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

Report Reference No...... :	TLJS20022421799
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Date of issue..... :	February 27, 2020
Reviewing Laboratory..... :	Shanghai Global Testing Services Co., Ltd Floor 2nd, Building D-1, No. 128, Shenfu Road, Minhang District, Shanghai, China.
Applicant's name.....:	KFN ApS
Address..... :	Bondesvadvej 15 DK 8300 Odder
Manufacturer's name.....:	KFN ApS
Address..... :	Bondesvadvej 15 DK 8300 Odder
Factory's name..... :	Same as Manufacturer
Address..... :	Same as Manufacturer
Review specification:	
Standard..... :	☒EN 60601-1:2006+A12:2014
Review procedure..... :	CB
Non-standard Review method…….:	N/A
Review Report Form No..... :	EN 60601-1
Review Report Form Originator..... :	GTS
Master TRF..... :	Dated 2009-01
Review item description..... :	4 Wheeler Explorer
Trade Mark..... :	/
Model/Type reference..... :	1013-1, 1013-2
Ratings..... :	36V

Possible review case verdicts: - review case does not apply to the test object..... : N(.A.) - review object does meet the requirement..... : P(ass) - review object does not meet the requirement.....: F(ail)
General remarks:
”(see remark #)” refers to a remark appended to the report. ”(see appended table)” refers to a table appended to the report. Throughout this report a comma is used as the decimal separator. The review results presented in this report relate only to the object reviewed. This report shall not be reproduced except in full without the written approval of the third party.

Testing:	
Date of receipt of review item:	February 27, 2020
Date(s) of performance of review:	February 24, 2020 to February 27, 2020

General product information: 4 Wheeler Explorer
Summary of reviewing: This review report includes: Annex I: **4** page(s) of photo documentation.
Copy of marking plate

4 Wheeler Explorer Model 1013-1, 1013-2 KFN ApS	CE

4	**GENERAL REQUIREMENTS**		
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse	Requirement applied as described throughout the report	P
	Definitions/ requirements using the term PATIENT considered as applicable to individual(s) for whom ME EQUIPMENT or ME SYSTEM is designed for		P
4.2	A RISK MANAGEMENT PROCESS complying with ISO 14971 was performed .....:	Hazard analysis performed by 1013-1, 1013-2 ISO14971	P
	ISO 14971applied with the specified considerations:	See attached Risk Analysis	P
	– Term “medical device” assumed same as ME EQUIPMENT or ME SYSTEM	Considered	P
	– Term “fault conditions” not limited to SINGLE FAULT CONDITIONS	Considered	P
	– Policy to determine acceptable RISK, and acceptability of RESIDUAL RISK(s) established by MANUFACTURER	Considered	P
	– Verifiable requirements of this and associated standards complied with for particular RISKS including RESIDUAL RISKs presumed to be acceptable unless there was OBJECTIVE EVIDENCE to the contrary	Considered	P
	Requirements for inspection of RISK MANAGEMENT FILE considered satisfied based on MANUFACTURER’S established RISK MANAGEMENT PROCESS, acceptable levels of RISK, and acceptable RESIDUAL RISK(s) according to the policy for determining acceptable RISK	Considered	P
4.3	ESSENTIAL PERFORMANCE functions identified according to MANUFACTURER’S policy for RISK acceptability in RISK MANAGEMENT FILE	Considered	P
	ESSENTIAL PERFORMANCE functions maintained following particular Reviews as applicable		P
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE	Yes	P
4.5	Alternative means of addressing particular RISKS considered acceptable based on MANUFACTURER’S justification that RESIDUAL RISKS resulting from application of alternative means are ≤ to RESIDUAL RISKS resulting from requirements of this standard	Considered	N
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 7.2.10		P
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by 4.2	Unit was safe during all single fault Reviews, see Review data.	P

	a) ME EQUIPMENT with a single means of reducing a RISK having negligible probability of failure considered SINGLE FAULT SAFE, or	Considered	P
	b) a SINGLE FAULT CONDITION occurred, except as follows:	Considered	N
	– initial fault detected during EXPECTED SERVICE LIFE of ME EQUIPMENT and before a second means for reducing a RISK failed (e.g. suspended masses with MECHANICAL PROTECTIVE DEVICES), or	Considered	N
	– probability that the second means of reducing the RISK would fail during EXPECTED SERVICE LIFE of ME EQUIPMENT was negligible	Considered	N
	Two failures resulting from a SINGLE FAULT CONDITION causing a secondary SINGLE FAULT CONDITION considered as one SINGLE FAULT CONDITION	Considered	N
	Only one fault applied at a time during the Reviews under SINGLE FAULT CONDITION	Considered	N
	Results of RISK ANALYSIS used to determine which failures should be Reviewed	Considered	N
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically	Considered	N
	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	Considered	N
	Evaluation done by applying the principles of RISK MANAGEMENT taking into account reliability, TENSILE SAFETY FACTORS, and rating of components	Considered	N
	During simulation of SINGLE FAULT CONDITIONS, highly probable or undetectable component failures simulated	Considered	N
	Requirements and relevant Reviews of this clause not applied to failures of DOUBLE or REINFORCED INSULATION or COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS	Considered	N
	Specific requirements and Reviews associated with SINGLE FAULT CONDITIONS in 13.2 applied together with the Reviews for failures identified from evaluation of the results of RISK ANALYSIS	Considered	N
	SINGLE FAULT CONDITIONS applied one at a time as described in 13.2 did not lead directly to the HAZARDOUS SITUATIONS in 13.1, or any other outcome resulting in an unacceptable RISK	Considered	N
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used in accordance with their applicable ratings, except as specified, or by RISK MANAGEMENT PROCESS	See CCL at end of this Review report	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:	See CCL at end of this Review report	P
	a) applicable safety requirements of a relevant IEC or ISO standard .....:	See CCL at end of this Review report	P
	b) requirements of this standard applied in the absence of a relevant IEC or ISO standard		N
	Reviews conducted on motors (13.28 & 13.2.13.3) and transformers (15.5.3) together with evaluation of their insulation system according to Table 22 represent all required Reviews	No motors or TX	N
	ME SYSTEM components providing isolation from non-ME EQUIPMENT evaluated to Clause 16	No such isolation	N
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK	None	N
	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
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 .....:	Connects to Mains Supply	N
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS is 250 V for HAND-HELD ME EQUIPMENT (V).....:	No hand-held ME equipment	P
	– 250 V d.c. or single-phase a.c., or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V).....:		P
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS		P
	SUPPLY MAINS characteristics are as follows:		-
	– overvoltage category II for mains transients, except when a higher category specified by MANUFACTURER.....:		P
	– no voltage >110 % or < 90 % of NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% of NOMINAL voltage).....:	+/-10% used	P
	– voltages that are practically sinusoidal and forming a practically symmetrical supply system in case of poly-phase supply	Considered	N

	– a frequency of ≤ 1 kHz (Hz)..... :		N
	– a frequency deviation of ≤ 1 Hz from NOMINAL frequency up to 100 Hz and ≤ 1 % from NOMINAL frequency from 100 Hz to 1 kHz (Hz, or % deviation from NOMINAL frequency)..... :	Review at 50 and 60Hz	P
	– protective measures per IEC 60364-4-41..... :	Considered	
	– a d.c. voltage (as measured by a moving coil meter or equivalent method) having a peak-to-peak ripple ≤ 10 % of average value (V dc)..... :	A.C Voltage	N
	Peak voltage applied when peak-to-peak ripple exceeded 10 % of average value	Considered	N
	Additional safety measures applied to ME EQUIPMENT or ME SYSTEM intended to be operated from a SUPPLY MAINS with characteristics different from SUPPLY MAINS described in this clause..... :	Standard supply mainly to be used.	N
4.11	Power input		
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in instructions for use did not exceed marked rating by more than 10 %..... :	<10% See appended Table 4.11	P
	– Measurements on ME EQUIPMENT or a ME SYSTEM marked with one or more RATED voltage ranges made at both upper and lower limits of the range	See Review results	P
	Measurements made at a voltage equal to the mean value of the range when each marking of RATED input was related to the mean value of relevant voltage range	See Review results	P
	– Steady state current measured with a true r.m.s reading instrument	Yes	P
	Power input, expressed in volt-amperes, measured with a volt-ampere meter or calculated as the product of steady state current (measured as described above) and supply voltage	Not marked VA	P
	A supplier certification used in place of the above measurement as the basis for steady state current or power input specification		P

5	**GENERAL REQUIREMENTS FOR ReviewING ME EQUIPMENT**		-
5.1	TYPE REVIEWS determined in consideration of Clause 4, in particular 4.2	Considered	-
	Review not performed when analysis indicated condition being Reviewed was adequately evaluated by other Reviews or methods..... :	Considered	P
	Results of RISK ANALYSIS used to determine combination(s) of simultaneous faults to be Reviewed	Considered	P

	RISK ANALYSIS revised, necessarily, based on Review results	Considered	P
5.2	TYPE REVIEWS conducted on one representative sample under investigation	On representative sample Reviewed.	P
	Multiple samples used simultaneously when validity of results was not significantly affected	As above	P
5.3	a) Reviews conducted within the range of environmental conditions specified in the technical description .....:	Review per specs.	P
	b) ME EQUIPMENT shielded from other influences that might affect the validity of Reviews	Considered	P
	c) Review conditions modified and results adjusted accordingly when ambient temperature could not be maintained	Temperature was maintaned	P
5.4	a) ME EQUIPMENT Reviewed under least favorable working conditions specified in instructions for use and identified during RISK ANALYSIS, except as noted	Worst case condition used	P
	b) ME EQUIPMENT with adjustable or controlled operating values by anyone other than SERVICE PERSONNEL adjusted to values least favorable for the relevant Review according to instructions for use	Worst case condition used	P
	c) When Review results influenced by inlet pressure and flow or chemical composition of a cooling liquid, Reviews performed within the limits of these characteristics based on technical description	No such connections	P
	d) Potable water used for cooling		P
5.5	a) Effects of deviations of supply voltage from its RATED value on Review results taken into account	Review at +/- 10%	P
	Supply voltage during Reviews was the least favorable of the voltages specified in 4.10 or voltages marked on ME EQUIPMENT (V) ..... :	Review at +/- 10%	P
	b) ME EQUIPMENT with a MAINS PART intended for connection to a.c. SUPPLY MAINS Reviewed only with a.c. at marked RATED frequency ± 1 Hz up to and including 100 Hz, and ± 1 % above 100 Hz ..:	Reviewed at 50 and 60Hz	P
	ME EQUIPMENT marked with a RATED frequency range Reviewed at the least favorable frequency within the range (Hz)..... :	Reviewed at 50 and 60Hz	P
	c) ME EQUIPMENT with more than one RATED voltage, or for both a.c. and d.c., Reviewed in conditions (see 5.4) related to the least favorable voltage, nature of supply, and type of current.....:	Reviewed at 50 and 60Hz	P

	Some Reviews performed to determine the least favorable supply configuration	Input Reviewing performed at various conditions to determine least favourable conditions	P
	d) ME EQUIPMENT with a MAINS PART for connection to d.c. SUPPLY MAINS Reviewed with d.c. only	No such connections	N
	Possible effects of polarity on operation of ME EQUIPMENT was taken into account based on instructions for use	Standard IEC inlets and cord used.	N
	e) ME EQUIPMENT Reviewed with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favorable conditions.....:	Reviewed with all accessories	P
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use..... :	Reviewed with specified medical grade isolation transformer	P
5.6	When failure occurred or probability of future failure detected during sequence of Reviews, per agreement with manufacturer, all Reviews affecting results conducted on a new sample	No failures occurred during Reviewing	P
	Alternatively, upon repair and modification of the sample, only the relevant Reviews conducted	The power supply unit was detached and treaded simultanceously with the Equipment	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 Reviews of 8.7.4 and 8.8.3		P
	Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS opened and detached		P
	ME EQUIPMENT heated to a temperature between T and T + 4 °C for at least 4 h and placed in a humidity chamber with a relative humidity of 93 % ± 3 % and an ambient within 2 °C of T in the range of + 20 °C to + 32 °C for 48 h	93% RH 30°C for 48h	P
	When RISK MANAGEMENT PROCESS indicated ME EQUIPMENT can be exposed to high humidity for extended periods (i.e., out-door use), Review time extended proportionally (h).....:	Not for extended exposures	P
	ME EQUIPMENT reassembled after humidity treatment when necessary	Considered	P
5.8	Unless stated otherwise, Reviews in this standard sequenced as in Annex B to prevent results of one Review on a subsequent Review	Annex B reference.	P
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		P
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS..... :		P

5.9.2	ACCESSIBLE PARTS		-
5.9.2.1	ACCESSIBLE PARTS identified by inspection	See below	P
	Accessibility, when necessary, determined using standard Review finger of Fig 6 applied in a bent or straight position as follows:		P
	– for all positions in NORMAL USE, except ME EQUIPMENT for use on the floor with a mass in any operational condition > 45 kg not tilted	Considered	P
	Cabinet mounted ME EQUIPMENT Reviewed in final mounting position	Not cabinet mounted	N
	–after opening of ACCESS COVERS and removal of parts, including lamps, fuses and fuse-holders, without a TOOL or based on instructions for use	No user access covers	N
	Openings preventing entry of Review finger of Fig 6 mechanically Reviewed with a straight un-jointed Review finger of the same dimensions with a force of 30 N	No openings that allow Review finger access	N
	When the straight un-jointed Review finger entered, Review with the standard Review finger (Fig 6) was repeated, if necessary, by pushing the finger through the opening	No openings that allow Review finger access	N
5.9.2.2	Review hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s	No openings that allow Review finger access	N
	All additional parts that became accessible checked using standard Review finger and by inspection	No such mechanisms	N
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS		N
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, etc. required use of a TOOL, and inspection of RISK MANAGEMENT FILE indicated the relevant part is unlikely to detach unintentionally during EXPECTED SERVICE LIFE of ME EQUIPMENT		N

6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		-
6.1	ME EQUIPMENT, parts thereof, and APPLIED PARTS, classified against electric shock as follows:	See below	P
6.2	CLASS I ME EQUIPMENT, externally powered		P
	CLASS II ME EQUIPMENT, externally powered		N
	INTERNALLY POWERED ME EQUIPMENT		N

	EQUIPMENT with means of connection to a SUPPLY MAINS complied with the requirements for CLASS I or CLASS II ME EQUIPMENT when so connected, and with the requirements for INTERNALLY POWERED ME EQUIPMENT when not connected to SUPPLY MAINS		P
	TYPE B APPLIED PART		N
	TYPE BF APPLIED PART		P
	TYPE CF APPLIED PART		N
	DEFIBRILLATION-PROOF APPLIED PARTS		N
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter (IPN_1N_2) as detailed in IEC 60529.....:		P
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use (e.g., by ethylene oxide gas, gamma ray irradiation, etc.).....:		N
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2	Not intended for used in an oxyen rich environment	N
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION.....:	Continuous operation	P

7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		-
7.1.1	RISK of poor USABILITY associated with the design of ME EQUIPMENT'S identification and marking addressed in a USABILITY ENGINEERING PROCESS		P
7.1.2	Markings specified in 7.2-7.6 met the requirements when ME EQUIPMENT or its parts were so positioned that viewpoint was the intended position of the OPERATOR; or at any point within the base of a cone subtended by an angle of 30° to the axis normal to center of plane of marking and at 1 m	See clause 7.2 to 7.6	P
	Ambient luminance was the least favorable level in the range of 100 to 1500 lx, and observer had a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20), corrected when necessary (lx).....:	Label is adequate	P
	– markings were clearly legible for warning statements, instructive statements, safety signs, and drawings on outside of ME EQUIPMENT from position of person performing related function	Label is adequate	P
	– markings were clearly legible for FIXED ME EQUIPMENT when the ME EQUIPMENT mounted in its position of NORMAL USE	No fixed ME equipment	P
	– markings were clearly legible for TRANSPORTABLE and STATIONARY ME EQUIPMENT not FIXED in NORMAL USE or after dislodging ME EQUIPMENT from a wall against which it was positioned, or after turning ME EQUIPMENT from its position of NORMAL USE and for dismountable rack units, after removal from rack	Marking visible when not attached to patient	P

	– markings inside ME EQUIPMENT or parts were clearly legible when viewed from the intended position of person performing related function	Marking on the parts	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	Cannot easily remove label Label passes label durability Review.	P
	a) After Reviews, adhesive labels didn't loosen up or curl up at edges and markings complied with 7.1.2		P
	b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after durability of marking Review		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 ..... :	Required markings are applied to unit.	P
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS.....:		P
	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 "Do Not Reuse" or with symbol 28 of Table D.1 (ISO 7000-1051, DB:2004-01).....:		P
7.2.2	Name or trademark of MANUFACTURER marked on ME EQUIPMENT and its detachable components.... :	Name markings on unit	P
	MODEL OR TYPE REFERENCE also marked, except when misidentification would not present an unacceptable RISK..... :	Model marked on label	P
	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 (e.g., SERVICE PERSONNEL).... :		P
	Marking identification on outside of ME EQUIPMENT considered optional	Required markings are applied to unit	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	Not used	N
	Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted..... :	Symbol used	P
7.2.4	ACCESSORIES marked with name or trademark of their MANUFACTURER or supplier, and with a MODEL or TYPE REFERENCE.....:	Marked	P
	Markings applied to individual packaging when not practical to apply to ACCESSORIES	Marked	P

7.2.5	MODEL or TYPE REF. of equipment to be connected to ME EQUIPMENT to provide power, is marked adjacent to the relevant connection point when this connection could result in an unacceptable RISK.....:		P
7.2.6	Following markings appear on outside of part containing SUPPLY MAINS connection and, preferably, adjacent to connection point, except for PERMANENTLY INSTALLED ME EQUIPMENT	See below	P
	NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT, preferably, adjacent to supply connection terminals for PERMANENTLY INSTALLED ME EQUIPMENT (V, V-V)..... :	Voltage marked outside of ME equipment.	P
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V)..... :	Rated voltage range marked	P
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)..... :	None	N
	– nature of supply (e.g., No. of phases, except single-phase) and type of current.....:	~	P
	Symbols 1-5, Table D.1 (symbols of IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033, all DB: 2002-10) used, optionally, for same parameters .....:		P
	– RATED supply frequency or RATED frequency range in hertz.....:	50/60Hz	P
	– symbol 9 of Table D.1 (symbol IEC 60417-5172, DB: 2003-02) used for CLASS II ME EQUIPMENT.....:	Not class II	P
7.2.7	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 (VA)..... :	Single current rating	P
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (VA).....:		P
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA).....:		N
	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 (VA).....:		N
7.2.8	Output connectors		P
7.2.8.1	See 16.9.2.1 b) for MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT	None	P

7.2.8.2	Output connectors of ME EQUIPMENT, except MULTIPLE SOCKET-OUTLETS or connectors intended only for specified equipment or ACCESSORIES, marked with RATED output voltage, RATED current or power and output frequency (when applicable)..... :	All connectors providing power intended for specified accessories	P
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)..... :		P
	Marking of IPX0 and IP0X Codes optional		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):	See below	P
	TYPE B APPLIED PARTS with symbol 19 of Table D.1 (IEC 60417-5840, DB: 2002-10), not applied to give impression of being inscribed within a square to differentiate with symbol IEC 60417-5333..... :	None	N
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 (IEC 60417-5333, DB: 2002-10)..... :		P
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 (IEC 60417-5335, DB: 2002-10)..... :	None	N
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 (IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336, all DB: 2002-10) :	None	N
	Proper symbol marked adjacent to or on connector for APPLIED PART, except marked on APPLIED PART when there is no connector, or connector used for more than one APPLIED PART and different APPLIED PARTS with different classifications..... :		P
	Safety sign 2 of Table D.2 (safety sign ISO 7010-W001) placed near relevant outlet when protection against effect of discharge of a cardiac defibrillator is partly in the PATIENT cable..... :		P
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of appropriate cables included in instructions for use..... :	No such parts	N
7.2.11	ME EQUIPMENT not marked to the contrary assumed to be suitable for CONTINUOUS OPERATION	Continuous operation is possible	P
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum “on” and “off” time..... :		N
7.2.12	Type and full rating of a fuse (voltage, current, operating speed and breaking capacity) marked adjacent to ACCESSIBLE fuse-holder..... :	No replaceable fuses	N
7.2.13	A safety sign CLEARLY LEGIBLE and visible after INSTALLATION in NORMAL USE applied to a prominent location of EQUIPMENT that produce physiological effects capable of causing HARM to PATIENT or OPERATOR not obvious to OPERATOR..... :	No such effects	N

	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use..... :		N
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10)	No voltage over 1000V	N
7.2.15	Requirements for cooling provisions marked (e.g., supply of water or air)..... :	Marked on the unit rear	P
7.2.16	ME EQUIPMENT with limited mechanical stability	No stability issue based on small size of unit	P
7.2.17	Packaging marked with special handling instructions for transport and/or storage.....:	No special instruction	N
	Permissible environmental conditions for transport and storage marked on outside of packaging.....:		N
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK.....:	No such risk	N
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile..... :	No sterile	P
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector..... :	No such connections	N
7.2.19	Symbol 7 of Table D.1 (IEC 60417-5017, DB:2002-10) marked on FUNCTIONAL EARTH TERMINAL..... :	No such terminals	N
7.2.20	Protective means, required to be removed to use a particular function of ME EQUIPMENT with alternate applications, marked to indicate the necessity for replacement when the function is no longer needed .....:	None	N
	No marking applied when an interlock provided		N
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		P
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near heater or in heater itself (W)..... :	No heating elements or lamps	N
	An identifying marking referring to instruction in ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for use with heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL..... :		N
7.3.2	Symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10), or safety sign 3 of Table D.2 used to mark presence of HIGH VOLTAGE parts.....:	No voltage over 1000V	N
7.3.3	Type of battery and mode of insertion when applicable is marked..... :	No batteries	N

	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 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
	An identifying marking also provided referring to instructions in ACCOMPANYING DOCUMENTS..... :		N
7.3.4	Fuses and replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible only by a TOOL, identified by type and full rating adjacent to component (V, A, operating speed and breaking capacity), or by a reference to information in ACCOMPANYING DOCUMENTS..... :		P
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1 (IEC 60417-5019, DB: 2002-10), except for the PROTECTIVE EARTH TERMINAL in an APPLIANCE INLET according to IEC 60320-1..... :		P
	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
7.3.6	Symbol 7 of Table D.1 (IEC 60417-5017, DB: 2002 -10) marked on FUNCTIONAL EARTH TERMINALS..... :	No PE	N
7.3.7	Terminals for supply conductors marked adjacent to terminals, except when interchanging connections would not result in a HAZARD	Part of inlet	P
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings		P
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3 (Code in IEC 60445)		P
	When marking for connection to a 3-phase supply is necessary, it complies with IEC 60445	Single phase	N
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		P
7.3.8	Statement, “For supply connections, use wiring materials suitable for at least X °C” (X > than max temperature measured in terminal box or wiring compartment under NORMAL USE and CONDITIONS)”, or equivalent marked at or near the point supply connections made under conditions of this clause	IEC inlet used	P
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		P

7.4	Marking of controls and instruments		P
7.4.1	The “on” and “off” positions of switch used 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, DB: 2002-10, and IEC 60417-5008, DB: 2002-10), or	Power switch marked On/Off	P
	– indicated by an adjacent indicator light, or	As above	P
	– indicated by other unambiguous means	As above	P
	The “on/off” positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1 (IEC 60417-5010 DB: 2002-10), and	No such switches	N
	– status indicated by an adjacent indicator light, or		N
	– status indicated by other unambiguous means		N
	The “on/off” positions of push button switch with momentary on position marked with symbol 15 of Table D.1 (symbol 60417-5011 DB: 2002-10), or	No such switches	N
	– status indicated by an adjacent indicator light, or		N
	– status indicated by other unambiguous means		N
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means		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, or		P
	– an indication of direction in which magnitude of the function changes	As above	P
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 31 except the base quantities listed in Table 1 expressed in the indicated units		P
	ISO 1000 applied for application of SI units, their multiples, and certain other units	As above	P
	All Markings in Subclause 7.4 complied with Reviews and criteria of 7.1.2 and 7.1.3		P
7.5	Safety signs		
	Markings used to convey a warning, prohibition or mandatory action mitigating a RISK not obvious to OPERATOR are safety signs from ISO 7010	Appropriate warning symbols used	P
	One of the following methods used when a safety sign was not available to indicate a particular desired meaning:	As above	P
	a) A safety sign constructed according to safety signs 1.4 and 8 of Table D.2 (i.e., ISO 3864-1:2002, Clause 7)	As above	P

	b) Safety sign 2 of Table D.2 (general warning sign ISO 7010:2003-W001) placed together with a supplementary symbol or an affirmative statement describing the anticipated principal RISK(S) (e.g., “Causes burns”, “Risk of explosion”, etc.)	As above	P
	c) Safety sign 4 of Table D.2 (general prohibition sign ISO 7010:2003-P001) placed together with a supplementary symbol or a statement describing what is prohibited (“Do not open”, etc.)	As above	P
	d) Safety sign 9 of Table D.2 (general mandatory action sign ISO 7010:2003-M001) placed together with a supplementary symbol or a text statement consisting of a command describing the required action (e.g., “Wear protective gloves”, etc.)	As above	P
	Affirmative statement together with safety sign placed in instructions for use due to insufficient space on ME EQUIPMENT	As above	P
	Specified colors in ISO 3864-1 used for safety signs..... :		P
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		P
	Safety signs including any supplementary symbols or text described in instructions for use		P
7.6	Symbols		-
7.6.1	Meanings of symbols used for marking described in instructions for use		P
7.6.2	Symbols required by this standard conform to IEC or ISO publication referenced	Symbols used are according to this standard	P
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable	None	P
7.7	Colors of the insulation of conductors		P
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation		P
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations		P
7.7.3	Green and yellow insulation identify only following conductors:	See below	P
	– PROTECTIVE EARTH CONDUCTORS	Green / yellow only for PE	P
	– conductors specified in 7.7.2		P
	– POTENTIAL EQUALIZATION CONDUCTORS		P
	– FUNCTIONAL EARTH CONDUCTORS		P
7.7.4	Neutral conductors of POWER SUPPLY CORDS are “light blue” specified in IEC 60227-1 or IEC 60245-1	Approved power cord used	P
7.7.5	Colors of conductors in POWER SUPPLY CORDS are in accordance with IEC 60227-1 or IEC 60245-1	Approved power cord used	P

7.8	Indicator lights and controls		P
7.8.1	Colors of indicator lights and their meanings are as follows (Dot-matrix and other alphanumeric displays not considered indicator lights):	See below	P
	Red: Warning (i.e., immediate response by OPERATOR required)	Red not used	N
	Yellow: Caution (i.e., prompt response by OPERATOR required)	Not used	N
	Green: Ready for use		P
	Other color: Meaning other than red, yellow, or green (color, meaning).....:		P
7.8.2	Red used only for emergency control		P
7.9	ACCOMPANYING DOCUMENTS		P
7.9.1	ME EQUIPMENT accompanied by documents containing at least instructions for use, and a technical description	Provide in manual	P
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:	See below	P
	– name or trade-name of MANUFACTURER and an address the RESPONSIBLE ORGANIZATION can be referred to.....:	Provided in manual	P
	– MODEL or TYPE REFERENCE.....:	Provided in manual	P
	When ACCOMPANYING DOCUMENTS provided electronically (e.g., on CDROM), RISK MANAGEMENT PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT (to cover emergency operation)		P
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	Provide in manual	P
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	adequate	P
7.9.2	Instructions for use include the required information		P
7.9.2.1	– intended use of ME EQUIPMENT,		P
	– frequently used functions, and		P
	– known contraindication(s) to use of ME EQUIPMENT		P
	Classifications specified in Clause 6, all markings specified in 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	English provide, manufacturer responsible for translation to the appropriate language of any European Union country.	P

7.9.2.2	Instructions for use include all warning and safety notices	See below	P
	Warning statement for CLASS I ME EQUIPMENT indicating: "WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth"		P
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments		P
	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"	No such outlets	P
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	Considered	P
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply indicating "power supply is specified as a part of ME EQUIPMENT or combination is specified as a ME SYSTEM"		N
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source		P
	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	No batteries	P
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided.....:	None	P
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK	No hazards from loss of power	P
7.9.2.5	Instructions for use includes a description of ME EQUIPMENT, its functions, and significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, and 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	No hazardous material	P
	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		P

	APPLIED PARTS specified	Provided in manual	P
7.9.2.6	Information provided indicating where the installation instructions may be found (e.g. technical description), or information on qualified personnel who can perform the installation	Provided in manual	P
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 separable plug is used as isolation means to meet 8.11.1 a)		N
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 together with information on treatment and handling required prior to use of ME EQUIPMENT, its parts, or ACCESSORIES	Provided in manual	P
7.9.2.9	All necessary information provided to operate ME EQUIPMENT according to its specification including explanation of controls, displays and signals, sequence of operation, connection/disconnection of detachable parts or ACCESSORIES, replacement of material consumed during operation	Provided in manual	P
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use		P
7.9.2.10	A list of all system messages, error messages, and fault messages provided, except when messages are self-explanatory, an explanation of messages including important causes and possible action(s) that can be taken to resolve the problem indicated by the message	Provided in manual	P
7.9.2.11	Necessary information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT		P
7.9.2.12	Detailed information provided on cleaning, disinfection, and sterilization methods, and applicable parameters (i.e., temperature, pressure, humidity, time limits and number of cycles) that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified	Provided in manual	P
	Not applied to materials, components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	Considered	P
7.9.2.13	Detailed instructions provided on preventive inspection, maintenance, calibration, and frequency of such maintenance		P
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT		P

	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application, but not necessarily details of actual performance of such maintenance		P
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries intended to be maintained by anyone other than SERVICE PERSONNEL		P
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	Provided in manual	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 service) to ensure compliance with this standard		P
7.9.2.15	RISKS associated with disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified, and instructions provided on minimizing these RISKS	None	P
7.9.2.16	Information specified in 7.9.3 or where it can be found (e.g. in a service manual) included in instructions for use	Provided in manual	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:	See below	P
	– information in clause 7.2		P
	– permissible environmental conditions of use including conditions for transport and storage		P
	– all characteristics of ME EQUIPMENT including range(s), accuracy, and precision of displayed values or where they can be found		P
	– special installation requirements such as max. permissible apparent impedance of SUPPLY MAINS	Not applicable	N
	– permissible range of values of inlet pressure and flow, and chemical composition of cooling liquid used for cooling	Not applicable	N
	– a description of means of isolating ME EQUIPMENT from SUPPLY MAINS, when such means not in ME EQUIPMENT	Not applicable	N
	– a description of means for checking oil level in partially sealed oil filled ME EQUIPMENT or its parts when applicable	Not applicable	N
	– a warning statement addressing HAZARDS that can result from unauthorized modification of ME EQUIPMENT according to following examples:	Warning provided in the manual	P

	"WARNING: No modification of this equipment is allowed"	Similar warning provided in the manual	P
	"WARNING: Do not modify this equipment without authorization of the manufacturer"	Similar warning provided in the manual	P
	"WARNING: If this equipment is modified, appropriate inspection and Reviewing must be conducted to ensure continued safe use of equipment"	Similar warning provided in the manual	P
	Technical description separable from instructions for use contains required information, as follows		P
	– information in Clause 7.2		P
	– all applicable classifications specified in Clause 6, and warning and safety notices and explanation of safety signs marked on ME EQUIPMENT		P
	– a brief description of ME EQUIPMENT, how it functions, and its significant physical and performance characteristics		P
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description		P
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	Not permanently connected.	N
	– 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	Inlet provided	P
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and		P
	– 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		P
7.9.3.3	A statement in technical description indicates, upon request, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions, or other information to assist SERVICE PERSONNEL to repair parts	Not serviceable	P
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**		-
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS	See 8.4	P
	NORMAL CONDITION considered as simultaneous occurrence of situations identified in Clause 8.1a)	Considered.	P
	SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b)	Considered.	P
	ACCESSIBLE PARTS determined according to 5.9	Considered.	P
	LEAKAGE CURRENTS measured according to 8.7	Considered.	P
8.2	Requirements related to power sources		P
8.2.1	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM	Equipment Reviewed with isolation transformer	P
	Reviews performed with ME EQUIPMENT connected to separate power supply when one specified	Equipment Reviewed with isolation transformer	P
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined	Equipment Reviewed with isolation transformer	P
8.2.2	No HAZARDOUS SITUATION other than absence of ESSENTIAL PERFORMANCE developed when a connection with wrong polarity made for ME EQUIPMENT supplied from an external d.c. source	AC input	P
	ME EQUIPMENT connected with correct polarity did not present an unacceptable RISK		P
	Protective devices that can be reset by anyone without a TOOL restore correct operation on reset		P
8.3	Classification of APPLIED PARTS		P
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	Type BF	N
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART	Type BF	P
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	As above	P
	d) Requirements of a TYPE B APPLIED PART applied to a part in 4.6 to be subjected to requirements for an APPLIED PART (except marking)	Type BF	N
	Requirements for a TYPE BF or CF APPLIED PART applied as in RISK MANAGEMENT PROCESS	Addressed in risk analysis	P
8.4	Limitation of voltage, current or energy		P
8.4.1	Limits specified in 8.4.2 not applied to currents intended to flow through body of PATIENT to produce a physiological effect during NORMAL USE	Considered.	N

8.4.2	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 per Cl. 8.7.4:	See Review records	N
	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 Review records	N
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, was negligible in NORMAL USE, and the OPERATOR is instructed not to touch relevant part and PATIENT simultaneously:	Considered.	P
	– accessible contacts of connectors	Considered.	P
	– contacts of fuseholders accessible during replacement of fuse	None	P
	– contacts of lampholders accessible after removal of lamp	None	P
	– 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	Considered	P
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.).....:	See Review records	P
	Limit of 60 V d.c applied with no more than 10 % peak-to-peak ripple, and when ripple > specified value, 42.4 V peak limit applied (V d.c.).....:	See Review records	P
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential up to 2 V (VA or J).....:	See Review records	P
	LEAKAGE CURRENT limits referred to in 8.4.2 b) applied when voltages higher than limits in 8.4.2 c) were present (mA).....:	See Review records	P
	d) Voltage and energy limits specified in c) above also applied to the following:	See Review records	P
	– internal parts, other than contacts of plugs, connectors and socket-outlets, touchable by Review pin in Fig 8 inserted through an opening in an ENCLOSURE; and	See Review records	P
	– internal parts touchable by a metal Review rod with a diameter of 4 mm and a length of 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls using a TOOL	See Review records	P
	Review pin or the Review rod inserted through relevant openings with minimal force of no more than 1 N	See Review records	P

	Review 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	See Review records	P
	Review repeated with a TOOL specified in instructions for use	See Review records	P
	Review rod freely and vertically suspended through openings on top of ENCLOSURE	See Review records	P
	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	See Review records	P
	A TOOL is required when it is possible to prevent the devices from operating	See Review records	P
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one s after disconnecting the plug of ME EQUIPMENT or its parts (V).....:	See Review records	P
	A triggering circuit used to ensure disconnection occurred at peak of supply voltage waveform	See Review records	P
	When voltage exceeded 60 V, measured or calculated stored charge did not exceed 45 µC... :	See Review records	P
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, did not exceed 60 V or calculated stored charge did not exceed 45 µC..... :	No access covers	P
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL	None	P
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 (IEC 60417-5036, DB: 2002-10), and manual discharging device specified in technical description..... :	No such device	N
8.5	Separation of parts		P
8.5.1	MEANS OF PROTECTION (MOP)		P
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in Cl. 8.4		P
	Each MEANS OF PROTECTION categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking into account 4.6, and flow chart in Fig A.12	REINFORCED INSULATION PROVIDED FOR MOPP AND MOOP	P
	Varnishing, enameling, oxidation, and similar protective finishes and coatings with sealing compounds replasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION	NOT CONSIDERED PROTECTION	P

	Coatings and other insulation intended as a MEANS OF PROTECTION complying with IEC 60950-1:2001 considered acceptable as a MEANS OF OPERATOR PROTECTION but not automatically as a MEANS OF PATIENT PROTECTION	NOT CONSIDERED PROTECTION	P
	RISK MANAGEMENT PROCESS taken into consideration for MEANS OF PATIENT PROTECTION	ADEQUATE INSULATION PROVIDED	P
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10	SEE 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	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength Review of 8.8 at Review voltage of Table 6		P
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		P
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with 8.6	See 8.6	P
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength Review for two MEANS OF PATIENT PROTECTION considered equivalent to one MEANS OF PATIENT PROTECTION	Non outside of approved power supply	N
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance (V_{TW}, C_N).....:	Non outside of approved power supply	N
8.5.1.3	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:	See below	P
	– dielectric strength Review of 8.8 at Review voltage of Table 6; or		P
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION	See above	P
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:	See below	P
	– limits of Tables 13 to 16 (inclusive); or		P
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION	See above	P
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6, or	See 8.6	P
	– requirements and Reviews of IEC 60950-1 for protective earthing	See above	P
	A Y2 capacitor complying with IEC 60384-14 and passing dielectric strength Review for one MEANS OF OPERATOR PROTECTION considered equivalent to one MEANS OF OPERATOR PROTECTION	None outside of approved power supply	N

	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength Review for two MEANS OF OPERATOR PROTECTION considered equivalent to two MEANS OF OPERATOR PROTECTION	None outside of approved power supply	N
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance (V_{TW}, C_N) :	None outside of approved power supply	N
	Points where insulation, CREEPAGE, CLEARANCES, impedances of components, or PROTECTIVE EARTH CONNECTIONS prevent ACCESSIBLE PARTS from exceeding limits in 8.4 identified for Reviews relative to 8.5.1.1 to 8.5.1.3, and if a failure at that point regarded as a NORMAL or SINGLE FAULT CONDITION		N
	Each MEANS OF PROTECTION categorized relative to ME EQUIPMENT part(s) it protects from exceeding the allowable limits		N
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements as APPLIED PARTS, considered MEANS OF PATIENT PROTECTION		N
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION		N
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 MAX. MAINS VOLTAGE and complied with limit for PATIENT LEAKAGE CURRENT with 110 % of MAX. MAINS VOLTAGE applied (mA). :	Considered	P
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART	Considered	P
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function	Considered	P
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS	Considered	P
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	Considered	P
	LEAKAGE CURRENT Reviews conducted per 8.7.4	See Review record	P
	Dielectric strength Review conducted per 8.8.3	Review performed, see Review records	P
	CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable	See relevant clauses	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 parts	P

8.5.2.2	PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED,	No such connections, type only	P
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and		N
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low		N
	LEAKAGE CURRENT Reviews conducted per 8.7.4		N
	Dielectric strength Review conducted per 8.8.3		N
	Relevant CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		N
	The RISK MANAGEMENT FILE reviewed		N
8.5.2.3	A connector on a PATIENT lead located at the end of the lead remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE		P
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT	No such parts	N
	– 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		N
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm		N
	– 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 dielectric strength of 1500 V, and complying with 8.8.4.1		N
	– required Review 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		N
8.5.3	MAXIMUM MAINS VOLTAGE		P
	– MAXIMUM MAINS VOLTAGE determined to be the highest RATED supply voltage for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT including INTERNALLY POWERED ME EQUIPMENT with a means of connection to a SUPPLY MAINS (V)..... :		P
	When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V	As above	N
	– MAXIMUM MAINS VOLTAGE was the highest RATED phase to neutral supply voltage for polyphase ME EQUIPMENT (V)..... :	As above	N

	– for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V	As above	N
8.5.4	WORKING VOLTAGE		P
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED voltage range resulting in highest measured value (V).....:		P
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple did not exceed 10 % of average value or peak voltage when peak-to-peak ripple exceeded 10 % of average value (V)..... :	As above	P
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V).....:	As above	P
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth	As above	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).....:	As above	P
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	No such parts	N
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V).....:	No such parts	N
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	No defib proof	N
8.5.5.1	Classification “DEFIBRILLATION-PROOF APPLIED PART” applied to one APPLIED PART in its entirety, but not separate functions of same APPLIED PART		N
	Possibility of an OPERATOR receiving a shock from such parts taken into consideration in RISK MANAGEMENT PROCESS		N
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		N
	a) Hazardous electrical energies, during a discharge of a cardiac defibrillator to a PATIENT connected to a DEFIBRILLATION PROOF APPLIED PART, as determined by peak voltage measured between points Y1 and Y2 of Figs 9 and 10 exceeding 1 V, did not appear on:		N

	– ENCLOSURE including connectors in PATIENT leads and cables when connected to ME EQUIPMENT, and excluding connecting lead from a DEFIBRILLATION-PROOF APPLIED PART or its connector when it was disconnected from ME EQUIPMENT (V_P).....:		N
	– SIGNAL INPUT/OUTPUT PARTS (V_P).....:		N
	– Review metal foil with minimum area equal to base of ME EQUIPMENT where ME EQUIPMENT was placed on (V_P)..... :		N
	– or, PATIENT CONNECTIONS of other APPLIED PARTS regardless of classification as a DEFIBRILLATION-PROOF APPLIED PART (V_P).....:		N
	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
	ME EQUIPMENT connected to circuit of Fig 9 for common-mode Review, and Review voltage applied to all PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PART connected together, excluding those PROTECTIVELY EARTHED or functionally earthed		N
	Peak voltage at Y1 and Y2 after operation of S (V_P).....:		N
	Peak voltage at Y1 and Y2 after operation of S with V_T reversed (V_P).....:		N
	ME EQUIPMENT connected to circuit of Fig 10 for differential-mode Review, and voltage applied to each PATIENT connection of DEFIBRILLATION-PROOF APPLIED PART in turn with all remaining PATIENT CONNECTIONS of the same DEFIBRILLATION-PROOF APPLIED PART connected to earth		N
	A single PATIENT CONNECTION APPLIED PART not subjected to differential-mode Review		N
	– ME EQUIPMENT, except for PERMANENTLY INSTALLED ME EQUIPMENT, Reviewed with and without PROTECTIVE EARTH CONDUCTOR connected		N
	– insulating surfaces of APPLIED PARTS covered with metal foil or, when appropriate, immersed in a 0.9 % saline solution		N
	– external connections to a FUNCTIONAL EARTH TERMINAL removed		N
	– parts specified in 8.5.5.1 a) not PROTECTIVELY EARTHED connected in turn to a display device		N
	– ME EQUIPMENT connected to SUPPLY MAINS and operated in accordance with instructions for use		N
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 1 with 2,3, & 4 connected to earth (V_P).....:		N

	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 2 with 1,3, & 4 connected to earth (V_P).....:		N
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 3 with 1, 2, & 4 connected to earth (V_P).....:		N
	Peak voltage at Y1 and Y2 after the operation of S, V_T applied to PATIENT CONNECTION 4 with 1, 2, & 3 connected to earth (V_P)..... :		N
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 1 with 2,3, & 4 connected to earth, V_T reversed (V_P)..... :		N
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 2 with 1,3, & 4 connected to earth, V_T reversed (V_P)..... :		N
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 3 with 1, 2, & 4 connected to earth, V_T reversed (V_P)..... :		N
	Peak voltage at Y1 and Y2 after operation of S, V_T applied to PATIENT CONNECTION 4 with 1, 2, & 3 connected to earth, V_T reversed (V_P)..... :		N
	ME EQUIPMENT continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE after the recovery time stated in ACCOMPANYING DOCUMENTS		N
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load to at least 90 % of energy delivered to this load with ME EQUIPMENT disconnected (J).....:		N
	Review voltage applied to each PATIENT CONNECTION or APPLIED PART in turn with all remaining PATIENT CONNECTIONS of same APPLIED PART connected to earth using circuit of Fig 11 and ACCESSORIES recommended by instructions as follows:		N
	a) APPLIED PART or PATIENT CONNECTION connected to Review circuit		N
	b) Capacitor C charged to 5 kV d.c. with switch S in position A		N
	c) Capacitor C discharged by actuating switch S to position B, and measured energy E1 delivered to 100 Ω load (E1, J)..... :		N
	d) ME EQUIPMENT under Review removed from Review circuit and repeated steps b) and c), measuring energy E2 delivered to 100 Ω load (E2, J).....:		N
	e) Energy E1 was at least 90 % of E2 (E1, J).....:		N
8.6	Protective earthing, functional earthing and potential equalization of ME EQUIPMENT		P
8.6.1	Requirements of 8.6.2 to 8.6.8 applied	See below	P

	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	PED connection via IEC60320 inlet	P
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.....:	As above	P
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and clamping means cannot be loosened without TOOL		P
	Screws for internal PROTECTIVE EARTH CONNECTIONS are completely covered or protected against accidental loosening from outside.....:		P
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL	PE pin on inlet is the PE terminal	P
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing	As above	P
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	Not used for moving part	P
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop	See Review records	P
	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	Values not exceeded	P
8.6.5	Poorly conducting surface coatings on conductive elements removed at the point of contact	PE only used for internal power supply	P
	Coating not removed when requirements for impedance and current-carrying capacity met		P
8.6.6	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	IEC connection used for all PE	P
	This requirement applied also where interchangeable parts are PROTECTIVELY EARTHED	As above	P
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR complies with following:	None	N

	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE		N
	– RISK of accidental disconnection minimized in NORMAL USE		N
	– Terminal allows conductor to be detached without a TOOL		N
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		N
	– Terminal marked with symbol 8 of Table D.1 (i.e., symbol IEC 60417-5021, DB: 2002-10)		N
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		N
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		N
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION	Not used for PE	N
8.6.9	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 only as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL and colored green and yellow	Not class II	N
	Two MEANS OF PROTECTION provided by insulation of internal screens and all internal wiring connected to them with a related explanation in technical description.....:		N
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		P
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3	See 8.7.3	P
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Tables 8.7A, 8.7B, 8.7C, and 8.7.4.7	Limits not exceed, see Review records	P
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except	Clause taken into consideration	P
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)	Clause taken into consideration	P
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time	Clause taken into consideration	P
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION	Clause taken into consideration	P

	SINGLE FAULT CONDITIONS not applied at same time as special Review conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE	Clause taken into consideration	P
8.7.3	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), and limits apply to d.c., a.c., composite waveforms, and unless otherwise stated, they are d.c. or r.m.s	Limits not exceed, see Review records	P
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 and 4, and values of a.c. are relative to currents having a frequency not less than 0.1 Hz	Limits not exceed, see Review records	P
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC}).....:	Limits not exceed, see Review records	P
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC})..... :	Limits not exceed, see Review records	P
	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 [10] (I_{ENC}, I_{ESFC})..:	No such requirment	P
	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.....:	Limit not exceed, see Review records	P
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements		P
8.7.4.1	Figs 13-19 used to measure LEAKAGE and PATIENT AUXILIARY CURRENTS	Limits not exceed, see Review records.	P
	When other Review Figs. yielding accurate results used, but results appeared close to permissible values, or when validity of results was in question, applicable Review Figs used as deciding factor	Limits not exceed, see Review records.	P
	a) EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and AUXILIARY CURRENTS measured with ME EQUIPMENT running at operating temperature of 11.1.3 c)	Limits not exceed, see Review records.	P
	b) Number of Reviews reduced when examination of circuit arrangement, components, and materials of ME EQUIPMENT indicated no possibility of any HAZARDOUS SITUATION	Limits not exceed, see Review records.	P
8.7.4.2	ME EQUIPMENT for connection to a SUPPLY MAINS connected to an appropriate power source	Clause taken into consideration	P
	Reviews on single-phase ME EQUIPMENT conducted at both supply polarities	Limits not exceeded, see Review record.	P
	INTERNALLY POWERED ME EQUIPMENT Reviewed without connections to a measuring supply circuit	Not internally powered.	P
8.7.4.3	a) CORD connected ME EQUIPMENT Reviewed using the cord	Inlet provided	P

	b) ME EQUIPMENT with an APPLIANCE INLET connected to measuring supply circuit via a 3 m DETACHABLE POWER SUPPLY CORD or a length and type specified in instructions for use (m)..... :	Clause taken into consideration	P
	c) PERMANENTLY INSTALLED ME EQUIPMENT connected to measuring supply circuit by shorReview possible connection	Not permanently installed.	N
	d) Measuring arrangements were as follows:	Clause taken into consideration	P
	1) APPLIED PARTS, including PATIENT cables (when present), placed on an insulating surface with a dielectric constant of approximately 1 (e.g., expanded polystyrene) and approximately 200 mm above an earthed metal surface	Clause taken into consideration	P
	2) Reference earth of measuring circuits connected to protective earth of SUPPLY MAINS when an isolating transformer was not used for LEAKAGE CURRENT measurements	Isolation transformer used	P
8.7.4.4	a) Source of LEAKAGE CURRENT loaded with measuring device or PATIENT AUXILIARY CURRENT with an impedance of approximately 1000 Ω for d.c., a.c. and composite waveforms ≤ 1 MHz	Clause taken into consideration	P
	b) Evaluation of current and current components based on 8.7.3 a) obtained automatically when a measuring device in Fig 12a) or a similar circuit used, allowing measurement of total effect of all frequencies with a single instrument	Clause taken into consideration	P
	When currents and current components with frequencies >1 kHz exceeded 10 mA limit in 8.7.3 e), they were measured by appropriate means	Clause taken into consideration	P
	c) Voltage measuring instrument in Fig 12 a) used with a min input resistance of 1 M Ω and a max input capacitance of 150 pF indicating true r.m.s. value of voltage with an indicating error ≤ ± 5 % of indicated value	Clause taken into consideration	P
	Scale indicates current through measuring device including automatic evaluation of components with frequencies > 1 kHz enabling direct comparison of reading with limits in 8.7.3	Clause taken into consideration	P
	Requirements limited to a frequency < than 1 MHz when proven by oscilloscope frequencies > such an upper limit do not occur in measured current (Max Frequency Hz).....:	Clause taken into consideration	P
8.7.4.5	a) CLASS I ME EQUIPMENT Reviewed based on Fig 13	See Review records	P
	b) Current measured on more than one PROTECTIVE EARTH CONDUCTOR was aggregate current in protective earthing system of installation	See Review records	P
	c) MANUFACTURER specified a Review PROCEDURE and configuration for measurement of EARTH LEAKAGE CURRENT for FIXED ME EQUIPMENT with connections to earth through building structure	No such configuration	P

8.7.4.6	a) ME EQUIPMENT Reviewed according to Fig 14, using an appropriate measuring supply circuit	Clause taken into consideration	P
	Measurement made with MD between earth and each part of the ENCLOSURE not PROTECTIVELY EARTHED	Clause taken into consideration	P
	Measurement made with MD between parts of ENCLOSURE not PROTECTIVELY EARTHED	Clause taken into consideration	P
	Measurement made with MD between earth and any part of ENCLOSURE, normally, PROTECTIVELY EARTHED under SINGLE FAULT CONDITION of interruption of any PROTECTIVE EARTH CONDUCTOR	Clause taken into consideration	P
	INTERNALLY POWERED ME EQUIPMENT investigated for TOUCH CURRENT only between parts of ENCLOSURE, not between ENCLOSURE and earth, except when 8.7.4.6 c) was applicable	Clause taken into consideration	P
	b) A metal foil 20x10 cm max applied in contact with ENCLOSURE or relevant part of ENCLOSURE made fully or partly of insulating material	Clause taken into consideration	P
	Metal foil shifted, when possible, to determine highest value of TOUCH CURRENT	Clause taken into consideration	P
	Metal foil was not in touch with any PROTECTIVELY EARTHED metal parts of ENCLOSURE, except metal parts of ENCLOSURE not PROTECTIVELY EARTHED partly or fully covered by metal foil	Clause taken into consideration	P
	Metal foil arranged to contact parts of ENCLOSURE normally PROTECTIVELY EARTHED when measuring TOUCH CURRENT under SINGLE FAULT CONDITION of interruption of a PROTECTIVE EARTH CONDUCTOR	Clause taken into consideration	P
	Foil size increased based on area of contact when surface of ENCLOSURE in contact with PATIENT or OPERATOR was larger than 20x10 cm (cmxcm).....:	Clause taken into consideration	P
	c) ME EQUIPMENT with a SIGNAL INPUT/OUTPUT PART additionally Reviewed using transformer T2 when required (see 8.1 a))	Clause taken into consideration	P
	Transformer T2 voltage set at 110 % of MAXIMUM MAINS VOLTAGE, and specific pin configuration used when applying external voltage determined to be worst case based on Review or circuit analysis	Clause taken into consideration	P
8.7.4.7	a) ME EQUIPMENT with an APPLIED PART Reviewed based on Fig 15, and an ENCLOSURE, other than an APPLIED PART, of insulating material placed in a position of NORMAL USE on a flat metal surface and connected to earth	Clause taken into consideration	P
	b) ME EQUIPMENT with an F-TYPE APPLIED PART additionally Reviewed based on Fig 16, and SIGNAL INPUT/OUTPUT PARTS not previously permanently earthed connected to earth	Clause taken into consideration	P
	Transformer T2 voltage in Fig 16 set at 110 % of MAXIMUM MAINS VOLTAGE	Clause taken into consideration	P

	Non-PROTECTIVELY EARTHED metal ACCESSIBLE PARTS including PATIENT CONNECTIONS of other APPLIED PARTS, when present, connected to earth	Clause taken into consideration	P
	c) ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART, additionally Reviewed according to Fig 17when required	Clause taken into consideration	P
	Transformer T2 voltage set at 110 % of MAXIMUM MAINS VOLTAGE, and specific pin configuration used when applying external voltage was worst case based on Review or circuit analysis	Clause taken into consideration	P
	d) ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART not PROTECTIVELY EARTHED or a TYPE BF APPLIED PART with metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED additionally Reviewed based on Fig 18	Clause taken into consideration	P
	Transformer T2 voltage set at 110 % of MAXIMUM MAINS VOLTAGE	Clause taken into consideration	P
	Due to adequate separation of parts involved, this Review was not conducted	Clause taken into consideration	P
	e) An APPLIED PART with an insulating surface Reviewed using metal foil as in 8.7.4.6, or it was immersed in a 0.9 % saline solution.....:	Clause taken into consideration	P
	Size of foil increased corresponding to area of contact when surface of APPLIED PART in contact with PATIENT was larger than 20 cm x 10 cm (cm x cm).....:	Clause taken into consideration	P
	Metal foil or saline solution considered as the only patient connection for APPLIED PART concerned	Clause taken into consideration	P
	f) Fluid used as PATIENT CONNECTION replaced by 0.9 % saline solution, and electrode placed in saline solution considered as PATIENT CONNECTION for APPLIED PART concerned	Clause taken into consideration	P
	g) PATIENT LEAKAGE CURRENT for TYPE B and TYPE BF APPLIED PARTS measured from and to all PATIENT CONNECTIONS of a single function connected directly together or loaded as in NORMAL USE	Clause taken into consideration	P
	– PATIENT LEAKAGE CURRENT for TYPE CF APPLIED PARTS measured from and to every PATIENT CONNECTION in turn	Not CF	P
	PATIENT LEAKAGE CURRENT measurements made with the least favorable detachable part specified in instructions for use	Clause taken into consideration	P
	h) Total PATIENT LEAKAGE CURRENT measured from and to all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B, BF, or CF APPLIED PARTS) connected together	Clause taken into consideration	P
	Functional earth disconnected before the Review when necessary	No external FE connection	P

	i) Measuring device connected to each PATIENT CONNECTION in turn since PATIENT CONNECTIONS of APPLIED PART are loaded under NORMAL USE	Clause taken into consideration	P
8.7.4.8	ME EQUIPMENT with an APPLIED PART except for one with only a single PATIENT CONNECTION Reviewed based on Fig 19 with a measuring supply circuit	Clause taken into consideration	P
	PATIENT AUXILIARY CURRENT measured between a single PATIENT CONNECTION and all other PATIENT CONNECTIONS, connected directly together or loaded as in NORMAL USE	Clause taken into consideration	P
8.7.4.9	PATIENT LEAKAGE and AUXILIARY CURRENTS for ME EQUIPMENT with multiple PATIENT CONNECTIONS did not exceed limits for NORMAL CONDITION while one or more PATIENT CONNECTIONS are	Clause taken into consideration	P
	– disconnected from the PATIENT; and	Clause taken into consideration	P
	– disconnected from the PATIENT and earthed	Clause taken into consideration	P
	Actual measurements limited to representative number of combinations.....:	Clause taken into consideration	P
8.8	Insulation		P
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION and insulation between parts of opposite polarity of MAINS PART on SUPPLY MAINS side of mains fuse or OVER-CURRENT RELEASE (as one MEANS OF PROTECTION)		P
	Insulation exempted from Review (complies with 4.8)		P
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not Reviewed as in 8.8		P
8.8.2	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		P
	a) 0.4 mm, min, distance through insulation, or		P
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:	No solid insulation outside of approved components, other than enclosure.	P
	– at least two layers of material, each passed the appropriate dielectric strength Review, or		P
	– three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength Review		P
	Dielectric strength Review for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		P

	Dielectric strength Review for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		P
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		P
	c) Wire with solid insulation, other than solvent based enamel, complying with a)	No solid insulation outside of approved components, other than enclosure.	P
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L	No solid insulation outside of approved components, other than enclosure.	P
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	No solid insulation outside of approved components, other than enclosure.	P
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		P
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		P
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		P
	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 Review voltages of TYPE REVIEWS in L.3 equal 1.6 times of normal values		P
	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..... :		P
	Finished component complied with routine dielectric strength Reviews of 8.8.3		P
	Reviews of Annex L not repeated since material data sheets confirm compliance		P
8.8.3	Solid insulating materials with a safety function withstood dielectric strength Review voltages applied in accordance with methods of this Clause	Enclosure passed the dielectric strength Review	P
	a) Waveform and frequency of Review voltage resulted in dielectric stress on insulation at least equal to that in NORMAL USE		P
	Review voltage with a different waveform and frequency than the voltage in NORMAL USE applied when manufacturer demonstrated dielectric stress on insulation Reviewed was not diminished (waveform, frequency Hz)..... :	Sinusoidal, 60Hz used	P

	Review performed with a 50 or 60 Hz sinusoidal voltage in NORMAL USE, and relevant insulation subjected to a non-sinusoidal a.c. voltage	Sinusoidal, 60Hz used	P
	Review voltage for WORKING VOLTAGE applicable to insulation was ≥ than in Table 6	Sinusoidal, 60Hz used	P
	b) No breakdown occurred during Reviews	See breakdown occurred	P
	Breakdown indicated by a rapid uncontrolled increase in current when insulation unable to restrict flow of current	See breakdown occurred	P
	Corona discharge or a single momentary flashover not regarded as insulation breakdown	See breakdown occurred	P
	c) A large part or entire ME EQUIPMENT Reviewed when individual solid insulation could not be Reviewed, different types and levels of insulation not overstressed, and following was considered	Necessary parts were Reviewed	P
	– Metal foil used on non-conductive surfaces of ENCLOSURE or part of it positioned to prevent flashover at edges of insulation linings	Enclosure wrapped in foil during Review	P
	When applicable, metal foil moved to Review all parts of surface	Considered	P
	– Circuits on either side of insulation under Review connected or short-circuited to prevent stress on components within circuits	Considered	P
	– IEC 60384-14 Certified capacitors across insulation under Review disconnected during Review	None	N
8.8.4	Insulation other than wire insulation		P
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT	Mold stress Review performed on enclosure	P
	ME EQUIPMENT and RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength Reviews	Moisture not seen as an issue for plastic enclosure. Dielectric strength Review and mechanical Reviews performed.	P
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat	Review performed	P
	Reviews conducted in absence of satisfactory evidence for resistance to heat:	Review performed	P
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure Review using apparatus of Fig 21	Ball enclosure Review performed	P
	Surface of part placed in a heating cabinet at 75° C ± 2 °C or ambient temperature indicated in technical description ± 2 ° C plus temperature rise of relevant part of insulating material measured during Review of 11.1, higher of the two (° C)..... :	Review at 75°C	P

	A steel ball 5 mm in diameter pressed against the surface with a force of 20 N		P
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure Review in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ± 2 °C plus temperature rise determined during Review of 11.1 of relevant part, higher of the two (° C).....:	No such parts requiring Reviewing	P
	Impression made by the ball after 1 h was 2 mm or less in diameter (mm)..... :		P
	Review not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION		P
8.8.4.2	Resistance to environmental stress		P
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt or dust resulting from wear of parts within ME EQUIPMENT to the extent CREEPAGE and CLEARANCES would be reduced below 8.9	Enclosure not likely to be affected	P
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	Not used	N
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	Not used	N
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen not less than 97 % pure, to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples	Not used	N
	Samples kept in cylinder at 70 °C ± 2 °C for 96 h, and immediately afterwards, taken out of cylinder and left at room temperature for at least 16 h	Not used	N
	There were no cracks visible to naked eyes	Not used	N
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		P
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are ≥ to values in Tables 11 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15	See Review records	P
8.9.1.2	Tables 11 to 16 (inclusive) not applied to CREEPAGE and CLEARANCES forming MEANS OF OPERATOR PROTECTION per IEC 60950-1 for INSULATION CO-ORDINATION and used under conditions compliance was Reviewed		P
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	Clause taken into consideration	P

8.9.1.4	When min CREEPAGE derived from Tables 11 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE	Clause taken into consideration	P
8.9.1.5	ME EQUIPMENT RATED to operate at an altitude of 2000 m	Assumed use up to 2000m	P
	ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m).....:	As above	P
	Operating altitude corresponding to actual air pressure for ME EQUIPMENT intended for pressurized environments (e.g., aircraft) used in determining multiplication factor from Table 8, and AIR CLEARANCE was multiplied by this factor	Not for use in such evironmenmts	P
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE	Considered	P
8.9.1.6	When WORKING VOLTAGE was between those in Tables 11 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows:	used	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)..... :		P
	– CLEARANCES for PEAK WORKING VOLTAGES above 2800 V peak or d.c. determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm)..... :		P
	– 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)..... :	Group IIb assumbed	P
	Material group evaluated using 50 drops of solution A based on Review data for material according to IEC 60112	As above	P
	Material of unknown group considered group IIIb	As above	P
8.9.1.8	– Pollution degree 1: Micro-environment sealed to exclude dust and moisture	Pollution degree 2 assumed	P
	– Pollution degree 2: Micro-environment with non-conductive pollution, except occasional temporary conductivity caused by condensation	Pollution degree 2 assumed	P
	– Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation	Pollution degree 2 assumed	P
	– Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions	Pollution degree 2 assumed	P

	Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION	Pollution degree 2 assumed	P
	Where insulation between MAINS PART and earth might be compromised, measures such as maintenance ensure that micro-environment is mitigated to a lower pollution degree	Pollution degree 2 assumed	P
8.9.1.9	Applicable value of MAINS TRANSIENT VOLTAGE determined from overvoltage category according to IEC 60664-1 and NOMINAL a.c. MAINS VOLTAGE using Table 10 (V_{MT} peak, V_{MN} r.m.s.)..... :	Overvoltag category II assumed, which corresponds to a transient voltage of 2500V	P
8.9.1.10	Required 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	Considered	P
8.9.1.11	Overvoltage category II applied according to IEC 60664-1	Overvoltage category II assumed	P
	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	As above	P
	When PATIENT protection (Table 12) was required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, guidance provided on values required in the rationale for 8.9 used	As above	P
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)	Considered	P
	Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT	Considered	P
	Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS	Considered	P
	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	Considered	P
	Table 15 column for circuits not subject to transient overvoltages applied to:	Considered	P
	– d.c. SECONDARY CIRCUITS reliably connected to earth and have capacitive filtering limiting peak-to-peak ripple to 10 % of d.c. voltage, and	Considered	P
	– circuits in INTERNALLY POWERED ME EQUIPMENT	None	P
8.9.1.13	Table 15 for PEAK WORKING VOLTAGES above 1400 V peak or d.c. not applied because all the following conditions were met:	Considered	P
	– CLEARANCE was at least 5 mm	Considered	P

	– insulation complied with dielectric strength Review of 8.8.3 using an a.c. Review voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, or	Considered	P
	– a d.c. Review voltage equal to peak value of a.c. Review voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, and	Considered	P
	– CLEARANCE path was partly or entirely through air or along the surface of an insulating material of material group I	Considered	P
	Dielectric strength Review 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	Considered	P
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	Considered	P
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1	No such parts	P
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied	Considered	P
	b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths	Considered	P
	c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION is such that the relevant parts are rigid and located by molding, or there is no reduction of a distance below specified value by deformation or movement of parts	Considered	P
	Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE	Considered	P
8.9.3	Spaces filled by insulating compound		P
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 do not exist	None	N
	Thermal cycling, humidity preconditioning, and dielectric strength Reviews in 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4 conducted		P
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 Review (clause 8.8.3), Review voltage multiplied by 1.6		P

	Cracks or voids in insulating compound affecting homogeneity of material did not occur		P
8.9.3.3	For situations where insulating compound forms a cemented joint with other insulating parts, three samples Reviewed for reliability of joint		P
	A winding of solvent-based enameled wire replaced for the Review by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples Reviewed as follows:		P
	– 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 Review of 8.8.3 except at 1.6 times the Review voltage		P
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength Review of 8.8.3 at 1.6 times the Review voltage		P
8.9.3.4	One sample containing the cemented joint subjected to a sequence of temperature cycling Reviews for 10 times		P
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES		P
	CREEPAGE AND CLEARANCES measured using Figs 22 to 31 (inclusive)	Considered	P
	Corners with included angles less than 80° assumed to be bridged with an insulating link of 1 mm moved into the least favorable position	Considered	P
	Distance of 1 mm or more across the top of a groove did not constitute a CREEPAGE DISTANCE	Considered	P
	CREEPAGE and CLEARANCES between parts moving relative to each other measured with the parts in their least favorable positions	Considered	P
	Calculated CREEPAGE DISTANCE was never less than measured AIR CLEARANCE	Considered	P
	Coatings of varnish, enamel, or oxide disregarded	Considered	P
	Coverings of insulating materials equivalent to a sheet of insulating material of equal thickness with respect to their electrical, thermal, and mechanical properties considered as insulation	Considered	P
	Minimum values in Tables 11 to 16 (inclusive) applied to sum of sections for CREEPAGE or CLEARANCES for one or two MEANS OF PROTECTION interrupted by one or more floating conductive parts (distances less than 1 mm disregarded)	Considered	P
	Walls of grooves transverse to CREEPAGE DISTANCE counted as CREEPAGE DISTANCE only when width of the groove was more than 1 mm, otherwise grooves disregarded	Considered	P

	CREEPAGE DISTANCES for a barrier placed on surface of insulation or held in a recess measured over barrier only when dust and moisture could not penetrate into the joint or recess	Considered	P
	Measurements for ME EQUIPMENT with an APPLIANCE INLET made with an appropriate connector inserted	Considered	P
	For other ME EQUIPMENT with POWER SUPPLY CORDS measurements made with conductors of largest cross-sectional area specified by MANUFACTURER and without conductors	Considered	P
	Movable parts placed in the least favorable position, and nuts and screws with non-circular heads tightened in the least favorable position	Considered	P
	CREEPAGE and CLEARANCES through slots or openings in external parts measured to the standard Review finger of Fig 6	Considered	P
	Measurements made applying a 2 N force on points of bare conductors using a standard Review finger (as in Fig 6) complied with requirements for CREEPAGE DISTANCES and AIR CLEARANCES	Considered	P
	Measurements made applying a 30 N force to outside of metal ENCLOSURE using a standard Review finger (as in Fig 6) complied with requirements for CREEPAGE and CLEARANCES	Considered	P
	When relevant, CREEPAGE and CLEARANCES measured after use of Review hook in 5.9.2.2	Considered	P
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	No such parts	P
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION	Adequate	P
	Conductors and connectors of ME EQUIPMENT when breaking free at their joint and moving about their support point are not capable of touching circuit points resulting in a HAZARDOUS SITUATION as indicated in RISK MANAGEMENT FILE	No such conduct	P
	Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION	Considered	P
	Stranded conductors are not solder-coated when secured by clamping means to prevent poor contact which could create HAZARDOUS SITUATIONS	Considered	P
8.10.3	Flexible cords detachable without a TOOL used to interconnect different parts of ME EQUIPMENT provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS of 8.4 when a connection is loosened or broken as indicated by measurement or using Review finger	Complies	P

8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		P
8.10.4.1	Control devices of ME EQUIPMENT and their associated 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	No such equipment	P
	d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple		P
	42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit		P
8.10.4.2	Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT at both ends of cable to control device complied with 8.11.3 when breaking free or shorting between conductors could result in a HAZARDOUS SITUATION	No such cord	P
	This requirement applied to other HAND-HELD parts when disturbance or breaking of one or more of connections could result in a HAZARDOUS SITUATION		P
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	No moving parts	P
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION as shown by manual Reviews and RISK MANAGEMENT FILE	Unit not be opened after initial assembly at factory	P
8.10.6	Guiding rollers of insulated conductors prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead concerned in NORMAL USE	No such parts	N
8.10.7	a) Insulating sleeve that can only be removed by breaking or cutting, or secured at both ends, is used on internal wiring of when needed	Not used	P
	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	Not used	P
	c) Insulated conductors subject to temperatures > 70 °C in NORMAL USE provided with insulation of heat-resistant material when compliance is likely to be impaired due to deterioration of insulation	No such temps	P
8.11	MAINS PARTS, components and layout		P
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles		P

	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	Not perm installed	P
	b) Means of isolation incorporated in ME EQUIPMENT, and external means described in technical description	Disconnect provided	P
	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	Switch part of approved inlet	P
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or other external flexible lead	Switch part of approved inlet	P
	e) Direction of movement of actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447	Switch mounted horizontally, ON is to the Left	P
	f) A suitable plug device such as an APPLIANCE COUPLER or a flexible cord with a MAINS PLUG used in non-PERMANENTLY INSTALLED ME EQUIPMENT to isolate it from SUPPLY MAINS considered to comply with 8.11.1 a)	Inlet also provided	P
	g) A fuse or a semiconductor device not used as an isolating means in the sense of this clause	Not used	P
	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	Disconnected provided	P
	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	Disconnected provided	P
	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)		P
	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		P
	Standard Review finger of Fig 6 applied		P
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	None	P
8.11.3	POWER SUPPLY CORDS		P
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD		P

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, designation 53)	<HAR> cords used	P
	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	<HAR> cords used	P
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)..... :		P
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	IEC6030 inlet	P
8.11.3.5	Cord anchorage (for APPLIANCE COUPLERS not complying with IEC 60320-1)		P
	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	See 8.11.3.4	P
	b) Cord anchorage of POWER SUPPLY CORD is made of and arranged as follows when a total insulation failure of POWER SUPPLY CORD caused conductive non-PROTECTIVELY EARTHED ACCESSIBLE PARTS to exceed limits of 8.4:		N
	– insulating material, or		N
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		N
	– metal provided with an insulating lining affixed to cord anchorage, except when it is a flexible bushing forming part of the cord guard in 8.11.3.6, and complying with the requirements for one MEANS OF PROTECTION		N
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage		N
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals when cord anchorage fails		N
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N

	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18		N
	Cord subjected to a torque in Table 18 for 1 min immediately after pull Reviews		P
	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 normally connected position		P
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		P
	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		P
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	See 8.11.3.4	P
	Cord guard complied with Review of IEC 60335-1:2001, Clause 25.14, or		P
	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 (D in mm) attached to the free end of cord (g).....:		P
	Cord guard of temperature-sensitive material Reviewed at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		P
	Radius of curvature of the cord, immediately after mass was attached, was not less than 1.5 x D...		P
8.11.4	MAINS TERMINAL DEVICES		P
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	Inlet provided	P
	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		P
	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		P
	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		P
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		P

	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL closely grouped to provide convenient means of connection	Inlet provided	P
	b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6	Inlet provided	P
	c) Marking of MAINS TERMINAL DEVICES complied with 7.3	Inlet provided	P
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL	Inlet provided	P
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area in Table 17 stripped 8 mm and with a single free wire bent in every possible direction without pulling back insulating sheath or making sharp bends around partitions	Inlet provided	P
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	Inlet provided	P
8.11.4.4	Terminals with clamping means for a rewirable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened as verified by Review of 8.11.3.4	Inlet provided	P
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewirable POWER SUPPLY CORD to allow easy introduction and connection of conductors, and covers fitted without damage to conductors or their insulation	Inlet provided	P
	Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation Review	Inlet provided	P
8.11.5	Mains fuses and OVER-CURRENT RELEASES		P
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection according to 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT		P
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	Not per installed	P
	– 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	Fused provided	P
	Effect of short-circuit fault conditions in other circuits taken into consideration before eliminating fuses or OVER-CURRENT RELEASES	Fused provided	P

	Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit	Adequate fuse used	P
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR	No fuse in PE	P
	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 greatero	Approved fuse used	P
	Justification for omission of fuses or OVER-CURRENT RELEASES is in RISK MANAGEMENT FILE	Fused provided	P
8.11.6	Internal wiring of the MAINS PART		P
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE and protective devices is not < minimum required for POWER SUPPLY CORD as in 8.11.3.3 (mm^2 Cu)..... :		P
	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		P
	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		P

9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		-
9.1	ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3)	Complies	P
9.2	HAZARDS associated with moving parts		-
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	P
	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
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its function		N
	Warnings marked on ME EQUIPMENT or included in instructions for use when HAZARDS persisted after implementing all reasonable protective measures		N
9.2.2	TRAPPING ZONE		N
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:	No trapping zone	N
	– Gaps in Clause 9.2.2.2, or		N

	– Safe distances in Clause 9.2.2.3, or		N
	– GUARDS and protective measures in 9.2.2.4, or		N
	– Continuous activation in Clause 9.2.2.5		N
	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

9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions specified in Table 20		N
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 13852		N
	Distances measured from expected positions of OPERATOR, PATIENT, and others near EQUIPMENT in NORMAL USE or under foreseeable misuse		N
9.2.2.4	GUARDS and protective measures		N
9.2.2.4.1	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when GUARDS and protective measures were of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK based on results of applicable Reviews in 15.3 for ENCLOSURES		N
9.2.2.4.2	FIXED GUARDS securely held in place by systems that cannot be dismantled without a TOOL		N
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open		N
	– 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
	– absence or failure of one of their components prevents starting, and stops moving parts		N
	Movable GUARDS complied with all applicable Reviews as confirmed by review of RISK MANAGEMENT FILE		N
9.2.2.4.4	Protective measures provided in control system prevented moving parts from starting to move while in reach of persons		N
	– protective measures prevented TRAPPING ZONE from reach, or, when it was reached, system movement stopped once ME EQUIPMENT started to move, and in the latter case, no HAZARD or damage resulted		N

	– when protective measure was in a SINGLE FAULT CONDITION, and an unacceptable RISK could arise, one or more emergency stopping device(s) provided		N
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N
9.2.2.5	Continuous activation		N
	TRAPPING ZONE not considered to present a MECHANICAL HAZARD where impractical to make TRAPPING ZONE inaccessible when:		N
	a) movement was in OPERATOR'S field of view		N
	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
	Manually operated movements complied with this clause since mass and velocity allowed adequate control of positioning without causing an unacceptable RISK		N
	c) when in a SINGLE FAULT CONDITION of continuous activation system an unacceptable RISK could arise, one or more emergency stopping device(s) provided in ME EQUIPMENT		N
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT, when contact with ME EQUIPMENT could result in a HAZARDOUS SITUATION, limited to allow OPERATOR control of positioning without resulting in an unacceptable RISK		N
	Over travel (stopping distance) of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		N
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N
9.2.3	Other HAZARDS associated with moving parts		P
9.2.3.1	Controls positioned, recessed, or protected by other means and could not be accidentally actuated to result in unacceptable RISK, except when ergonomic considerations for a PATIENT with special needs require otherwise	No controls	N
9.2.3.2	RISK due to over travel (past range limits) of ME EQUIPMENT parts reduced to an acceptable level, and stops or other means with mechanical strength to withstand intended loading in NORMAL USE and foreseeable misuse provided limiting measure in NORMAL and SINGLE FAULT CONDITION	None	N
	RISK MANAGEMENT FILE reviewed and all conditions confirmed	No moving parts	N
9.2.4	Emergency stopping devices		N

	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:	No emergency stopping device.	N
	a) Emergency stopping device reduced RISK to an acceptable level		N
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original HAZARD		N
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N
	g) Means for stopping of movements operate as a result of one single action		N
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N
	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, DB:2002-10) or “STOP”		N
	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
	k) Emergency stopping device is suitable for its application		N
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N
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 protective measure, or emergency stopping, and	No moving parfs	N
	– Uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		N
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented		N
	– 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

	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in an unacceptable RISK avoided or covered	No sharp edges or rough surface	N
	RISK MANAGEMENT FILE reviewed and all conditions confirmed	Unit examied	N
9.4	Instability HAZARDS		P
9.4.1	ME EQUIPMENT, other than FIXED and hand-held, for placement on a surface did not overbalance (tip over) or move unexpectedly, to the degree that it could present an unacceptable RISK to PATIENT, or OPERATOR as Reviewed in 9.4.2 to 9.4.4		P
9.4.2	Instability – overbalance		N
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
9.4.2.2	Instability excluding transport		P
	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 consisting of a hard and flat surface		P
	A warning notice provided stating “Transport only under conditions clearly 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 Review	No required	N
9.4.2.3	Instability from horizontal and vertical forces		P
	a) ME EQUIPMENT with a mass of 25 kg or more, other than FIXED ME EQUIPMENT for use on floor, did not overbalance due to pushing, resting, etc	＜25 kg	N/A
	Surfaces of ME EQUIPMENT 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)		P
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a force of 25 % of its weight, but not more than 220 N, applied in different directions, except a direction with an upward component		P

	b) ME EQUIPMENT, other than FIXED ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping, except when a legible warning of this RISK provided on ME EQUIPMENT (e.g., safety signs 6 and 7 of Table D.2, safety signs ISO 7010-P018, or ISO 7010-P019 as appropriate)		P
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a constant downward 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		P
9.4.2.4	Castors and wheels		N
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	No castor or wheels	N
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 for use indicated more than one person needed (N).....:		N
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg configured with a SAFE WORKING LOAD, moved as in NORMAL USE 10 times in forward direction over (up and down) a solid vertical plane obstruction installed on the floor with wheels impacting the obstruction at a speed of 0.4 m/s ± 0.1 m/s for manual or with max speed for motor driven MOBILE ME EQUIPMENT		N
	ME EQUIPMENT went up the obstruction without overbalancing or any other unacceptable RISK as determined by examination of ME EQUIPMENT, its parts, and RISK MANAGEMENT FILE		N
	There was no reduction of CREEPAGE and CLEARANCES below 8.9, no access to parts exceeding limits in 8.4, and no access to moving parts capable of causing HARM, and		N
	– Assessment criteria in Clause 9 and 11.6 used		N
	– Dielectric strength Review of 8.8.3 conducted to evaluate integrity of solid SUPPLEMENTARY or REINFORCED INSULATION		N
	– CREEPAGE DISTANCES and AIR CLEARANCES measured compared favorably with min distances in clause 8.9		N
	Small chips not adversely affecting protection against electric shock or moisture, disregarded		N
9.4.3	Instability from unwanted lateral movement (including sliding)		N
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	No such equipment	N

	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements of ME EQUIPMENT or its parts in transport position	No such equipment	N
	c) No unacceptable RISK due to 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 the worst-case position	No such equipment	N
	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).....:	No such equipment	N
	RISK due to any initial movement assessed taking into consideration NORMAL USE of ME EQUIPMENT	No such equipment	N
9.4.3.2	Instability excluding transport		P
	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)...:	No such equipment	N
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT		N
	b) TRANSPORTABLE or STATIONARY ME EQUIPMENT for use on the floor and 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	No such equipment	N
	Further movement of ME EQUIPMENT (after initial elastic movement), was no more than 50 mm when a force of 25 % of weight of unit, but less than 220 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
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT		N
9.4.4	Grips and other handling devices		N
	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 HAZARDS		N
	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
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carring by two or more persons as confirmed by actual carrying		N

	c) Carrying handles and grips and their means of attachment withstood application of a force four times weight of ME EQUIPMENT in different directions of NORMAL USE and transport (N)..... :		N
	Force distributed between multiple handles, when supplied, of PORTABLE ME EQUIPMENT by measuring percentage of ME EQUIPMENT weight sustained by each handle with ME EQUIPMENT in normal carrying position (N).....:		N
	Each handle of ME EQUIPMENT with multiple handles able of be carried by only one handle was capable of sustaining total force (N).....:		N
	Force applied uniformly over a 7 cm length of handle at centre, starting at zero and gradually increased to Review value in 5 to 10 s and maintained for 1 min		N
	Handles did not break loose, did not exhibit permanent distortion, cracking, or other evidence of breakdown		N
9.5	Expelled parts HAZARD		P
9.5.1	Suitability of means of protecting against unacceptable RISK of expelled parts determined by assessment and examination of RISK MANAGEMENT FILE	No parts likely to be expelled from unit	P
9.5.2	Cathode ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965		N
9.6	Acoustic energy (including infra- and ultrasound) and vibration		N
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK as confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and Reviews of 9.6.2 and 9.6.3		P
9.6.2	Acoustic energy		P
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE, except for auditory alarm signals	See below	P
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA) .....:		P
	– 140 dB un-weighted sound pressure level for impulsive or impact acoustic energy (noise) (dB) :		P
	Maximum A-weighted sound pressure level was measured at min distances of PATIENT, OPERATOR, or other persons from source of noise in NORMAL USE (or calculated per ISO 3746, ISO 9614-1 or IEC61672-1) under following conditions:		P
	a) ME EQUIPMENT operated under worst-case NORMAL CONDITION		P
	b) All protective means provided or called for in ACCOMPANYING DOCUMENTS were in place during sound measurement		P

	c) Sound level meters used in measurement conform to IEC 61672-1 and IEC 61672-2		P
	d) Review room was semi-reverberant with hard reflecting floor, distance between any wall or other object and surface of ME EQUIPMENT was ≥ 3 m		P
9.6.2.2	RISK MANAGEMENT FILE examined for RISKS associated with infrasound or ultrasound, when present, addressed in RISK MANAGEMENT PROCESS		P
9.6.3	Hand-transmitted vibration		N
	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 per ISO 5349-1 at points of hand contact with PATIENT or OPERATOR		P
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2).....:		P
	– Accelerations for different times, inversely proportional to square root of time (m/s^2)..... :		P
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N
9.7.1	Requirements of this clause applied to vessels and parts of ME EQUIPMENT subject to pressure resulting in rupture and unacceptable RISK	No pressurized parts	N
	Parts of a pneumatic or hydraulic system used as a support system, additionally, complied with 9.8		N
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met following requirements based on examination of RISK MANAGEMENT FILE:		N
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		N
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		N
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		N
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply		N
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N
	– 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

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) RATED maximum supply pressure from an external source		N
	b) Pressure setting of a pressure-relief device provided as part of assembly		N
	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
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 examination of ME EQUIPMENT and RISK MANAGEMENT FILE, and by functional Reviews		N
9.7.5	A pressure vessel withstood a HYDRAULIC REVIEW PRESSURE when pressure was > 50 kPa, and product of pressure and volume was > 200 kPa.l		N
	HYDRAULIC REVIEW PRESSURE was MAXIMUM PERMISSIBLE WORKING PRESSURE times a factor obtained from Fig 32, and pressure was gradually raised to specified Review value and held for 1 min		N
	Sample did not burst, was not permanently deformed, and no leaks developed		N
	No leakage occurred at a gasket at a pressure below 40 % of required Review value, or below MAXIMUM PERMISSIBLE WORKING PRESSURE..... :		N
	No leakage occurred for pressure vessels intended for toxic, flammable, or otherwise hazardous substances, and for other pressure vessels, leakage resulting in an unacceptable RISK did not occur (e.g., high pressure fluid jet)		N
	When unmarked pressure vessels and pipes could not be hydraulically Reviewed, integrity verified by other suitable Reviews.....:		N
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 under different conditions of NORMAL USE		N
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 Reviews:		N
	a) Connected as close as possible to pressure vessel or parts of system it is intended to protect		N

	b) Installed to be readily accessible for inspection, maintenance, and repair		N
	c) Could be adjusted or rendered inoperative without a TOOL		N
	d) With discharge opening located and directed as to not to release material towards any person		N
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		N
	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
	g) No shut-off valve provided between a pressure-relief device and parts it is intended to protect		N
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N
9.8	HAZARDS associated with support systems		N
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK	No support system	N
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		N
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		N
	– RISK ANALYSIS of support systems included HAZARDS from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions		N
	– 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
	– Instructions on attachment of structures to a floor, wall, ceiling, etc. included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials		N
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		N

9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or when support is a foot rest		N
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and processing of materials		N
	When Review results were part of information, Reviewing consisted of application of a Review load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under Review was in equilibrium after 1 min, or not resulted in an unacceptable RISK		N
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		N
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS minimize RISK of physical injuries and accidental loosening of secured joints		N
	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 or suspended by ME EQUIPMENT or its parts		N
	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
	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
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		N
	Max allowable PATIENT mass > 135 kg stated in ACCOMPANYING DOCUMENTS		N
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance		N
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
	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) 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
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and Reviews:		N
	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
	Damage or deflection resulting in an unacceptable RISK did not occur on foot rest and its secured joints		N
	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
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and by a Review:		N
	PATIENT support/suspension system set in most unfavorable 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 center of load 60 mm from outer edge of support or suspension system for at least one minute (Kg).....:		N
	Deflection of support/suspension system resulting in an unacceptable RISK did not occur		N
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE did not result in an unacceptable RISK as confirmed by following Review:		N
	PATIENT support/suspension system set in most unfavorable NORMAL USE position, and a mass as in Fig 33 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 (Kg)..... :		N
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES		N
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
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		N
	– Designed based on TOTAL LOAD, and includes effects of SAFE WORKING LOAD when applicable		N

	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N
	– Activated before travel (movement) produced an unacceptable RISK		N
	– Takes into account Clauses 9.2.5 and 9.8.4.3		N
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing		N
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
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		N
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		N
	– Further use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE		N
	– 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 again		N
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.2 (i.e., safety sign 7010-W001)		N
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE or its location relative to MECHANICAL PROTECTIVE DEVICE is obvious to service personnel		N
	– Compliance confirmed by examination of ME EQUIPMENT, ACCOMPANYING DOCUMENTS, RISK MANAGEMENT FILE, specifications and processing of materials, and following Review:		N
	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
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		N
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		N
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		N
	Support system parts have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 1 and 2, and are not impaired by wear		N

	Support system parts impaired by wear, however, they have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 3 and 4		N
	Examination of ME EQUIPMENT and RISK MANAGEMENT FILE confirmed compliance		N

10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		N
10.1	X-Radiation		N
10.1.1	X-radiation dose-rate was ≤ 36 pA/kg (5 µSv/h) (0.5 mR/h) 5 cm from surface of ME EQUIPMENT including background radiation for ME EQUIPMENT not producing therapeutic/diagnostic X-radiation but producing ionizing radiation	No X-radiation	N
	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
	ME EQUIPMENT operated as in NORMAL USE at most unfavorable RATED MAINS VOLTAGE and controls adjusted to emit maximum radiation		N
	Internal preset controls not intended for adjustment during EXPECTED SERVICE LIFE of ME EQUIPMENT not taken into consideration		N
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE (see IEC 60601-1-3 & 1.3)		N
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N
10.3	RISK associated with microwave radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N
10.4	Relevant requirements of IEC 60825-1:1993 applied to lasers, light emitting diodes (LEDs), and laser light barriers or similar products		N
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
10.6	RISK associated with infrared radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE		N

11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		**P**
11.1	Excessive temperatures in ME EQUIPMENT		P
11.1.1	Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and 23 operating in worst-case NORMAL USE at maximum rated ambient operating temperature T	See Review records	P
	Surfaces of Review corner did not exceed 90 °C		P
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	None	N
11.1.2	Temperature of APPLIED PARTS		P
11.1.2.1	Temperatures, hot or cold surfaces, and when appropriate, clinical effects of APPLIED PARTS supplying heat to a PATIENT determined and documented in RISK MANAGEMENT FILE and instructions for use	Not supplying heat	N
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 with respect to body surface, maturity of PATIENTS, medications taken, surface pressure, as documented in RISK MANAGEMENT FILE	See Review records	P
	Surfaces of APPLIED PARTS cooled below ambient temperatures that can also result in HAZARD evaluated as part of RISK MANAGEMENT PROCESS	No cooling	N
11.1.3	Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE	Temperature measurement made.	P
	Review corner not used where engineering judgment and rationale by MANUFACTURER indicated Review corner will not impact measurements, as documented in RISK MANAGEMENT FILE	Review corner necessary based on unit size and intended use.	P
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE	Considered	P
	a) ME EQUIPMENT positioned for Reviews in accordance with this clause	Considered	P
	b) Supply voltage was in accordance with this clause	Considered	P
	c) Thermal stabilization for temperature Reviews has been established, and	Temperature stabilized	P
	– Non-CONTINUOUS OPERATION: After operating in standby/quiescent mode until THERMAL STABILITY reached, ME EQUIPMENT operated in NORMAL USE over consecutive cycles until THERMAL STABILITY was achieved again, or for 7 h, the shorter of the two, and RATED “on”/“off” periods used	Continuous operation	N

	– CONTINUOUS OPERATION: ME EQUIPMENT operated until THERMAL STABILITY reached	Temps stabilized	P
	d) Temperatures measured based on this clause using thermocouples and/or for copper windings, by-the-change-of-resistance method	Thermocoupler used	P
	e) THERMAL CUT-OUTS were not de-activated, and Review criteria was based on this clause	None	P
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	None	P
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 Reviews for ENCLOSURES in 15.3	Enclosure has adequate strength –see mechanical strength Reviews records	P
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		N
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of fire under NORMAL or SINGLE FAULT CONDITIONS when source of ignition is in contact with ignitable material	Not for use in oxygen rich environments.	N
	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) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT in NORMAL and SINGLE FAULT CONDITIONS under any of following conditions:		N
	1) when temperature of material raised to its ignition temperature		N
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures resulting in sparking or increasing material temperature to its ignition temperature		N
	3) when parts affecting safety cracked or changed their outer shape exposing temperatures > 300 °C or sparks due to overheating		N
	4) when temperatures of parts or components exceeded 300 °C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N
	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
	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
	Alternative Review in this clause did not identify existence of ignition sources at highest voltage or current, respectively		N

	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three.....:		N
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, each by itself, or in combination		N
	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
	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
	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
	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		P
	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 having reached PATIENT		P
11.2.2.2	RISK of ignition under least favorable conditions did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to appropriate location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT when electrical components mounted on the outside of ME EQUIPMENT or an ME SYSTEM		N
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
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		N

	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		N
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered		N
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2).....:		N
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3).....:		N
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a).....:		N
	– 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
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas.....:		N
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT		P
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2	Meets this clause	P
	Following constructional requirements were met	See below	P
	Or, following constructional requirements specifically analyzed in RISK MANAGEMENT FILE	See below	P
	Specific justification provided when requirement not met	Considered	P
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials	UL approved wire used rated VW-1	P
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as determined by examination of data on materials	Connectors and PCBs are V-0	P
	In absence of Certification, FV Reviews based on EC 60695-11-10 conducted on 3 samples of complete parts or sections of a part, including area with minimum thickness and ventilation openings	Adequate into provided	P
	b) Fire ENCLOSURE met following:	See below	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	N
	2) No openings on the sides within the area that is included within the inclined line C in Fig 39	Side / top openings are acceptable	P

	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and made of metal, except magnesium, or of non-metallic materials, except constructions based on Table 25 and a mesh, FV-2 or better for TRANSPORTABLE ME EQUIPMENT and FV-1 or better for fixed ME EQUIPMENT, or STATIONARY ME EQUIPMENT per IEC 60695-11-10, as determined by examination of ENCLOSURE or flammability classification based on 11.3 a)	Enclosure rated V-0	P
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anesthetics		N
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable anesthetics (CATEGORY AP) or anesthetics with oxidants (CATEGORY APG) comply with Annex G	Not AP or APG	N
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		N
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE	Not for use with flammable agents.	N
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT		P
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT	Cleaning method specified in manual does not pose a hazard.	P
11.6.2	Overflow in ME EQUIPMENT		N
	Liquid reservoir liable to be overfilled or to overflow in NORMAL USE completely filled and 15 % of its capacity poured in over a period of 1 min, and except when restricted, TRANSPORTABLE ME EQUIPMENT tilted through an angle of 15° in least favorable direction(s), and when necessary refilled starting from position of NORMAL USE		N
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT Reviews and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet	n	N
11.6. 3	Spillage on ME EQUIPMENT and ME SYSTEM	No liquid used	P
	ME EQUIPMENT and ME SYSTEMS handling liquids in NORMAL USE positioned as in 5.4 a) and liquid with composition, volume, duration of spill, point of contact, and Review conditions based on RISK MANAGEMENT PROCESS poured steadily on a point on top of ME EQUIPMENT		N

	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT Reviews and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet	IPX0	N
11.6.4	Leakage	No liquid used	N
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		P
	ME EQUIPMENT with IP Code placed in least favorable position of NORMAL USE and subjected to Reviews of IEC 60529 (IP Code).....:	IPX0	N
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT Reviews and there were no bridging of insulation or electrical components that could result in a HAZARDOUS SITUATION in NORMAL CONDITION or in a SINGLE FAULT CONDITION		N
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 in accordance with methods specified in instructions for use including any cooling or drying period	Cleaning method specified in manual does not pose any hazards.	P
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT Reviews and there was no deterioration resulting in an unacceptable RISK	Same above	P
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT, their parts and ACCESSORIES, evaluated by MANUFACTURER and assurance that no unacceptable RISK will occur verified by RISK MANAGEMENT FILE review	Same above	P
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		N
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented according to ISO 11134, ISO 11135, or ISO 11137 as appropriate	Not sterilized	N
	After the Review, ME EQUIPMENT complied with the appropriate dielectric strength and LEAKAGE CURRENT Reviews and there was no deterioration resulting in an unacceptable RISK		N
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE		N
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented according to ISO 10993		N
11.8	Interruption and restoration of power supply did not result in a HAZARDOUS SITUATION, except interruption of its intended function	No hazards from power supply interruption.	P

12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		P
12.1	RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review		P
12.2	RISK of poor USABILITY, including those associated with identification, marking, and documents addressed in a USABILITY ENGINEERING PROCESS as confirmed by review of provided records		P
12.3	The need for alarm systems as a means of RISK CONTROL and RISKS associated with operation or failure of alarm system addressed in RISK MANAGEMENT PROCESS		P
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 by review of RISK MANAGEMENT FILE		P
12.4.2	When applicable, need for indication of parameters associated with hazardous output addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		P
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 as confirmed by review of 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		P
12.4.5	Diagnostic or therapeutic radiation		N
12.4.5.1	Adequate provisions made to protect PATIENTS, OPERATORS, other persons, and sensitive devices in vicinity of unwanted or excessive radiation emitted by ME EQUIPMENT designed to produce radiation for diagnostic or therapeutic purposes	No such radiaion	N
	Radiation safety ensured by compliance with requirements of appropriate standards		N
12.4.5.2	RISKS associated with diagnostic X-rays addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		N
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE		N
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

12.4.6	When applicable, RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE		N

13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		P
13.1	Specific HAZARDOUS SITUATIONS		P
13.1.1	None of HAZARDOUS SITUATIONS in 13.1.2-13.1.4, inclusive, occurred when SINGLE FAULT CONDITIONS applied, one at a time, as in 4.7 and 13.2	See relevant clauses	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 hazards created during fault Reviewing	P
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur	No deformation of enclosure	P
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 when measured as in 11.1.3	See Review records	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 Review records	P
	–Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C were not exceeded	See Review records	P
	Limits for windings in Tables 26, 27, and 31 not exceeded	No windings providing insulation outside of approved power supply	P
	Table 22 not exceeded in all other cases	See Review records	P
	Temperatures measured according to 11.1.3	See Review records	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:	Review performed	P
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit, or	Review performed	P
	– Parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by examination of design documentation	Review performed	P
	After Reviews of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function	No such device	P
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed	See Review records	P
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed	See Review records	P

13.1.4	ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS	No mechanical hazards created	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) also applied in least favorable combination	Considered	P
13.2.2 – 13.2.12	ME EQUIPMENT complied with 13.2.2 -13.2.12	Complied	P
13.2.13	ME EQUIPMENT remained safe after Reviews of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to room temperature	Complied	P
	ME EQUIPMENT examined for compliance or appropriate Reviews such as dielectric strength of motor insulation according to 8.8.3 conducted	No motors	P
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION (see 8.8), the ball-pressure Review specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during Reviews of 13.2.13.2 to 13.2.13.4 (inclusive).	Review performed at 75°C	P
13.2.13.2	ME EQUIPMENT with heating elements		N
	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 Reviews of 13.2.13.2 b) & 13.2.13.2 c)	No heating elements	N
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met Reviews of 13.2.13.2 b) and 13.2.13.2 c)		N
	a 3) other ME EQUIPMENT with heating elements met Review of 13.2.13.2 b)		N
	When more than one Review was applicable to same ME EQUIPMENT, Reviews performed consecutively		N
	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
	Review repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		N
	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
	b) ME EQUIPMENT with heating elements Reviewed per 11.1without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favorable of the two (V).....:		N

	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY		N
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		N
	Review duration was equal to RATED operating time for non-CONTINUOUS OPERATION		N
	c) Heating parts of ME EQUIPMENT Reviewed with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and		N
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS		N
	2) When more than one control provided, they were disabled in turn		N
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		N
13.2.13.3	ME EQUIPMENT with motors		N
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by Reviews of 13.2.8-13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable	No motors	N
	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 Review		N
	a 2) Reviews on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor and heating parts operated simultaneously to produce the least favorable condition		N
	a 3) Reviews performed consecutively when more Reviews were applicable to the same ME EQUIPMENT		N
	b) Motor met running overload protection Review of this clause when:		N
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended		N
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C).....:		N
	Motor removed from ME EQUIPMENT and Reviewed separately when load could not be changed in appropriate steps		N

	Running overload Review 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
	Review not conducted where electronic drive circuits maintained a substantially constant drive current		N
	Review not conducted based on other justifications (justification).....:		N
	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
13.2.13.4	ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION		N
	ME EQUIPMENT other than HAND-HELD EQUIPMENT, EQUIPMENT kept switched on manually or kept under load by hand, and with a timer and a back-up timer system, 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	Units is rated for continuous operation	N
	When a load-reducing device operated in NORMAL USE, Review continued with ME EQUIPMENT running idle		N
	Motor winding temperatures did not exceed values in 13.2.10 (Insulation Class, Maximum temperature measured °C).....:		N

14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		N
14.1	Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE; or		N
	when application of ISO 14971 showed that failure of PESS does not lead to unacceptable RISK		N
	Every PROCESS has been followed throughout the PEMS DEVELOPMENT LIFE-CYCLE and a RECORD of PROCESS has been made available as confirmed by examination of RISK MANAGEMENT FILE and assessment of PROCESSES cited in this Clause		N
	MANUFACTURER considered the need for additional RISK CONTROL measures when unable to follow all PROCESSES identified in Clause 14 for each constituent component of PEMS as confirmed by examination of RISK MANAGEMENT FILE and assessment of PROCESSES cited in this Clause		N
	Assessment of PROCESSES cited in this Clause made by internal audits		N

14.2	Documents produced from application of Clause 14 have been maintained and form a part of RISK MANAGEMENT FILE in addition to RECORDS and documents required by ISO 14971		N
	Documents required by Clause 14 reviewed, approved, issued and changed in accordance with a formal document control PROCEDURE		N
14.3	RISK MANAGEMENT plan required by 3.5 of ISO 14971 includes reference to PEMS VALIDATION plan		N
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented		N
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		N
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone		N
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules		N
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		N
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		N
	Problem resolution system meets the prescribed criteria depending on type of product:		N
	– it is documented as a part of PEMS DEVELOPMENT LIFE-CYCLE		N
	– it allows reporting of potential or existing problems affecting BASIC SAFETY or ESSENTIAL PERFORMANCE		N
	– it includes an assessment of each problem for associated RISKS		N
	– it identifies criteria that must be met for the issue to be closed		N
	– it identifies the action to be taken to resolve each problem		N
14.6	RISK MANAGEMENT PROCESS		N
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including NETWORK/DATA COUPLING, components of third-party origin and legacy subsystems when compiling list of known or foreseeable HAZARDS		N
	In addition to the material in ISO 14971, Annex D, list of possible sources for HAZARDS associated with PEMS includes specified causes		N

	– failure of NETWORK/DATA COUPLING to provide characteristics necessary for PEMS to achieve its BASIC SAFETY or ESSENTIAL PERFORMANCE		N
	– undesired feedback [physical and data] (possibilities include: unsolicited input, out of range or inconsistent input, and input originating from electromagnetic interference)		N
	– unavailable data		N
	– lack of integrity of data		N
	– incorrect data		N
	– incorrect timing of data		N
	– unintended interactions within and among PESS		N
	– unknown aspects or quality of third-party software		N
	– unknown aspects or quality of third-party PESS		N
	– lack of data security, particularly vulnerability to tampering, unintended interaction with other programs and viruses		N
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 6.1 of ISO 14971		N
14.7	There is 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		N
14.8	An architecture satisfying the requirement is specified for PEMS and each of its subsystems		N
	The architecture specification makes use of considers the specified items to reduce RISK to an acceptable level, where appropriate:		N
	a) COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS		N
	b) fail-safe functions		N
	c) redundancy		N
	d) diversity;		N
	e) partitioning of functionality		N
	f) defensive design potentially limiting hazardous effects by restricting available output power or by introducing means to limit travel of actuators		N
	g) allocation of RISK CONTROL measures to subsystems and components of PEMS		N
	h) failure modes of components and their effects;		N
	i) common cause failures		N
	j) systematic failures		N

	k) Review interval duration and diagnostic coverage		N
	l) maintainability		N
	m) protection from reasonably foreseeable misuse		N
	n) NETWORK/DATA COUPLING specification, when applicable		N
14.9	Design is broken up into subsystems, each with a design and Review specification where appropriate, and descriptive data on design environment included in RISK MANAGEMENT FILE		N
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures:		N
	– milestone(s) when VERIFICATION is to be performed for each function		N
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		N
	– selection and utilization of VERIFICATION tools		N
	– coverage criteria for VERIFICATION		N
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY and ESSENTIAL PERFORMANCE and requiring checks for unintended functioning of PEMS used to perform and document PEMS VALIDATION		N
	The person with overall responsibility for PEMS VALIDATION is independent of design team, and no member of a design team can be responsible for PEMS VALIDATION of their own design		N
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE referencing methods and results of PEMS VALIDATION		N
14.12	This Clause applied when any or all of the design was result of a modification of an earlier design		N
	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE		N
14.13	Technical description includes the following information when PEMS is intended to be connected to other equipment outside control of PEMS MANUFACTURER by NETWORK/DATA COUPLING:		N
	a) characteristics of NETWORK/DATA COUPLING necessary for PEMS to achieve its INTENDED USE		N
	b) list of HAZARDOUS SITUATIONS resulting from a failure of NETWORK/DATA COUPLING to provide the specified characteristics		N

	c) instructions to RESPONSIBLE ORGANIZATION containing following information and warnings:		N
	– connection of PEMS to a NETWORK/DATA COUPLING that includes other equipment could result in previously unidentified RISKS to PATIENTS, or OPERATORS and RESPONSIBLE ORGANIZATION should identify, analyze, and control such RISKS		N
	– subsequent changes to NETWORK/DATA COUPLING introducing new RISKS and requiring new analysis; and changes to NETWORK/DATA COUPLING include:		N
	– changes in NETWORK/DATA COUPLING configuration		N
	– connection of additional items to NETWORK/DATA COUPLING		N
	– disconnecting items from NETWORK/DATA COUPLING		N
	– update of equipment connected to NETWORK/DATA COUPLING		N
	– upgrade of equipment connected to NETWORK/DATA COUPLING		N

15	**CONSTRUCTION OF ME EQUIPMENT**		N
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS, as confirmed by examination of RISK MANAGEMENT FILE		N
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, and 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
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring	Unit to be returned to manufacturer for repairs	N
15.3	Mechanical strength		N
15.3.1	Mold stress relief, push, impact, drop, and rough handling Reviews did not result in unacceptable RISK and ME EQUIPMENT displayed adequate mechanical strength	Na hazards result from these Reviews	N
15.3.2	Push Review conducted by subjecting external parts of ENCLOSURE to a steady force of 250 N ± 10 N for 5 s applied to a circular plane surface 30 mm in diameter, except bottom of ENCLOSURE of an ME EQUIPMENT >18 kg, using a suitable Review tool		N
	No damage resulting in an unacceptable RISK sustained as determined by examination of RISK MANAGEMENT FILE	No hazards occurred from Review	N

15.3.3	Impact Review conducted by subjecting a complete ENCLOSURE or its largest non-reinforced area, except for HAND-HELD ME EQUIPMENT and parts, to a free falling 500 g ± 25 g solid smooth steel ball, approx. 50 mm in diameter from a height of 1.3 m		N
	Review not applied to flat panel displays, platen glass of ME EQUIPMENT, or cathode ray tubes	Considered	N
	No damage resulting in an unacceptable RISK sustained as shown in RISK MANAGEMENT FILE	No hazards occurred from Review	N
15.3.4	Drop Review		N
15.3.4.1	Each sample of HAND-HELD ME EQUIPMENT 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 (hardwood > 600 kg/m3) lying flat on a concrete or rigid base	Not hand-held	N
	No unacceptable RISK resulted		N
15.3.4.2	Each sample of PORTABLE ME EQUIPMENT and PORTABLE part with SAFE WORKING LOAD lifted to a height as in Table 29 above a 50 mm ± 5 mm thick hardwood board at least the size of sample lying flat on a concrete floor or rigid base, dropped 3 times from each orientation in NORMAL USE	Drop Review performed	N
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE	No hazard created	N
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 specified Reviews:	Not considered mobile per the definition in this standard.	N
	a) Ascending step shock Review conducted on the sample by pushing it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s against an ascending hardwood step obstruction attached to a floor without the sample going over obstruction		N
	b) Descending step shock Review conducted on the sample by pushing it 3 times in its normal direction of travel at 0.4 m/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 descending step until full descent was achieved		N
	c) Door frame shock Review conducted on the sample by moving it 3 times in its normal direction of travel at 0.4 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) affixed to a vertical rigid support with movement perpendicular to face of obstacle		N

	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE		N
15.3.6	When appropriate, review of available data and examination of ENCLOSURE constructed from molded or formed thermoplastic material indicated shrinkage or distortion of material due to release of internal stresses caused by molding or forming operations will not result in an unacceptable RISK	Review performed, see below	N
	Mould stress relief Review conducted in the absence of data by placing one sample of complete ME EQUIPMENT, ENCLOSURE and framework, or for large EQUIPMENT, a portion of ENCLOSURE, in a circulating air oven at 10 °C over than max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C, for 7 h	Mold stress Review performed	N
	No damage resulting in an unacceptable RISK	No harzards created	N
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	Material acceptable for intended use	N
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant Reviews 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	Material acceptable for intended use	N
15.4	ME EQUIPMENT components and general assembly		N
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular:	Connection are all keyed differently	N
	a) Plugs for connection of PATIENT leads cannot be connected to other outlets on same ME EQUIPMENT intended for other functions, except when RISK MANAGEMENT FILE provides proof that no unacceptable RISK could result	Connection are all keyed differently	N
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable as verified by review of RISK MANAGEMENT FILE	No gas connections	N
15.4.2	Temperature and overload control devices		N
15.4.2.1	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could result in a HAZARDOUS SITUATION by resetting action as verified by review of RISK MANAGEMENT FILE	No such devices	N
	b) THERMAL CUT-OUTS with a safety function to be reset by a soldering operation affecting operating value not fitted in ME EQUIPMENT as verified by examination of design and RISK MANAGEMENT FILE		N

	c) An independent non-SELF-RESETTING THERMAL CUT-OUT is, additionally, provided where a failure of a THERMOSTAT could constitute a HAZARD as verified by examination of design and RISK MANAGEMENT FILE		N
	d) Based on design and RISK MANAGEMENT FILE review, loss of function of ME EQUIPMENT due to operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION		N
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		N
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety of ME EQUIPMENT as verified by following Reviews:		N
	Positive temperature coefficient devices (PTC's) complied with IEC 60730-1: 1999, clauses 15, 17, J.15, and J.17 as applicable		N
	ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13		N
	SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) Certified in accordance with appropriate IEC standards		N
	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
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		N
	In the absence of certification per IEC standards, or data from MANUFACTURER demonstrating reliability of component to perform its safety-related function, manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		N
	Thermal protective devices Reviewed separately from ME EQUIPMENT when engineering judgment indicated Review results would not be impacted		N
	g) Protective device, provided on ME EQUIPMENT incorporating a fluid filled container with heating means, operated when heater switched on with container empty preventing occurrence of an unacceptable RISK due to overheating		N
	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 examination of design and RISK MANAGEMENT FILE		N

15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS		N
15.4.3	Batteries		N
15.4.3.1	Battery housings from which gases can escape during charging or discharging likely to result in a HAZARD ventilated to minimize RISK of accumulation and ignition as verified by examination of design and RISK MANAGEMENT FILE	No batteries	N
	Battery compartments prevent accidental short circuiting of battery when this could result in a HAZARDOUS SITUATION as verified by examination of design and RISK MANAGEMENT FILE		N
15.4.3.2	Means provided to prevent incorrect connection of polarity when a HAZARDOUS SITUATION may develop by incorrect connection or replacement of a battery		N
15.4.3.3	Overcharging of battery prevented by virtue of design when it could result in an unacceptable RISK as verified by review of design		N
15.4.3.4	Lithium batteries that could become a HAZARD complied with appropriate Reviews of IEC 60086-4		N
	Reviews of IEC 60086-4 waived on the lithium battery based on examination of design		N
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 cross-sectional area and layout of internal wiring or rating of connected components can result in a fire		N
	Protective device has adequate breaking capacity to interrupt the maximum fault current		N
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is included in RISK MANAGEMENT FILE		N
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	No such condition	N
	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	No such equipment	N
	Requirement not applied to heated stylus-pens for recording purposes	No heaters	N

	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	No such outputs	N
	Colors of indicator lights complied with 7.8.1	See 7.8.1	P
	Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE	No batteries	N
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 preset levels	N
15.4.6	Actuating parts of controls of ME EQUIPMENT		N
15.4.6.1	a) Actuating parts cannot be pulled off or loosened up during NORMAL USE		N
	b) Indication of scales (e.g., “on” “off” positions, etc.) always corresponds to position of controls with adjustment that can result in a HAZARDOUS SITUATION for PATIENT or OPERATOR while ME EQUIPMENT is in use		N
	c) Incorrect connection of indicating device to relevant component prevented by adequate construction when it could be separated without use of a TOOL		N
	When torque values in 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 with respect to shaft		N
	Reviews 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
15.4.6.2	Stops of adequate mechanical strength provided on rotating or movable parts of controls of ME EQUIPMENT where necessary to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter when this could cause a HAZARDOUS SITUATION		N
	Torque values in Table 30 applied 10 times in each direction to rotating controls for minimum 2 s		N
	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 required in NORMAL USE		N
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		N
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1	Not cord connected or foot operated	N
	b) Foot-operated control device supported an actuating force of 1350 N (i.e., weight of an adult human being) 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

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
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		N
15.4.7.3	a) Foot-operated control device is at least IPX1 and complies with Reviews of IEC 60529 (IP Code).....:		N
	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).....:		N
	Probability of occurrence estimated as part of RISK MANAGEMENT PROCESS		N
	ACCOMPANYING DOCUMENTS, design, and RISK MANAGEMENT FILE examined to confirm compliance		N
15.4.8	Aluminium wires less than 16 mm^2 in cross-sectional area not used		N
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
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		N
	A pressure-release device operating during NORMAL USE is, optionally, provided		N
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N
	ME EQUIPMENT and technical description examined, and manual Reviews conducted to confirm compliance with above requirements	See Attachment #s	N
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		N
15.5.1	Overheating		N
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating in the event of short circuit or overload of output windings and comply with this Clause and Reviews of 15.5.1.2 and 15.5.1.3	No transformer outside of approved power supply or approved isolation transformers	N
	During Reviews, windings did't open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		N
	Dielectric strength Review of 8.8.3 conducted on transformer after short circuit and overload Reviews		N

15.5.1.2	Transformer output winding short circuited, and Review continued until protective device operated or THERMAL STABILITY achieved	No transformer outside of approved power supply or approved isolation transformers	N
	Short circuit applied directly across output windings for transformers not Reviewed according to 5X frequency and 5X voltage Review of 15.5.2		N
15.5.1.3	Multiple overload Reviews conducted on windings with more than one protective device to evaluate worst-case NORMAL USE loading and protection	No transformer outside of approved power supply or approved isolation transformers	N
15.5.2	Transformer windings provided with adequate insulation to prevent internal short-circuits that could cause overheating which could result in a HAZARDOUS SITUATION	No transformer outside of approved power supply or approved isolation transformers	N
	Dielectric strength Reviews were conducted in accordance with requirements of this Subclause with no breakdown of insulation system and no detectable deterioration of transformer		N
	a) For RATED voltage ≤ 500 V or RATED frequency ≤ 60 Hz, Review voltage = 5 times RATED voltage or 5 times upper limit of RATED voltage range of that winding and a frequency ≥ 5 times RATED frequency (RATED frequency is the normal operating frequency of transformer input voltage)		N
	b) For rated voltage > 500 V or RATED frequency > 60 Hz = twice RATED voltage or twice the upper limit of RATED voltage range of that winding and a frequency ≥ twice RATED frequency		N
	Review voltage at winding with highest RATED voltage did not exceed Review voltage in Table 6 for one MEANS OF PROTECTION, when RATED voltage of such a winding was considered as WORKING VOLTAGE		N
	When above occurred, Review voltage on primary winding reduced accordingly, and Review frequency adapted to produce in the core approximately magnetic induction present in NORMAL USE		N
	– 3-phase transformers Reviewed using a 3-phase Reviewing device or by 3 consecutive Reviews using a single-phase Reviewing device		N
	– Value of Review voltage with respect to core and to any screen between primary and secondary windings was based on specification of relevant transformer		N
	Connection point for neutral of SUPPLY MAINS on primary winding connected to core and screen when provided, except when core and screen are for connection to an unearthed part of circuit		N

	Connections to core omitted where core of transformer was isolated from all external conductive connections		N
	Core and screen connected to a source with an appropriate voltage and frequency with respect to neutral connection point		N
	In the absence of a neutral connection point, each side of primary winding in turn connected to core and screen when provided, except when core and screen specified for connection to an unearthed part of circuit		N
	Core and screen connected to a source with an appropriate voltage and frequency with respect to each side of primary winding in turn		N
	– All windings not intended for connection to SUPPLY MAINS left open, and common earth connection point of windings or a point nearly at earth potential connected to core, except when core is for connection to an unearthed circuit part		N
	Core connected to a source with an appropriate voltage and frequency with respect to windings		N
	– Initially, no more than half prescribed voltage applied and raised over 10 s to full value, maintained for 1 min, and then reduced gradually and switched off		N
	– Reviews not conducted at resonant frequencies		N
	Slight corona discharges neglected, provided they ceased when Review voltage temporarily dropped to a lower value higher than WORKING VOLTAGE and discharges did not provoke a drop in Review voltage		N
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with IEC 61558-1:1997, Clause 5.12	No transformer outside of approved power supply or approved isolation transformers	N

16	**ME SYSTEMS**		P
16.1	ME SYSTEM did not result in an unacceptable RISK after installation or subsequent modification		P
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM taken into account		P
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard		P
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards		P
	– Reviews performed in NORMAL CONDITION, except as specified	Considered	P

	– Reviews performed under operating conditions specified by MANUFACTURER of ME SYSTEM	Considered	P
	Safety Reviews previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated	Considered	P
	RISK MANAGEMENT methods, optionally, used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR to determine configurations with highest RISKS and measures needed to ensure ME SYSTEM will not present an unacceptable RISK in any configuration	Considered	P
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards		P
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM	No such equipment	N
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM		P
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM	Provided in manual	P
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM	Manual covers the system	P
	ACCOMPANYING DOCUMENTS are, optionally, provided in electronic format (e.g. electronic file format or CD ROM) and ME SYSTEM is capable of displaying or printing these documents	Manual provided as hardcopy	P
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER	Manual covers the system	P
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER	Manual covers the system	P
	c) the required information is provided:	Manual covers the system	P
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM	Included in manual	P
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard	Included in manual	P
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM	Included in manual	P
	– additional safety measures to be applied during installation of ME SYSTEM	Included in manual	P
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT		P
	– additional measures to be applied during preventive maintenance	Included in manual	P

	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor	None	N
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM	None	N
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM		P
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM		P
	– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM		P
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer		P
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET		P
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage		P
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT		P
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:	Included in manual	P
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES	Included in manual	P
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard	Included in manual	P
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, sufficiently, describe the other equipment to ensure compliance with these requirements		P
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, etc., after removal of covers, connectors, etc., without use of a TOOL operated at a voltage ≤ voltage in 8.4.2 c) supplied from a source separated from SUPPLY MAINS by two MEANS OF OPERATOR PROTECTION	No such parts	N
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed	No such devices	N

	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION appropriate for highest voltage occurring across SEPARATION DEVICE during a fault condition		N
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V)..... :		N
16.6	LEAKAGE CURRENTS		P
16.6.1	TOUCH CURRENT in NORMAL CONDITION, from or between parts of ME SYSTEM within the PATIENT ENVIRONMENT, did not exceed 100 µA	See Review records	N
	TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, from or between parts of ME SYSTEM within PATIENT ENVIRONMENT	See Review records	N
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET did not exceed 5 mA.... :	None	N
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values specified for ME EQUIPMENT in Tables 3 and 4	See Review records	P
	Total PATIENT LEAKAGE CURRENT, optionally, measured at installation	Type Review performed	P
	Measurements made using a device as in 8.7.4.4	Clause taken into consideration	P
16.6.4	Measurements		P
16.6.4.1	a) TOUCH CURRENT, PATIENT and total EARTH LEAKAGE CURRENTS of MULTIPLE SOCKET-OUTLET measured after ME SYSTEM reached operating temperature as follows:	No such outlet other than on approved isolation transformer	N
	– ME SYSTEMS intended for non-CONTINUOUS OPERATION operated in standby/quiescent mode until THERMAL STABILITY, and then ME SYSTEM operated in NORMAL USE over consecutive cycles at RATED “on”/“off” periods until THERMAL STABILITY was again achieved, or for 7h, whichever shorter		N
	– ME SYSTEMS intended for CONTINUOUS OPERATION operated until THERMAL STABILITY		N
	b) ME SYSTEM connected to a supply at highest RATED MAINS VOLTAGE		P
	ME SYSTEM connected to local SUPPLY MAINS prior to its clinical use when characteristics of SYSTEM could only be measured properly after installation at RESPONSIBLE ORGANIZATION		P
	Number of Reviews reduced where examination of circuit arrangement, components, and materials of ME SYSTEM indicated no possibility of HAZARD		P
16.6.4.2	a) ME SYSTEM Reviewed after assembly based on ACCOMPANYING DOCUMENTS	System Reviewed, see Review records	P

	b) The reference earth of measuring circuits connected to protective earth of SUPPLY MAINS when an isolating transformer not used for LEAKAGE CURRENT measurements	Clause taken into consideration	P
16.7	ME SYSTEM complied with applicable requirements of Clause 9 when a MECHANICAL HAZARD existed	No mechanical hazards	P
16.8	Interruption and restoration of relevant power connections of ME SYSTEM one at a time and all connections simultaneously did not result in a HAZARDOUS SITUATION other than interruption of its intended function	No hazards created from power losss	P
16.9	ME SYSTEM connections and wiring		P
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where a HAZARDOUS SITUATION could otherwise exist	Key connector used	P
	– Connectors complied with Clause 15.4.1	Connector are adequate	P
	– Plugs for connection of PATIENT leads could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no HAZARDOUS SITUATION could result	Keyed connector used	P
16.9.2	MAINS PARTS, components and layout	See below	P
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or	No such outlet other than on approved isolation transformer	N
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		N
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		N
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 (i.e., safety sign ISO 7010-W001) visible in NORMAL USE, and	No such outlet other than on approved isolation transformer	N
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		N
	– marked to indicate the equipment or equipment parts it may safely be attached to		N
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT		N
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:	No such outlet other than on approved isolation transformer	N
	– CREEPAGE and CLEARANCES complied with 8.9		N
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets		N

	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6, except total impedance for ME SYSTEM was up to 400 mΩ, or higher when conditions of 8.6.4 b) met (mΩ).....:		N
	– ENCLOSURE complied with 8.4.2 d)		N
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable		N
	– RATINGS of components are not in conflict with conditions of use		N
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL		N
	– POWER SUPPLY CORD complied with 8.11.3		N
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:	No such outlets other than on approved isolation tranformer	N
	– Separating transformer complied with IEC 61558-2-1, except requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 were not applied		N
	– Separating transformer is CLASS I		N
	– Degree of protection against ingress of water specified as in IEC 60529		N
	– Separating transformer assembly marked according to 7.2 and 7.3		N
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083		N
16.9.2.2	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part of ME SYSTEM without simultaneous disconnection of electrical supply to that part		N
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by a TOOL		N
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage	PE connected via IEC inlet	P

17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		P
	RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review.....:	EMC Reviewing performance, see separate Review report	P
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS.....:	EMC Reviewing performance, see separate Review report	P

	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems	EMC Reviewing performance, see separate Review report	P

G	**ANNEX G, PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		N
G.2	Locations and basic requirements		N
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5	Not AP or APG equipment	N
G.2.2	FLAMMABLE ANESTHETIC MIXTURE WITH AIR occurring due to a leakage or discharge of a FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE from an ENCLOSURE considered 5 to 25 cm from point of occurrence		N
G.2.3	A FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE contained in a completely or partly enclosed ME EQUIPMENT part and in PATIENT'S respiratory tract 5 cm from an ENCLOSURE part where leakage or discharge occurs		N
G.2.4	ME EQUIPMENT or parts thereof specified for use with FLAMMABLE ANESTHETIC MIXTURE WITH AIR (in a location defined in G.2.2) are CATEGORY AP or APG ME EQUIPMENT and complied with G.4 and G.5		N
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (location per G.2.2) are CATEGORY APG ME EQUIPMENT and comply with G.4 and G.6		N
	ME EQUIPMENT in G.2.3 to G.2.5 met appropriate Reviews of G.3-G.5 conducted after Reviews of 11.6.6 and 11.6.7		N
G.3	Marking, ACCOMPANYING DOCUMENTS		N
G.3.1	CATEGORY APG ME EQUIPMENT marked on a prominent location with a green-colored band ≥ 2 cm wide imprinted with characters "APG" according to symbol 23 in Table D.1 (i.e., symbol IEC 60417-5332, DB: 2002-10)..... :		N
	Length of green-colored band is ≥ 4 cm, and size of marking is as large as possible for particular case		N
	When above marking not possible, relevant information included in instructions for use..... :		N
	Marking complied with Reviews and criteria of 7.1.2 and 7.1.3		N

G.3.2	CATEGORY AP ME EQUIPMENT marked on a prominent location with a green-colored circle ≥ 2 cm in diameter, imprinted with characters "AP" according to symbol 22 in Table D.1 (i.e., symbol IEC 60417- 5331, DB: 2002-10) .....:		N
	Marking is as large as possible for the particular case		N
	When above marking not possible, the relevant information included in instructions for use.....:		N
	Marking complied with Reviews and criteria of 7.1.2 and 7.1.3		N
G.3.3	The marking according to G.3.2 and G.3.3 placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts, and not repeated on detachable parts that can only be used with the marked EQUIPMENT		N
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts		N
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG		N
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT		N
G.4.1	a) CREEPAGE and CLEARANCES between points of POWER SUPPLY CORD connection are according to Table 12 for one MEANS OF PATIENT PROTECTION		N
	b) Connections, except those in circuits described in G.5.3 and G.6.3, protected against accidental disconnection in NORMAL USE or connection and disconnection can be performed only with a TOOL		N
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD, except when circuit complied with G.5.3 and G.6.3		N
G.4.2	Construction details		N
	a) Opening of an ENCLOSURE providing protection against penetration of gases or vapors into ME EQUIPMENT or its parts possible only with a TOOL		N
	b) ENCLOSURE complies with requirements to minimize arcing and sparking due to penetration of foreign objects.....:		N
	– no openings on top covers of ENCLOSURE, except for openings for controls covered by control knobs		N
	– openings in side-covers prevented penetration of a solid cylindrical Review rod of 4 mm in diameter applied in all possible directions without appreciable force		N
	– openings in base plates prevented penetration of a solid cylindrical Review rod of 12 mm in diameter applied in all directions without appreciable force		N

	c) Short circuiting conductor(s) to a conductive part without presence of explosive gasses where insulation may contact a part containing a FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE, ignitable gases alone, or oxygen, did not result in loss of integrity of the part, an unacceptable temperature, or other HAZARD		N
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures		N
	– Use of antistatic materials with a limited electrical resistance as specified in G.4.3 b).....:		N
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor of medical room		N
	b) Electrical resistance limits of anesthetic tubing, mattresses and pads, castor tires, and other antistatic material complied with ISO 2882 based on measurements according to ISO 1853, ISO 2878 and ISO 23529.....:		N
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or more than 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5		N
G.5	Requirements and Reviews for CATEGORY AP ME EQUIPMENT, parts and components thereof		N
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE ANESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5 (inclusive)		N
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5.....:		N
G.5.2	ME EQUIPMENT, its parts, and components in contact with gas mixtures in NORMAL USE and CONDITIONS not producing sparks and not resulting in surface temperatures above 150 °C in case of restricted vertical air circulation by convection, or 200 °C in case of unrestricted vertical air circulation measured at 25 °C comply with G.5.1. :		N
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:		N
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1..... :		N

	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ..... :		N
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 ..... :		N
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3.....:	I	N
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1		N
	No extrapolation made for voltages above 42 V		N
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2		N
	No extrapolation made for voltages above 242 V		N
	U_{max}, additionally, determined using actual resistance R when the equivalent resistance R was less than 8000 Ω		N
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3		N
	No extrapolation made for inductances larger than 900 mH		N
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open, taking into consideration MAINS VOLTAGE variations in 4.10		N
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed, taking into consideration MAINS VOLTAGE variations required in 4.10		N
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks		N
	– Peak value taken into account when a.c. supplied		N
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit.....:		N
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max} , and C_{max} determined together with application of Figs G.1-G.3..... :		N
	Alternatively, compliance was verified by examination of design data		N
G.5.4	External ventilation with internal overpressure		N
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:		N

	a) FLAMMABLE ANESTHETIC MIXTURES WITH AIR that might have penetrated into ENCLOSURE of ME EQUIPMENT or part removed by ventilation before EQUIPMENT energized, and penetration of such mixtures during operation was prevented by maintenance of overpressure by means of air without flammable gases, or by physiologically acceptable inert gas (e.g., nitrogen)		N
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa)..... :		N
	Overpressure maintained at the site of potential ignition even when air or inert gas could escape through openings in ENCLOSURE necessary for normal operation of ME EQUIPMENT or its parts		N
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE so that the displaced volume of air or inert gas was at least five times the volume of ENCLOSURE		N
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present		N
	c) Ignition sources de-energized automatically by means located in a place where G.4 does not apply, or complied with G.5 when during operation overpressure dropped below 50 Pa (Pa).....:		N
	d) External surface of ENCLOSURE in which internal overpressure was maintained did not exceed 150 °C in 25 °C ambient under NORMAL USE and CONDITION (°C).....:		N
G.5.5	ENCLOSURES with restricted breathing		N
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:		N
	a) A FLAMMABLE ANESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing when it was surrounded by a FLAMMABLE ANESTHETIC MIXTURE WITH AIR of a high concentration for at least 30 min without any pressure difference inside ENCLOSURE		N
	b) Gasket or sealing material used to maintain tightness complied with aging Review B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h...:		N
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained when the cords were stressed by bending or pulling		N
	Cords are fitted with adequate anchorages to limit stresses		N
	After the Review in G.5.4 b), an internal overpressure of 400 Pa was created and 30 pulls of the value in Table G.1 applied to each flexible cord in axial direction of cord inlet and in the least favorable perpendicular direction for 1 s		N

	Overpressure not reduced below 200 Pa		N
	Reviews waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		N
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C)..... :		N
	Steady state operating temperature of ENCLOSURE also measured (°C)..... :		N
G.6	Requirements and Reviews for CATEGORY APG ME EQUIPMENT, parts and components thereof		N
G.6.1	ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION		N
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION Review after attaining thermal steady state (max. 3 h) over a period of 10 min in a 12.2 % ± 0.4 ether by volume/oxygen mixture		N
G.6.2	Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to at least one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION..... :		N
G.6.3	Review of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS..... :		N
	a) no sparks produced and temperatures did not exceed 90 °C, or		N
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U_{max} and I_{max} occurring in their circuits complied with the requirements, taking C_{max} and L_{max} into consideration:		N
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 ..... :		N
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5.....:		N
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 ..... :		N
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 .....:		N
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated		N
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10		N
	– I_{max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10		N

	– C_{max} and L_{max} are values occurring in relevant circuit		N
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω		N
	– Peak value taken into consideration when a.c. supplied		N
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		N
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage limiting or current-limiting devices preventing limits of Figs G.4- G.6 from exceeding, two independent components applied, to obtain the required limitation even in case of a first fault (short or open circuit) in one of these components		N
	Above requirement not applied to transformers complying with this standard		N
	Above requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture		N
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or		N
	Temperature measurements made in accordance with 11.1, or		N
	U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6..... :		N
	Alternatively, compliance verified by comparison with design data		N
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1		N
	Current-carrying part of heating element is not in direct contact with FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE		N
G.7	Review apparatus for flammable mixtures		N
	Review apparatus used was in accordance with this Clause and Fig G.7		N

L	**ANNEX L, INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**	N

L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex covering round winding wires between 0.05 mm and 5.00 mm diameters		N
L.2	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component		N
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		N
L.3	The wire subjected to Reviews of L.3.1 to L.3.4 at a temperature between 15 °C and 35 °C and a relative humidity between 45 % and 75 %, unless otherwise specified (°C, % Humidity)..... :		N
L.3.1	Dielectric strength Review of 8.8.3 for the appropriate type and number of MOP(s) conducted by preparing the sample according to IEC 60851-5:1996, Clause 4.4.1 for a twisted pair with Review voltages at least twice Tables 6 and 7, but not less than following with no breakdown:		N
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N
	– 6000 V for REINFORCED INSULATION (V)..... :		N
L.3.2	Sample subjected to flexibility and adherence Review 8 of IEC 60851-3:1996, clause 5.1.1, using mandrel diameters of Table L.1		N
	Sample examined according to IEC 60851-3: 1997, clause 5.1.1.4, followed by dielectric Review of clause 8.8.3, except Review voltage applied between wire and mandrel with no breakdown		N
	Review voltage was at least the voltage in Tables 6 and 7but not less than the following:		N
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N
	– 3000 V for REINFORCED INSULATION (V)..... :		N
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa		N
L.3.3	Sample subjected to heat shock Review 9 of IEC 60851-6:1996, followed by dielectric strength Review of clause 8.8.3, except Review voltage applied between the wire and mandrel		N
	Review voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N
	– 3000 V for REINFORCED INSULATION (V)..... :		N
	Oven temperature set based on Table L.2 (°C)....:		N

	Mandrel diameter and tension applied as in L.3.2, ((118 MPa ± 11.8 MPa (118 N/mm^2 ± 11.8 N/mm^2))..... :		N
	Dielectric strength Review conducted at room temperature after removal from the oven		N
L.3.4	Five samples prepared as in L.3.2 subjected to dielectric strength and bending Reviews by removing each sample from the mandrel and placing it in a container surrounded by min. 5 mm of metal shot		N
	The ends of conductor in the sample were sufficiently long to avoid flash over, and the shot was no more than 2 mm in diameter and consisted of stainless, nickel, or nickel-plated iron		N
	The shot was gently poured into container until sample covered by at least 5 mm of shot, and the shot cleaned periodically with a suitable solvent (e.g., 1.1,1-trichloroethane)		N
	Review voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N
	– 3000 V for REINFORCED INSULATION (V)..... :		N
	Review voltage applied between the shot and conductor.		N
	Mandrel diameter and tension applied as in L.3.2, ((118 MPa ± 11.8 MPa (118 N/mm^2 ± 11.8 N/mm^2))..... :		N
L.4	Reviews during manufacture		N
L.4.1	Production line dielectric strength Reviews conducted by the manufacture according to L.4.2 and L.4.3		N
L.4.2	Review voltage for routine Reviewing (100 % Reviewing) is at least the voltage in Tables 6 and 7 but not less than the following:		N
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V)..... :		N
L.4.3	Sampling Reviews conducted using twisted pair samples according to IEC 60851-5:1996, clause 4.4.1		N
	Minimum breakdown Review voltage is at least twice the voltage in Tables 6 and 7 but not less than:		N
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION		N
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION		N

Review records

4.11	**TABLE: Power Input**	

Operating Conditions / Ratings	Voltage, (V)	Frequency, (Hz)	Power Rated	(W) Measured	input Rated	Current(A) measured

Supplementary Information:

7.1.3	**TABLE: Durability of marking Review 1**	P

Characteristics of the Marking Label Reviewed:		Remarks
Material (composition) of Marking Label .....:	PET (Rating label)	
Ink/other printing material or process.....:		
Method of application of ink to the Label.....:	adhesive	
Other.....:		
Material (composition) of Warning Label .....:	PET (Indicating label)	
Ink/other printing material or process.....:		
Method of application of ink to the Label.....:	adhesive	
Other.....:		

Supplementary information:

[1] Marking rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit, and then for 15 s with a cloth rag soaked with isopropyl alcohol.

8.4.3	**TABLE: ME EQUIPMENT intended to be connected 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
Maximum allowable voltage (V).....:		60									Remarks
Voltage measured (V)											
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10	
Plug pins 1 and 2											
Plug pin 1 and plug earth pin											
Plug pin 2 and plug earth pin											
Plug pin 1 and enclosure											
Plug pin 2 and enclosure											
Maximum allowable stored charge when measured voltage exceeded 60 V (μC).....:		45									Remarks
Calculated stored charge (μC)											
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10	
Plug pins 1 & 2											
Plug pin 1 & plug earth pin											
Plug pin 2 and plug earth pin											
Plug pin 1 and enclosure											
Plug pin 2 and enclosure											
Supplementary information:											

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

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

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

Supplementary information:

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

Review Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with Review voltage	Review voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks

Supplementary information:

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

Applied part with Review voltage	Review voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks

Supplementary information:

8.5.5.2	**TABLE: DEFIBRILLATION-PROOF APPLIED PARTS OR PATIENT CONNECTIONS OF DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction** **Review –measurement of Energy delivered to a 100 Ω load**	N

Review Voltage applied to	Measured Energy E1, (mJ)	Measured Energy E2, (mJ)	Energy E1 as % of E2, (%)
PATIENT CONNECTION 1 or APPLIED PART with PATIENT CONNECTIONS 2, 3, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 2 or APPLIED PART with PATIENT CONNECTIONS 1, 3, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 3 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 4 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 3 of the same APPLIED PART connected to earth			

Supplementary information:

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

Type of ME EQUIPMENT & impedance measured between parts	Review current (A)	Voltage drop measured between parts, (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)
PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part	25	-	74	100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part	N	N	N	N
ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part	N	N	N	N
Supplementary information:				

8.7A	**TABLE: Patient leakage currents and patient auxiliary currents under normal & single fault conditions – type b applied parts (μA)**	N

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	N	N	50	N
				a.c	N	50	500	N
PATIENT LEAKAGE CURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	N	N	50	N
				a.c	N	45	500	N
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	N	N	50	N
				a.c	N	50	500	N
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	N	N	100	N
				a.c	N	45	1000	N
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	N	N	100	N
				a.c	N	50	1000	N

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d)
Note 2: For TOUCH CURRENT see 8.7.3 c)
Note 3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

Note 4: In addition to conditions indicated in the Table, Reviews 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 Reviews of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

8.7B	**TABLE: Patient leakage currents and patient auxiliary currents under normal & single fault conditions – type bf applied parts (μA)**	N

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10		50	
				a.c	100		500	
PATIENT LEAKAGE CURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10		50	
				a.c	100		500	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10		50	
				a.c	100		500	
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	50		100	
				a.c	500		1000	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	50		100	
				a.c	500		1000	

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)
2: For TOUCH CURRENT see 8.7.3 c)
3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, Reviews 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 Reviews of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

8.7C	**TABLE: Patient leakage currents and patient auxiliary currents under normal & single fault conditions – type cf applied parts (μA)**	N

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10		50	
				a.c	10		50	
PATIENT LEAKAGE CURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10		50	
				a.c	10		50	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10		50	
				a.c	10		50	
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	50		100	
				a.c	50		100	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	50		100	
				a.c	50		100	

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)
2: For TOUCH CURRENT see 8.7.3 c)
3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, Reviews 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 Reviews of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

8.7.3A	**TABLE: Patient leakage currents and patient auxiliary currents under normal & single fault conditions – type b applied parts (mA r.m.s) – measurements made with a non-frequency-weighted device (μA)**	N

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10		10	
				a.c	10		10	
PATIENT LEAKAGE CURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10		10	
				a.c	10		10	
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	10		10	
				a.c	10		10	

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)
2: For TOUCH CURRENT see 8.7.3 c)
3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, Reviews 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 Reviews of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

8.7.3B	**TABLE: Patient leakage currents and patient auxiliary currents under normal & single fault conditions – type bf applied parts (mA r.m.s) – measurements made with a non-frequency-weighted device (μA)**	N

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10		10	
				a.c	10		10	
PATIENT LEAKAGE CURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10		10	
				a.c	10		10	
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	10		10	
				a.c	10		10	

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)
2: For TOUCH CURRENT see 8.7.3 c)
3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, Reviews 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 Reviews of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

8.7.3C	**TABLE: Patient leakage currents and patient auxiliary currents under normal & single fault conditions – type cf applied parts (mA r.m.s) – measurements made with a non-frequency-weighted device (μA)**	N

Current Type	Description	Clause Ref.	Measuring Circuit	a.c/ d.c	NC allowed	NC actual	SFC allowed	SFC actual
PATIENT AUX CURRENT	—	8.7.4.8	Fig 19	d.c	10		10	
				a.c	10		10	
PATIENT LEAKAGE CURRENT	From PATIENT CONNECTION to earth	8.7.4.7a)	Fig 15	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c)	Fig 17	d.c	10		10	
				a.c	10		10	
Total PATIENT LEAKAGE CURRENT See NOTE 3	With same types of APPLIED PART connected together	8.7.4.7a) and 8.7.4.7h)	Fig 15 and Fig 20	d.c	10		10	
				a.c	10		10	
	Caused by an external voltage on a SIP/SOP	8.7.4.7c) and 8.7.4.7h)	Fig 17 and Fig 20	d.c	10		10	
				a.c	10		10	

Supplementary information:

1: For EARTH LEAKAGE CURRENT see 8.7.3 d)
2: For TOUCH CURRENT see 8.7.3 c)
3: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

4: In addition to conditions indicated in the Table, Reviews 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 Reviews of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

8.7.3D	**TABLE: Patient leakage currents under special Review conditions identified in 8.7.4.7 (mA r.m.s) –measurement with a non-frequency-weighted device (μA)**	N

Current Type	Description (Note 1)	Clause Ref.	Measuring Circuit	TYPE B APPLIED PART allowed	TYPE B APPLIED PART actual	TYPE BF APPLIED PART allowed	TYPE BF APPLIED PART actual	TYPE CF APPLIED PART allowed	TYPE CF APPLIED PART actual
PATIENT LEAKAGE CURRENT	Caused by an external voltage on PATIENT CONN of an F-TYPE APPLIED PART	8.7.4.7b	Fig 16	N	N	10		10	
	Caused by an external voltage on ACCESSIBLE metal part not PROTECTIVELY EARTHED	8.7.4.7d	Fig 18	10		10		See Note 3	See Note 3
Total PATIENT LEAKAGE CURRENT See NOTE 3	Caused by an external voltage on PATIENT CONN of an F-TYPE APPLIED PART	8.7.4.7b and 8.7.4.7h	Fig 16 and Fig 20	N	N	10		10	
	Caused by an external voltage on ACCESSIBLE metal part not PROTECTIVELY EARTHED	8.7.4.7d and 8.7.4.7h	Fig 18 and Fig 20	10		10		See Note 3	See Note 3

Supplementary information:

1: The condition referred to in Table IV of the second edition as "MAINS VOLTAGE ON APPLIED PART", and treated in that edition as a SINGLE FAULT CONDITION, is treated in this edition as a special Review condition. The Review with MAXIMUM MAINS VOLTAGE on a non-PROTECTIVELY EARTHED ACCESSIBLE PART is also a special Review condition, but the allowable values are the same as for SINGLE FAULT CONDITION. See the rationales for 8.5.2.2 and 8.7.4.7d.

2: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

3: This condition is not Reviewed with TYPE CF APPLIED PARTS because it is covered by the Review with MAXIMUM MAINS VOLTAGE on the APPLIED PART. See also the rationale for 8.7.4.7 d).

4: In addition to conditions indicated in the Table, Reviews 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 Reviews of clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

8.7.4.7	**TABLE: Patient leakage currents under special Review conditions identified in 8.7.4.7 (μA)**	N

Current Type	Description (Note 1)	Clause Ref.	Measuring Circuit	TYPE B APPLIED PART allowed	TYPE B APPLIED PART actual	TYPE BF APPLIED PART allowed	TYPE BF APPLIED PART actual	TYPE CF APPLIED PART allowed	TYPE CF APPLIED PART actual
PATIENT LEAKAGE CURRENT	Caused by an external voltage on PATIENT CONN of an F-TYPE APPLIED PART	8.7.4.7b	Fig 16	N	N	5000		50	
	Caused by an external voltage on ACCESSIBLE metal part not PROTECTIVELY EARTHED	8.7.4.7d	Fig 18	500		500		See Note 3	See Note 3
Total PATIENT LEAKAGE CURRENT See NOTE 3	Caused by an external voltage on PATIENT CONN of an F-TYPE APPLIED PART	8.7.4.7b and 8.7.4.7h	Fig 16 and Fig 20	N	N	5000		100	
	Caused by an external voltage on ACCESSIBLE metal part not PROTECTIVELY EARTHED	8.7.4.7d and 8.7.4.7h	Fig 18 and Fig 20	1000		1000		See Note 3	See Note 3

Supplementary information:

1: The condition referred to in Table IV of the second edition as "MAINS VOLTAGE ON APPLIED PART", and treated in that edition as a SINGLE FAULT CONDITION, is treated in this edition as a special Review condition. The Review with MAXIMUM MAINS VOLTAGE on a non-PROTECTIVELY EARTHED ACCESSIBLE PART is also a special Review condition, but the allowable values are the same as for SINGLE FAULT CONDITION. See the rationales for 8.5.2.2 and 8.7.4.7d.

2: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

3: This condition is not Reviewed with TYPE CF APPLIED PARTS because it is covered by the Review with MAXIMUM MAINS VOLTAGE on the APPLIED PART. See also the rationale for 8.7.4.7 d).

4: In addition to conditions indicated in the Table, Reviews 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 Reviews of clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

8.8.3 A	**TABLE: Dielectric strength Review of solid insulating materials with safety function – means of operator protection (moop) - 1 min duration**						N
PEAK WORKING VOLTAGE (U) V peak	PEAK WORKING VOLTAGE (U) V d.c.	A.C. Review voltages in V r.m.s[1]					Dielectric breakdown[2] Yes/No
		Type of insulation Reviewed (area from insulation diagram)	MEANS OF OPERATOR PROTECTION (MOOP)				
			Protection from MAINS PART		Protection from SECONDARY CIRCUITS		
			One MOOP	Two MOOP	One MOOP	Two MOOP	
240	-	BI A-a1 Between Live parts and Accessible metal parts with are protectively earthened (Basic insulation)	1500				N
240	-	DI A-a2 Between Live parts and parts of the enclosure not protectively earthended. (Double insulation / Reinforce insulation)	4000				N

Supplementary information:

[1] Alternatively, as specified in the Table (i.e., __dc), a d.c. Review voltage equal to the peak value of the a.c. Review 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 Review of 11.1.1, and D) after relevant Reviews of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

8.8.3 B	**TABLE: Dielectric strength Review of solid insulating materials with safety function – means of patient protection (moop) - 1 min duration**						N
PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.	A.C. Review voltages in V r.m.s[1]					Dielectric breakdown[2] Yes/No
		Type of insulation Reviewed (area from insulation diagram)	MEANS OF PATIENT PROTECTION (MOOP)				
			Protection from MAINS PART		Protection from SECONDARY CIRCUITS		
			One MOOP	Two MOOP	One MOOP	Two MOOP	

Supplementary information:

[1] Alternatively, as specified in the Table (i.e., __dc), a d.c. Review voltage equal to the peak value of the a.c. Review 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 Review of 11.1.1, and D) after relevant Reviews of Subclause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate mater, cleaning & disinfection, & sterilization).

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

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

Supplementary information:
Note 1: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE

8.9.3.2	**Table: Thermal cycling Reviews on one sample of insulating compound forming solid insulation between conductive parts**	N

Review Sequence No.	Each Review duration and temperature	Dielectric Review voltage (V = Review voltage in 8.8.3 times 1.6)	Dielectric strength Review immediately after humidity preconditioning according to 5.7 except for 48 h only, Breakdown: Yes/No

Supplementary information:

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

8.9.3.4	**Table: Thermal cycling Reviews on one sample of cemented joint (see 8.9.3.3)**		N
Review Sequence No.	Each Review duration and temperature	Dielectric Review voltage (V = Review voltage in 8.8.3 times 1.6)	Dielectric strength Review immediately after humidity preconditioning according to 5.7 except for 48 h only, Breakdown: Yes/No
Supplementary information: [1] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.			

8.10	**TABLE: List of critical components**	

Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity [1]

9.2.2.2	**TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996)**	P

Part of body	Allowable adult gap[1], mm	Measured adult gap, mm	Allowable children gap[1], mm	Measured children gap, mm	Remarks

Supplementary information:
[1] In general, gaps for adults used, except when the device is specifically designed for use with children, values for children applied.

10.1.1	**TABLE: Measurement of X - radiation**	N

Maximum allowable radiation pA/kg (μSv/h) (mR/h)	36 (5 μSv/h) (0.5 mR/h)	
Surface area under Review Surface no./ Description[1]	Measured radiation pA/kg (μSv/h) (mR/h)	Remarks
1/ /		
2/ /		
3/ /		
4/ /		
5/ /		
6/ /		
7/ /		
8/ /		
9/ /		
10/ /		

Supplementary information:
[1] Measurements made at a distance of 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access (pA/kg)

11.1.	**TABLE: Excessive temperatures in ME EQUIPMENT**					P
Model No./Part No./Type No. ..... :						
Maximum rated ambient operating temperature T (°C)..... :	40					
Supply voltage, 110 % of max. RATED voltage, for ME EQUIPMENT with heating elements operated as in NORMAL USE, all heating elements energized unless prevented by switching interlocks (V)	N/A					
Supply voltage, least favorable voltage between 90 % of min. RATED voltage and 110 % of max. RATED voltage, for motor operated ME EQUIPMENT operated under normal load and normal DUTY CYCLE (V)	1,1x36					
Normal DUTY CYCLE for motor operated ME EQUIPMENT (s on, s off)	N/A					
Supply voltage, 110 % of max. RATED voltage for combined heating, motor operated, and other ME EQUIPMENT (V)	N/A					
Supply voltage, 90 % of min. RATED voltage for combined heating, motor operated, and other ME EQUIPMENT (V)	N/A					
Class of insulation system (A, E, B, F, H)	E					
Classification of individual insulating materials or Relative Thermal Index (°C)	65					
Supplementary information:						

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT – measurement of maximum temperature during NORMAL USE for parts other than APPLIED PARTS and parts likely to be touched**				P
Model No.....:					
Review ambient (°C) ..... :	40				
RATED supply voltage (V).....:	36				

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22 or 23, (°C)	Max measured temperature[2], (°C)	Remarks

Supplementary information:
[1] Maximum allowable temperature on surfaces of Review corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3 e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.

11.1.2.1	**TABLE: Excessive temperatures in ME EQUIPMENT – measurement of temperatures, hot or cold surfaces, during NORMAL USE for APPLIED PARTS intended to supply heat to a PATIENT**				N
Model No.....:					
Review ambient (°C) ..... :					
RATED supply voltage (V).....:					

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from RISK MANAGEMENT FILE, (°C)	Max measured temperature[2], (°C)	Remarks

Supplementary information:
[1] See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.
[2] Max temperature determined in accordance with 11.1.3 e)

11.1.2.2	**TABLE: Excessive temperatures in ME EQUIPMENT – measurement of maximum temperature during NORMAL USE for APPLIED PARTS not intended to supply heat to a PATIENT**				N
Model No.....:					
Review ambient (°C) ..... :					
RATED supply voltage (V).....:					

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 24 (°C)	Max measured temperature[1], (°C)	Remarks

Supplementary information:

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

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

Supplementary information:

11.2.2.1	**TABLE: alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source**	N

Areas where sparking might cause ignition:	Remarks
1.	
2.	
3.	
5.	
6.	

Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):	Remarks
1.	
2.	
3.	
4.	
5.	
6.	

Review parameters selected representing worst case conditions for ME EQUIPMENT:		Remarks
Oxygen concentration (%)..... :		
Fuel..... :		
Current (A)..... :		
Voltage (V)..... :		
Capacitance (μF)..... :		
Inductance or resistance (h or Ω)..... :		
No. of trials (300 Min)..... :		
Sparks resulted in ignition (Yes/No)..... :		

Supplementary information:

Review procedure of 11.2.2.1 a) 5) & Figs 35-37 used for Reviews. For circuits not in Figs 35-37, Review voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur.

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

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

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

Supplementary information:				

13.2	**TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive**	N

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2	Electrical SINGLE FAULT CONDITIONS according to 8.1:	—	—
13.2.3	Overheating of transformers according to 15.5:	—	—
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favorable 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 favorable of the two:	—	—
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate Review conditions (sealed rechargeable batteries exempted)	—	—
13.2.7	Impairment of cooling that could result in a HAZARD using Review 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:	—	—

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	—	—
	Not used such construction	V measured =	
		V measured =	
13.2.10	Additional Review criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:	—	—
	For every Review in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or at the upper limit of RATED voltage range for specified time:		
	Temperatures of windings determined at the end of specified Review 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		
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] Review 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.

15.4.6	**TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull Reviews**	N

Rotating control under Review	Torque from Table 30 (Nm)	Gripping diameter “d” of control knob (mm) [1]	Axial force applied (N)	Unacceptable RISK occurred Yes/No	Remarks

Supplementary information:
[1] Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)

15.5.1.2	**TABLE: transformer short circuit Review short-circuit applied at end of windings or at the first point that could be short circuited under single fault condition**	N
Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V) [1]:		—
RATED input frequency (Hz):		—

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

Supplementary information:
[1] Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.

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

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

Supplementary information:

[1] Loads on other windings between no load and their NORMAL USE load.

Time durations:

- IEC 60127-1 fuse: 30 min at current from Table 32.
  Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, Review current from Table 32 used until THERMAL STABILITY achieved.
- Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a).

This portion concluded at specified time or when a second protective device opened.

15.5.2	**TABLE: Transformer dielectric strength after humidity preconditioning of 5.7**				N
Transformer Model/Type/Part No.	Review voltage applied between	REVIEW voltage (V)	Review frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No
	Primary & secondary windings				
	Primary winding & frame				
	Secondary winding & frame				
Supplementary information: Reviews conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for Review parameters & other details					

16.6.1	**TABLE: leakage currents in me system _ touch current measurements**				N
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	Allowable TOUCH CURRENT in NORMAL CONDITION (μA)	Measured TOUCH CURRENT in NORMAL CONDITION (μA)	Allowable TOUCH CURRENT in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, (μA)	Measured TOUCH CURRENT in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, (μA)	
	100		500		
	100		500		
	100		500		
	100		500		
	100		500		
	100		500		
	100		500		
	100		500		
	100		500		
	100		500		
	100		500		
Supplementary information:					

Attachment No. 1
ISO 14971 Gap Analysis Checklist
(optional)

Clause	Title	Item	Comments
3.2	Risk Management process	**Procedure describing the risk management process**	Pass.
3.3	Management Responsibilities	**a. Policy** for determining acceptable risk.	Pass.
		b. Assignment of group/individual with risk management responsibility.	Pass.
		c Procedure for assigning staff to risk management work.	Pass. , Review engineer, medical specialist, quality engineer who are qualified by local government administration.
		d. Procedure(s) for review of risk management, e.g., management design reviews, internal audits, etc.	Pass. Every model performed management assessment. Internal audit: every 6 months
3.4	Qualification of personnel	Training records for risk management training, tools training, etc.	Pass. Certification of qualified Review engineer Certification of qualified medical specialist.
3.5	Risk Management Plan	**a. Procedure for plan development.**	Pass.
		b. Description of device	Pass
		c. Verification plan	Pass
		d. Allocation of responsibilities	Pass
		e. Summary of review activities.	Pass
		f. Evidence of risk acceptability criteria.	Pass
3.6	Risk Management File	Evidence of file structure for all risk management activities.	Pass
4.1	Risk Analysis Procedure	**Procedure for risk analysis.**	Pass
4.2	Intended use/intended purpose, etc.	Record of safety issue analysis.	Pass
4.3	Hazard Identification	Record of hazard analysis	Pass
4.4	Risk estimation	**a. Definition of methods used for estimating risks**	Pass
		b. Description of method(s) used.	Pass
		c. Record of risk estimation activities.	
5.0	Risk evaluation	a. Record of risk evaluation activities.	Pass
		b. Method(s) for dealing with non-quantifiable risks	Pass

Clause	Title	Item	Comments
6.1	Risk reduction	**Procedure for risk control activities**	Pass
6.2	Option analysis	Record of risk control option analysis (including risk-benefit analysis, if appropriate).	Pass
6.3	Implementation of risk control measures	Design inputs from risk management activities	Pass
6.4	Residual risk evaluation	Evidence, e.g., from design verification activities.	Pass
6.5	Risk-Benefit Analysis	Evidence as necessary…see 6.2.	Pass
6.6	Other generated hazards	Record of review of all risk controls for impact on new hazards.	Pass
7	Overall risk evaluation	Records of related meetings, analysis, etc.	Pass
8	Risk management report	**a. Procedure for generating a Risk Management report.** b. Summary of risk management activities c. Traceability of hazards to residual risks d. Clearances.	Pass Pass Pass Pass
9	Post-production information	**a. Procedures for linking information into risk management review**: manufacturing CAPA Servicing Purchasing etc. Records implementing procedures	Pass Pass Pass. Procedure for Corrective Action Preventive Action is available Pass Pass Pass Pass

Note: Bold letters indicate critical elements that should be present even at the very beginning of implementation.

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
	4 -	General requirements	
4.2	Risk Management Process for ME Equipment or ME Systems	Compliance is checked by inspection of the risk management file. The requirements of this clause and all requirements of this standard referring to inspection of the risk management file are considered to be satisfied if the manufacturer has: established a risk management process; and established acceptable levels of risks; and demonstrated that the residual risk is acceptable. Does the manufacturer have a risk management process according to ISO14971 in place? Was this process used for the device being considered? If so, a limited number of more detailed questions can be addressed at this point: Are all risk management procedures (that meet the requirements of ISO14971, including acceptability criteria) developed and applied for the device considered (clauses 4-9 of ISO14971)? Is there a risk management plan (including resources and commitment) for the device considered (clause 3 of ISO14971)? Is the overall residual risk for the device considered acceptable? N/A. Not PEMS (Programmable electrical medical systems)	3 to 9
4.3	Essential performance	Compliance is checked by inspection of the risk management file. Have, apart from the essential performance identified in the particular standards, hazardous situations be identified whereby the residual risk is unacceptable due to the absence of performance of the device? Yes. If so, has this performance been identified as essential performance for the device during the risk assessment	4 5 6.4

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		process? Yes. If so, have risk control measures or particular Reviews been identified to check whether this performance is maintained? Yes. If so, has this been checked by inspection or by functional Review? Yes.	
4.4	Expected service life	Compliance is checked by inspection of the risk management file. Has the expected service life of the device been identified? Yes.	Inspection
4.5	Equivalent safety for ME Equipment of ME System	Compliance is checked by inspection of the risk management file. Are there particular risks for which alternative means of controlling these risks are applied such that the resulting risk level is acceptable for these risks? N/A If so, have these risks been identified as such during the risk assessment process? Yes. If so, is the resulting risk level equal or less than the residual risk that results from applying the requirements of this standard? Yes.	4 5
4.6	ME equipment or ME system parts that contact the patient	Compliance is checked by inspection of the risk management file. Have parts been identified during the risk management process which can come into contact with the patient but fall outside the definition of applied parts? Yes. If so, are all the relevant requirements and Reviews of this	4 to 9

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		standard applied? Yes. If so, are there residual risks which are not acceptable? Yes. If so, are risk controls measures implemented that make the residual risk acceptable? Yes.	
4.7	Single Fault Condition for ME Equipment	Compliance is determined by applying the specific requirements and Reviews associated with the single fault conditions identified in 13.2, and Reviews for the failures identified from evaluation of the results of the risk analysis. Compliance is determined if the introduction of any of the single fault conditions described in 13.2, one at the time, does not lead directly to the hazardous situations described 13.1, or any other outcome that results in an unacceptable risk. Are there single fault conditions which lead directly to hazardous situations described in 13.1 or to risks that are unacceptable? Yes.	4 to 9
4.8	Components of ME Equipment	Compliance is checked by inspection and, where necessary, by Review. The Reviews of this standard for motors (see 13.2.8 and 13.2.13.3) and transformers (see 15.5.3) are considered to be comprehensive and together with the evaluation of the motor or transformer insulation system according to Table 22 represent all Reviewing required by this standard. ME system components that provide isolation from non-ME equipment are evaluated to clause 16. Are specific exceptions made for any component of the device under investigation to allow it to be used not in accordance with its specified rating? N/A All components are verified according IEC / ISO standard. If so, are these exceptions formulated as the result of the risk management process?	4 to 9

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		If so, have inspection or Review requirements been formulated to make the hazardous situations acceptable?	
4.9	Use of components with high-integrity characteristics in ME	Compliance is checked by inspection of the risk management file and the selection criteria for the components with high-integrity characteristics. Are components with high-integrity characteristics applied? Yes If so, have the risks associated with its use been identified as such during the risk assessment process, or in other words are they selected and evaluated consistent with their conditions of use and reasonably foreseeable misuse during the expected service life of the ME equipment? Yes	4 5
	5 -	General requirements for Reviewing MEE	
5.1	Type Reviews	The Reviews to be performed are determined taking into consideration the requirements of clause 4, in particular 4.2. For the selection of the Reviews to be performed, is a risk management process according to ISO14971 applied? Yes If so, this requirement is fulfilled. The results of the risk analysis are used to determine which combination(s) of simultaneous faults are to be Reviewed. For the determination of which combination(s) of simultaneous faults have to be Reviewed, is a risk assessment applied?	4 to 9
5.4 a)	Other conditions	Unless otherwise specified in this standard, ME equipment is to be Reviewed under the least favorable working conditions as specified in the Instructions for Use that are identified during the risk analysis. For Reviewing of the ME equipment, have the least favorable working conditions been identified via the risk analysis? Yes	4
5.7	Humidity preconditioning treatment	Where the risk management process suggests that the ME equipment can be exposed to high humidity for extended periods, the period is extended appropriately. Has it been determined via the application of the risk management process whether the ME equipment can be exposed to high humidity for extended periods?	3 - 9

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		Yes If so, is the period for Reviewing been extended appropriately following the conclusions of the risk management process? Yes	
5.9.2.3	Actuating mechanisms	Inspection of the risk management file demonstrates that the relevant part is unlikely to become detached unintentionally during the expected service life of the ME equipment. Has the result of the risk analysis demonstrated that the relevant part is unlikely to become detached unintentionally during the expected service life time of the ME equipment and that an acceptable residual risk results? Yes	4
	7-	MEE Identification, markings and documents	
7.1.1	Usability of the identification, marking and documents	*Compliance is checked by inspection of the usability engineering process.* Has the manufacturer addressed in a usability engineering process the risk of poor usability? Yes	4
7.9.1	General accompanying documents format. (see also Table C.4)	*Compliance is checked by inspection of the risk management file.* Has the manufacturer applied the risk management process to determine which information also needs to be provided as hard copy or as marking on the ME equipment? Yes	4 5
	8 -	Protection against electrical hazards from MEE	
8.1 b	Fundamental rule of protection against electric shock	Has the manufacturer identified in their risk analysis if the interruption of any one power carrying conductor between MEE parts in separate enclosures might cause permitted limits (voltage, current, energy) to be exceeded? Yes If so, then during product safety verification, this must be one of the SFC's Reviewed. Yes Has the manufacturer identified in their risk management process that a component's movement must be considered as a SFC because its lack of securement (8.10.1) over the	4.3 4.4

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		expected service life of the MEE may cause permitted limits (voltage, current, energy) to be exceeded? If so, then during product safety verification, this must be one of the SFC's Reviewed. Yes	
8.3 d	Classification of applied parts	Has the manufacturer identified in their risk management process the need for parts (not being applied parts) to be subject to the requirements for an applied part of Type BF or Type CF? If so, then during product safety verification, these parts are to be Reviewed accordingly. N/A	4.3 4.4 5
8.4.2 c	Accessible parts including applied parts	Has the manufacturer identified parts (not being applied parts) where a current exceeding the allowable touch current could flow, either directly or through the body of an operator, however, the risk analysis determined that the probability in normal use is negligible? Yes If so, then during product safety verification, these identified parts do not require touch current Reviewing. Inspect the instructions for use includes instructions for the operator not to touch the relevant part and the patient simultaneously.	4
8.5.2.2	Type B applied parts	Has the manufacturer identified in their risk management file, unearthed Type B applied parts that are not separated from unearthed conductive accessible parts, however, determined that the level of risk that the unearthed accessible part will make contact with a source of voltage or leakage current above permitted limits is acceptably low? N/A. All of type B applied part are earthened. If so, accepted. If not, then one means of protection is required.	4 5
8.5.2.3	PATIENT Leads	Has the manufacturer identified in their risk management process connectors for electrical connections on a patient lead at the end of the lead remote from the patient and that contains	4 5

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		a conductive part that is not separated from all patient connections by one MOPP for a working voltage equal to the maximum mains voltage, that will not present an unacceptable risk from contact with objects other than a mains socket or a flat surface (e.g. corners or edges)? N/A. Not used patient leads. If so, during product safety verification, the Review using a straight unjointed Review finger with a force of 10 N is not required, however, the remaining inspections of this clause are required.	
8.6.3	Protective earthing of moving parts	Does the manufacturer's risk management file indicate the need to bond moving parts to the protective earth connection? Yes If so, has the manufacturer demonstrated the reliability of the connection during the expected service life?	4-6
8.8.4.1	Mechanical strength and resistance to heat	Has the manufacturer identified in the risk management file the need for insulations of all types, considering its resistance to heat in the application and the expected service life? Has the manufacturer identified any specific Review protocols that must be performed during product safety verification? If so, conduct the Reviews required in this clause and any additional Reviews or inspections identified in the risk management file.	4-6
8.10.1	Fixing of components	Has the manufacturer identified components the movement of which could result in an unacceptable risk in their risk management file? If so, verify that such identified components are securely mounted and will remain so for the expected service life.	4-6
8.10.2	Fixing of wiring	Has the manufacturer identified in their risk management file the need to restrain by double securement any conductors and connectors where if they were to break free and touch circuit points this could result in a hazardous situation? Yes	4-6

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		If so, inspect the construction and restraint of these conductors and connectors to ensure that they are held in place by use of double securement.	
8.10.5	Mechanical protection of wiring	Has the manufacturer identified in the risk management file the need to protect against contact with moving parts, friction at sharp corners and edges or damage during assembly or the opening or closing of access covers of internal cables, wiring, cord forms or components, where the damage or insulation damage could result in a hazardous situation? Yes If so, inspect these parts carefully considering their location and potential damage during assembly, disassembly, contact with moving parts and friction at sharp corners and edges.	4-6
8.11.5	Mains fuses and over-current releases	Has the manufacturer provided justification for omission of fuses or over-current releases in the risk management file? Yes If so, inspect the circuit according to the requirements of this clause ensuring double insulation and acceptable fault condition Reviews results.	4-6
	9 -	Protection against mechanical hazards of MEE and MES	
9.2.1	HAZARDs associated with moving parts - General	- Are protective measures used to reduce the risk from contact with moving parts? Yes. -Considering use as indicated in the Accompanying Documents or reasonably foreseeable misuse and bearing in mind the ease of access, the ME Equipment function, the shape of the parts, the energy and speed of the motion and the benefits to the patient, is this risk reduced to an acceptable level? Yes - Is exposure to moving parts needed for MEE to perform its intended function? Yes - Have all reasonable protective measures including warning markings on the MEE where the hazards persist been	3 to 9

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		implemented? Yes	
9.2.2.4.3	Movable guards	- The risks caused by mechanical hazards associated with moving parts and reduced by use of the movable guards are addressed? Yes	3 to 9
9.2.2.4.4	Protective measures	- The risks caused by mechanical hazards associated with moving parts and reduced by the use of protective measures incorporated in the control system are addressed? Yes	3 to 9
9.2.2.5 c	Continuous activation	- The risks caused by mechanical hazards associated with accessibility to a trapping zone and reduced by use of the continuous activation of the movement control are addressed? Yes	3 to 9
9.2.2.6	Speed of movement(s)	- The risks caused by mechanical hazards associated with the speed of movement are addressed? Yes	3 to 9
9.2.3.2	Over travel	- The risks caused by mechanical hazards associated with the over travel are addressed? Yes	3 to 9
9.2.4	Emergency stopping devices	- Does the MEE use emergency stopping devices? Np - Are risks caused by mechanical hazards which are reduced by the use of the emergency stopping devices reduced to an acceptable level? Yes	3 to 9
9.2.5	Release of patient	- The risks caused by mechanical hazards associated with release of patient are addressed? N/A	3 to 9
9.3	Hazards associated with surfaces, corners and edges	- The risks caused by mechanical hazards associated with surfaces, corners and edges are addressed? Yes	3 to 9

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
9.4.2.4.3	Movement over a threshold	- Are the risks caused by mechanical hazards associated with movement over a threshold addressed? N/A. Permanent installation ME equipment.	3 to 9
9.5.1	Protective means	- Have the risks caused by mechanical hazards associated with expelled parts been addressed? N/A. Not impossible to cause expelled parts.	3 to 9
9.6.1	Acoustic energy - General	- Have the risks caused by mechanical hazards associated with acoustic energy and vibration been addressed? Yes	3 to 9
9.6.2.2	Infrasound and ultrasound energy	- Have the risks caused by mechanical hazards associated with infrasound and ultrasound energy been addressed? Yes	3 to 9
9.7.2	Pneumatic and hydraulic parts	- Have the risks caused by mechanical hazards associated with pneumatic and hydraulic parts been addressed? N/A. Not use pneumatic and hydraulic part.	3 to 9
9.7.4	Pressure rating of ME equipment parts	- Have the risks caused by mechanical hazards associated with pressure rating of MEE parts been addressed? N/A. Not use parts or sub-assembly related to pressure parts.	3 to 9
9.7.6	Pressure-control device	Have the risks caused by mechanical hazards associated with pressure – control device been addressed? Not. Not use pressure-control device.	3 to 9
9.7.7	Pressure-relief device	Have the risks caused by mechanical hazards associated with a pressure-relief device been addressed? Not use pressure relief device.	3 to 9
9.8.1	Hazards associated with support systems - General	Have the risks caused by hazards arising from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions been addressed? Yes Were all of the following failures considered: excessive deflection, plastic deformation, ductile or brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep, and material deterioration?	3 to 9

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		Yes Were the following residual stresses resulting from the manufacturing process, e.g. machining, assembling, welding, heat treatment or surface coating considered? Yes	
9.8.2	Tensile safety factor	When not according to Table 21, what alternative method was used to determine the tensile safety factor? Yes Have the risks related to the value of the tensile factor been addressed? Yes	3 to 9
9.8.3.1	Strength of patient or operator support or suspension systems - General	Have the risks caused by mechanical hazards associated with support or suspensions of the patient (including particular applications) been addressed? Yes	3 to 9
9.8.3.2 a&b	Static forces due to loading from persons	Have the risks caused by mechanical hazards associated with static forces due to loading from persons been addressed? N/A. No such construction.	3 to 9
9.8.4.1	Systems with mechanical protective devices-General	Does the MEE use mechanical protective devices? Yes Does the mechanical protective device activate before travel (movement) produces an unacceptable risk? Yes	3 to 9
9.8.4.3	Mechanical protective device intended for single activation	Does the MEE use mechanical protective devices intended for single activation? Yes Where risks caused by mechanical hazards which have been reduced by the use of mechanical protective devices intended for single activation:	3 to 9
9.8.5	Systems without mechanical protective devices	Has the manufacturer determined that the use of mechanical protective devices in the MEE is not required? Yes Has the manufacturer justified the reasons not to use	4

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		mechanical protective devices? Yes	
	10 -	Protection against unwanted and excessive radiation hazards	
10.1.2	ME equipment intended to produce diagnostic or therapeutic X-radiation	When applicable, has the manufacturer identified hazards and hazardous situations associated with production of X-radiation in the risk management file? N/A	3-9
10.2	Alpha, beta, gamma, neutron and other particle radiation	When applicable, has the manufacturer identified hazards and hazardous situations associated with production of alpha, beta, gamma, neutron or other particle radiation in the risk management file? N/A	3-9
10.3	Microwave radiation	When applicable, has the manufacturer identified hazards and hazardous situations associated with production of microwave radiation in the risk management file? N/A	3-9
10.5	Other visible electromagnetic radiation	When applicable, has the manufacturer identified hazards and hazardous situations associated with production of visible electromagnetic radiation in the risk management file? N/A	3-9
10.6	Infrared radiation	When applicable, has the manufacturer identified hazards and hazardous situations associated with production of infrared radiation in the risk management file? N/A	3-9
10.7	Ultraviolet radiation	When applicable, has the manufacturer identified hazards and hazardous situations associated with production of ultraviolet radiation in the risk management file? N/A	3-9
	11 -	Protection against excessive temperatures and other hazards	
11.1.1		Maximum temperature during normal use	
	Table 23	Has the manufacturer identified parts of the ME Equipment that are likely to be touched in normal or foreseeable misuse that can contact more than 10% of the surface area operator or patient's body or 10% of the surface area of the patient's or operator's head?	3-5

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		Yes Has the manufacturer identified the duration of continuous or aggregate contact? Yes Has the manufacturer identified and addressed such risks? Yes Has the RM process determined suitable limits for temperature based on the risk acceptability criteria and risk benefit analysis in association with patient state of health and whether adult, paediatric or neonate? Yes	
	Table 24	Has the manufacturer identified applied parts of the ME Equipment that can contact more than 10% of the surface area operator or patient's body or 10% of the surface area of the patient's or operator's head during normal or foreseeable misuse? Yes Has the manufacturer identified the duration of continuous or aggregate contact of these applied parts? yes Has the manufacturer identified and addressed such risks? Yes Has the RM process determined suitable limits for temperature based on the risk acceptability criteria? Yes If the temperature limits exceed the values in table 24 has a favourable risk benefit analysis in association with patient state of health and whether adult, paediatric or neonate been documented? Yes	3-9
11.1.2.1	Applied parts intended to supply heat to a patient	Is any part of the ME Equipment intended to supply heat or otherwise intended to cool a patient? Has the manufacturer identified and addressed the clinical risks associated with hazards? Has the manufacturer disclosed such risks? N/A	3-4
11.1.2.2	Applied parts not intended to supply	Does the ME equipment have any applied parts that are not intended to heat or cool the patient that could in normal or	3-9

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Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
	heat to a patient	foreseeable misuse exceed 41 °C or cool below ambient temperature? Yes	
11.1.3	Measurements	Has the manufacturer identified hazardous situations that relate to maximum heating effect of nearby surfaces? Yes If no hazardous situations are apparent has the manufacturer made appropriate declarations in the RMF? Yes Has the manufacturer identified all conditions of intended use and foreseeable misuse to determine occurrence and duration of contact with parts and applied parts that could be touched? Yes	3-5
11.1.3 e	Measurements	Has the manufacturer identified hazardous situations that relate to maximum heating effect of nearby surfaces? Yes If no hazardous situations are apparent has the manufacturer made appropriate declarations in the RMF? Yes Has the manufacturer identified all conditions of intended use and foreseeable misuse to determine occurrence and duration of contact with parts and applied parts that could be touched? Yes	6.3
11.2.2.1 a&b	Risk of fire in an oxygen rich environment	Has the manufacturer identified that there is a risk of fire from an oxygen rich environment? Where scenario number 3 is applicable, has the manufacturer conducted a risk assessment to determine hazards associated with leaks or component failures causing a source of ignition been conducted? N/A.	3-9
11.3	Constructional requirements for fire enclosures of ME equipment	Have the specific requirements of this clause been employed to comply with cl 13.1.2? Has the manufacturer analysed and addressed risks of not complying with the constructional requirements and showed than an equivalent level of risk / benefit has been provided? Yes	3-9
11.5	ME equipment and ME systems	Is the ME Equipment intended to (or can it through foreseeable misuse) come into contact with flammable agents?	3-9

EN 60601-1:2006+A12:2014 3rd edition risk management requirements guidance for the application of EN ISO 14971:2012 1st edition			
Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
	intended for use in conjunction with flammable agents	N/A	
11.6.3	Spillage on ME equipment and ME system	Does the ME Equipment require the handling of liquids in normal or foreseeable misuse? N/A. Could the wetting of the ME equipment result in a hazardous situation? Has the manufacturer identified hazardous situations relating to the worst case volume and type of liquid? N/A Has the manufacturer identified hazardous situations relating to the worst location for the equipment to spill? N/A	3-9
11.6.6	Cleaning and disinfection of ME equipment and ME systems	Has the manufacturer identified the parts of the ME equipment which may be subject to cleaning or disinfection in normal or foreseeable misuse and the type of cleaning or disinfection? Yes Based on the ESL of the ME equipment has the manufacturer extrapolated the number of cleaning processes to which the equipment will be subjected? Yes Has the manufacturer identified all related hazards and addressed such risks in the RMF? Yes	3-9
11.6.7	Sterilization of ME equipment and ME systems	Has the manufacturer identified the parts of the ME equipment which may be subject to sterilization in normal or foreseeable misuse and the type of sterilization? Yes	3-9
11.6.8	Compatibility with substances used with the ME equipment	Has the manufacturer identified all substances to which the ME Equipment may come into contact with in normal or foreseeable misuse? Yes	3-9
	12 -	Accuracy of controls and instruments and protection against hazardous outputs	
12.1	Accuracy of controls and	Has the manufacturer identified all controls and instruments contained on the ME Equipment? Yes	3-9

EN 60601-1:2006+A12:2014 3rd edition risk management requirements guidance for the application of EN ISO 14971:2012 1st edition			
Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
	instruments	Has the manufacturer conducted a hazard analysis to identify the risks associated with the accuracy of the above identified controls and instruments? Yes	
12.3	Alarm systems	Has the manufacturer considered in their option analysis the inclusion of alarms as a means to mitigate the risk of accuracy of controls and instruments for controlling hazards against hazardous outputs? Yes If yes, has the use of alarms been implemented as a means of mitigating the risk of accuracy of controls and instruments for controlling hazards against hazardous outputs? If yes, has the manufacturer in their risk analysis explored and addressed the hazards of operation or failure of the alarm systems? Yes Does the residual risk of such hazards meet IEC 60601-1-8? Yes	3-9
12.4.1	Intentional exceeding of safety limits	Has the manufacturer identified risks associated with the intentional exceeding of safety limits? Yes Has the manufacturer addressed such risks to comply with the manufacturer's risk acceptability criteria? Yes	3-9
12.4.2	Indication of parameters relevant to safety	Has the manufacturer identified all functions related to the delivery of energy or substances to the patient? Yes Has the manufacturer explored such functions for hazardous situations in which these functions can produce an output to the patient? Yes	3-9
12.4.3	Accidental selection of excessive output values	Has the manufacturer identified all features of the ME Equipment that provide an output to the patient for therapeutic purposes? Yes Has the manufacturer identified which of these features have multiple purposes that require different intensities for different treatments? Yes	3-9

EN 60601-1:2006+A12:2014 3rd edition risk management requirements guidance for the application of EN ISO 14971:2012 1st edition			
Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		Has the manufacturer identified hazards associated with accidental selection of excessive output values? Yes	
12.4.4	Incorrect output	Has the manufacturer identified all features of the ME Equipment that provide an output? Yes Has the manufacturer identified hazards associated with incorrect output? Yes	3-9
12.4.5.2	Diagnostic X-ray equipment	Has the manufacturer identified if the product emits intentional X-ray radiation for diagnostic purposes? N/A Has the manufacturer identified and explored risks associated with emission of X-Ray radiation for diagnostic purposes? N/A	3-9
12.4.5.3	Radiotherapy equipment	Has the manufacturer identified if the product is intended for radiotherapy purposes? N/A Has the manufacturer identified and explored risks associated with emission radiation for therapeutic purposes? N/A	3-9
12.4.5.4	Other ME equipment producing diagnostic or therapeutic radiation	Has the manufacturer identified if the product is intended for radiotherapy purposes? N/A Has the manufacturer identified and explored risks associated with emission radiation for therapeutic purposes? N/A	3-9
12.4.6	Diagnostic or therapeutic acoustic pressure	Has the manufacturer identified if the equipment emits an acoustic pressure output? Has the manufacturer identified and explored risks associated with emission of such acoustic pressure? N/A	3-9
	13 -	Hazardous situations and fault conditions	
13.2.6	Leakage of liquid	Has the manufacturer determined the appropriate Review conditions for the evaluation of liquid leakage?	3-6
	14 –	Programmable electrical medical systems (PEMS)	

EN 60601-1:2006+A12:2014 3rd edition risk management requirements guidance for the application of EN ISO 14971:2012 1st edition			
Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
14.1	Programmable electrical medical systems - General	Does the application of ISO 14971 demonstrate that the failure of the PESS does not lead to an unacceptable RISK? N/A	4 5
14.2	Programmable electrical medical systems - Documentation	Have all PEMS records and documents been maintained and included in the risk management file? N/A	3.4 4.2
14.3	Programmable electrical medical systems - Risk management plan	Does the risk management plan include a reference to the PEMS validation plan? N/A	3.3
14.4	PEMS Development Life Cycle	Does each milestone in the PEMS development life cycle identify the risk management activities that must be completed before that milestone? N/A	3
14.6.1	Identification of known and foreseeable hazards	Has the manufacturer considered those hazards associated with the software and hardware aspects of the PEMS including those associated with Network/Data coupling and legacy subsystems? N/A	4.3
14.6.2	Risk control	Has the manufacturer identified suitable tools and procedures to implement risk control measures? N/A Are these tools and procedures appropriate to ensure that each risk control measure effectively reduces the identified risks? N/A	6
14.7	Requirement specification	Does the requirement specification include and distinguish any risk control measures? N/A	6
14.8	Architecture	Does the architecture specification reduce the risk to an acceptable level, where appropriate, using levels a) – f)? N/A Does the architecture specification take into consideration allocation of risk control measures?	4 to 6

EN 60601-1:2006+A12:2014 3rd edition risk management requirements guidance for the application of EN ISO 14971:2012 1st edition			
Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		N/A	
14.9	Design and Implementation	Is descriptive data regarding the design environment included in the risk management file? N/A	4 and 6
14.10	Verification	Is the result of the verification activity documented? N/A Have all functions that implement risk control measures been verified? N/A	4 to 6
14.11	Programmable electrical medical systems - PEMS validation	Has the manufacturer documented the professional relationships of the members of the PEMS Validation team with members of the design team? N/A Is a reference to the methods and results of the PEMS Validation included in the risk management file? N/A	3.3 4 to 6
	15 -	Construction of MEE	
15.1	Construction of ME equipment - Arrangements of controls and indicators of ME equipment	Has the manufacturer identified in the risk management process the risks associated with the arrangement of controls and indicators? Yes If so, inspect for the arrangement of controls and indicators. Yes	3-8
15.3.2	Push Review	After the push Review, were damages sustained that result in an unacceptable risk identified? Yes	3 to 5
15.3.3	Impact Review	After the impact Review, were damages sustained that resulted in an unacceptable risk identified? Yes	3 to 5
15.3.4.2	Portable ME equipment	After the drop Review, were damages sustained that resulted in an unacceptable risk identified? N/A. Permanent installation ME equipment.	3 to 5

EN 60601-1:2006+A12:2014 3rd edition risk management requirements guidance for the application of EN ISO 14971:2012 1st edition			
Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
15.3.5	Rough handling Review	After the rough handling Review, were damages sustained that resulted in an unacceptable risk identified? N/A. Permanent installation ME equipment.	3 to 5
15.4.1	Construction of connectors	Has the manufacturer identified electrical, hydraulic, and pneumatic or gas connection terminals and connectors removable without the use of a tool where incorrect connection to other outlets intended for other functions would not result in unacceptable risks? Yes. If so, ensure that incorrect connection does not result in an unacceptable risk. (Gas connectors must comply with item b) of this clause). Yes	3 to 9
15.4.2.1 a	Temperature and overload control devices - Application	Has the manufacturer identified in the risk management file, any automatic resetting thermal cut-outs or over-current releases where their use would not result in an unacceptable risk? N/A. Not used any auto resetting thermal cut-outs or over current release. If so, ensure that the resetting of these devices does not result in unacceptable risks. N/A	3 to 4
15.4.2.1 b	Application	Has the manufacturer identified in the risk management file the use of thermal cut-outs with a safety function? N/A. Not used such thermal cut-outs If so, ensure that such components are not of the types that have to be reset by a soldering operation that can affect the operating value.	3 to 5
15.4.2.1 c	Application	Has the manufacturer identified the use of a thermostat in the MEE in the risk management file? N/A. Not used such construction. If so, inspect for an independent non-self-resetting thermal cut-out with a setting outside the maximum range of the	3 to 4

EN 60601-1:2006+A12:2014 3rd edition risk management requirements guidance for the application of EN ISO 14971:2012 1st edition			
Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		thermostat but within the safe temperature limit for its intended function.	
15.4.2.1 d	Application	Has the manufacturer identified that loss of function of the MEE could result in a hazardous situation? N/A. Not used such thermal cut-outs or over-current release. If so, ensure that the operation of a thermal cut-out or over-current release does not result in an unacceptable risk.	3 to 4
15.4.2.1 h	Application	Has the manufacturer identified the need for fusing each lead for the use of tubular heating elements in the risk management file? N/A. Not incorporates tubular heating elements. If so, inspect for fuses in both leads and fault either lead to ground and ensure over-heating does not occur.	3 to 5
15.4.3.1	Housing	Has the manufacturer identified the need for ventilated battery housings where gases that could result in a hazard can escape during charging or discharging? N/A. No battery used. If so, inspect the battery housings for proper ventilation. Has the manufacturer identified the need for battery polarity connection construction such that short-circuiting is not possible? Yes If so, inspect the battery connection and ensure that incorrect connection is not possible.	3 to 5
15.4.3.5	Excessive current and voltage protection	Has the manufacturer provided justification for the omission of fuses or over-current releases in the risk management file? If so, protection against fire caused by excessive currents is by inspection of the design and the risk management file and no additional Reviewing is required.	3 to 5
15.4.5	Pre-set controls	Where applicable, has the manufacturer addressed the risk associated with pre-set controls?	3 to 9
15.4.7.3	Entry of liquids	Has the manufacturer conducted risk analysis for foot operated	3 to 4

EN 60601-1:2006+A12:2014 3rd edition risk management requirements guidance for the application of EN ISO 14971:2012 1st edition			
Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
b		control devices during their risk management process? N/A. Not use foot-operated device. If so, is the probability of occurrence of the intended normal use in areas where liquids are likely to be found low enough such that foot-operated control devices that contain electrical circuits do not have to be classified IPX6 according to IEC 60529? N/A. If so, then perform Reviewing at the manufacturer's lesser IPX_ rating. Note IPX1 is the minimum rating. N/A. If not, then verify compliance to IPX6 classification. N/A.	
	16 -	ME Systems	
16.1	General Requirements for ME Systems	After installation or subsequent modification, does the ME system result in an unacceptable risk? N/A. Not ME Systems. Have hazards arising from combining various equipment to constitute an ME system been considered? Is the level of safety equivalent to ME system complying with this standard IEC 60601-1 within the patient environment? N/A. Not ME Systems If the ME System is reconfigurable, have risk management methods been used to determine which configurations constitute the highest risks and which measures are needed to ensure that the reconfiguration does not constitute an unacceptable risk?	3 to 5
	17 –	Electromagnetic compatibility of MEE and MES	
17	Electromagnetic compatibility of ME equipment and ME systems	Does the risk management process address the risks associated with the electromagnetic phenomena existing at the locations where the ME equipment or ME System is intended to be used as indicated in the accompanying documents? Yes	3 to 9

EN 60601-1:2006+A12:2014 3rd edition risk management requirements guidance for the application of EN ISO 14971:2012 1st edition			
Clause	Subject	Considerations for application of RM criteria	Evidence EN ISO 14971:2012
		Does the risk management process address the risks associated with the introduction by the ME equipment or ME system of electromagnetic phenomena into the environment that might degrade the performance of other devices, electrical equipment, and systems? Yes	

Note:

This document includes clauses from IEC 60601-1 which have guidance for inspection requirements of the manufacturer's risk management file, risk control measures and risk management process.

The document does not address other clauses from IEC 60601-1 which include key terms for example RISK (with or without qualifying words such as unacceptable, acceptable and significant), HAZARD, HAZARDOUS SITUATION. These clauses do not necessarily require the manufacturer to include them in their risk management process.

Additional information
The Task Force MEE Terms of Reference will basically be but not limited to: • Establish a consensus with methods acceptable to determine compliance with all the relevant clauses (related to ISO 14971) of IEC 60601-1 Ed. 3. • Develop a Guideline document & Work Instruction on how to implement the relevant clauses (related to ISO 14971) of IEC 60601-1 Ed. 3. • Develop a Checklist aiming at to assist ME Industry, Official Authorities and Stakeholders around the world, Reviewing Laboratories and Certification Bodies to properly deal with Risk Management • Develop an addendum to the Review Report Form IEC 60601-1 to cover the overall requirements pertaining to ISO 14971. • To set up the content of possible trainings to cover Risk Management issues; To be the Advisory Group on common understanding of ISO 14971 related to IEC 60601-1

ATTACHMENT TO Review REPORT IEC 60601-1
EUROPEAN GROUP DIFFERENCES AND NATIONAL DIFFERENCES

Medical electrical equipment

Part 1: General requirements for basic safety and essential performance

Differences according to.....:	EN 60601-1:2006+A12:2014
Attachment Form No..... :	EU_GD_IEC60601_1A
Attachment Originator.....:	Electrosuisse
Master Attachment..... :	2009-11

	CENELEC COMMON MODIFICATIONS (EN)		
	The text of the International Standard IEC60601-1:2005 was approved by CENELEC as a European Standard without any modification		P

- End of Review Report -

Type of equipment, model: 4 Wheeler Explorer, 1013-1, 1013-2

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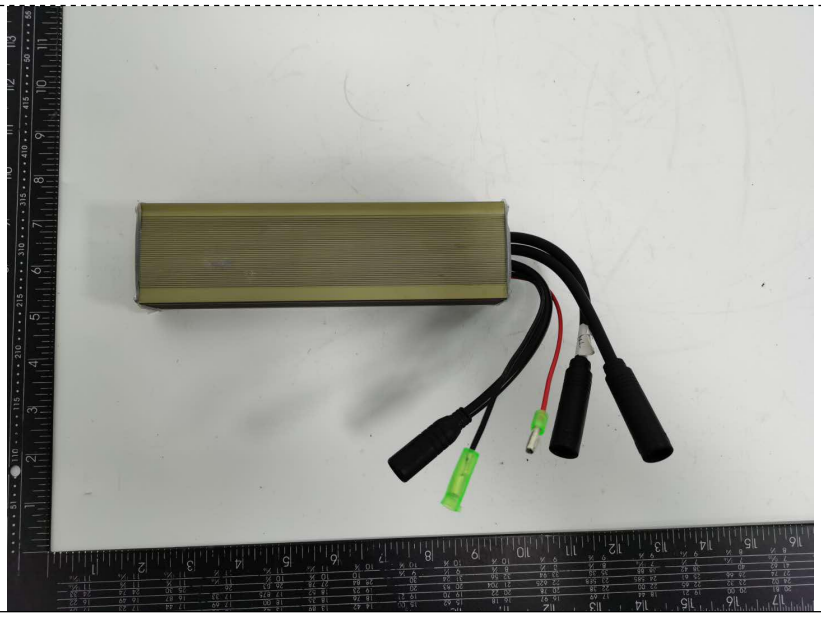

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- End of Annex I -