



GUIDELINES FOR RISK MANAGEMENT IN MEDICAL ELECTRICAL EQUIPMENT

See Appendix A

1. Scope

The scope of these guidelines is to give an uniform approach on how to assess compliance with the relevant clauses of IEC 60601-1:2005 related to ISO 14971:2000.

2. Reference documents

IEC 60601-1:2005 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

ISO 14971:2000, *Medical devices – Application of risk management to medical devices*

IECEE - CB Scheme - TRF60601-1_d

3. Terms and definitions

For the purposes of this Guide, the terms and definitions of ISO 14971:2000 and IEC 60601-1:2005 apply.

For the purpose of this document the Risk Management System is a management system intended to address all activities related to ISO14971.

4. Application of Risk Management Principle for IEC 60601-1:2005 CB Scheme investigations

4.1 General

The third edition of IEC 60601-1 is the primary standard in a series of standards that covers safety and essential performance of medical electrical equipment. It is the first IEC standard in the scope of the CB Scheme that incorporates risk management principles according to ISO 14971. The introduction of Risk Management is the reason for this guide.

The existence of a CB Test Certificate does not establish solely legal market entry. However, it could be used to help substantiate a request for legal market access.

This guideline is related solely to the IECEE CB Scheme and is intended for use by those individuals with a working knowledge of risk management for medical electrical equipment and the provisions of the IEC 60601-1:2005.

5. Guidance on how to address Risk Management principles in the IEC 60601-1 CB Scheme investigations

5.1 General principles

There is a general requirement to perform the risk management process as specified in ISO 14971 (IEC 60601-1, Clause 4.2.)

The registration to ISO 13485 is not sufficient to demonstrate that a risk management process compliant with ISO 14971 requirements is performed.

There can be no investigation to IEC 60601-1 third edition without the manufacturer's Risk Management File being available.



In the clauses of IEC 60601-1 there are three types of references to ISO 14971 Risk Management requirements:

1. Direct reference to Risk Management Process as specified by ISO 14971 (for example clause 4.2).
2. Test related references to give appropriate alternative to the application of laboratory testing with specific pass/fail criteria or to select appropriate tests to be performed on the specific product (for example clause 5.7).
3. Indirect reference to offer additional elements to be considered in the implementation of the Risk Management Process specified by ISO 14971 for the specific product. (for example clause 14.1)

The CB Test Report and Certificate confirms that there is a Risk Management Process performed which complies with ISO 14971. This does not mean that a complete Risk Management System in compliance with ISO 14971 is in place. However, the CB Test Report is only a snapshot in time and does not necessarily assess top management responsibilities, such as, but not limited to, provision of adequate resources and assignment of qualified personnel.

In view of the above and similar to the second edition, the CB report according to IEC60601-1:2005 is not necessarily a guarantee of certification by an accepting NCB.

A separate certification of registration to ISO 14971 means that a risk management system fully conforming to ISO 14971 is in place, but does not provide the risk management device specific documentation necessary to meet the requirements of IEC 60601-1. IEC 60601-1 requires specific Risk Management activities to be done and the CB test report requires objective evidence that these activities have been performed for the device in question.

A CB Scheme Certificate does not imply that an audit of the manufacturer's Risk Management System was conducted.

A certificate of registration may be requested for local or regional certification to IEC 60601-1 as it relates to follow-up services. There may be differences in requirements that are the subject of local legal market entry requirements.

To assess the requirements for Risk Management process required by IEC 60601-1, the CB Scheme utilizes an addendum embedded within the IEC60601-1 TRF containing reference to the manufacturer's documents intended to support objective evidence of compliance.

The table in Appendix A provides mapping with all the Risk Management clauses of IEC60601-1:2005 and the clauses in ISO 14971 that are referenced in the TRF Addendum.

In filling in the TRF addendum, the user of the map should consider applicability of clauses to the Device Under Test.

5.2 Workflow

1. Based on the TRF, establish the relevant clauses of IEC60601-1 that have to be supported by RM documentation
2. Verify the required documentation and identify the relevant reference points to be listed in the TRF
3. In case the use of RM influences the tests
 - 3.1. Identify the test to be conducted
 - 3.2. Identify the test parameters and conditions to be used performing the tests



3.3. Verify the pass/fail criteria. The pass/fail criteria and the rationale for acceptance shall be reported in the TRF.

3.4. Perform the test and report the result in the TRF

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Clause	60601-1:2005 Topic	3.2	3.3	3.4	3.5
		Risk Management Process	Management Responsibilities	Qualification of Personnel	Risk Management Plan
4	General requirements				
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS				
4.2	RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS				
4.3	ESSENTIAL PERFORMANCE				
4.4	EXPECTED SERVICE LIFE				
4.5	Equivalent safety for ME EQUIPMENT or ME SYSTEMS				
4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT				
4.7	SINGLE FAULT CONDITION for ME EQUIPMENT				
4.8	Components of ME EQUIPMENT				
4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT				
4.10	Power supply				
4.10.1	Source of power for ME EQUIPMENT				
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS				
4.11	Power input				
5	General requirements for testing				
5.1	TYPE TESTS				
5.2	Number of samples				
5.3	Ambient temperature, humidity, atmospheric pressure				
5.4	Other conditions				
5.5	Supply voltages, type of current, nature of supply, frequency				
5.6	Repairs and modifications				
5.7	Humidity preconditioning treatment				
5.8	Sequence of tests				
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS				
5.9.1	APPLIED PARTS				
5.9.2	ACCESSIBLE PARTS				
5.9.2.1	Test finger				
5.9.2.2	Test hook				
5.9.2.3	Actuating mechanisms				

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6	Classification				
6.1	General				
6.2	Protection against electric shock				
6.3	Protection against harmful ingress of water or particulate matter				
6.4	6.4 Method(s) of sterilization				
6.5	Suitability for use in an OXYGEN RICH ENVIRONMENT				
6.6	Mode of operation				
7	Identification, marking and documents				
7.1	General				
7.1.1	USABILITY of the identification, marking and documents				
7.1.2	Legibility of markings				
7.1.3	Durability of markings				
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1)				
7.2.1	Minimum requirements for marking on ME EQUIPMENT and on interchangeable				
7.2.2	Identification				
7.2.3	Consult ACCOMPANYING DOCUMENTS				
7.2.4	ACCESSORIES				
7.2.5	ME EQUIPMENT intended to receive power from other equipment				
7.2.6	Connection to the SUPPLY MAINS				
7.2.7	Electrical input power from the SUPPLY MAINS				
7.2.8	Output connectors				
7.2.8.1	Mains power output				
7.2.8.2	Other power sources				
7.2.9	IP classification				
7.2.10	APPLIED PARTS				
7.2.11	Mode of operation				
7.2.12	Fuses				
7.2.13	Physiological effects (safety signs and warning statements)				
7.2.14	HIGH VOLTAGE TERMINAL DEVICES				
7.2.15	Cooling conditions				
7.2.16	Mechanical stability				

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7.2.17	Protective packaging				
7.2.18	External pressure source				
7.2.19	FUNCTIONAL EARTH TERMINALS				
7.2.20	Removable protective means				
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2)				
7.3.1	Heating elements or lampholders				
7.3.2	HIGH VOLTAGE parts				
7.3.3	Batteries				
7.3.4	Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES				
7.3.5	PROTECTIVE EARTH TERMINALS				
7.3.6	FUNCTIONAL EARTH TERMINALS				
7.3.7	Supply terminals				
7.3.8	Temperature of supply terminals				
7.4	Marking of controls and instruments (see also Table C.3)				
7.4.1	Power switches				
7.4.2	Control devices				
7.4.3	Units of measure				
7.5	Safety signs				
7.6	Symbols				
7.6.1	Explanation of symbols				
7.6.2	Symbols from Annex D				
7.6.3	Symbols for controls and performance				
7.7	Colours of the insulation of conductors				
7.7.1	PROTECTIVE EARTH CONDUCTOR				
7.7.2	PROTECTIVE EARTH CONNECTIONS				
7.7.3	Green and yellow insulation				
7.7.4	Neutral conductor				
7.7.5	POWER SUPPLY CORD conductors				
7.8	Indicator lights and controls				
7.8.1	Colours of indicator lights				

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7.8.2	Colours of controls				
7.9	ACCOMPANYING DOCUMENTS				
7.9.1	General (see also Table C.4)				
7.9.2	Instructions for use (see also Table C.5)				
7.9.2.1	General				
7.9.2.2	Warning and safety notices				
7.9.2.3	ME EQUIPMENT specified for connection to a separate power supply				
7.9.2.4	Electrical power source				
7.9.2.5	ME EQUIPMENT description				
7.9.2.6	Installation				
7.9.2.7	Isolation from the SUPPLY MAINS				
7.9.2.8	Start-up PROCEDURE				
7.9.2.9	Operating instructions				
7.9.2.10	Messages				
7.9.2.11	Shutdown PROCEDURE				
7.9.2.12	Cleaning, disinfection and sterilization				
7.9.2.13	Maintenance				
7.9.2.14	ACCESSORIES, supplementary equipment, used material				
7.9.2.15	Environmental protection				
7.9.2.16	Reference to the technical description				
7.9.3	Technical description (see also Table C.6)				
7.9.3.1	General				
7.9.3.2	Replacement of fuses, POWER SUPPLY CORDS and other parts				
7.9.3.3	Circuit diagrams, component part lists, etc.				
7.9.3.4	Mains isolation				
8	Protection against electrical HAZARDS from ME EQUIPMENT				
8.1	Fundamental rule of protection against electric shock				
8.2	Requirements related to power sources				
8.2.1	Connection to a separate power source				

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8.2.2	Connection to an external d.c. power source				
8.3	Classification of APPLIED PARTS				
8.4	Limitation of voltage, current or energy				
8.4.1	PATIENT CONNECTIONS intended to deliver current				
8.4.2	ACCESSIBLE PARTS including APPLIED PARTS				
8.4.3	ME EQUIPMENT intended to be connected to a power source by a plug				
8.4.4	Internal capacitive circuits				
8.5	Separation of parts				
8.5.1	MEANS OF PROTECTION (MOP)				
8.5.1.1	General				
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)				
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)				
8.5.2	Separation of PATIENT CONNECTIONS				
8.5.2.1	F-TYPE APPLIED PARTS				
8.5.2.2	TYPE B APPLIED PARTS				
8.5.2.3	PATIENT leads				
8.5.3	MAXIMUM MAINS VOLTAGE				
8.5.4	WORKING VOLTAGE				
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS				
8.5.5.1	Defibrillation protection				
8.5.5.2	Energy reduction test				

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8.6	Protective earthing, functional earthing and potential equalization of ME Equipment				
8.6.1	Applicability of requirements				
8.6.2	PROTECTIVE EARTH TERMINAL				
8.6.3	Protective earthing of moving parts				
8.6.4	Impedance and current-carrying capability				
8.6.5	Surface coatings				
8.6.6	Plugs and sockets				
8.6.7	POTENTIAL EQUALIZATION CONDUCTOR				
8.6.8	FUNCTIONAL EARTH TERMINAL				
8.6.9	CLASS II ME EQUIPMENT				
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS				
8.7.1	General requirements				
8.7.2	SINGLE FAULT CONDITIONS				
8.7.3	Allowable values				
8.7.4	Measurements				
8.7.4.1	General				
8.7.4.2	Measuring supply circuits				
8.7.4.3	Connection to the measuring supply circuit				
8.7.4.4	Measuring device (MD)				
8.7.4.5	Measurement of the EARTH LEAKAGE CURRENT				
8.7.4.6	Measurement of the TOUCH CURRENT				
8.7.4.7	Measurement of the PATIENT LEAKAGE CURRENT				
8.7.4.8	Measurement of the PATIENT AUXILIARY CURRENT				
8.7.4.9	ME EQUIPMENT with multiple PATIENT CONNECTIONS				
8.8	Insulation				
8.8.1	General				
8.8.2	Distance through solid insulation or use of thin sheet material				
8.8.3	Dielectric strength				
8.8.4	Insulation other than wire insulation				
8.8.4.1	Mechanical strength and resistance to heat				

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8.8.4.2	Resistance to environmental stress				
8.9	CREEPAGE DISTANCES and AIR CLEARANCES				
8.9.1	Values				
8.9.1.1	General				
8.9.1.2	CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1				
8.9.1.3	CREEPAGE DISTANCES across glass, mica, ceramic and similar materials				
8.9.1.4	Minimum CREEPAGE DISTANCE				
8.9.1.5	ME EQUIPMENT RATED for high altitudes				
8.9.1.6	Interpolation				
8.9.1.7	Material groups classification				
8.9.1.8	Pollution degree classification				
8.9.1.9	Overtoltage category classification				
8.9.1.10	AIR CLEARANCE for MAINS PARTS				
8.9.1.11	SUPPLY MAINS overvoltage				
8.9.1.12	SECONDARY CIRCUITS				
8.9.1.13	PEAK WORKING VOLTAGES above 1 400 V peak or d.c.				
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION				
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED				
8.9.2	Application				
8.9.3	Spaces filled by insulating compound				
8.9.3.1	General				
8.9.3.2	Insulating compound forming solid insulation between conductive parts				
8.9.3.3	Insulating compound forming a cemented joint with other insulating parts				
8.9.3.4	Thermal cycling				
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES				
8.10	Components and wiring				
8.10.1	Fixing of components				
8.10.2	Fixing of wiring				
8.10.3	Connections between different parts of ME EQUIPMENT				

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8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices				
8.10.4.1	Limitation of operating voltages				
8.10.4.2	Connection cords				
8.10.5	Mechanical protection of wiring				
8.10.6	Guiding rollers for insulated conductors				
8.10.7	Insulation of internal wiring				
8.11	MAINS PARTS, components and layout				
8.11	Isolation from the SUPPLY MAINS				
8.11.2	MULTIPLE SOCKET-OUTLETS				
8.11.3	POWER SUPPLY CORDS				
8.11.3.1	Application				
8.11.3.2	Types				
8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors				
8.11.3.4	APPLIANCE COUPLERS				
8.11.3.5	Cord anchorage				
8.11.3.6	Cord guards				
8.11.4	MAINS TERMINAL DEVICES				
8.11.4.1	General requirements for MAINS TERMINAL DEVICES				
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES				
8.11.4.3	Fixing of mains terminals				
8.11.4.4	Connections to mains terminals				
8.11.4.5	Accessibility of the connection				
8.11.5	Mains fuses and OVER-CURRENT RELEASES				
8.11.6	Internal wiring of the MAINS PART				
9	Mechanical Hazards				
9.1	MECHANICAL HAZARDS of ME EQUIPMENT				
9.2	HAZARDS associated with moving parts				
9.2.1	General				
9.2.2	TRAPPING ZONE				
9.2.2.1	General				
9.2.2.2	Gaps				
9.2.2.3	Safe distances				

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9.2.2.4	GUARDS and protective measures				
9.2.2.4.1	Access to TRAPPING ZONES				
9.2.2.4.2	FIXED GUARDS				
9.2.2.4.3	Movable GUARDS				
9.2.2.4.4	Protective measures				
9.2.2.5	Continuous activation				
9.2.2.6	Speed of movement(s)				
9.2.3	Other HAZARDS associated with moving parts				
9.2.3.1	Unintended movement				
9.2.3.2	Overtravel				
9.2.4	Emergency stopping devices				
9.2.5	Release of PATIENT				
9.3	HAZARD associated with surfaces, corners and edges				
9.4	Instability HAZARDS				
9.4.1	General				
9.4.2	Instability – overbalance				
9.4.2.1	Instability in transport position				
9.4.2.2	Instability excluding transport				
9.4.2.3	Instability from horizontal and vertical forces				
9.4.2.4	Castors and wheels				
9.4.2.4.1	General				
9.4.2.4.2	Force for propulsion				
9.4.2.4.3	Movement over a threshold				

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9.4.3	Instability from unwanted lateral movement (including sliding)				
9.4.3.1	Instability in transport				
9.4.3.2	Instability excluding transport				
9.4.4	Grips and other handling devices				
9.5	Expelled parts HAZARD				
9.5.1	Protective means				
9.5.2	Cathode ray tubes				
9.6	Acoustic energy (including infra- and ultrasound) and vibration				
9.6.1	General				
9.6.2	Acoustic energy				
9.6.2.1	Audible acoustic energy				
9.6.2.2	Infrasound and ultrasound energy				
9.6.3	Hand-transmitted vibration				
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure				
9.7.1	General				
9.7.2	Pneumatic and hydraulic parts				
9.7.3	Maximum pressure				
9.7.4	Pressure rating of ME EQUIPMENT parts				
9.7.5	Pressure vessels				
9.7.6	Pressure-control device				
9.7.7	Pressure-relief device				
9.7.8	RATED maximum supply pressure				
9.8	HAZARDS associated with support systems				
9.8.1	General				

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9.8.2	TENSILE SAFETY FACTOR				
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems				
9.8.3.1	General				
9.8.3.2	Static forces due to loading from persons				
9.8.3.3	Dynamic forces due to loading from persons				
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES				
9.8.4.1	General				
9.8.4.2	Use after activation of a MECHANICAL PROTECTIVE DEVICE				
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended for single activation				
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES				
10	Radiation Hazards				
10.1	X-Radiation				
10.1.1	ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation				
10.1.2	ME EQUIPMENT Intended to produce diagnostic or therapeutic X-radiation				
10.2	Alpha, beta, gamma, neutron and other particle radiation				
10.3	Microwave radiation				
10.4	Lasers and light emitting diodes (LEDs)				
10.5	Other visible electromagnetic radiation				
10.6	Infrared radiation				

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11.1	Excessive temperatures in ME EQUIPMENT				
11.1.1	Table 23 Parts likely to be touched				
11.1.1	Table 24 Skin contact with AP				
11.1.2	Temperature of APPLIED PARTS				
11.1.2.1	APPLIED PARTS intended to supply heat to a PATIENT				
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT				
11.1.3	Measurements				
11.1.4	GUARDS				
11.2	Fire prevention				
11.2.1	Strength and rigidity required to prevent fire in ME EQUIPMENT				
11.2.2	ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS				

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11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT				
11.2.2.2	External exhaust outlets for OXYGEN RICH ENVIRONMENT				
11.2.2.3	Electrical connections in OXYGEN RICH ENVIRONMENTS				
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS in conjunction with ME EQUIPMENT and ME SYSTEMS				
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT				
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics				
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents				
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT				
11.6.1	General				
11.6.2	Overflow in ME EQUIPMENT				
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM				
11.6.4	Leakage				
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS				
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS				
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS				
11.6.8	Compatibility with substances used with the ME EQUIPMENT				
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS				

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11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT				
12	Accuracy and hazardous outputs				
12.1	Accuracy of controls and instruments				
12.2	USABILITY				
12.3	Alarm systems				
12.4	Protection against hazardous output				
12.4.1	Intentional exceeding of safety limits				
12.4.2	Indication of parameters relevant to safety				
12.4.3	Accidental selection of excessive output values				
12.4.4	Incorrect output				
12.4.5	Diagnostic or therapeutic radiation				
12.4.5.1	Limits				
12.4.5.2	Diagnostic X-ray equipment				
12.4.5.3	Radiotherapy equipment				
12.4.5.4	Other ME EQUIPMENT producing diagnostic or therapeutic radiation				
12.4.6	Diagnostic or therapeutic acoustic pressure				
13	Hazardous situations and fault conditions				
13.1	Specific Hazardous Situations				
13.1.1	General				
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature				
13.1.3	Exceeding LEAKAGE CURRENT or voltage limits				
13.1.4	Specific MECHANICAL HAZARDS				
13.2	SINGLE FAULT CONDITIONS				

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13.2.2	Electrical SINGLE FAULT CONDITION				
13.2.3	Overheating of transformers in ME EQUIPMENT				
13.2.4	Failure of THERMOSTATS				
13.2.5	Failure of temperature limiting devices				
13.2.6	Leakage of liquid				
13.2.7	Impairment of cooling that could result in a HAZARD				
13.2.8	Locking of moving parts				
13.2.9	Interruption and short circuiting of motor capacitors				
13.2.10	Additional test criteria for motor operated ME EQUIPMENT				
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				
13.2.13	Overload				
13.2.13.1	General overload test conditions				
13.2.13.2	ME EQUIPMENT with heating elements				
13.2.13.3	ME EQUIPMENT with motors				
13.2.13.4	ME EQUIPMENT RATED for non-CONTINUOUS OPERATION				
14	Programmable electrical medical systems				
14.1	General				
14.2	Documentation				
14.3	Risk MANAGEMENT plan				
14.4	PEMS DEVELOPMENT LIFE-CYCLE				
14.5	Problem resolution				
14.6	RISK MANAGEMENT PROCESS				
14.6.1	Identification of known and foreseeable HAZARDS				
14.6.2	RISK CONTROL				
14.7	Requirement specification				
14.8	Architecture				

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Clause	60601-1:2005 Topic	3.2	3.3	3.4	3.5
		Risk Management Process	Management Responsibilities	Qualification of Personnel	Risk Management Plan
14.9	Design and implementation				
14.10	VERIFICATION				
14.11	PEMS VALIDATION				
14.12	Modification				
14.13	Connection of PEMS by NETWORK/DATA COUPLING to other equipment				
15	Construction				
15.1	Arrangements of controls and indicators of ME EQUIPMENT				
15.2	Serviceability				
15.3	Mechanical strength				
15.3.1	General				
15.3.2	Push test				
15.3.3	Impact test				
15.3.4	Drop test				
15.3.4.1	HAND-HELD ME EQUIPMENT				
15.3.4.2	PORTABLE ME EQUIPMENT				
15.3.5	Rough handling test				
15.3.6	Mould stress relief test				
15.3.7	Environmental influences				
15.4	ME EQUIPMENT components and general assembly				
15.4.1	Construction of connectors				
15.4.2	Temperature and overload control devices				

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		Risk Management Process	Management Responsibilities	Qualification of Personnel	Risk Management Plan
15.4.2.1	Application				
15.4.2.2	Temperature settings				
15.4.3	Batteries				
15.4.3.1	Housing				
15.4.3.2	Connection				
15.4.3.3	Protection against overcharging				
15.4.3.4	Lithium batteries				
15.4.3.5	Excessive current and voltage protection				
15.4.4	Indicators				
15.4.5	Pre-set controls				
15.4.6	Actuating parts of controls of ME EQUIPMENT				
15.4.6.1	Fixing, prevention of maladjustment				
15.4.6.2	Limitation of movement				
15.4.7	Cord-connected HAND-HELD and foot-operated control devices (see also 8.10.4)				
15.4.7.1	Mechanical strength				
15.4.7.2	Accidental operation of ME EQUIPMENT				
15.4.7.3	Entry of liquids				
15.4.8	Internal wiring of ME EQUIPMENT				
15.4.9	Oil containers				

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Clause	60601-1:2005 Topic	3.2	3.3	3.4	3.5
		Risk Management Process	Management Responsibilities	Qualification of Personnel	Risk Management Plan
15.5	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5				
15.5.1	Overheating				
15.5.1.1	Transformers				
15.5.1.2	Short-circuit test				
15.5.1.3	Overload test				
15.5.2	Dielectric strength				
15.5.3	Construction of transformers used to provide separation as required by 8.5				
16	Medical electrical systems				
16.1	General requirements for the ME SYSTEMS				
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM				
16.3	Power supply				
16.4	ENCLOSURES				
16.5	SEPARATION DEVICES				
16.6	LEAKAGE CURRENTS				
16.6.1	TOUCH CURRENT				
16.6.2	EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET				
16.6.3	PATIENT LEAKAGE CURRENT				
16.6.4	Measurements				
16.6.4.1	General conditions for ME SYSTEMS				
16.6.4.2	Connection of the ME SYSTEM to the measuring supply circuit				
16.7	Protection against MECHANICAL HAZARDS				
16.8	Interruption of the power supply to parts of an ME SYSTEM				
16.9	ME SYSTEM connections and wiring				
16.9.1	Connection terminals and connectors				
16.9.2	MAINS PARTS, components and layout				
16.9.2.1	MULTIPLE SOCKET-OUTLET				
16.9.2.2	PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS				
16.9.2.3	Protection of conductors				
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS				

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		Risk Management Process	Management Responsibilities	Qualification of Personnel	Risk Management Plan
	Protection against HAZARDS of ignition of flammable anaesthetic mixtures				
G.1	Introduction				
G.1.1	Applicability				
G.1.2	Industrial equipment and components				
G.1.3	Requirements for ME EQUIPMENT				
G.2	Locations and basic requirements				
G.2.1	Parts of CATEGORY APG ME EQUIPMENT				
G.2.2	FLAMMABLE ANAESTHETIC MIXTURE WITH AIR				
G.2.3	FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE				
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR				
G.2.5	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE				
G.3	Marking, ACCOMPANYING DOCUMENTS				
G.3.1	CATEGORY APG marking				
G.3.2	CATEGORY AP marking				
G.3.3	Placement of markings				
G.3.4	ACCOMPANYING DOCUMENTS				
G.3.5	Marking when parts of ME EQUIPMENT are CATEGORY AP or CATEGORY APG				
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT				
G.4.1	Electrical connections				
G.4.2	Construction details				
G.4.3	Prevention of electrostatic charges				
G.4.4	Corona				
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components thereof				
G.5.1	General				
G.5.2	Temperature limits				
G.5.3	Low-energy circuits				
G.5.4	External ventilation with internal overpressure				
G.5.5	ENCLOSURES with restricted breathing				
G.6	Requirements and tests for CATEGORY APG ME EQUIPMENT, parts and components thereof				
G.6.1	General				
G.6.2	Power supply				

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Clause	60601-1:2005 Topic	3.2	3.3	3.4	3.5
		Risk Management Process	Management Responsibilities	Qualification of Personnel	Risk Management Plan
G.6.3	Temperatures and low-energy circuits				
G.6.4	Heating elements				
G.7	Test apparatus for flammable mixtures				

Means these clauses of ISO 14971 are not required

Means requires risk management investigation

Means simply a heading no text

Reference clause to another

Means no risk management activity required

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Clause	60601-1:2005 Topic	3.6	4	4.1	4.2
		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
4	General requirements				
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS				
4.2	RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS				
4.3	ESSENTIAL PERFORMANCE				
4.4	EXPECTED SERVICE LIFE				
4.5	Equivalent safety for ME EQUIPMENT or ME SYSTEMS				
4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT				
4.7	SINGLE FAULT CONDITION for ME EQUIPMENT				
4.8	Components of ME EQUIPMENT				
4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT				
4.10	Power supply				
4.10.1	Source of power for ME EQUIPMENT				
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS				
4.11	Power input				
5	General requirements for testing				
5.1	TYPE TESTS				
5.2	Number of samples				
5.3	Ambient temperature, humidity, atmospheric pressure				
5.4	Other conditions				
5.5	Supply voltages, type of current, nature of supply, frequency				
5.6	Repairs and modifications				
5.7	Humidity preconditioning treatment				
5.8	Sequence of tests				
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS				
5.9.1	APPLIED PARTS				
5.9.2	ACCESSIBLE PARTS				
5.9.2.1	Test finger				
5.9.2.2	Test hook				
5.9.2.3	Actuating mechanisms				

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		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
6	Classification				
6.1	General				
6.2	Protection against electric shock				
6.3	Protection against harmful ingress of water or particulate matter				
6.4	6.4 Method(s) of sterilization				
6.5	Suitability for use in an OXYGEN RICH ENVIRONMENT				
6.6	Mode of operation				
7	Identification, marking and documents				
7.1	General				
7.1.1	USABILITY of the identification, marking and documents				
7.1.2	Legibility of markings				
7.1.3	Durability of markings				
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1)				
7.2.1	Minimum requirements for marking on ME EQUIPMENT and on interchangeable				
7.2.2	Identification				
7.2.3	Consult ACCOMPANYING DOCUMENTS				
7.2.4	ACCESSORIES				
7.2.5	ME EQUIPMENT intended to receive power from other equipment				
7.2.6	Connection to the SUPPLY MAINS				
7.2.7	Electrical input power from the SUPPLY MAINS				
7.2.8	Output connectors				
7.2.8.1	Mains power output				
7.2.8.2	Other power sources				
7.2.9	IP classification				
7.2.10	APPLIED PARTS				
7.2.11	Mode of operation				
7.2.12	Fuses				
7.2.13	Physiological effects (safety signs and warning statements)				
7.2.14	HIGH VOLTAGE TERMINAL DEVICES				
7.2.15	Cooling conditions				
7.2.16	Mechanical stability				

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		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
7.2.17	Protective packaging				
7.2.18	External pressure source				
7.2.19	FUNCTIONAL EARTH TERMINALS				
7.2.20	Removable protective means				
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2)				
7.3.1	Heating elements or lampholders				
7.3.2	HIGH VOLTAGE parts				
7.3.3	Batteries				
7.3.4	Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES				
7.3.5	PROTECTIVE EARTH TERMINALS				
7.3.6	FUNCTIONAL EARTH TERMINALS				
7.3.7	Supply terminals				
7.3.8	Temperature of supply terminals				
7.4	Marking of controls and instruments (see also Table C.3)				
7.4.1	Power switches				
7.4.2	Control devices				
7.4.3	Units of measure				
7.5	Safety signs				
7.6	Symbols				
7.6.1	Explanation of symbols				
7.6.2	Symbols from Annex D				
7.6.3	Symbols for controls and performance				
7.7	Colours of the insulation of conductors				
7.7.1	PROTECTIVE EARTH CONDUCTOR				
7.7.2	PROTECTIVE EARTH CONNECTIONS				
7.7.3	Green and yellow insulation				
7.7.4	Neutral conductor				
7.7.5	POWER SUPPLY CORD conductors				
7.8	Indicator lights and controls				
7.8.1	Colours of indicator lights				

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Clause	60601-1:2005 Topic	3.6	4	4.1	4.2
		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
7.8.2	Colours of controls				
7.9	ACCOMPANYING DOCUMENTS				
7.9.1	General (see also Table C.4)				
7.9.2	Instructions for use (see also Table C.5)				
7.9.2.1	General				
7.9.2.2	Warning and safety notices				
7.9.2.3	ME EQUIPMENT specified for connection to a separate power supply				
7.9.2.4	Electrical power source				
7.9.2.5	ME EQUIPMENT description				
7.9.2.6	Installation				
7.9.2.7	Isolation from the SUPPLY MAINS				
7.9.2.8	Start-up PROCEDURE				
7.9.2.9	Operating instructions				
7.9.2.10	Messages				
7.9.2.11	Shutdown PROCEDURE				
7.9.2.12	Cleaning, disinfection and sterilization				
7.9.2.13	Maintenance				
7.9.2.14	ACCESSORIES, supplementary equipment, used material				
7.9.2.15	Environmental protection				
7.9.2.16	Reference to the technical description				
7.9.3	Technical description (see also Table C.6)				
7.9.3.1	General				
7.9.3.2	Replacement of fuses, POWER SUPPLY CORDS and other parts				
7.9.3.3	Circuit diagrams, component part lists, etc.				
7.9.3.4	Mains isolation				
8	Protection against electrical HAZARDS from ME EQUIPMENT				
8.1	Fundamental rule of protection against electric shock				
8.2	Requirements related to power sources				
8.2.1	Connection to a separate power source				

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Clause	60601-1:2005 Topic	3.6	4	4.1	4.2
		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
8.2.2	Connection to an external d.c. power source				
8.3	Classification of APPLIED PARTS				
8.4	Limitation of voltage, current or energy				
8.4.1	PATIENT CONNECTIONS intended to deliver current				
8.4.2	ACCESSIBLE PARTS including APPLIED PARTS				
8.4.3	ME EQUIPMENT intended to be connected to a power source by a plug				
8.4.4	Internal capacitive circuits				
8.5	Separation of parts				
8.5.1	MEANS OF PROTECTION (MOP)				
8.5.1.1	General				
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)				
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)				
8.5.2	Separation of PATIENT CONNECTIONS				
8.5.2.1	F-TYPE APPLIED PARTS				
8.5.2.2	TYPE B APPLIED PARTS				
8.5.2.3	PATIENT leads				
8.5.3	MAXIMUM MAINS VOLTAGE				
8.5.4	WORKING VOLTAGE				
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS				
8.5.5.1	Defibrillation protection				
8.5.5.2	Energy reduction test				

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Clause	60601-1:2005 Topic	3.6	4	4.1	4.2
		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
8.6	Protective earthing, functional earthing and potential equalization of ME Equipment				
8.6.1	Applicability of requirements				
8.6.2	PROTECTIVE EARTH TERMINAL				
8.6.3	Protective earthing of moving parts				
8.6.4	Impedance and current-carrying capability				
8.6.5	Surface coatings				
8.6.6	Plugs and sockets				
8.6.7	POTENTIAL EQUALIZATION CONDUCTOR				
8.6.8	FUNCTIONAL EARTH TERMINAL				
8.6.9	CLASS II ME EQUIPMENT				
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS				
8.7.1	General requirements				
8.7.2	SINGLE FAULT CONDITIONS				
8.7.3	Allowable values				
8.7.4	Measurements				
8.7.4.1	General				
8.7.4.2	Measuring supply circuits				
8.7.4.3	Connection to the measuring supply circuit				
8.7.4.4	Measuring device (MD)				
8.7.4.5	Measurement of the EARTH LEAKAGE CURRENT				
8.7.4.6	Measurement of the TOUCH CURRENT				
8.7.4.7	Measurement of the PATIENT LEAKAGE CURRENT				
8.7.4.8	Measurement of the PATIENT AUXILIARY CURRENT				
8.7.4.9	ME EQUIPMENT with multiple PATIENT CONNECTIONS				
8.8	Insulation				
8.8.1	General				
8.8.2	Distance through solid insulation or use of thin sheet material				
8.8.3	Dielectric strength				
8.8.4	Insulation other than wire insulation				
8.8.4.1	Mechanical strength and resistance to heat				

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Clause	60601-1:2005 Topic	3.6	4	4.1	4.2
		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
8.8.4.2	Resistance to environmental stress				
8.9	CREEPAGE DISTANCES and AIR CLEARANCES				
8.9.1	Values				
8.9.1.1	General				
8.9.1.2	CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1				
8.9.1.3	CREEPAGE DISTANCES across glass, mica, ceramic and similar materials				
8.9.1.4	Minimum CREEPAGE DISTANCE				
8.9.1.5	ME EQUIPMENT RATED for high altitudes				
8.9.1.6	Interpolation				
8.9.1.7	Material groups classification				
8.9.1.8	Pollution degree classification				
8.9.1.9	Overvoltage category classification				
8.9.1.10	AIR CLEARANCE for MAINS PARTS				
8.9.1.11	SUPPLY MAINS overvoltage				
8.9.1.12	SECONDARY CIRCUITS				
8.9.1.13	PEAK WORKING VOLTAGES above 1 400 V peak or d.c.				
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION				
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED				
8.9.2	Application				
8.9.3	Spaces filled by insulating compound				
8.9.3.1	General				
8.9.3.2	Insulating compound forming solid insulation between conductive parts				
8.9.3.3	Insulating compound forming a cemented joint with other insulating parts				
8.9.3.4	Thermal cycling				
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES				
8.10	Components and wiring				
8.10.1	Fixing of components				
8.10.2	Fixing of wiring				
8.10.3	Connections between different parts of ME EQUIPMENT				

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		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices				
8.10.4.1	Limitation of operating voltages				
8.10.4.2	Connection cords				
8.10.5	Mechanical protection of wiring				
8.10.6	Guiding rollers for insulated conductors				
8.10.7	Insulation of internal wiring				
8.11	MAINS PARTS, components and layout				
8.11	Isolation from the SUPPLY MAINS				
8.11.2	MULTIPLE SOCKET-OUTLETS				
8.11.3	POWER SUPPLY CORDS				
8.11.3.1	Application				
8.11.3.2	Types				
8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors				
8.11.3.4	APPLIANCE COUPLERS				
8.11.3.5	Cord anchorage				
8.11.3.6	Cord guards				
8.11.4	MAINS TERMINAL DEVICES				
8.11.4.1	General requirements for MAINS TERMINAL DEVICES				
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES				
8.11.4.3	Fixing of mains terminals				
8.11.4.4	Connections to mains terminals				
8.11.4.5	Accessibility of the connection				
8.11.5	Mains fuses and OVER-CURRENT RELEASES				
8.11.6	Internal wiring of the MAINS PART				
9	Mechanical Hazards				
9.1	MECHANICAL HAZARDS of ME EQUIPMENT				
9.2	HAZARDS associated with moving parts				
9.2.1	General				
9.2.2	TRAPPING ZONE				
9.2.2.1	General				
9.2.2.2	Gaps				
9.2.2.3	Safe distances				

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		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
9.2.2.4	GUARDS and protective measures				
9.2.2.4.1	Access to TRAPPING ZONES				
9.2.2.4.2	FIXED GUARDS				
9.2.2.4.3	Movable GUARDS				
9.2.2.4.4	Protective measures				
9.2.2.5	Continuous activation				
9.2.2.6	Speed of movement(s)				
9.2.3	Other HAZARDS associated with moving parts				
9.2.3.1	Unintended movement				
9.2.3.2	Overtravel				
9.2.4	Emergency stopping devices				
9.2.5	Release of PATIENT				
9.3	HAZARD associated with surfaces, corners and edges				
9.4	Instability HAZARDS				
9.4.1	General				
9.4.2	Instability – overbalance				
9.4.2.1	Instability in transport position				
9.4.2.2	Instability excluding transport				
9.4.2.3	Instability from horizontal and vertical forces				
9.4.2.4	Castors and wheels				
9.4.2.4.1	General				
9.4.2.4.2	Force for propulsion				
9.4.2.4.3	Movement over a threshold				

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Clause	60601-1:2005 Topic	3.6	4	4.1	4.2
		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
9.4.3	Instability from unwanted lateral movement (including sliding)				
9.4.3.1	Instability in transport				
9.4.3.2	Instability excluding transport				
9.4.4	Grips and other handling devices				
9.5	Expelled parts HAZARD				
9.5.1	Protective means				
9.5.2	Cathode ray tubes				
9.6	Acoustic energy (including infra- and ultrasound) and vibration				
9.6.1	General				
9.6.2	Acoustic energy				
9.6.2.1	Audible acoustic energy				
9.6.2.2	Infrasound and ultrasound energy				
9.6.3	Hand-transmitted vibration				
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure				
9.7.1	General				
9.7.2	Pneumatic and hydraulic parts				
9.7.3	Maximum pressure				
9.7.4	Pressure rating of ME EQUIPMENT parts				
9.7.5	Pressure vessels				
9.7.6	Pressure-control device				
9.7.7	Pressure-relief device				
9.7.8	RATED maximum supply pressure				
9.8	HAZARDS associated with support systems				
9.8.1	General				

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Clause	60601-1:2005 Topic	3.6	4	4.1	4.2
		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
9.8.2	TENSILE SAFETY FACTOR				
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems				
9.8.3.1	General				
9.8.3.2	Static forces due to loading from persons				
9.8.3.3	Dynamic forces due to loading from persons				
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES				
9.8.4.1	General				
9.8.4.2	Use after activation of a MECHANICAL PROTECTIVE DEVICE				
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended for single activation				
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES				
10	Radiation Hazards				
10.1	X-Radiation				
10.1.1	ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation				
10.1.2	ME EQUIPMENT Intended to produce diagnostic or therapeutic X-radiation				
10.2	Alpha, beta, gamma, neutron and other particle radiation				
10.3	Microwave radiation				
10.4	Lasers and light emitting diodes (LEDs)				
10.5	Other visible electromagnetic radiation				
10.6	Infrared radiation				

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		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
10.7	Ultraviolet radiation				
11	Temperature and Other Hazards				
11.1	Excessive temperatures in ME EQUIPMENT				
11.1.1	Table 23 Parts likely to be touched				
11.1.1	Table 24 Skin contact with AP				
11.1.2	Temperature of APPLIED PARTS				
11.1.2.1	APPLIED PARTS intended to supply heat to a PATIENT				
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT				
11.1.3	Measurements				
11.1.4	GUARDS				
11.2	Fire prevention				
11.2.1	Strength and rigidity required to prevent fire in ME EQUIPMENT				
11.2.2	ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS				

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Clause	60601-1:2005 Topic	3.6	4	4.1	4.2
		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT				
11.2.2.2	External exhaust outlets for OXYGEN RICH ENVIRONMENT				
11.2.2.3	Electrical connections in OXYGEN RICH ENVIRONMENTS				
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS in conjunction with ME EQUIPMENT and ME SYSTEMS				
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT				
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics				
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents				
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT				
11.6.1	General				
11.6.2	Overflow in ME EQUIPMENT				
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM				
11.6.4	Leakage				
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS				
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS				
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS				
11.6.8	Compatibility with substances used with the ME EQUIPMENT				
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS				

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		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT				
12	Accuracy and hazardous outputs				
12.1	Accuracy of controls and instruments				
12.2	USABILITY				
12.3	Alarm systems				
12.4	Protection against hazardous output				
12.4.1	Intentional exceeding of safety limits				
12.4.2	Indication of parameters relevant to safety				
12.4.3	Accidental selection of excessive output values				
12.4.4	Incorrect output				
12.4.5	Diagnostic or therapeutic radiation				
12.4.5.1	Limits				
12.4.5.2	Diagnostic X-ray equipment				
12.4.5.3	Radiotherapy equipment				
12.4.5.4	Other ME EQUIPMENT producing diagnostic or therapeutic radiation				
12.4.6	Diagnostic or therapeutic acoustic pressure				
13	Hazardous situations and fault conditions				
13.1	Specific Hazardous Situations				
13.1.1	General				
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature				
13.1.3	Exceeding LEAKAGE CURRENT or voltage limits				
13.1.4	Specific MECHANICAL HAZARDS				
13.2	SINGLE FAULT CONDITIONS				

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		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
13.2.1	General				
13.2.2	Electrical SINGLE FAULT CONDITION				
13.2.3	Overheating of transformers in ME EQUIPMENT				
13.2.4	Failure of THERMOSTATS				
13.2.5	Failure of temperature limiting devices				
13.2.6	Leakage of liquid				
13.2.7	Impairment of cooling that could result in a HAZARD				
13.2.8	Locking of moving parts				
13.2.9	Interruption and short circuiting of motor capacitors				
13.2.10	Additional test criteria for motor operated ME EQUIPMENT				
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				
13.2.13	Overload				
13.2.13.1	General overload test conditions				
13.2.13.2	ME EQUIPMENT with heating elements				
13.2.13.3	ME EQUIPMENT with motors				
13.2.13.4	ME EQUIPMENT RATED for non-CONTINUOUS OPERATION				
14	Programmable electrical medical systems				
14.1	General				
14.2	Documentation				
14.3	Risk MANAGEMENT plan				
14.4	PEMS DEVELOPMENT LIFE-CYCLE				
14.5	Problem resolution				
14.6	RISK MANAGEMENT PROCESS				
14.6.1	Identification of known and foreseeable HAZARDS				
14.6.2	RISK CONTROL				
14.7	Requirement specification				
14.8	Architecture				

APPENDIX A					
Clause	60601-1:2005 Topic	3.6	4	4.1	4.2
		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
14.9	Design and implementation				
14.10	VERIFICATION				
14.11	PEMS VALIDATION				
14.12	Modification				
14.13	Connection of PEMS by NETWORK/DATA COUPLING to other equipment				
15	Construction				
15.1	Arrangements of controls and indicators of ME EQUIPMENT				
15.2	Serviceability				
15.3	Mechanical strength				
15.3.1	General				
15.3.2	Push test				
15.3.3	Impact test				
15.3.4	Drop test				
15.3.4.1	HAND-HELD ME EQUIPMENT				
15.3.4.2	PORTABLE ME EQUIPMENT				
15.3.5	Rough handling test				
15.3.6	Mould stress relief test				
15.3.7	Environmental influences				
15.4	ME EQUIPMENT components and general assembly				
15.4.1	Construction of connectors				
15.4.2	Temperature and overload control devices				

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		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
15.4.2.1	Application				
15.4.2.2	Temperature settings				
15.4.3	Batteries				
15.4.3.1	Housing				
15.4.3.2	Connection				
15.4.3.3	Protection against overcharging				
15.4.3.4	Lithium batteries				
15.4.3.5	Excessive current and voltage protection				
15.4.4	Indicators				
15.4.5	Pre-set controls				
15.4.6	Actuating parts of controls of ME EQUIPMENT				
15.4.6.1	Fixing, prevention of maladjustment				
15.4.6.2	Limitation of movement				
15.4.7	Cord-connected HAND-HELD and foot-operated control devices (see also 8.10.4)				
15.4.7.1	Mechanical strength				
15.4.7.2	Accidental operation of ME EQUIPMENT				
15.4.7.3	Entry of liquids				
15.4.8	Internal wiring of ME EQUIPMENT				
15.4.9	Oil containers				

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		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
15.5	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5				
15.5.1	Overheating				
15.5.1.1	Transformers				
15.5.1.2	Short-circuit test				
15.5.1.3	Overload test				
15.5.2	Dielectric strength				
15.5.3	Construction of transformers used to provide separation as required by 8.5				
16	Medical electrical systems				
16.1	General requirements for the ME SYSTEMS				
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM				
16.3	Power supply				
16.4	ENCLOSURES				
16.5	SEPARATION DEVICES				
16.6	LEAKAGE CURRENTS				
16.6.1	TOUCH CURRENT				
16.6.2	EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET				
16.6.3	PATIENT LEAKAGE CURRENT				
16.6.4	Measurements				
16.6.4.1	General conditions for ME SYSTEMS				
16.6.4.2	Connection of the ME SYSTEM to the measuring supply circuit				
16.7	Protection against MECHANICAL HAZARDS				
16.8	Interruption of the power supply to parts of an ME SYSTEM				
16.9	ME SYSTEM connections and wiring				
16.9.1	Connection terminals and connectors				
16.9.2	MAINS PARTS, components and layout				
16.9.2.1	MULTIPLE SOCKET-OUTLET				
16.9.2.2	PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS				
16.9.2.3	Protection of conductors				
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS				

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		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
	Protection against HAZARDS of ignition of flammable anaesthetic mixtures				
G.1	Introduction				
G.1.1	Applicability				
G.1.2	Industrial equipment and components				
G.1.3	Requirements for ME EQUIPMENT				
G.2	Locations and basic requirements				
G.2.1	Parts of CATEGORY APG ME EQUIPMENT				
G.2.2	FLAMMABLE ANAESTHETIC MIXTURE WITH AIR				
G.2.3	FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE				
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR				
G.2.5	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE				
G.3	Marking, ACCOMPANYING DOCUMENTS				
G.3.1	CATEGORY APG marking				
G.3.2	CATEGORY AP marking				
G.3.3	Placement of markings				
G.3.4	ACCOMPANYING DOCUMENTS				
G.3.5	Marking when parts of ME EQUIPMENT are CATEGORY AP or CATEGORY APG				
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT				
G.4.1	Electrical connections				
G.4.2	Construction details				
G.4.3	Prevention of electrostatic charges				
G.4.4	Corona				
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components thereof				
G.5.1	General				
G.5.2	Temperature limits				
G.5.3	Low-energy circuits				
G.5.4	External ventilation with internal overpressure				
G.5.5	ENCLOSURES with restricted breathing				
G.6	Requirements and tests for CATEGORY APG ME EQUIPMENT, parts and components thereof				
G.6.1	General				
G.6.2	Power supply				

APPENDIX A					
Clause	60601-1:2005 Topic	3.6	4	4.1	4.2
		Risk Management File	Risk Analysis	Risk Analysis Process	Intended Use
G.6.3	Temperatures and low-energy circuits				
G.6.4	Heating elements				
G.7	Test apparatus for flammable mixtures				

Means these clauses of ISO 14971 are not required

Means requires risk management investigation

Means simply a heading no text

Reference clause to another

Means no risk management activity required

APPENDIX A		ISO 14971:2000 Clauses			
Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
4	General requirements				
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS				
4.2	RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS				
4.3	ESSENTIAL PERFORMANCE				
4.4	EXPECTED SERVICE LIFE				
4.5	Equivalent safety for ME EQUIPMENT or ME SYSTEMS				
4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT				
4.7	SINGLE FAULT CONDITION for ME EQUIPMENT				
4.8	Components of ME EQUIPMENT				
4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT				
4.10	Power supply				
4.10.1	Source of power for ME EQUIPMENT				
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS				
4.11	Power input				
5	General requirements for testing				
5.1	TYPE TESTS				
5.2	Number of samples				
5.3	Ambient temperature, humidity, atmospheric pressure				
5.4	Other conditions				
5.5	Supply voltages, type of current, nature of supply, frequency				
5.6	Repairs and modifications				
5.7	Humidity preconditioning treatment				
5.8	Sequence of tests				
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS				
5.9.1	APPLIED PARTS				
5.9.2	ACCESSIBLE PARTS				
5.9.2.1	Test finger				
5.9.2.2	Test hook				
5.9.2.3	Actuating mechanisms				

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Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
6	Classification				
6.1	General				
6.2	Protection against electric shock				
6.3	Protection against harmful ingress of water or particulate matter				
6.4	6.4 Method(s) of sterilization				
6.5	Suitability for use in an OXYGEN RICH ENVIRONMENT				
6.6	Mode of operation				
7	Identification, marking and documents				
7.1	General				
7.1.1	USABILITY of the identification, marking and documents				
7.1.2	Legibility of markings				
7.1.3	Durability of markings				
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1)				
7.2.1	Minimum requirements for marking on ME EQUIPMENT and on interchangeable				
7.2.2	Identification				
7.2.3	Consult ACCOMPANYING DOCUMENTS				
7.2.4	ACCESSORIES				
7.2.5	ME EQUIPMENT intended to receive power from other equipment				
7.2.6	Connection to the SUPPLY MAINS				
7.2.7	Electrical input power from the SUPPLY MAINS				
7.2.8	Output connectors				
7.2.8.1	Mains power output				
7.2.8.2	Other power sources				
7.2.9	IP classification				
7.2.10	APPLIED PARTS				
7.2.11	Mode of operation				
7.2.12	Fuses				
7.2.13	Physiological effects (safety signs and warning statements)				
7.2.14	HIGH VOLTAGE TERMINAL DEVICES				
7.2.15	Cooling conditions				
7.2.16	Mechanical stability				

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Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
7.2.17	Protective packaging				
7.2.18	External pressure source				
7.2.19	FUNCTIONAL EARTH TERMINALS				
7.2.20	Removable protective means				
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2)				
7.3.1	Heating elements or lampholders				
7.3.2	HIGH VOLTAGE parts				
7.3.3	Batteries				
7.3.4	Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES				
7.3.5	PROTECTIVE EARTH TERMINALS				
7.3.6	FUNCTIONAL EARTH TERMINALS				
7.3.7	Supply terminals				
7.3.8	Temperature of supply terminals				
7.4	Marking of controls and instruments (see also Table C.3)				
7.4.1	Power switches				
7.4.2	Control devices				
7.4.3	Units of measure				
7.5	Safety signs				
7.6	Symbols				
7.6.1	Explanation of symbols				
7.6.2	Symbols from Annex D				
7.6.3	Symbols for controls and performance				
7.7	Colours of the insulation of conductors				
7.7.1	PROTECTIVE EARTH CONDUCTOR				
7.7.2	PROTECTIVE EARTH CONNECTIONS				
7.7.3	Green and yellow insulation				
7.7.4	Neutral conductor				
7.7.5	POWER SUPPLY CORD conductors				
7.8	Indicator lights and controls				
7.8.1	Colours of indicator lights				

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Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
7.8.2	Colours of controls				
7.9	ACCOMPANYING DOCUMENTS				
7.9.1	General (see also Table C.4)				
7.9.2	Instructions for use (see also Table C.5)				
7.9.2.1	General				
7.9.2.2	Warning and safety notices				
7.9.2.3	ME EQUIPMENT specified for connection to a separate power supply				
7.9.2.4	Electrical power source				
7.9.2.5	ME EQUIPMENT description				
7.9.2.6	Installation				
7.9.2.7	Isolation from the SUPPLY MAINS				
7.9.2.8	Start-up PROCEDURE				
7.9.2.9	Operating instructions				
7.9.2.10	Messages				
7.9.2.11	Shutdown PROCEDURE				
7.9.2.12	Cleaning, disinfection and sterilization				
7.9.2.13	Maintenance				
7.9.2.14	ACCESSORIES, supplementary equipment, used material				
7.9.2.15	Environmental protection				
7.9.2.16	Reference to the technical description				
7.9.3	Technical description (see also Table C.6)				
7.9.3.1	General				
7.9.3.2	Replacement of fuses, POWER SUPPLY CORDS and other parts				
7.9.3.3	Circuit diagrams, component part lists, etc.				
7.9.3.4	Mains isolation				
8	Protection against electrical HAZARDS from ME EQUIPMENT				
8.1	Fundamental rule of protection against electric shock				
8.2	Requirements related to power sources				
8.2.1	Connection to a separate power source				

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Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
8.2.2	Connection to an external d.c. power source				
8.3	Classification of APPLIED PARTS				
8.4	Limitation of voltage, current or energy				
8.4.1	PATIENT CONNECTIONS intended to deliver current				
8.4.2	ACCESSIBLE PARTS including APPLIED PARTS				
8.4.3	ME EQUIPMENT intended to be connected to a power source by a plug				
8.4.4	Internal capacitive circuits				
8.5	Separation of parts				
8.5.1	MEANS OF PROTECTION (MOP)				
8.5.1.1	General				
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)				
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)				
8.5.2	Separation of PATIENT CONNECTIONS				
8.5.2.1	F-TYPE APPLIED PARTS				
8.5.2.2	TYPE B APPLIED PARTS				
8.5.2.3	PATIENT leads				
8.5.3	MAXIMUM MAINS VOLTAGE				
8.5.4	WORKING VOLTAGE				
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS				
8.5.5.1	Defibrillation protection				
8.5.5.2	Energy reduction test				

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Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
8.6	Protective earthing, functional earthing and potential equalization of ME Equipment				
8.6.1	Applicability of requirements				
8.6.2	PROTECTIVE EARTH TERMINAL				
8.6.3	Protective earthing of moving parts				
8.6.4	Impedance and current-carrying capability				
8.6.5	Surface coatings				
8.6.6	Plugs and sockets				
8.6.7	POTENTIAL EQUALIZATION CONDUCTOR				
8.6.8	FUNCTIONAL EARTH TERMINAL				
8.6.9	CLASS II ME EQUIPMENT				
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS				
8.7.1	General requirements				
8.7.2	SINGLE FAULT CONDITIONS				
8.7.3	Allowable values				
8.7.4	Measurements				
8.7.4.1	General				
8.7.4.2	Measuring supply circuits				
8.7.4.3	Connection to the measuring supply circuit				
8.7.4.4	Measuring device (MD)				
8.7.4.5	Measurement of the EARTH LEAKAGE CURRENT				
8.7.4.6	Measurement of the TOUCH CURRENT				
8.7.4.7	Measurement of the PATIENT LEAKAGE CURRENT				
8.7.4.8	Measurement of the PATIENT AUXILIARY CURRENT				
8.7.4.9	ME EQUIPMENT with multiple PATIENT CONNECTIONS				
8.8	Insulation				
8.8.1	General				
8.8.2	Distance through solid insulation or use of thin sheet material				
8.8.3	Dielectric strength				
8.8.4	Insulation other than wire insulation				
8.8.4.1	Mechanical strength and resistance to heat				

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		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
8.8.4.2	Resistance to environmental stress				
8.9	CREEPAGE DISTANCES and AIR CLEARANCES				
8.9.1	Values				
8.9.1.1	General				
8.9.1.2	CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1				
8.9.1.3	CREEPAGE DISTANCES across glass, mica, ceramic and similar materials				
8.9.1.4	Minimum CREEPAGE DISTANCE				
8.9.1.5	ME EQUIPMENT RATED for high altitudes				
8.9.1.6	Interpolation				
8.9.1.7	Material groups classification				
8.9.1.8	Pollution degree classification				
8.9.1.9	Overvoltage category classification				
8.9.1.10	AIR CLEARANCE for MAINS PARTS				
8.9.1.11	SUPPLY MAINS overvoltage				
8.9.1.12	SECONDARY CIRCUITS				
8.9.1.13	PEAK WORKING VOLTAGES above 1 400 V peak or d.c.				
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION				
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED				
8.9.2	Application				
8.9.3	Spaces filled by insulating compound				
8.9.3.1	General				
8.9.3.2	Insulating compound forming solid insulation between conductive parts				
8.9.3.3	Insulating compound forming a cemented joint with other insulating parts				
8.9.3.4	Thermal cycling				
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES				
8.10	Components and wiring				
8.10.1	Fixing of components				
8.10.2	Fixing of wiring				
8.10.3	Connections between different parts of ME EQUIPMENT				

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		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices				
8.10.4.1	Limitation of operating voltages				
8.10.4.2	Connection cords				
8.10.5	Mechanical protection of wiring				
8.10.6	Guiding rollers for insulated conductors				
8.10.7	Insulation of internal wiring				
8.11	MAINS PARTS, components and layout				
8.11	Isolation from the SUPPLY MAINS				
8.11.2	MULTIPLE SOCKET-OUTLETS				
8.11.3	POWER SUPPLY CORDS				
8.11.3.1	Application				
8.11.3.2	Types				
8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors				
8.11.3.4	APPLIANCE COUPLERS				
8.11.3.5	Cord anchorage				
8.11.3.6	Cord guards				
8.11.4	MAINS TERMINAL DEVICES				
8.11.4.1	General requirements for MAINS TERMINAL DEVICES				
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES				
8.11.4.3	Fixing of mains terminals				
8.11.4.4	Connections to mains terminals				
8.11.4.5	Accessibility of the connection				
8.11.5	Mains fuses and OVER-CURRENT RELEASES				
8.11.6	Internal wiring of the MAINS PART				
9	Mechanical Hazards				
9.1	MECHANICAL HAZARDS of ME EQUIPMENT				
9.2	HAZARDS associated with moving parts				
9.2.1	General				
9.2.2	TRAPPING ZONE				
9.2.2.1	General				
9.2.2.2	Gaps				
9.2.2.3	Safe distances				

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Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
9.2.2.4	GUARDS and protective measures				
9.2.2.4.1	Access to TRAPPING ZONES				
9.2.2.4.2	FIXED GUARDS				
9.2.2.4.3	Movable GUARDS				
9.2.2.4.4	Protective measures				
9.2.2.5	Continuous activation				
9.2.2.6	Speed of movement(s)				
9.2.3	Other HAZARDS associated with moving parts				
9.2.3.1	Unintended movement				
9.2.3.2	Overtravel				
9.2.4	Emergency stopping devices				
9.2.5	Release of PATIENT				
9.3	HAZARD associated with surfaces, corners and edges				
9.4	Instability HAZARDS				
9.4.1	General				
9.4.2	Instability – overbalance				
9.4.2.1	Instability in transport position				
9.4.2.2	Instability excluding transport				
9.4.2.3	Instability from horizontal and vertical forces				
9.4.2.4	Castors and wheels				
9.4.2.4.1	General				
9.4.2.4.2	Force for propulsion				
9.4.2.4.3	Movement over a threshold				

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Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
9.4.3	Instability from unwanted lateral movement (including sliding)				
9.4.3.1	Instability in transport				
9.4.3.2	Instability excluding transport				
9.4.4	Grips and other handling devices				
9.5	Expelled parts HAZARD				
9.5.1	Protective means				
9.5.2	Cathode ray tubes				
9.6	Acoustic energy (including infra- and ultrasound) and vibration				
9.6.1	General				
9.6.2	Acoustic energy				
9.6.2.1	Audible acoustic energy				
9.6.2.2	Infrasound and ultrasound energy				
9.6.3	Hand-transmitted vibration				
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure				
9.7.1	General				
9.7.2	Pneumatic and hydraulic parts				
9.7.3	Maximum pressure				
9.7.4	Pressure rating of ME EQUIPMENT parts				
9.7.5	Pressure vessels				
9.7.6	Pressure-control device				
9.7.7	Pressure-relief device				
9.7.8	RATED maximum supply pressure				
9.8	HAZARDS associated with support systems				
9.8.1	General				

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Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
9.8.2	TENSILE SAFETY FACTOR				
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems				
9.8.3.1	General				
9.8.3.2	Static forces due to loading from persons				
9.8.3.3	Dynamic forces due to loading from persons				
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES				
9.8.4.1	General				
9.8.4.2	Use after activation of a MECHANICAL PROTECTIVE DEVICE				
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended for single activation				
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES				
10	Radiation Hazards				
10.1	X-Radiation				
10.1.1	ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation				
10.1.2	ME EQUIPMENT Intended to produce diagnostic or therapeutic X-radiation				
10.2	Alpha, beta, gamma, neutron and other particle radiation				
10.3	Microwave radiation				
10.4	Lasers and light emitting diodes (LEDs)				
10.5	Other visible electromagnetic radiation				
10.6	Infrared radiation				

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		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
10.7	Ultraviolet radiation				
11	Temperature and Other Hazards				
11.1	Excessive temperatures in ME EQUIPMENT				
11.1.1	Table 23 Parts likely to be touched				
11.1.1	Table 24 Skin contact with AP				
11.1.2	Temperature of APPLIED PARTS				
11.1.2.1	APPLIED PARTS intended to supply heat to a PATIENT				
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT				
11.1.3	Measurements				
11.1.4	GUARDS				
11.2	Fire prevention				
11.2.1	Strength and rigidity required to prevent fire in ME EQUIPMENT				
11.2.2	ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS				

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Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT				
11.2.2.2	External exhaust outlets for OXYGEN RICH ENVIRONMENT				
11.2.2.3	Electrical connections in OXYGEN RICH ENVIRONMENTS				
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS in conjunction with ME EQUIPMENT and ME SYSTEMS				
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT				
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics				
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents				
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT				
11.6.1	General				
11.6.2	Overflow in ME EQUIPMENT				
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM				
11.6.4	Leakage				
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS				
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS				
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS				
11.6.8	Compatibility with substances used with the ME EQUIPMENT				
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS				

APPENDIX A		ISO 14971:2000 Clauses			
Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT				
12	Accuracy and hazardous outputs				
12.1	Accuracy of controls and instruments				
12.2	USABILITY				
12.3	Alarm systems				
12.4	Protection against hazardous output				
12.4.1	Intentional exceeding of safety limits				
12.4.2	Indication of parameters relevant to safety				
12.4.3	Accidental selection of excessive output values				
12.4.4	Incorrect output				
12.4.5	Diagnostic or therapeutic radiation				
12.4.5.1	Limits				
12.4.5.2	Diagnostic X-ray equipment				
12.4.5.3	Radiotherapy equipment				
12.4.5.4	Other ME EQUIPMENT producing diagnostic or therapeutic radiation				
12.4.6	Diagnostic or therapeutic acoustic pressure				
13	Hazardous situations and fault conditions				
13.1	Specific Hazardous Situations				
13.1.1	General				
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature				
13.1.3	Exceeding LEAKAGE CURRENT or voltage limits				
13.1.4	Specific MECHANICAL HAZARDS				
13.2	SINGLE FAULT CONDITIONS				

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Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
13.2.1	General				
13.2.2	Electrical SINGLE FAULT CONDITION				
13.2.3	Overheating of transformers in ME EQUIPMENT				
13.2.4	Failure of THERMOSTATS				
13.2.5	Failure of temperature limiting devices				
13.2.6	Leakage of liquid				
13.2.7	Impairment of cooling that could result in a HAZARD				
13.2.8	Locking of moving parts				
13.2.9	Interruption and short circuiting of motor capacitors				
13.2.10	Additional test criteria for motor operated ME EQUIPMENT				
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				
13.2.13	Overload				
13.2.13.1	General overload test conditions				
13.2.13.2	ME EQUIPMENT with heating elements				
13.2.13.3	ME EQUIPMENT with motors				
13.2.13.4	ME EQUIPMENT RATED for non-CONTINUOUS OPERATION				
14	Programmable electrical medical systems				
14.1	General				
14.2	Documentation				
14.3	Risk MANAGEMENT plan				
14.4	PEMS DEVELOPMENT LIFE-CYCLE				
14.5	Problem resolution				
14.6	RISK MANAGEMENT PROCESS				
14.6.1	Identification of known and foreseeable HAZARDS				
14.6.2	RISK CONTROL				
14.7	Requirement specification				
14.8	Architecture				

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		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
14.9	Design and implementation				
14.10	VERIFICATION				
14.11	PEMS VALIDATION				
14.12	Modification				
14.13	Connection of PEMS by NETWORK/DATA COUPLING to other equipment				
15	Construction				
15.1	Arrangements of controls and indicators of ME EQUIPMENT				
15.2	Serviceability				
15.3	Mechanical strength				
15.3.1	General				
15.3.2	Push test				
15.3.3	Impact test				
15.3.4	Drop test				
15.3.4.1	HAND-HELD ME EQUIPMENT				
15.3.4.2	PORTABLE ME EQUIPMENT				
15.3.5	Rough handling test				
15.3.6	Mould stress relief test				
15.3.7	Environmental influences				
15.4	ME EQUIPMENT components and general assembly				
15.4.1	Construction of connectors				
15.4.2	Temperature and overload control devices				

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		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
15.4.2.1	Application				
15.4.2.2	Temperature settings				
15.4.3	Batteries				
15.4.3.1	Housing				
15.4.3.2	Connection				
15.4.3.3	Protection against overcharging				
15.4.3.4	Lithium batteries				
15.4.3.5	Excessive current and voltage protection				
15.4.4	Indicators				
15.4.5	Pre-set controls				
15.4.6	Actuating parts of controls of ME EQUIPMENT				
15.4.6.1	Fixing, prevention of maladjustment				
15.4.6.2	Limitation of movement				
15.4.7	Cord-connected HAND-HELD and foot-operated control devices (see also 8.10.4)				
15.4.7.1	Mechanical strength				
15.4.7.2	Accidental operation of ME EQUIPMENT				
15.4.7.3	Entry of liquids				
15.4.8	Internal wiring of ME EQUIPMENT				
15.4.9	Oil containers				

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Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
15.5	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5				
15.5.1	Overheating				
15.5.1.1	Transformers				
15.5.1.2	Short-circuit test				
15.5.1.3	Overload test				
15.5.2	Dielectric strength				
15.5.3	Construction of transformers used to provide separation as required by 8.5				
16	Medical electrical systems				
16.1	General requirements for the ME SYSTEMS				
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM				
16.3	Power supply				
16.4	ENCLOSURES				
16.5	SEPARATION DEVICES				
16.6	LEAKAGE CURRENTS				
16.6.1	TOUCH CURRENT				
16.6.2	EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET				
16.6.3	PATIENT LEAKAGE CURRENT				
16.6.4	Measurements				
16.6.4.1	General conditions for ME SYSTEMS				
16.6.4.2	Connection of the ME SYSTEM to the measuring supply circuit				
16.7	Protection against MECHANICAL HAZARDS				
16.8	Interruption of the power supply to parts of an ME SYSTEM				
16.9	ME SYSTEM connections and wiring				
16.9.1	Connection terminals and connectors				
16.9.2	MAINS PARTS, components and layout				
16.9.2.1	MULTIPLE SOCKET-OUTLET				
16.9.2.2	PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS				
16.9.2.3	Protection of conductors				
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS				

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Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
	Protection against HAZARDS of ignition of flammable anaesthetic mixtures				
G.1	Introduction				
G.1.1	Applicability				
G.1.2	Industrial equipment and components				
G.1.3	Requirements for ME EQUIPMENT				
G.2	Locations and basic requirements				
G.2.1	Parts of CATEGORY APG ME EQUIPMENT				
G.2.2	FLAMMABLE ANAESTHETIC MIXTURE WITH AIR				
G.2.3	FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE				
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR				
G.2.5	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE				
G.3	Marking, ACCOMPANYING DOCUMENTS				
G.3.1	CATEGORY APG marking				
G.3.2	CATEGORY AP marking				
G.3.3	Placement of markings				
G.3.4	ACCOMPANYING DOCUMENTS				
G.3.5	Marking when parts of ME EQUIPMENT are CATEGORY AP or CATEGORY APG				
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT				
G.4.1	Electrical connections				
G.4.2	Construction details				
G.4.3	Prevention of electrostatic charges				
G.4.4	Corona				
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components thereof				
G.5.1	General				
G.5.2	Temperature limits				
G.5.3	Low-energy circuits				
G.5.4	External ventilation with internal overpressure				
G.5.5	ENCLOSURES with restricted breathing				
G.6	Requirements and tests for CATEGORY APG ME EQUIPMENT, parts and components thereof				
G.6.1	General				
G.6.2	Power supply				

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Clause	60601-1:2005 Topic	4.3	4.4	5	6
		Identification of Hazards	Estimation of Risks	Risk Evaluation	Risk Control
G.6.3	Temperatures and low-energy circuits				
G.6.4	Heating elements				
G.7	Test apparatus for flammable mixtures				

Means these clauses of ISO 14971 are not required

Means requires risk management investigation

Means simply a heading no text

Reference clause to another

Means no risk management activity required

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Clause	60601-1:2005 Topic	6.1	6.2	6.3	6.4	6.5
		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
4	General requirements					
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS					
4.2	RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS					
4.3	ESSENTIAL PERFORMANCE					
4.4	EXPECTED SERVICE LIFE					
4.5	Equivalent safety for ME EQUIPMENT or ME SYSTEMS					
4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT					
4.7	SINGLE FAULT CONDITION for ME EQUIPMENT					
4.8	Components of ME EQUIPMENT					
4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT					
4.10	Power supply					
4.10.1	Source of power for ME EQUIPMENT					
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS					
4.11	Power input					
5	General requirements for testing					
5.1	TYPE TESTS					
5.2	Number of samples					
5.3	Ambient temperature, humidity, atmospheric pressure					
5.4	Other conditions					
5.5	Supply voltages, type of current, nature of supply, frequency					
5.6	Repairs and modifications					
5.7	Humidity preconditioning treatment					
5.8	Sequence of tests					
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS					
5.9.1	APPLIED PARTS					
5.9.2	ACCESSIBLE PARTS					
5.9.2.1	Test finger					
5.9.2.2	Test hook					
5.9.2.3	Actuating mechanisms					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
6	Classification					
6.1	General					
6.2	Protection against electric shock					
6.3	Protection against harmful ingress of water or particulate matter					
6.4	6.4 Method(s) of sterilization					
6.5	Suitability for use in an OXYGEN RICH ENVIRONMENT					
6.6	Mode of operation					
7	Identification, marking and documents					
7.1	General					
7.1.1	USABILITY of the identification, marking and documents					
7.1.2	Legibility of markings					
7.1.3	Durability of markings					
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1)					
7.2.1	Minimum requirements for marking on ME EQUIPMENT and on interchangeable					
7.2.2	Identification					
7.2.3	Consult ACCOMPANYING DOCUMENTS					
7.2.4	ACCESSORIES					
7.2.5	ME EQUIPMENT intended to receive power from other equipment					
7.2.6	Connection to the SUPPLY MAINS					
7.2.7	Electrical input power from the SUPPLY MAINS					
7.2.8	Output connectors					
7.2.8.1	Mains power output					
7.2.8.2	Other power sources					
7.2.9	IP classification					
7.2.10	APPLIED PARTS					
7.2.11	Mode of operation					
7.2.12	Fuses					
7.2.13	Physiological effects (safety signs and warning statements)					
7.2.14	HIGH VOLTAGE TERMINAL DEVICES					
7.2.15	Cooling conditions					
7.2.16	Mechanical stability					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
7.2.17	Protective packaging					
7.2.18	External pressure source					
7.2.19	FUNCTIONAL EARTH TERMINALS					
7.2.20	Removable protective means					
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2)					
7.3.1	Heating elements or lampholders					
7.3.2	HIGH VOLTAGE parts					
7.3.3	Batteries					
7.3.4	Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES					
7.3.5	PROTECTIVE EARTH TERMINALS					
7.3.6	FUNCTIONAL EARTH TERMINALS					
7.3.7	Supply terminals					
7.3.8	Temperature of supply terminals					
7.4	Marking of controls and instruments (see also Table C.3)					
7.4.1	Power switches					
7.4.2	Control devices					
7.4.3	Units of measure					
7.5	Safety signs					
7.6	Symbols					
7.6.1	Explanation of symbols					
7.6.2	Symbols from Annex D					
7.6.3	Symbols for controls and performance					
7.7	Colours of the insulation of conductors					
7.7.1	PROTECTIVE EARTH CONDUCTOR					
7.7.2	PROTECTIVE EARTH CONNECTIONS					
7.7.3	Green and yellow insulation					
7.7.4	Neutral conductor					
7.7.5	POWER SUPPLY CORD conductors					
7.8	Indicator lights and controls					
7.8.1	Colours of indicator lights					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
7.8.2	Colours of controls					
7.9	ACCOMPANYING DOCUMENTS					
7.9.1	General (see also Table C.4)					
7.9.2	Instructions for use (see also Table C.5)					
7.9.2.1	General					
7.9.2.2	Warning and safety notices					
7.9.2.3	ME EQUIPMENT specified for connection to a separate power supply					
7.9.2.4	Electrical power source					
7.9.2.5	ME EQUIPMENT description					
7.9.2.6	Installation					
7.9.2.7	Isolation from the SUPPLY MAINS					
7.9.2.8	Start-up PROCEDURE					
7.9.2.9	Operating instructions					
7.9.2.10	Messages					
7.9.2.11	Shutdown PROCEDURE					
7.9.2.12	Cleaning, disinfection and sterilization					
7.9.2.13	Maintenance					
7.9.2.14	ACCESSORIES, supplementary equipment, used material					
7.9.2.15	Environmental protection					
7.9.2.16	Reference to the technical description					
7.9.3	Technical description (see also Table C.6)					
7.9.3.1	General					
7.9.3.2	Replacement of fuses, POWER SUPPLY CORDS and other parts					
7.9.3.3	Circuit diagrams, component part lists, etc.					
7.9.3.4	Mains isolation					
8	Protection against electrical HAZARDS from ME EQUIPMENT					
8.1	Fundamental rule of protection against electric shock					
8.2	Requirements related to power sources					
8.2.1	Connection to a separate power source					

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Clause	60601-1:2005 Topic	6.1	6.2	6.3	6.4	6.5
		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
8.2.2	Connection to an external d.c. power source					
8.3	Classification of APPLIED PARTS					
8.4	Limitation of voltage, current or energy					
8.4.1	PATIENT CONNECTIONS intended to deliver current					
8.4.2	ACCESSIBLE PARTS including APPLIED PARTS					
8.4.3	ME EQUIPMENT intended to be connected to a power source by a plug					
8.4.4	Internal capacitive circuits					
8.5	Separation of parts					
8.5.1	MEANS OF PROTECTION (MOP)					
8.5.1.1	General					
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)					
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)					
8.5.2	Separation of PATIENT CONNECTIONS					
8.5.2.1	F-TYPE APPLIED PARTS					
8.5.2.2	TYPE B APPLIED PARTS					
8.5.2.3	PATIENT leads					
8.5.3	MAXIMUM MAINS VOLTAGE					
8.5.4	WORKING VOLTAGE					
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS					
8.5.5.1	Defibrillation protection					
8.5.5.2	Energy reduction test					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
8.6	Protective earthing, functional earthing and potential equalization of ME Equipment					
8.6.1	Applicability of requirements					
8.6.2	PROTECTIVE EARTH TERMINAL					
8.6.3	Protective earthing of moving parts					
8.6.4	Impedance and current-carrying capability					
8.6.5	Surface coatings					
8.6.6	Plugs and sockets					
8.6.7	POTENTIAL EQUALIZATION CONDUCTOR					
8.6.8	FUNCTIONAL EARTH TERMINAL					
8.6.9	CLASS II ME EQUIPMENT					
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS					
8.7.1	General requirements					
8.7.2	SINGLE FAULT CONDITIONS					
8.7.3	Allowable values					
8.7.4	Measurements					
8.7.4.1	General					
8.7.4.2	Measuring supply circuits					
8.7.4.3	Connection to the measuring supply circuit					
8.7.4.4	Measuring device (MD)					
8.7.4.5	Measurement of the EARTH LEAKAGE CURRENT					
8.7.4.6	Measurement of the TOUCH CURRENT					
8.7.4.7	Measurement of the PATIENT LEAKAGE CURRENT					
8.7.4.8	Measurement of the PATIENT AUXILIARY CURRENT					
8.7.4.9	ME EQUIPMENT with multiple PATIENT CONNECTIONS					
8.8	Insulation					
8.8.1	General					
8.8.2	Distance through solid insulation or use of thin sheet material					
8.8.3	Dielectric strength					
8.8.4	Insulation other than wire insulation					
8.8.4.1	Mechanical strength and resistance to heat					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
8.8.4.2	Resistance to environmental stress					
8.9	CREEPAGE DISTANCES and AIR CLEARANCES					
8.9.1	Values					
8.9.1.1	General					
8.9.1.2	CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1					
8.9.1.3	CREEPAGE DISTANCES across glass, mica, ceramic and similar materials					
8.9.1.4	Minimum CREEPAGE DISTANCE					
8.9.1.5	ME EQUIPMENT RATED for high altitudes					
8.9.1.6	Interpolation					
8.9.1.7	Material groups classification					
8.9.1.8	Pollution degree classification					
8.9.1.9	Overtoltage category classification					
8.9.1.10	AIR CLEARANCE for MAINS PARTS					
8.9.1.11	SUPPLY MAINS overvoltage					
8.9.1.12	SECONDARY CIRCUITS					
8.9.1.13	PEAK WORKING VOLTAGES above 1 400 V peak or d.c.					
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION					
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED					
8.9.2	Application					
8.9.3	Spaces filled by insulating compound					
8.9.3.1	General					
8.9.3.2	Insulating compound forming solid insulation between conductive parts					
8.9.3.3	Insulating compound forming a cemented joint with other insulating parts					
8.9.3.4	Thermal cycling					
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES					
8.10	Components and wiring					
8.10.1	Fixing of components					
8.10.2	Fixing of wiring					
8.10.3	Connections between different parts of ME EQUIPMENT					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices					
8.10.4.1	Limitation of operating voltages					
8.10.4.2	Connection cords					
8.10.5	Mechanical protection of wiring					
8.10.6	Guiding rollers for insulated conductors					
8.10.7	Insulation of internal wiring					
8.11	MAINS PARTS, components and layout					
8.11	Isolation from the SUPPLY MAINS					
8.11.2	MULTIPLE SOCKET-OUTLETS					
8.11.3	POWER SUPPLY CORDS					
8.11.3.1	Application					
8.11.3.2	Types					
8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors					
8.11.3.4	APPLIANCE COUPLERS					
8.11.3.5	Cord anchorage					
8.11.3.6	Cord guards					
8.11.4	MAINS TERMINAL DEVICES					
8.11.4.1	General requirements for MAINS TERMINAL DEVICES					
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES					
8.11.4.3	Fixing of mains terminals					
8.11.4.4	Connections to mains terminals					
8.11.4.5	Accessibility of the connection					
8.11.5	Mains fuses and OVER-CURRENT RELEASES					
8.11.6	Internal wiring of the MAINS PART					
9	Mechanical Hazards					
9.1	MECHANICAL HAZARDS of ME EQUIPMENT					
9.2	HAZARDS associated with moving parts					
9.2.1	General					
9.2.2	TRAPPING ZONE					
9.2.2.1	General					
9.2.2.2	Gaps					
9.2.2.3	Safe distances					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
9.2.2.4	GUARDS and protective measures					
9.2.2.4.1	Access to TRAPPING ZONES					
9.2.2.4.2	FIXED GUARDS					
9.2.2.4.3	Movable GUARDS					
9.2.2.4.4	Protective measures					
9.2.2.5	Continuous activation					
9.2.2.6	Speed of movement(s)					
9.2.3	Other HAZARDS associated with moving parts					
9.2.3.1	Unintended movement					
9.2.3.2	Overtravel					
9.2.4	Emergency stopping devices					
9.2.5	Release of PATIENT					
9.3	HAZARD associated with surfaces, corners and edges					
9.4	Instability HAZARDS					
9.4.1	General					
9.4.2	Instability – overbalance					
9.4.2.1	Instability in transport position					
9.4.2.2	Instability excluding transport					
9.4.2.3	Instability from horizontal and vertical forces					
9.4.2.4	Castors and wheels					
9.4.2.4.1	General					
9.4.2.4.2	Force for propulsion					
9.4.2.4.3	Movement over a threshold					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
9.4.3	Instability from unwanted lateral movement (including sliding)					
9.4.3.1	Instability in transport					
9.4.3.2	Instability excluding transport					
9.4.4	Grips and other handling devices					
9.5	Expelled parts HAZARD					
9.5.1	Protective means					
9.5.2	Cathode ray tubes					
9.6	Acoustic energy (including infra- and ultrasound) and vibration					
9.6.1	General					
9.6.2	Acoustic energy					
9.6.2.1	Audible acoustic energy					
9.6.2.2	Infrasound and ultrasound energy					
9.6.3	Hand-transmitted vibration					
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure					
9.7.1	General					
9.7.2	Pneumatic and hydraulic parts					
9.7.3	Maximum pressure					
9.7.4	Pressure rating of ME EQUIPMENT parts					
9.7.5	Pressure vessels					
9.7.6	Pressure-control device					
9.7.7	Pressure-relief device					
9.7.8	RATED maximum supply pressure					
9.8	HAZARDS associated with support systems					
9.8.1	General					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
9.8.2	TENSILE SAFETY FACTOR					
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems					
9.8.3.1	General					
9.8.3.2	Static forces due to loading from persons					
9.8.3.3	Dynamic forces due to loading from persons					
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES					
9.8.4.1	General					
9.8.4.2	Use after activation of a MECHANICAL PROTECTIVE DEVICE					
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended for single activation					
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES					
10	Radiation Hazards					
10.1	X-Radiation					
10.1.1	ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation					
10.1.2	ME EQUIPMENT Intended to produce diagnostic or therapeutic X-radiation					
10.2	Alpha, beta, gamma, neutron and other particle radiation					
10.3	Microwave radiation					
10.4	Lasers and light emitting diodes (LEDs)					
10.5	Other visible electromagnetic radiation					
10.6	Infrared radiation					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
10.7	Ultraviolet radiation					
11	Temperature and Other Hazards					
11.1	Excessive temperatures in ME EQUIPMENT					
11.1.1	Table 23 Parts likely to be touched					
11.1.1	Table 24 Skin contact with AP					
11.1.2	Temperature of APPLIED PARTS					
11.1.2.1	APPLIED PARTS intended to supply heat to a PATIENT					
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT					
11.1.3	Measurements					
11.1.4	GUARDS					
11.2	Fire prevention					
11.2.1	Strength and rigidity required to prevent fire in ME EQUIPMENT					
11.2.2	ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT					
11.2.2.2	External exhaust outlets for OXYGEN RICH ENVIRONMENT					
11.2.2.3	Electrical connections in OXYGEN RICH ENVIRONMENTS					
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS in conjunction with ME EQUIPMENT and ME SYSTEMS					
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT					
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics					
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents					
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT					
11.6.1	General					
11.6.2	Overflow in ME EQUIPMENT					
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM					
11.6.4	Leakage					
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS					
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS					
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS					
11.6.8	Compatibility with substances used with the ME EQUIPMENT					
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT					
12	Accuracy and hazardous outputs					
12.1	Accuracy of controls and instruments					
12.2	USABILITY					
12.3	Alarm systems					
12.4	Protection against hazardous output					
12.4.1	Intentional exceeding of safety limits					
12.4.2	Indication of parameters relevant to safety					
12.4.3	Accidental selection of excessive output values					
12.4.4	Incorrect output					
12.4.5	Diagnostic or therapeutic radiation					
12.4.5.1	Limits					
12.4.5.2	Diagnostic X-ray equipment					
12.4.5.3	Radiotherapy equipment					
12.4.5.4	Other ME EQUIPMENT producing diagnostic or therapeutic radiation					
12.4.6	Diagnostic or therapeutic acoustic pressure					
13	Hazardous situations and fault conditions					
13.1	Specific Hazardous Situations					
13.1.1	General					
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature					
13.1.3	Exceeding LEAKAGE CURRENT or voltage limits					
13.1.4	Specific MECHANICAL HAZARDS					
13.2	SINGLE FAULT CONDITIONS					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
13.2.1	General					
13.2.2	Electrical SINGLE FAULT CONDITION					
13.2.3	Overheating of transformers in ME EQUIPMENT					
13.2.4	Failure of THERMOSTATS					
13.2.5	Failure of temperature limiting devices					
13.2.6	Leakage of liquid					
13.2.7	Impairment of cooling that could result in a HAZARD					
13.2.8	Locking of moving parts					
13.2.9	Interruption and short circuiting of motor capacitors					
13.2.10	Additional test criteria for motor operated ME EQUIPMENT					
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					
13.2.13	Overload					
13.2.13.1	General overload test conditions					
13.2.13.2	ME EQUIPMENT with heating elements					
13.2.13.3	ME EQUIPMENT with motors					
13.2.13.4	ME EQUIPMENT RATED for non-CONTINUOUS OPERATION					
14	Programmable electrical medical systems					
14.1	General					
14.2	Documentation					
14.3	Risk MANAGEMENT plan					
14.4	PEMS DEVELOPMENT LIFE-CYCLE					
14.5	Problem resolution					
14.6	RISK MANAGEMENT PROCESS					
14.6.1	Identification of known and foreseeable HAZARDS					
14.6.2	RISK CONTROL					
14.7	Requirement specification					
14.8	Architecture					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
14.9	Design and implementation					
14.10	VERIFICATION					
14.11	PEMS VALIDATION					
14.12	Modification					
14.13	Connection of PEMS by NETWORK/DATA COUPLING to other equipment					
15	Construction					
15.1	Arrangements of controls and indicators of ME EQUIPMENT					
15.2	Serviceability					
15.3	Mechanical strength					
15.3.1	General					
15.3.2	Push test					
15.3.3	Impact test					
15.3.4	Drop test					
15.3.4.1	HAND-HELD ME EQUIPMENT					
15.3.4.2	PORTABLE ME EQUIPMENT					
15.3.5	Rough handling test					
15.3.6	Mould stress relief test					
15.3.7	Environmental influences					
15.4	ME EQUIPMENT components and general assembly					
15.4.1	Construction of connectors					
15.4.2	Temperature and overload control devices					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
15.4.2.1	Application					
15.4.2.2	Temperature settings					
15.4.3	Batteries					
15.4.3.1	Housing					
15.4.3.2	Connection					
15.4.3.3	Protection against overcharging					
15.4.3.4	Lithium batteries					
15.4.3.5	Excessive current and voltage protection					
15.4.4	Indicators					
15.4.5	Pre-set controls					
15.4.6	Actuating parts of controls of ME EQUIPMENT					
15.4.6.1	Fixing, prevention of maladjustment					
15.4.6.2	Limitation of movement					
15.4.7	Cord-connected HAND-HELD and foot-operated control devices (see also 8.10.4)					
15.4.7.1	Mechanical strength					
15.4.7.2	Accidental operation of ME EQUIPMENT					
15.4.7.3	Entry of liquids					
15.4.8	Internal wiring of ME EQUIPMENT					
15.4.9	Oil containers					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
15.5	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5					
15.5.1	Overheating					
15.5.1.1	Transformers					
15.5.1.2	Short-circuit test					
15.5.1.3	Overload test					
15.5.2	Dielectric strength					
15.5.3	Construction of transformers used to provide separation as required by 8.5					
16	Medical electrical systems					
16.1	General requirements for the ME SYSTEMS					
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM					
16.3	Power supply					
16.4	ENCLOSURES					
16.5	SEPARATION DEVICES					
16.6	LEAKAGE CURRENTS					
16.6.1	TOUCH CURRENT					
16.6.2	EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET					
16.6.3	PATIENT LEAKAGE CURRENT					
16.6.4	Measurements					
16.6.4.1	General conditions for ME SYSTEMS					
16.6.4.2	Connection of the ME SYSTEM to the measuring supply circuit					
16.7	Protection against MECHANICAL HAZARDS					
16.8	Interruption of the power supply to parts of an ME SYSTEM					
16.9	ME SYSTEM connections and wiring					
16.9.1	Connection terminals and connectors					
16.9.2	MAINS PARTS, components and layout					
16.9.2.1	MULTIPLE SOCKET-OUTLET					
16.9.2.2	PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS					
16.9.2.3	Protection of conductors					
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
	Protection against HAZARDS of ignition of flammable anaesthetic mixtures					
G.1	Introduction					
G.1.1	Applicability					
G.1.2	Industrial equipment and components					
G.1.3	Requirements for ME EQUIPMENT					
G.2	Locations and basic requirements					
G.2.1	Parts of CATEGORY APG ME EQUIPMENT					
G.2.2	FLAMMABLE ANAESTHETIC MIXTURE WITH AIR					
G.2.3	FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE					
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR					
G.2.5	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE					
G.3	Marking, ACCOMPANYING DOCUMENTS					
G.3.1	CATEGORY APG marking					
G.3.2	CATEGORY AP marking					
G.3.3	Placement of markings					
G.3.4	ACCOMPANYING DOCUMENTS					
G.3.5	Marking when parts of ME EQUIPMENT are CATEGORY AP or CATEGORY APG					
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT					
G.4.1	Electrical connections					
G.4.2	Construction details					
G.4.3	Prevention of electrostatic charges					
G.4.4	Corona					
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components thereof					
G.5.1	General					
G.5.2	Temperature limits					
G.5.3	Low-energy circuits					
G.5.4	External ventilation with internal overpressure					
G.5.5	ENCLOSURES with restricted breathing					
G.6	Requirements and tests for CATEGORY APG ME EQUIPMENT, parts and components thereof					
G.6.1	General					
G.6.2	Power supply					

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		Risk Reduction	Risk Control Option Analysis	Implementation of risk control measures	Residual risk evaluation	Risk/Benefit Analysis
G.6.3	Temperatures and low-energy circuits					
G.6.4	Heating elements					
G.7	Test apparatus for flammable mixtures					

Means these clauses of ISO 14971 are not required

Means requires risk management investigation

Means simply a heading no text

Reference clause to another

Means no risk management activity required

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Clause	60601-1:2005 Topic	6.6	6.7	7	8	9
		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
4	General requirements					
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS					
4.2	RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS					
4.3	ESSENTIAL PERFORMANCE					
4.4	EXPECTED SERVICE LIFE					
4.5	Equivalent safety for ME EQUIPMENT or ME SYSTEMS					
4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT					
4.7	SINGLE FAULT CONDITION for ME EQUIPMENT					
4.8	Components of ME EQUIPMENT					
4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT					
4.10	Power supply					
4.10.1	Source of power for ME EQUIPMENT					
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS					
4.11	Power input					
5	General requirements for testing					
5.1	TYPE TESTS					
5.2	Number of samples					
5.3	Ambient temperature, humidity, atmospheric pressure					
5.4	Other conditions					
5.5	Supply voltages, type of current, nature of supply, frequency					
5.6	Repairs and modifications					
5.7	Humidity preconditioning treatment					
5.8	Sequence of tests					
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS					
5.9.1	APPLIED PARTS					
5.9.2	ACCESSIBLE PARTS					
5.9.2.1	Test finger					
5.9.2.2	Test hook					
5.9.2.3	Actuating mechanisms					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
6	Classification					
6.1	General					
6.2	Protection against electric shock					
6.3	Protection against harmful ingress of water or particulate matter					
6.4	6.4 Method(s) of sterilization					
6.5	Suitability for use in an OXYGEN RICH ENVIRONMENT					
6.6	Mode of operation					
7	Identification, marking and documents					
7.1	General					
7.1.1	USABILITY of the identification, marking and documents					
7.1.2	Legibility of markings					
7.1.3	Durability of markings					
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1)					
7.2.1	Minimum requirements for marking on ME EQUIPMENT and on interchangeable					
7.2.2	Identification					
7.2.3	Consult ACCOMPANYING DOCUMENTS					
7.2.4	ACCESSORIES					
7.2.5	ME EQUIPMENT intended to receive power from other equipment					
7.2.6	Connection to the SUPPLY MAINS					
7.2.7	Electrical input power from the SUPPLY MAINS					
7.2.8	Output connectors					
7.2.8.1	Mains power output					
7.2.8.2	Other power sources					
7.2.9	IP classification					
7.2.10	APPLIED PARTS					
7.2.11	Mode of operation					
7.2.12	Fuses					
7.2.13	Physiological effects (safety signs and warning statements)					
7.2.14	HIGH VOLTAGE TERMINAL DEVICES					
7.2.15	Cooling conditions					
7.2.16	Mechanical stability					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
7.2.17	Protective packaging					
7.2.18	External pressure source					
7.2.19	FUNCTIONAL EARTH TERMINALS					
7.2.20	Removable protective means					
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2)					
7.3.1	Heating elements or lampholders					
7.3.2	HIGH VOLTAGE parts					
7.3.3	Batteries					
7.3.4	Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES					
7.3.5	PROTECTIVE EARTH TERMINALS					
7.3.6	FUNCTIONAL EARTH TERMINALS					
7.3.7	Supply terminals					
7.3.8	Temperature of supply terminals					
7.4	Marking of controls and instruments (see also Table C.3)					
7.4.1	Power switches					
7.4.2	Control devices					
7.4.3	Units of measure					
7.5	Safety signs					
7.6	Symbols					
7.6.1	Explanation of symbols					
7.6.2	Symbols from Annex D					
7.6.3	Symbols for controls and performance					
7.7	Colours of the insulation of conductors					
7.7.1	PROTECTIVE EARTH CONDUCTOR					
7.7.2	PROTECTIVE EARTH CONNECTIONS					
7.7.3	Green and yellow insulation					
7.7.4	Neutral conductor					
7.7.5	POWER SUPPLY CORD conductors					
7.8	Indicator lights and controls					
7.8.1	Colours of indicator lights					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
7.8.2	Colours of controls					
7.9	ACCOMPANYING DOCUMENTS					
7.9.1	General (see also Table C.4)					
7.9.2	Instructions for use (see also Table C.5)					
7.9.2.1	General					
7.9.2.2	Warning and safety notices					
7.9.2.3	ME EQUIPMENT specified for connection to a separate power supply					
7.9.2.4	Electrical power source					
7.9.2.5	ME EQUIPMENT description					
7.9.2.6	Installation					
7.9.2.7	Isolation from the SUPPLY MAINS					
7.9.2.8	Start-up PROCEDURE					
7.9.2.9	Operating instructions					
7.9.2.10	Messages					
7.9.2.11	Shutdown PROCEDURE					
7.9.2.12	Cleaning, disinfection and sterilization					
7.9.2.13	Maintenance					
7.9.2.14	ACCESSORIES, supplementary equipment, used material					
7.9.2.15	Environmental protection					
7.9.2.16	Reference to the technical description					
7.9.3	Technical description (see also Table C.6)					
7.9.3.1	General					
7.9.3.2	Replacement of fuses, POWER SUPPLY CORDS and other parts					
7.9.3.3	Circuit diagrams, component part lists, etc.					
7.9.3.4	Mains isolation					
8	Protection against electrical HAZARDS from ME EQUIPMENT					
8.1	Fundamental rule of protection against electric shock					
8.2	Requirements related to power sources					
8.2.1	Connection to a separate power source					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
8.2.2	Connection to an external d.c. power source					
8.3	Classification of APPLIED PARTS					
8.4	Limitation of voltage, current or energy					
8.4.1	PATIENT CONNECTIONS intended to deliver current					
8.4.2	ACCESSIBLE PARTS including APPLIED PARTS					
8.4.3	ME EQUIPMENT intended to be connected to a power source by a plug					
8.4.4	Internal capacitive circuits					
8.5	Separation of parts					
8.5.1	MEANS OF PROTECTION (MOP)					
8.5.1.1	General					
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)					
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)					
8.5.2	Separation of PATIENT CONNECTIONS					
8.5.2.1	F-TYPE APPLIED PARTS					
8.5.2.2	TYPE B APPLIED PARTS					
8.5.2.3	PATIENT leads					
8.5.3	MAXIMUM MAINS VOLTAGE					
8.5.4	WORKING VOLTAGE					
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS					
8.5.5.1	Defibrillation protection					
8.5.5.2	Energy reduction test					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
8.6	Protective earthing, functional earthing and potential equalization of ME Equipment					
8.6.1	Applicability of requirements					
8.6.2	PROTECTIVE EARTH TERMINAL					
8.6.3	Protective earthing of moving parts					
8.6.4	Impedance and current-carrying capability					
8.6.5	Surface coatings					
8.6.6	Plugs and sockets					
8.6.7	POTENTIAL EQUALIZATION CONDUCTOR					
8.6.8	FUNCTIONAL EARTH TERMINAL					
8.6.9	CLASS II ME EQUIPMENT					
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS					
8.7.1	General requirements					
8.7.2	SINGLE FAULT CONDITIONS					
8.7.3	Allowable values					
8.7.4	Measurements					
8.7.4.1	General					
8.7.4.2	Measuring supply circuits					
8.7.4.3	Connection to the measuring supply circuit					
8.7.4.4	Measuring device (MD)					
8.7.4.5	Measurement of the EARTH LEAKAGE CURRENT					
8.7.4.6	Measurement of the TOUCH CURRENT					
8.7.4.7	Measurement of the PATIENT LEAKAGE CURRENT					
8.7.4.8	Measurement of the PATIENT AUXILIARY CURRENT					
8.7.4.9	ME EQUIPMENT with multiple PATIENT CONNECTIONS					
8.8	Insulation					
8.8.1	General					
8.8.2	Distance through solid insulation or use of thin sheet material					
8.8.3	Dielectric strength					
8.8.4	Insulation other than wire insulation					
8.8.4.1	Mechanical strength and resistance to heat					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
8.8.4.2	Resistance to environmental stress					
8.9	CREEPAGE DISTANCES and AIR CLEARANCES					
8.9.1	Values					
8.9.1.1	General					
8.9.1.2	CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1					
8.9.1.3	CREEPAGE DISTANCES across glass, mica, ceramic and similar materials					
8.9.1.4	Minimum CREEPAGE DISTANCE					
8.9.1.5	ME EQUIPMENT RATED for high altitudes					
8.9.1.6	Interpolation					
8.9.1.7	Material groups classification					
8.9.1.8	Pollution degree classification					
8.9.1.9	Overvoltage category classification					
8.9.1.10	AIR CLEARANCE for MAINS PARTS					
8.9.1.11	SUPPLY MAINS overvoltage					
8.9.1.12	SECONDARY CIRCUITS					
8.9.1.13	PEAK WORKING VOLTAGES above 1 400 V peak or d.c.					
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION					
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED					
8.9.2	Application					
8.9.3	Spaces filled by insulating compound					
8.9.3.1	General					
8.9.3.2	Insulating compound forming solid insulation between conductive parts					
8.9.3.3	Insulating compound forming a cemented joint with other insulating parts					
8.9.3.4	Thermal cycling					
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES					
8.10	Components and wiring					
8.10.1	Fixing of components					
8.10.2	Fixing of wiring					
8.10.3	Connections between different parts of ME EQUIPMENT					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices					
8.10.4.1	Limitation of operating voltages					
8.10.4.2	Connection cords					
8.10.5	Mechanical protection of wiring					
8.10.6	Guiding rollers for insulated conductors					
8.10.7	Insulation of internal wiring					
8.11	MAINS PARTS, components and layout					
8.11	Isolation from the SUPPLY MAINS					
8.11.2	MULTIPLE SOCKET-OUTLETS					
8.11.3	POWER SUPPLY CORDS					
8.11.3.1	Application					
8.11.3.2	Types					
8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors					
8.11.3.4	APPLIANCE COUPLERS					
8.11.3.5	Cord anchorage					
8.11.3.6	Cord guards					
8.11.4	MAINS TERMINAL DEVICES					
8.11.4.1	General requirements for MAINS TERMINAL DEVICES					
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES					
8.11.4.3	Fixing of mains terminals					
8.11.4.4	Connections to mains terminals					
8.11.4.5	Accessibility of the connection					
8.11.5	Mains fuses and OVER-CURRENT RELEASES					
8.11.6	Internal wiring of the MAINS PART					
9	Mechanical Hazards					
9.1	MECHANICAL HAZARDS of ME EQUIPMENT					
9.2	HAZARDS associated with moving parts					
9.2.1	General					
9.2.2	TRAPPING ZONE					
9.2.2.1	General					
9.2.2.2	Gaps					
9.2.2.3	Safe distances					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
9.2.2.4	GUARDS and protective measures					
9.2.2.4.1	Access to TRAPPING ZONES					
9.2.2.4.2	FIXED GUARDS					
9.2.2.4.3	Movable GUARDS					
9.2.2.4.4	Protective measures					
9.2.2.5	Continuous activation					
9.2.2.6	Speed of movement(s)					
9.2.3	Other HAZARDS associated with moving parts					
9.2.3.1	Unintended movement					
9.2.3.2	Overtravel					
9.2.4	Emergency stopping devices					
9.2.5	Release of PATIENT					
9.3	HAZARD associated with surfaces, corners and edges					
9.4	Instability HAZARDS					
9.4.1	General					
9.4.2	Instability – overbalance					
9.4.2.1	Instability in transport position					
9.4.2.2	Instability excluding transport					
9.4.2.3	Instability from horizontal and vertical forces					
9.4.2.4	Castors and wheels					
9.4.2.4.1	General					
9.4.2.4.2	Force for propulsion					
9.4.2.4.3	Movement over a threshold					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
9.4.3	Instability from unwanted lateral movement (including sliding)					
9.4.3.1	Instability in transport					
9.4.3.2	Instability excluding transport					
9.4.4	Grips and other handling devices					
9.5	Expelled parts HAZARD					
9.5.1	Protective means					
9.5.2	Cathode ray tubes					
9.6	Acoustic energy (including infra- and ultrasound) and vibration					
9.6.1	General					
9.6.2	Acoustic energy					
9.6.2.1	Audible acoustic energy					
9.6.2.2	Infrasound and ultrasound energy					
9.6.3	Hand-transmitted vibration					
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure					
9.7.1	General					
9.7.2	Pneumatic and hydraulic parts					
9.7.3	Maximum pressure					
9.7.4	Pressure rating of ME EQUIPMENT parts					
9.7.5	Pressure vessels					
9.7.6	Pressure-control device					
9.7.7	Pressure-relief device					
9.7.8	RATED maximum supply pressure					
9.8	HAZARDS associated with support systems					
9.8.1	General					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
9.8.2	TENSILE SAFETY FACTOR					
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems					
9.8.3.1	General					
9.8.3.2	Static forces due to loading from persons					
9.8.3.3	Dynamic forces due to loading from persons					
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES					
9.8.4.1	General					
9.8.4.2	Use after activation of a MECHANICAL PROTECTIVE DEVICE					
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended for single activation					
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES					
10	Radiation Hazards					
10.1	X-Radiation					
10.1.1	ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation					
10.1.2	ME EQUIPMENT Intended to produce diagnostic or therapeutic X-radiation					
10.2	Alpha, beta, gamma, neutron and other particle radiation					
10.3	Microwave radiation					
10.4	Lasers and light emitting diodes (LEDs)					
10.5	Other visible electromagnetic radiation					
10.6	Infrared radiation					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
10.7	Ultraviolet radiation					
11	Temperature and Other Hazards					
11.1	Excessive temperatures in ME EQUIPMENT					
11.1.1	Table 23 Parts likely to be touched					
11.1.1	Table 24 Skin contact with AP					
11.1.2	Temperature of APPLIED PARTS					
11.1.2.1	APPLIED PARTS intended to supply heat to a PATIENT					
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT					
11.1.3	Measurements					
11.1.4	GUARDS					
11.2	Fire prevention					
11.2.1	Strength and rigidity required to prevent fire in ME EQUIPMENT					
11.2.2	ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT					
11.2.2.2	External exhaust outlets for OXYGEN RICH ENVIRONMENT					
11.2.2.3	Electrical connections in OXYGEN RICH ENVIRONMENTS					
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS in conjunction with ME EQUIPMENT and ME SYSTEMS					
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT					
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics					
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents					
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT					
11.6.1	General					
11.6.2	Overflow in ME EQUIPMENT					
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM					
11.6.4	Leakage					
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS					
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS					
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS					
11.6.8	Compatibility with substances used with the ME EQUIPMENT					
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT					
12	Accuracy and hazardous outputs					
12.1	Accuracy of controls and instruments					
12.2	USABILITY					
12.3	Alarm systems					
12.4	Protection against hazardous output					
12.4.1	Intentional exceeding of safety limits					
12.4.2	Indication of parameters relevant to safety					
12.4.3	Accidental selection of excessive output values					
12.4.4	Incorrect output					
12.4.5	Diagnostic or therapeutic radiation					
12.4.5.1	Limits					
12.4.5.2	Diagnostic X-ray equipment					
12.4.5.3	Radiotherapy equipment					
12.4.5.4	Other ME EQUIPMENT producing diagnostic or therapeutic radiation					
12.4.6	Diagnostic or therapeutic acoustic pressure					
13	Hazardous situations and fault conditions					
13.1	Specific Hazardous Situations					
13.1.1	General					
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature					
13.1.3	Exceeding LEAKAGE CURRENT or voltage limits					
13.1.4	Specific MECHANICAL HAZARDS					
13.2	SINGLE FAULT CONDITIONS					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
13.2.1	General					
13.2.2	Electrical SINGLE FAULT CONDITION					
13.2.3	Overheating of transformers in ME EQUIPMENT					
13.2.4	Failure of THERMOSTATS					
13.2.5	Failure of temperature limiting devices					
13.2.6	Leakage of liquid					
13.2.7	Impairment of cooling that could result in a HAZARD					
13.2.8	Locking of moving parts					
13.2.9	Interruption and short circuiting of motor capacitors					
13.2.10	Additional test criteria for motor operated ME EQUIPMENT					
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					
13.2.13	Overload					
13.2.13.1	General overload test conditions					
13.2.13.2	ME EQUIPMENT with heating elements					
13.2.13.3	ME EQUIPMENT with motors					
13.2.13.4	ME EQUIPMENT RATED for non-CONTINUOUS OPERATION					
14	Programmable electrical medical systems					
14.1	General					
14.2	Documentation					
14.3	Risk MANAGEMENT plan					
14.4	PEMS DEVELOPMENT LIFE-CYCLE					
14.5	Problem resolution					
14.6	RISK MANAGEMENT PROCESS					
14.6.1	Identification of known and foreseeable HAZARDS					
14.6.2	RISK CONTROL					
14.7	Requirement specification					
14.8	Architecture					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
14.9	Design and implementation					
14.10	VERIFICATION					
14.11	PEMS VALIDATION					
14.12	Modification					
14.13	Connection of PEMS by NETWORK/DATA COUPLING to other equipment					
15	Construction					
15.1	Arrangements of controls and indicators of ME EQUIPMENT					
15.2	Serviceability					
15.3	Mechanical strength					
15.3.1	General					
15.3.2	Push test					
15.3.3	Impact test					
15.3.4	Drop test					
15.3.4.1	HAND-HELD ME EQUIPMENT					
15.3.4.2	PORTABLE ME EQUIPMENT					
15.3.5	Rough handling test					
15.3.6	Mould stress relief test					
15.3.7	Environmental influences					
15.4	ME EQUIPMENT components and general assembly					
15.4.1	Construction of connectors					
15.4.2	Temperature and overload control devices					

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		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
15.4.2.1	Application					
15.4.2.2	Temperature settings					
15.4.3	Batteries					
15.4.3.1	Housing					
15.4.3.2	Connection					
15.4.3.3	Protection against overcharging					
15.4.3.4	Lithium batteries					
15.4.3.5	Excessive current and voltage protection					
15.4.4	Indicators					
15.4.5	Pre-set controls					
15.4.6	Actuating parts of controls of ME EQUIPMENT					
15.4.6.1	Fixing, prevention of maladjustment					
15.4.6.2	Limitation of movement					
15.4.7	Cord-connected HAND-HELD and foot-operated control devices (see also 8.10.4)					
15.4.7.1	Mechanical strength					
15.4.7.2	Accidental operation of ME EQUIPMENT					
15.4.7.3	Entry of liquids					
15.4.8	Internal wiring of ME EQUIPMENT					
15.4.9	Oil containers					

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Clause	60601-1:2005 Topic	6.6	6.7	7	8	9
		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
15.5	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5					
15.5.1	Overheating					
15.5.1.1	Transformers					
15.5.1.2	Short-circuit test					
15.5.1.3	Overload test					
15.5.2	Dielectric strength					
15.5.3	Construction of transformers used to provide separation as required by 8.5					
16	Medical electrical systems					
16.1	General requirements for the ME SYSTEMS					
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM					
16.3	Power supply					
16.4	ENCLOSURES					
16.5	SEPARATION DEVICES					
16.6	LEAKAGE CURRENTS					
16.6.1	TOUCH CURRENT					
16.6.2	EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET					
16.6.3	PATIENT LEAKAGE CURRENT					
16.6.4	Measurements					
16.6.4.1	General conditions for ME SYSTEMS					
16.6.4.2	Connection of the ME SYSTEM to the measuring supply circuit					
16.7	Protection against MECHANICAL HAZARDS					
16.8	Interruption of the power supply to parts of an ME SYSTEM					
16.9	ME SYSTEM connections and wiring					
16.9.1	Connection terminals and connectors					
16.9.2	MAINS PARTS, components and layout					
16.9.2.1	MULTIPLE SOCKET-OUTLET					
16.9.2.2	PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS					
16.9.2.3	Protection of conductors					
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS					

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Clause	60601-1:2005 Topic	6.6	6.7	7	8	9
		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
	Protection against HAZARDS of ignition of flammable anaesthetic mixtures					
G.1	Introduction					
G.1.1	Applicability					
G.1.2	Industrial equipment and components					
G.1.3	Requirements for ME EQUIPMENT					
G.2	Locations and basic requirements					
G.2.1	Parts of CATEGORY APG ME EQUIPMENT					
G.2.2	FLAMMABLE ANAESTHETIC MIXTURE WITH AIR					
G.2.3	FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE					
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR					
G.2.5	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE					
G.3	Marking, ACCOMPANYING DOCUMENTS					
G.3.1	CATEGORY APG marking					
G.3.2	CATEGORY AP marking					
G.3.3	Placement of markings					
G.3.4	ACCOMPANYING DOCUMENTS					
G.3.5	Marking when parts of ME EQUIPMENT are CATEGORY AP or CATEGORY APG					
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT					
G.4.1	Electrical connections					
G.4.2	Construction details					
G.4.3	Prevention of electrostatic charges					
G.4.4	Corona					
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components thereof					
G.5.1	General					
G.5.2	Temperature limits					
G.5.3	Low-energy circuits					
G.5.4	External ventilation with internal overpressure					
G.5.5	ENCLOSURES with restricted breathing					
G.6	Requirements and tests for CATEGORY APG ME EQUIPMENT, parts and components thereof					
G.6.1	General					
G.6.2	Power supply					

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Clause	60601-1:2005 Topic	6.6	6.7	7	8	9
		Risk arising from risk control measures	Completeness of Risk Control	Residual Risk Evaluation	Risk Management Report	Production and Post Production Information
G.6.3	Temperatures and low-energy circuits					
G.6.4	Heating elements					
G.7	Test apparatus for flammable mixtures					

Means these clauses of ISO 14971 are not required

Means requires risk management investigation

Means simply a heading no text

Reference clause to another

Means no risk management activity required

APPENDIX A				
Clause	60601-1:2005 Topic			
		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
4	General requirements			
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS			
4.2	RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS			Requires a risk management process in accordance with ISO 14971 and that the risks from the device are managed using the manufacturer's process.
4.3	ESSENTIAL PERFORMANCE			Affects the compliance criteria for specific tests.
4.4	EXPECTED SERVICE LIFE			Impacts some of the verification testing the manufacturer must conduct.
4.5	Equivalent safety for ME EQUIPMENT or ME SYSTEMS			Provides an alternate compliance means of compliance when an equivalent or lower residual level of risk results.
4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT			Affects the basic safety verification of parts that can contact the patient.
4.7	SINGLE FAULT CONDITION for ME EQUIPMENT	All parts		Risk management is used to facilitate the considerations of single fault conditions to be applied.
4.8	Components of ME EQUIPMENT	b)	a)	Component rating exceptions may be made by the use of risk management.
4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT			Risk management may be used to determine the need for the use of High-Integrity components.
4.10	Power supply			
4.10.1	Source of power for ME EQUIPMENT			
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS			
4.11	Power input			
5	General requirements for testing			
5.1	TYPE TESTS			Provides verification testing input.
5.2	Number of samples			
5.3	Ambient temperature, humidity, atmospheric pressure			
5.4	Other conditions	a)	b), c), d)	Provides verification testing input.
5.5	Supply voltages, type of current, nature of supply, frequency			
5.6	Repairs and modifications			
5.7	Humidity preconditioning treatment			Provides verification testing input.
5.8	Sequence of tests			
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS			
5.9.1	APPLIED PARTS			
5.9.2	ACCESSIBLE PARTS			
5.9.2.1	Test finger			
5.9.2.2	Test hook			
5.9.2.3	Actuating mechanisms			Determines accessibility of actuating mechanisms.

APPENDIX A				
Clause	60601-1:2005 Topic			
		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
6	Classification			
6.1	General			
6.2	Protection against electric shock			
6.3	Protection against harmful ingress of water or particulate matter			
6.4	6.4 Method(s) of sterilization			
6.5	Suitability for use in an OXYGEN RICH ENVIRONMENT			
6.6	Mode of operation			
7	Identification, marking and documents			
7.1	General			
7.1.1	USABILITY of the identification, marking and documents			The Usability Engineering Process includes the risk of poor usability.
7.1.2	Legibility of markings			
7.1.3	Durability of markings			
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1)			
7.2.1	Minimum requirements for marking on ME EQUIPMENT and on interchangeable			
7.2.2	Identification			Risk management may be used to demonstrate that marking is not necessary.
7.2.3	Consult ACCOMPANYING DOCUMENTS			
7.2.4	ACCESSORIES			
7.2.5	ME EQUIPMENT intended to receive power from other equipment			The risk management file may indicate the need for a specific power supply and require marking for risk control.
7.2.6	Connection to the SUPPLY MAINS			
7.2.7	Electrical input power from the SUPPLY MAINS			
7.2.8	Output connectors			
7.2.8.1	Mains power output			
7.2.8.2	Other power sources			
7.2.9	IP classification			
7.2.10	APPLIED PARTS			
7.2.11	Mode of operation			
7.2.12	Fuses			
7.2.13	Physiological effects (safety signs and warning statements)			The RMF may have considered physiological effects in the risk assessment and may have indicated the need for marking as a risk control measure.
7.2.14	HIGH VOLTAGE TERMINAL DEVICES			
7.2.15	Cooling conditions			
7.2.16	Mechanical stability			

APPENDIX A				
Clause	60601-1:2005 Topic			
		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
7.2.17	Protective packaging			The risk assessment may include the need for protective packaging and identify marking as a risk control measure.
7.2.18	External pressure source			
7.2.19	FUNCTIONAL EARTH TERMINALS			
7.2.20	Removable protective means			
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2)			
7.3.1	Heating elements or lampholders			
7.3.2	HIGH VOLTAGE parts			
7.3.3	Batteries			The risk assessment may include the need for adequately training personnel to change lithium batteries or fuel cells and provide marking and IFU requirements as risk control measures.
7.3.4	Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES			
7.3.5	PROTECTIVE EARTH TERMINALS			
7.3.6	FUNCTIONAL EARTH TERMINALS			
7.3.7	Supply terminals			The risk assessment may identify any hazardous situations from supply terminal connections.
7.3.8	Temperature of supply terminals			
7.4	Marking of controls and instruments (see also Table C.3)			
7.4.1	Power switches			
7.4.2	Control devices			The risk management file may indicate the need for control marking based on risk assessment.
7.4.3	Units of measure			
7.5	Safety signs	b)	a), c), d)	Risk assessment may include risk control measures requiring the use of safety sign(s) to convey a warning, prohibition or mandatory action.
7.6	Symbols			
7.6.1	Explanation of symbols			
7.6.2	Symbols from Annex D			
7.6.3	Symbols for controls and performance			
7.7	Colours of the insulation of conductors			
7.7.1	PROTECTIVE EARTH CONDUCTOR			
7.7.2	PROTECTIVE EARTH CONNECTIONS			
7.7.3	Green and yellow insulation			
7.7.4	Neutral conductor			
7.7.5	POWER SUPPLY CORD conductors			
7.8	Indicator lights and controls			
7.8.1	Colours of indicator lights			

APPENDIX A				
Clause	60601-1:2005 Topic			
		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
7.8.2	Colours of controls			
7.9	ACCOMPANYING DOCUMENTS			
7.9.1	General (see also Table C.4)			Risk management provides consideration for which information needs to be provided as hard copy or as marking on the device.
7.9.2	Instructions for use (see also Table C.5)			
7.9.2.1	General			
7.9.2.2	Warning and safety notices			Inspect IFU accordingly.
7.9.2.3	ME EQUIPMENT specified for connection to a separate power supply			
7.9.2.4	Electrical power source			Risk assessment may indicate the need for risk control measures for removing batteries and for loss of power.
7.9.2.5	ME EQUIPMENT description			Risk assessment may indicate the need for risk control measures for providing IFU advice for patient or operator protection from materials or ingredients.
7.9.2.6	Installation			
7.9.2.7	Isolation from the SUPPLY MAINS			
7.9.2.8	Start-up PROCEDURE			
7.9.2.9	Operating instructions			
7.9.2.10	Messages			
7.9.2.11	Shutdown PROCEDURE			
7.9.2.12	Cleaning, disinfection and sterilization			
7.9.2.13	Maintenance			
7.9.2.14	ACCESSORIES, supplementary equipment, used material			
7.9.2.15	Environmental protection			Risk assessment may indicate the need for risk control measures for the disposal of waste products, residues and of the MEE and accessories at the end of their useful life and advice for minimizing these risks.
7.9.2.16	Reference to the technical description			
7.9.3	Technical description (see also Table C.6)			
7.9.3.1	General			
7.9.3.2	Replacement of fuses, POWER SUPPLY CORDS and other parts			Risk assessment may include the need for risk control measures with regard to replacement of components and associated hazards.
7.9.3.3	Circuit diagrams, component part lists, etc.			
7.9.3.4	Mains isolation			
8	Protection against electrical HAZARDS from ME EQUIPMENT			
8.1	Fundamental rule of protection against electric shock	b)	a)	Provides verification tests input for SFC's when applicable.
8.2	Requirements related to power sources			
8.2.1	Connection to a separate power source			

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		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
8.2.2	Connection to an external d.c. power source			
8.3	Classification of APPLIED PARTS	d)	a), b), c)	Risk assessment may identify the need for risk control measures for parts (not being applied parts) that can come into contact with the patient and at what level these parts require protection means.
8.4	Limitation of voltage, current or energy			
8.4.1	PATIENT CONNECTIONS intended to deliver current			
8.4.2	ACCESSIBLE PARTS including APPLIED PARTS	c)	a), b), d), e)	Risk assessment may reveal that contacts of connectors or fuseholders or lampholders or parts inside an access cover do not require touch leakage current limitation because the probability of contact is low enough.
8.4.3	ME EQUIPMENT intended to be connected to a power source by a plug			
8.4.4	Internal capacitive circuits			
8.5	Separation of parts			
8.5.1	MEANS OF PROTECTION (MOP)			
8.5.1.1	General			Risk assessment and any risk control measures for insulation coatings that provide a means for patient protection may be included in the risk management file.
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)			
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)			
8.5.2	Separation of PATIENT CONNECTIONS			
8.5.2.1	F-TYPE APPLIED PARTS			
8.5.2.2	TYPE B APPLIED PARTS			Risk management may be used to exempt the one means of patient protection separation requirement between unearthed Type B Applied Parts and unearthed conductive accessible parts.
8.5.2.3	PATIENT leads			Risk management may be used to provide exemption from testing with the straight unjointed test finger because unacceptable risk from contact with corners and edges will not occur.
8.5.3	MAXIMUM MAINS VOLTAGE			
8.5.4	WORKING VOLTAGE			
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS			
8.5.5.1	Defibrillation protection		a), b)	For the situation of an applied part with multiple functions where separate functions are not all defibrillator-proof, the risk assessment and any risk control measures includes consideration for shock hazards because of the lack of separation.
8.5.5.2	Energy reduction test			

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		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
8.6	Protective earthing, functional earthing and potential equalization of ME Equipment			
8.6.1	Applicability of requirements			
8.6.2	PROTECTIVE EARTH TERMINAL			
8.6.3	Protective earthing of moving parts			The risk management file may include the identification of the need for moving parts to be protectively earthed and the connection reliability during the expected service life.
8.6.4	Impedance and current-carrying capability			
8.6.5	Surface coatings			
8.6.6	Plugs and sockets			
8.6.7	POTENTIAL EQUALIZATION CONDUCTOR			The risk management file may include consideration for the accidental disconnection of the potential equalization conductor.
8.6.8	FUNCTIONAL EARTH TERMINAL			
8.6.9	CLASS II ME EQUIPMENT			
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS			
8.7.1	General requirements			
8.7.2	SINGLE FAULT CONDITIONS			
8.7.3	Allowable values			
8.7.4	Measurements			
8.7.4.1	General			
8.7.4.2	Measuring supply circuits			
8.7.4.3	Connection to the measuring supply circuit			
8.7.4.4	Measuring device (MD)			
8.7.4.5	Measurement of the EARTH LEAKAGE CURRENT			
8.7.4.6	Measurement of the TOUCH CURRENT			
8.7.4.7	Measurement of the PATIENT LEAKAGE CURRENT			
8.7.4.8	Measurement of the PATIENT AUXILIARY CURRENT			
8.7.4.9	ME EQUIPMENT with multiple PATIENT CONNECTIONS			
8.8	Insulation			
8.8.1	General			
8.8.2	Distance through solid insulation or use of thin sheet material			
8.8.3	Dielectric strength			
8.8.4	Insulation other than wire insulation			
8.8.4.1	Mechanical strength and resistance to heat	a)	b)	Risk assessment and any risk control measures for resistance to heat of insulation (other than wire insulation) is included in the risk management file.

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		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
8.8.4.2	Resistance to environmental stress			
8.9	CREEPAGE DISTANCES and AIR CLEARANCES			
8.9.1	Values			
8.9.1.1	General			
8.9.1.2	CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1			
8.9.1.3	CREEPAGE DISTANCES across glass, mica, ceramic and similar materials			
8.9.1.4	Minimum CREEPAGE DISTANCE			
8.9.1.5	ME EQUIPMENT RATED for high altitudes			
8.9.1.6	Interpolation			
8.9.1.7	Material groups classification			
8.9.1.8	Pollution degree classification			
8.9.1.9	Overtoltage category classification			
8.9.1.10	AIR CLEARANCE for MAINS PARTS			
8.9.1.11	SUPPLY MAINS overvoltage			
8.9.1.12	SECONDARY CIRCUITS			
8.9.1.13	PEAK WORKING VOLTAGES above 1 400 V peak or d.c.			
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION			
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED			
8.9.2	Application			
8.9.3	Spaces filled by insulating compound			
8.9.3.1	General			
8.9.3.2	Insulating compound forming solid insulation between conductive parts			
8.9.3.3	Insulating compound forming a cemented joint with other insulating parts			
8.9.3.4	Thermal cycling			
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES			
8.10	Components and wiring			
8.10.1	Fixing of components			The need for securely mounting components is included in the risk management file.
8.10.2	Fixing of wiring			The need for securing conductors and connectors and not solder coating stranded conductors to prevent a hazardous situation from detachment is considered in the risk management file.
8.10.3	Connections between different parts of ME EQUIPMENT			

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		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices			
8.10.4.1	Limitation of operating voltages			
8.10.4.2	Connection cords			
8.10.5	Mechanical protection of wiring	a), b)		The risk management file risk assessment and risk control measures may include protection of cables, wiring, cord forms or components from damage by moving parts, friction at sharp corners or edges, assembly or opening or closing access covers.
8.10.6	Guiding rollers for insulated conductors			
8.10.7	Insulation of internal wiring			
8.11	MAINS PARTS, components and layout			
8.11	Isolation from the SUPPLY MAINS			
8.11.2	MULTIPLE SOCKET-OUTLETS			
8.11.3	POWER SUPPLY CORDS			
8.11.3.1	Application			
8.11.3.2	Types			
8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors			
8.11.3.4	APPLIANCE COUPLERS			
8.11.3.5	Cord anchorage			
8.11.3.6	Cord guards			
8.11.4	MAINS TERMINAL DEVICES			
8.11.4.1	General requirements for MAINS TERMINAL DEVICES			
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES			
8.11.4.3	Fixing of mains terminals			
8.11.4.4	Connections to mains terminals			
8.11.4.5	Accessibility of the connection			
8.11.5	Mains fuses and OVER-CURRENT RELEASES			If the manufacturer omits fuses or over-current releases, the risk management file includes justification for the omission.
8.11.6	Internal wiring of the MAINS PART			
9	Mechanical Hazards			
9.1	MECHANICAL HAZARDS of ME EQUIPMENT			
9.2	HAZARDS associated with moving parts			
9.2.1	General			Risk management is used to assess, control and consider the residual risk associated with moving parts.
9.2.2	TRAPPING ZONE			
9.2.2.1	General			
9.2.2.2	Gaps			
9.2.2.3	Safe distances			

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		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
9.2.2.4	GUARDS and protective measures			
9.2.2.4.1	Access to TRAPPING ZONES			Risk management may be used for guards and protective measures.
9.2.2.4.2	FIXED GUARDS			
9.2.2.4.3	Movable GUARDS			The risk management file includes considerations movable guards that can be opened without the use of a tool.
9.2.2.4.4	Protective measures			The risk management file includes considerations for protective measures providing protection from moving parts.
9.2.2.5	Continuous activation	a), b), c)		The risk management file includes considerations for continuous activation controls and the need for emergency stopping devices in regards to moving parts and trapping zones.
9.2.2.6	Speed of movement(s)			The risk management file includes consideration for the speed of moving parts and the overtravel after activation to stop movement.
9.2.3	Other HAZARDS associated with moving parts			
9.2.3.1	Unintended movement			Inspect controls for unintended movement hazards.
9.2.3.2	Overtravel			The risk management file includes considerations for overtravel and end stops or other stopping means.
9.2.4	Emergency stopping devices	a), b), e)	c), d), f), g), h), i), j), k)	The risk management file includes considerations for emergency stopping devices.
9.2.5	Release of PATIENT			The risk management file includes considerations for the release of the patient.
9.3	HAZARD associated with surfaces, corners and edges			The risk management file includes considerations for hazards associated with surfaces, corners and edges.
9.4	Instability HAZARDS			
9.4.1	General			Follow the requirements given in clauses 9.4.2 to 9.4.4.
9.4.2	Instability – overbalance			
9.4.2.1	Instability in transport position			
9.4.2.2	Instability excluding transport			
9.4.2.3	Instability from horizontal and vertical forces	a), b)		
9.4.2.4	Castors and wheels			
9.4.2.4.1	General			Equipment with castors or wheels may include a risk assessment and risk control measures for when the equipment is moved or parked.
9.4.2.4.2	Force for propulsion			
9.4.2.4.3	Movement over a threshold			For mobile equipment weighing over 45 kg, the risk management file includes risk assessment and any risk control measures when passing over a 20 mm high 80 mm wide step.

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		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
9.4.3	Instability from unwanted lateral movement (including sliding)			
9.4.3.1	Instability in transport	a), b), c), d)		Instability in transport from unwanted lateral movement may be included in the risk management file.
9.4.3.2	Instability excluding transport	a), b)		Instability excluding transport from unwanted lateral movement may be included in the risk management file.
9.4.4	Grips and other handling devices			
9.5	Expelled parts HAZARD			
9.5.1	Protective means			The risk management file includes an assessment and any risk control measures regarding the need for protective means from expelled parts.
9.5.2	Cathode ray tubes			
9.6	Acoustic energy (including infra- and ultrasound) and vibration			
9.6.1	General			Where applicable, the risk management file includes a risk assessment and any risk control measures for protection from acoustic energy and vibration.
9.6.2	Acoustic energy			
9.6.2.1	Audible acoustic energy			
9.6.2.2	Infrasound and ultrasound energy			Where applicable, the risk management file includes a risk assessment and any risk control measures for protection from infrasound and ultrasound energy.
9.6.3	Hand-transmitted vibration			
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure			
9.7.1	General			
9.7.2	Pneumatic and hydraulic parts			The risk management file includes considerations for parts subject to pneumatic or hydraulic pressure.
9.7.3	Maximum pressure			
9.7.4	Pressure rating of ME EQUIPMENT parts			Where applicable, the risk management file includes consideration for the necessary pressure rating of parts in both normal and single fault condition.
9.7.5	Pressure vessels			Risk management may include an assessment for leakage from parts under pressure.
9.7.6	Pressure-control device			Where applicable, the risk management file includes consideration for pressure control device performance and operation point.
9.7.7	Pressure-relief device	a), b), c), d), e), f), g), h)		Where applicable, the risk management file includes consideration for pressure relief device operation discharge and characteristics identified herein.
9.7.8	RATED maximum supply pressure			
9.8	HAZARDS associated with support systems			
9.8.1	General			Where applicable, the risk management file includes

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		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
9.8.2	TENSILE SAFETY FACTOR			consideration for hazards associated with support systems.
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems			
9.8.3.1	General			Where applicable, the risk management file includes consideration for the strength of patient or operator support or suspension systems.
9.8.3.2	Static forces due to loading from persons	a), b)		Where applicable, the risk management file includes consideration for static forces due to loading from persons.
9.8.3.3	Dynamic forces due to loading from persons			The RMF may be helpful with determination of unacceptable risks caused by dynamic forces due to loading from persons.
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES			
9.8.4.1	General	b)	a)	Where applicable, the risk management file includes consideration for mechanical protective devices.
9.8.4.2	Use after activation of a MECHANICAL PROTECTIVE DEVICE			
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended for single activation			Where applicable, the risk management file includes consideration for mechanical protective device(s) intended for single activation.
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES			Where applicable, the risk management file includes consideration for not requiring the use of a mechanical protective device(s).
10	Radiation Hazards			
10.1	X-Radiation			
10.1.1	ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation			
10.1.2	ME EQUIPMENT Intended to produce diagnostic or therapeutic X-radiation			Where applicable, the risk management file includes considerations for unintended X-radiation.
10.2	Alpha, beta, gamma, neutron and other particle radiation			Where applicable, the risk management file includes considerations for alpha, beta, gamma, neutron and other partial radiation.
10.3	Microwave radiation			Where applicable, the risk management file includes considerations for microwave radiation.
10.4	Lasers and light emitting diodes (LEDs)			
10.5	Other visible electromagnetic radiation			Where applicable, the risk management file includes considerations for visible electromagnetic radiation other than that produced by lasers and light emitting diodes.
10.6	Infrared radiation			Where applicable, the risk management file includes considerations for infrared radiation other than that produced by lasers and light emitting diodes.

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		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
10.7	Ultraviolet radiation			Where applicable, the risk management file includes considerations for ultraviolet radiation other than that produced by lasers and light emitting diodes.
11	Temperature and Other Hazards			
11.1	Excessive temperatures in ME EQUIPMENT			
11.1.1	Table 23 Parts likely to be touched			Where applicable, the risk management file includes consideration for the temperature of parts likely to be touched by either unhealthy skin or surface area's greater than 10 % of the total body surface or greater than 10 % of the total head surface.
11.1.1	Table 24 Skin contact with AP			Where applicable, the risk management file includes consideration for the temperature of applied parts for either unhealthy skin or surface area's greater than 10 % of the total body surface or greater than 10 % of the total head surface.
11.1.2	Temperature of APPLIED PARTS			
11.1.2.1	APPLIED PARTS intended to supply heat to a PATIENT			Where applicable, the risk management file includes consideration for the temperature and clinical effects from applied parts intended to supply heat to a patient.
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT			Where applicable, the risk management file includes consideration for the clinical effects with respect to characteristics such as body surface, maturity of patients, medications being taken or surface pressure when applied part temperature exceed 41 ° C or are cooled below ambient temperature.
11.1.3	Measurements	e) is 6.3 only	a), b), c), d)	The risk management file may include judgements that temperature measurement is not necessary or the use of the test corner is not necessary and the probability of occurrence of contact and of the duration of contact for parts likely to be touched and for applied parts. Any alternative test methods are justified in the risk management file.
11.1.4	GUARDS			
11.2	Fire prevention			
11.2.1	Strength and rigidity required to prevent fire in ME EQUIPMENT			
11.2.2	ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS			

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		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT	a), b)		The risk management file may provide justification for deviations from worst-case limits (lower oxygen concentrations or less flammable fuel). Determination for the acceptable design configuration that provides an acceptable residual risk of fire in an oxygen rich environment.
11.2.2.2	External exhaust outlets for OXYGEN RICH ENVIRONMENT			Risk management may be used for external exhaust outlets and electrical components location in an oxygen rich environment.
11.2.2.3	Electrical connections in OXYGEN RICH ENVIRONMENTS			
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS in conjunction with ME EQUIPMENT and ME SYSTEMS			
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT		a), b)	The risk management file may be used to analyze risk for the construction of fire enclosures.
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics			
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents			The risk management file includes consideration for the possibility of fire and associated mitigations.
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT			
11.6.1	General			
11.6.2	Overflow in ME EQUIPMENT			Risk management may include risk assessment and risk control measure for equipment which incorporates a liquid reservoir.
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM			Where applicable, the risk management file includes consideration for the type of liquids, volume, duration of spill and location. This is an input for test verification.
11.6.4	Leakage			
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS			
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS			The risk management file is used to capture the results of multiple cleanings over the expected service life.
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS			The risk management file includes risk assessment and risk control measures for parts that are sterilized.
11.6.8	Compatibility with substances used with the ME EQUIPMENT			The risk management file includes, where applicable, compatibility with substances.
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS			

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		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT			
12	Accuracy and hazardous outputs			
12.1	Accuracy of controls and instruments			The risk management file includes risk assessment and any risk control measures associated with the accuracy of controls.
12.2	USABILITY			Follow these requirements and those in IEC 60601-1-6.
12.3	Alarm systems			The risk management file includes the need for alarm systems as a risk control measure and addresses any risk associated with the operation or failure of the alarm system.
12.4	Protection against hazardous output			
12.4.1	Intentional exceeding of safety limits			The risk management file includes a risk assessment associated with hazardous output from intentional exceeding of safety limits.
12.4.2	Indication of parameters relevant to safety			The risk management file includes the need for the indication of parameters that are associated with hazardous output.
12.4.3	Accidental selection of excessive output values			Risk management is used to address the risk of accidental selection of excessive output values when equipment provides both low-intensity and high-intensity outputs.
12.4.4	Incorrect output			Risk management is used to address the risk associated with incorrect output.
12.4.5	Diagnostic or therapeutic radiation			
12.4.5.1	Limits			
12.4.5.2	Diagnostic X-ray equipment			Risk management is used to address the risk associated with diagnostic X-rays.
12.4.5.3	Radiotherapy equipment			Risk management is used to address the risk associated with radiotherapy.
12.4.5.4	Other ME EQUIPMENT producing diagnostic or therapeutic radiation			Risk management is used to address the risk associated with diagnostic or therapeutic radiatio other than diagnostic X-ray and radiotherapy.
12.4.6	Diagnostic or therapeutic acoustic pressure			Risk management is used to address the risk associated with diagnostic or therapeutic acoustic pressure.
13	Hazardous situations and fault conditions			
13.1	Specific Hazardous Situations			
13.1.1	General			
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature			
13.1.3	Exceeding LEAKAGE CURRENT or voltage limits			
13.1.4	Specific MECHANICAL HAZARDS			
13.2	SINGLE FAULT CONDITIONS			

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		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
13.2.1	General			
13.2.2	Electrical SINGLE FAULT CONDITION			
13.2.3	Overheating of transformers in ME EQUIPMENT			
13.2.4	Failure of THERMOSTATS			
13.2.5	Failure of temperature limiting devices			
13.2.6	Leakage of liquid			Risk management is used to determine the appropriate test conditions for leakage of liquids.
13.2.7	Impairment of cooling that could result in a HAZARD			
13.2.8	Locking of moving parts			
13.2.9	Interruption and short circuiting of motor capacitors			
13.2.10	Additional test criteria for motor operated ME EQUIPMENT			
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			
13.2.13	Overload			
13.2.13.1	General overload test conditions			
13.2.13.2	ME EQUIPMENT with heating elements			
13.2.13.3	ME EQUIPMENT with motors			
13.2.13.4	ME EQUIPMENT RATED for non-CONTINUOUS OPERATION			
14	Programmable electrical medical systems			
14.1	General			Risk management can be used to demonstrate that the failure of the PESS does not lead to an unacceptable risk.
14.2	Documentation			Thr risk management file includes the documents required from clause 14 application.
14.3	Risk MANAGEMENT plan			Thr risk management plan includes PEMS Validation Plan.
14.4	PEMS DEVELOPMENT LIFE-CYCLE			
14.5	Problem resolution			
14.6	RISK MANAGEMENT PROCESS			
14.6.1	Identification of known and foreseeable HAZARDS			Risk Analysis includes hazards associated with PEMS hardware and software aspects including Network/Data Coupling.
14.6.2	RISK CONTROL			Validated tools and procedures are selected and identified to implement each risk control measure.
14.7	Requirement specification			
14.8	Architecture			

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		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
14.9	Design and implementation			The risk management file includes descriptive data regarding the design environment.
14.10	VERIFICATION			Verification of all functions that implement risk control measure, basic safety and essential performance.
14.11	PEMS VALIDATION			The risk management file includes all professional relationships of the members of the PEMS development team and the design team and also a reference to the methods and results of the PEMS Validation.
14.12	Modification			
14.13	Connection of PEMS by NETWORK/DATA COUPLING to other equipment			
15	Construction			
15.1	Arrangements of controls and indicators of ME EQUIPMENT			Risk management addresses the risks associated with the arrangement of controls and indicators.
15.2	Serviceability			Risk control measures may identify the need for parts to be accessible for inspection, replacement and maintenance.
15.3	Mechanical strength			
15.3.1	General			
15.3.2	Push test			Risk management is used to identify risk associated with pushing.
15.3.3	Impact test			Risk management is used to identify risks associated with impacts.
15.3.4	Drop test			
15.3.4.1	HAND-HELD ME EQUIPMENT			Risk management may be used to identify risks associated with hand-held equipment drops.
15.3.4.2	PORTABLE ME EQUIPMENT			Risk management is used to identify risks associated with portable equipment handling.
15.3.5	Rough handling test			Risk management is used to identify risks associated with mobile equipment caused by ascending step, descending step and door frame shock.
15.3.6	Mould stress relief test			Risk management may provide evidence of unacceptable risk for inspection after mold stress relief testing.
15.3.7	Environmental influences			
15.4	ME EQUIPMENT components and general assembly			
15.4.1	Construction of connectors	a), b)		Risk management is used to address the risk of electrical, hydraulic, pneumatic and gas connection terminals and connectors.
15.4.2	Temperature and overload control devices			

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Clause	60601-1:2005 Topic			
		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
15.4.2.1	Application	a)		Risk management is used to address the risk of automatic resetting thermal cut-outs and over-current releases.
		b)		Risk management is used to address the risk of thermal cut-outs that have to be reset by a soldering operation.
		c)		Risk management is used to address the risk of the failure of thermostat and the need for an over temperature thermal cut-out.
		d)	e), f), g)	Risk management is used to address the risk of the loss of function caused by the operation of a thermal cut-out or over-current release.
		h)		Risk management is used to address the risk associated with heating elements making a conductive connection to earth that could result in over-heating.
15.4.2.2	Temperature settings			
15.4.3	Batteries			
15.4.3.1	Housing			Risk management is used to address both battery ventilation and accidental short-circuiting.
15.4.3.2	Connection			The risk management file may provide some guidance for the incorrect connection or replacement of batteries.
15.4.3.3	Protection against overcharging			The risk management file may address risks associated with over-charging the batteries.
15.4.3.4	Lithium batteries			
15.4.3.5	Excessive current and voltage protection			Risk management is used to justify the omission of fuses or over-current releases providing protection from excessive battery current.
15.4.4	Indicators			
15.4.5	Pre-set controls			Risk management is used to address the risks associated with pre-set controls.
15.4.6	Actuating parts of controls of ME EQUIPMENT			
15.4.6.1	Fixing, prevention of maladjustment			
15.4.6.2	Limitation of movement			
15.4.7	Cord-connected HAND-HELD and foot-operated control devices (see also 8.10.4)			
15.4.7.1	Mechanical strength			
15.4.7.2	Accidental operation of ME EQUIPMENT			
15.4.7.3	Entry of liquids	b)	a)	Risk management is used to determine the probability of foot switches being used in areas where liquids are likely to be found.
15.4.8	Internal wiring of ME EQUIPMENT			
15.4.9	Oil containers			

APPENDIX A				
Clause	60601-1:2005 Topic			
		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
15.5	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5			
15.5.1	Overheating			
15.5.1.1	Transformers			
15.5.1.2	Short-circuit test			
15.5.1.3	Overload test			
15.5.2	Dielectric strength			
15.5.3	Construction of transformers used to provide separation as required by 8.5			
16	Medical electrical systems			
16.1	General requirements for the ME SYSTEMS			Risk management is used to determine which configurations constitute the highest risks and which risk control measures are needed in any possible configuration to prevent an unacceptable risk.
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM			
16.3	Power supply			
16.4	ENCLOSURES			
16.5	SEPARATION DEVICES			
16.6	LEAKAGE CURRENTS			
16.6.1	TOUCH CURRENT			
16.6.2	EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET			
16.6.3	PATIENT LEAKAGE CURRENT			
16.6.4	Measurements			
16.6.4.1	General conditions for ME SYSTEMS			
16.6.4.2	Connection of the ME SYSTEM to the measuring supply circuit			
16.7	Protection against MECHANICAL HAZARDS			
16.8	Interruption of the power supply to parts of an ME SYSTEM			
16.9	ME SYSTEM connections and wiring			
16.9.1	Connection terminals and connectors			
16.9.2	MAINS PARTS, components and layout			
16.9.2.1	MULTIPLE SOCKET-OUTLET			
16.9.2.2	PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS			
16.9.2.3	Protection of conductors			
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS			Risk management is used to address the risk associated with use of the equipment in electromagnetic environments where it is expected to be used and the equipment's electromagnetic effect on that environment.

APPENDIX A				
Clause	60601-1:2005 Topic			
		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
	Protection against HAZARDS of ignition of flammable anaesthetic mixtures			
G.1	Introduction			
G.1.1	Applicability			Risk management is used to determine the probability of occurrence of ignition from anaesthetic mixtures depending on their concentration, ignition energy or high surface temperatures and the energy of sparking..
G.1.2	Industrial equipment and components			
G.1.3	Requirements for ME EQUIPMENT			
G.2	Locations and basic requirements			
G.2.1	Parts of CATEGORY APG ME EQUIPMENT			
G.2.2	FLAMMABLE ANAESTHETIC MIXTURE WITH AIR			
G.2.3	FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE			
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR			
G.2.5	ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE			
G.3	Marking, ACCOMPANYING DOCUMENTS			
G.3.1	CATEGORY APG marking			
G.3.2	CATEGORY AP marking			
G.3.3	Placement of markings			
G.3.4	ACCOMPANYING DOCUMENTS			
G.3.5	Marking when parts of ME EQUIPMENT are CATEGORY AP or CATEGORY APG			
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT			
G.4.1	Electrical connections			
G.4.2	Construction details			
G.4.3	Prevention of electrostatic charges			
G.4.4	Corona			
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components thereof			
G.5.1	General			
G.5.2	Temperature limits			
G.5.3	Low-energy circuits			
G.5.4	External ventilation with internal overpressure			
G.5.5	ENCLOSURES with restricted breathing			
G.6	Requirements and tests for CATEGORY APG ME EQUIPMENT, parts and components thereof			
G.6.1	General			
G.6.2	Power supply			

APPENDIX A				
Clause	60601-1:2005 Topic			
		Sub-parts applicable to risk management	Sub-parts not applicable to risk management	General- How risk management affects the requirement(s). Comments
G.6.3	Temperatures and low-energy circuits			
G.6.4	Heating elements			
G.7	Test apparatus for flammable mixtures			

Means these clauses of ISO 14971 are not required

Means requires risk management investigation

Means simply a heading no text

Reference clause to another

Means no risk management activity required