IEC/ EN 60601-1 Medical electrical equipment

Part 1: General requirements for basic safety and essential performance

Report Reference No. .....:	UT108058
Date of issue.....:	September 26 , 2019
Total number of pages .....:	120
Testing Laboratory .....:	Universal Testing Inc.
Address .....:	2F, No.13, Lane 28, Sec. 1, Huanshan Rd., NeiHu, Taipei 114, Taiwan
Applicant's name .....:	Hivox Biotek Inc.
Address .....:	5F,No.123,Xingde Rd., Sanchong District. 241, New Taipei City, Taiwan, R.O.C.
Test specification:	
Standard .....:	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1: 2012 , EN 60601-1 : 2006 + A1 (2013) ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
Test procedure .....:	According to above
Non-standard test method …….. :	None
Test item description .....:	TENS/ EMS/ MSG
Trade Mark .....:	N/A
Manufacturer .....:	Hivox Biotek Inc.
Model/Type reference .....:	SL880H , EM59
Ratings .....:	I/P: DC 3.7 V (internal rechargeable battery)

Tested by (name + signature) ……:

Tony Cheng / Vice Manager 

Approved by (+ signature) ……:

Steven Chang / Assistant GM 

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

Photos – 3 pages

Name and address of factory (ies) :

Hivox Electronics Co., Ltd.
No. 11, Donghuan Second Road, Huangjiang Town, Dongguan City, Guangdong Province, People's Republic of China

Test Report History:
This report may consist of more than one report and is valid only with additional or previous issued reports:

Ref. No.	Item

deSummary of compliance with National Differences

List of countries addressed:

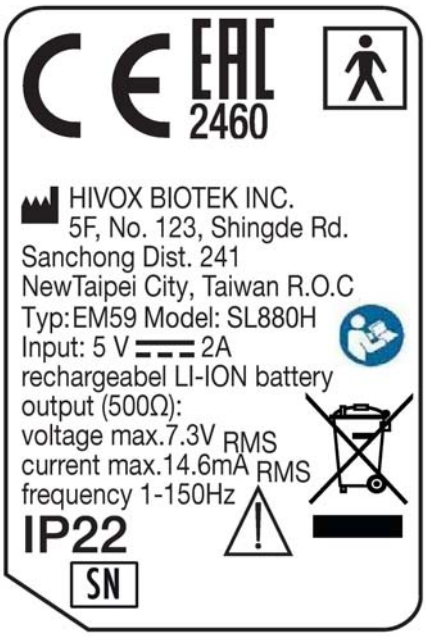
EU, USA

☒ The product fulfils the requirements of EN 60601-1 : 2006 + A1 (2013), ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (insert standard number and edition and delete the text in parenthesis or delete the whole sentence if not applicable)

The compliance statements of the results in the report are based on the decision rule in test procedures or technical standards. If the applicable test procedures or technical standards do not include the decision rule, the lab will not consider the measurement uncertainties (according to IEC Guide 115 Procedure 2) in the compliance judgements.

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	Hand held
Device type (component/sub-assembly/ equipment/ system). :	Equipment
Intended use (Including type of patient, application location) . :	A self-adhesive TENS device with a heat function to provide pain relief for menstrual complaints and pain caused by endometriosis. For home and private use.
Mode of operation ..... :	Continuous
Supply connection ..... :	Internally powered
Accessories and detachable parts included.....:	2 pair of self-adhesive electrodes and one USB-C charging cable
Other options include ..... :	
Testing	
Date of receipt of test item(s) ..... :	August 22, 2019
Dates tests performed ..... :	August 22 – September 26 , 2019
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

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.

General product information:

A hand-held battery operated transcutaneous electrical nerve stimulator / neuromuscular electrical stimulator with electrodes to put on the skin to relieve pain. It is fitted with dual isolated output channels with adjustable output. The output wave form is bi-phasic rectangular pulse, with adjustable pulse rate from 1 Hz to 150 Hz and pulse width from 50 us to 450 us. There are three operation modes to choose with a built-in timer up to 100 minutes. An internal 3.7Vdc rechargeable lithium battery is the only power source. Battery is charged by any 5Vdc UBS output port. It is tested and complied with Type BF applied part requirements. Not for use in the environment of ignitable gases. Not for direct cardiac application. Protection against ingress of water is IP22. Both models are completely the same except the identification.

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

INSULATION DIAGRAM

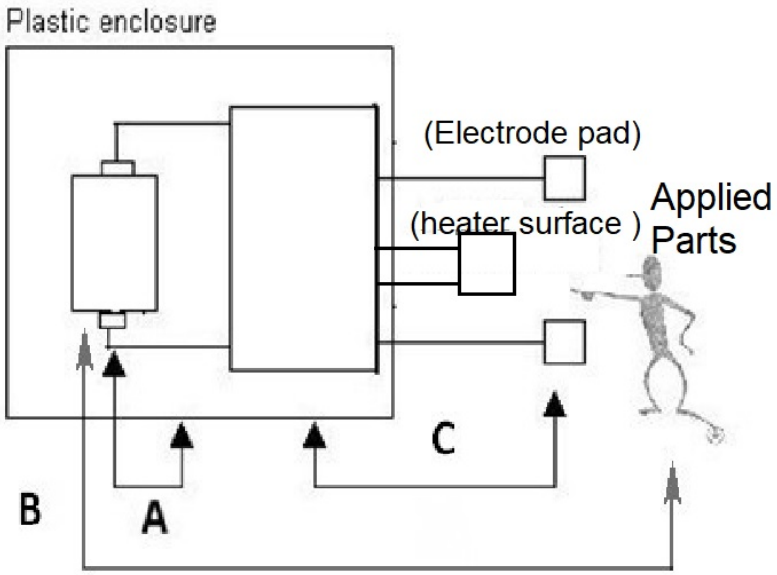


TABLE: To insulation diagram		P
Pollution degree..... :	II	—
Overvoltage category ..... :	N/A	—
Altitude ..... :	3000	—
Additional details on parts considered as applied parts ..... :	☒ None ☐ Areas (See Clause 4.6 for details)	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage Vrms	Working voltage Vpk	**Required creepage (mm)**	**Required clearance (mm)**	**Measured creepage (mm)**	**Measured clearance (mm)**	**Remarks**
A	A – a2 2 MOPP	IIIb	3.7 Vdc	--	3.4	1.6	4.0	4.0	
B	B – a 2 MOPP	IIIb	3.7 Vdc	--	3.4	1.6	--	--	See below
C	B – d 1 MOPP	IIIb	250 Vac	354 Vac	4.0	2.5	--	--	See below
Remark									
Area	Insulation between								

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

A	Between internal live parts to enclosure
B	Between internal live parts to applied part (the electrode); impedance , checked with the leakage current test.
C	Between enclosure to applied part(the electrode), checked with the dielectric strength and the leakage current test.

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

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

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

EN / 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		P
4.2.2	General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007).....:	See Appended RM Results Table 4.2.2.	P
4.2.3	Evaluating RISK		P
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level		P
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN .....:	RISK MANAGEMENT PLAN Document: RMR-SL880H-001	P
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		P
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		P
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.		P
4.3	Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.		P
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.		P
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		P
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE.....:	See Appended Table 4.3	P
	- RISK CONTROL measures implemented		P
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		P
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE .....:	2 years	P

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Clause	Requirement + Test	Result - Remark	Verdict
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.....:	no alternative means used	N/A
	Alternative means based scientific data or clinical opinion or comparative studies.....:		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.....:	See Appended Insulation Diagram Table and RM Results Table 4.6	P
	Assessment identified the APPLIED PART TYPE requirements .....:		N/A
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2.....:	See Appended RM Results Table 4.7	P
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically .....:	See Appended Table 13.2 for simulated physical test	P
	RISK associated with failure of component during EXPECTED SERVICE LIFE of ME EQUIPMENT taken into account to evaluate if a component should be subjected to failure simulation		P
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified.....:	all components used within their ratings	P
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS		P
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following		P
	a) Applicable safety requirements of a relevant IEC or ISO standard		P
	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 with high-integrity not used	N/A

EN / IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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 .....:		N/A
4.10	Power supply		P
4.10.1	ME EQUIPMENT is suitable for connection to a SUPPLY MAINS, specified to be connected to a separate power supply, can be powered by an INTERNAL ELECTRICAL POWER SOURCE, or a combination of the three .....:	Internally powered	P
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:	Not to connected to mains	N/A
	- 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) ..... :		N/A
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS		N/A
4.11	Power input		N/A
	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% ..... :	DC powered equipment	N/A
	– Measurements on ME EQUIPMENT or a ME SYSTEM marked with one or more RATED voltage ranges made at both upper and lower limits of the range.:		N/A
	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		N/A
	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.....:		N/A

5	GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT		P
5.1	TYPE TESTS determined in consideration of Clause 4, in particular 4.2	Tests performed. See appended table	P
	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods .....:	See Appended RM Results Table 5.1	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE identified combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION.		P
	- Testing determined BASIC SAFETY and ESSENTIAL PERFORMANCE were maintained.		P
5.2	TYPE TESTS conducted on one representative sample under investigation; multiple samples used simultaneously when validity of results was not significantly affected.....:		P
5.3	a) Tests conducted within the environmental conditions specified in technical description	Max operating temperature considered	P
	Temperature (ºC), Relative Humidity (%) .....:	Temperature: 5 to +40 degree C; Humidity : 15 to 93 %	—
	Atmospheric Pressure (kPa).....:	700 to 1060 hPa	—
	b) ME EQUIPMENT shielded from other influences that might affect the validity of tests	Tests done in controlled environment	P
	c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained .....:	Only when conducting the temperature test	P
5.4	a) ME EQUIPMENT tested under least favourable working conditions specified in instructions for use .....:		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	Considered	P
	c) When test results influenced by inlet pressure and flow or chemical composition of a cooling liquid, tests performed within the limits in technical description .....:	No such conditions	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) .....:	DC powered equipment. Only the rated voltage is used.	N/A
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)..... :		N/A
	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 ..... :	Single rated voltage.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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 ..... :	No alternative accessories and components specified	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 ..... :		P
	Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS were opened and detached	No manually detachable parts. Enclosure sealed with glue.	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 for 48 h for units rated IPX0	T = 25 ℃	P
	- For units rated higher than IPX0 test time extended to 168 h. ..... :	IP22. Tests done for 168 hr.	P
5.8	Unless stated otherwise, tests in this standard sequenced as in Annex B to prevent influencing results of any subsequent test	Test sequence in Annex B followed	P
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		P
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS ..... :	See clause 4.6 Remark	P
5.9.2	ACCESSIBLE PARTS		P
5.9.2.1	Accessibility, when necessary, determined using standard test finger of Fig 6 applied in a bent or straight position	See Appended Table 5.9.2	P

EN / IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Openings preventing entry of test finger of Fig. 6 mechanically tested with a straight un-jointed test finger of the same dimensions with a force of 30 N		P
	When the straight un-jointed test finger entered, test with the standard test finger (Fig 6) was repeated, if necessary, by pushing the finger through the opening	Test finger can not enter	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	Test hook can not enter	N/A
	All additional parts that became accessible checked using standard test finger and by inspection	No such parts	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 such parts	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	Complies with the requirements for internally powered ME equipment	P
	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 ..... :	IPX2, see separate IP test report No. DH1909120020A-1 issued by DEKRA IST Reliability Services Inc.	P
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use ..... :	No such need	N/A

EN / 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	Not to be used in oxygen rich environment	N/A
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION ..... :	Continuous	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 Table 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 and 8.10	P
	b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after marking durability test ..... :	See appended Tables 7.1.3 and 8.10	P
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		P
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) ..... :	No such parts	N/A
7.2.2	ME EQUIPMENT marked with:		P
	– the name or trademark and contact information of the MANUFACTURER		P
	– a MODEL OR TYPE REFERENCE	See attached copy of Marking Plate	P
	– a serial number or lot or batch identifier; and	Lot no marked	P
	– the date of manufacture or use by date	Lot no also represents the manufacture date	P

EN / IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or		N/A
	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 ..... :		P
7.2.3	Symbol 11 on Table D.1 (ISO 7000-1641, DB: 2004-01) used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS		N/A
	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 ....:	Accessories inspected: self-adhesive electrodes	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
	- the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or		N/A
	–safety sign ISO 7010-M002 (see Table D.2, safety sign 10) adjacent to the relevant connection point and listing of the required details in the instructions for use; or		N/A
	– Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use.		N/A
7.2.6	Connection to the Supply Mains		N/A
	Except for PERMANENTLY INSTALLED ME EQUIPMENT, marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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
	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).....:	Marked 2A	P
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W).....:		P
	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		N/A
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)..... :		—

EN / IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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.....:	IP22	P
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols as follows (not applied to parts identified according to 4.6).....:		P
	TYPE B APPLIED PARTS with symbol 19 of Table D.1 (IEC 60417-5840, 2002-10), not applied in such a way as to give the impression of being inscribed within a square in order to distinguish it from symbol IEC 60417-5333.....:		N/A
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 (IEC 60417-5333, 2002-10).....:		P
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 (IEC 60417-5335, 2002-10).....:		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 (IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336, all 2002-10).....:		N/A
	Proper symbol marked adjacent to or on connector for APPLIED PART, except marked on APPLIED PART when there is no connector, or connector used for more than one APPLIED PART and different APPLIED PARTS with different classifications.....:		P
	Safety sign 2 of Table D.2 (ISO 7010-W001) placed near relevant outlet when protection against effect of discharge of a cardiac defibrillator is partly in the PATIENT cable .....:		N/A
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use .....:		N/A
7.2.11	ME EQUIPMENT not marked to the contrary assumed to be suitable for CONTINUOUS OPERATION		P
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum “on” and “off” time .....:	Continuous operation	N/A
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder	Not used	N/A
	Fuse type.....:		—
	Voltage (V) and Current (A) rating..... :		—
	Operating speed (s) and Breaking capacity ..... :		—

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Clause	Requirement + Test	Result - Remark	Verdict
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 .....:	Not used	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) .....:	No cooling requirements	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 .....:	no special requirements	N/A
	Permissible environmental conditions for transport and storage marked on outside of packaging.....:		P
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK .....:		N/A
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization		N/A
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and .....:		N/A
	- where required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE, the RATED flow rate also marked		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 .....:	No such condition	N/A
	No marking applied when an interlock provided		N/A
7.2.21	MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms.....:	_____ kg	N/A
	- The marking is obvious that it applies to the whole of the MOBILE ME EQUIPMENT when loaded with its SAFE WORKING LOAD and		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- is separate and distinct from any markings related to maximum bin, shelf or drawer loading requirements.		N/A
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		P
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W) .....:	heating element is an integral part of the device and not replaceable	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	Heating element not changeable	N/A
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 ..... :	Battery is built-in type and not replaceable	N/A
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL.....:		N/A
	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.....:		N/A
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL	No such parts	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

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Clause	Requirement + Test	Result - Remark	Verdict
7.3.7	Terminals for supply conductors marked adjacent to terminals, except when no unacceptable RISK would result when interchanging connections.....:		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
	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		P
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	Only use a functional setup switch with symbol IEC 60417-5009 (2002-10) (Table D.1, Symbol 29).	N/A
	– status indicated by adjacent indicator light	LED indicator light of the heater and the output will be on when power button is pressed	P
	– 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

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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	Indicated on the button	P
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE ..... :		N/A
	– or an indication of direction in which magnitude of the function changes	with ∧ / ∨ for the output magnitude	P
	Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009 (2002-10) (Table D.1, Symbol 29).		P
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units		N/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 ..... :	See Appended Tables 7.1.2 and 7.1.3.	P
7.5	Safety signs		P
	Safety sign with established meaning used.		P
	Markings used to convey a warning, prohibition or mandatory action mitigating a RISK not obvious to OPERATOR are safety signs from ISO 7010 ..... :	Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used	P
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT		P
	Specified colours in ISO 3864-1 used for safety signs..... :		P
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		N/A
	Safety signs including any supplementary text or symbols described in instructions for use		N/A
	- and in a language acceptable to the intended OPERATOR		P
7.6	Symbols		P
7.6.1	Meanings of symbols used for marking described in instructions for use..... :	Described	P
7.6.2	Symbols required by this standard conform to IEC or ISO publication referenced	Conforms to IEC 60417 or ISO7000	P

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Clause	Requirement + Test	Result - Remark	Verdict
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable		P
7.7	Colours of the insulation of conductors		N/A
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation		N/A
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations		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
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		P
7.8.1	Red indicator lights mean: Warning (i.e., immediate response by OPERATOR required)	Red indicator lights for low battery warning	P
	Yellow indicator lights mean: Caution (i.e., prompt response by OPERATOR required)		N/A
	Green indicator lights mean: Ready for use		P
	Other colours, if used: Meaning other than red, yellow, or green (colour, meaning) ..... :		N/A
7.8.2	Red used only for emergency control	Emergency control not used	P
7.9	ACCOMPANYING DOCUMENTS		P
7.9.1	ME EQUIPMENT accompanied by documents containing at least instructions for use, and a technical description		P
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		P
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to ..... :		P
	– MODEL or TYPE REFERENCE ..... :		P

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Clause	Requirement + Test	Result - Remark	Verdict
	When ACCOMPANYING DOCUMENTS provided electronically (e.g., on CD ROM), USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT (for emergency operation)	Provided with hard copy	N/A
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	Permissive environmental locations described	P
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	Suitable for ordinary persons	P
7.9.2	Instructions for use include the required information		P
7.9.2.1	– use of ME EQUIPMENT as intended by the MANUFACTURER:		P
	– frequently used functions,		P
	– known contraindication(s) to use of ME EQUIPMENT		P
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient	Only customer services or authorized retailers are allowed to open and/or repair	N/A
	– name or trademark and address of the MANUFACTURER		P
	– MODEL OR TYPE REFERENCE		P
	Instruction for use included the following when the PATIENT is an intended OPERATOR:		P
	– the PATIENT is an intended OPERATOR		P
	– warning against servicing and maintenance while the ME EQUIPMENT is in use		P
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and	All functions in the user's manual	P
	–maintenance the PATIENT can perform	Maintenance in the user's manual	P
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT		P
	Instructions for use are in a language acceptable to the intended operator		P
7.9.2.2	Instructions for use include all warning and safety notices		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Warning statement for CLASS I ME EQUIPMENT indicating: "WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth"	Not a class I equipment	N/A
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments		N/A
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference		P
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET indicating, "connecting electrical equipment to MSO effectively leads to creating an ME SYSTEM, and can result in a reduced level of safety"		N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	Not a ME system	N/A
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply indicating "power supply is specified as a part of ME EQUIPMENT or combination is specified as a ME SYSTEM"		N/A
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source		N/A
	Warning to remove primary batteries when ME EQUIPMENT is not likely to be used for some time when leakage from battery would result in an unacceptable RISK..... :	Use rechargeable battery	N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided ..... :	Internal battery not replaceable	N/A
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK..... :	No such concern	N/A
7.9.2.5	Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE		P
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to when such exposure can constitute an unacceptable RISK		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected		N/A
	APPLIED PARTS specified		P
7.9.2.6	Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation	No installation requirement	N/A
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device when an APPLIANCE COUPLER or MAINS PLUG or other separable plug is used as isolation means to meet 8.11.1 a)		N/A
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation including initial control settings, and connection to or positioning of PATIENT prior to use of ME EQUIPMENT, its parts, or ACCESSORIES		P
7.9.2.9	Information provided to operate ME EQUIPMENT including explanation of controls, displays and signals, sequence of operation, connection of detachable parts or ACCESSORIES, replacement of material consumed during operation		P
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use		P
7.9.2.10	A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message	A trouble shooting guide provided	P
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT		P
7.9.2.12	Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified		P
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use		N/A
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT		P
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	No such parts for service personnel maintenance	N/A
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	To charge the battery at least 2 times a year	P
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	Described	P
	Other equipment providing power to ME SYSTEM sufficiently described (e.g. part number, RATED VOLTAGE, max or min power, protection class, intermittent or continuous duty)		N/A
7.9.2.15	Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for use .....:		P
7.9.2.16	Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)	Included in the instruction manual	P
7.9.2.17	Instruction for use for ME EQUIPMENT emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation		N/A
7.9.2.18	The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile indicate that they have been sterilized and the method of sterilization		N/A
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization		N/A
7.9.2.19	The instructions for use contain a unique version identifier .....:	Version no provided	P
7.9.3	Technical description		P
7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use including the following:		P
	– information as in clause 7.2		P
	– permissible environmental conditions of use including conditions for transport and storage		P

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Clause	Requirement + Test	Result - Remark	Verdict
	– all characteristics of ME EQUIPMENT including range(s), accuracy, and precision of displayed values or where they can be found		P
	– special installation requirements such as maximum permissible apparent impedance of SUPPLY MAINS	No such installation requirement	N/A
	– permissible range of values of inlet pressure and flow, and chemical composition of cooling liquid used for cooling	No such requirement	N/A
	– a description of means of isolating ME EQUIPMENT from SUPPLY MAINS, when such means not in ME EQUIPMENT		N/A
	– a description of means for checking oil level in partially sealed oil filled ME EQUIPMENT or its parts when applicable	Oil not used	N/A
	– a warning statement addressing HAZARDS that can result from unauthorized modification of ME EQUIPMENT according to following examples		P
	"WARNING: No modification of this equipment is allowed"		P
	"WARNING: Do not modify this equipment without authorization of the manufacturer"		N/A
	"WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment"		N/A
	- information pertaining to ESSENTIAL PERFORMANCE and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency	no such condition	N/A
	Technical description separable from instructions for use contains required information, as follows		N/A
	– information as in clause 7.2	Technical description is part of the instruction manual	N/A
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT		N/A
	– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and		P
	a unique version identifier.....:	Version no provided	P

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Clause	Requirement + Test	Result - Remark	Verdict
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description	no such condition	N/A
7.9.3.2	The technical description contains the following required information		P
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT, when type and rating of fuses are not apparent from information on RATED current and mode of operation of ME EQUIPMENT ..... :		N/A
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and if so, instructions for correct connection and anchoring to ensure compliance with 8.11.3	No power cord used	N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	No such components	N/A
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component		N/A
7.9.3.3	Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair	No service personnel repairable parts	N/A
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description		P

8	PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT		**P**
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS		P
	NORMAL CONDITION considered as simultaneous occurrence of situations identified in 8.1a)		P
	SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b)..... :		P
	ACCESSIBLE PARTS determined according to 5.9		P
	LEAKAGE CURRENTS measured according to 8.7		P
8.2	Requirements related to power sources		N/A
8.2.1	Connection to a separate power source		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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	With internal batteries only	N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified	Tested with the internal batteries	N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		N/A
8.2.2	Connection to an external d.c. power source		N/A
	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	Use internal DC source. Equipment doesn't work with batteries in wrong polarity	N/A
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE		N/A
	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		P
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF		N/A
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART		N/A
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	Type BF applied part	P
8.4	Limitation of voltage, current or energy		P
8.4.1	PATIENT CONNECTIONS intended to deliver Current		P
	Limits in 8.4.2 not applied to currents intended to flow through body of PATIENT to produce a physiological effect during NORMAL USE	Requirement in IEC 60601-2-20 applies	P
8.4.2	ACCESSIBLE PARTS and APPLIED PARTS		P
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT per Tables 3 and 4 when measured according to Clause 8.7.4..... :	See appended Table 8.7	P

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Clause	Requirement + Test	Result - Remark	Verdict
	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) ..... :	See appended Table 8.7	P
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed		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	No such parts	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
	– 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	Test pin can not enter	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	No top openings or opening for adjustment	N/A
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N	Test pin can not enter	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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	No preset controls	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	No top openings	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	No such parts	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
8.5	Separation of parts		P
8.5.1	MEANS OF PROTECTION (MOP)		P
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4		P
	Each MEANS OF PROTECTION categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking into account Clause 4.6, and flow chart in Fig A.12		P

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Clause	Requirement + Test	Result - Remark	Verdict
	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		P
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		P
	Insulation, CREEPAGE, CLEARANCES, components or earth connections not complying with 8.5.1.2 and 8.5.1.3 not considered as MEANS OF PROTECTION, and failure of these parts regarded as NORMAL CONDITION		P
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		P
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of Clause 8.8 at test voltage of Table 6	Main unit enclosure	P
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		P
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6		N/A
	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:	The equipment is evaluated to provide two means of patient protection.	N/A
	– dielectric strength test of 8.8 at test voltage of Table 6; or		N/A
	– 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	See Attachment #	N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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		P
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to maximum MAINS VOLTAGE and complied with limit for PATIENT LEAKAGE CURRENT at 110 % of max. MAINS VOLTAGE ..... :	See appended Table 8.7 for measured leakage current	P
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		N/A
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		P
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS ..... :		N/A
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART		P
	LEAKAGE CURRENT tests conducted per 8.7.4..... :	See appended Table 8.7	P
	Dielectric strength test conducted per 8.8.3 ..... :	See appended Table 8.8.3	P

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Clause	Requirement + Test	Result - Remark	Verdict
	CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		P
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s	No such protective device	N/A
8.5.2.2	PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED..... :		N/A
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and		N/A
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4..... :		N/A
	Dielectric strength test conducted per 8.8.3 ..... :		N/A
	Relevant CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		N/A
	The RISK MANAGEMENT FILE reviewed		N/A
8.5.2.3	A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE		P
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT..... :	See Appended RM Results Table 8.5.2.3	P
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter		P
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm		P
	– conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1		N/A
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N, except when RISK MANAGEMENT PROCESS indicated no unacceptable RISK existed from contact with objects other than a mains socket or a flat surface:	See Appended RM Results Table 8.5.2.3	P

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Clause	Requirement + Test	Result - Remark	Verdict
8.5.3	MAXIMUM MAINS VOLTAGE		P
	– MAXIMUM MAINS VOLTAGE determined to be the highest RATED supply voltage for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT, as well as INTERNALLY POWERED ME EQUIPMENT with a means of connection to a SUPPLY MAINS (V) ..... :	No mains voltage	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
	– for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V		P
8.5.4	WORKING VOLTAGE		P
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V)..... :	3.7Vdc	P
	– 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) ..... :	See Insulation Diagram and Insulation Table	P
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth		P
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V) ..... :		P
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages		N/A
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V) ..... :		N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	Not with defibrillation proof applied part	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety, but not separate functions of same APPLIED PART		N/A
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		N/A
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ..... :		N/A
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS ..... :		N/A
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load to at least 90% of energy delivered to this load with ME EQUIPMENT disconnected ..... :		N/A
8.6	Protective and functional earthing and potential equalization of ME EQUIPMENT		N/A
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, except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE :		N/A

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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		N/A
	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		N/A
	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		N/A
	– 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		N/A

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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		P
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3 .... :	See appended Tables 8.7	P
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7 ..... :	See appended Tables 8.7	P
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		P
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		N/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	Only provided with reinforced 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		P
8.7.3	Allowable Values		P
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b ..... :	See appended Table 8.7	P
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz ..... :	See appended Table 8.7	P

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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})..... :	See appended Table 8.7	P
	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..... :	See appended Table 8.7	P
	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 ..... :	See appended Table 8.7	P
8.8	Insulation		P
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing	Insulations as means of protection are tested	P
	Insulation exempted from test (complies with clause 4.8)	No exemption	N/A
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	Provided with patient protection See Attachment #	N/A
8.8.2	Distance through solid insulation or use of thin sheet material		N/A
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:	Working voltage is 3.7Vdc	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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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		P
	Solid insulating materials with a safety function withstood dielectric strength test voltages ..... :	See appended Table 8.8.3	P
8.8.4	Insulation other than wire insulation		P

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Clause	Requirement + Test	Result - Remark	Verdict
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		P
	ME EQUIPMENT and design documentation examined ..... :		P
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests ..... :	See Appended RM Results Table 8.8.4.1	P
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat ..... :		N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat..... :		P
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus ..... :	See Table 8.8.4.1 Tested at 75℃. Impression diameter 0.69 mm max Measured 39.2℃ at 40 ℃ ambient in 11.1	P
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C) ..... :		N/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		P
	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		P
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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		P
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		P
	- 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	No such material used	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		P
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) ..... :	Up to 3000m (700 hPa) as described in the user's manual	P
	Operating altitude corresponding to actual air pressure for ME EQUIPMENT intended for pressurized environments (e.g., aircraft) used to determine multiplication factor from Table 8, and AIR CLEARANCE was multiplied by this factor		N/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:		P
	– CREEPAGE DISTANCES determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ..... :	See Insulation Diagram/Table.	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– CLEARANCES for PEAK WORKING VOLTAGES above 2800 V peak or d.c. determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ..... :	See Insulation Diagram/Table.	N/A
	– for AIR CLEARANCES corresponding to PEAK WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied		P
8.9.1.7	Material groups classified in accordance with Table 9 (Material Group)..... :	See Insulation Diagram/Table.	P
	Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112 ..... :		N/A
	Material of unknown group considered IIIb	Group IIIb considered	P
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	Pollution degree 2 considered	P
	– 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) ..... :		—

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Clause	Requirement + Test	Result - Remark	Verdict
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	No mains parts	N/A
8.9.1.11	SUPPLY MAINS overvoltage category II applied according to IEC 60664-1	Not connected to mains	N/A
	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	Not MOOP	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

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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
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	All evaluated as two means of patient 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		P
	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		N/A
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

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Clause	Requirement + Test	Result - Remark	Verdict
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
	– 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		P
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely as indicated in RISK MANAGEMENT FILE .... :	See Appended RM Results Table 8.10.1	P
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION :		P
	Conductors and connectors of ME EQUIPMENT when breaking free at their joint are not capable of touching circuit points resulting in a HAZARDOUS SITUATION described in 13.1	No such conductors or connectors	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		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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
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		P
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION described in 13.1 ..... :		P
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION described in 13.1		P
8.10.6	Guiding rollers of insulated conductors prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead concerned in NORMAL USE		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 ..... :	No insulating sleeve used	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	No sheath of flexible cord used	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 ..... :	See appended Table 11.1.1 No components has the temperature over 70℃ during normal use.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.11	MAINS PARTS, components and layout		N/A
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles..... :	No MAINS PARTS, components and layout	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
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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
	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		N/A
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD		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

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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		N/A
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		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		N/A
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N/A
	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

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Clause	Requirement + Test	Result - Remark	Verdict
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
	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		N/A
	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
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts of opposite polarity within MAINS PART, and between all parts of MAINS PART and earth, and such provisions continued within all components		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
	Justification for omission of fuses or OVER-CURRENT RELEASES documented		N/A
8.11.6	Internal wiring of the MAINS PART		N/A
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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 fault, and subsequent simulation of a fault in a single insulation in MAINS PART did not result in any of the HAZARDOUS SITUATIONS in 13.1.2		N/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)		P
9.2	HAZARDS associated with moving parts		N/A
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level.....:	No moving parts	N/A
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)		N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and		N/A
	RISK CONTROLS implemented ..... :		N/A
9.2.2	TRAPPING ZONE		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:		N/A
	– Gaps in Clause 9.2.2.2, or		N/A
	– Safe distances in Clause 9.2.2.3, or		N/A
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or		N/A
	– Continuous activation in Clause 9.2.2.5		N/A
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM		N/A
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20.....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008 ..... :		N/A
	Distances measured from expected positions of OPERATOR, PATIENT, and others near EQUIPMENT in NORMAL USE or under foreseeable misuse		N/A
9.2.2.4	GUARDS and other RISK CONTROL measures		N/A
9.2.2.4.1	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when GUARDS or other RISK CONTROL measures are of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK based on results of applicable tests in 15.3 for ENCLOSURES .....:		N/A
9.2.2.4.2	FIXED GUARDS held in place by systems that can only be dismantled with a TOOL		N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open		N/A
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,		N/A
	– absence or failure of one of their components prevents starting, and stops moving parts		N/A
	Movable GUARDS complied with any applicable tests		N/A
9.2.2.4.4	Other RISK CONTROL designed and incorporated into to the control system stops movement if a TRAPPING ZONE is reached and motion has started, and		N/A
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or		N/A
	ME EQUIPMENT is SINGLE FAULT SAFE		N/A
9.2.2.5	Continuous activation		N/A
	Continuous activation used as a RISK CONTROL, where impractical to make the TRAPPING ZONE inaccessible, complies with the following		N/A
	a) movement was in OPERATOR'S field of view		N/A
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR as long as OPERATOR response to deactivate device relied upon to prevent HARM		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or		N/A
	- the continuous activation system is SINGLE FAULT SAFE		N/A
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT, when contact with ME EQUIPMENT could result in a unacceptable RISK, limited to allow OPERATOR control of the movement		N/A
	Over travel (stopping distance) of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		N/A
9.2.3	Other MECHANICAL HAZARDS associated with moving parts		N/A
9.2.3.1	Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated		N/A
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or		N/A
	- activation does not result in an unacceptable RISK		N/A
9.2.3.2	Over travel past range limits of the ME EQUIPMENT prevented .....:		N/A
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse .....:		N/A
9.2.4	Emergency stopping devices		N/A
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power .....:		N/A
	a) Emergency stopping device reduced RISK to an acceptable level		N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N/A
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N/A
	g) Means for stopping of movements operate as a result of one single action		N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 (symbol IEC 60417-5638, 2002-10) or "STOP"		N/A
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed		N/A
	k) Emergency stopping device is suitable for its application		N/A
9.2.5	Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping ..... :		N/A
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		N/A
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented		N/A
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way		N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered.....:		P
9.4	Instability HAZARDS		N/A
9.4.1	ME EQUIPMENT, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE	Hand held equipment	N/A
9.4.2	Instability – overbalance		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when not specified, as in 9.4.2.2, and placed on a 10° inclined plane from horizontal consisting of a hard and flat surface (e.g., concrete floor covered with 2 to 4 mm thick vinyl material) .....:		N/A
9.4.2.2	Instability excluding transport		N/A
	ME EQUIPMENT or its parts prepared based on a) to g), inclusive, did not overbalance when placed in different positions of NORMAL USE, except transport positions, on a 5° inclined plane from horizontal (hard and flat surface) .....:		N/A
	A warning provided, stating “Transport only under conditions described in instructions for use or marked on ME EQUIPMENT with an indication of RESIDUAL RISK if ME EQUIPMENT or its parts overbalances” when overbalance occurred during 10° inclined plane test		N/A
9.4.2.3	Instability from horizontal and vertical forces		N/A
	a) ME EQUIPMENT or its parts with a mass of 25kg or more, other than FIXED ME EQUIPMENT for use on floor, did not overbalance due to pushing or resting		N/A
	Surfaces of ME EQUIPMENT or its parts where a RISK of overbalancing exists from pushing, leaning, resting etc., permanently marked with a CLEARLY LEGIBLE warning of the RISK (e.g., safety sign 5 of Table D.2, safety sign ISO 7010-P017) and visible during NORMAL USE		N/A
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a force of 15% of its weight, but not more than 150 N, applied in different directions, except a direction with an upward component		N/A
	b) ME EQUIPMENT or its parts, other than FIXED ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping		N/A
	ME EQUIPMENT or its parts, other than FIXED ME EQUIPMENT, for use on the floor or on a table, where a RISK of overbalancing exists due to sitting or stepping permanently marked with a CLEARLY LEGIBLE warning of the RISK (e.g., safety signs 6 and 7 of Table D.2, safety signs ISO 7010-P018, or ISO 7010-P019 as appropriate) and visible during NORMAL USE .....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a constant force of 800 N applied at the point of maximum moment to working surfaces, offering an foothold or sitting surface of a min 20 x 20 cm area, and at a height ≤ 1 m from the floor .....:		N/A
9.4.2.4	Castors and wheels		N/A
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT (e.g., castors or wheels) did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE		N/A
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT along a hard and flat horizontal surface did not exceed 200 N applied at a height of 1 m above floor or highest point on ME EQUIPMENT when < 1 m high, except when instructions indicated more than one person needed (N) .....:		N/A
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg configured with a SAFE WORKING LOAD, moved 10 times in forward direction over a solid vertical plane obstruction with wheels impacting the obstruction at a speed of 0.8 m/s ± 0.1 m/s for manual or with max speed for motor driven MOBILE ME EQUIPMENT :		N/A
	ME EQUIPMENT went up the obstruction without overbalancing		N/A
	BASIC SAFETY and ESSENTIAL PERFORMANCE was maintained.....:		N/A
9.4.3	Instability from unwanted lateral movement (including sliding)		N/A
9.4.3.1	a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control		N/A
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements of ME EQUIPMENT or its parts in transport position		N/A
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position or worst case NORMAL USE position with SAFE WORKING LOAD, and locking device activated, on a 10° inclined hard flat surface with castors in worst-case position		N/A
	Following initial elastic movement, creepage, and pivoting of castors, no further movement of MOBILE ME EQUIPMENT > 50 mm (in relation to inclined plane) occurred (mm).....:		N/A
	RISK due to any initial movement assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.4.3.2	Instability excluding transport		N/A
	a) Further movement of ME EQUIPMENT (after initial elastic movement) was less than 50 mm when MOBILE ME EQUIPMENT with a SAFE WORKING LOAD positioned on a 5° inclined hard flat surface with wheel locked or braking system activated (mm)..:		N/A
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
	b) MOBILE ME EQUIPMENT with a SAFE WORKING LOAD prepared as in 9.4.2.2 and placed on a horizontal plane with locking device activated and castors, when supplied, in their worst case position		N/A
	Further movement of ME EQUIPMENT (after initial elastic movement), was no more than 50 mm when a force of 15 % of weight of unit, but less than 150 N, applied in different directions, except a direction with an upwards component, at highest point of ME EQUIPMENT but ≤ 1.5 m from floor .....:		N/A
9.4.4	Grips and other handling devices		N/A
	a) ME EQUIPMENT other than PORTABLE EQUIPMENT or its part with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method, except when handling is obvious and causing unacceptable RISK		N/A
	Handles, when supplied, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS		N/A
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying		N/A
	c) Carrying handles and grips and their means of attachment withstood loading test.....:		N/A
9.5	Expelled parts HAZARD		N/A
9.5.1	Suitability of means of protecting against unacceptable RISK of expelled parts determined by assessment and examination of RISK MANAGEMENT FILE .....:		N/A
9.5.2	Cathode ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965.....:		N/A
9.6	Acoustic energy (including infra- and ultrasound) and vibration		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK based on the tests of 9.6.2 and 9.6.3, and		N/A
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity.....:		N/A
9.6.2	Acoustic energy		N/A
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE, except for auditory ALARM SIGNALS		N/A
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA).....:		—
	- 83 dBA (when halving the cumulative exposure time) (dBA).....:		—
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB).....:		—
9.6.2.2	RISK MANAGEMENT FILE examined for RISKS associated with infrasound or ultrasound addressed in RISK MANAGEMENT PROCESS .....:		N/A
9.6.3	Hand-transmitted vibration		N/A
	Means provided, except for INTENDED USE vibrations, to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values measured at points of hand contact with PATIENT or OPERATOR		N/A
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2).....:		N/A
	– Accelerations for different times, inversely proportional to square root of time (m/s^2).....:		N/A
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N/A
9.7.1	Requirements of this clause applied to vessels and parts of ME EQUIPMENT subject to pressure resulting in rupture and unacceptable RISK		N/A
	Parts of a pneumatic or hydraulic system used as a support system, comply with 9.8		N/A
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE.....:		N/A
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		N/A
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		N/A
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply		N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N/A
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity		N/A
9.7.3	Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:		N/A
	a) RATED maximum supply pressure from an external source		N/A
	b) Pressure setting of a pressure-relief device provided as part of assembly		N/A
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device		N/A
9.7.4	Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests .....:		N/A
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was > 50 kPa, and product of pressure and volume was more than 200 kPaI .....:		N/A
9.7.6	Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE .....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.7.7	Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests .....:		N/A
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair		N/A
	c) Could be adjusted or rendered inoperative without a TOOL		N/A
	d) With discharge opening located and directed as to not to release material towards any person		N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		N/A
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure		N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect		N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N/A
9.8	HAZARDS associated with support systems		N/A
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK .....:		N/A
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		N/A
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		N/A
	– RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions		N/A
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials		N/A
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		N/A
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest		N/A
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing .....:		N/A
	When test were conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK .....:		N/A
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		N/A
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints :		N/A
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts		N/A
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER		N/A
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications		N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		N/A
	Max allowable PATIENT mass > 135 kg stated in ACCOMPANYING DOCUMENTS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance .....:		N/A
9.8.3.2	Part of SAFE WORKING LOAD representing mass of PATIENTS or OPERATORS is distributed on support/suspension surface representing human body as in Fig A.19		N/A
	Part of SAFE WORKING LOAD representing mass of ACCESSORIES deployed as in NORMAL USE and, when not defined, at worst case position permitted by configuration or ACCESSORIES attachment on support/suspension parts		N/A
	a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m^2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR .....:		N/A
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests .....:		N/A
	PATIENT support/suspension system positioned horizontally in most disadvantageous position in NORMAL USE, and a mass 2 x 135 kg or twice intended person's load (the greater used), applied to foot rest over an area of 0.1 m^2 for 1 min (Kg).:		N/A
	Damage or deflection greater than 5° from normal did not occur		N/A
	BASIC SAFETY and ESSENTIAL PERFORMANCE was maintained		N/A
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK		N/A
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test .....:		N/A
	PATIENT support/suspension system set in most unfavourable NORMAL USE position, and a mass of 60 % of part of SAFE WORKING LOAD simulating PATIENT or OPERATOR, or a min 80 kg, placed on support or suspension system with centre of load 60 mm from outer edge of support or suspension system for at least 1 min (Kg) .....:		N/A
	Deflection of support/suspension from normal greater than 5° did not occur, and		N/A
	- BASIC SAFETY and ESSENTIAL PERFORMANCE was maintained		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE maintained BASIC SAFETY and ESSENTIAL PERFORMANCE confirmed by following test		N/A
	PATIENT support/suspension system set in most unfavourable NORMAL USE position, and a mass equal to SAFE WORKING LOAD simulating PATIENT or OPERATOR dropped from 150 mm above seat area on an area of support/ suspension a PATIENT or OPERATOR can sit.....:		N/A
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES		N/A
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided when a support system or its parts impaired by wear have a TENSILE SAFETY FACTOR ≥ to values in Table 21, rows 5 and 6, but less than 3 and 4 .....:		N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		N/A
	– Designed based on TOTAL LOAD, and includes effects of SAFE WORKING LOAD when applicable		N/A
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N/A
	– Activated before travel (movement) produced an unacceptable RISK		N/A
	– Takes into account Clauses 9.2.5 and 9.8.4.3		N/A
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests .....:		N/A
9.8.4.2	Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE (e.g., a secondary cable)		N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		N/A
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		N/A
	– Further use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE ..:		N/A
	– ACCOMPANYING DOCUMENTS instruct once MECHANICAL PROTECTIVE DEVICE is activated, SERVICE PERSONNEL shall be called, and MECHANICAL PROTECTIVE DEVICE must be replaced before ME EQUIPMENT can be used		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.2 (i.e., safety sign ISO 7010-W001)		N/A
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE or its location relative to MECHANICAL PROTECTIVE DEVICE is obvious to service personnel		N/A
	– Compliance confirmed by examination of ME EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and following test.....:		N/A
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT		N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		N/A
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		N/A
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		N/A
	Support system parts have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 1 and 2, and are not impaired by wear.....:		N/A
	Support system parts impaired by wear, however, they have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 3 and 4		N/A
	Examination of ME EQUIPMENT, design documentation and RISK MANAGEMENT FILE confirmed compliance		N/A

10	PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS		**N/A**
10.1	X-Radiation		N/A
10.1.1	The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT including background radiation for ME EQUIPMENT not producing therapeutic/diagnostic X-radiation but producing ionizing radiation .....:	No radiating elements used or present	N/A
	Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Amount of radiation measured by means of an ionizing chamber radiation monitor with an effective area of 10 cm^2 or by other instruments producing equal results		N/A
	ME EQUIPMENT operated as in NORMAL USE at most unfavourable RATED MAINS VOLTAGE and controls adjusted to emit maximum radiation		N/A
	Internal pre-set controls not intended for adjustment during EXPECTED SERVICE LIFE of ME EQUIPMENT not taken into consideration		N/A
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or :		N/A
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....:		N/A
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE .....:		N/A
10.3	The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2 at any point 50 mm away from a surface of the ME EQUIPMENT under reference test conditions		N/A
	Microwave radiation is propagated intentionally for example, at waveguide output ports		N/A
10.4	Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.		N/A
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE...:		N/A
10.6	RISK associated with infrared radiation other than emitted by lasers and LEDS, as applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....:		N/A
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS, as applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....:		N/A

11	PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS	**P**
11.1	Excessive temperatures in ME EQUIPMENT	P

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Clause	Requirement + Test	Result - Remark	Verdict
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	Test corner not used during the test to simulate the actual use condition	N/A
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	Thermal cut-out not used	N/A
11.1.2	Temperature of APPLIED PARTS		P
11.1.2.1	APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in both NORMAL CONDITION and SINGLE FAULT CONDITION.. :		N/A
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:		P
	Maximum Temperature..... :	Up to 43℃	—
	Conditions for safe contact, e.g. duration or condition of the PATIENT ..... :	Contact time (program set time) is 5 to 100 minutes	—
	Clinical effects with respect to characteristics such as body surface, maturity of PATIENTS, medications being taken or surface pressure documented in the RISK MANAGEMENT FILE		N/A
	APPLIED PARTS surface temperature of equal to or less than 41°C		N/A
	Analysis documented in the RISK MANAGEMENT FILE show that APPLIED PART temperatures are not affected by operation of the ME EQUIPMENT including SINGLE FAULT CONDITIONS. Measurement of APPLIED PART temperature according to 11.1.3 is not conducted ..... :	applied part temperature measured according to 11.1.3	N/A
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS ..... :	no such condition	N/A
11.1.2.2	APPLIED PARTS not supplying heat to a PATIENT met Table 24 with max surface temperatures > 41 °C disclosed in instructions for use, and clinical effects regarding maturity of PATIENTS, body surface, surface pressure, medications taken, as shown in RISK MANAGEMENT FILE ..... :		N/A
	Surfaces of APPLIED PARTS cooled below ambient temperatures that can also result in HAZARD evaluated as part of RISK MANAGEMENT PROCESS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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 ..... :	Measurements made with the equipment operated continuously till thermal stability	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
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE	All external parts of the equipment are considered likely to be touched	P
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	No such parts needing guards	N/A
11.2	Fire prevention		P
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
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of fire under NORMAL or SINGLE FAULT CONDITIONS when source of ignition in contact with ignitable material ..... :		N/A
	Requirements of 13.1.1 applied to oxygen concentrations up to 25 % at one atmosphere or partial pressures up to 27.5 kPa for higher atmospheric pressures		N/A
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT in NORMAL and SINGLE FAULT CONDITIONS under any of the following conditions		N/A
	1) when temperature of material raised to its ignition temperature		N/A
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature		N/A
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating		N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE ..... :		N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively..... :		N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three..... :		N/A
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination ..... :		N/A
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3 ..... :		N/A
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%)..... :		N/A
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes		N/A
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE ..... :		N/A
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
11.2.2.2	RISK of ignition under least favourable conditions did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT when electrical components mounted outside of ME EQUIPMENT or ME SYSTEM		N/A
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks due to loosening or breaking, except when limited in power and energy to values in 11.2.2.1 a) 5)		N/A
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		N/A
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		N/A
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered		N/A
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2) ..... :		N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) ..... :		N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) ..... :		N/A
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a)..... :		N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas..... :		N/A
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT		P
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2..... :	fire enclosure provided	P
	Constructional requirements were met, or		P
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE ..... :		N/A
	Justification, when requirement not met..... :		N/A
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials ..... :		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of materials data ..... :	Complied with UL94 requirements	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:		P
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm	No bottom openings	P
	2) No openings on the sides within the area included within the inclined line C in Fig 39	No side openings	P
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials, except constructions based on Table 25 and a mesh; FV-2 or better for TRANSPORTABLE ME EQUIPMENT, FV-1 or better for fixed EQUIPMENT, or STATIONARY EQUIPMENT per IEC 60695-11-10, determined by ENCLOSURE examination or flammability classification based on 11.3a) ..... :		P
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics		N/A
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable anaesthetics (CATEGORY AP) or anaesthetics with oxidants (CATEGORY APG) comply with Annex G		N/A
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		N/A
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE ..... :		N/A
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT		P
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT ..... :	See Appended Table 11.6.1	P

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Clause	Requirement + Test	Result - Remark	Verdict
11.6.2	Overflow in ME EQUIPMENT	Does not use liquids in normal use	N/A
	ME EQUIPMENT incorporates a reservoir or liquid storage that is liable to be overfilled or to overflow in NORMAL USE, liquid overflowing from the reservoir or chamber did not wet any MEANS OF PROTECTION that is liable to be adversely affected by such a liquid, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE ..... :		N/A
	Maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.		N/A
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.		N/A
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM	Does not use liquids in normal use	N/A
	ME EQUIPMENT and ME SYSTEMS handling liquids in NORMAL USE positioned as in 5.4 a) and liquid with composition, volume, duration of spill and point of contact based on the RISK ANALYSIS and test conditions based on RISK MANAGEMENT PROCESS poured steadily on a point on top of ME EQUIPMENT ..... :		N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and un-insulated electrical parts or electrical insulation of parts that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION were not wet ..... :		N/A
11.6.4	Leakage	Liquids not used with equipment in normal use	N/A
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		P

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)..... :	IP22	P
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION ..... :		P
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS		P
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected once using methods specified in instructions for use including any cooling or drying period ..... :	See Appended Table 11.6	P
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests, with no deterioration resulting in an unacceptable RISK present..... :	See appended Tables 8.7 8.8.3	P
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER and assurance that the processes did not cause a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE ..... :		P
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented according to ISO 11135-1, ISO 11137-1, or ISO 17665-1 as appropriate..... :	No parts intended to be sterilized or disinfected	N/A
	After the test, ME EQUIPMENT complied with the appropriate dielectric strength and LEAKAGE CURRENT tests and there was no deterioration resulting in an unacceptable RISK ..... :		N/A
	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE	See Appended RM Results Table 11.6.8	P
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented per ISO 10993	Evaluated separately by the applicant	N/E
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		P

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Clause	Requirement + Test	Result - Remark	Verdict
12	ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS		P
12.1	RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review..... :		N/A
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING PROCESS complying with IEC 60601-1-6..... :	See separate report no. UFE-SL880H -001 based on IEC 60601-1-6	P
12.3	MANUFACTURER implemented an ALARM SYSTEM that complies with IEC 60601-1-8. ..... :	Alarm system not necessary.	N/A
12.4	Protection against hazardous output		P
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE ..... :	All outputs are considered safe	N/A
12.4.2	When applicable, need for indication of parameters associated with hazardous output addressed in RISK MANAGEMENT PROCESS ..... :	No hazardous outputs provided	N/A
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit designed to provide low and high-intensity outputs for different treatments addressed in RISK MANAGEMENT PROCESS, confirmed in RISK MANAGEMENT FILE ..... :		P
12.4.4	When applicable, RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE .... :	See Appended RM Results Table 12.4.4	P
12.4.5	Diagnostic or therapeutic radiation		N/A
12.4.5.1	Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation emitted by ME EQUIPMENT designed to produce radiation for diagnostic/therapeutic purposes		N/A
	Radiation safety ensured by compliance with requirements of appropriate standards		N/A
12.4.5.2	ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3..... :		N/A
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
12.4.5.4	RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE ..... :		N/A
12.4.6	When applicable, RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE ..... :		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		P
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature		P
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur	No emission of flams, molten plastic, poisonous or ignitable substance occurred	P
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur	No deformation of enclosure occurred	P
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 when measured as in 11.1.3 ..... :	See appended Tables 11.1.1	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 ..... :	See appended Tables 11.1.1	P
	–Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C were not exceeded		P
	Limits for windings in Tables 26, 27, and 31 not exceeded		N/A
	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 ..... :		P
	- or secondary circuits mounted on materials with a minimum flame rating of FV1, and		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and		N/A
	- 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		P
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function	Not used	N/A
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed..... :	See appended Table 8.7	P
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed ..... :	See appended Table 8.7	P
13.1.4	ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS		P
13. 2	SINGLE FAULT CONDITIONS		P
13.2.1	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 ..... :	See appended Table 13.2	P
13.2.2 – 13.2.12	ME EQUIPMENT complied with 13.2.2 -13.2.12..... :	See appended Table 13.2	P
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to within 3 °C of the temperature in the test environment		P
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		P
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION (see 8.8), the 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).		P
13.2.13.2	ME EQUIPMENT with heating elements		P

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Clause	Requirement + Test	Result - Remark	Verdict
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, or for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests of 13.2.13.2 b) & 13.2.13.2 c)		N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests of 13.2.13.2 b) and 13.2.13.2 c)		N/A
	a 3) other ME EQUIPMENT with heating elements met test of 13.2.13.2 b)		P
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		N/A
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration		N/A
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		N/A
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself		N/A
	b) ME EQUIPMENT with heating elements tested per clause 11.1without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V) ..... :	Tested with a fully charged battery to run till no power	P
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY		N/A
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION		N/A
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and		N/A
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS		N/A
	2) When more than one control provided, they were disabled in turn		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		N/A
13.2.13.3	ME EQUIPMENT with motors		N/A
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable		N/A
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		N/A
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition		N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		N/A
	b) Motor met running overload protection test of this clause when:		N/A
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended		N/A
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C) ..... :		N/A
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		N/A
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload		N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		N/A
	Test not conducted based on other justifications (justification)..... :		N/A
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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)		**P**
14.1	Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE, or		N/A
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK ..... :	See Appended RM Results Table 14.1	P
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK		P
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304 ..... :		P
	Software development process applied according to Clause 5 of IEC 62304..... :		P
	Software development process for Software risk management applied according to Clause 7 of IEC 62304 ..... :		P
	Software development process Configuration Management applied according to Clause 8 of IEC 62304 ..... :		P
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304 ..... :		P
14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process ..... :		P
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan		P
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented		P

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Clause	Requirement + Test	Result - Remark	Verdict
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		P
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone		P
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules		P
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		P
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained where appropriate		P
	Problem resolution system meets prescribed criteria depending on type of product:		P
	– it is documented as a part of PEMS DEVELOPMENT LIFE-CYCLE		P
	– it allows reporting of potential or existing problems affecting BASIC SAFETY or ESSENTIAL PERFORMANCE		P
	– it includes an assessment of each problem for associated RISKS		P
	– it identifies criteria that must be met for the issue to be closed		P
	– it identifies the action to be taken to resolve each problem		P
14.6	RISK MANAGEMENT PROCESS		P
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS ..... :	See Appended RM Results Table 14.6.1	P
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2..... :	See Appended RM Results Table 14.6.2	P
14.7	A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem..... :	See Appended RM Results Table 14.7	P

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Clause	Requirement + Test	Result - Remark	Verdict
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems ..... :	See Appended RM Results Table 14.8	P
	The architecture specification makes use of considers the specified items to reduce RISK to an acceptable level, where appropriate:		P
	a) COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS		P
	b) fail-safe functions		P
	c) redundancy		P
	d) diversity;		P
	e) partitioning of functionality		P
	f) defensive design potentially limiting hazardous effects by restricting available output power or by introducing means to limit travel of actuators		P
	g) allocation of RISK CONTROL measures to subsystems and components of PEMS		P
	h) failure modes of components and their effects;		P
	i) common cause failures		P
	j) systematic failures		P
	k) test interval duration and diagnostic coverage		P
	l) maintainability		P
	m) protection from reasonably foreseeable misuse		P
	n) IT-NETWORK specification, when applicable		N/A
14.9	Design is broken up into subsystems, each with a design and test specification where appropriate, and descriptive data on design environment documented ..... :		N/A
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures..... :	See Appended RM Results Table 14.10	P
	– milestone(s) when VERIFICATION is to be performed for each function		P
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		P
	– selection and utilization of VERIFICATION tools		P
	– coverage criteria for VERIFICATION		P

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Clause	Requirement + Test	Result - Remark	Verdict
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE ..... :	See Appended RM Results Table 14.11	P
	Methods used for PEMS VALIDATION documented		P
	The person with overall responsibility for PEMS VALIDATION is independent of design team, and no member of a design team is responsible for PEMS VALIDATION of their own design		P
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE		P
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE		P
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304 ..... :		P
	Software Process for Software changes applied according to Clause 5 of IEC 62304 ..... :		P
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304 ..... :		P
	Configuration management of software changes applied per Clause 8 of IEC 62304 ..... :		P
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304 ..... :		P
14.13	For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following ..... :		N/A
	a) Purpose of the PEMS connection to an IT-NETWORK		N/A
	b) required characteristics of the IT-NETWORK		N/A
	c) required configuration of the IT-NETWORK		N/A
	d) technical specifications of the network connection, including security specifications		N/A
	e) intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK		N/A
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the characteristics required		N/A
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties		N/A
	– Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS		N/A
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis		N/A
	- Changes to the IT-NETWORK include: - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment		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	No such parts	N/A
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		N/A
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 ..... :	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P

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Clause	Requirement + Test	Result - Remark	Verdict
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 ..... :	Hand held equipment	N/A
	No damage resulting in an unacceptable RISK sustained		N/A
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 ..... :	See Appended Table 15.3	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) ..... :		N/A
	No damage resulting in an unacceptable RISK sustained		N/A
15.3.5	Each sample of MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests ..... :		N/A
	a) Ascending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0. 8m/s ± 0.1 m/s against an ascending hardwood step obstruction without the sample going over the obstruction		N/A
	b) Descending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0.8m/s ± 0.1 m/s in order to fall over a vertical step affixed flat on a rigid base with direction of movement perpendicular to face of the step until full descent achieved		N/A
	c) Door frame shock test conducted on the sample by moving it 3 times in its normal direction of travel at 0.8 m/s ± 0.1 m/s, or for motor driven EQUIPMENT, at maximum possible speed against a hardwood vertical obstacle higher than EQUIPMENT contact point(s)		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	No damage resulting in an unacceptable RISK sustained		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		P
	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 ..... :	Enclosure temperature measured at 40℃ ambient is 39.2℃. Test done at 70℃ oven for 7 hrs.	P
	No damage resulting in an unacceptable RISK	No warping, cracking or breaking. No exposure of live parts.	P
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		N/A
15.4	ME EQUIPMENT components and general assembly		P
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular ..... :	Only one connector for USB battery charging. Incorrect connection is not possible.	N/A
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions, except when no unacceptable RISK could result ... :	One outlet only for both patient lead and charger. See attachment #	N/A
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection ..... :	See attachment #	N/A
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 ..... :	No such components.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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	Thermostat not used	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..... :	No gases during charging or discharging Unit is covered by plastic enclosure without opening	P
	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 ..... :	Equipment doesn't work when battery installed with incorrect polarity	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 ..... :		P
15.4.3.4	Primary lithium batteries comply with IEC 80086-4		N/A
	Secondary lithium batteries comply with IEC 62133	Test report No. NCT19022283XI1-1 by Shenzhen NCT Testing Technology Co., Ltd.	P
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 ..... :	No protective device provided within battery circuit since only provide one 3.7V voltage and 2000mAh battery to unit. It would be less than 15W in single fault condition and would not cause a fire hazard.	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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.. :		P
	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		P
	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		P
	Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE	The battery level symbol in display flashes .	P
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS when applicable as verified by review of RISK MANAGEMENT FILE..... :	No pre-set controls.	N/A
15.4.6	Actuating parts of controls of ME EQUIPMENT		N/A
15.4.6.1	a) Actuating parts cannot be pulled off or loosened up during NORMAL USE		N/A
	b) Controls secured so that the indication of any scale always corresponds to the position of the control		N/A
	c) Incorrect connection of indicating device to relevant component prevented by adequate construction when it could be separated without use of a TOOL		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	When torque values per Table 30 applied between control knob and shaft of rotating controls for not less than 2 s, 10 times in each direction, knobs did not rotate ..... :		N/A
	Tests conducted by applying an axial force of 60 N for electrical components and 100 N for other components for 1 min when an axial pull was required in NORMAL USE with no unacceptable RISK ..... :		N/A
15.4.6.2	Stops of adequate mechanical strength provided on rotating/ movable parts of controls of ME EQUIPMENT where necessary to prevent an unexpected change from max to min, or vice-versa, of the controlled parameter..... :		N/A
	Torque values in Table 30 applied 10 times in each direction to rotating controls for 2 sec..... :		N/A
	No unexpected change of the controlled parameter resulted from the application of an axial force of 60 N for electrical components and 100 N for other components to rotating or movable parts of controls for 1 min when an axial pull was likely to be applied ..... :	No axial pull	N/A
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		N/A
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1		N/A
	b) Foot-operated control device supported an actuating force of 1350 N for 1 min applied over an area of 30 mm diameter in its position of NORMAL USE with no damage to device causing an unacceptable RISK..... :		N/A
15.4.7.2	Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface ..... :		N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		N/A
15.4.7.3	a) Foot-operated control device is at least IPX1 & complies with tests of IEC 60529 (IP Code)..... :	IP Code = ____	N/A
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6 and complies with IEC 60529 if in NORMAL USE liquids are likely to be found (IP Code)..... :	IP Code = ____	N/A
15.4.8	Aluminium wires less than 16 mm^2 in cross-sectional area are not used		P

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Clause	Requirement + Test	Result - Remark	Verdict
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed to prevent loss of oil in any position		N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		N/A
	A pressure-release device operating during NORMAL USE is, optionally, provided		N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		N/A
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		N/A
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
	Transformer windings provided with adequate insulation to prevent internal short-circuits that could cause overheating which could result in a HAZARDOUS SITUATION		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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**
17	ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS		**N/E**
	RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review .... :		N/E
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS..... :		N/E
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems		N/E
ANNEX G	PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES		**N/A**
ANNEX L	INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict

AAMI Deviations from IEC 60601-1 : 2005 + A1 : 2012

Clause	Requirement + Test	Result - Remark	Verdict
4.8 b)	Where there is no relevant IEC/ISO standard, the relevant ANSI standard applies; if no relevant ANSI standard exists, the requirement of this standard shall be applied	The requirement of this standard applies	P
4.10.2	Max. rated voltage of 600Vac for polyphase ME equipment and ME systems with a rated input ≦ 4kVA and all other ME equipment and ME systems Than hand-held or DC or single phase AC equipment	Not a polyphase equipment or ME system	N/A
6.6	X-ray systems shall be classified as long time operation(＞5 min) or momentary operation (＜5 sec)		N/A
7.2.11	X-ray systems shall be marked as long time operation or momentary operation		N/A
7.2.21	cylinders containing medical gases and their connections points shall be colored in accordance with the requirements of NFPA 99		N/A
8.2	All fixed ME equipment and permanently installed ME equipment shall be Class I ME equipment	Not a fixed ME equipment or permanently installed ME equipment	N/A
8.6.1	enclosure of X-ray equipment operating over 600Vac,850Vdc mains voltage, or containing voltages up to 50Vpeak and enclosed in protectively earthed enclosure as well as connections to X-ray tubes and other high voltage components that include high voltage shielded cables shall be protectively earthed		N/A
	non-current carrying conductive parts of X-ray equipment likely to become energized shall be protectively earthed		N/A
8.7.3 d)	The allowable values of the earth leakage current are 5 mA in normal condition and 10 mA in single fault condition	Equipment is internally powered	N/A
8.11	Permanently connected ME equipment shall have provision for the connection of one of the wiring systems that is in accordance with the NEC	Not a permanently connected ME equipment	N/A
	The installation of connecting cords between equipment parts shall meet the requirements of the NEC, as applicable.		N/A
	Cable used as external interconnection between units shall be		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	1) if exposed to abuse, Type SJT, SJTO, SJO, ST, SO,STO or equivalent or similar multiple-conductor appliance-wiring material such as a computer cable		N/A
	2) if not exposed to abuse, Types as above or i) Types SPT-2, SP-2 or SPE-2 or equivalent ii) Types SVr, SVRO,SVE or equivalent or similar multiple-conductor appliance-wiring material or iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8mm or more, Enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm or more		N/A
	Receptacles provided as part of ME equipment or ME systems for use in the patient care areas of pediatric wards, rooms, or areas shall be listed tamper resistant or shall employ a listed tamper resistant cover in accordance with the NEC.		N/A
	b) ME equipment provided with NEMA configuration non-locking plug types 120V/15A, 125V/20A, 250V/15A, 250V/20A A “ Hospital Grade” plug shall be provided and the POWER SUPPLY CORD shall be marked	battery operated equipment	N/A
8.11.3.2	Flexible cord shall be of a type acceptable for the particular application with a voltage not less than The appliance rated voltage and have an ampacity as given in the NEC, not less than the current rating of the appliance		N/A
8.11.3.3	X-Ray equipment with an attachment plug, the current rating on a hospital grade plug should be 2X the maximum input current of the equipment		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
3.2	RM report No. RMR-SL880H - 001 Introduction	Adequate Resources provided	P
3.2	RM report No. RMR- SL880H - 001 Introduction	Adequate assignment of qualified personnel	P
3.2	RM report No. RMR- SL880H - 001 Introduction	Provided according to ISO 14971. Define the policy for determining acceptable risk, taking into account relevant international standards, and national or regional regulations	P
3.3	RM report No. RMR- SL880H - 001 Introduction	qualification of personnel described	P
3.4a	RM report No. RMR- SL880H - 001 Introduction	scope of planned risk management activities described	P
3.4b	RM report No. RMR- SL880H - 001 Introduction	adequate assignment of responsibility and authorities	P
3.4c	RM report No. RMR- SL880H - 001 Introduction	risk management review activities described	P
3.4d	RM report No. RMR- SL880H - 001 Introduction	Each risk evaluated with 5 severity levels ,5 probability levels and a RPN to decide the acceptance. Risk control needed if RPN over 15. Risk acceptable if RPN lower than15.	P
3.4e	RM report No. RMR- SL880H - 001 Introduction	verification activity described	P
3.5	RM report No. RMR- SL880H - 001 Introduction	risk management file provided	P
4.1	RM report No. RMR- SL880H - 001 Risk Analysis	Description and identification of the product defined. Person and organization carrying out the analysis identified. Date of the analysis described.	P
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	Intended use/purpose, characteristics related to safety described	P
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard analysed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
5	RM report No. RMR- SL880H - 001 Risk Analysis	Each hazard evaluated with probability / severity to decide RPN	P
6.1	RM report No. RMR- SL880H - 001 Risk Control	Risk control measures described	P
6.2	RM report No. RMR- SL880H - 001 Risk Control	Risk reduction option analyzed in each risk	P
6.3	RM report No. RMR- SL880H - 001 Risk Control	Adopted risk control measures described	P
6.4	RM report No. RMR- SL880H - 001 Risk Control	Residual risk evaluated using the same acceptance level	P

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
6.5	RM report No. RMR- SL880H - 001 Risk Control	All residual risks accepted. Risk/benefit not analysed	N/A
6.6 a	RM report No. RMR- SL880H - 001 Risk Control	Evaluated and judged no other generated hazards	P
6.6 b	RM report No. RMR- SL880H - 001 Risk Control	New risk from control measures evaluated	P
6.7	RM report No. RMR- SL880H - 001 Risk Control	All identified hazards have been considered and the associated activities recorded in the risk management report.	P
7	RM report No. RMR- SL880H - 001 Overall Residual Risk Evaluation	Overall residual risk evaluated and accepted	P
8	RM report No. RMR- SL880H - 001 Conclusion	risk management process reviewed and a conclusion is made	P
Supplementary Information:			

4.3	**TABLE: ESSENTIAL PERFORMANCE**	**P**
List of ESSENTIAL PERFORMANCE functions	MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)	Remarks
Essential Performance Considered	RM report product safety characteristics Item 34	
Supplementary Information: ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.		

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**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	Intended use/purpose, characteristics related to safety described. The enclosure is regarded as the part in contact with the patient.	P
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard analysed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
5	RM report No. RMR- SL880H - 001 Risk Analysis	Each hazard evaluated with probability / severity to decide RPN	P

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Clause	Requirement + Test	Result - Remark	Verdict

4.6	**RM RESULTS TABLE: ME Equipment or system parts contacting the patient**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2	RM report No. RMR- SL880H - 001 Risk Control	Risk reduction option analyzed in each risk	P
6.3	RM report No. RMR- SL880H - 001 Risk Control	Adopted risk control measures described	P
6.4	RM report No. RMR- SL880H - 001 Risk Control	Residual risk evaluated	P
6.5	RM report No. RMR- SL880H - 001 Risk Control	All residual risks accepted. Risk/benefit not analysed	N/A
Supplementary Information:			

4.7	**RM RESULTS TABLE: Single Fault Condition for ME Equipment**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	Intended use/purpose, characteristics related to safety considered for the simulation of the fault condition.	P
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard analysed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Failures that are highly probable and/or detectable have been simulated	P
Supplementary Information:			

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**					**N/A**
Operating Conditions / Ratings	Voltage (V)	Frequency (Hz)	Current (A)	Power (W or VA)	Power factor (cos φ)	
Supplementary Information:						

5.1	**RM RESULTS TABLE: Type Tests**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	Tests according to this standard were done considering the Intended use/purpose and characteristics related to safety	P

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Clause	Requirement + Test	Result - Remark	Verdict

5.1	**RM RESULTS TABLE: Type Tests**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard analysed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
Supplementary Information:			

5.9.2	**TABLE: Determination of ACCESSIBLE parts**	**P**
Location	Determination method (NOTE1)	Comments
All accessible surface	visual, test finger, test pin	All accessible surface
Supplementary information: NOTE 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) ..... :	100/1500	Clearly legible
Inside Markings (Clause 7.3) ..... :		
Controls & Instruments (Clause 7.4) ..... :		
Safety Signs (Clause 7.5) ..... :		
Symbols (Clause 7.6) ..... :		
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 ..... :	Screen print on the electrode	P
Ink/other printing material or process ..... :	Ink	
Material (composition) of Warning Label ..... :	Print	
Ink/other printing material or process ..... :		
Other ..... :		
Supplementary information:		

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Clause	Requirement + Test	Result - Remark	Verdict

7.1.3	TABLE: Durability of marking test	P
Characteristics of the Marking Label tested:		Remarks
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	N/A

7.2.13	RM RESULTS TABLE: Physiological effects (safety signs and warning)	N/A

7.2.17	RM RESULTS TABLE: Protective packaging	N/A

7.3.3	RM RESULTS TABLE: Batteries	N/A

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		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	Intended use/purpose, characteristics related to safety described	P
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard analyzed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
5	RM report No. RMR- SL880H - 001 Risk Analysis	Each risk evaluated	P
6.3	RM report No. RMR- SL880H - 001 Risk Control	Adopted risk control measures to use safety sign described	P
Supplementary information:			

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

8.1 b	RM RESULTS TABLE: Fundamental rule of protection against electric shock - accidental detachment of conductors and connectors		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict

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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**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard analyzed	P
Supplementary information:			

8.4.2	**TABLE: TABLE: Working Voltage / Power Measurement**	**N/A**

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**

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**

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

8.5.2.3	**RM RESULTS TABLE: PATIENT Leads**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	Patient leads with remote connector used for the equipment	P
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Accessible metal parts of the connector may detach and touch the ground	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
5	RM report No. RMR- SL880H - 001 Risk Analysis	Each risk evaluated	P
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**

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Clause	Requirement + Test	Result - Remark	Verdict

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**

8.7	**TABLE: leakage current**				**P**
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	Maximum allowed values: 5 mA NC; 10 mA SFC	
Fig. 14 - Touch Current (TC)	—	—	Before/after humidity	Maximum allowed values: 100 µA NC; 500 µA SFC	
NC	3.7Vdc	--	0.4/0.4	Enclosure to enclosure	
When tested with a non-frequency weighed test equipment					
NC	3.7Vdc	--	23.5/23.8	Enclosure to enclosure	
Fig. 15 - Patient Leakage Current (P)	—	—	Before/after humidity	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)	
NC	3.7Vdc	--	5.7/5.6	Electrode as the AP	
SFC	3.7Vdc	--	5.9/6.0	(R1 short-circuited)	
SFC	3.7Vdc	--	6.0/5.8	(HR2 short-circuited)	
When tested with a non-frequency weighed test equipment					
NC	3.7Vdc	--	54.9/55.7	Electrode as the AP	
SFC	3.7Vdc	--	57.3/56.2	(R1 short-circuited)	
SFC	3.7Vdc	--	56.2/54.3	(HR2 short-circuited)	
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	Before/after humidity	Maximum allowed values: Type B: N/A Type BF AP: 5000 µA Type CF AP: 50 µA	
SFC	250	60	73.1/75.6	Electrode as the AP	
When tested with a non-frequency weighed test equipment					
SFC	250	60	610/598	Electrode as the AP	

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Clause	Requirement + Test	Result - Remark	Verdict

Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
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 µA Type CF: N/A
Fig. 19 – Patient Auxiliary Current	—	—	Before/after humidity	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current)
NC	3.7Vdc	--	18.4/18.6	Applied part to applied part
SFC	3.7Vdc	--	19.1/18.8	Applied part to applied part (R1 short)
SFC	3.7Vdc	--	18.6/19.1	Applied part to applied part (HR2 short)
When tested with a non-frequency weighed test equipment				
NC	3.7Vdc	--	411/421	Applied part to applied part
SFC	3.7Vdc	--	436/433	Applied part to applied part (R1 short)
SFC	3.7Vdc	--	422/426	Applied part to applied part (HR2 short)
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	Before/after humidity	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
NC	3.7Vdc	--	5.7/5.8	Enclosure to applied part
SFC	3.7Vdc	--	6.7/6.6	Enclosure to applied part (R1 short)
SFC	3.7Vdc	--	6.4/6.6	Enclosure to applied part (HR2 short)
When tested with a non-frequency weighed test equipment				
NC	3.7Vdc	--	113.2/117.2	Enclosure to applied part
SFC	3.7Vdc	--	126.8/126.7	Enclosure to applied part (R1 short)

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Clause	Requirement + Test	Result - Remark	Verdict

SFC	3.7Vdc	--	121.3/119.4	Enclosure to applied part (HR2 short)
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 µA NC; 100µA SFC (d.c. current); 500 µA NC;1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA 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	—	—	Before/after humidity	Maximum allowed values: Type B: NA Type BF: 5000 µA Type CF: 100 µA
SFC	250	60	73.7/74.8	
When tested with a non-frequency weighed test equipment				
SFC	250	60	766/771	
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 µA Type CF: N/A
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC

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 % 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).

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Clause	Requirement + Test	Result - Remark	Verdict

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)**				**P**
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.		
A	2 MOPP	--	3.7Vdc	1414Vdc	No
C	1 MOPP	353Vpeak(250V rms)	--	1500Vac	No

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**		**P**
	Allowed impression diameter (mm) .....:	≤ 2 mm	—
	Force (N) .....:	20	—

Part/material	Test temperature (°C)	Impression diameter (mm)
Enclosure/External insulating parts	75	0.69
Insulating material supporting un-insulated Mains Parts		

Supplementary information:

8.8.4.1	**RM RESULTS TABLE: Mechanical strength and resistance to heat**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	Intended use/purpose, characteristics related to safety described and the suitable material is chosen for strength and heat resistance.	P

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Clause	Requirement + Test	Result - Remark	Verdict

8.8.4.1	RM RESULTS TABLE: Mechanical strength and resistance to heat		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard analyzed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
5	RM report No. RMR- SL880H - 001 Risk Analysis	Each risk evaluated with 5 severity levels ,5 probability levels and a matrix chart to decide the acceptance.	P
6.2	RM report No. RMR- SL880H - 001 Risk Control	Risk reduction option analyzed in each risk	P
6.3	RM report No. RMR- SL880H - 001 Risk Control	Adopted risk control measures described	P
6.4	RM report No. RMR- SL880H - 001 Risk Control	Residual risk evaluated	P
6.5	RM report No. RMR- SL880H - 001 Risk Control	All residual risks accepted. Risk/benefit not analyzed	N/A
Supplementary information:			

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

8.9.3.2	Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts	N/A

8.9.3.4	Table: Thermal cycling tests on one sample of cemented joint (see 8.9.3.3)	N/A

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]
Plastic Enclosure	Covestro Deutschland AG	2805	PC, V-2, 115℃. 1.5mm thickness min.	UL 94	UL
Screen cover	Evonik Industries AG	S-10	PMMA 90℃ HB, 1.5 mm thick min	UL 94	UL
PWB	Various	Various	94V-1 min. 105 ℃	UL 94, UL 796	UL
Internal wire	Various	Various	VW-1 105 ℃ min. 30Vac min	UL758	UL
Battery	Dongguan KingNair Energy	KNE705048P	3.7Vdc 2000mAh Li-ion	IEC62133-2	Report No. NCT19026336XI 1-1 by Shenzhen

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Clause	Requirement + Test	Result - Remark	Verdict

	Technology Co.,Ltd.		Polymer battery rechargeable		NCT Testing Technology Co.,Ltd.
Heater sensor (Q37, Q38)	Ruimeike	CJ2302N	MOSFET	20V 3A	
Heater fuse (F1, F2)	Bourns	MF-PSMF	PTC resettable 6V 2A		UL,TUV
Charging IC (U2)	H&M Semi	HM4056D	MOSFET Charge voltage 4.2V, charge current 1000 mA max		
Belt Clip	Chi Mei Corporation	PA-757	ABS , HB, 85℃	UL94	UL
Electrode	Shenzhen Genvan Silicone Materials Co.,Ltd.	GA1053	Silicone		
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**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	Intended use/purpose, characteristics related to safety described and the suitable fixing means is chosen	P
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard analysed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
5	RM report No. RMR- SL880H - 001 Risk Analysis	Each risk evaluated with 5 severity levels, 5 probability levels and a matrix chart to decide the acceptance.	P
6.2	RM report No. RMR- SL880H - 001 Risk Control	Risk reduction option analyzed in each risk	P
6.3	RM report No. RMR- SL880H - 001 Risk Control	Adopted risk control measures described	P
6.4	RM report No. RMR- SL880H - 001 Risk Control	Residual risk evaluated	P
6.5	RM report No. RMR- SL880H - 001 Risk Control	All residual risks accepted. Risk/benefit not analysed	N/A
Supplementary information:			

8.11.3.5	**TABLE: Cord anchorages**	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
8.11.3.6	**TABLE: Cord guard**		**N/A**
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	**RM RESULTS TABLE: Over travel**		**N/A**
9.2.4	**RM RESULTS TABLE: Emergency stopping devices**		**N/A**
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**
9.4.2.4.3	**RM RESULTS TABLE: 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**

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Clause	Requirement + Test	Result - Remark	Verdict
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**
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**
Model No..... :	1) EM59	2) EM59	
Test ambient (°C) ..... :	38.8	38.8	
Test supply voltage/frequency (V/Hz)[4]..... :	3.7Vdc	3.7Vdc	
Conditions	1) Normal	2) Q37 short-circuited	

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Clause	Requirement + Test	Result - Remark	Verdict

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)		
				1)	2)	Remark (contact time)
EM59	1	U3 body	105	40.1/41.3	40/41.2	
	2	PCB near U3	105	39.9/41.1	39.8/41	
	3	L3 coil	105	39.3/40.5	38.9/40.1	
	4	C9 body	105	39.3/40.5	39/40.2	
	5	L4 body	105	39.7/40.9	38.8/40	
	6	Battery body	105	38.8/40	38.4/39.6	
	7	Enclosure inside near battery	115	38.2/39.4	37.5/38.8	
	8	Enclosure outside near battery	48	38/39.2	37.2/38.5	1 min ≦ t
	9	Control button	71	39.2/40.4	39.2/40.4	1 s ≦ t < 10 s
	10	Panel surface	71	39.2/40.4	39.2/40.4	1 s ≦ t < 10 s
	11	Patient lead near electrode	48	38.7/39.9	38.6/39.8	1 min ≦ t
	12	Applied part (electrodes)	43	38.2/39.4	38.7/39.9	10 min ≦ t
	13	ambient	--	38.8/ 40.0	38.8/40	

Supplementary information:

[1] Maximum allowable temperature on surfaces of test corner is 90 °C

[2] Max temperature determined in accordance with 11.1.3e)

[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.

[4] Supply voltage:

- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] **APPLIED PARTS** intended to supply heat to a **PATIENT - S**ee RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

11.1.1	**RM RESULTS TABLE: Maximum temperature during normal use (Table 23 or 24)**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	Touch surface and duration of the patient and the operator considered. Worst conditions to create highest temperature considered and tested	P

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Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	**RM RESULTS TABLE: Maximum temperature during normal use (Table 23 or 24)**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard from excessive temperature analysed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
5	RM report No. RMR- SL880H - 001 Risk Analysis	Each risk evaluated	P
6.2	RM report No. RMR- SL880H - 001 Risk Control	Risk reduction option analyzed in each risk	P
6.3	RM report No. RMR- SL880H - 001 Risk Control	Adopted risk control measures described	P
6.4	RM report No. RMR- SL880H - 001 Risk Control	Residual risk evaluated	P
6.5	RM report No. RMR- SL880H - 001 Risk Control	All residual risks accepted. Risk/benefit not analysed	N/A
Supplementary information:			

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**

11.1.3	**RM RESULTS TABLE: Measurements**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	The max allowed operating ambient is considered during the test. The enclosure is considered as equivalent to the applied part and the temperature is measured to compare with the limit of an applied part.	P
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard from excessive temperature analysed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
5	RM report No. RMR- SL880H - 001 Risk Analysis	Each risk evaluated	P
6.2	RM report No. RMR- SL880H - 001 Risk Control	Risk reduction option analyzed in each risk	P
6.3	RM report No. RMR- SL880H - 001 Risk Control	Adopted risk control measures described	P
6.4	RM report No. RMR- SL880H - 001 Risk Control	Residual risk evaluated	P

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Clause	Requirement + Test	Result - Remark	Verdict

11.1.3	**RM RESULTS TABLE: Measurements**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
6.5	RM report No. RMR- SL880H - 001 Risk Control	All residual risks accepted. Risk/benefit not analyzed	N/A
Supplementary information:			

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**		**P**
Clause / Test Name	Test Condition	Part under test	Remarks
cleaning	Soft cloth dampened with water	Complete unit	No hazard
Supplementary information:			

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

11.6.5	**RM RESULTS TABLE: Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	Considering the actual use condition and the requirement of IEC 60601-1-11 for home use equipment to decide the IP class as IP22	P
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard from ingress of liquid analysed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
5	RM report No. RMR- SL880H - 001 Risk Analysis	Each risk evaluated	P
Supplementary information:			

11.6.7	**RM RESULTS TABLE: Sterilization of ME equipment and ME systems**	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict

11.6.8	**RM RESULTS TABLE: Compatibility with substances used**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	The electrode pad is in contact with the patient during the use	P
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard from pad material characteristics analysed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
5	RM report No. RMR- SL880H - 001 Risk Analysis	Each hazard evaluated with probability / severity to decide RPN	P
6.2	RM report No. RMR- SL880H - 001 Risk Control	Risk reduction option analyzed in each risk	P
6.3	RM report No. RMR- SL880H 0-001 Risk Control	Adopted risk control measures described	P
6.4	RM report No. RMR- SL880H - 001 Risk Control	Residual risk evaluated	P
6.5	RM report No. RMR- SL880H - 001 Risk Control	All residual risks accepted. Risk/benefit not analyzed	P

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**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	Intended use/purpose, characteristics related to safety described	P
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard analysed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
5	RM report No. RMR- SL880H - 001 Risk Analysis	Each hazard evaluated with probability / severity to decide RPN	P
6.2	RM report No. RMR- SL880H - 001 Risk Control	Risk reduction option analyzed in each risk	P
6.3	RM report No. RMR- SL880H - 001 Risk Control	Adopted risk control measures described	P
6.4	RM report No. RMR- SL880H - 001 Risk Control	Residual risk evaluated	P

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Clause	Requirement + Test	Result - Remark	Verdict

12.4.4	**RM RESULTS TABLE: Incorrect output**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.5	RM report No. RMR- SL880H - 001 Risk Control	All residual risks accepted. Risk/benefit not analysed	P
Supplementary information:			

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**

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 SITUATION (Yes/No)
13.2.2	Electrical SINGLE FAULT CONDITIONS per Clause 8.1:	—	—
	Q37 short-circuited	Unit works normally. No obvious temperature rise. See appended table 11.1.1	NO
	R1 short-circuited	Unit works normally. No obvious temperature rise.	NO
	C6 short-circuited	Unit stops working. No obvious temperature rise.	NO
13.2.3	Overheating of transformers per Clause 15.5:	—	—
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—

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Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—
13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	—	—
	Single ventilation fans locked consecutively		
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls		
	Simulated blocking of filters		
	Flow of a cooling agent interrupted		
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	—	—
		V measured =	
		V measured =	
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:	—	—
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or upper limit of RATED voltage range for specified time:		
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices		
	Temperatures measured as specified in 11.1.3 d)		
	Temperatures did not exceed limits of Table 26		

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Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	—	—
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	—	—
Supplementary information: [1] Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.			

13.2.6	**RM RESULTS TABLE: Leakage of liquid**	**N/A**

14.1	**RM RESULTS TABLE: Programmable electrical medical systems - General**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard from software analyzed. See details in the software validation report SVR-SL880H-001	P
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented See details in the software validation report SVR-SL880H-001	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Each risk evaluated with 5 probability and 5 severity levels See details in the software validation report SVR-SL880H-001	P
5	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard analyzed See details in the software validation report SVR-SL880H-001	P
Supplementary information:			

14.6.1	**RM RESULTS TABLE: Identification of known and foreseeable hazards**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented See details in the software validation report SVR-SL880H-001	P
Supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

14.6.2	**RM RESULTS TABLE: Risk control**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.1	RM report No. RMR- SL880H - 001 Risk Analysis	Risk control measures described See details in the software validation report SVR-SL880H-001	P
Supplementary information:			

14.7	**RM RESULTS TABLE: Requirement specification**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	RM report No. RMR- SL880H - 001 Risk Analysis	Adopted risk control measures described See details in the software validation report SVR-SL880H-001	P
Supplementary information:			

14.8	**RM RESULTS TABLE: Architecture**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	RM report No. RMR- SL880H - 001 Risk Analysis	Adopted risk control measures described See details in the software validation report SVR-SL880H-001	P
Supplementary information:			

14.10	**RM RESULTS TABLE: Verification**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	RM report No. RMR- SL880H - 001 Risk Analysis	Adopted risk control measures described See details in the software validation report SVR-SL880H-001	P
Supplementary information:			

14.11	**RM RESULTS TABLE: PEMS validation**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	RM report No. RMR- SL880H - 001 Risk Analysis	Adopted risk control measures described. See details in the software validation report SVR-SL880H-001	P
Supplementary information:			

14.13	**RM RESULTS TABLE: Connection of PEMS by NETWORK/DATA COUPLING to other equipment**	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict

15.3	**TABLE: Mechanical Strength tests [1)]**			**P**
Clause	Name of Test	Test conditions	Observed results/Remarks	
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	No damage after the test	
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	No damage after the test	
15.3.4.1	Drop Test (hand-held)	Free fall height (m) = 1	No damage after the test	
15.3.4.2	Drop Test (portable)	Drop height (cm) =	N/A	
15.3.5	Rough handling test	Travel speed (m/s) =	N/A	
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) = 70	No wrapping, cracking or breaking. No exposure of live parts.	
Supplementary information: [1)]As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows).				

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**		**P**
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	Internal rechargeable battery is used and may be subject to over charging	P
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard from long term over charging analysed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
Supplementary information:			

15.4.4	**RM RESULTS TABLE: Indicators**	**P**

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Clause	Requirement + Test	Result - Remark	Verdict

Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	RM report No. RMR- SL880H - 001 Risk Analysis	An internal non-luminous heat element is used	P
4.3	RM report No. RMR- SL880H - 001 Risk Analysis	Known or foreseeable hazard from prolonged use analysed	P
4.4	RM report No. RMR- SL880H - 001 Risk Analysis	Risk for each hazard documented	P
Supplementary information:			

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**

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**

15.5.1.3	**TABLE: transformer overload test – conducted only when protective device under short-circuit test operated**	**N/A**

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

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**

SP	**TABLE: Additional or special tests conducted**	**N/A**

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

Attachment Photos

Overall View

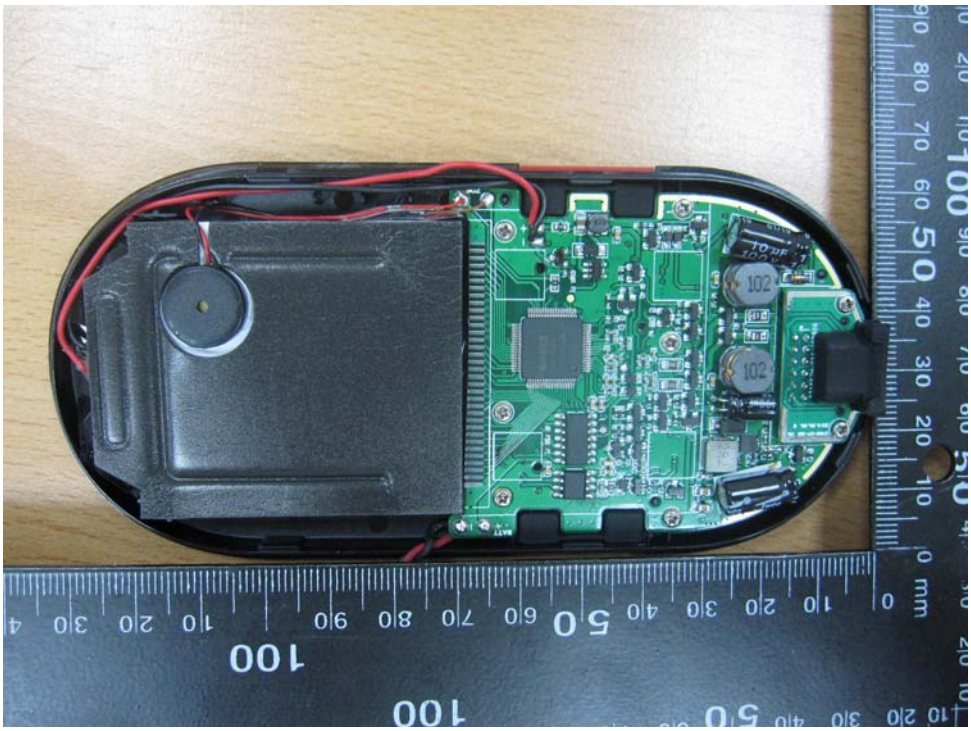
(Top and Side)

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

(Bottom and Side)

(Inner View-1)

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



(Inner View-2)

(Inner View-3)