TEST REPORT
IEC 60601-1
Part 1: General requirements for basic safety and essential performance

Report Number..... :	LCS200327012AS
Date of issue ..... :	2020-04-03
Total number of pages ..... :	74
Name of Testing Laboratory preparing the Report..... :	Shenzhen LCS Compliance Testing Laboratory Ltd.
Applicant's name..... :	Shenzhen Qiangwei Electronic Co., Ltd
Address ..... :	4F, Building 3, Xialingpai Industrial Zone, Dalang Subdistrict, Longhua District, Shenzhen, China
Test specification:	
Standard..... :	IEC 60601-1:2005 (Third Edition) + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1 (2012 reprint)
Test procedure ..... :	Type test
Non-standard test method..... :	N/A
Test Report Form No. ..... :	IEC60601_1J_PS
Test Report Form(s) Originator..... :	UL(US)
Master TRF ..... :	2014-09

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General disclaimer:

The test results presented in this report relate only to the object tested.
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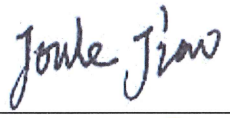
Test item description.....:	Infrared Thermometer
Trade Mark .....:	N/A
Manufacturer.....:	Same as applicant
Model/Type reference.....:	K3
Ratings.....:	Input: 4.2V⎓, 1A;

Testing procedure and testing location:			
☒	Testing Laboratory:	Shenzhen LCS Compliance Testing Laboratory Ltd.	
Testing location/ address .....:		Room 101, 201, Building A and Room 301, Building C, Juji Industrial Park, Yabianxueziwei, Shajing Street, Bao'an District, Shenzhen, Guangdong, China	
	Tested by.....:	Jowie Jiao Project Handler	
	Checked by.....:	Olivia Yang Reviewer	
	Approved by.....:	Hart Qiu Technical Director	

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List of Attachments (including a total number of pages in each attachment):

Attachment No. 1: 3 pages of photo documentation.

Summary of testing

Tests performed (name of test and test clause):

The submitted samples were found to comply with the requirements of:

- IEC 60601-1:2005
- IEC 60601-1:2005/AMD1:2012
- EN 60601-1:2006+A1:2013+A11:2011+A12:2014

Exceptions:
The following clauses / collaterals were not part of the manufacturers order and therefore excluded from this testing:

Clause 11.7 Biocompatibility, referencing ISO 10993

Clause 12.2 Usability, referencing IEC 60601-1-6

Clause 17 EMC, referencing IEC 60601-1-2

Testing location:

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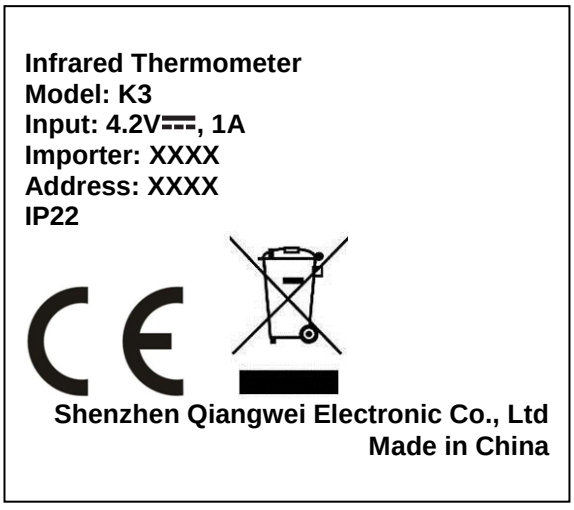
Summary of compliance with National Differences:
N/A

Copy of marking plate:



Note:
1. The height of CE symbol ≥ 5.0mm, the height of WEEE symbol ≥ 7.0mm.

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GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	Portable
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 ..... :	Not directly connected to the mains
Accessories and detachable parts included ..... :	N/A
Other options include..... :	N/A
Testing	
Date of receipt of test item(s) ..... :	2020-03-27
Dates tests performed ..... :	From 2020-03-27 to 2020-04-03
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A
- test object does meet the requirement..... :	Pass (P)
- test object was not evaluated for the requirement..... :	N/E (collateral standards only)
- test object does not meet the requirement..... :	Fail (F)
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

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General remarks:

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

This Test Report Form is intended for the investigation of power supplies in accordance with IEC 60601-1:2005, 3rd edition + AM1. The Risk Management was evaluated by manufacturer.

Additional test data and/or information may be provided in the attachments to this report.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ Yes ☒ Not applicable

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies) ..... :	Same as manufacturer

General product information:

1) The maximum operating temperature is +40°C.

2) The unit weight: 0.152kg.

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

TABLE: INSULATION DIAGRAM		N/A
Pollution degree ..... :	2	—
Overvoltage category..... :	Not directly connected to the mains	—
Altitude (m) ..... :	2000	—
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	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			V_{rms}	V_{pk}					
--	--	--	--	--	--	--	--	--	--

Supplementary Information:

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IEC 60601-1			
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	Evaluated by manufacturer	N/A
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.	Evaluated by manufacturer	N/A
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE .....:	Evaluated by manufacturer	N/A
4.5	Alternative means of addressing particular RISKS considered acceptable based on MANUFACTURER'S justification that RESIDUAL RISKS resulting from application of alternative means are comparable to the RESIDUAL RISKS resulting from requirements of this standard .....:	Evaluated by manufacturer	N/A
4.6	RISK 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 .....:	Evaluated by manufacturer	N/A
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2 .....:	Evaluated by manufacturer	N/A
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically .....:		N/A
	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		N/A
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified .....:	See appended Table 8.10	P
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS		N/A
	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		P

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		P
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK .....:	Components which are certified to IEC and/or national standards are used correctly within their ratings. (see appended table 8.10)	P
	COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS selected and evaluated consistent with their conditions of use and reasonable foreseeable misuse during EXPECTED SERVICE LIFE of ME EQUIPMENT by reviewing RISK MANAGEMENT FILE .....:		P
4.10	Power supply		-
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 .....:	Powered by internally electrical power source	P
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:		P
	- 250 V for HAND-HELD ME EQUIPMENT (V) .....:		N/A
	– 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V).....:		P
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS		N/A
4.11	Power input		-
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%.....:		P
	– 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		P
	Measurements made at a voltage equal to the mean value of the range when each marking of RATED input was related to the mean value of relevant voltage range		P
	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 .....:		P

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5	GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT		P
5.1	TYPE TESTS determined in consideration of Clause 4, in particular 4.2	Type test	P
	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods.....:		P
	RISK MANAGEMENT FILE identified combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION.	‘	N/A
5.2	TYPE TESTS conducted on one representative sample under investigation; multiple samples used simultaneously when validity of results was not significantly affected .....:	Multiple samples used	P
5.3	a) Tests conducted within the environmental conditions specified in technical description		P
	Temperature (ºC), Relative Humidity (%) .....:	Refer to accompanying documents for detail	—
	Atmospheric Pressure (kPa) .....:	Refer to accompanying documents for detail	—
	b) ME EQUIPMENT shielded from other influences that might affect the validity of tests		P
	c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained .....:	Considered	P
5.4	a) ME EQUIPMENT tested under least favourable working conditions specified in instructions for use .....:	Considered	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		N/A
	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.....:		N/A
	d) Potable water used for cooling		N/A
5.5	a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V) .....:	Considered	P
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz) .....:	Considered	P

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current.....:	Considered	P
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered .....:		N/A
	e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions .....:		N/A
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use		N/A
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
	Alternatively, upon repair and modification of the sample, only the relevant tests conducted		P
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 .....:	Considered	P
	Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS were opened and detached		N/A
	ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber (relative humidity 93%±3%) and an ambient within 2 °C of T in the range of + 20 °C to + 32 °C		P
	- For 48 h for units rated IPX0		N/A
	- For units rated higher than IPX0 test time extended to 168 h.....:	IP22	P
5.8	Unless stated otherwise, tests in this standard sequenced as in Annex B to prevent influencing results of any subsequent test		P
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		-
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS .....:		N/A
5.9.2	ACCESSIBLE PARTS		-

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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	No openings	N/A
	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/A
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		N/A
	All additional parts that became accessible checked using standard test finger and by inspection		N/A
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 actuating mechanisms used	N/A
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, etc. required use of a TOOL .....:		N/A

6	CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS		P
6.2	CLASS I ME EQUIPMENT, externally powered		N/A
	CLASS II ME EQUIPMENT, externally powered		N/A
	INTERNALLY POWERED ME EQUIPMENT		P
	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/A
	TYPE B APPLIED PART		N/A
	TYPE BF APPLIED PART		P
	TYPE CF APPLIED PART		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS		N/A
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter (IPN_1N_2) as per IEC 60529 .....:	IP22	P
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use .....:		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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		N/A
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION .....:	Classified for continuous operation	P
7	ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS		P
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6 .....:	See appended Tables 7.1.2	P
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.....:	See appended Tables 7.1.3	P
	b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after marking durability test.....:	See appended Tables 7.1.3	P
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		-
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 .....:	See attached copy of Marking Plate	P
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS.....:		N/A
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT		P
	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/A
7.2.2	ME EQUIPMENT marked with:		-
	– the name or trademark and contact information of the MANUFACTURER		P
	– a MODEL OR TYPE REFERENCE		N/A
	– a serial number or lot or batch identifier; and		N/A
	– the date of manufacture or use by date		N/A
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or		N/A

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	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and		N/A
	– a MODEL OR TYPE REFERENCE		N/A
	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/A
7.2.3	Symbol 11 on Table D.1 (ISO 7000-1641, DB: 2004-01) used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS		P
	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.... :		P
	- with a MODEL or TYPE REFERENCE		P
	– a serial number or lot or batch identifier		P
	– the date of manufacture or use by date		P
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		P
7.2.5	ME EQUIPMENT intended to receive power from other electrical equipment in an ME SYSTEM and compliance with the requirements of this standard is dependent on that other equipment, one of the following is provided:		N/A
7.2.6	Connection to the Supply Mains		-
	Except for PERMANENTLY INSTALLED ME EQUIPMENT, marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point	Not connected to the mains	N/A
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT, preferably, adjacent to SUPPLY MAINS connection		N/A
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V) ..... :		N/A
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V) ..... :		N/A
	– Nature of supply (e.g., No. of phases, except single-phase) and type of current ..... :		N/A

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	Symbols 1-5, Table D.1 (symbols of IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033, all 2002-10) used, optionally, for same parameters ..... :		N/A
	– RATED supply frequency or RATED frequency range in hertz ..... :		N/A
	– Symbol 9 of Table D.1 (symbol IEC 60417-5172, 2003-02) used for CLASS II ME EQUIPMENT ..... :		N/A
7.2.7	RATED input in amps or volt-amps, (A, VA) .....:		N/A
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) .....:		N/A
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W)..... :		N/A
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W)..... :		N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA)..... :		N/A
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W) ..... :		N/A
7.2.8	Output connectors		-
7.2.8.1	See 16.9.2.1 b) for MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT		N/A
7.2.8.2	Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment		N/A
	Rated Voltage (V), Rated Current (A)..... :		—
	Rated Power (W), Output Frequency (Hz) ..... :		—
7.2.9	ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2), marking optional for ME EQUIPMENT or parts rated IPX0. ..... :	IPX0	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)..... :		N/A
7.2.11	ME EQUIPMENT not marked to the contrary assumed to be suitable for CONTINUOUS OPERATION	Continuous operation	P

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum “on” and “off” time..... :		N/A
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder		N/A
	Fuse type ..... :		—
	Voltage (V) and Current (A) rating ..... :		—
	Operating speed (s) and Breaking capacity ..... :		—
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..... :		N/A
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use ..... :		N/A
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)		N/A
7.2.15	Requirements for cooling provisions marked (e.g., supply of water or air)..... :		N/A
7.2.16	ME EQUIPMENT with limited mechanical stability		N/A
7.2.17	Packaging marked with special handling instructions for transport and/or storage ..... :	Refer to packaging	P
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and .....:		N/A
7.2.19	Symbol 7 of Table D.1 (IEC 60417-5017, 2002-10) marked on FUNCTIONAL EARTH TERMINAL ..... :		N/A
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 ..... :		N/A
	No marking applied when an interlock provided		N/A
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		-
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)..... :		N/A
	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/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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..... :		N/A
7.3.3	Type of battery and mode of insertion when applicable is marked ..... :		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) .....:		N/A
	An identifying marking also provided referring to instructions in ACCOMPANYING DOCUMENTS ..... :		P
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL		N/A
	Identified by specification adjacent to the component, or		N/A
	by reference to ACCOMPANYING DOCUMENTS		N/A
	Voltage (V) and Current (A) rating ..... :		—
	Operating speed(s), size & breaking capacity ..... :		—
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1 (IEC 60417-5019, 2002-10), except for the PROTECTIVE EARTH TERMINAL in an APPLIANCE INLET according to IEC 60320-1		N/A
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		N/A
7.3.6	Symbol 7 of Table D.1 (IEC 60417-5017, 2002 -10) marked on FUNCTIONAL EARTH TERMINALS		N/A
7.3.7	Terminals for supply conductors marked adjacent to terminals, ... :		N/A
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings		N/A
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3 (Code in IEC 60445)		N/A
	Marking for connection to a 3-phase supply, if necessary, complies with IEC 60445		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		N/A
7.3.8	"For supply connections, use wiring materials suitable for at least X °C" (where X > than max temperature measured in terminal box or wiring compartment under NORMAL USE), or equivalent, marked at the point of supply connections		N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		N/A
7.4	Marking of controls and instruments		N/A
7.4.1	The "on" & "off" positions of switch to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 (IEC 60417-5007, 2002-10, and IEC 60417-5008, 2002-10), or		N/A
	– indicated by an adjacent indicator light, or		N/A
	– indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1 (IEC 60417-5010 2002-10), and		N/A
	– status indicated by adjacent indicator light		N/A
	– status indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 (symbol 60417-5011 2002-10), or		N/A
	– status indicated by adjacent indicator light		N/A
	– status indicated by other unambiguous means		N/A
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means		N/A
	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/A
	– or an indication of direction in which magnitude of the function changes		N/A
	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).		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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/A
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units		N/A
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3 ..... :		N/A
7.5	Safety signs		-
	Safety sign with established meaning used.		N/A
	Markings used to convey a warning, prohibition or mandatory action mitigating a RISK not obvious to OPERATOR are safety signs from ISO 7010 ..... :		N/A
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT		N/A
	Specified colours in ISO 3864-1 used for safety signs..... :		N/A
7.6	Symbols		-
7.6.1	Meanings of symbols used for marking described in instructions for use..... :	Refer to accompanying documents for details	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		N/A
7.7	Colours of the insulation of conductors		-
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation	No Protective earth conductor	N/A
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations	No such protective earth connections	N/A
7.7.3	Green and yellow insulation identify only following conductors:		N/A
	– PROTECTIVE EARTH CONDUCTORS		N/A
	– conductors specified in 7.7.2		N/A
	– POTENTIAL EQUALIZATION CONDUCTORS		N/A
	– FUNCTIONAL EARTH CONDUCTORS		N/A
7.7.4	Neutral conductors of POWER SUPPLY CORDS are “light blue” specified in IEC 60227-1 or IEC 60245-1		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1		N/A
7.8	Indicator lights and controls		-
7.8.1	Red indicator lights mean: Warning (i.e., immediate response by OPERATOR required)		N/A
	Yellow indicator lights mean: Caution (i.e., prompt response by OPERATOR required)		N/A
	Green indicator lights mean: Ready for use		N/A
	Other colours, if used: Meaning other than red, yellow, or green (colour, meaning) ..... :		N/A
7.8.2	Red used only for emergency control		N/A
7.9	ACCOMPANYING DOCUMENTS	Provided and checked	P
8	PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT		N/A
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS		N/A
	NORMAL CONDITION considered as simultaneous occurrence of situations identified in 8.1a)		N/A
	SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b) ..... :		N/A
	ACCESSIBLE PARTS determined according to 5.9		N/A
	LEAKAGE CURRENTS measured according to 8.7		N/A
8.2	Requirements related to power sources		-
8.2.1	Connection to a separate power source		-
	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/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		N/A
8.2.2	No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source		N/A
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset		N/A
8.3	Classification of APPLIED PARTS		N/A
8.4	Limitation of voltage, current or energy		-
8.4.1	PATIENT CONNECTIONS intended to deliver Current		N/A
	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/A
8.4.2	ACCESSIBLE PARTS and APPLIED PARTS		-
	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) ..... :		N/A
	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		N/A
	– accessible contacts of connectors		N/A
	– contacts of fuseholders accessible during replacement of fuse		N/A
	– contacts of lampholders accessible after removal of lamp		N/A
	– 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		N/A
	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.) ..... :		N/A
	Limit of 60 V 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/A
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J) ..... :		N/A
	LEAKAGE CURRENT limits referred to in 8.4.2 b) applied when voltages higher than limits in 8.4.2 c) were present (mA) ..... :		N/A
	d) Voltage and energy limits specified in c) above also applied to the following:		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– 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/A
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by the RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL		N/A
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		N/A
	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/A
	Test repeated with a TOOL specified in instructions for use		N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE		N/A
	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/A
	A TOOL is required when it is possible to prevent the devices from operating		N/A
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one sec after disconnecting the plug of ME EQUIPMENT or its parts (V) ..... :		N/A
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC..... :		N/A
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 45µC ..... :		N/A
	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/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 (IEC 60417-5036, 2002-10), and manual discharging device specified in technical description .....:		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.5	Separation of parts		N/A
8.5.1	MEANS OF PROTECTION (MOP)		N/A
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		N/A
	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		N/A
	Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION		N/A
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		N/A
	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		N/A
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		N/A
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of Clause 8.8 at test voltage of Table 6		N/A
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6		N/A
	A Y (Y1 or Y2) capacitor complying with IEC 60384-14 considered one MEANS OF PATIENT PROTECTION .....:		N/A
	Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c. .....:		N/A
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N/A
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) .....:		—
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)		N/A
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		N/A
	– dielectric strength test of 8.8 at test voltage of Table 6; or		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N/A
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		N/A
	– limits of Tables 13 to 16 (inclusive); or		N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6		N/A
	– or with requirements and tests of IEC 60950-1 for protective earthing ..... :		N/A
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION ..... :		N/A
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION ..... :		N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N/A
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (μF) ..... :		—
	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		N/A
	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 ..... :		N/A
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION ..... :		N/A
8.5.2	Separation of PATIENT CONNECTIONS		N/A
8.5.3	MAXIMUM MAINS VOLTAGE		-
	– 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/A
	When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V		N/A
	– MAXIMUM MAINS VOLTAGE was the highest RATED phase to neutral supply voltage for poly-phase ME EQUIPMENT (V) ..... :		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V		N/A
8.5.4	WORKING VOLTAGE		N/A
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V) ..... :		N/A
	– WORKING 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/A
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V) ..... :		N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS		N/A
8.6	Protective and functional earthing and potential equalization of ME EQUIPMENT		-
8.6.1	Requirements of 8.6.2 to 8.6.8 applied		N/A
	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/A
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/A
	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/A
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside ..... :		N/A
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		N/A
	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/A
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop.....:		N/A
	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/A
8.6.5	Surface coatings		-
	Poorly conducting surface coatings on conductive elements removed at the point of contact		N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		N/A
8.6.6	Plugs and sockets		-
	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/A
	- applied also where interchangeable parts are PROTECTIVELY EARTHED		N/A
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR		-
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE		N/A
	–accidental disconnection avoided in NORMAL USE		N/A
	– Terminal allows conductor to be detached without a TOOL		N/A
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		N/A
	– Terminal marked with symbol 8 of Table D.1		N/A
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		N/A
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		N/A
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION		N/A
8.6.9	Class II ME EQUIPMENT		-

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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/A
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.		N/A
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS		N/A
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		-
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3		N/A
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7 ..... :		N/A
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		N/A
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		N/A
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		N/A
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		N/A
	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		N/A
8.7.3	Allowable Values		-
	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..... :		N/A
	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 ..... :		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC}) ..... :		N/A
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC}) ..... :		N/A
	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 ..... :		N/A
	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 ..... :		N/A
	f) LEAKAGE CURRENTS that can flow in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION. :		N/A
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements ..... :		N/A
8.8	Insulation		-
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing		N/A
	Insulation exempted from test (complies with clause 4.8)		N/A
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		N/A
8.8.2	Distance through solid insulation or use of thin sheet material		-
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		N/A
	a) 0.4 mm, min, distance through insulation, or		N/A
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		N/A
	– at least two layers of material, each passed the appropriate dielectric strength test..... :		N/A
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test..... :		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		N/A
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		N/A
	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/A
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		N/A
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L		N/A
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		N/A
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		N/A
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		N/A
	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/A
	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/A
	Finished component complied with routine dielectric strength tests of 8.8.3 ..... :		N/A
	Tests of Annex L not repeated since material data sheets confirm compliance ..... :		N/A
8.8.3	Dielectric Strength		-
	Solid insulating materials with a safety function withstood dielectric strength test voltages ..... :		N/A
8.8.4	Insulation other than wire insulation		-
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT and design documentation examined .....:		N/A
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests .....:		N/A
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat .....:		N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat.....:		N/A
	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 Fig 21 apparatus .....:		N/A
	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/A
	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		N/A
8.8.4.2	Resistance to environmental stress		-
	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/A
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION		N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION		N/A
	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/A
	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/A
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		-

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are ≥ to values in Tables 12 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15		N/A
	- Insulation between parts of opposite polarity of the MAINS PART on the supply mains side of any mains fuse or OVER-CURRENT RELEASE, one MEANS OF OPERATOR PROTECTION are ≥ to values in Table 13, Table 14 and Table 16		N/A
8.9.1.2	Tables 12 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/A
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		N/A
8.9.1.4	When min CREEPAGE derived from Tables 12 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE		N/A
8.9.1.5	ME EQUIPMENT RATED to operate at an altitude of 2000 m		N/A
	ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m) ..... :		N/A
	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/A
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE		N/A
8.9.1.6	When WORKING VOLTAGE was between those in Tables 12 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows:		N/A
	– 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)..... :		N/A
	– 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)..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– for AIR CLEARANCES corresponding to PEAK WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied		N/A
8.9.1.7	Material groups classified in accordance with Table 9 (Material Group)..... :		N/A
	Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112 ..... :		N/A
	Material of unknown group considered IIIb		N/A
8.9.1.8	– Pollution degree 1: Micro-environment sealed to exclude dust and moisture		N/A
	– Pollution degree 2: Micro-environment with non-conductive pollution, except occasional conductivity caused by condensation		N/A
	– Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation		N/A
	– Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions		N/A
	Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION		N/A
	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		N/A
	Means employed according to Annex M to reduce the pollution degree.....:		N/A
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/A
	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		N/A
8.9.1.11	SUPPLY MAINS overvoltage category II applied according to IEC 60664-1		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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/A
	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/A
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)		N/A
	Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT		N/A
	Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS		N/A
	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/A
	Table 15 column for circuits not subject to transient over-voltages applied to:		N/A
	– 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/A
	– circuits in INTERNALLY POWERED ME EQUIPMENT		N/A
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:		N/A
	– CLEARANCE was at least 5 mm		N/A
	– 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
	– 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/A
	– CLEARANCE path was partly or entirely through air or along the surface of an insulating material of material group I		N/A
	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/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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		N/A
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		N/A
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION described in 13.1 for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied .....:		N/A
	b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths		N/A
	c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION is such that the relevant parts are rigid and located by moulding, or there is no reduction of a distance below specified value by deformation or movement of parts		N/A
	Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE		N/A
8.9.3	Spaces filled by insulating compound		-
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		N/A
	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/A
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/A
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		N/A
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint		N/A
	A winding of solvent-based enamelled 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/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– 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/A
	– 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/A
8.9.3.4	One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times.....:		N/A
8.10	Components and wiring		-
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 ....:		N/A
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION		N/A
	Conductors and connectors of ME EQUIPMENT when breaking free at their joint are not capable of touching circuit points resulting in a HAZARDOUS SITUATION described in 13.1		N/A
	Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION		N/A
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS described in 13.1 due to poor contact		N/A
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 test finger .....:		N/A
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		-
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 PROTECTION		N/A
	d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple		N/A
	42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.10.4.2	Connection and anchorage at both ends 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 described in 13.1		N/A
	This requirement applied to other HAND-HELD parts when disturbance or breaking of one or more of connections could result in a HAZARDOUS SITUATION described in 13.1		N/A
8.10.5	Mechanical protection of wiring		-
	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 described in 13.1..... :		N/A
	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 described in 13.1		N/A
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		N/A
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 ..... :		N/A
	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		N/A
	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..... :		N/A
8.11	MAINS PARTS, components and layout		-
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles..... :		N/A
	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)		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	PERMANENTLY INSTALLED ME EQUIPMENT provided with means to isolate its circuits electrically from the SUPPLY MAINS are capable of being locked in the off position if reconnection would result in a HAZARDOUS SITUATION or		N/A
	– any OPERATOR including SERVICE PERSONNEL is unable to view the means of isolation from their intended position		N/A
	The locking mechanism by the RESPONSIBLE ORGANIZATION, and		N/A
	- the isolation device specified in the ACCOMPANYING DOCUMENTS		N/A
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description .....:		N/A
	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 .....:		N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead		N/A
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		N/A
	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 with no SUPPLY MAINS switch to isolate it from SUPPLY MAINS considered to comply with 8.11.1 a) .....:		N/A
	g) A fuse or a semiconductor device not used as an isolating means		N/A
	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/A
	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		N/A
	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/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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/A
	Standard test finger of Fig 6 applied		N/A
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2		N/A
8.11.3	POWER SUPPLY CORDS		-
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD	No POWER SUPPLY CORDS	N/A
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design. 53) ..... :		N/A
	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/A
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 (mm^2 Cu) ..... :		N/A
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 ..... :		N/A
8.11.3.5	Cord anchorage (for APPLIANCE COUPLERS not complying with IEC 60320-1)		N/A
	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		N/A
	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/A
	– insulating material, or		N/A
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		N/A
	– 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/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage		N/A
	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/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N/A
	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/A
	Cord subjected to a torque in Table 18 for 1 min immediately after pull tests		N/A
	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/A
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N/A
	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/A
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		N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N/A
	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 D^2 gram attached to the free end of cord (g) ..... :		N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		N/A
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D ..... :		N/A
8.11.4	MAINS TERMINAL DEVICES		-

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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	No MAINS TERMINAL DEVICES	N/A
	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/A
	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/A
	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		
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		-
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection		N/A
	b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6		N/A
	c) Marking of MAINS TERMINAL DEVICES complied with 7.3		N/A
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		N/A
	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/A
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/A
8.11.4.4	Terminals with clamping means for a rewireable 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/A
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewireable POWER SUPPLY CORD to allow for connection of conductors, and covers fitted without damage to conductors or their insulation		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation test		N/A
8.11.5	Mains fuses and OVER-CURRENT RELEASES		-
	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 ..... :		N/A
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT		N/A
	Effect of short-circuit fault conditions in other circuits VERIFIED before eliminating fuses or OVER-CURRENT RELEASES		N/A
	Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit ..... :		N/A
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		N/A
	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		N/A
8.11.6	Internal wiring of the MAINS PART		-
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices is not less than minimum required for POWER SUPPLY CORD as in clause 8.11.3.3 (mm^2 Cu) ..... :		N/A
	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 .. :		N/A
	When necessary, ME EQUIPMENT connected to a SUPPLY MAINS with max available short-circuit current, 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/A
9	PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS		P
9.1	ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3)		N/A
9.2	HAZARDS associated with moving parts		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered.....:	Smoothed and rounded	P
9.4	Instability HAZARDS		N/A
9.5	Expelled parts HAZARD		N/A
9.6	Acoustic energy (including infra- and ultrasound) and vibration		N/A
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N/A
9.8	HAZARDS associated with support systems		N/A
10	PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS		N/A
	X-Radiation		N/A
11	PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS		P
11.1	Excessive temperatures in ME EQUIPMENT		-
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 .....:	See appended Table 11.1.1 and appended RM Results Table 11.1.1	P
	Surfaces of test corner did not exceed 90 °C		P
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION		N/A
11.1.2	Temperature of APPLIED PARTS		N/A
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 .....:		N/A
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE		P
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL		N/A
11.2	Fire prevention		-
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire caused by reasonably foreseeable misuse and met mechanical strength tests for ENCLOSURES in 15.3		P
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered		N/A
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT		-
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2 .....:		N/A
	Constructional requirements were met, or		P
	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 .....:	UL approved internal wiring used	P
	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 .....:	PCB: min. V-0	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/A
	b) Fire ENCLOSURE met following:		N/A
	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		N/A
	2) No openings on the sides within the area included within the inclined line C in Fig 39		N/A
	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	Not evaluated for use in the presence of flammable anaesthetics.	N/A
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	Not evaluated for use in the presence of flammable agent.	N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	IP22	P
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code) ..... :		N/A
	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 ..... :		N/A
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		N/A
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		N/A
12	ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS		N/A
12.1	RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review..... :		N/A
	PROTECTION AGAINST HAZARDOUS OUTPUT ..... :		N/A
13	HAZARDOUS SITUATIONS AND FAULT CONDITIONS		P
13.1	Specific HAZARDOUS SITUATIONS		P
13.1.1	None of HAZARDOUS SITUATIONS in 13.1.2-13.1.4, inclusive, occurred when SINGLE FAULT CONDITIONS applied, one at a time, as in 4.7 and 13.2	See 13.1.2-13.1.4.	P
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature		-
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur	No such emission occurs.	P
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur	.	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

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	–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		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/A
	- or secondary circuits mounted on materials with a minimum flame rating of FV1, and		N/A
	- Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and		P
	- Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and		N/A
	- Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide		N/A
	- or components in the circuit have HIGH INTEGRITY CHARACTERISTICS.....:		N/A
	– or parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation		N/A
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		N/A
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed.....:		N/A
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed .....:		N/A
13.1.4	ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS		N/A
13. 2	SINGLE FAULT CONDITIONS		-
13.2.1	During application of SINGLE FAULT CONDITIONS in 13.2.2 -13.2.13, inclusive, NORMAL CONDITIONS in 8.1 a) applied in least favourable combination .....:	Considered	P
13.2.2 – 13.2.12	ME EQUIPMENT complied with 13.2.2 -13.2.12 .....:	See appended Table 13.2	P

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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 °C of the temperature in the test environment		N/A
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		N/A
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION (see 8.8), the ball-pressure 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).		N/A
13.2.13.2	ME EQUIPMENT with heating elements	No Heating Elements provided	N/A
13.2.13.3	ME EQUIPMENT with motors	DC motor stopped	P
13.2.13.4	ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION		N/A
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated		N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle		N/A
	Motor winding temperatures did not exceed values in 13.2.10 ..... :		N/A
	Insulation Class..... :		—
	Maximum temperature measured (°C) ..... :		—
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)		N/A
	Requirements of this clause not applied to power supply	No Such Parts/ PESS not relied upon for Basic Safety or Essential Performance	N/A
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:		P
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

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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
	No damage resulting in an unacceptable RISK sustained		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 .....:		P
	No damage resulting in an unacceptable RISK sustained		P
15.3.4	Drop test		P
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD allowed to fall freely once from each of 3 different positions as in NORMAL USE from height specified in ACCOMPANYING DOCUMENTS, or from 1 m onto a 50 mm ± 5 mm thick hardwood board lying flat on a concrete or rigid base .....:		P
	No unacceptable RISK resulted		P
15.3.4.2	Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD lifted to a height as in Table 29 above a 50 ± 5 mm thick hardwood board lying flat on a concrete floor or rigid base, dropped 3 times from each orientation in NORMAL USE (cm) ..... :	After test, no damaged	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.5	Rough handling tests for MOBILE ME EQUIPMENT		N/A
15.3.6	Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Mould-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C .....:		N/A
	No damage resulting in an unacceptable RISK		N/A
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT		P
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK		P
15.4	ME EQUIPMENT components and general assembly		-
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular .....:	Considered	P
15.4.2	Temperature and overload control devices		N/A
15.4.2.1	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION described in 13.1by resetting action as verified by review of the design documentation and RISK MANAGEMENT FILE .....:		N/A
	b) THERMAL CUT-OUTS with a safety function that are reset by a soldering not fitted in ME EQUIPMENT		N/A
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided where a failure of a THERMOSTAT could in a HAZARDOUS SITUATION described in 13.1; the temperature of operation of the additional device is outside that attainable at the extreme setting of the normal control device, but within the temperature limit for the ME EQUIPMENT.....:		N/A
	d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION described in 13.1 or the loss of ESSENTIAL PERFORMANCE .....:		N/A
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety of ME EQUIPMENT as verified by following tests:		N/A
	Positive temperature coefficient devices (PTC's) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17 as applicable		N/A
	ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13 .....:		N/A
	SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) Certified according to appropriate standards		N/A
	In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) operated 200 times		N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		N/A
	When certification based on IEC standards, or data from MANUFACTURER demonstrating reliability of component to perform its safety-related function is not available, manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		N/A
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		N/A
	g) Protective device, provided on ME EQUIPMENT incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating		N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating in both leads where a conductive connection to earth could result in overheating as verified by review of design and RISK MANAGEMENT FILE .....:		N/A
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS		N/A
15.4.3	Batteries		P
15.4.3.1	Battery housings from which gases can escape during charging or discharging are ventilated to prevent unacceptable RISK from accumulation of gasses and possible ignition.....:	Carbon-Zinc battery	P

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Battery compartments designed to prevent accidental short circuiting of battery when this could result in a HAZARDOUS SITUATION as described in clause 13.1		P
15.4.3.2	Means provided to prevent incorrect connection of polarity when a HAZARDOUS SITUATION may develop by incorrect connection or replacement of a battery .....:		N/A
15.4.3.3	Overcharging of battery prevented by virtue of design when it could result in an unacceptable RISK as verified by review of design .....:		N/A
15.4.3.4	Primary lithium batteries comply with IEC 60086-4		N/A
	Secondary lithium batteries comply with IEC 62133		N/A
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire caused by excessive currents when (in case of a short circuit) layout of internal wiring, cross-sectional area, rating of connected components can result in a fire .....:		N/A
	Protective device has adequate breaking capacity to interrupt the maximum fault current		N/A
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented		N/A
	Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPS provided, or		N/A
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION described in clause 13.1		N/A
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for NORMAL USE, except when apparent to OPERATOR from normal operating position, and marking of 7.4.1 are insufficient for this purpose :		N/A
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s, except when apparent to OPERATOR from normal operating position		N/A
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational when a HAZARDOUS SITUATION could exist, except when apparent to OPERATOR from normal operating position		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Requirement not applied to heated stylus-pens for recording purposes		N/A
	Indicator lights provided on ME EQUIPMENT to indicate an output exists where an accidental or prolonged operation of output circuit could constitute a HAZARDOUS SITUATION		N/A
	Colours of indicator lights complied with 7.8.1		N/A
	Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE		N/A
15.4.5	Pre-set controls		N/A
15.4.6	Actuating parts of controls of ME EQUIPMENT		N/A
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		N/A
15.4.8	Aluminium wires less than 16 mm^2 in cross-sectional area are not used		N/A
15.4.9	Oil container in PORTABLE ME EQUIPMENT		N/A
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		-
15.5.1	Overheating		N/A
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating in the event of short circuit or overload of output windings and comply with this Clause and tests of 15.5.1.2 – 3 ..... :		N/A
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		N/A
	Dielectric strength test of 8.8.3 conducted on transformer after short circuit and overload tests		N/A
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved ..... :		N/A
	Short circuit applied directly across output windings for transformers not tested according to 5X frequency and 5X voltage test of 15.5.2 a) or 2x frequency and 2x voltage test of 15.5.2 b)		N/A
15.5.1.3	Multiple overload tests conducted on windings with more than one protective device to evaluate worst-case NORMAL USE loading and protection..... :		N/A
15.5.2	Transformers operating at a frequency above 1 kHz tested in accordance with clause 8.8.3 ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Transformer windings provided with adequate insulation to prevent internal short-circuits that could cause overheating which could result in a HAZARDOUS SITUATION		N/A
	Dielectric strength tests were conducted in accordance with requirements of this clause with no breakdown of insulation system and no detectable deterioration of transformer .....:		N/A
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with .....:		N/A
	- Means provided to prevent displacement of end turns beyond the inter-winding insulation		N/A
	- protective earth screens with a single turn have insulated overlap not less than 3mm and the width of the screen is at least equal to the axial winding length of the primary side		N/A
	- Exit of wires form internal windings of toroid transformers protected with double sleeving providing 2 MOPs and a total wall thickness of 0.3mm extending 20mm from the windings		N/A
	- insulation between primary and secondary windings complies with 8.8.2		N/A
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4 and the exceptions of this sub-clause		N/A
16	ME SYSTEMS		N/A
	Evaluation of ME SYSTEMS .....:		N/A
17	ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS		N/E
	RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review.....:	Refer to IEC 60601-1-2 report	N/E
ANNEX G	PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES		N/A
	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANESTHETIC MIXTURE WITH AIR occurs		N/A
ANNEX L	INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION		N/A
L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex covering round winding wires between 0.05 mm and 5.00 mm diameters		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
L.2	Wire construction		N/A
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component		N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		N/A
L.3	Type Test		N/A
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified		N/A
	Temperature (°C) ..... :		—
	Humidity (%) ..... :		—
L.3.1	Dielectric strength		N/A
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted by preparing the sample according to IEC 60851-5:1996, Clause 4.4.1 for a twisted pair with test voltages at least twice Tables 6 & 7, but not less than below with no breakdown:		N/A
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 6000 V for REINFORCED INSULATION (V) ..... :		N/A
L.3.2	Flexibility and adherence		N/A
	Sample subjected to flexibility and adherence test 8 of IEC 60851-3:1996, clause 5.1.1, using mandrel diameters of Table L.1		N/A
	Sample examined according to IEC 60851-3: 1997, clause 5.1.1.4, followed by dielectric test of clause 8.8.3, except test voltage applied between wire and mandrel with no breakdown		N/A
	Test voltage was at least the voltage in Tables 6 and 7but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa ..... :		N/A
L.3.3	Heat Shock		N/A
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3, except test voltage applied between the wire and mandrel		N/A

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Oven temperature based on Table L.2 (°C) ..... :		—
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm^2) ..... :		N/A
	Dielectric strength test conducted at room temperature after removal from the oven		N/A
L.3.4	Retention of electric strength after bending		N/A
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Test voltage applied between the shot and conductor.		N/A
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm^2) ..... :		N/A
L.4	Tests during manufacture		-
L.4.1	Production line dielectric strength tests conducted by the manufacture according to L.4.2 and L.4.3 :	See attached manufacturer's routine testing verification	N/A
L.4.2	Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:		N/A
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V)..... :	See manufacturer's routine testing verification	N/A
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V)..... :	See manufacturer's routine testing verification	N/A
L.4.3	Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1) ..... :	See manufacturer's routine testing verification	N/A
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:		
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION ..... :	See manufacturer's routine testing verification	N/A
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION..... :	See manufacturer's routine testing verification	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT	N/A

4.3	TABLE: ESSENTIAL PERFORMANCE	N/A

4.5	RM RESULTS TABLE: Equivalent Safety for ME Equipment of ME System	N/A

4.6	RM RESULTS TABLE: ME Equipment or system parts contacting the patient	N/A

4.7	RM RESULTS TABLE: Single Fault Condition for ME Equipment	N/A

4.8	RM RESULTS TABLE: Components of ME Equipment	N/A

4.9	RM RESULTS TABLE: Use of components with high-integrity characteristics	N/A

4.11	TABLE: Power Input					P
Operating Conditions / Ratings	Voltage (V)	Frequency (Hz)	Current (A)	Power (W ~~or VA~~)	Power factor (cos φ)	
Normal working	4.2	--	0.8	3.36	--	
Supplementary Information:						

5.1	RM RESULTS TABLE: Type Tests	N/A

5.9.2	TABLE: Determination of ACCESSIBLE parts	P
Location	Determination method (NOTE1)	Comments
Plastic enclosure	Visual	--
Supplementary information: 1) The determination methods are: visual; rigid test finger; jointed test finger; test hook.		

7.1.2	TABLE: Legibility of Marking	P
Markings tested	Ambient Illuminance (lx)	Remarks
Outside Markings (Clause 7.2) .....:	100 lx to 1.500 lx	Clearly legible
Inside Markings (Clause 7.3) .....:	100 lx to 1.500 lx	Clearly legible
Controls & Instruments (Clause 7.4) .....:	-	-
Safety Signs (Clause 7.5) .....:	-	-
Symbols (Clause 7.6) .....:	100 lx to 1.500 lx	Clearly legible

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Clause	Requirement + Test	Result - Remark	Verdict

7.1.2	TABLE: Legibility of Marking	P

Supplementary information:

Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR or if not defined at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.

7.1.3	TABLE: Durability of marking test	P

Characteristics of the Marking Label tested:		Remarks
Material of Marking Label .....:	Plastic	After the rub test, rating label still legible and durable
Ink/other printing material or process.....:	Laser engraved	-
Material (composition) of Warning Label .....:	-	-
Ink/other printing material or process.....:	-	-
Other.....:	-	-

Supplementary information:
Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96%, and then for 15 s with a cloth rag soaked with isopropyl alcohol.

7.2.2	RM RESULTS TABLE: Identification	P
7.2.13	RM RESULTS TABLE: Physiological effects (safety signs and warning)	N/A
7.2.17	RM RESULTS TABLE: Protective packaging	P
7.3.3	RM RESULTS TABLE: Batteries	P
7.3.7	RM RESULTS TABLE: Supply terminals	N/A
7.4.2	RM RESULTS TABLE: Control devices	N/A
7.5	RM RESULTS TABLE: Safety signs	N/A
7.9.2.4	RM RESULTS TABLE: Electrical power source	N/A
7.9.3.2	RM RESULTS TABLE: Replacement of fuses, power supply cords, other parts	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

8.1 b	RM RESULTS TABLE: Fundamental rule of protection against electric shock - accidental detachment of conductors and connectors	N/A

8.4.2	TABLE: Low voltage reliability					N/A
Test supply voltage/frequency (V/Hz)[1] ..... :						--
Location From/To	Measured values					Remarks
	Vrms	~~Vpk or~~ Vdc	Peak-to-peak ripple[2]	Power ~~W~~/VA	Energy (J)	
--	--	--	--	--	--	--
Supplementary Information: 1) The input supply voltage to the ME EQUIPMENT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4. 2) If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2.2.						

8.4.3	TABLE: ME EQUIPMENT for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply	N/A

Maximum allowable voltage (V) ..... :	60V

Voltage measured (V)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
Plug pins 1 and 2	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and enclosure	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and enclosure	--	--	--	--	--	--	--	--	--	--

Maximum allowable stored charge when measured voltage exceeded 60 v (μc) ..... :	N/A

Calculated stored charge (μc)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
Plug pins 1 and 2	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and enclosure	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and enclosure	--	--	--	--	--	--	--	--	--	--
Supplementary information:										

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8.4.4	TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT	N/A

Maximum allowable residual voltage (V):	60 V
Maximum allowable stored charge when residual voltage exceeded 60 V:	45 μC

Description of the capacitive circuit (i.e., accessible capacitor or circuit parts)	Measured residual voltage (V)	Calculated stored charge (μC)	Remarks
--	--	--	--
Supplementary information:			

8.5.2.2	RM RESULTS TABLE: Type B applied parts	N/A

8.5.2.3	RM RESULTS TABLE: PATIENT Leads	N/A

8.5.4	Table: working voltage measurement	N/A
Test supply voltage/frequency (V/Hz) ..... :	--	

Location	From	To	RMS voltage (V)	Peak voltage (V)	Comments
--	--	--	--	--	--
Supplementary Information:					

8.5.5.1a	TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies	N/A

8.5.5.1b	TABLE: defibrillation-proof applied parts – verification of recovery time	N/A

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 Ω load	N/A

8.6.3	RM RESULTS TABLE: Protective earthing of moving parts	N/A

8.6.4	TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS	N/A

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

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Supplementary information:

PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 mΩME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part - Limit 100 mΩ

ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a PROTECTIVELY EARTHED part - Limit 200 mΩ

ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part - Limit 200 mΩ

8.7	TABLE: leakage current	N/A

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks
Fig. 13 - Earth Leakage (ER)	—	—	Before/After HUMIDITY (μA)	Maximum allowed values: 5 mA NC; 10 mA SFC
--	--	--	--	--
Fig. 14 - Touch Current (TC)	—	—	Before/After HUMIDITY (μA)	Maximum allowed values: 100 uA NC; 500 uA SFC
--	--	--	--	--
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) Type CF AP: 10 uA NC; 50 uA SFC (d.c. or a.c. current) With non-frequency-weighted device: Maximum allowed values:10mA
--	--	--	--	--
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 uA Type CF AP: 50 uA With non-frequency-weighted device: Maximum allowed values:10mA
--	--	--	--	--
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC(d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC; 50

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				uA SFC (d.c. or a.c. current)
--	--	--	--	--
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 uA Type CF: N/A
--	--	--	--	--
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current); 100 uA NC; 500 uA SFC (a.c.) ; Type CF AP: 10 uA NC;50 uA SFC (d.c. or a.c. current)
--	--	--	--	--
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC; 1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
--	--	--	--	--
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current); 500 uA NC;1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current)
--	--	--	--	--
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000uA Type CF: 100 uA
--	--	--	--	--
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 uA Type CF: N/A
--	--	--	--	--

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 %

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of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

ER - Earth leakage current TC – Touch current P - Patient leakage current PA – Patient auxiliary current TP – Total Patient current PM - Patient leakage current with mains on the applied parts 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

8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)	N/A

Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1]	Dielectric breakdown after 1 minute Yes/No[2]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
--	--	--	--	--	--

Supplementary information:

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.

[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

8.8.4.1	TABLE: Resistance to heat - Ball pressure test of thermoplastic parts		N/A
	Allowed impression diameter (mm) .....:	≤ 2 mm	—
	Force (N).....:	20	—

Part/material	Test temperature (°C)	Impression diameter (mm)
--	--	--
Insulating material supporting un-insulated Mains Parts		
--	--	--
Supplementary information:		

8.8.4.1	RM RESULTS TABLE: Mechanical strength and resistance to heat	N/A

8.9.2	TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4	N/A

Specific areas of circuits short-circuited and test conditions	Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE[1]	HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No	Remarks

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Supplementary information:			

8.9.3.2 and 8.9.3.4	Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts		N/A
Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No
1	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
2	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
3	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
4	68 h at T1 ± 2 °C = ___°C [1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
Supplementary information: [1] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.			

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8.9.3.3 and 8.9.3.4	Table: Thermal cycling tests on one sample of cemented joint		N/A
Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No
1	68 h at T1 ± 2 °C = ___°C[1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
2	68 h at T1 ± 2 °C = ___°C[1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
3	68 h at T1 ± 2 °C = ___°C[1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
4	68 h at T1 ± 2 °C = ___°C[1]		
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		

Supplementary information:

[1] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

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8.10	TABLE: List of critical components				P
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity [1]
Non-metallic enclosure	FORMOSA CHEMICALS & FIBRE CORP PLASTICS DIV	ANC100	V-0, 60°C, Min1.5mm	UL 746	UL E162823
PCB	SHEN ZHEN TIE FA TECHNOLOGY LTD	TF-M, TF-2	V-0, 130°C	UL 94, UL 796	UL E346897
Supplementary information: 1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.					

8.10.1	RM RESULTS TABLE: Fixing of components	N/A

8.11.3.5	TABLE: Cord anchorages				N/A
Cord under test		Mass of equipment (kg)	Pull (N)	Torque Nm)	Remarks
--		--	--	--	--
--		--	--	--	--
--		--	--	--	--
Supplementary information:					

8.11.3.6	TABLE: Cord guard			N/A
Cord under test		Test mass	Measured curvature	Remarks
--		--	--	--
--		--	--	--
--		--	--	--
Supplementary information:				

9.2.1	RM RESULTS TABLE: HAZARDS associated with moving parts - General	N/A

9.2.2.2	TABLE: Measurement of gap “a” according to Table 20 (ISO 13852: 1996)	N/A

9.2.3.2	TABLE: Over-travel End Stop Test	N/A

9.2.4	RM RESULTS TABLE: Emergency stopping devices	N/A

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9.2.5	RM RESULTS TABLE: Release of patient		N/A
9.4.2.1	TABLE: Instability—overbalance in transport position		N/A
9.4.2.2	TABLE: Instability—overbalance excluding transport position		N/A
9.4.2.3	TABLE: Instability—overbalance from horizontal and vertical forces		N/A
9.4.2.4.2	TABLE: Castors and wheels – Force for propulsion		N/A
9.4.2.4.3	TABLE: Castors and wheels – Movement over a threshold		N/A
9.4.3.1	TABLE: Instability from unwanted lateral movement (including sliding) in transport position		N/A
9.4.3.2	TABLE: Instability from unwanted lateral movement (including sliding) excluding transport position		N/A
9.4.4	TABLE: Grips and other handling devices		N/A
9.5.1	RM RESULTS TABLE: Protective means		N/A
9.6.1	RM RESULTS TABLE: Acoustic energy - General		N/A
9.6.2.2	RM RESULTS TABLE: Infrasound and ultrasound energy		N/A
9.7.2	RM RESULTS TABLE: Pneumatic and hydraulic parts		N/A
9.7.5	TABLE: Pressure vessels		N/A
9.7.7	RM RESULTS TABLE: Pressure-relief device		N/A
9.8.1	RM RESULTS TABLE: Hazards associated with support systems - General		N/A
9.8.2	RM RESULTS TABLE: Tensile safety factor		N/A
9.8.3.1	RM RESULTS TABLE: Strength of patient or operator support or suspension systems - General		N/A

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9.8.3.2	TABLE: PATIENT support/suspension system - Static forces		N/A
9.8.3.3	TABLE: Support/Suspension System – Dynamic forces due to loading from persons		N/A
9.8.5	RM RESULTS TABLE: Systems without mechanical protective devices		N/A
10.1.1	TABLE: Measurement of X - radiation		N/A
10.1.2	RM RESULTS TABLE: ME equipment intended to produce diagnostic or therapeutic X-radiation		N/A
10.2	RM RESULTS TABLE: Alpha, beta, gamma, neutron & other particle radiation		N/A
10.5	RM RESULTS TABLE: Other visible electromagnetic radiation		N/A
10.6	RM RESULTS TABLE: RISK associated with infrared radiation other than emitted by lasers and LEDS		N/A
10.7	RM RESULTS TABLE: RISK associated with ultraviolet radiation other than emitted by lasers and LEDS		N/A

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				P
	Test model …….. :	K3			—
	Supply voltage (V/Hz) …….. :	4.2Vd.c.	4.2Vd.c.	--	—
	Ambient Tmin (°C) …….. :	See below	Shift to 40	--	—
	Ambient Tmax (°C) …….. :	--	--	--	—
	EUT position…….. :	--	--	--	—
Maximum measured temperature T of part/at:		T (°C)			Allowed T_{max} (°C)
PCB near U7		36.5	51.5	--	130
C13		37.8	52.8	--	105
Internal wire		35.8	50.8	--	80
Plastic enclosure inside near battery		35.7	50.7	--	85
Plastic enclosure outside near battery		32.0	47.0	--	48
LCD panel		33.1	48.1	--	48
Test corner		32.3	47.3	--	90

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Ambient	25.0	40.0	--	--
Supplementary information: 1) External surfaces of this equipment that are likely to be touched for a time t: 1min≤t. 2) The maximum operated temperature is +40°C.				

11.1.1	RM RESULTS TABLE: Maximum temperature during normal use (Table 23 or 24)	N/A

11.1.2.1	RM RESULTS TABLE: Applied parts intended to supply heat to patient	N/A

11.1.2.2	RM RESULTS TABLE: Applied parts not intended to supply heat to patient	N/A

11.1.3	TABLE: Temperature of windings by change-of-resistance method							N/A
Temperature T of winding:	t_1 (°C)	R_1 (Ω)	t_2 (°C)	R_2 (Ω)	T (°C)	Allowed T_{max} (°C)	Insulation class	
--	--	--	--	--	--	--	--	
--	--	--	--	--	--	--	--	
Supplementary information:								

11.1.3	RM RESULTS TABLE: Measurements	N/A

11.2.2.1	RM RESULTS TABLE: Risk of fire in an oxygen rich environment	N/A

11.2.2.1	TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source	N/A

11.3	RM RESULTS TABLE: Constructional requirements for fire enclosures of ME equipment	N/A

11.5	RM RESULTS TABLE: ME equipment and ME systems intended for use in conjunction with flammable agents	N/A

11.6.1	TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances			N/A
Clause / Test Name	Test Condition	Part under test	Remarks	
--	--	--	--	
Supplementary information:				

11.6.3	RM RESULTS TABLE: Spillage on ME equipment and ME system	N/A

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11.6.5	RM RESULTS TABLE: Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		N/A
11.6.7	RM RESULTS TABLE: Sterilization of ME equipment and ME systems		N/A
11.6.8	RM RESULTS TABLE: Compatibility with substances used		N/A
12.1	RM RESULTS TABLE: Accuracy of controls and equipment		N/A
12.4.1	RM RESULTS TABLE: Intentional exceeding of safety limits		N/A
12.4.2	RM RESULTS TABLE: Indication of parameters relevant to safety		N/A
12.4.3	RM RESULTS TABLE: Accidental selection of excessive output values		N/A
12.4.4	RM RESULTS TABLE: Incorrect output		N/A
12.4.5.3	RM RESULTS TABLE: Radiotherapy equipment		N/A
12.4.5.4	RM RESULTS TABLE: Other ME equipment producing diagnostic or therapeutic radiation		N/A
12.4.6	RM RESULTS TABLE: Diagnostic or therapeutic acoustic pressure		N/A

13.1.2	TABLE: measurement of power or energy dissipation in parts & components to waive 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	N/A

Power dissipated less than (W)..... :	15
Energy dissipated less than (J) .....:	900

Part or component tested	Measured power dissipated (W)	Calculated energy dissipated (J)	SINGLE FAULT CONDITIONS waived (Yes/No)	Remarks
Supplementary information:				

13.2	TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive		P
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS

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	Component No.	Fault	Supply voltage (V)	Test time	Fuse #	Fuse current (A)		SITUATION (Yes/No)
13.2.2	Electrical SINGLE FAULT CONDITIONS per Clause 8.1:						—	—
	C13	SC	4.2Vd.c.	10mins	--	--	Unit shut down immediately, recoverable. After test, no damage, no hazard.	No
	Q1 pin 1-3	SC	4.2Vd.c	10mins	--	--	Unit shut down immediately, recoverable. After test, no damage, no hazard.	No
	U7pin1-5	SC	4.2Vd.c.	10mins	--	--	Unit shut down immediately, recoverable. After test, no damage, no hazard.	No
	U7 pin2-4	SC	4.2Vd.c	10mins	--	--	Unit shut down immediately, recoverable. After test, no damage, no hazard.	No
13.2.3	Overheating of transformers per Clause 15.5:						—	—
	--						--	--

Supplementary information:
1) SC: short circuit; 2) Ambient temperature during above tests: 24.0 to 26.0°C.

13.2.6	RM RESULTS TABLE: Leakage of liquid	N/A
14.1	RM RESULTS TABLE: Programmable electrical medical systems - General	N/A
14.6.1	RM RESULTS TABLE: Identification of known and foreseeable hazards	N/A
14.6.2	RM RESULTS TABLE: Risk control	N/A
14.7	RM RESULTS TABLE: Requirement specification	N/A
14.8	RM RESULTS TABLE: Architecture	N/A
14.10	RM RESULTS TABLE: Verification	N/A
14.11	RM RESULTS TABLE: PEMS validation	N/A
14.13	RM RESULTS TABLE: Connection of PEMS by NETWORK/DATA COUPLING to other equipment	N/A
15.3	TABLE: Mechanical Strength tests [1)]	P

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Clause	Name of Test	Test conditions	Observed results/Remarks
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	After test, no damaged.
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	After test, no damaged.
15.3.4.1	Drop Test (hand-held)	Free fall height (m) =	N/A
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5	After test, no damaged.
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	After test, no damaged.
Supplementary information:			

15.4.1	RM RESULTS TABLE: Construction of connectors	N/A
15.4.2.1 a	RM RESULTS TABLE: THERMAL CUT-OUTS and OVER-CURRENT RELEASES	N/A
15.4.2.1 c	RM RESULTS TABLE: Independent non-SELF-RESETTING THERMAL CUT-OUT	N/A
15.4.2.1 d	RM RESULTS TABLE: Loss of function of ME EQUIPMENT	N/A
15.4.2.1 h	RM RESULTS TABLE: ME EQUIPMENT with tubular heating elements	N/A
15.4.3.1	RM RESULTS TABLE: Housing	N/A
15.4.3.2	RM RESULTS TABLE: Connection	N/A
15.4.3.3	RM RESULTS TABLE: Protection against overcharging	N/A
15.4.4	RM RESULTS TABLE: Indicators	N/A
15.4.5	RM RESULTS TABLE: Pre-set controls	N/A
15.4.6	TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests	N/A

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15.5.1.2	TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION	N/A
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)[1] .:		—
RATED input frequency (Hz) .....:		—

Winding tested	Class of insulation (A, B, E, F, or H)	Type of protective device (fuse, circuit breaker) /Ratings	Protective device operated Yes/No	Time to THERMAL STABILITY ~~(when protective device did not operate)~~ (Min)	Maximum allowed temp from Table 31 (ºC)	Maximum winding temp measured (ºC)	Ambient (ºC)
--	--	--	--	--	--	--	--

Supplementary information:

1) Refer to Table 13.2 for details.

15.5.1.3	TABLE: transformer overload test – conducted only when protective device under short-circuit test operated	N/A
Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1] ..... :		--
RATED input frequency (Hz) ..... :		--
Test current just below minimum current that would activate protective device & achieve THERMAL STABILITY under method a) (A) ..... :		See below
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted ..... :		-

Winding tested	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (ºC)	Maximum winding temp measured (ºC)	Ambient (ºC)
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Supplementary information:

1) Refer to Table 13.2 for details.

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7	N/A

Transformer Model/Type/ Part No	Test voltage applied between	Test voltage, (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No
	Primary & secondary windings				
	Primary winding & frame				
	Secondary winding & frame				

Supplementary information: Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details

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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

16.1	RM RESULTS TABLE: General requirements for ME Systems	N/A

16.6.1	TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS	N/A

16.9.1	RM RESULTS TABLE: Connection terminals and connectors	N/A

17	RM RESULTS TABLE: Electromagnetic compatibility of ME equipment and ME systems	N/A

	TABLE: Additional or special tests conducted	N/A

Clause and Name of Test	Test type and condition	Observed results
Supplementary information:		

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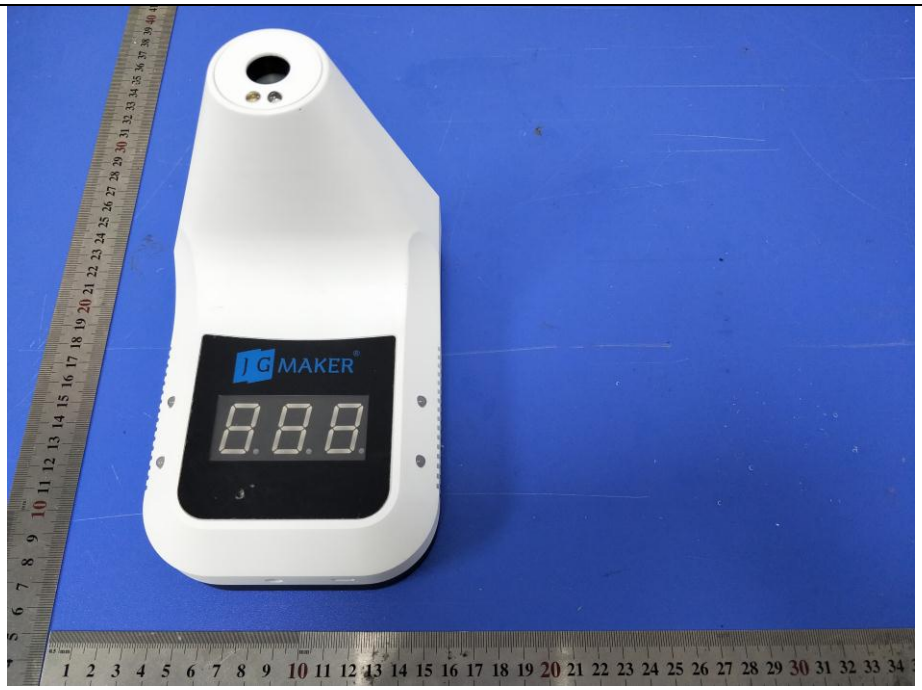
Details of: External View-1

Details of: External View-2



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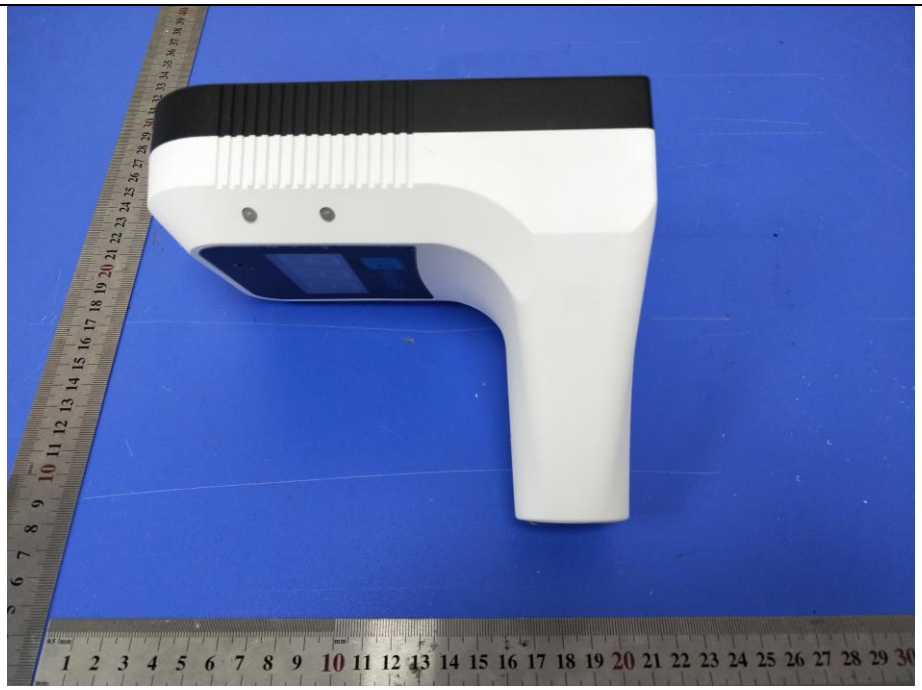
Details of: External View-3



Details of: Internal View-1

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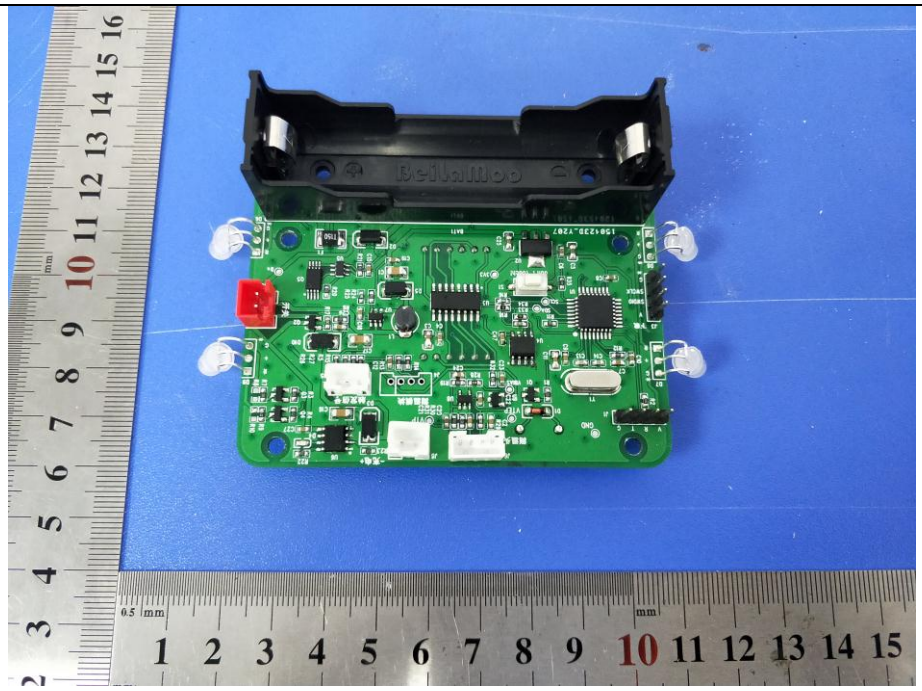
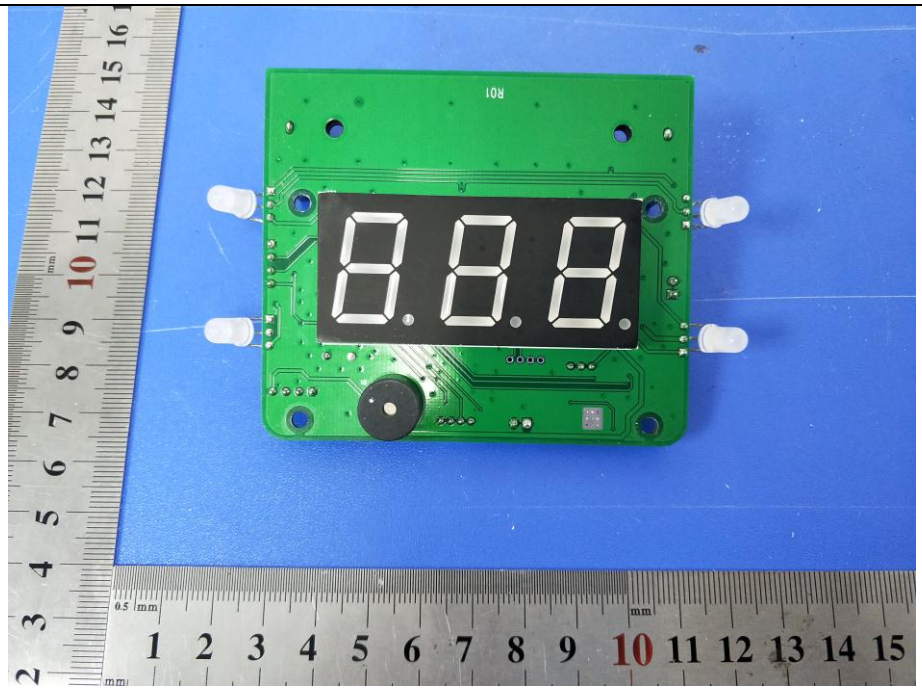
Details of: PCB board View-1



Details of: PCB board View-2



----------END OF TEST REPORT----------

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