MECA IEC 60601-1, Edition 3.1 Risk Management Guidance-Review Document

The purpose of this document is to identify the IEC 60601-1 risk management requirements, and to specify where applicable items are located in your device risk management documentation.

External References:
IEC 60601-1:2012, Edition 3 + Amendment 1 (Edition 3.1); ISO 14971:2007 Medical devices - Application of risk management to medical devices
Note: For ISO 14971 requirements in Clause 4.2.2, see separate MECA ISO 14971 Risk Management Guidance-Review Document
Note: This document is not a replacement for the IEC 60601-1 or ISO 14971 standard, and does not include the full text of any referenced clauses or requirements, so a purchased copy of the standards should also be used.

Where requirement is not applicable, note "N/A".
Where the requirement is applicable, provide:
Risk management information specified or location of the required risk management items (document number and page or section)

Clause	Document, Location, Information	Requirement
4.2	-	**Risk Management process for ME Equipment & ME Systems**
4.2.2	***See separate MECA ISO 14971 Guidance Document***	Risk Management Process complies with ISO 14971 (2007)
4.2.3	-	**Evaluating Risk**
4.2.3.1a	*(Information)*	*Base, Collateral, and Particular standard addressing hazards and providing acceptance criteria:* *- Presume residual risk reduced to acceptable level, unless evidence to contrary*
4.2.3.1b	RM file location:	Base, Collateral, and Particular standard addressing hazards without acceptance criteria: - Manufacturer provides acceptance criteria in risk management file
4.2.3.1c	RM file location:	Base, Collateral, and Particular standard addressing hazards without providing requirements or acceptance criteria: - Manufacturer determines applicability in RM file (if hazardous situations exist) - Manufacturer determines acceptance criteria in RM file
4.2.3.2	Risks not addressed: RM file location:	Risk Management Process (per 4.2.2) addresses hazards and/or hazardous situations not specifically addressed in the Base, Collateral, and Particular standards
4.3	-	**Essential Performance**
4.3	RM file reference to Essential Performance:	The manufacturer shall identify the performance of the **clinical functions** (other than that related to Basic Safety) that is necessary to achieve intended use or could affect safety of the equipment/system
4.3	RM file location of performance limits:	Performance limits specified between fully functional and total loss of identified performance in Normal Condition and Single Fault Condition
4.3	RM file location of evaluation:	Risk of loss or degradation of identified performance beyond limits is evaluated, and constitutes essential performance
4.3	List of functions, including requirements from Collateral and Particular standards:	**Clinical** Functions with unacceptable risk identified as Essential Performance.
4.3	RM file location of risk control measures:	Risk control measures implemented to address loss or degradation of essential performance
4.3	RM file location of effectiveness verification:	Methods specified to verify effectiveness of risk control measures
4.3	*(Information)*	*The generation of an alarm signal may be the risk control measure that is considered essential performance*
4.3	*(Information)*	*Demonstration of risk control measures operate in presence of conditions that result in loss of essential performance*
4.3	*(Information)*	*Applicable Collateral and Particular standards may specify requirements for essential performance*
4.3	Document essential performance:	ESSENTIAL PERFORMANCE Functional testing to verify essential performance (also repeated after specified tests)
4.4	Specified expected service life in RMF:	Expected Service Life of the equipment shall be defined in the RMF
4.5	Alternative risk used for:	Alternative Risk Control Measures or Test Methods for ME Equipment, ME Systems
4.5	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Alternative Risk Control Measures or Test Methods (Equivalent Safety) **Only applicable where the equipment/system does not comply with one or more stated requirements in the standard** Where an alternative method of demonstrating compliance to the standard is used (Equivalent safety), manufacturer must use scientific data, clinical opinion, or comparative study that the resulting residual risk remains acceptable and is comparable to the standard. This review provided in the risk management file
4.5	Document name, location:	Scientific data, clinical opinion, comparative study
4.6	Parts: Type Applied Part:	Parts of the equipment not rated as applied parts that can contact the patient defined. Requirements for Type B Applied Parts applied, unless assessment identifies the need for Type BF or CF Applied Part to apply.

Clause	Document, Location, Information	Requirement
4.6	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	ME Equipment or ME System Parts That Contact the Patient Evaluation of the likelihood that parts (other than applied parts) will contact the patient provided in the risk management file Such parts will be required to meet all requirements for applied parts, except labeling *- Have parts been identified during the risk management process which can come into contact with the patient but fall outside the definition of applied parts?* *- If so, are all the relevant requirements and tests of this standard applied?* *- If so, are there residual risks which are not acceptable?* *- If so, are risk controls measures implemented that make the residual risk acceptable?*
4.7	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation:	Single Fault Conditions for ME Equipment Under SFC, there shall be no unacceptable risks. The means used to reduce risk shall be adequate to assure that the risk remains acceptable throughout the useful life taking maintenance into consideration as long as the fault will be detected and repaired before harm occurs The RMF shall evaluate possible faults for detectability. *- Compliance is determined if the introduction of any of the single fault conditions described in 13.2, one at the time, does not lead directly to the hazardous situations described in 13.1, or any other outcome that results in an unacceptable risk.* *- Are there single fault conditions which lead directly to hazardous situations described in 13.1 or to risks that are unacceptable?*
4.7	Theoretically simulated failure of components: (or tested)	Failure of any one component at a time that could result in a hazardous situation, including those in 13.1, simulated physically or theoretically
4.7	Failure simulation:	Risk associated with failure of component during expected service life of ME equipment taken into account to evaluate if a component should be subjected to failure simulation
4.7	*(Information)*	*"fault conditions" not limited to Single Fault Conditions, but multiple faults only conducted if likelihood and detection cause it to be considered a normal condition (per WG14).*
4.8	Components not used within ratings:	Component Ratings All components and wiring whose failure could result in a hazardous situation used according to their applicable ratings, except as specified in this standard, or by risk management process.
4.8	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Components of ME Equipment **Only applicable where components used outside their ratings** Risk management process assesses components for use outside their ratings provided in the risk management file *- Are specific exceptions made for any component of the device under investigation to allow it to be used not in accordance with its specified rating?* *- If so, are these exceptions formulated as the result of the risk management process?* *- If so, have inspection or test requirements been formulated to make the hazardous situations acceptable?*
4.8	RM reference to specific risks:	Risk management process assesses components for use as Means Of Protection
4.9	High reliability components:	High-Integrity Components used when a fault in a particular component can generate an unacceptable risk
4.9	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Components With High-Integrity **Only applicable where a single failure of a single component leads directly to an unacceptable risk. The mitigation is to ensure the component has high integrity characteristics through application of this clause.** If high integrity components used, identified in the RMF - Are components with high-integrity characteristics applied? - If so, have the risks associated with its use been identified during the risk assessment process? (were they selected and evaluated consistent with their conditions of use and reasonably foreseeable misuse during the expected service life of the ME equipment)?
5.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation:	Type Tests **Always applicable** Results of risk analysis used to determine combination(s) of simultaneous faults to be tested (Not Single Fault Conditions, but all equipment faults) *- The tests to be performed are determined taking into consideration the requirements of clause 4.* *- For the selection of the tests to be performed, is a risk management process according to ISO14971:2000 applied?* *- If so, this requirement is fulfilled.* *- The results of the risk analysis are used to determine which combination(s) of simultaneous faults are to be tested.* *- For the determination of which combination(s) of simultaneous faults have to be tested, is a risk assessment applied?*
7.2.2	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.4 Residual risk evaluation:	Identification **Only applicable where equipment or accessories not marked with manufacturer/model** If not marked, the risk management file includes an assessment of the risks relating to misidentification of all detachable parts. *- ME Equipment and its detachable parts not marked with the name or trademark of the manufacturer and with a Model or Type reference does not present an unacceptable risk?*

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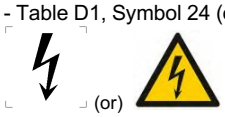
7.2.3	Non-obvious risk(s) IFU used to mitigate:	Consult Accompanying Documents - Table D2, safety sign 10 MUST be used if risk management uses the acompanying documents to reduce risk to an acceptable level, but only when the manufacturer uses the IFU as a risk control measure for a specific risk 
7.2.13	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.3 Implementation risk control:	Physiological Effects (Safety Signs and Warning) **Only applicable where there are physiological effects that can cause harm to the patient and are not obvious to the operator** Nature of hazard and precautions for avoiding or minimizing the associated risk described in IFU. (Risk management to address risk of harm) *- Do the instructions for use describe the nature of the hazard and the precautions for avoiding it or minimizing the associated risk?*
7.2.17	Safety sign provided:	When premature unpacking of me equipment could result in an unacceptable risk, - Packaging marked with a suitable safety sign
7.2.17	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.3 Implementation risk control: 6.4 Residual risk evaluation:	Protective Packing **Only applicable where premature unpacking of the equipment could result in an unacceptable RISK (e.g. sterile packaging)** Risk management file includes the assessment to determine risk of premature unpacking of the ME Equipment or its parts , that could result in an unacceptable risk. *- Can premature unpacking of ME Equipment or its parts result in an unacceptable risk?* *- Is the packaging marked with a suitable safety sign?*
7.3.2	High voltage safety sign used: Risk management determination:	High Voltage Parts: - Table D1, Symbol 24 (or) Table D2, safety sign 3 used to mark presence of high voltage parts  (or) Risk management could determine that the safety sign is the most appropriate choice if the personnel exposed to the high voltage parts have minimal training or might otherwise be unaware that it is present.
7.3.3	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.3 Implementation risk control:	Batteries **Only applicable to equipment with batteries used to operate the equipment (excludes coin cells for memory backup)** Risk management file includes an assessment to determine if the replacement of lithium batteries or fuel cells leads to an unacceptable risk if replaced incorrectly. If so, marking is required. *- Are there lithium batteries or fuel cells which are incorporated where incorrect replacement could result in an unacceptable risk?* *- If so, is there a warning indicating that replacement by inadequately trained personnel could result in a hazard?*
7.3.3	Warning provided in IFU:	- Accompanying documents contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a hazard, if risk is determined (above)
7.3.7	RM reference to specific risks (ISO 14971) 4.3 Hazard identification:	Supply Terminals **Only applicable to permanently installed equipment** If not marked, the RMF includes an assessment of the risks resulting from misconnections *- Are Terminals for supply conductors marked adjacent to the terminals?* *- If not, does the identification of known or foreseeable hazards (risk management file) demonstrate that no hazardous situation can result if connections are interchanged?*
7.4.2	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control:	Control Devices **Only applicable where a change in a control setting in normal use could result in an unacceptable risk to the patient** Risk management file identifies controls, where a change in setting in normal use results in an unacceptable risk *- In normal use, can the change of the setting of a control result in an unacceptable risk to the patient?* *- If so, review the manufacturers risk management file for risk analysis, risk evaluation, and where necessary implementation of risk control.*
7.5	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.3 Implementation risk control:	Safety Signs **Only applicable when safety signs used** Risk management process identifies markings used to convey a warning, prohibition or mandatory action that mitigate a risk not obvious to the operator *- Is marking used to convey a warning, prohibition or mandatory action that mitigates a risk that is not obvious to the operator?* *- If so, review the manufacturers risk management file for risk analysis, risk evaluation and where necessary implementation of risk control.*

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7.9.2.4	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.3 Implementation risk control:	Electrical Power Source **Only applicable to equipment with batteries intended to operate the equipment (excludes coin cells for memory backup)** Assessment of risk(s) associated with leakage of batteries provided in the risk management file *- If leakage from a battery would result in an unacceptable risk, do the instructions for use include a warning to remove the battery if the ME Equipment is not likely to be used for some time?* *- If so, review the manufacturer's risk management file for risk analysis, risk evaluation and where necessary implementation of risk control.* *- If loss of power would result in an unacceptable risk, do the instructions for use include a Warning that the ME Equipment must be connected to an appropriate power source?* *- If so, review the manufacturers risk management file for risk analysis, risk evaluation, and where necessary, implementation of risk control.*
7.9.2.5	Material/ingredient information:	- Information provided on materials and ingredients that the patient or operator is exposed to, if exposure can constitute an unacceptable risk
7.9.3.2	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Replacement of Fuses, Power Supply Cords, Other Parts **Only applicable where there are service replaceable fuses, power cords or other parts** Risk management file includes an assessment to determine if replacement of components results in any unacceptable risks, when replacement is specified *- Where replacement of a component could result in an unacceptable risk, are there appropriate warnings to identify the nature of the hazard?* *- If the Manufacturer specifies the component as replaceable by service personnel, is all information necessary to safely replace the component?* *- Review the manufacturers risk management file for risk analysis, risk evaluation, and where necessary risk control measures.*
8.1	RM reference to specific risks (ISO 14971) 4.3 Hazard identification:	Accidental Detachment of Conductors and Connectors **Only applicable where accidental detachment of conductors & connectors could lead to a hazardous situation (e.g. excessive leakage current)** Risk management file identifies conductors and connectors that may result in a hazardous situation if they break free *- Has the manufacturer identified in their risk management process accidental detachment of conductors and connectors?* *- If so, this must be one of the single fault conditions tested during product safety verification*
8.5.2.2	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation:	Type B Applied Parts **Only applicable to equipment with Type B applied parts** The risk management file reviewed for risk of metal accessible parts contacting source of voltage or leakage currents above limits *- Has the manufacturer identified in their risk management file, unearthed Type B applied parts that are not separated from unearthed conductive accessible parts, however, determined that the level of risk that the unearthed accessible part will make contact with a source of voltage or leakage current above permitted limits is acceptably low?* *- If so, accepted.* *- If not, then one means of protection is required.*
8.5.2.3	Test Documented in Clause 5.9.2 No unacceptable risk documented:	Test finger cannot make contact with conductive part when applied against access openings with 10 N force - Except when risk management process indicated no unacceptable risk existed from contact with objects other than a mains socket or a flat surface
8.5.2.3	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation:	Patient Leads or Patient Cables **Only applicable to equipment with patient leads that do not meet the test finger contact test** If test finger can contact conductive parts, risk management process indicated no unacceptable risk *- Has the manufacturer identified in their risk management process, connectors for electrical connections on a patient lead at the end of the lead (remote from the patient) that contains a conductive part that is not separated from all patient connections by 1 MOPP (for a working voltage equal to the maximum mains voltage) that will not present an unacceptable risk from contact with objects other than a mains socket or a flat surface?* *- If so, during product safety verification, the test using a straight, rigid test finger with a force of 10 N is not required, however, the remaining inspections of this clause are required.*
8.6.3	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Protective Earthling of Moving Parts **Only applicable to equipment with protectively earthed moving parts** Assessment of risk(s) associated with reliability of protective earth conductor for the expected service life of the ME Equipment provided in the risk management file *- Does the manufacturer's risk management file indicate the need to bond moving parts to the protective earth connection?* *- If so, has the manufacturer demonstrated the reliability of the connection during the expected service life?*
8.8.4.1	Insulation: RM reference:	If ball pressure test not conducted, manufacturer provides satisfactory evidence of resistance to heat

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8.8.4.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Mechanical Strength and Resistance to Heat **Only applicable if testing not conducted** When necessary (guidance below), Risk Management file addresses resistance to heat, in addition to: - Resistance to Moisture (Clause 11.6) - Dielectric Withstand (Clause 8.8.3) - Mechanical Strength (Clause 15.3) Design data for insulation contained in the design history file, for expected service life of equipment *- Has the manufacturer identified in the risk management file the need for insulations of all types, considering its resistance to heat in the application and the expected service life?* *- Has the manufacturer identified any specific test protocols that must be performed during product safety verification?* *- If so, conduct the tests required in this clause and any additional tests or inspections identified in the risk management file.*
8.10.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Fixing of Components **Always applicable** Assessment of risk(s) associated with unwanted movement that could result in an unacceptable risk provided in the risk management file *- Has the manufacturer identified components the movement of which could result in an unacceptable risk in their risk management file?* *- If so, verify that such identified components are securely mounted and will remain so for the expected service life.*
9.2.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Mechanical hazards associated with moving parts **Only applicable to equipment with moving parts** Assessment of risk(s) associated with moving parts addressed in risk management file *- Are protective measures used to reduce the risk from contact with moving parts?* *- Considering use as indicated in the Accompanying Documents or reasonably foreseeable misuse and considering the ease of access, the ME Equipment function, the shape of the parts, the energy and speed of the motion and the benefits to the patient, is this risk reduced to an acceptable level?* *- Is exposure to moving parts needed for MEE to perform its intended function?* *- Have all reasonable protective measures including warning markings on the MEE where the hazards persist been implemented?*
9.2.4	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Emergency Stopping Devices **Only applicable to equipment with moving parts and an emergency stop** Use of an emergency stopping device to reduce the risk to an acceptable level provided in the risk management file *- Does the ME Equipment use an emergency stopping device?* *- Are risks caused by mechanical hazards which are reduced by the use of the emergency stopping devices reduced to an acceptable level?*
9.2.5	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Release of Patient **Only applicable to equipment that restrains the patient** Assessment of risks to the patient with breakdown of the equipment provided in the risk management file *- The risks caused by mechanical hazards associated with release of the patient addressed?*
9.5.1	RM reference to specific risks (ISO 14971) 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Protective Means for Expelled Parts **Only applicable to equipment where expelled parts are possible** Assessment of risk(s) associated with suitability of protection against expelled parts provided in the risk management file *- Have the risks caused by mechanical hazards associated with expelled parts been addressed?*
9.6.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Acoustic Energy and Vibration **Only applicable where equipment exceeds the limits specified in 9.6.2 and 9.6.3 or the risk management file identifies the possibility of unacceptable risk associated with acoustic energy or vibration** Assessment of risk(s) associated with acoustic energy provided in the risk management file *- Have the risks caused by mechanical hazards associated with acoustic energy and vibration been addressed?*
9.6.2.2	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Infrasound and Ultrasound Energy **Only applicable to equipment that generates infrasound or ultrasound energy** Assessment of risk(s) associated with infrasound and ultrasound energy provided in the risk management file *- Have the risks caused by mechanical hazards associated with infrasound and ultrasound been addressed?*

Clause	Document, Location, Information	Requirement
9.7.2	RM reference to specific risks (ISO 14971) 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Pneumatic and Hydraulic Parts **Only applicable to equipment with parts subject to pneumatic or hydraulic pressure (even where the pressure/volume is below 200KPaL)** Pneumatic and hydraulic parts of ME equipment or accessories met requirements based on examination of the risk management file *- Have risks caused by mechanical hazards associated with pneumatic and hydraulic parts been addressed?*
9.7.7	RM reference to specific risks (ISO 14971) 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Pressure-Relief Devices **Only applicable to equipment with pressure vessels where it is possible to exceed the maximum permissible working pressure** Assessment of risk(s) associated with the discharge opening of the pressure relief device provided in the risk management file *- Have the risks caused by mechanical hazards associated with a pressure-relief device been addressed?*
9.8.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Mechanical Hazards Associated With Support Systems **Only applicable to equipment with support systems (suspended masses, patient, operator or other, e.g. shelving)** Support system mechanical hazards from static, dynamic, vibration, foundation, and other movements, impact and pressure loading, temperature, environmental, manufacture, and service conditions provided in the risk management file *- Have the risks caused by hazards arising from specified conditions been addressed?* *- Were all of the following failures considered: excessive deflection, plastic deformation, ductile or brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep, and material deterioration?*
9.8.2	RM reference to specific risks (ISO 14971) 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Tensile Safety Factor **Only applicable to equipment with support systems** Assessment of structural integrity of support system provided in the risk management file *- When not according to Table 21, what alternative method was used to determine the tensile safety factor?* *- Have the risks related to the value of the tensile factor been addressed?*
9.8.2	RM reference to specific risks (ISO 14971) 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Loading Test Results Not In Equilibrium After 1 Minute **Only applicable to equipment with support systems that do not meet the loading test equilibrium results requirement** If testing demonstrates equipment not at equilibrium after 1 minute, assessment of the results provided in the risk management file *- When not according to Table 21, what alternative method was used to determine the tensile safety factor?* *- Have the risks related to the value of the tensile factor been addressed?*
9.8.3.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Strength of Patient or Operator Support or Suspension Systems **Only applicable to equipment supporting/suspending the patient or operator** Assessment of risk(s) associated with accidental loosening of fixings and physical injuries provided in the risk management file *- Have the risks caused by mechanical hazards associated with the support or suspension of the patient (including particular applications) been addressed?*
9.8.5	RM reference to specific risks (ISO 14971) 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Systems Without Mechanical Protective Devices **Only applicable to equipment with support systems that do not have a mechanical protective device** Assessment of wear on the support system provided in the risk management file *- Has the manufacturer determined that the use of mechanical protective devices in the ME Equipment is not required?* *- Has the manufacturer justified the reasons not to use mechanical protective devices?*
10.1.2	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	ME Equipment Intended to Produce Diagnostic or Therapeutic X-Radiation **Only applicable to equipment intentionally producing X-radiation for diagnostic or therapeutic purposes** Risks associated with diagnostic or therapeutic X-Ray radiation shall be addressed in the risk analysis and provided in the risk management file *- When applicable, has the manufacturer identified hazards and hazardous situations associated with production of x-radiation in the risk management file?*
10.2	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Alpha, Beta, Gamma, Neutron and Other Particle Radiation **Only applicable to equipment producing Alpha, Beta, Gamma, Neutron or other particle radiation** Assessment of the risk of particle radiation provided in the risk management file *- When applicable, has the manufacturer identified hazards and hazardous situations associated with production of alpha, beta, gamma, neutron or other particle radiation in the risk management file?*

Clause	Document, Location, Information	Requirement
10.5	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Other Visible Electromagnetic Radiation **Only applicable to equipment producing visible radiation (other than laser and LED)** Risk associated with visible electromagnetic radiation other than that emitted by lasers or LEDs addressed in the risk management process and indicated in the risk management file *- When applicable, has the manufacturer identified hazards and hazardous situations associated with production of visible electromagnetic radiation in the risk management file?*
10.6	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Risk Associated With Infrared Radiation, Other Than Emitted by Lasers and LEDs **Only applicable to equipment emitting infrared radiation (excluding emissions from Lasers & LEDs)** Risk associated with infrared radiation other than that emitted by lasers or LEDs addressed in the risk management process and indicated in the risk management file *- When applicable, has the manufacturer identified hazards and hazardous situations associated with production of infrared radiation in the risk management file?*
10.7	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Risk Associated with Ultraviolet Radiation, Other Than Emitted by Lasers and LEDs **Only applicable to equipment emitting ultraviolet radiation (excluding emissions from Lasers & LEDs)** Risk associated with ultraviolet radiation other than that emitted by lasers or LEDs addressed in the risk management process and indicated in the risk management file *- When applicable, has the manufacturer identified hazards associated with production of ultraviolet radiation in the risk management file?*
11.1.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Maximum Temperature During Normal Use **Only applicable where the applied part is in contact with 10% of the head or body; or where the temperatures of applied or accessible parts exceed the limits for the maximum duration based on the material and contact times defined in Tables 23 and 24** Assessment of duration of contact with applied parts and accessible parts provided in the risk management file *- Has the manufacturer identified parts of the ME Equipment that are likely to be touched in normal or foreseeable misuse that can contact more than 10% of the surface area of the operator or patient's body, or 10% of the surface area of the operator or patient's or head?* *- Has the manufacturer identified the duration of continuous or aggregate contact?*
11.1.2.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Applied parts intended to supply heat to patient **Only applicable to equipment with applied parts intended to supply heat to the patient as part of the intended use** Temperature and clinical effects documented in the risk management file *- Is any part of the ME Equipment intended to supply heat or otherwise intended to cool a patient?* *- Has the manufacturer identified and addressed the clinical risks associated with hazards?* *- Has the manufacturer disclosed such risks?*
11.1.2.2	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Applied parts NOT intended to supply heat to patient **Only applicable to equipment with applied parts not intended to supply heat to the patient as part of the intended use, and exceeds 41C in Normal or Single Fault condition** Clinical effects with respect to characteristics (e.g. body surface, maturity of patient, medication being taken, surface pressure) provided in the risk management file *- Does the ME equipment have any applied parts that are not intended to heat the patient that could in normal or foreseeable misuse exceed 41 °C?* *- If so, clinical effects addressed*
11.1.2.2	RM reference to specific risks:	If applied part temperatures not affected by operation of equipment in Normal or Single Fault Condition, analysis documented in risk management file and applied part temperature of 11.1.3 not conducted
11.1.2.2	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Applied parts cooled below ambient temperature **Only applicable to equipment with applied parts that are cooled below ambient temperature** Evaluation of risk of cooling provided in the risk management file *- Does the ME equipment have any applied parts that cool the patient below ambient temperature?* *- If so, clinical effects addressed*
11.1.3	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Temperature Measurements **Only applicable when excluding temperature testing, based on risk management** No temperature measurement required where Manufacturer's engineering judgement indicates that the temperature limits cannot be exceeded. The judgement shall be provided in the risk management file *- Has the manufacturer provided engineering judgement to exclude any temperature measurements?*

Clause	Document, Location, Information	Requirement
11.1.3	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Test Corner Not Used **Only applicable when excluding the use of the test corner in temperature testing** Test corner not required for temperature measurement when Manufacturer's engineering judgement indicates that it will not impact measurements (limit is 90C for test corner) *- Has the manufacturer identified hazardous situations that relate to maximum heating effect of nearby surfaces?* *- If no hazardous situations are apparent has the manufacturer made appropriate declarations in the RMF?*
11.1.3	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Duration of Contact For Accessible and Applied Parts **Only applicable if there are accessible parts over 48C and applied parts over 41C** Parts likely to be touched and duration of contact for accessible and applied parts provided in the risk management file *- Has the manufacturer identified all conditions of intended use and foreseeable misuse to determine occurrence and duration of contact with parts and applied parts that could be touched?*
11.1.3e)	RM reference to specific risks:	Where thermal regulatory device makes temperature test method inappropriate, alternative methods for measurement provided in the risk management file
11.2.2.1 a) 5)	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Risk of Fire in an Oxygen Rich Environment **Only applicable for equipment used in an Oxygen rich environment** Justification from worst case limits in 4 and 5, based on lower oxygen concentrations or less flammable fuels provided in the risk management file *- Has the manufacturer identified that there is a risk of fire from an oxygen rich environment?*
11.2.2.1 b)	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Residual Risk of Fire With Oxygen Rich Environment **Only applicable for equipment used in an Oxygen rich environment** Assessment of the methods below, to determine if the configurations below (alone or in combination) provide an acceptable residual risk *- Where scenario number 3 is applicable, has the manufacturer conducted a risk assessment to determine hazards associated with leaks or component failures causing a source of ignition been conducted?*
11.3	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Constructional Requirements for Fire Enclosures When Construction Requirements Not Met **Only applicable to equipment where there is >15 W or 900 J of energy and no fire enclosure is provided** The specified fire enclosure requirements that have NOT been met are specifically analyzed in the risk management file *- Have the specific requirements of this clause been employed to comply with cl 13.1.2?* *- Has the manufacturer analyzed and addressed risks of not complying with the constructional requirements and showed than an equivalent level of risk / benefit has been provided?*
11.3	Specific requirement that is not met: Justification:	Specific justification(s) when fire enclosure requirements not met
11.5	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	ME Equipment and ME Systems Intended For Use in Conjunction of Flammable Agents **Only applicable to equipment intended for use in conjunction with flammable agents** Assessment of the possibility of fire and associated mitigations when used with flammable agents, provided in the risk management file *- Is the ME Equipment intended to (or can it through foreseeable misuse) come into contact with flammable agents?*
11.6.3	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Spillage on ME Equipment and ME Systems **Only applicable to equipment that utilizes liquid, or where the risk management process identifies a risk of spillage on the equipment based on the intended use (environment)** Testing specifications for spillage provided in the risk management file For equipment falling under this requirement, the intended use and intended use environment reviewed to determine the following items needed to perform this test: 1) Liquid to be used 2) Quantity to be used 3) Location of the spill 4) Duration of the spill 5) Pass/fail criteria *- Does the ME Equipment require the handling of liquids in normal or foreseeable misuse?* *-Could the wetting of the ME equipment result in a hazardous situation?* *- Has the manufacturer identified hazardous situations relating to the worst case volume and type of liquid?* *- Has the manufacturer identified hazardous situations relating to the worst location for the equipment to be spilled on?*

Clause	Document, Location, Information	Requirement
11.6.3	Liquid to be used: Quantity to be used: Location of the spill: Duration of the spill: Pass/fail criteria:	From Risk Management review (above), the identified test items provided
11.6.7	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Sterilization of ME Equipment and ME Systems **Only applicable to sterile/sterilizable equipment or equipment parts** Assessment of risk(s) associated with deterioration following sterilization provided in the risk management file *- Has the manufacturer identified the parts of the ME equipment which may be subject to sterilization in normal or foreseeable misuse, and the type of sterilization?*
11.6.8	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Compatibility With Substances ME Equipment May Come Into Contact With **Always applicable** Assessment of risk(s) associated with compatibility of substances used with ME Equipment provided in the risk management file *- Has the manufacturer identified all substances to which the ME Equipment may come into contact with in normal or foreseeable misuse?*
12.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Accuracy of Controls and Equipment **Only applicable to equipment where inaccurate controls could lead to risk** Assessment of risk(s) associated with accuracy of controls and instruments provided in the risk management file *- Has the manufacturer identified all controls and instruments contained on the ME Equipment?* *- Has the manufacturer conducted a hazard analysis to identify the risks associated with the accuracy of the above identified controls and instruments?*
12.4.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Intentional Exceeding of Safety Limits **Only applicable where equipment intentionally exceeds safety limits as part of the intended use.** **NOTE: where the exceeding of limits is Normal Condition, not a Single Fault Condition** Assessment of risk(s) associated with hazardous output arising from intentionally exceeding of safety limits addressed in the risk management process *- Has the manufacturer identified risks associated with the intentional exceeding of safety limits?* *- Has the manufacturer addressed such risks to comply with the manufacturer's risk acceptability criteria?*
12.4.2	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Indication of Hazardous Output, Relevant to Safety **Only applicable to equipment where the indication of any hazardous output is required as a risk mitigation** Assessment of risk(s) associated with hazardous output provided in the risk management file *- Has the manufacturer identified all functions related to the delivery of energy or substances to the patient?* *- Has the manufacturer explored such functions for hazardous situations in which these functions can produce an output to the patient?*
12.4.3	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Accidental Selection of Excessive Output Values **Only applicable to equipment where an excessive output is possible (e.g. where both high and low output modes are possible)** Assessment of risk(s) associated withof accidental selection of excessive output values for ME Equipment with a multi-purpose unit provided in the risk management file *- Has the manufacturer identified all features of the ME Equipment that provide an output to the patient for therapeutic purposes?* *- Has the manufacturer identified which of these features have multiple purposes that require different intensities for different treatments?* *- Has the manufacturer identified hazards associated with accidental selection of excessive output values?*
12.4.4	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Incorrect Output **Only applicable to equipment where an incorrect output (e.g. energy or substance) can be applied to the patient** Assessment of risk(s) associated with incorrect output provided in the risk management file *- Has the manufacturer identified all features of the ME Equipment that provide an output?* *- Has the manufacturer identified hazards associated with incorrect output?*
12.4.5.3	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Radiotherapy Equipment **Only applicable to radiotherapy equipment** Assessment of risk(s) associated with radiotherapy provided in the risk management file *- Has the manufacturer identified if the product is intended for radiotherapy purposes?* *- Has the manufacturer identified and explored risks associated with emission radiation for therapeutic purposes?*

Clause	Document, Location, Information	Requirement
12.4.5.4	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Other ME Equipment Producing Diagnostic or Therapeutic Radiation **Only applicable to equipment producing diagnostic or therapeutic radiation** Assessment of risk(s) associated with ME Equipment producing diagnostic or therapeutic radiation, other than for diagnostic X-Rays and radiotherapy provided in the risk management file *- Has the manufacturer identified if the product is intended for radiotherapy purposes?* *- Has the manufacturer identified and explored risks associated with emission radiation for therapeutic purposes?*
12.4.6	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Diagnostic or Therapeutic Acoustic Pressure **Only applicable to equipment producing diagnostic or therapeutic acoustic pressure** Assessment of risk(s) associated with diagnostic or therapeutic acoustic pressure provided in the risk management file *- Has the manufacturer identified if the equipment emits an acoustic pressure output?* *- Has the manufacturer identified and explored risks associated with emission of such acoustic pressure?*
13.2.6	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Leakage of Liquid **Only applicable to equipment that utilizes liquid (internally or externally)** Assessment of risk(s) associated with leakage of liquid in single fault condition provided in the risk management file *- Has the manufacturer determined the appropriate test conditions for the evaluation of liquid leakage?*
14.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation:	Software - Programmable Electrical Medical Systems (PEMS) **Only applicable where software (PEMS) provides basic safety or essential performance, or where the failure of the programmable electronic subsystems (PESS) leads to an unacceptable risk** Application of risk management demonstrated that failure of software does not lead to an unacceptable risk *- Does the application of ISO 14971 demonstrate that the failure of the PEMS does not lead to an unacceptable risk?*
14.6.1	RM reference to specific risks (ISO 14971) 4.3 Hazard identification:	Software - Identification of Known and Foreseeable Hazards **Only applicable where software (PEMS) provides basic safety or essential performance or where the failure of the programmable electronic subsystems (PESS) leads to an unacceptable risk** Assessment of risk(s) associated with known or foreseeable hazards associated with software, hardware, incorporation of PEMS into an IT-network, components of 3rd party origin and legacy subsystems, provided in the risk management file *- Has the manufacturer considered those hazards associated with the software and hardware aspects of the PEMS including those associated with Network/Data coupling and legacy systems?*
14.6.2	RM reference to specific risks (ISO 14971) 6.1: Risk reduction	Software - Risk Control **Only applicable where software (PEMS) provides basic safety or essential performance or where the failure of the programmable electronic subsystems (PESS) leads to an unacceptable risk** Suitability of tools and procedures to validate each risk control measure provided in the risk management file *- Has the manufacturer identified suitable tools and procedures to implement risk control measures?* *- Are these tools and procedures appropriate to ensure that each risk control measure effectively reduces the identified risks?*
14.7	RM reference to specific risks (ISO 14971) 6.3 Implementation risk control:	Software - Requirement Specification **Only applicable where software (PEMS) provides basic safety or essential performance or where the failure of the programmable electronic subsystems (PESS) leads to an unacceptable risk** Documented requirement specification for programmable electrical medical systems (PEMS) and programmable electronic subsystems (PESS) which includes essential performance and risk control measures, implemented by that system or subsystem provided in the risk management file Compliance with this requirement achieved through application of IEC 62304 *- Does the requirement specification include and distinguish any risk control measures?*

Clause	Document, Location, Information	Requirement
14.8	RM reference to specific risks (ISO 14971) 6.3 Implementation risk control:	Software - Architecture **Only applicable where software (PEMS) provides basic safety or essential performance or where the failure of the programmable electronic subsystems (PESS) leads to an unacceptable risk** Software architecture specifying the requirement is specified for programmable electrical medical systems (PEMS) and programmable electronic subsystems (PESS) The architecture specification shall make use of: a) Components with high-integrity characteristics b) fail-safe functions c) redundancy d) diversity e) partitioning of functionality f) defensive design (limits on potentially hazardous effects by restricting the available output power or by introducing means to limit the travel of actuators) Compliance with this requirement achieved through application of IEC 62304 taking into account the specific items listed in this clause *- Does the architecture specification reduce the risk to an acceptable level, where appropriate, using risk levels (see list a-f above)* *- Does the architecture specification take into consideration allocation of risk control measures?*
14.10	RM reference to specific risks (ISO 14971) 6.3 Implementation risk control:	Software - Verification **Only applicable where software (PEMS) provides basic safety or essential performance or where the failure of the programmable electronic subsystems (PESS) leads to an unacceptable risk** Information used to verify and document functions implementing basic safety, essential performance, or risk control measures specified in verification plan *- Is the result of the verification activity documented?* *- Have all functions that implement risk control measures been verified?*
14.11	RM reference to specific risks (ISO 14971) 6.3 Implementation risk control:	Software - Validation **Only applicable where software (PEMS) provides basic safety or essential performance or where the failure of the programmable electronic subsystems (PESS) leads to an unacceptable risk** Person with responsibility for PEMS validation is independent. Relationships of members of PEMS validation team with members of design team documented in risk management file. *- Has the manufacturer documented the professional relationships of the members of the PEMS validation team with members of the design team?* *- Is a reference to the methods and results of the PEMS validation included in the risk management file?*
14.13f	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control:	Software - PEMS Intended to be Incorporated Into an IT-network **Only applicable where software (PEMS) provides basic safety or essential performance or where the failure of the programmable electronic subsystems (PESS) leads to an unacceptable risk** List of hazardous situations resulting from failure of IT-network provided the characteristics required to meet purpose of PEMS connection to IT-network *- Is there a list of the hazardous situations resulting from a failure of the network/data coupling provided with the specified characteristics?* *- Review the manufacturers risk management file for any risk analysis, risk evaluation and any necessary risk control measures.* *- Does a connection of the PEMS to a network/data coupling that includes other equipment result in previously unidentified risks to patients, operators or third parties?* *- Review the manufacturers risk management file for any risk analysis, risk evaluation and any necessary risk control measures.*
15.4.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Construction of Connectors **Only applicable to equipment with electrical, hydraulic, pneumatic or gas connections that are removable without the use of a tool and incorrect connection leads to an unacceptable risk** Incorrect connection of accessible connectors, removable without a tool, prevented where there is an unacceptable risk *- Has the manufacturer identified electrical, hydraulic, and pneumatic or gas connection terminals and connectors removable without the use of a tool where incorrect connection to other outlets intended for other functions would not result in unacceptable risks?* *- If so, ensure that incorrect connection does not result in an unacceptable risk. (Gas connectors must comply with item b) of this clause).*
15.4.2.1 a)	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation:	Thermal Cut-Outs and Over-Current Releases **Only applicable to equipment with automatic resetting thermal cut-outs or over-current releases where resetting could result in a hazardous situation** Automatic resetting thermal cutouts and overcurrent releases not used when their use could lead to a hazardous situation *- Has the manufacturer identified in the risk management file, any automatic resetting thermal cut-outs or over-current releases where their use would not result in an unacceptable risk?* *- If so, ensure that the resetting of these devices does not result in unacceptable risks.*

Clause	Document, Location, Information	Requirement
15.4.2.1 c)	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation:	Independent Non-Self-Resetting Thermal Cut-Outs **Only applicable to equipment with a thermostat where the failure of the thermostat constitutes a hazard, addressed by an additional thermal cut-out** Additional, independent non-self-resetting thermal cut-out is provided where a failure of a thermostat would lead to a hazardous situation (per clause 13.1) *- Has the manufacturer identified the use of a thermostat in the MEE in the risk management file?* *- If so, inspect for an independent non-self-resetting thermal cutout with a setting outside the maximum range of the thermostat but within the safe temperature limit for its intended function.*
15.4.2.1 d)	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation:	Loss of Function of ME Equipment **Only applicable to equipment with a thermal cut-out or over-current release** Loss of function of ME Equipment caused by activation of thermal cut-out or overcurrent release does not result in a loss of essential performance or a hazardous situation (per clause 13.1) *- Has the manufacturer identified that loss of function of the MEE could result in a hazardous situation?* *- If so, ensure that the operation of a thermal cut-out or overcurrent release does not result in an unacceptable risk.*
15.4.2.1 h)	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation:	ME Equipment With Tubular Heating Elements **Only applicable to equipment with tubular heating elements where a conductive connection to earth from the leads results in overheating** ME Equipment with tubular heating elements provided with protection against overheating where connection of either lead to earth could result in overheating. *- Has the manufacturer identified the need for fusing each lead for the use of tubular heating elements in the risk management file?* *- If so, inspect for fuses in both leads and fault either lead to ground and ensure over-heating does not occur.*
15.4.3.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation:	(Battery) Housings **Only applicable to equipment with batteries (and housings)** Battery housings adequately ventilated that the risk of gas accumulation and possible ignition, as well as the risk of accidental short circuits do not result in a hazardous situations (per 13.1) *- Has the manufacturer identified the need for ventilated battery housings where gases that could result in a hazard can escape during charging or discharging?* *- If so, inspect the battery housings for proper ventilation.* *- Has the manufacturer identified the need for battery polarity connection construction such that short-circuiting is not possible?* *- If so, inspect the battery connection and ensure that incorrect connection is not possible.*
15.4.3.2	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation:	(Battery) Connection **Only applicable to equipment with batteries** Assessment of risk(s) associated with incorrect connection or replacement of batteries provided in the risk management file *- If a hazardous situation might develop by the incorrect connection or replacement of a battery, verify the ME Equipment is fitted with a means of preventing incorrect polarity of connection.* *- Review the manufacturers risk management file for any risk analysis.*
15.4.3.3	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation:	(Battery) Protection Against Overcharging **Only applicable to equipment with rechargeable batteries where overcharging could result in an unacceptable risk** Assessment of risk(s) associated with overcharging of batteries provided in the risk management file *- Does overcharging of any battery of equipment result in an unacceptable risk?* *- Does the design prevent overcharging?* *- Review the manufacturers risk management file for any risk analysis.*
15.4.4	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation:	Indicators (for Non-Luminous Heaters, Accidental/Prolonged Output) **Only applicable to equipment with non-luminous heaters** Indicator lights provided, indicating: Non-luminous heaters are operational, unless it is apparent to the operator from normal operating position, or no hazardous situation exists. Accidental or prolonged operation of output that could be a hazard *- Are indicator lights provided on ME Equipment incorporating non-luminous heaters to indicate that the heaters are operational, if a hazardous situation could exist unless it is otherwise apparent to the operator from the normal operating position?* *- Review the manufacturers risk management file for any risk analysis.* *- Are indicator lights provided on ME Equipment to indicate that an output exists where an accidental or prolonged operation of the output circuit could constitute a hazardous situation?* *- Review the manufacturers risk management file for any risk analysis.*
15.4.5	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Pre-Set Controls **Only applicable to equipment with pre-set controls (e.g. power cycle sets controls to a specific setting)** Assessment of risk(s) associated with pre-set controls provided in the risk management file *- Where applicable, has the manufacturer addressed the risk associated with pre-set controls?*

Clause	Document, Location, Information	Requirement
16.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation:	General Requirements For ME Systems **Only applicable to equipment intended to be part of a system** Assessment of risk(s) associated with the installation and modification of ME System provided in the risk management file *- After installation or subsequent modification, does the ME system result in an unacceptable risk?* *- Have hazards arising from combining various equipment to constitute an ME system been considered?* *- Is the level of safety equivalent to ME system complying with this standard IEC 60601-1 within the patient environment?*
16.9.1	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Connection Terminals and Connectors **Only applicable to systems with electrical, hydraulic, pneumatic or gas connections that are removable without the use of a tool and incorrect connection leads to an unacceptable risk** Assessment of risk(s) associated with plugs for connection of patient leads or cables likely to be in the patient environment provided in the risk management file *- Are the design and construction of electrical, hydraulic, pneumatic and gas connection terminals, and connectors such that incorrect connection of accessible connectors, removable without the use of a tool, can be prevented where a hazardous situation could otherwise exist?* *- Review the manufacturers risk management file for any risk analysis, risk evaluation and risk control measures.* *- Are plugs for patient leads designed to prevent connection to other outlets of the same ME System that are likely to be located in the patient environment unless no hazardous situation can result?* *- Review the manufacturers risk management file for any risk analysis, risk evaluation and risk control measures.*
17	RM reference to specific risks (ISO 14971) 4.2 Intended use, purpose: 4.3 Hazard identification: 4.4 Risk estimation: 5 Risk evaluation: 6.2 Option analysis: 6.3 Implementation risk control: 6.4 Residual risk evaluation: 6.5 Risk/benefit analysis:	Electromagnetic Compatibility of ME Equipment and ME Systems **Always applicable** Assessment of risk(s) associated with introduction of electromagnetic phenomena into the environment the equipment or system is used, or Introduction by the equipment or system of the electromagnetic phenomena into the environment that may degrade other devices or systems, provided in the risk management file *- Does the risk management process address the risks associated with the electromagnetic phenomena existing at the locations where the ME equipment or ME System is intended to be used as indicated in the accompanying documents?* *- Does the risk management process address the risks associated with the introduction by the ME equipment or ME system of electromagnetic phenomena into the environment that might degrade the performance of other devices, electrical equipment, and systems?*