e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions		P
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use		N
5.6	When failure occurred or probability of future failure detected during sequence of tests, per agreement with manufacturer, all tests affecting results conducted on a new sample		P

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Clause	Requirement – Test	Result - Remark	Verdict
	Alternatively, upon repair and modification of the sample, only the relevant tests conducted		N
5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3	Before the test of 8.7.4 and 8.8.3, the humidity preconditioning is performance	P
	Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS were opened anddetached	Total equipment	P
	ME EQUIPMENT heated to a temperature between T and T + 4 °C for at least 4 h and placed in a humidity chamber with a relative humidity of 93 % ± 3 % and an ambient within 2 °C of T in the range of + 20 °C to + 32 °C for 48 h		N
	- For units rated higher than IPX0 test time extended to 168 h		N
5.8	Sequence of tests		P
5.9	Determination of applied parts and accessible parts		P
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS		N
5.9..2	Accessible parts		P
5.9.2.1	Accessibility, when necessary, determined using standard test finger of Fig 6 applied in a bent or straight position		P
	Openings preventing entry of test finger of Fig. 6 mechanically tested with a straight un-jointed test finger of the same dimensions with a force of 30 N		P
	When the straight un-jointed test finger entered, test with the standard test finger (Fig 6) was repeated, if necessary, by pushing the finger through the opening		N
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s	Not inserted	P
	All additional parts that became accessible checked using standard test finger and by inspection		N
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS	No such conductive parts used	N
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, etc. required use of a TOOL		N

6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEM**		**P**
6.1	General		P
6.2	CLASS I ME EQUIPMENT, externally powered		N
	CLASS II ME EQUIPMENT , externally powered		N
	INTERNALLY POWERED ME EQUIPMENT		P

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Clause	Requirement – Test	Result - Remark	Verdict
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements		N
	TYPE B APPLIED PART		N
	TYPE BF APPLIED PART		P
	TYPE CF APPLIED PART		N
	DEFIBRILLATION-PROOF APPLIED PARTS		N
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter (IPN1N2) as per IE C 60529	IP22 equipment.	P
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use	No part is intended to be sterilized.	N
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2	Not intended for use in an oxygen rich environment.	N
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION	Continuous Operation	P
7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		**P**
7.1	General		P
7.1.1	Usability of the identification ,marking and documents		P
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6	See Usability report provide by manufacture	N/E
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE		P
	a) After tests, adhesive labels didn't loosen up or curl up at edges and markings complied with requirements in Clause 7.1.2		P
	b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after marking durability test		P
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT		N
	A material, component, ACCESSORY, or ME EQUIPMENT intended for a single use, or its packaging marked "Single Use Only", "Do Not Reuse" or with symbol 28 of Table D.1 (ISO 7000-1051, DB:2004-01)		N
7.2	Marking on the outside of ME equipment or ME equipment parts	See marking plate and the marking on the enclosure	P

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Clause	Requirement – Test	Result - Remark	Verdict
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings		P
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS		P
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT		N
	A material, component, ACCESSORY, or ME EQUIPMENT intended for a single use, or its packaging marked "Single Use Only", “Do Not Reuse” or with symbol 28 of Table D.1 (ISO 7000-1051, DB:2004-01)		N
7.2.2	ME EQUIPMENT marked with:		P
	– the name or trademark and contact information of the MANUFACTURER		P
	– a MODEL OR TYPE REFERENCE		P
	– a serial number or lot or batch identifier; and		P
	– the date of manufacture or use by date		P
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or		N
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and		N
	– a MODEL OR TYPE REFERENCE		N
	Software forming part of a PEMS identified with a unique identifier, such as revision level or date of release/issue, and identification are available to designated persons		N
7.2.3	Symbol 11 on Table D.1 (ISO 7000-1641, DB: 2004-01) used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS		N
	Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted		P
7.2.4	ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and		N
	- with a MODEL or TYPE REFERENCE		N
	– a serial number or lot or batch identifier		N
	– the date of manufacture or use by date		N
7.2.5	ME equipment intended to receive power from other equipment		N
7.2.6	Connection to the supply mains		N

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Clause	Requirement – Test	Result - Remark	Verdict
	Except for PERMANENTLY INSTALLED ME EQUIPMENT, marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection poin		N
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT, preferably, adjacent to SUPPLY MAINS connection		N
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V)		N
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)		N
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)		N
7.2.7	Electrical input power from the supply mains		N
7.2.8	Output connectors	No output connectors	N
7.2.8.1	Mains power output		N
7.2.8.2	Other power sources		N
7.2.9	IP classification	IP22	P
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols as follows (not applied to parts identified according to 4.6)		P
	TYPE B APPLIED PARTS with symbol 19 of Table D.1 (IEC 60417-5840, 2002-10), not applied in such a way as to give the impression of being inscribed within a square in order to distinguish it from symbol IEC 60417-5333		N
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 (IEC 60417-5333, 2002-10)	 symbol marked	P
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 (IEC 60417-5335, 2002-10)		N
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 (IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336, all 2002-10)		N
	Proper symbol marked adjacent to or on connector for APPLIED PART, except marked on APPLIED PART when there is no connector, or connector used for more than one APPLIED PART and different APPLIED PARTS with different classifications		P
	Safety sign 2 of Table D.2 (ISO 7010-W001) placed near relevant outlet when protection against effect of discharge of a cardiac defibrillator is partly in the PATIENT cable		N
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use		N

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Clause	Requirement – Test	Result - Remark	Verdict
7.2.11	ME EQUIPMENT not marked to the contrary assumed to be suitable for CONTINUOUS OPERATION	Continuous operation	P
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder	No accessible fuse used in ME equipment	N
7.2.13	A safety sign CLEARLY LEGIBLE and visible after INSTALLATION in NORMAL USE applied to a prominent location of EQUIPMENT that produce physiological effects capable of causing HARM to PATIENT or OPERATOR not obvious to OPERATOR	No such physiological effects	N
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use		N
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1 (symbol IEC 60417-5036, 2002-10)	No such terminal used in ME equipment	N
7.2.15	Requirements for cooling provisions marked (e.g., supply of water or air)		N
7.2.16	ME EQUIPMENT with limited mechanical stability		N
7.2.17	Packaging marked with special handling instructions for transport and/or storage		N
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and		N
7.2.19	Symbol 7 of Table D.1 (IEC 60417-5017, 2002-10) marked on FUNCTIONAL EARTH TERMINAL	No functional earth terminal.	N
7.2.20	Protective means, required to be removed to use a particular function of ME EQUIPMENT with alternate applications, marked to indicate the necessity for replacement when the function is no longer needed	No such protective means used for the ME equipment	N
	No marking applied when an interlock provided		N
7.2.21	MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms		N
	- The marking is obvious that it applies to the whole of the MOBILE ME EQUIPMENT when loaded with its SAFE WORKING LOAD and		N
	- is separate and distinct from any markings related to maximum bin, shelf or drawer loading requirements.		N
7.3	Marking on the inside of ME equipment or ME equipment parts		P
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W)	No heating elements or lampholder used in ME equipment	N
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL		N
7.3.2	Symbol 24 of Table D.1 (symbol IEC 60417-5036, 2002-10), or safety sign 3 of Table D.2 used to mark presence of HIGH VOLTAGE parts	No such high voltage parts used in ME equipment	N

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Clause	Requirement – Test	Result - Remark	Verdict
7.3.3	Type of battery and mode of insertion when applicable is marked	Indicated	P
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL		P
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement by inadequately trained personnel would result in an unacceptable RISK (e.g., excessive temperatures, fire or explosion)		P
	An identifying marking also provided referring to instructions in ACCOMPANYING DOCUMENTS	Refer to user manual	P
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVERCURRENT RELEASES, accessible by use of a TOOL	No such fuse used in ME equipment	N
	Identified by specification adjacent to the component, or		N
	by reference to ACCOMPANYING DOCUMENTS		N
	Voltage (V) and Current (A) rating		N
	Operating speed(s), size & breaking capacity		N
7.3.5	Protective earth terminals		N
7.3.6	Functional earth terminals		N
7.3.7	Supply terminals		N
7.3.8	Temperature of supply terminals		N
7.4	Marking of controls and instruments		P
7.4.1	Power switches		N
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means	By figures	P
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE		N
	– or an indication of direction in which magnitude of the function changes		N
	Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009 (2002-10) (Table D.1, Symbol 29).		P
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units		N
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units		P
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3	See Appended Tables 7.1.2 and 7.1.3.	P
7.5	Safety signs		N
	Safety sign with established meaning used.	No safety sign used	N

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Clause	Requirement – Test	Result - Remark	Verdict
	Markings used to convey a warning, prohibition or mandatory action mitigating a RISK not obvious to OPERATOR are safety signs from ISO 7010		N
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT		N
	Specified colours in ISO 3864-1 used for safety signs		N
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		N
	Safety signs including any supplementary text or symbols described in instructions for use		N
	- and in a language acceptable to the intended OPERATOR		N
7.6	Symbols		P
7.6.1	Meanings of symbols used for marking described in instructions for use	Refer to the user manual	P
7.6.2	Symbols required by this standard conform to IEC or ISO publication referenced		P
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable		P
7.7	Colours of the insulation of conductors		N
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation	No protective earth conductor used.	N
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations	See above.	N
7.7.3	Green and yellow insulation identify only following conductors:	No any insulation identified as green and yellow.	N
	– PROTECTIVE EARTH CONDUCTORS		N
	– conductors specified in 7.7.2		N
	– POTENTIAL EQUALIZATION CONDUCTORS		N
	– FUNCTIONAL EARTH CONDUCTORS		N
7.7.4	Neutral conductors of POWER SUPPLY CORDS are “light blue” specified in IEC 60227-1 or IEC 60245-1	No power supply cord	N
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1		N
7.8	Indicator lights and controls		N
7.8.1	Colours of indicator lights		N
7.8.2	Colours of controls		N
7.9	Accompanying documents		P

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Clause	Requirement – Test	Result - Remark	Verdict
7.9.1	ME EQUIPMENT accompanied by documents containing at least instructions for use, and a technical description		P
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable		P
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to		P
	– MODEL or TYPE REFERENCE		P
	When ACCOMPANYING DOCUMENTS provided electronically (e.g., on CD ROM), USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT (for emergency operation)		N
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use		N
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended		N
7.9.2	Instructions for use		P
7.9.2.1	– use of ME EQUIPMENT as intended by the MANUFACTURER:		P
	– frequently used functions		P
	– known contraindication(s) to use of ME EQUIPMENT		N
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient		P
	– name or trademark and address of the MANUFACTURER		P
	– MODEL OR TYPE REFERENCE		P
	Instruction for use included the following when the PATIENT is an intended OPERATOR:		P
	– the PATIENT is an intended OPERATOR		P
	– warning against servicing and maintenance while the ME EQUIPMENT is in use		P
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and		P
	–maintenance the PATIENT can perform		P
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT		P
	Instructions for use are in a language acceptable to the intended operator		P
7.9.2.2	Instructions for use include all warning and safety notices		P
	Warning statement for CLASS I ME EQUIPMENT indicating: "WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth"		N

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Clause	Requirement – Test	Result - Remark	Verdict
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments		N
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference		N
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET indicating, "connecting electrical equipment to MSO effectively leads to creating an ME SYSTEM, and can result in a reduced level of safety"		N
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS		N
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply indicating "power supply is specified as a part of ME EQUIPMENT or combination is specified as a ME SYSTEM"		N
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source		N
	Warning to remove primary batteries when ME EQUIPMENT is not likely to be used for some time when leakage from battery would result in an unacceptable RISK		P
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided		P
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK		N
7.9.2.5	Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE	Refer to user manual	P
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to when such exposure can constitute an unacceptable RISK		N
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected		N
	APPLIED PARTS specified		P
7.9.2.6	Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation		N
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device when an APPLIANCE COUPLER or MAINS PLUG or other separable plug is used as isolation means to meet 8.11.1 a)		N

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Clause	Requirement – Test	Result - Remark	Verdict
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation including initial control settings, and connection to or positioning of PATIENT prior to use of ME EQUIPMENT, its parts, or ACCESSORIES	Refer to user manual	P
7.9.2.9	Information provided to operate ME EQUIPMENT including explanation of controls, displays and signals, sequence of operation, connection of detachable parts or ACCESSORIES, replacement of material consumed during operation	Refer to user manual	P
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use		P
7.9.2.10	A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message		P
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT		P
7.9.2.12	Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified		P
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use		N
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency		P
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT		P
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application		N
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL		N
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided		N
	Other equipment providing power to ME SYSTEM sufficiently described (e.g. part number, RATED VOLTAGE, max or min power, protection class, intermittent or continuous duty)		N
7.9.2.15	Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for use		P

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Clause	Requirement – Test	Result - Remark	Verdict
7.9.2.16	Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)		P
7.9.2.17	Instruction for use for ME EQUIPMENT emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation		N
7.9.2.18	The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile indicate that they have been sterilized and the method of sterilization		N
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization		N
7.9.2.19	The instructions for use contain a unique version identifier	Version __A1___	P
7.9.3	Technical description		P
7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use including the following		P
	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use including the following		P
	– information as in clause 7.2		
	– permissible environmental conditions of use including conditions for transport and storage		P
	– all characteristics of ME EQUIPMENT including range(s), accuracy, and precision of displayed values or where they can be found		P
	– special installation requirements such as maximum permissible apparent impedance of SUPPLY MAINS		N
	– permissible range of values of inlet pressure and flow, and chemical composition of cooling liquid used for cooling		N
	– a description of means of isolating ME EQUIPMENT from SUPPLY MAINS, when such means not in ME EQUIPMENT		N
	– a description of means for checking oil level in partially sealed oil filled ME EQUIPMENT or its parts when applicable		N
	– a warning statement addressing HAZARDS that can result from unauthorized modification of ME EQUIPMENT according to following examples		P
	"WARNING: No modification of this equipment is allowed"		P
	"WARNING: Do not modify this equipment without authorization of the manufacturer"		N
	"WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment"		N

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Clause	Requirement – Test	Result - Remark	Verdict
	- information pertaining to ESSENTIAL PERFORMANCE and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency		P
	Technical description separable from instructions for use contains required information, as follows *(Technical description is not separable from instructions for use)*		N
	– information as in clause 7.2		N
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT		
	– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and		N
	a unique version identifier		N
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description		N
7.9.3.2	Replacement of fuses, power supply cords and other parts		N
7.9.3.3	Circuit diagrams, component part lists, etc		N
7.9.3.4	Mains isolation		N
8	**Protection against electrical hazards from ME equipment**		P
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS		P
	NORMAL CONDITION considered as simultane occurrence of situations identified in 8.1a)		P
	SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b)		P
	ACCESSIBLE PARTS determined according to 5.9		P
	LEAKAGE CURRENTS measured according to 8.7	See appended table 8.7	P
8.2	Requirements related to power sources		N
8.2.1	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM		N
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		N
	All FIXED ME EQUIPMENT and PERMANENTLY INSTALLED MEDICAL EQUIPMENT shall be CLASS I ME EQUIPMENT.		N

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Clause	Requirement – Test	Result - Remark	Verdict
8.2.2	No HAZARDOUS SITUATION other than absence of ESSENTIAL PERFORMANCE developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source	No external d.c. source used	N
	ME EQUIPMENT connected with correct polarity did not present an unacceptable RISK		N
	Protective devices that can be reset by anyone without a TOOL restore correct operation on reset		N
8.3	Classification of APPLIED PARTS		P
	a) A PPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	No APPLIED PARTS.	N
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART		N
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	Type BF applied part	P
	d) Requirements of a TYPE B APPLIED PART applied to a part in 4.6 to be subjected to requirements for an APPLIED PART (except marking)		N
	Requirements for a TYPE BF or CF APPLIED PART applied as in RISK MANAGEMENT PROCESS		N
8.4	Limitation of voltage, current or energy		P
8.4.1	PATIENT CONNECTIONS intended to deliver Current		N
	Limits in 8.4.2 not applied to currents intended to flow through body of PATIENT to produce a physiological effect during NORMAL USE		N
8.4.2	ACCESSIBLE PARTS including APPLIED PARTS		P
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT per Tables 3 and 4 when measured according to Clause 8.7.4 :	See appended Table 8.7	P
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT in Cl. 8.7.3 c) when measured per Clause 8.7.4 (mA)		P
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed		P
	- accessible contacts of connectors		P

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Clause	Requirement – Test	Result - Remark	Verdict
	– contacts of fuseholders accessible during replacement of fuse		N
	– contacts of lampholders accessible after removal of lamp		N
	– parts inside an ACCESS COVER that can be opened without a TOOL , or where a TOOL is needed but the instructions for use instruct an OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER	Battery electrode can be accessible when access cover opened.	P
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.).	Max.3.0Vd.c.	N
	Limit of 60V d.c applied with no more than 10% peak-to-peak ripple, and when ripple larger than specified value, 42.4 V peak limit applied (V d.c.):		N
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential up to 2 V (VA or J) ..	Complied 3.0Vd.c. max. for the ME equipment, Much less than 240Vac nor 20J.	P
	LEAKAGE CURRENT limits referred to in 8.4.2 b) applied when voltages higher than limits in 8.4.2 c) were present (mA)	Not higher than limits in 8.4.2	N
	d) Voltage and energy limits specified in c) above also applied to the following		N
	– internal parts, other than contacts of plugs, connectors and socket-outlets, touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and		N
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length of 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls using a TOOL		N
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		N
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N		N
	Test repeated with a TOOL specified in instructions for use		N
	Test rod freely and vertically suspended through openings on top of ENCLOSURE		N
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION		N

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Clause	Requirement – Test	Result - Remark	Verdict
	A TOOL is required when it is possible to prevent the devices from operating		N
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one s after disconnecting the plug of ME EQUIPMENT or its parts (V) .	See appended Table 8.4.3	N
	A triggering circuit used to ensure disconnection occurred at peak of supply voltage waveform		N
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC		N
8.4.4	Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45 µC.		N
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		N
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 (IEC 60417-5036, DB: 2002-10), and manual discharging device specified in technical description		N
8.5	Separation of parts		P
8.5.1	MEANS OF PROTECTION (MOP)		P
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4	Refer to insulation diagram	P
	Each MEANS OF PROTECTION categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking into account Clause 4.6, and flow chart in Fig A.12		P
	Varnishing, enameling, oxidation, and similar protective finishes and coatings with sealing compounds replasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION		P
	Coatings and other insulation intended as a MEANS OF PROTECTION complying with IEC 60950-1:2001 considered acceptable as a MEANS OF OPERATOR PROTECTION but not automatically as a MEANS OF PATIENT PROTECTION		N
	RISK MANAGEMENT PROCESS taken into consideration for MEANS OF PATIENT PROTECTION		P
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		P

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Clause	Requirement – Test	Result - Remark	Verdict
	Insulation, CREEPAGE, CLEARANCES , components or earth connections not complying with 8.5.1.2 and 8.5.1.3 not considered as MEANS OF PROTECTION and failure of these parts regarded as NORMAL CONDITION		P
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		P
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of Clause 8.8 at test voltage of Table 6		P
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		P
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6		N
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength test for two MEANS OF PATIENT PROTECTION considered equivalent to one MEANS OF PATIENT PROTECTION		N
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N
	Voltage Total Working (V) and C Nominal (F) :		P
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)		P
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		P
	– dielectric strength test of 8.8 at test voltage of Table 6; or		P
	– requirements of IEC 60950-1 for INSULATION COORDINATION		N
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		P
	– limits of Tables 13 to 16 (inclusive); or		P
	– requirements of IEC 60950-1 for INSULATION COORDINATION		N
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6	No protective earth connections provided	N
	– or with requirements and tests of IEC 60950-1 for protective earthing		N
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION		N
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION		N
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N
	Voltage Total Working (V) and C Nominal (F)		N

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Clause	Requirement – Test	Result - Remark	Verdict
	Points at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION		P
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION		P
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION		P
8.5.2	Separation of PATIENT CONNECTIONS		P
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to maximum MAINS VOLTAGE and complied with limit for PATIENT LEAKAGE CURRENT at 110 % of max. MAINS VOLTAGE.		P
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		N
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		N
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS .		P
	Classification as TYPE BF, CF , or DEFIBRILLATION-PROOF applied to one entire APPLIED PART		P
	LEAKAGE CURRENT tests conducted per 8.7.4		P
	Dielectric strength test conducted per 8.8.3		P
	CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		N
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s		P
8.5.2.2	PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED	Not TYPE B APPLIED PART	N

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Clause	Requirement – Test	Result - Remark	Verdict
8.5.2.3	A connector on a PATIENT lead located at the end of the lead remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE		N
8.5.3	MAXIMUM MAINS VOLTAGE		P
	- MAXIMUM MAINS VOLTAGE determined to be the highest RATED supply voltage for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT, as well as INTERNALLY POWERED ME EQUIPMENT with a means of connection to a SUPPLY MAINS (V) .		N
	When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V		N
	- MAXIMUM MAINS VOLTAGE was the highest RATED phase to neutral supply voltage for poly-phase ME EQUIPMENT (V) ...		N
	– for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V		P
8.5.4	WORKING VOLTAGE		P
	- Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V) :	3.0Vd.c.	P
	- W ORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V)..... :		N
	- W ORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V) ..... :	See Insulation Diagram and Insulation Table	P
	- Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth		P
	- WORKING VOLTAGE between PATIENT CONNECTIONS of an F- TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V)		P
	- WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages		N
	- WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V)		N

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Clause	Requirement – Test	Result - Remark	Verdict
8.5.5	DEFIBRILLATION- PROOF APPLIED PARTS		N
8.5.5.1	Classification " DEFIBRILLATION- PROOF APPLIED PART" applied to one APPLIED PART in its entirety, but not separate functions of same APPLIED PART		N
	Possibility of an OPERATOR receiving a shock from such parts taken into consideration in RISK MANAGEMENT PROCESS		N
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION- PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		N
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator		N
	b) M E EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS		N
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load to at least 90% of energy delivered to this load with ME EQUIPMENT disconnected		N
8.6	Protective and functional earthing and potential equalization of ME EQUIPMENT		N
8.6.1	Requirements of 8.6.2 to 8.6.8 applied		N
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8		N
8.6.2	PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR:		N
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL		N
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside:		N
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		N
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		N

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Clause	Requirement – Test	Result - Remark	Verdict
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part, except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE :		N
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop		N
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits:		N
8.6.5	Surface coatings		N
	Poorly conducting surface coatings on conductive elements removed at the point of contact		N
	Coating not removed when requirements for impedance and current-carrying capacity met		N
8.6.6	Plugs and sockets		N
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections		N
	- applied also where interchangeable parts are PROTECTIVELY EARTHED	No interchangeable part	N
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR		N
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE	No such terminal used	N
	– RISK of accidental disconnection minimized in NORMAL USE		N
	– Terminal allows conductor to be detached without a TOOL		N
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		N
	– Terminal marked with symbol 8 of Table D.1 (i.e., symbol IEC 60417-5021)		N
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		N
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		N
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION	No functional earth terminal used	N

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Clause	Requirement – Test	Result - Remark	Verdict
8.6.9	Class II ME EQUIPMENT		N
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow		N
	Two MEANS OF PROTECTION provided by insulation of internal screens and all internal wiring connected to them with a related explanation in technical description:		N
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		P
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3 .... :	See appended Tables 8.7	P
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7 ..... :	See appended Tables 8.7	P
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		P
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		N
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		N
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION	No such test method used.	N
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		P
8.7.3	Allowable Values		P
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b :	See appended Table 8.7	P
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz :	See appended Table 8.7	P
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (ITNC, ITSFC).... :	See appended Table 8.7	P

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Clause	Requirement – Test	Result - Remark	Verdict
	d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITIONa nd 10 mA in SINGLE FAULT CONDITION.		N
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 .... :	Not permanently installed me equipment	N
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device..... :	Not with a non-frequency- weighted device	N
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements:	See appended Table 8.7	P
8.8	Insulation		P
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION and insulation between parts of opposite polarity of MAINS PART on SUPPLY MAINS side of mains fuse or OVER- CURRENT RELEASE		P
	Insulation exempted from test (complies with clause 4.8)		N
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		N
8.8.2	Distance through solid insulation or use of thin sheet material		N
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		N
	a) 0.4 mm, min, distance through insulation, or		N
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		N
	– at least two layers of material, each passed the appropriate dielectric strength test, or		N
	– three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test		N
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		N
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		N

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Clause	Requirement – Test	Result - Remark	Verdict
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		N
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		N
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		N
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L		N
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		N
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		N
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		N
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values		N
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension:		N
	Finished component complied with routine dielectric strength tests of 8.8.3:		N
	Tests of Annex L not repeated since material data sheets confirm compliance :		N
8.8.3	Dielectric Strength		P
	Solid insulating materials with a safety function withstood dielectric strength test voltages:	See appended Table 8.8.3	P
8.8.4	Insulation other than wire insulation		P
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		P
	ME EQUIPMENT and RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests:	See Appended RM Results Table 8.8.4.1	P
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat.:	See Table 8.10. The enclosure and PCB material had been approved.	N

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Clause	Requirement – Test	Result - Remark	Verdict
	Tests conducted in absence of satisfactory evidence for resistance to heat.:		P
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using apparatus of Fig 21	See Table 8.10. The enclosure and PCB material had been approved.	P
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C):		N
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION		P
8.8.4.2	Resistance to environmental stress		N
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9		N
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION		N
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION		N
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples		N
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h		N
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		P
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are to values in Tables 11 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15	Refer to insulation diagram table	P
8.9.1.2	Tables 11 to 16 (inclusive) not applied to CREEPAGE and CLEARANCES forming MEANS OF OPERATOR PROTECTION per IEC 60950-1 for INSULATION CO-ORDINATION and used under conditions compliance was tested		N

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Clause	Requirement – Test	Result - Remark	Verdict
8.9.1.3	Specified min CLEARANCE applied as min CREEPAGE for CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics	No such components used	N
8.9.1.4	When min CREEPAGE derived from Tables 11 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE		P
8.9.1.5	ME EQUIPMENT RATED to operate at an altitude of 2000 m		P
	ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m):	≤2000m	P
	Operating altitude corresponding to actual air pressure for ME EQUIPMENT intended for pressurized environments (e.g., aircraft) used to determine multiplication factor from Table 8, and AIR CLEARANCE was multiplied by this factor		N
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE		N
8.9.1.6	When WORKING VOLTAGE was between those in Tables 11 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows:		P
	– CREEPAGE DISTANCES determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm):	See Insulation Diagram/Table.	P
	– CLEARANCES for PEAK WORKING VOLTAGES above 2800 V peak or d.c. determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) :	See Insulation Diagram/Table.	P
	– for AIR CLEARANCES corresponding to PEAK WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied	No PEAK WORKING VOLTAGE up to 2800 V peak or d.c.	N
8.9.1.7	Material groups classified in accordance with Table 9 (Material Group):	See Insulation Diagram/Table.	P
	Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112	Material group considered group IIIb	N
	Material of unknown group considered IIIb	Group IIIb	P
8.9.1.8	– Pollution degree 1: Micro-environment sealed to exclude dust and moisture		N
	– Pollution degree 2: Micro-environment with non-conductive pollution, except occasional conductivity caused by condensation		P
	– Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation		N

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Clause	Requirement – Test	Result - Remark	Verdict
	– Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions		N
	Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION		N
	Where insulation between MAINS PART and earth might be compromised, measures such as maintenance ensure that micro-environment is mitigated to a lower pollution degree	Pollution degree 2	N
8.9.1.9	Overvoltage category classification; value of MAINS TRANSIENT VOLTAGE determined from overvoltage category per IEC60664-1 and NOMINAL a.c. MAINS VOLTAGE using Table 10		N
	V MT Peak (V) :		—
	V MN r.m.s (V) .:		—
8.9.1.10	AIR CLEARANCE for MAINS PARTS (operating on RATED MAINS VOLTAGES up to 300 V) were values for r.m.s. or d.c. RATED MAINS VOLTAGE in Table 13 plus additional CLEARANCE in Table 14 for PEAK WORKING VOLTAGE	Operating on rated mains voltages is 110	N
8.9.1.11	SUPPLY MAINS overvoltage category II applied according to IEC 60664-1	Overvoltage category II	N
	For ME EQUIPMENT intended for overvoltage category III, Tables 13 to 15 (inclusive) not used for clearance, instead values in the next MAINS TRANSIENT VOLTAGE column upwards used		N
	When PATIENT protection (Table 12) is required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, guidance provided on values required in the rationale for Cl. 8.9 used		N
8.9.1.12	A SECONDARY CIRCUIT derived from a SUPPLY MAINS, normally, considered to be overvoltage category I according to IEC 60664-1 when the MAINS PART is overvoltage category II (Table 15)	The secondary circuit was considered to be overvoltage category I.	N
	Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT		N
	Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS		N
	Table 15 applied when SECONDARY CIRCUIT was separated from MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in SECONDARY CIRCUIT were below the levels expected for overvoltage category I		N
	Table 15 column for circuits not subject to transient overvoltages applied to:		N

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Clause	Requirement – Test	Result - Remark	Verdict
	– d.c. SECONDARY CIRCUITS reliably connected to earth and have capacitive filtering limiting peak-to- peak ripple to 10 % of d.c. voltage, and		N
	– circuits in INTERNALLY POWERED ME EQUIPMENT		N
8.9.1.13	For PEAK WORKING VOLTAGES above 1400 V peak or d.c. Table 15 not applied since all the following conditions were met:	No PEAK WORKING VOLTAGES above 1400 V peak or d.c.	N
	– CLEARANCE was at least 5 mm		N
	– insulation complied with dielectric strength test of 8.8.3 using an a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, or		N
	– a d.c. test voltage equal to peak value of a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, and		N
	– CLEARANCE path was partly or entirely through air or along the surface of an insulating material of material group I		N
	Dielectric strength test conducted only across part(s) of the path that are through air when CLEARANCE path was also partly along surface of a non- group I material		N
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION obtained by doubling values in Table 16 for one MEANS OF OPERATOR PROTECTION		P
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1	No such applied parts	N
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied :		N
	b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths	Evaluated in approved switching power supply board	N
	c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION is such that the relevant parts are rigid and located by molding, or there is no reduction of a distance below specified value by deformation or movement of parts		P
	Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE		N
8.9.3	Spaces filled by insulating compound		N

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Clause	Requirement – Test	Result - Remark	Verdict
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound were such that CLEARANCES and CREEPAGE DISTANCES don't exist	No such insulation components used	N
	Thermal cycling, humidity preconditioning, and dielectric strength tests in 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4 conducted		N
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (clause 8.8.3), test voltage multiplied by 1.6:		N
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		N
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint		N
	A winding of solvent-based enameled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		N
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling, it was subjected to dielectric strength test of 8.8.3 except at 1.6 times the test voltage ..... :		N
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of 8.8.3 at 1.6 times the test voltage		N
8.9.3.4	One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times:		N
8.10	Components and wiring		P
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely as indicated in RISK MANAGEMENT FILE:		P
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION:		P
	Conductors and connectors of ME EQUIPMENT when breaking free at their joint are not capable of touching circuit points resulting in a HAZARDOUS SITUATION as indicated in RISK MANAGEMENT FILE		P
	Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION		P

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Clause	Requirement – Test	Result - Remark	Verdict
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS due to poor contact		P
8.10.3	Flexible cords detachable without a TOOL used to interconnect different parts of ME EQUIPMENT provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS of 8.4 when a connection is loosened or broken as shown by measurement or using test finger		P
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		N
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF ROTECTION	No such parts used	N
	d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple		N
	42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit		N
8.10.4.2	Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT at both ends of cable to control device complied with 8.11.3 when breaking free or shorting between conductors could result in a HAZARDOUS SITUATION		N
	This requirement applied to other HAND-HELD parts when disturbance or breaking of one or more of connections could result in a HAZARDOUS SITUATION		N
8.10.5	Mechanical protection of wiring		P
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION .:		P
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION as shown by manual tests and RISK MANAGEMENT FILE		P
8.10.6	Guiding rollers of insulated conductors prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead concerned in NORMAL USE	No guiding rollers used	N
8.10.7	a) Insulating sleeve that can only be removed by breaking or cutting, or secured at both ends, is used on internal wiring of when needed:	See appended Table 8.10	N

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Clause	Requirement – Test	Result - Remark	Verdict
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics	The mechanical or thermal stresses did not over its RATED characteristics	N
	c) Insulated conductors subject to temperatures > 70 °C in NORMAL USE provided with insulation of heat-resistant material when compliance is likely to be impaired due to deterioration of insulation :	No more than 70 °C	N
8.11	MAINS PARTS, components and layout		N
	a)To reflect agreement with the NEC, add t he following requirements to this clause: Permanently connected ME EQUIPMENT shall have provision for the connection of one of the wiring systems that is in accordance with the NEC.	Not permanently connected ME EQUIPMENT	N
	b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, V/20 A “Hospital Grade” mains plug shall be provided and the POWER SUPPLY CORD shall be marked.		P
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles :		N
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	Not PERMANENTLY INSTALLED ME EQUIPMENT.	N
	b) Means of isolation incorporated in ME EQUIPMENT, and external means described in technical description	Incorporated in ME EQUIPMENT.	N
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE and CLEARANCES in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV :	See appended Table 8.10	N
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead		N
	e) Direction of movement of actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		N
	f) A suitable plug device such as an APPLIANCE COUPLER or a flexible cord with a MAINS PLUG used in non-PERMANENTLY INSTALLED ME EQUIPMENT to isolate it from SUPPLY MAINS considered to comply with 8.11.1 a):	Appliance coupler used See appended Table 8.10	N
	g) A fuse or a semiconductor device not used as an isolating means		N

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Clause	Requirement – Test	Result - Remark	Verdict
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device		N
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering	No such devices used	N
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage (symbol 10 of Table D.1 is insufficient)		N
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		N
	Standard test finger of Fig 6 applied		N
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	No multiple socket-outlets integral with ME equipment	N
8.11.3	POWER SUPPLY CORDS		N
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD		N
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord(IEC 60227-1:1993, Annex A, design. 53):		N
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE:		N
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 (mm2 Cu) :		N
	To reflect agreement with NFPA 99, for X-Ray ME EQUIPMENT with an attachment plug, the current rating on a hospital grade plug should be 2X the maximum input current of the equipment.		N
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6:	See appended Table 8.10	N
8.11.3.5	Cord anchorage (for APPLIANCE COUPLERS not complying with IEC 60320-1)		N

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Clause	Requirement – Test	Result - Remark	Verdict
	a) Conductors of POWER SUPPLY CORD provided with strain relieve and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage	APPLIANCE COUPLERS is complying with IEC 60320-1, see appended table 8.10	N
	b) Cord anchorage of POWER SUPPLY CORD is made of and arranged as follows when a total insulation failure of POWER SUPPLY CORD caused conductive non-PROTECTIVELY EARTHED ACCESSIBLE PARTS to exceed limits of 8.4:		N
	– insulating material, or		N
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		N
	– metal provided with an insulating lining affixed to cord anchorage, except when it is a flexible bushing forming part of the cord guard in 8.11.3.6, and complying with the requirements for one MEANS OF PROTECTION		N
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage		N
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals when cord anchorage fails		N
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 :		N
	Cord subjected to a torque in Table 18 for 1 min immediately after pull tests		N
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position		N
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage		N

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Clause	Requirement – Test	Result - Remark	Verdict
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals when cord anchorage fails		N
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18:		N
	Cord subjected to a torque in Table 18 for 1 min immediately after pull tests		N
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position		N
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged		N
8.11.3.6	POWER SUPPLY CORDS other than for STATIONARY ME EQUIPMENT protected against excessive bending at inlet opening of equipment or of MAINS CONNECTOR by means of an insulating cord guard or by means of an appropriately shaped opening	No Cord guards used	N
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D2 gram attached to the free end of cord (g):		N
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		N
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D:		N
8.11.4	MAINS TERMINAL DEVICES		N
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD replaceable by SERVICE PERSONNEL provided with MAINS TERMINAL DEVICES ensuring reliable connection	Not such device.	N

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Clause	Requirement – Test	Result - Remark	Verdict
	Terminals alone are not used to keep conductors in position, except when barriers are provided such that CREEPAGE and CLEARANCES cannot be reduced below 8.9 if any conductor breaks away		N
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked according to 7.3.7 used as terminals intended for external conductors		N
	Screws and nuts clamping external conductors do not serve to secure any other component, except they also clamp internal conductors when unlikely to be displaced when fitting the supply conductors		N
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection	No such terminals used	N
	b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6		N
	c) Marking of MAINS TERMINAL DEVICES complied with 7.3		N
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		N
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction		N
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced below 8.9 after fastening and loosening a conductor of largest cross-sectional area 10 times		N
8.11.4.4	Terminals with clamping means for a rewirable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened as verified by test of 8.11.3.4		N
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a re-wirable POWER SUPPLY CORD to allow for connection of conductors, and covers fitted without damage to conductors or their insulation		N
	Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation test		N
8.11.5	Mains fuses and OVER-CURRENT RELEASES		P

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Clause	Requirement – Test	Result - Remark	Verdict
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection per clause 8.6.9, and in at least one supply lead for other single- phase CLASS II ME EQUIPMENT :	CLASS I ME EQUIPMENT	N
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	Not PERMANENTLY INSTALLED ME EQUIPMENT	N
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts of opposite polarity within MAINS PART, and between all parts of MAINS PART and earth, and such provisions continued within all components	Not omitted fuses or OVER-CURRENT RELEASES.	N
	Effect of short-circuit fault conditions in other circuits taken into consideration before eliminating fuses or OVER-CURRENT RELEASES		N
	Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit :	See appended Table 8.10	N
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR	Fuse not provided in a PROTECTIVE EARTH CONDUCTOR	N
	Fuses complying with IEC 60127 have high breaking capacity (1 500 A) and prospective short-circuit current > 35 A or 10 times current rating of the fuse, whichever is greater	See appended Table 8.10	N
	Justification for omission of fuses or OVER-CURRENT RELEASES is in RISK MANAGEMENT FILE		N
8.11.6	Internal wiring of the MAINS PART		N
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE and protective devices is not less than minimum required for POWER SUPPLY CORD as in clause8.11.3.3 (mm2 Cu):		N
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits sufficient to prevent fire in case of fault currents . :	See appended Table 8.10	N
	When necessary, ME EQUIPMENT connected to a SUPPLY MAINS with max available short-circuit fault, and subsequent simulation of a fault in a single insulation in MAINS PART did not result in any of the HAZARDOUS SITUATIONS in 13.1.2		N
9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPENT AND ME SYSTEMS**		P
9.1	Mechanical hazards of ME equipment		P
9.2	Hazards associated with moving parts		N
9.2.1	General		N

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Clause	Requirement – Test	Result - Remark	Verdict
9.2.2	Trapping zone		N
9.2.2.1	General		N
9.2.2.2	Gaps		N
9.2.2.3	Safe distances		N
9.2.2.4	Guards and protective measures		N
9.2.2.4.1	Access to trapping zones		N
9.2.2.4.2	Fixed guards		N
9.2.2.4.3	Movable guards		N
9.2.2.4.4	Protective measures		N
9.2.2.5	Continuous activation		N
9.2.2.6	Speed of movement(s)		N
9.2.3	Other hazards associated with moving parts		N
9.2.3.1	Unintended movement		N
9.2.3.2	Overtravel		N
9.2.4	Emergency stopping devices		N
9.2.5	Release of patient		N
9.3	Hazard associated with surfaces, corners and edges	No rough surfaces, sharp corners or edges existed for the ME equipment	P
9.4	Instability hazards		N
9.4.1	General		N
9.4.2	Instability-overbalance		N
9.4.2.1	Instability transport position		N
9.4.2.2	Instability excluding transport		N
9.4.2.3	Instability from horizontal and vertical forces		N
9.4.2.4	Castors and wheels		N
9.4.2.4.1	General		N
9.4.2.4.2	Force for propulsion		N
9.4.2.4.3	Movement over a threshold		N
9.4.3	Instability from unwanted lateral movement(including sliding)		N
9.4.3.1	Instability in transport		N
9.4.3.2	Instability excluding transport		N
9.4.4	Grips and other handling devices		N
9.5	Expelled parts hazard		N
9.5.1	Protective means		N
9.5.2	Cathode ray tubes		N

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Clause	Requirement – Test	Result - Remark	Verdict
9.6	Acoustic energy(including infra-and ultrasound) and vibration		N
9.6.1	General		P
9.6.2	Acoustic energy		P
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE, except for auditory ALARM SIGNALS		P
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA)		N
	- 83 dBA (when halving the cumulative exposure time) (dBA)	45dB	P
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB)		N
9.6.2.2	Infrasound and ultrasound energy		N
9.6.3	Hand-transmitted vibration		N
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N
9.7.1	General		N
9.7.2	Pneumatic and hydraulic parts		N
9.7.3	Maximum pressure		N
9.7.4	Pressure rating of ME equipment parts		N
9.7.5	Pressure vessels		N
9.7.6	Pressure-control device		N
9.7.7	Pressure-relief device		N
9.7.8	Rated maximum supply pressure		N
9.8	Hazards associated with support systems		N
9.8.1	General		N
9.8.2	Tensile safety factor		N
9.8.3	Strength of patient or operator support or suspension systems		N
9.8.3.1	General		N
9.8.3.2	Static forces due to loading from persons		N
9.8.3.3	Dynamic forces due to loading from persons		N
9.8.4	Systems with mechanical protective devices		N
9.8.4.1	General		N
9.8.4.2	Use after activation of a mechanical protective device		N
9.8.4.3	Mechanical protective device intended for single activation		N

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Clause	Requirement – Test	Result - Remark	Verdict
9.8.5	Systems without mechanical protective devices		N
10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		**N**
10.1	X-Radiation		N
10.1.1	ME equipment not intended to produce diagnostic or therapeutic X-radiation		N
10.1.2	ME equipment intended to produce diagnostic or therapeutic X-radiation		N
10.2	Alpha, beta, gamma ,neutron and other particle radiation		N
10.3	Microwave radiation		N
10.4	Lasers and light emitting diodes(LEDs)		N
10.5	Other visible electromagnetic radiation		N
10.6	Infrared radiation		N
10.7	Ultraviolet radiation		N
11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		**P**
11.1	Excessive temperatures in ME equipment		P
11.1.1	Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and 23 operating in worst-case NORMAL USE at maximum rated ambient operating temperature T		P
	Surfaces of test corner did not exceed 90 °C	No heating element, test in normal use condition, not use test corner	N
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	No thermal-cut out used in ME equipment	N
11.1.2	Temperature of applied parts		P
11.1.2.1	Applied parts intended to supply heat to a patient	Applied part not supply heat to patient	N
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in both NORMAL CONDITION and SINGLE FAULT CONDITION		P
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual	Not exceed 41°C	N
	Clinical effects with respect to characteristics such as body surface, maturity of PATIENTS, medications being taken or surface pressure documented in the RISK MANAGEMENT FILE		N
	APPLIED PARTS surface temperature of equal to or less than 41°C		P

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Clause	Requirement – Test	Result - Remark	Verdict
	Analysis documented in the RISK MANAGEMENT FILE show that APPLIED PART temperatures are not affected by operation of the ME EQUIPMENT including SINGLE FAULT CONDITIONS. Measurement of APPLIED PART temperature according to 11.1.3 is not conducted		P
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS		N
11.1.3	Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE	Temperature measurement test carried out	N
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE	No such judgment and rationale	N
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE		P
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	No such guards used for the ME equipment	N
11.2	Fire prevention		P
11.2.1	Strength and rigidity required to prevent fire in ME equipment		P
11.2.2	ME equipment and ME systems used in conjunction with oxygen rich environments		N
11.2.2.1	Risk of fire in an oxygen rich environment		N
11.2.2.2	External exhaust outlets for oxygen rich environment		N
11.2.2.3	Electrical connections in oxygen rich environments		N
11.2.3	Single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems		N
11.3	Constructional requirements for fire enclosures of ME equipment		P
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2		P
	Constructional requirements were met, or		P
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE		N
	Justification, when requirement not met		N
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials		P

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Clause	Requirement – Test	Result - Remark	Verdict
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of materials data		P
	If no FV Certification, FV tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings		N
	b) Fire ENCLOSURE met following:		P
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm		P
	2) No openings on the sides within the area included within the inclined line C in Fig 39		P
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials, except constructions based on Table 25 and a mesh; FV-2 or better for TRANSPORTABLE ME EQUIPMENT, FV-1 or better for fixed EQUIPMENT, or STATIONARY EQUIPMENT per IEC 60695-11-10, determined by ENCLOSURE examination or flammability classification based on 11.3a)		P
11.4	ME equipment and ME systems intended for use with flammable anaesthetics		N
11.5	ME equipment and ME systems intended for use in conjunction with flammable agents		N
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME equipment		P
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT	See Appended Table 11.6.1	P
11.6.2	Overflow in ME equipment		N
	ME EQUIPMENT incorporates a reservoir or liquid storage that is liable to be overfilled or to overflow in NORMAL USE, liquid overflowing from the reservoir or chamber did not wet any MEANS OF PROTECTION that is liable to be adversely affected by such a liquid, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		N

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Clause	Requirement – Test	Result - Remark	Verdict
	Maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.		N
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.		N
11.6.3	Spillage on ME equipment and me system		N
	ME EQUIPMENT and ME SYSTEMS handling liquids in NORMAL USE positioned as in 5.4 a) and liquid with composition, volume, duration of spill and point of contact based on the RISK ANALYSIS and test conditions based on RISK MANAGEMENT PROCESS poured steadily on a point on top of ME EQUIPMENT	No handing liquids in normal use	P
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and un-insulated electrical parts or electrical insulation of parts that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION were not wet		P
11.6..4	Leakage	See 13.2.6	P
11.6.5	Ingress of water or particulate matter into ME equipment and ME systems		P
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)		P
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION		P
11.6.6	Cleaning and disinfection of ME equipment and me systems		P
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected once using methods specified in instructions for use including any cooling or drying period		P

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Clause	Requirement – Test	Result - Remark	Verdict
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests, with no deterioration resulting in an unacceptable RISK present		P
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER and assurance that the processes did not cause a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		P
11.6.7	Sterilization of ME equipment and ME systems		N
11.6.8	Compatibility with substances used with the ME equipment		N
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented per ISO 10993	Evaluated by the manufacture	N/E
11.8	Interruption of the power supply/supply mains to ME equipment		P
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		**P**
12.1	RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review	See Appended RM Results Table 12.1	P
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING PROCESS complying with IEC 60601-1-6	Evaluated by the manufacture	N/E
12.3	MANUFACTURER implemented an ALARM SYSTEM that complies with IEC 60601-1-8.	No alarm system	N
12.4	Protection against hazardous output		P
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE		N
12.4.2	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE		N
12.4.3	Accidental selection of excessive output values		N
12.4.4	When applicable, RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		P
12.4.5	Diagnostic or therapeutic radiation		N
12.4.5.1	Limits		N
12.4.5.2	Diagnostic X-ray equipment		N
12.4.5.3	Radiotherapy equipment		N
12.4.5.4	Other ME equipment producing diagnostic or therapeutic radiation		N

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Clause	Requirement – Test	Result - Remark	Verdict
12.4.6	Diagnostic or therapeutic acoustic pressure		N
13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		**P**
13.1	Specific hazardous situations		P
13.1.1	General		P
13.1.2	Emissions, deformation of enclosure or exceeding maximum temperature		P
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		P
	Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		P
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 when measured as in 11.1.3		P
	Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 when measured and adjusted as in 11.1.3		P
	–Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C were not exceeded		P
	Limits for windings in Tables 26, 27, and 31 not exceeded		P
	Table 22 not exceeded in all other cases		P
	Temperatures measured according to 11.1.3	No such windings used in ME equipment	P
	SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where:		P
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit in SINGLE FAULT CONDITION		N
	- or secondary circuits mounted on materials with a minimum flame rating of FV1, and		N
	- Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and		N
	- Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and		N
	- Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide		N
	- or components in the circuit have HIGH INTEGRITY CHARACTERISTICS		N

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Clause	Requirement – Test	Result - Remark	Verdict
	– or parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation	See appended Table 8.10, and the certification documents of the material of the fire ENCLOSURE	P
	After tests of this Clause, settings of THERMAL CUTOUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		N
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed		P
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed		P
13.1.4	ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS		P
13.2	Single fault conditions		P
13.2.1	General		P
13.2.2-13.2.12	ME EQUIPMENT complied with 13.2.2 -13.2.12		P
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to within 3℃ of the temperature in the test environment		P
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		P
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION (see 8.8), the ballpressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).	Ball-pressure test for nonmetallic enclosure has been carried out at 75°C	P
13.2.13.2	ME equipment with heating elements		N
13.2.13.3	ME equipment with motors		N
13.2.13.4	ME equipment rated for non-continuous operation		N

14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		**P**
14.1	Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE, or	These requirements of clause applied to this device.	N
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK		P
	Requirements of 14.13 applied to PEMS intended to be incorporated into an IT NETWORK		P
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304		P
	Software development process applied according to Clause 5 of IEC 62304		P

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Clause	Requirement – Test	Result - Remark	Verdict
	Software development process for Software risk management applied according to Clause 7 of IEC 62304		P
	Software development process Configuration Management applied according to Clause 8 of IEC 62304		P
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304		P
14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process		P
14.3	Risk management plan		P
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented		P
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		P
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone		P
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules		P
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		P
14.5	Problem resolution	See the software files provided by the manufacturer	P
14.6	Risk management process		P
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of thirdparty origin, legacy subsystems when compiling list of known or foreseeable HAZARDS		P
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2		P
14.7	A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem		P
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems	See Appended RM Results Table 14.8	P
14.9	Design is broken up into subsystems, each with a design and test specification where appropriate, and descriptive data on design environment documented		P

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Clause	Requirement – Test	Result - Remark	Verdict
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures		P
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE		P
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE		P
14.13	For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following		N
15	**CONSTRUCTION of ME EQUIPMENT**		**P**
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS in accordance with IEC 60601-1-6, when applicable	Evaluated by manufacture	N/E
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance		P
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		P
15.3	Mechanical strength		P
15.3.1	Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		P
15.3.2	Push test conducted by subjecting external parts of ENCLOSURE to a steady force of 250 N ± 10 N for 5 s applied to a circular (30mm) plane surface, except bottom of ENCLOSURE of an ME EQUIPMENT >18 kg, using a suitable test tool		P
15.3.3	Impact test conducted by subjecting a complete ENCLOSURE or its largest non-reinforced area, except for HAND-HELD ME EQUIPMENT and parts, to a free falling 500 g ± 25 g solid smooth steel ball, approx. 50 mm in diameter from a height of 1.3 m		N
15.3.4	Drop test		P
15.3.4.1	Hand-held ME equipment		P
15.3.4.2	Portable ME equipment		N
15.3.5	Rough handling test		N
15.3.6	Mould stress relief test		P
15.3.7	Environmental influences		P
15.4	ME equipment components and general assembly		P

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Clause	Requirement – Test	Result - Remark	Verdict
15.4.1	Construction of connectors		N
15.4.2	Temperature and overload control devices		N
15.4.2.1	Application		N
15.4.2.2	Temperature settings		N
15.4.3	Batteries		P
15.4.3.1	Housing		P
15.4.3.2	Connection		P
15.4.3.3	Protection against overcharging		N
15.4.3.4	Lithium batteries		N
15.4.3.5	Excessive current and voltage protection		P
15.4.4	Indicators		P
15.4.5	Pre-set controls		N
15.4.6	Actuating parts of controls of ME equipment		N
15.4.6.1	Fixing, prevention of maladjustment		N
15.4.6.2	Limitation of movement		N
15.4.7	Cord-connected hand-held and foot-operated control devices		N
15.4.7.1	Mechanical strength		N
15.4.7.2	Accidental operation of ME equipment		N
15.4.7.3	Entry of liquids		N
15.4.8	Internal wiring of ME equipment		N
15.4.9	Oil containers		N
15.5	Mains supply transformers of ME equipment and transformers providing separation in accordance with 8.5		N
15.5.1	Overheating		N
15.5.1.1	Transformers		N
15.5.1.2	Short-circuit test		N
15.5.1.3	Overload test		N
15.5.2	Dielectric strength		N
15.5.3	Construction of transformers used to provide separation as required by 8.5		N
16	**ME SYSTEMS**		**N**
16.1	General requirements for the ME systems		N
16.2	Accompanying documents of an me system		N
16.3	Power supply		N
16.4	Enclosures		N
16.5	Separation devices		N

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Clause	Requirement – Test	Result - Remark	Verdict
16.6	Leakage currents		N
16.6.1	Touch current		N
16.6.2	Earth leakage current of multiple socket-outlet		N
16.6.3	Patient leakage current		N
16.6.4	Measurements		N
16.6.4.1	General conditions for ME systems		N
16.6.4.2	Connection of the ME systems to the measuring supply circuit		N
16.7	Protection against mechanical hazards		N
16.8	Interruption of the power supply to parts of an me system		N
16.9	Me system connections and wiring		N
16.9.1	Connection terminals and connectors		N
16.9.2	Mains parts, components and layout		N
16.9.2.1	Multiple socket-outlet		P
16.9.2.2	Protective earth connections in ME systems		P
16.9.2.3	Protection of conductors		P
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		N/E
	RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review:	Not evaluated in this report	N/E
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS:		N/E
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems		N/E
G	PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES		N
G.1	Introduction		N
G.1.1	Applicability		N
G.1.2	Industrial equipment and components		N
G.1.3	Requirements for ME equipment		N
G.2	Locations and basic requirements		N
G.2.1	Parts of category APG ME equipment		N
G.2.2	Flammable anaesthetic mixture with air		N
G.2.3	Flammable anaesthetic mixture with oxygen or nitrous oxide		N

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Clause	Requirement – Test	Result - Remark	Verdict
G.2.4	ME equipment specified for use with flammable anaesthetic mixture with air		N
G.2.5	ME equipment specified for use with flammable anaesthetic mixture with oxygen or nitrous oxide		N
G.3	Marking, accompanying documents		N
G.3.1	Category APG marking		N
G.3.2	Category AP marking		N
G.3.3	Placement of markings		N
G.3.4	Accompanying documents		N
G.3.5	Marking when parts of ME equipment are category AP or category APG		N
G.4	Common requirements for category AP and category APG ME equipment		N
G.4.1	Electrical connections		N
G.4.2	Construction details		N
G.4.3	Prevention of electrostatic charges		N
G.4.4	Corona		N
G.5	Requirements and tests for category AP ME equipment, parts and components thereof		N
G.5.1	General		N
G.5.2	Temperature limits		N
G.5.3	Low-energy circuits		N
G.5.4	External ventilation with internal overpressure		N
G.5.5	Enclosures with restricted breathing		N
G.6	Requirements and tests for category APG ME equipment, parts and components thereof		N
G.6.1	General		N
G.6.2	Power supply		N
G.6.3	Temperatures and low-energy circuits		N
G.6.4	Heating elements		N
G.7	Test apparatus for flammable mixtures		N
H	PEMS STRUCTURE,PEMS DEVELOP,ENT LIFE-CYCLE AND DOCUMENTATION		N
H.1	Examples for PEMS/PESS structures		N
H.2	PEMS development life-cycle model		N
H.3	Software processes		N
H.3.1	PEMS development life-cycle		N
H.3.2	Requirements specification		N
H.3.3	Third-party and off-the-shelf (OTS) software		N

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Clause	Requirement – Test	Result - Remark	Verdict
H.3.4	Integration		N
H.3.5	Configuration management		N
H.3.6	Modification/change control		N
H.4	Design and implementation		N
H.5	Documentation		N
H.6	Network/data coupling		N
H.6.1	General		N
H.6.2	System integration responsibilities		N
H.7	Design considerations for network/data coupling		N
H.7.1	Introduction		N
H.7.2	Causes of hazards associated with network/data coupling		N
H.7.3	Network classification based on the consequence to the patient		N
H.7.3.1	Consequence to the patient		N
H.7.3.2	Class C network/data coupling (patient vital data, time critical)		N
H.7.3.3	Class B network/data coupling (patient vital data, non-time critical)		N
H.7.3.4	Class A network/data coupling		N
H.7.4	network/data coupling parameters		N
I	ME SYSTEMS ASPECTS		N
I.1	Combinations of ME equipment and non-ME equipment		N
I.1.1	Introduction		N
I.1.2	Localities in a medical environment		N
I.1.3	Basic principles		N
I.1.4	Examples of ME systems		N
I.2	Examples of application of multiple socket-outlets(MSO)		N
J	SURVEY OF INSULATION PATHS		N
K	SIMPLIFIED PATIENT LEAKAGE CURRENT DIAGRAMS		N
L	INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION		N

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Clause	Requirement – Test	Result - Remark	Verdict
L.1	Introduction		N
L.2	Wire construction		N
L.3	Type test		N
L.3.1	Dielectric strength		N
L.3.2	Flexibility and adherence		N
L.3.3	Heat shock		N
L.3.4	Retention of electric strength after bending		N
L.4	Tests during manufacture		N
L.4.1	General		N
L.4.2	Routine testing		N
L.4.3	Sampling tests		N

4.11	**TABLE: Power Input**			**N**
Un(V)	I(rating)	In(W)	P(rating)	Condition/status
Supplementary Information: The maximum measured power is less than 110% of the rating				

5.9.2	**TABLE: TABLE: Determination of ACCESSIBLE parts**	**P**
Location	Determination method (NOTE1)	Comments
Enclosure	visual	No any internal parts can be accessible after using of rigid test finger, jointed test finger, test hook
Supplementary information: NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.		

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Clause	Requirement – Test	Result - Remark	Verdict

7.1.2	TABLE: Legibility of Marking		P
Markings tested		Ambient Illuminance (lx)	Remarks
Outside Markings (Clause 7.2)		100/500lx	Clearly legible
Inside Markings (Clause 7.3)		100/500lx	Clearly legible
Controls & Instruments (Clause 7.4)		100/500lx	Clearly legible
Safety Signs (Clause 7.5)		100/500lx	Clearly legible
Symbols (Clause 7.6)		100/500lx	Clearly legible
Supplementary information:			
NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.			

7.1.3	**TABLE: durability of marking test**		**P**
Location	Checked by	Time	Result
Material of Marking Label	Polyester label	15s	Marking remained legible and did not peel away from surface
Ink/other printing material or process	Ink	15s	Marking remained legible and did not peel away from surface

8.4.3	**TABLE: residual voltage in attachment plug**									**N**
Maximum allowable voltage (V)..... ....:										3
Voltage measured between:	Measurements (V)									
	1	2	3	4	5	6	7	8	9	10
Line and Neutral										
Line and Earth										
Neutral and Earth										
Remark: Measurement made only once since oscilloscope was used to capture the peak voltage										

8.4.4	**TABLE: residual voltage or energy in capacitors**				**N**
Capacitor and location	Residual voltage (V)	Time after disconnection (s)	Capacitance value	Residual energy (mJ)	Remark
Remark: Measurement made only once since oscilloscope was used to capture the peak voltage					

8.5.5.1a	**TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies**				**N**
Test Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks

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Clause	Requirement – Test	Result - Remark	Verdict

Supplementary information: No defibrillation-proof applied part.					

8.5.5.1b	**TABLE: defibrillation-proof applied parts – verification of recovery time**				N
Applied part with test voltage		Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks
Supplementary information: No defibrillation-proof applied part.					

8.5.5.2	**TABLE: DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 load**	**N**

Test Voltage applied to	Measured Energy E1, (mJ)	Measured Energy E2, (mJ)	Energy E1 as % of E2, (%)
PATIENT CONNECTION 1 or APPLIED PART with PATIENT CONNECTIONS 2, 3, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 2 or APPLIED PART with PATIENT CONNECTIONS 1, 3, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 3 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 4 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 3 of the same APPLIED PART connected to earth			
Supplementary information: For compliance: E1 must at least 90% of E2 E1= Measured energy delivered to 100 with ME Equipment connected; E2= Measured energy delivered to 100 without ME equipment connected.			

8.6.4	**TABLE: Impedance and current-carrying capability of protective earth connections**	**N**

Type of ME EQUIPMENT & impedance measured between parts	Test current (A) / Duration (s)	Voltage drop measured x between parts (V)	Maximum calculated impedance (m)	Maximum allowable impedance (m)

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Clause	Requirement – Test	Result - Remark	Verdict

Supplementary information:

8.7	TABLE: Leakage current				P
Type of leakage current and test Condition (including single fault)		Supply voltage	Supply frequency	Measured max. value	Remarks
Fig. 13 - Earth Leakage (ER)		-	-	-	Maximum allowed values:5 mA NC; 10 mA SFC
Fig. 14 - Touch Current (TC)		-	-	-	Maximum allowed values: 100 µA NC; 500 µA SFC
TC. NC		3.0Vdc	-	0/0	B/A
Fig. 15 - Patient Leakage Current (P)		-	-	-	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
P, NC		3.0Vdc	-	a.c.: 0/0 d.c.:0/0	B/A
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)		-	-	-	Maximum allowed values: Type B: N/A Type BF AP: 5000 µA Type CF AP: 50 µA
PM; SFC; S9=R		264V	-	0/0	B/A
PM; SFC; S9=N		264V	-	0/0	B/A
Remark: Record at least maximum measured value for each test required by Clause 8 and the specific conditions of the test circuit and equipment.					
Abbreviations used:					
ER – Earth leakage current EN – Enclosure leakage current P - Patient leakage current PM – Patient leakage current with mains on the 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

8.8.3	TABLE: dielectric strength			P
Insulation under test (area from insulation diagram)	Insulation type: (OP – operational /BI- basic/ SI- supplementary/ DI- double / RI- reinforced)	Reference voltage (V)	Test Voltage (V)	Remarks Breakdown
C	2MOPP	3.0	1000	No
D	1MOPP	250	1500	No
Supplementary information:				

8.8.4.1	TABLE: TABLE: Resistance to heat - Ball pressure test of thermoplastic parts		P
	Allowed impression diameter (mm) .....:	2 mm	
	Force (N) ....:	20	
Part/material		Test temperature (C)	Impression diameter (mm)
Enclosure/External insulating parts		75	1.0
Supplementary information: The unit use metal and plastic enclosure, and plastic part pass the test			

1.5.1	TABLE: List of critical components			P
Object/part No.	Manufacturer/ trademark	Type/model	Technical data	Mark(s) of conformity1)
PCB	Zhonglianxing	FR-4	94V-0,130℃	UL Tested with appliance
Internal wire	DONGGUAN HUMEN TOP RICH WIRE & CABLE FACTORY	1571	22AWG, 80℃, VW-1, 30V	UL E315320
Enclosure	Shenzhen Dezhong plastic electronics Co., Ltd	PA-707	V-2;85 ºC	UL Tested with appliance
Current limiter	Various	Various	Umax: 6.0V Ihold: 0.75A Itrip: 1.50A Tmax: 85℃	UL

11.1.1	TABLE: Excessive temperatures in me equipment		P
	t1 (°C)……..:	24.3	—

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Clause	Requirement – Test	Result - Remark	Verdict

	t2 (°C)……:	24.4	---

temperature rise dT of part/at:	T (℃)	required Tmax (℃)
	264/50Hz	
PCB	42.0	130
Enclosure	41.1	60
Button	41.3	60
Battery	41.9	For reference
Applied part	40.8	41
Ambient	40.0	--

Supplementary information:
Supplementary information:
1 Maximum allowable temperature on surfaces of test corner is 90 °C.
2 Max temperature determined in accordance with 11.1.3e)
3 When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
4 Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.
5 APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects.
Also, see instructions for use.

11.6.1	TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances	**P**

Clause / Test Name	Test Condition	Reark
11.6.5/ ingress of water	IP22	No breakdown
11.6.6/ Cleaning	Cleaning (Following the cleaning method in the user manual)	No breakdown

13.2	**TABLE: fault condition tests**		**N**
	Ambient temperature (°C)	25°C	—

Test type, condition and clause reference	Observed results	Reark

15.3	TABLE: Mechanical Strength tests 1)	**P**

Clause	Name of Test	Test conditions	Observed results/Remarks
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	No damage, no breakdown
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	N/A
15.3.4.1	Drop Test (hand-held)	Free fall height (m) = 1m	No damage, no breakdown
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5	N/A
15.3.5	Rough handling test	Travel speed (m/s) =	N/A
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) = 70	No any shrinkage and distortion, no hazards

Supplementary information: 1)As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows).

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Clause	Requirement – Test	Result - Remark	Verdict
4	General requirements		P
4.1	Characteristics of SUPPLY MAINS specified in 4.10.2 of Part 1 applied, except ME EQUIPMENT or ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT complied with the following:	Supplied by internal batteries	N
	– Voltage for non-LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEMS did not exceed 110 % or was not below 85 % of NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% V)		P
	Voltage for LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEMS did not exceed 110 % or was not below 80 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% V)	non-LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEMS	P
4.2	* Environmental conditions for ME EQUIPMENT		P
4.2.1	Permissible environmental conditions of transport and storage, after ME EQUIPMENT is removed from its protective packaging and subsequently between uses, indicated in instructions for use		P
	ME EQUIPMENT, except STATIONARY EQUIPMENT, after being removed from its protective packaging, and subsequently between uses, operated within its specified NORMAL USE after transport or storage in the following environmental temperature range	Indicated in the user manual: -20°C to 50°C, 15-95%RH	P
	-25 °C without relative humidity control	More restricted range is specified	P
	+70 °C at a non-condensing relative humidity up to 93 %	As above	P
	For more restricted range of environmental transport and storage conditions between uses, the environmental conditions are:		P
	– Justified in the RISK MANAGEMENT FILE		P
	– Marked on the ME EQUIPMENT		P
	When not practicable, the more restricted range is disclosed in the instructions for use	Refer to instructions	P
	– Marked on the carrying case when the instructions for use indicate the ME EQUIPMENT is intended to be transported or stored in a carrying case between uses	No carrying used	N
	Environmental transport and storage test		P
	a) ME EQUIPMENT prepared for transportation or storage according to instructions for use (e.g., removal of batteries, emptying fluid reservoirs, etc.)		P
	b) ME EQUIPMENT exposed to its lowest specified environmental transport and storage conditions (temperature °C) (°C)	-24°C	P
	– For at least 24 h or, ensure ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	Thermal stability for 2h	P
	c) ME EQUIPMENT exposed to its highest specified environmental transport and storage conditions (temperature °C and relative humidity ± 3 %) (°C, ± %)	54°C, 98%RH	P

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Clause	Requirement – Test	Result - Remark	Verdict
	– For at least 24 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	Thermal stability for 2 h	P
	Transition from low to high conditions made slowly enough to provide a non-condensing environment		P
	d) At the end of this conditioning period, ME EQUIPMENT allowed to return and stabilize at the operating conditions of NORMAL USE		P
	e) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE		P
4.2.2	The permissible environmental operating conditions are indicated in the instructions for use		P
	ME EQUIPMENT complied with its specifications and all the requirements of this standard when operated in NORMAL USE under the following environmental operating conditions, except as indicated in the instructions for use:	Indicated in the user manual: 10°C to 40°C, 10 to 85%RH, 70kPa to 106kPa	P
	– a temperature range of +5 °C to +40 °C (°C)	More restricted range is specified	N
	– a relative humidity range of 15 % to 93 %, noncondensing (% RH)	More restricted range is specified	N
	– an atmospheric pressure range of 700 hPa to 1060 hPa (hPa)	70kPa to 106kPa	P
	When more restricted range of environmental operating conditions are stated in the instructions for use, they are justified or marked as follows		P
	– justified in the RISK MANAGEMENT FILE		P
	– marked on the ME EQUIPMENT, except when not practicable		N
	The more restricted range disclosed in the instructions for use; and	Refer to instructions	P
	– marked on the carrying case when the instructions for use indicated the ME EQUIPMENT is intended to be operated in a carrying case.	No carrying case	N
	ME EQUIPMENT complied with its specifications and requirements of this standard when operated in NORMAL USE under the specified environmental operating conditions		N
	When a more restricted range stated in the instructions for use, the RISK MANAGEMENT FILE inspected		P
	Environmental operating conditions test		P
	a) ME EQUIPMENT exposed to the ambient conditions		P
	– For at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h (h)	6H	P
	b) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE		P
	c) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE while at the lowest specified atmospheric pressure	70KPa	P

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Clause	Requirement – Test	Result - Remark	Verdict
	d) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE while at the highest specified atmospheric pressure	106KPa	P
	e) ME EQUIPMENT cooled to its lowest specified environmental operating conditions (temperature °C and relative humidity less than or equal to 15 %) (°C, RH %)	6 °C, 10 %RH	P
	f) ME EQUIPMENT held at its lowest specified environmental operating conditions for at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h (h)	6H	P
	g) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE		P
	h) ME EQUIPMENT heated to its highest specified environmental operating conditions (temperature °C and relative humidity ± 3 %) (°C, RH %)	44 °C, 88%RH	P
	i) ME EQUIPMENT held at its highest specified environmental operating conditions for at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h (h)	6H	P
	j) ME EQUIPMENT evaluated to its specifications and ensured that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE		P
4.2.3	TRANSIT-OPERABLE ME EQUIPMENT maintain BASIC SAFETY and ESSENTIAL PERFORMANCE in the presence of condensation and thermal shock when instructions for use state a wider range of environmental operating conditions than indicated in 4.2.2		N
4.2.3.1	Continuous operating conditions		N
4.2.3.2	* Environmental shock to TRANSIT-OPERABLE ME EQUIPMENT		N
5	* General requirements for testing ME EQUIPMENT		P
	In addition to the requirements of 5.9.2.1 of the general standard, parts of ME EQUIPMENT that are to be regarded as ACCESSIBLE PARTS are identified by inspection and, where necessary, by testing. In case of doubt, a part of ME EQUIPMENT that is to be regarded as an ACCESSIBLE PART is determined by a test with the small finger probe shown in Figure 1, applied in a bent or straight position:		P
	– for all positions of the ME EQUIPMENT when operated as in NORMAL USE; and		P
	– after opening ACCESS COVERS and removal of parts, including lamps, fuses and fuse holders, when: i) the ACCESS COVERS can be opened without the use of a TOOL, or ii) the instructions for use instruct a LAY OPERATOR to open the relevant ACCESS COVER.		P

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Clause	Requirement – Test	Result - Remark	Verdict
6	* Classification of ME EQUIPMENT and ME SYSTEMS		P
	– shall be CLASS II or INTERNALLY POWERED; – shall not have a FUNCTIONAL EARTH TERMINAL; and – if equipped with APPLIED PARTS, shall have either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.		P
7	ME EQUIPMENT identification, marking and documents		P
7.1	* USABILITY of the ACCOMPANYING DOCUMENTS		N/E
7.2	* Additional requirements for marking of IP classification	IP22	P
7.3	ACCOMPANYING DOCUMENTS		P
7.3.1	Contact information		P
	– for assistance, if needed, in setting up, using or maintaining the ME EQUIPMENT or ME SYSTEM; or – to report unexpected operation or events.	See operation instruction	P
7.3.2	LAY OPERATOR briefing information		P
	– precautions to be taken in the event of changes in the performance of the ME EQUIPMENT or ME SYSTEM;		P
	– precautions to be taken regarding the exposure of the ME EQUIPMENT or ME SYSTEM to reasonably foreseeable environmental conditions (e.g. to magnetic fields, electromagnetic fields, external electrical influences, ELECTROSTATIC DISCHARGE, pressure or variations in pressure, acceleration, thermal ignition sources);		P
	– adequate information regarding any medicinal substances that the ME EQUIPMENT is designed to administer, including any limitations in the choice of substances to be delivered;	No medicinal substances.	N
	– information on any medicinal substances or human blood derivatives incorporated into the ME EQUIPMENT or ACCESSORIES as an integral part; and.	No any medicinal substances or human blood derivatives incorporated into the ME EQUIPMENT or ACCESSORIES	N
	– the degree of accuracy claimed for ME EQUIPMENT with a measuring function		P
7.4	Instructions for use		P
7.4.1	Additional requirements for warning and safety notices		P
	– strangulation due to cables and hoses, particularly due to excessive length;		N
	–Inhalation or swallowing of small parts		P

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Clause	Requirement – Test	Result - Remark	Verdict
	– potential allergic reactions to accessible materials used in the ME EQUIPMENT;		N
	– contact injuries.		N
	The instructions for use include warnings to the effect that the following actions could be unsafe as applicable:		P
	– Use of ACCESSORIES, detachable parts, and materials not described in the instructions for use (see 7.9.2.14 of Part 1)		P
	Interconnection of this equipment to other equipment not described in the instructions for use (see 16.2 c) indent 9) of Part 1)		N
	– Modification of the equipment		P
	– Use of the ME EQUIPMENT outside its carrying case when some part of the protection required by this standard is provided by that carrying case (see 8.3.1 and 10.1)		N
7.4.2	* Additional requirements for an electrical power source		P
	– the typical operation time or number of PROCEDURES;		P
	– the typical service life of the INTERNAL ELECTRICAL POWER SOURCE; and	5 years	P
	– Behaviour of ME EQUIPMENT while the rechargeable INTERNAL ELECTRICAL POWER SOURCE is charging		P
7.4.3	Instructions for use include easily understood diagrams, illustrations, or photographs of the fully assembled and ready-to-operate ME EQUIPMENT including all controls, visual INFORMATION SIGNALS, and indicators provided (see 7.1)		P
7.4.4	Instructions for use include:		P
	– Easily understood diagrams, illustrations, or photographs showing proper connection of the PATIENT to the ME EQUIPMENT, ACCESSORIES and other equipment (see 7.1)		P
	– the time from switching "ON" until the ME EQUIPMENT is ready for NORMAL USE, when it exceeds 15 s (see 15.4.4 of Part 1) (s)		N
7.4.5	Instructions for use include a description of generally known conditions in the HOME HEALTHCARE ENVIRONMENT that can unacceptably affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT		P
	The steps that can be taken by the LAY OPERATOR to identify and resolve the above conditions		P
	At least the following issues are also included as applicable		P

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Clause	Requirement – Test	Result - Remark	Verdict
	- The effects of lint, dust, light (including sunlight), etc		P
	– the effects caused by pets, pests or children.		P
	- A list of known devices or other sources that can potentially cause interference problems		P
	The effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems		N
	- The effects caused by pets, pests or children		N
	The instructions for use explain the meaning of the IP classification marked on the ME EQUIPMENT, and on any carrying case provided with the ME EQUIPMENT as applicable		N
7.4.6	Instructions for use include a troubleshooting guide for use when there are indications of a ME EQUIPMENT malfunction during start-up or operation		P
	Troubleshooting guide discloses the necessary steps in the event of an ALARM CONDITION		N
7.4.7	*Instructions for use for ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES for other than single use that can be contaminated by contact with PATIENT, body fluids, or expired gases, during INTENDED USE, indicate the following:		P
	– Frequency of cleaning, cleaning and disinfection, or cleaning and sterilization, as appropriate, for ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES used on the same PATIENT including rinsing methods, drying, handling, and storage between uses (see 8.1 and 8.2); and		P
	– It is necessary to clean and disinfect, clean and sterilize the ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES for multiple PATIENT use between uses on different PATIENTS, including rinsing methods, drying, handling, and storage until re-use (see 8.1 and 8.2), or		P
	– ME EQUIPMENT, ME SYSTEMS and ACCESSORIES require professional hygienic maintenance prior to reuse and provide contact details for the source of these services (see 7.5.2)		P
7.4.8	Instructions for use include		P
	– Expected service life of the me equipment	5 years	P
	– EXPECTED SERVICE LIFE of parts and ACCESSORIES shipped with the ME EQUIPMENT	As above	P
	– SHELF LIFE of parts and ACCESSORIES shipped with ME EQUIPMENT when SHELF LIFE is less than the EXPECTED SERVICE LIFE		
7.4.9	Instructions for use include:		P
	– Information concerning the proper disposal of the ME EQUIPMENT, its parts and ACCESSORIES (see IEC 60601-1-9); and		P

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Clause	Requirement – Test	Result - Remark	Verdict
	A statement indicating the LAY RESPONSIBLE ORGANIZATION must contact its local authorities to determine the proper method of disposal of potentially bio hazardous parts and ACCESSORIES, as applicable	considered	P
7.4.10	Instructions for use includes the recommended placement of the remote parts of the DISTRIBUTED ALARM SYSTEM, when applicable, to ensure the OPERATOR can be notified at all times by an appropriate element of DISTRIBUTED ALARM SYSTEM within its specified range	No distributed alarm system	N/A
7.5	Technical description		N
7.5.1	The technical description for PERMANENTLY INSTALLED CLASS I ME EQUIPMENT includes		N
	– a warning to the effect that the ME EQUIPMENT installation, including a correct PROTECTIVE EARTH CONNECTION, must only be carried out by qualified SERVICE PERSONNEL;		N
	– the specifications of the PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR;		N
	– a warning to verify the integrity of the external protective earthing system;		N
	– a warning to connect and verify that the PROTECTIVE EARTH TERMINAL of the PERMANENTLY INSTALLED ME EQUIPMENT is connected to the external protective earthing system.		N
7.5.2	Additional requirements for professional hygienic maintenance		N
	– before and after any type of service PROCEDURE; – when the ME EQUIPMENT is transferred to another PATIENT.		N
8	Protection against excessive temperatures and other HAZARDS		P
8.1	A LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT can perform the cleaning or cleaning and disinfection PROCESSES when intended (see 7.4.7	See USABILITY ENGINEERING FILE, evaluated by the manufacture.	N/E
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS		N/E
8.2	A LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT can perform the cleaning and sterilization PROCESSES when intended (see 7.4.7)		P
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS		N/E
8.3	Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		P

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Clause	Requirement – Test	Result - Remark	Verdict
8.3.1	TRANSIT-OPERABLE, HANDHELD, and BODY-WORN ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529:1989 for IP22		N/A
	All other ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529:1989 for IP21	IP22	P
	For PORTABLE ME EQUIPMENT intended to be used only with a carrying case, this requirement was, optionally, met with the ME EQUIPMENT in its the carrying case	No such carrying case	N
	PORTABLE ME EQUIPMENT with the carrying case was inspected, and the tests of IEC 60529:1989 applied		N
	Maintenance of BASIC SAFETY and ESSENTIAL PERFORMANCE VERIFIED	Complied	N
8.3.2	ENCLOSURES of the non-ME EQUIPMENT parts of the ME SYSTEMS provide the degree of protection against harmful ingress of water or particulate matter equivalent to equipment complying with their respective IEC or ISO safety standards	Not ME SYSTEMS	N
	Tests of IEC 60529:1989 conducted with the equipment placed in the least favourable position of NORMAL USE and the ENCLOSURES inspected		N
8.4	Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT and ME SYSTEM		P
	A LIFE SUPPORTING ME EQUIPMENT or ME SYSTEM maintained its ESSENTIAL PERFORMANCE for a sufficient time or for a sufficient number of PROCEDURES when loss or failure of SUPPLY MAINS or INTERNAL ELECTRICAL POWER SOURCE occurred	Not such ME equipment or ME system	N
	The time or number of PROCEDURES remaining allowed alternative life-supporting methods to be employed		N
	Optionally, an INTERNAL ELECTRICAL POWER SOURCE was used to maintain ESSENTIAL PERFORMANCE Optionally, independent means were used to provide ESSENTIAL PERFORMANCE		P
	Optionally, independent means were used to provide ESSENTIAL PERFORMANCE	considered	P
	Instructions for use disclose the time or number of procedures available following a loss or failure of the electrical power supply		N
	Instructions for use describes the alternative lifesupporting methods to be employed	Not Life-supporting ME equipment or ME system	N
	The technical description describes methods that can be employed for longer periods		N
	LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM with no INTERNAL ELECTRICAL POWER SOURCE is equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY ALARM CONDITION indicating power failure	Not LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM.	N

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Clause	Requirement – Test	Result - Remark	Verdict
	LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM with an INTERNAL ELECTRICAL POWER SOURCE is equipped with an automatic switchover to INTERNAL ELECTRICAL POWER SOURCE and an ALARM SYSTEM that includes at least a LOW PRIORITY ALARM CONDITION indicating switch-over to INTERNAL ELECTRICAL POWER SOURCE		N
	LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM with an INTERNAL ELECTRICAL POWER SOURCE is equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION indicating the INTERNAL ELECTRICAL POWER SOURCE is nearing insufficient remaining power for operation		N
	TECHNICAL ALARM CONDITION provides sufficient time or sufficient number of procedures for a LAY OPERATOR to act	There is an icon to indicate low battery capacity.	P
	A TECHNICAL ALARM CONDITION of at least LOW PRIORITY remained active until the INTERNAL ELECTRICAL POWER SOURCE returned to a level above the ALARM LIMIT or until depleted		P
	It was not possible to inactivate the visual ALARM SIGNAL of this TECHNICAL ALARM CONDITION		P
	Functional tests conducted, and the RISK MANAGEMENT FILE inspected		P
9	Accessibility of small INTERNAL ELECTRICAL POWER SOURCEs		P
	– changes of controls; – unexpected movement; – potential for misconnection; – potential for improper operation, or unsafe use; – potential for confusion as to current operational mode; – change in the transfer of energy or substance; – exposure to environmental conditions specified in this standard; – exposure to biological materials; and – small parts being inhaled or swallowed.		P
10	Construction of ME EQUIPMENT		P
10.1	* Additional requirements for mechanical strength		P
10.1.1	Table 28, Mechanical strength test applicability, replaced by Table 1, Mechanical strength test applicability, non-TRANSIT-OPERABLE, and Table 2, Mechanical strength test applicability, TRANSITOPERABLE	non-TRANSIT-OPERABLE	P
10.1.2	ME EQUIPMENT, its parts, and mounting ACCESSORIES, intended for non-TRANSIT-OPERABLE use displayed adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, dropping and rough handling (not applicable to FIXED and STATIONARY ME EQUIPMENT)		P
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after mechanical tests		P

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Clause	Requirement – Test	Result - Remark	Verdict
	OPERATOR-re-settable protective devices that can be reset without the use of a TOOL were, optionally, reset prior to the evaluation of BASIC SAFETY and ESSENTIAL PERFORMANCE		P
	a) Shock tests conducted in accordance with IEC 60068-2-27:2008		P
	b) Broad-band random vibration tests conducted in accordance with IEC 60068-2-64:2008, using the following conditions:		P
10.1.3	ME EQUIPMENT, parts, and mounting ACCESSORIES for TRANSIT-OPERABLE use displayed adequate mechanical strength when subjected to pushing, impact, dropping, rough handling, and rigorous conditions of PATIENT movement in NORMAL USE as well as transportation by trolleys, carts, road vehicles, trains, ships, and aircraft	non-TRANSIT-OPERABLE, not used at the conditions of PATIENT movement in NORMAL USE.	N
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after the following tests:		N
10.2	Additional requirements for actuating parts of controls of ME EQUIPMENT		P
11	* Protection against strangulation or asphyxiation		P
	Means shall be provided to control the RISK of strangulation and asphyxiation of the PATIENT and others to an acceptable level.		P
12	Additional requirements for ELECTROMAGNETIC EMISSIONS of ME EQUIPMENT and ME SYSTEMS		N
13	Additional requirements for ALARM SYSTEMS of ME EQUIPMENT and ME SYSTEMS		N
13.1	* Additional requirement for generation of ALARM SIGNALS		N
13.2	* Additional requirement for ALARM SIGNAL volume		N
Annex A	General guidance and rationale		N
A.1	General guidance		N
A.2	Rationale for particular clauses and subclauses		N
Subclause 1.1	– Scope		N
Subclause 4.1	– Additional requirements for SUPPLY MAINS for ME EQUIPMENT and		N
Subclause 4.2	– Environmental conditions for ME EQUIPMENT		N
Subclause 4.2.2	– Environmental conditions of transport and storage between uses		N
Subclause 4.2.3	– Environmental operating conditions		N
Subclause 4.2.3.2	– Environmental shock to TRANSIT-OPERABLE ME EQUIPMENT		N

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Clause	Requirement – Test	Result - Remark	Verdict
Clause 5	– General requirements for testing ME EQUIPMENT		N
Clause 6	– Classification of ME EQUIPMENT and ME SYSTEMS		N
Subclause 7.1	– USABILITY of the ACCOMPANYING DOCUMENTS		N
Subclause 7.2	– Additional requirements for marking of IP classification		N
Subclause 7.4.2	– Additional requirements for an electrical power source		N
Subclause 7.4.7	– Additional requirements for cleaning, disinfection and sterilization		N
Subclause 8.1	– Additional requirements for cleaning, disinfection of ME EQUIPMENT and ME SYSTEMS, and		N
Subclause 8.2	– Additional requirements for sterilization of ME EQUIPMENT and ME SYSTEMS		N
Subclause 8.3.1	– Ingress of water or particulate matter into ME EQUIPMENT		N
Subclause 8.3.2	– Ingress of water or particulate matter into ME SYSTEMS		N
Subclause 8.5.1	– Indication of state		N
Subclause 10.1	– Additional requirements for mechanical strength		N
Subclause 10.1.2	– Requirements for mechanical strength for non-TRANSIT-OPERABLE ME EQUIPMENT		N
Subclause 10.1.3	– Requirements for mechanical strength for TRANSIT-O PERABLE ME EQUIPMENT		N
Subclause 11	– Protection against strangulation or asphyxiation		N
Subclause 13.1	– Additional requirements for generation of ALARM SIGNALS		N
Subclause 13.2	– Additional requirements for ALARM SIGNALS volume		N
Annex B	Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS		N
B.1	Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts		N
B.2	Accompanying documents, general		N
B.3	ACCOMPANYING DOCUMENTS, instructions for use		N
B.4	ACCOMPANYING DOCUMENTS, technical description		N
Annex C	Symbols on marking		N

	ISO 15223-1:2012, 5.3.4 (ISO 7000-0626 (2004-01))	Keep dry Indicates a medical device that needs to be protected from moisture.		N

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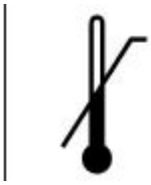
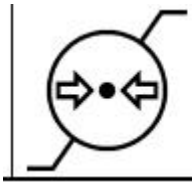
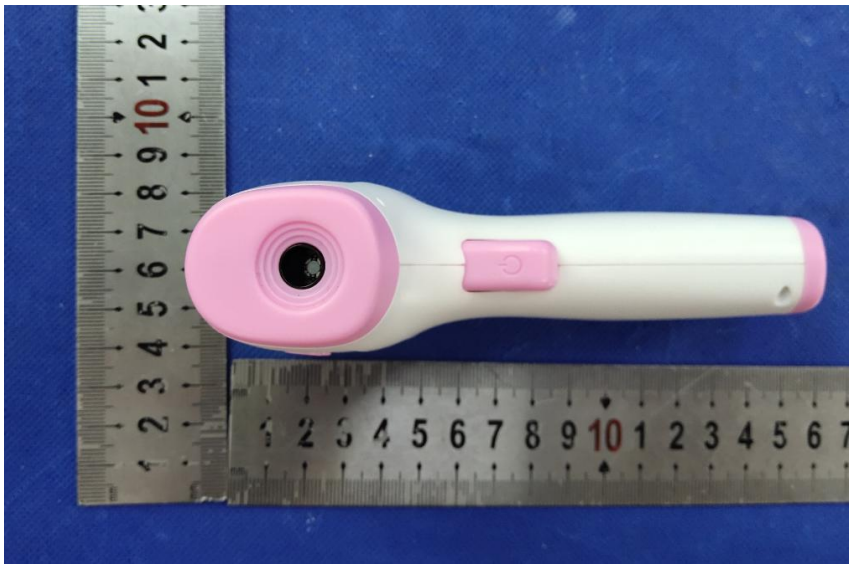
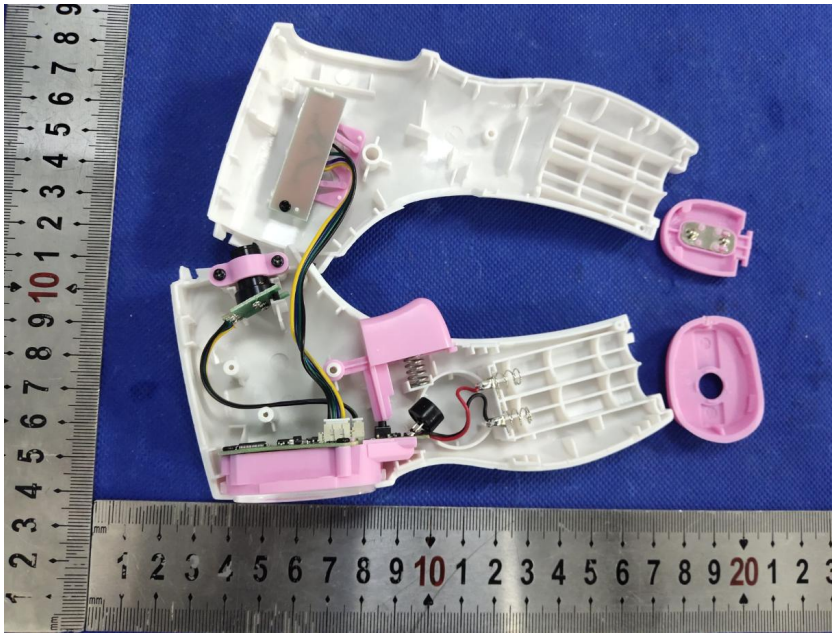
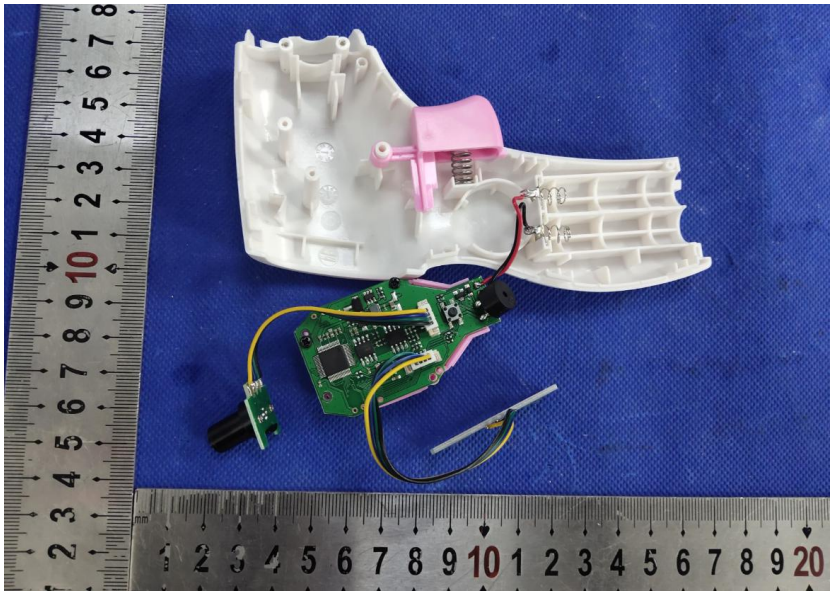
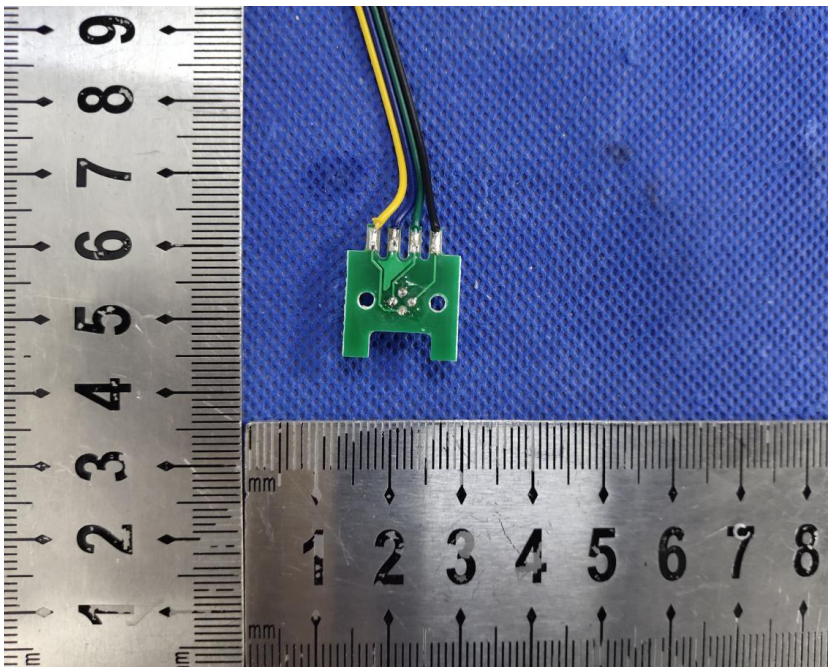
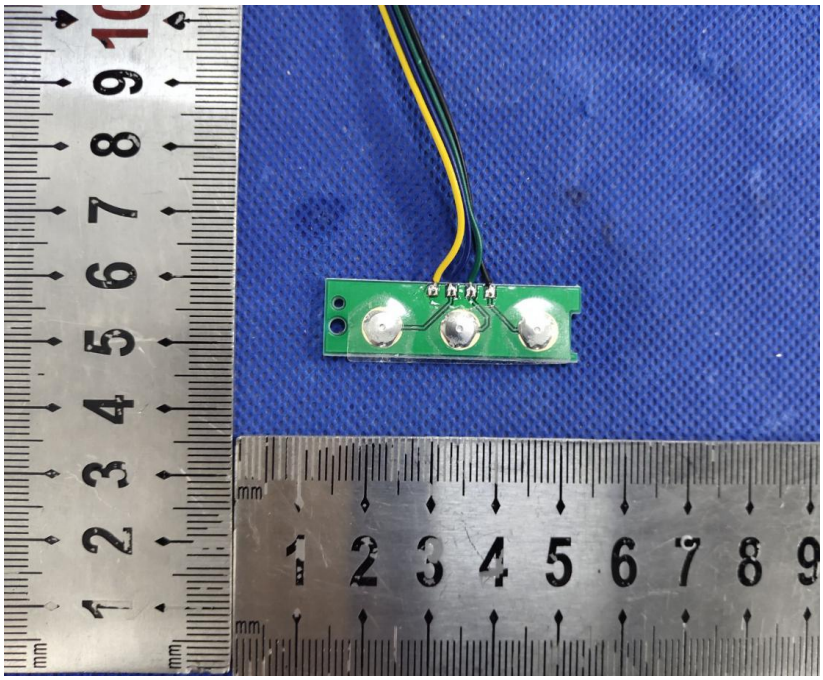
Clause	Requirement – Test	Result - Remark	Verdict

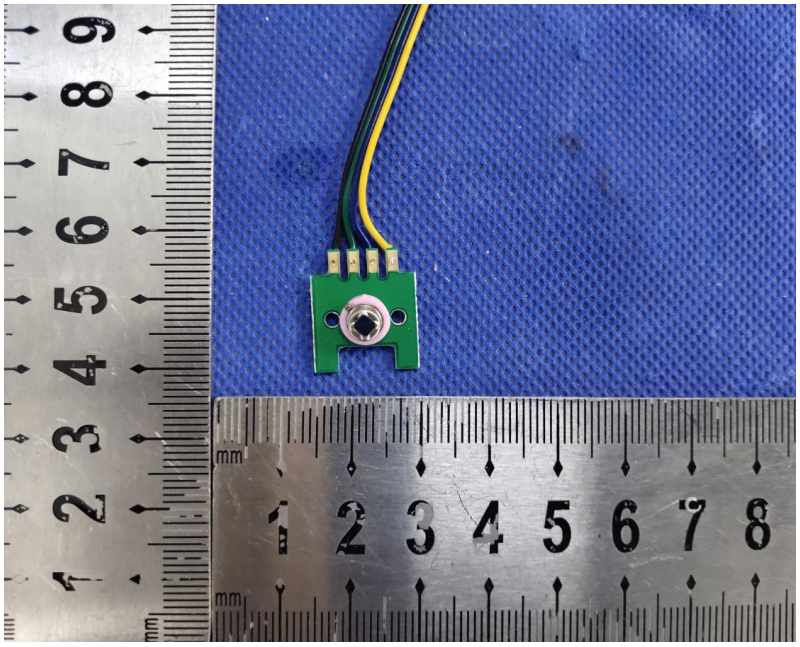
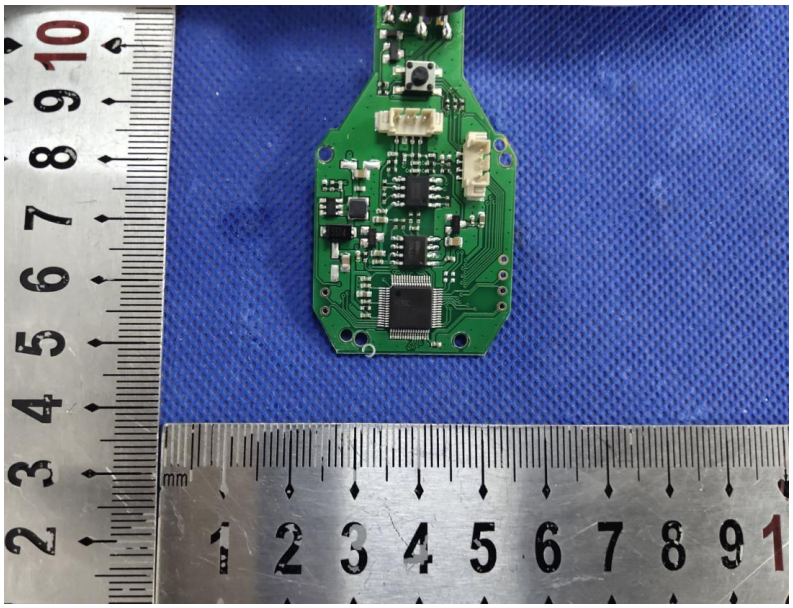
		ISO 15223-1:2012, 5.3.5 (ISO 7000-0534 (2004-01))	Lower limit of temperature Indicates the lower limit of temperature to which the medical device can be safely exposed. The lower limit of temperature shall be indicated adjacent to the lower horizontal line.		N
		ISO 15223-1:2012, 5.3.6 (ISO 7000-0533 (2004-01))	Upper limit of temperature Indicates the upper limit of temperature to which the medical device can be safely exposed. The upper limit of temperature shall be indicated adjacent to the upper horizontal line.		N
		ISO 15223-1:2012, 5.3.7 (ISO 7000-0632 (2004-01))	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed. The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.	No more than 55℃	P
		ISO 15223-1:2012, 5.3.8 (ISO 7000-2620 (2004-01))	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed. The humidity limitation shall be indicated adjacent to the upper and lower horizontal lines.		N
		ISO 15223-1:2012, 5.3.9 (ISO 7000-2621 (2004-01))	Atmospheric pressure limitation Indicates the range of atmospheric pressure to which the medical device can be safely exposed. The atmospheric pressure limitations shall be indicated adjacent to the upper and lower horizontal lines.		N

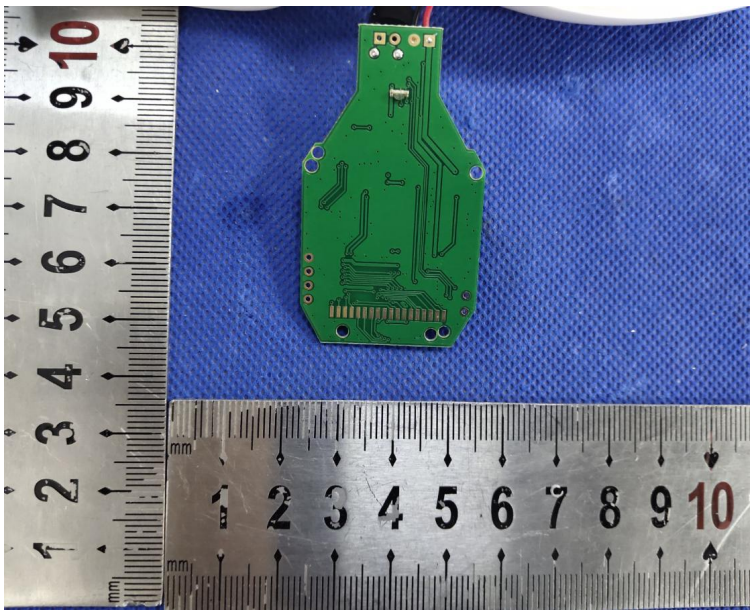
ANNEX A: Photo-documentation

Photo 1 view ☒ front ☐ back ☐ side ☐ top ☐ internal ☐ bottom	
Photo 2 **view** ☐ **front** ☒ **back** ☐ **side** ☐ **top** ☐ **internal** ☐ **bottom**	

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