F 028c – IEC 60601-1 Series Risk Management Compliance Report

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Purpose

The purpose of this form is to document the objective evidence required to show compliance with the Risk Management requirements from the referenced standard(s). This document also provides guidance on these requirements as they relate to the Risk Management Processes and the referenced standard(s).

Scope

This document provides a summary of the Risk Management Requirements listed in IEC 60601-1:2012 (Ed. 3.1), IEC 60601-1-8:2012 (Ed. 2.1), and IEC 60601-1-11:2015 (Ed. 2) along with the required risk management documentation required by the IECEE Test Report From and IECEE CB Scheme Operational Document OD2044 Rev. 2.2.

General Information

The following items outline general rules used throughout this document.

References to clauses within the standard are preceded by the term clause followed by the clause number. References to subclauses within the standard are by number only.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

“Shall” means that compliance with a requirement or a test is mandatory for compliance with this standard.

“Should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard.

“May” is used to describe a permissible way to achieve compliance with a requirement or test.

NOTE: This document is not a replacement for the standard, it does not include the full text of any referenced requirements, specifically NOTEs, EXAMPLES and Test Requirements.

Definitions and Acronyms

Definitions

Below are the definitions of terms used within this document.

Term	Definition
Clause (of standard)	One of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 4 includes sub-clauses 4.1, 4.2, etc.).
Subclause (of standard)	A numbered subdivision of a clause (e.g. 4.1, 4.2 and 4.10.1 are all sub-clauses of Clause 4).
Risk Management Process	A process complying with ISO 14971
Design Control Process	A process complying with Clause 7 of ISO 13485
Usability Engineering Process	A process complying with either IEC 60601-1-6 or IEC 62366

NOTE: All definitions of IEC 60601-1:2012, ISO 14971:2007 apply

Acronyms

Below are the acronyms used within this document.

Acronym	Term
DHF	Design History File (Technical File)
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
MEE	Medical Electrical Equipment
MES	Medical Electrical Systems
NCB	National Certification Body
RMF	Risk Management File
RM	Risk Management
SDLC	Software Development Life-Cycle (See IEC 62304)

Instructions for completing Risk Management Tables

The purpose of the following tables is to identify the clauses of IEC 60601-1 that interact with the risk management process, state the requirement, and provide guidance on what is required to prove compliance. The tables below are 2-part tables, the top section of the table identifies the requirement and guidance, along with a place to identify the quality system document (section, page...as precise as possible) where the objective evidence can be found and a verdict for the clause (Pass (P), Fail (F), Not Applicable (NA), Not Evaluated (NE)). The bottom section of the table contains the risk management tables required to be completed for each clause according to the IECEE Test Report Form, and the IECEE CB Scheme Operational Document OD2044. These tables are intended to identify the process requirement (steps) from ISO 14971:2007 that are related to the requirement from IEC 60601-1:2012. See Figure 1 below for an example.

The first two rows of each table identify the **Clause** and **Requirement Summary** from the standard and IEC 60601-1 TRF.

The "**Guidance**" row identifies **When a Clause is Applicable** and provides general guidance on the applicability of the requirement and/or recommendations on how this requirement should be addressed in specific product designs.

*NOTE: Any text in **blue font** is taken from the IECEE OD2044 document.*

The **Comment** row is provided for answering to questions (i.e. Service life of equipment is 5 years), or may be a justification of why the clause is not applicable (i.e. no batteries).

The "**RMF Reference(s)**" row is where the location of the required information is entered. **Must include: document or file name, revision, and location (section / Hazard ID / Row)**

Tables with Yellow Clauses are required for all equipment types where the clause is applicable.

For each applicable clause:
- Review the requirement summary & guidance rows (and standard, as necessary)
- Enter any comments necessary to answer a question or explain a verdict
- Enter the risk management file location(s) where the required evidence can be found

Notes:

The Clause verdicts will be filled in by MECA in the review of the referenced documents.

Every reference will need to be verified in the review, so a copy of every document referenced must be provided with this completed form.

All applicable tables must be completed before the risk management review is conducted.

When completing the tables, the expectation is that the references will be to Quality System Records specific to the Product/Product Family that is under evaluation.

Figure 1: Example Risk Table

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**4.6 ME Equipment or system parts contacting the patient**	Verdict
Requirement Summary	The RISK MANAGEMENT PROCESS shall include an assessment of whether parts that can come into contact with the PATIENT but fall outside of the definition of APPLIED PARTS need to be subject to the requirements for APPLIED PARTS. For the parts concerned, the requirements for TYPE B APPLIED PART shall be applied unless the assessment identifies a need for the requirements for a TYPE BF APPLIED PART or TYPE CF APPLIED PART to apply. If the RISK MANAGEMENT PROCESS determines that such parts are subject to the requirements for APPLIED PARTS, then all the relevant requirements and tests of this standard and of relevant collateral and particular standards shall apply, except that 7.2.10 does not apply to such parts. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance Complete comment and RMF Reference Section	The APPLIED PART consists of only the parts which **must** be in contact with the PATIENT for the device to perform it's intended use. Parts which are or may be in contact with the PATIENT based on the device construction (not that they need to be for the device to function properly) must be reviewed to determine if the only acceptable method to minimize the RISKS to the PATIENT is for those parts to be treated (designed/tested) as if they were APPLIED PARTS. This assessment should be documented in the DHF as part of the design input phase. And should also include an assessment if the part should meet the requirements of type B, BF or CF. Compliance is checked by inspection of the risk management file. Have parts been identified during the risk management process which can come into contact with the patient but fall outside the definition of applied parts? 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?	
Comment	Parts that should be treated as applied parts that fall outside of the definition of applied parts: LCD screen within reach of the patient	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	RMF file DOC-000-0000 Rev A Section 5 Hazard 1-5	

Risk Management Assessment Tracking:

Table 1 Documentation Review Tracking

Record documents reviewed during the assessment in the table below

Document Reference	Title	Revision/Date	Notes

Risk Management Tables

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**4.3 ESSENTIAL PERFORMANCE**	Verdict
Requirement Summary	Performance of clinical functions required to achieve the INTENDED USE or impacting BASIC SAFETY of the equipment must be identified in the risk management file as ESSENTIAL PERFORMANCE.	
Guidance	**Steps 1-4 required even if it is not believed there is Essential Performance** 1. Start with all functions 2. Remove all non-clinical functions 3. Remove all functions not tied to the intended use 4. Determine if the loss/degradation of remaining functions leads to unacceptable risk 5. For all functions where loss or degradation leads to unacceptable risk ESSENTIAL PERFORMANCE is the performance necessary to keep the risk acceptable Compliance is checked by inspection of the risk management file. Have, apart from the essential performance identified in the particular standards, hazardous situations been identified whereby the residual risk is unacceptable due to the absence of performance of the device? If so, has this performance been identified as essential performance for the device during the risk assessment process? If so, have risk control measures or particular tests been identified to check whether this performance is maintained? If so, has this been checked by inspection or by functional test?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**4.4 Expected Service Life**	Verdict
Requirement Summary	Expected Service Life of the equipment shall be stated in the risk management file	
Guidance	Compliance is checked by inspection of the risk management file. The EXPECTED SERVICE LIFE is the time period during which the ME EQUIPMENT or ME SYSTEM is expected to remain suitable for its INTENDED USE. It is also the period when all RISK CONTROL measures need to remain effective to ensure that RISKS remain acceptable. The EXPECTED SERVICE LIFE needs to be determined by the MANUFACTURER, as part of the RISK MANAGEMENT PROCESS, as a precondition for assessing compliance with many requirements of this standard, such as 4.5, 4.7, 7.1.3, 8.6.3, 9.8.2 and 11.6.6. In the ACCOMPANYING DOCUMENTS, the MANUFACTURER should provide information to allow the RESPONSIBLE ORGANIZATION to assess when the ME EQUIPMENT is approaching the end of its life. Such information should include the EXPECTED SERVICE LIFE as determined by the MANUFACTURER (e.g. in terms of years of service or number of uses) but could also include tests to be performed as part of preventive maintenance, or other criteria to allow the RESPONSIBLE	

	ORGANIZATION to make an appropriate determination. The need for such information and the appropriate way to present it should be addressed as part of the RISK MANAGEMENT PROCESS. In defining the EXPECTED SERVICE LIFE, the MANUFACTURER should assume that the RESPONSIBLE
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**4.5 Equivalent Safety for ME Equipment or ME System**	Verdict
Requirement Summary	Where this standard specifies a particular RISK CONTROL measure or test method, an alternative RISK CONTROL measure or test method is acceptable, provided that the MANUFACTURER can demonstrate through scientific data or clinical opinion or comparative studies that the RESIDUAL RISK that results from applying the alternative RISK CONTROL measure or test method remains acceptable and is comparable to the RESIDUAL RISK that results from applying the requirements of this standard. Comparative studies in this context mean studies comparing the effect of the alternative RISK CONTROL measure or test method with the RISK CONTROL measure or test method specified in this standard. NOTE Alternative RISK CONTROL measures can allow for exceeding limits specified in this standard or in its collateral or particular standards if additional measures for compensation are provided. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable where the equipment/system does not comply with one or more stated requirements in the standard** If a the device will contain constructions which do not comply with the stated requirements in this standard, or any of the requirements of this standard are modified, it should be clearly identified in the documentation (generally Verification Test Reports) what the deviation/modification was. Generally, if compliance with this standard is referenced as a risk mitigation in the RMF it is assumed that the documented deviation/modification is acceptable for mitigating the referenced risk. The assessment should clearly identify that the risk assumed by not complying with the standard is acceptable. Compliance is checked by inspection of the risk management file. Are there particular risks for which alternative means of controlling these risks are applied such that the resulting risk level is acceptable for these risks? If so, have these risks been identified as such during the risk assessment process? If so, is the resulting risk level equal or less than the residual risk that results from applying the requirements of this standard?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**4.6 ME Equipment or system parts contacting the patient**	Verdict
Requirement Summary	The RISK MANAGEMENT PROCESS shall include an assessment of whether parts that can come into contact with the PATIENT but fall outside of the definition of APPLIED PARTS need to be subject to the requirements for APPLIED PARTS. For the parts concerned, the requirements for TYPE B APPLIED PART shall be applied unless the assessment identifies a need for the requirements for a TYPE BF APPLIED PART or TYPE CF APPLIED PART to apply. If the RISK MANAGEMENT PROCESS determines that such parts are subject to the requirements for APPLIED PARTS, then all the relevant requirements and tests of this standard and of relevant collateral and particular standards shall apply, except that 7.2.10 does not apply to such parts. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	The APPLIED PART consists of only the parts which **must** be in contact with the PATIENT for the device to perform it's intended use. Parts which are or may be in contact with the PATIENT based on the device construction (not that they need to be for the device to function properly) must be reviewed to determine if the only acceptable method to minimize the RISKS to the PATIENT is for those parts to be treated (designed/tested) as if they were APPLIED PARTS. This assessment should be documented in the DHF as part of the design input phase. And should also include an assessment if the part should meet the requirements of type B, BF or CF. Compliance is checked by inspection of the risk management file. Have parts been identified during the risk management process which can come into contact with the patient but fall outside the definition of applied parts? 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**4.7 Single Fault Conditions of ME Equipment**	Verdict
Requirement Summary	ME EQUIPMENT shall be so designed and manufactured that it remains SINGLE FAULT SAFE, or the RISK remains acceptable as determined through application of 4.2. ME EQUIPMENT is considered SINGLE FAULT SAFE if: a) it employs a single means for reducing a RISK that has a negligible probability of failure (e.g., REINFORCED INSULATION, suspended masses without MECHANICAL PROTECTIVE DEVICES employing a TENSILE SAFETY FACTOR of 8X, COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS), or b) a SINGLE FAULT CONDITION occurs, but:	

	— the initial fault will be detected during the EXPECTED SERVICE LIFE of the ME EQUIPMENT and before a second means for reducing a RISK fails (e.g., suspended masses with MECHANICAL PROTECTIVE DEVICES); or — the probability that the second means of reducing the RISK will fail during the EXPECTED SERVICE LIFE of the ME EQUIPMENT is negligible. Where a SINGLE FAULT CONDITION causes another SINGLE FAULT CONDITION, the two failures are considered as one SINGLE FAULT CONDITION. During any test under SINGLE FAULT CONDITION, only one fault at a time shall be applied. The results of the RISK ANALYSIS shall be used to determine which failures shall be tested. The failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those mentioned in 3.1, shall be simulated, physically or theoretically. The evaluation of whether a component is subject to failure simulation shall take into account the RISK associated with the failure of the component during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. This evaluation shall be accomplished by applying the principles of RISK MANAGEMENT. The evaluation shall take into account issues such as reliability, TENSILE SAFETY FACTORS, and rating of components. Additionally, during the simulation of SINGLE FAULT CONDITIONS, component failures that are highly probable or undetectable shall be simulated. Compliance is determined by applying the specific requirements and tests associated with the SINGLE FAULT CONDITIONS identified in 13.2, and tests for the failures identified from evaluation of the results of the RISK ANALYSIS. Compliance is confirmed if the introduction of any of the SINGLE FAULT CONDITIONS described in 13.2, one at a time, does not lead directly to the HAZARDOUS SITUATIONS described in 13.1, or any other outcome that results in an unacceptable RISK.
Guidance	Evidence supporting compliance with this clause should be found in design input documentation as well as verification test reports documenting compliance with this standard. As noted in relation to clause 4.5 of this standard; listing of this standard as a risk mitigation with tracability to a design output (e.g.; verification test report) which clearly defines how the standard was applied to a specific product is sufficient for showing compliance with this requirement. Compliance is determined by applying the specific requirements and tests associated with the single fault conditions identified in 13.2, and tests for the failures identified from evaluation of the results of the risk analysis. Compliance is determined if the introduction of any of the single fault conditions described in 13.2, one at the time, does not lead directly to the hazardous situations described 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?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**4.8 Components of ME Equipment**	Verdict

Requirement Summary	All components, including wiring, the failure of which could result in a HAZARDOUS SITUATION shall be used in accordance with their specified ratings unless a specific exception is made in this standard or through the RISK MANAGEMENT PROCESS. The reliability of components that are used as MEANS OF PROTECTION shall be assessed for the conditions of use in the ME EQUIPMENT. They shall comply with one of the following (see also 4.5): a) the applicable safety requirements of a relevant IEC or ISO standard; b) where there is no relevant IEC/ISO standard, the relevant ANSI standard shall be applied; if no relevant ANSI standard exists, the requirements of this standard shall be applied. See Figure 5 for a schematic flow chart for (a) and (b). Compliance is checked by inspection and, where necessary, by test. The tests of this standard for motors (see 13.2.8 and 13.2.13.3) and transformers (see 15.5.3) are considered to be comprehensive and together with the evaluation of the motor or transformer insulation system according to Table 22 represent all testing required by this standard. ME SYSTEM components that provide isolation from non-ME EQUIPMENT are evaluated to clause 16.
Guidance	**Only applicable where a component is used outside of their ratings to determine if there are any associated risk.** Components which could result in a HAZARDOUS SITUATION should be defined as an output of the hazard analysis (e.g.; FMEA), any HAZARDOUS SITUATIONS identified should be mitigated according to the Risk Management procedure and documented in the RMF. Additionally, the DHF should contain an assessment of any components which are used outside their ratings to determine if there are any additional risks – if there are, these risks should be mitigated through application of the Risk Management Process. Compliance is checked by inspection and, where necessary, by test. The tests of this standard for motors (see 13.2.8 and 13.2.13.3) and transformers (see 15.5.3) are considered to be comprehensive and together with the evaluation of the motor or transformer insulation system according to Table 22 represent all testing required by this standard. ME system components that provide isolation from non-ME equipment are evaluated to clause 16. Are specific exceptions made for any component of the device under investigation to allow it to be used not in accordance with its specified rating? 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?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**4.9 Use of components with high-integrity characteristics**	Verdict
Requirement Summary	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS shall be used when a fault in a particular component can generate an unacceptable RISK. COMPONENTS WITH HIGH-	

	INTEGRITY CHARACTERISTICS shall be selected and evaluated consistent with their conditions of use and reasonably foreseeable misuse during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. Compliance is checked by inspection of the RISK MANAGEMENT FILE and the selection criteria for the COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS.
Guidance	**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)** This requirement applies only where a single component is used to prevent a SAFETY HAZARD as defined within the scope of this standard. The component specification created as part of the design process should contain sufficient definition of the component to verify it meets the requirements of a high interity componnet. All high-integrity components should be clearly identified in the DHF and tracable to the verification test report documenting compliance with this standard. Compliance is checked by inspection of the risk management file and the selection criteria for the components with high integrity characteristics. Are components with high-integrity characteristics applied? If so, have the risks associated with its use been identified as such during the risk assessment process, or in other words are they selected and evaluated consistent with their conditions of use and reasonably foreseeable misuse during the expected service life of the ME equipment?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**5.1 Type tests**	Verdict
Requirement Summary	The tests described in this standard are TYPE TESTS. The tests to be performed are determined taking into consideration the requirements of clause 4, in particular 4.2. A test need not be performed if analysis shows that the condition being tested has been adequately evaluated by other tests or methods. The combination of simultaneous independent faults that could result in a HAZARDOUS SITUATION shall be documented in the RISK MANAGEMENT FILE (see also 4.7). When testing is necessary to demonstrate that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained under such simultaneous independent faults, the related testing may be limited to worst case situations.	
Guidance	This is not a specific requirement, only clarification that the results of the HAZARD ANALYSIS should be used as a reference when evaluating compliance with this standard. Additionally, the results of testing against this standard should be reviewed to determine if the HAZARD ANALYSIS needs to be updated. The tests to be performed are determined taking into consideration the requirements of clause 4, in particular 4.2. 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? Annex A - Rationale in IEC 60601-1: *Because there are no reliable verifiable requirements defined in this standard for the prevention of faults, all possible simultaneous faults should be considered in accordance with 4.7.* *Where a SINGLE FAULT CONDITION remains undetected, further simultaneous faults should be considered in accordance with 4.7.*
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**7.2.2 Identification**	Verdict
Requirement Summary	ME EQUIPMENT shall be marked with: – the name or trademark and contact information of the MANUFACTURER; – a MODEL OR TYPE REFERENCE; – a serial number or lot or batch identifier; and – the date of manufacture or use by date, if applicable. NOTE See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture and use by date. The serial number, lot or batch identifier, and the date of manufacture may be provided in a human readable code or through automatic identification technology such as barcodes or RFID. Detachable components of the ME EQUIPMENT shall be marked with: – the name or trademark of the MANUFACTURER; and – a MODEL OR TYPE REFERENCE; unless misidentification does not result in an unacceptable RISK.	
Guidance	**Only applicable where a detachable component is not marked with mfr name/trademark model/type reference.** The labeling should be developed with this requirement taken into account. If there is an assessment relating to the risk of misidentification it should be included in the RMF. 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**7.2.13 Physiological effects (safety signs and warning)**	Verdict
Requirement Summary	ME EQUIPMENT producing physiological effects that are not obvious to the OPERATOR and can cause HARM to the PATIENT or OPERATOR shall bear a suitable safety sign (see 7.5). The safety sign shall appear in a prominent location so that it will be CLEARLY LEGIBLE in NORMAL USE after the ME EQUIPMENT has been PROPERLY INSTALLED. The instructions for use shall describe the nature of the HAZARD and the precautions for avoiding it or minimizing the associated RISK.	
Guidance	**Only applicable where there are physiological effects that can cause HARM to the PATIENT and are not obvious to the OPERATOR** The labeling should be developed with this requirement taken into account – including the use of the appropriate safety sign. Hazards related to physiological effects should be included in the RMF – there is no requirement for these to be reviewed as part of this clause. Do the instructions for use describe the nature of the HAZARD and the precautions for avoiding it or minimizing the associated RISK?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**7.2.17 Protective packing**	Verdict
Requirement Summary	If special handling measures have to be taken during transport or storage, the packaging shall be marked accordingly (see ISO 780). The permissible environmental conditions for transport and storage shall be marked on the outside of the packaging (see 7.9.3.1 and ISO 15223-1). Where premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK, the packaging shall be marked with a suitable safety sign (see 7.5). The packaging of ME EQUIPMENT or ACCESSORIES supplied sterile shall be marked as sterile and indicate the method of sterilization (see ISO 15223-1).	
Guidance	**Only applicable where premature unpacking of the equipment could result in an unacceptable RISK (e.g. sterile packaging)** The labeling should be developed with this requirement taken into account. Can premature unpacking of ME Equipment or its parts result in an unacceptable RISK? Is the packaging marked with a suitable safety sign?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**7.3.3 Batteries**	Verdict
Requirement Summary	The type of battery and the mode of insertion (if applicable) shall be marked (see 15.4.3.2). For batteries intended to be changed only by SERVICE PERSONNEL with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient. Where lithium batteries or fuel cells are incorporated and where incorrect replacement would result in an unacceptable RISK, a warning indicating that replacement by inadequately trained personnel could result in a HAZARD (such as excessive temperatures, fire, or explosion) shall be given in addition to the identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS.	
Guidance	**Only applicable to equipment with batteries used to operate the equipment (e.g. excludes coin cells for memory backup)** Devices with batteries should be designed and labeled taking this requirement into account. Any HAZARDs identified (as referenced in this requirement) must be disclosed in the instructions for use (ACCOMPANYING DOCUMENTS). General RISKS associated with the use of batteries should be included in the RMF. There is no requirement to review the RMF as part of this clause. 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**7.3.7 Supply terminals**	Verdict
Requirement Summary	Terminals for supply conductors shall be marked adjacent to the terminals unless it can be demonstrated that no unacceptable RISK can result if connections are interchanged. If ME EQUIPMENT is so small that the terminal marking cannot be affixed, they shall be included in the ACCOMPANYING DOCUMENTS. Terminals that are provided exclusively for the connection of the neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT shall be marked with the appropriate code from IEC 60445 (see Table D.3, Code 1). If marking for connection to a three-phase supply is necessary, it shall be according to IEC 60445. Markings that are on or adjacent to electrical connection points shall not be affixed to parts that have to be removed to make the connection. They shall remain visible after the connection has been made.	
Guidance	**Only applicable to PERMANENTLY INSTALLED equipment**	

	Supply terminals must be marked with their connection points unless it can be shown that there is no hazard resulting from miss connection. 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?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**7.4.2 Control devices**	Verdict
Requirement Summary	Different positions of control devices and different positions of switches on ME EQUIPMENT shall be indicated by figures, letters, or other visual means, e.g., by use of symbols IEC 60417-5264 (2002-10) and IEC 60417-5265 (2002- 10) (see Table D.1, symbols 16 and 17). If in NORMAL USE the change of setting of a control could result in an unacceptable RISK to the PATIENT, such controls shall be provided with either: — an associated indicating device, e.g., instruments or scale, or — an indication of the direction in which the magnitude of the function changes. See also 15.4.6.2. A control device or switch that brings the ME EQUIPMENT into the "stand-by" condition may be indicated by use of symbol IEC 60417-5009 (2002-10) (see Table D.1, Symbol 29).	
Guidance	**Only applicable where a change in a control setting in NORMAL USE could result in an unacceptable RISK to the PATIENT** The design of the control devices should be done taking this requirement into account. Additionally, application of a Usability Engineering Process should result in the information required here being developed and recorded in the DHF. 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.	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**7.5 Safety signs**	Verdict
Requirement Summary	For the purpose of this clause, markings used to convey a warning, prohibition, or mandatory action that mitigates a RISK that is not obvious to the OPERATOR shall be a safety sign selected from ISO 7010. If a safety sign with an established meaning is appropriately used, the use of the general warning sign ISO 7010:2003-W001 (see Table D.2, safety sign 2) is not required.	

	Where a safety sign is not available to indicate a particular desired meaning, the meaning may be obtained by one of the following methods. a) Constructing a safety sign according to ISO 3864-1:2002, clause 7 (for the corresponding templates, see Table D.2, safety signs 1, 4, and 8). b) Using the general warning sign ISO 7010:2003-W001 (see Table D.2, safety sign 2) placed together with a supplementary symbol or text. The text associated with the general warning sign shall be an affirmative statement (i.e., a safety notice) describing the principal RISK(S) foreseen (e.g., "Causes burns", "RISK of explosion", etc.). c) Using the general prohibition sign ISO 7010:2003-P001 (see Table D.2, safety sign 4) placed together with a supplementary symbol or text. The text associated with the general prohibition sign shall be a statement (i.e., a safety notice) describing what is prohibited (e.g., "Do not open", "Do not drop", etc.). d) Using the general mandatory action sign ISO 7010:2003-M001 (see Table D.2, safety sign 8) placed together with a supplementary symbol or text. The text associated with the general mandatory action sign shall be a command (i.e., a safety notice) describing required action (e.g., "Wear protective gloves", "Scrub before entering", etc.). If there is insufficient space to place the affirmative statement together with the safety sign on the ME EQUIPMENT, it may be placed in the instructions for use. Safety signs, including any supplementary symbol or text, shall be explained in the instructions for use (see 7.9.2). Compliance is checked by inspection.
Guidance	**Only applicable when safety signs are used on the equipment.** During the design of labeling – specifically labeling used as a RISK MITIGATION, there must be an assessment to determine if the item being mitigated is obvious to the OPERATOR. If it is, then a symbol is acceptable; if not then a safety sign is required. Evidence of the RISKS mitigated through the use of labeling should be noted in the RMF – a smaller subset of these where the mitigation is a symbol require this additional assessment. The DHF should contain the labeling requirements (design). 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.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**7.9.2.4 Electrical power source**	Verdict
Requirement Summary	For mains-operated ME EQUIPMENT with an additional power source not automatically maintained in a fully usable condition, the instructions for use shall include a warning statement referring to the necessity for periodic checking or replacement of such an additional power source.	

	If leakage from a battery would result in an unacceptable RISK, the instructions for use shall include a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time. If an INTERNAL ELECTRICAL POWER SOURCE is replaceable, the instructions for use shall state its specification. If loss of the power source would result in an unacceptable RISK, the instructions for use shall contain a warning that the ME EQUIPMENT must be connected to an appropriate power source.
Guidance	**Only applicable to equipment with batteries intended to operate the equipment (e.g. excludes coin cells for memory backup)** Devices with batteries (or other non-MAINS supplies) should be designed and labeled taking this requirement into account. Any HAZARDs identified (as referenced in this requirement) must be disclosed in the instructions for use (ACCOMPANYING DOCUMENTS). General RISKS associated with the use of batteries should be included in the RMF. There is no requirement to review the RMF as part of this clause. 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 manufacturers 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.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**7.9.3.2 Replacement of fuses, power supply cords, other parts**	Verdict
Requirement Summary	The technical description shall contain, as applicable, the following: — the required type and full rating of fuses used in the SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT, if the type and rating of these fuses are not apparent from the information concerning RATED current and mode of operation of ME EQUIPMENT; — for ME EQUIPMENT having a non-DETACHABLE POWER SUPPLY CORD, a statement as to whether the POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and if so, instructions for correct connection and anchoring to ensure that the requirements of 8.11.3 will continue to be met; — instructions for correct replacement of interchangeable or detachable parts that the MANUFACTURER specifies as replaceable by SERVICE PERSONNEL; and — where replacement of a component could result in an unacceptable RISK, appropriate warnings that identify the nature of the HAZARD and, if the MANUFACTURER specifies the component as replaceable by SERVICE PERSONNEL, all information necessary to safely replace the component.	

Guidance	**Only applicable where there are service replaceable fuses, power cords or other parts** The technical description should be developed taking this requirement into account. Where replacement of a component could result in an unacceptable RISK, is there appropriate warnings to identify the nature of the HAZARD and, 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.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**8.1 b Fundamental rule of protection against electric shock – accidental detachment of conductors and connectors (8th Dash)**	Verdict
Requirement Summary	— accidental detachment of conductors and connectors where breaking free could lead to a HAZARDOUS SITUATION. See also 8.10.2.	
Guidance	**Only applicable where accidental detachment of conductors & connectors could lead to a HAZARDOUS SITUATION (excessive leakage current)** This requirement only applies to parts where there are power carrying conductors running between separate parts of the ME EQUIPMENT (parts with separate enclosures). The design should be reviewed to determine if fault testing on these conductors should be conducted – if it is determined that fault testing is required, the results should be reviewed to determine if the construction is in compliance with the requirements of this standard. Has the manufacturer identified in their risk management process accidental detachment of conductors and connectors? If so, then during product safety verification, this must be one of the SFC's tested	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**8.5.2.2 Type B applied parts**	Verdict
Requirement Summary	The PATIENT CONNECTION(s) of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED shall be separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED, unless: — the metal ACCESSIBLE PART is physically contiguous with the APPLIED PART and can be regarded as a part of the APPLIED PART; and — the RISK that the metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low.	

	Compliance is checked by inspection, by the LEAKAGE CURRENT tests of 8.7.4, by the dielectric strength test of 8.8.3, by measurement of relevant CREEPAGE DISTANCES and AIR CLEARANCES, and by reference to the RISK MANAGEMENT FILE.
Guidance	**Only applicable to equipment with TYPE B APPLIED PARTS** The requirement related to risk is the 2nd bullet. The construction of the device (APPLIED PART and ACCESSIBLE PART) should be reviewed to determine if it is likely that the ACCESSIBLE PART will contact source voltages – this should be documented in the DHF. If the connection is possible, then the MOP shall be maintained in accordance with this requirement. 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.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**8.5.2.3 PATIENT leads or PATIENT cables**	Verdict
Requirement Summary	Any connector for electrical connections on a PATIENT lead that: — is at the end of the lead or cable that is remote from the PATIENT; and — contains a conductive part that is not separated from all PATIENT CONNECTION(S) by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE shall be constructed so that the said part cannot become connected to earth or possible hazardous voltage while the PATIENT CONNECTION(S) contact the PATIENT. In particular: — the said part shall not come into contact with a flat conductive plate of not less than 100 mm diameter; — the AIR CLEARANCE between connector pins and a flat surface shall be at least 0.5 mm; — if able to be plugged into a mains socket, the said part shall be protected from making contact with parts at MAINS VOLTAGE by insulating means providing a CREEPAGE DISTANCE of at least 1.0 mm and a dielectric strength of 1,500 V and complying with 8.8.4.1; — the straight unjointed test finger with the same dimensions as the standard test finger of Figure 6 shall not make electrical contact with the said part if applied in the least favorable position against the access openings with a force of 10 N, unless the RISK MANAGEMENT PROCESS demonstrates that no unacceptable RISK exists from contact with objects other than a mains socket or a flat surface (e.g., corners or edges). Compliance is checked by inspection and test as required.	
Guidance	**Only applicable to equipment with PATIENT leads**	

	This requirement does not make specific reference to the RMF, however it does require an assessment with the unjointed test finger unless the RISK MANAGEMENT PROCESS shows there is no risk. This assessment should be made as part of the design if the unjointed test finger can make contact the design should be reviewed to determine if it is acceptable. If the exception will be utilized, then the RMF should contain a pointer to the assessment. Has the manufacturer identified in their risk management process connectors for electrical connections on a patient lead at the end of the lead remote from the patient and that contains a conductive part that is not separated from all patient connections by one MOPP for a working voltage equal to the maximum mains voltage, that will not present an unacceptable risk from contact with objects other than a mains socket or a flat surface (e.g. corners or edges)? 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.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**8.6.3 Protective earthing of moving parts**	Verdict
Requirement Summary	Any PROTECTIVE EARTH CONNECTION shall not be used for a moving part unless the MANUFACTURER demonstrates that the connection will remain reliable during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. Compliance is checked by inspection of the ME EQUIPMENT and, if necessary, inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment with protectively earthed moving parts** The information required here should be part of the DHF – there should not be a need to assess this requirement through the application of the RISK MANAGEMENT PROCESS. 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**8.8.4.1 Mechanical strength and resistance to heat**	Verdict
Requirement Summary	The resistance to heat shall be retained by all types of insulation, including insulating partition walls, during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. Compliance is checked by inspection of the ME EQUIPMENT and the design documentation and, if necessary, inspection of the RISK MANAGEMENT FILE in conjunction with the following tests:	

	— resistance to moisture, etc. (see 11.6); — dielectric strength (see 8.8.3); — mechanical strength (see 15.3). Resistance to heat is established by the following tests, which need not be performed if satisfactory evidence of compliance is provided. a) For parts of the ENCLOSURE and other external insulating parts, the deterioration of which could result in an unacceptable RISK, by the ball-pressure test: ENCLOSURES and other external parts of insulating material, except the insulation of flexible cords and parts of ceramic material, are subjected to a ball-pressure test using the test apparatus shown in Figure 21. The surface of the part to be tested is placed in the horizontal position and a steel ball of 5 mm diameter is pressed against the surface with a force of 20 N. The test is performed in a heating cabinet at a temperature of 75 C ± 2 C or the ambient temperature indicated in the technical description (see 7.9.3.1) ± 2 C plus the temperature rise of the relevant part of insulating material measured during the test of 11.1, whichever is the higher. The ball is withdrawn after 1 h and the diameter of the impression made by the ball is measured. An impression greater than 2 mm in diameter constitutes a failure. b) For parts of insulating material that support uninsulated parts of the MAINS PART, the deterioration of which could influence the safety of the ME EQUIPMENT, by the ball-pressure test: A test is performed as described in (a) above, but at a temperature of 125 C ± 2 C or at the ambient temperature indicated in the technical description (see 7.9.3.1) ± 2 C plus the temperature rise that was determined during the test of 11.1 of the relevant part, whichever is the higher. The test is not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and the like, and on coil formers not used as REINFORCED INSULATION. NOTE—For SUPPLEMENTARY INSULATION and REINFORCED INSULATION of thermoplastic materials, see also 13.1.2.
Guidance	The design data for insulation should be contained within the DHF (the EXPECTED SERVICE LIFE should also be included in the DHF). 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.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**8.10.1 Fixing of components**	Verdict
Requirement Summary	Components of ME EQUIPMENT, the unwanted movement of which could result in an unacceptable RISK, shall be mounted securely to prevent such movement.	

	Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.
Guidance	Information on the fixing of components should be included in the DHF. Specific risks associated with components may be included in the RMF where a specific hazard exists (identified during the HAZARD ANALYSIS). 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.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**9.2.1 MECHANICAL HAZARDS associated with moving parts - General**	Verdict
Requirement Summary	ME EQUIPMENT with moving parts shall be designed, built, and laid out so that, when PROPERLY INSTALLED and used as indicated in the ACCOMPANYING DOCUMENTS or under reasonably foreseeable misuse, the RISKS associated with those moving parts are reduced to an acceptable level. The RISK from contact with the moving parts shall be reduced to an acceptable level by use of RISK CONTROL, bearing in mind the ease of access, the ME EQUIPMENT'S function, the shape of the parts, the energy and speed of the motion and the benefits to the PATIENT. The RESIDUAL RISK associated with moving parts is considered acceptable if exposure is needed for the ME EQUIPMENT to perform its intended functionand RISK CONTROL measures have been implemented (e.g. warnings).	
Guidance	**Only applicable to equipment with moving parts** The DHF and RMF should contain the evidence required. 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 bearing in mind the ease of access, the ME Equipment function, the shape of the parts, the energy and speed of the motion and the benefits to the patient, is this risk reduced to an acceptable level? 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**9.2.4 Emergency stopping devices**	Verdict

Requirement Summary	Where it is considered necessary to have one or more emergency stopping device(s), the emergency stopping device shall comply with all the following requirements. a) The emergency stopping device shall reduce the RISK to an acceptable level. b) The proximity and response of the OPERATOR to actuate the emergency stopping device can be relied on to prevent HARM. c) The emergency stopping device actuator shall be readily accessible to the OPERATOR. d) Emergency stopping device(s) shall not be part of the normal operation of the ME EQUIPMENT. e) Operation of an emergency switching or stopping means shall neither introduce a further MECHANICAL HAZARD nor interfere with the complete operation necessary to remove the original HAZARD. f) Emergency stopping device(s) shall be able to break the full load of the relevant circuit, taking into account possible stalled motor currents and the like. g) Means for stopping of movements shall operate as a result of one single action. h) The emergency stopping device shall have an actuator colored red designed to be distinctive and easily identifiable from that of other controls. i) An actuator that interrupts/opens mechanical movements shall be marked on, or immediately adjacent to, the face of the actuator with symbol IEC 60417-5638 (2002-10) (see Table D.1, symbol 18) or the word “STOP”. j) The emergency stopping device, once actuated, shall maintain the ME EQUIPMENT in the disabled condition until a deliberate action, different from that used to actuate it, is performed. k) The emergency stopping device shall be shown to be suitable for its application. Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE, and by functional test.	
Guidance	**Only applicable to equipment with moving parts and an emergency stop** The mechanical system should be design taking these requirements into account. The information required here should be included in the DHF. Does the MEE use emergency stopping devices? Are risks caused by mechanical hazards which are reduced by the use of the emergency stopping devices reduced to an acceptable level?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**9.2.5 Release of patient**	Verdict
Requirement Summary	Means shall be provided to permit the release of the PATIENT quickly and safely in the event of breakdown of the ME EQUIPMENT or failure of the power supply (see 11.8), activation of a RISK CONTROL or emergency stopping. Special attention shall be given to the following.	

	— Uncontrolled or unintended movement of the ME EQUIPMENT that could result in an unacceptable RISK shall be prevented. — Situations where the PATIENT is subjected to unacceptable RISKS due to the proximity of moving parts, removal of normal exit routes, or other HAZARDS, shall be prevented. — When, after removal of counterbalanced parts, other parts of the ME EQUIPMENT can move in a hazardous way, measures shall be provided to reduce the RISK to an acceptable level. Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE, and by functional tests.
Guidance	**Only applicable to equipment that restrains the patient** The mechanical system should be design taking these requirements into account. The information required here should be included in the DHF. The risks caused by mechanical hazards associated with release of the patient addressed?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**9.5.1 Protective means**	Verdict
Requirement Summary	Where expelled parts could result in an unacceptable RISK, the ME EQUIPMENT shall be provided with a means for protecting against such RISK. Compliance is checked by assessment of the suitability of the protective means and by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment where expelled parts are possible** The mechanical system should be design taking these requirements into account. The information required here should be included in the DHF. Have the risks caused by mechanical hazards associated with expelled parts been addressed?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**9.6.1 Acoustic energy - General**	Verdict
Requirement Summary	ME EQUIPMENT shall be designed so that human exposure to acoustic energy and vibration shall not result in an unacceptable RISK. Compliance is checked by the tests in 9.6.2 and 9.6.3, and, if necessary by inspection of the RISK MANAGEMENT FILE (taking into account the audibility of auditory alarm signals and PATIENT sensitivity).	

Guidance	**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.** For devices with sources of acoustic energy and vibration, there should be corresponding information in the RMF. Additionally the design should take these requirements into account. The information required here should be included in the DHF and/or RMF. Have the risks caused by mechanical hazards associated with acoustic energy and vibration been addressed?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**9.6.2.2 Infrasound and ultrasound energy**	Verdict
Requirement Summary	When applicable, the MANUFACTURER shall address the RISKS associated with infrasound or ultrasound in the RISK MANAGEMENT PROCESS. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment that generates infrasound or ultrasound energy** For devices with sources of infrasound or ultrasound, there should be corresponding information in the RMF. Additionally the design should take these requirements into account. The information required here should be included in the DHF and/or RMF. NOTE: there are particular (-2-x) standards for different types of Ultrasound which should be considered as needed. Have the risks caused by mechanical hazards associated with infrasound and ultrasound been addressed?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**9.7.2 Pneumatic and hydraulic parts**	Verdict
Requirement Summary	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES shall be so designed that: — no unacceptable RISK results from loss of pressure or loss of vacuum; — no unacceptable RISK results from a fluid jet caused by leakage or a component failure; — elements of the ME EQUIPMENT or an ACCESSORY, and especially pipes and hoses, that can lead to an unacceptable RISK shall be protected against harmful external effects; — reservoirs and similar vessels (e.g., hydro-pneumatic accumulators) that can lead to an unacceptable RISK are automatically depressurized when the ME EQUIPMENT is isolated from its power supply (e.g., pulling out the pneumatic plug at the connector mounted on the facility	

	wall). If this is not possible, means shall be provided for the isolation (e.g., cutting off from the peripheral circuit), or local depressurizing of reservoirs and similar vessels, and pressure indication; — all elements that can remain under pressure after isolation of the ME EQUIPMENT or an ACCESSORY from its power supply and that could result in an unacceptable RISK shall be provided with clearly identified exhaust devices, and a warning label drawing attention to the necessity of depressurizing these elements before any setting or maintenance activity on the ME EQUIPMENT or ACCESSORIES. Compliance is checked by inspection and examination of the RISK MANAGEMENT FILE.
Guidance	**Only applicable to equipment with parts subject to pneumatic or hydraulic pressure (even where the pressure/volume is below 200KPaL)** The mechanical system should be design taking these requirements into account. The information required here should be included in the DHF. Have risks caused by mechanical hazards associated with pneumatic and hydraulic parts been addressed?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**9.7.7 Pressure-relief devices**	Verdict
Requirement Summary	ME EQUIPMENT shall incorporate pressure-relief device(s) where the MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded. A pressure-relief device shall comply with all of the following requirements: a) it shall be connected as close as reasonably practical to the pressure vessel or parts of the system that it is intended to protect; b) it shall be so installed that it is readily accessible for inspection, maintenance, and repair; c) it shall not be capable of being adjusted or rendered inoperative without the use of a TOOL; d) it shall have its discharge opening so located and directed that the released material is not directed towards any person; e) it shall have its discharge opening so located and directed that operation of the device will not deposit material on parts that could result in an unacceptable RISK; f) it shall be of adequate discharge capacity to ensure that the pressure will not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE of the system to which it is connected by more than 10 % in the event of a failure in the control of the supply pressure; g) there shall be no shut-off valve between a pressure-relief device and the parts that it is intended to protect; h) the minimum number of cycles of operation shall be 100,000, except for one-time use devices such as bursting disks.	

	Compliance is checked by inspection of the MANUFACTURER's data for the component, inspection of the ME EQUIPMENT, inspection of the RISK MANAGEMENT FILE, and, where necessary, by functional test.
Guidance	**Only applicable to equipment with pressure vessels where it is possible to exceed the maximum permissible working pressure** The mechanical system should be design taking these requirements into account. The information required here should be included in the DHF. Have the risks caused by mechanical hazards associated with a pressure-relief device been addressed?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**9.8.1 MECHANICAL HAZARDS associated with support systems - General**	Verdict
Requirement Summary	Where ME EQUIPMENT parts are designed to support loads or to provide actuating forces, the following requirements shall be applied if a mechanical fault could constitute an unacceptable RISK. — The construction of the support, suspension, or actuation system shall be designed based upon Table 21 and the TOTAL LOAD. — Means of attachment of ACCESSORIES shall be designed such that any possibility of incorrect attachment that could result in an unacceptable RISK is avoided. — The RISK ANALYSIS of support systems shall consider MECHANICAL HAZARDS arising from static, dynamic, vibration, impact, and pressure loading, foundation, and other movements, temperature, environmental, manufacture, and service conditions. — All likely failure effects shall be considered in the RISK ANALYSIS. These include excessive deflection, plastic deformation, ductile or brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep, material deterioration, and residual stresses resulting from the manufacturing PROCESSES, e.g., machining, assembling, welding, heat treatment, or surface coating. — The ACCOMPANYING DOCUMENTS shall contain instructions on attachment of structures to a floor, wall, ceiling, etc. making adequate allowances for quality of the materials used to make the connection and shall list the required materials. Additionally there shall be advice on checking the adequacy of the surface of the structure to which the parts will be attached.	
Guidance	**Only applicable to equipment with support systems (suspended masses…patient, operator or other, e.g. shelving)** The mechanical system should be design taking these requirements into account. The information required here should be included in the DHF. This requirement does not make direct reference to the RMF. Have the risks caused by hazards arising from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions been addressed? 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?	

	Were the following residual stresses resulting from the manufacturing process, e.g. machining, assembling, welding, heat treatment or surface coating considered?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**9.8.2 Tensile safety factor**	Verdict
Requirement Summary	Support systems shall maintain structural integrity during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. TENSILE SAFETY FACTORS shall not be less than those shown in Table 21 unless an alternative method demonstrates structural integrity throughout the EXPECTED SERVICE LIFE of the ME EQUIPMENT, or the support is a foot rest. The requirements for foot rests are in 9.8.3.2 (a). See Table 21 Compliance with 9.8.1 and 9.8.2 is checked by inspection of the ME EQUIPMENT, the RISK MANAGEMENT FILE, the specifications of materials used and the processing specifications for these materials. If testing is needed to demonstrate compliance with 9.8.1 or 9.8.2, a test load equal to the TOTAL LOAD times the required TENSILE SAFETY FACTOR is gradually applied to the support assembly under test.. The support assembly under test is to be in equilibrium after 1 min, or otherwise not result in an unacceptable RISK.	
Guidance	**Only applicable to equipment with support systems** The mechanical system should be design taking these requirements into account. The information required here should be included in the DHF. 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**9.8.3.1 Strength of patient or operator support or suspension systems - General**	Verdict
Requirement Summary	ME EQUIPMENT parts serving for support or immobilization of PATIENTS shall be designed and manufactured sothere is no unacceptable RISK of physical injuries or of accidental loosening of fixings. The SAFE WORKING LOAD of ME EQUIPMENT or its parts serving for support or suspension of PATIENTS or OPERATORS shall be the sum of the mass of the PATIENTS or the mass of the OPERATORS plus the mass of ACCESSORIES intended by MANUFACTURERS to be supported or suspended by the ME EQUIPMENT or ME EQUIPMENT parts.	

	Unless otherwise stated by the MANUFACTURER, supporting and suspending parts for adult human PATIENTS or OPERATORS shall be designed for a PATIENT or OPERATOR having a minimum mass of 135 kg and ACCESSORIES having a minimum mass of 15 kg. Where a MANUFACTURER specifies particular applications (e.g., pediatric use), the maximum mass of the PATIENT included in the SAFE WORKING LOAD of the ME EQUIPMENT or its parts serving for support or suspension of PATIENTS may be adapted. When the maximum allowable value of the mass of the PATIENT is less than 135 kg, that value shall be marked on the ME EQUIPMENT and described in ACCOMPANYING DOCUMENTS. When the maximum allowable value of the mass of the PATIENT is more than 135 kg, that value shall be described in ACCOMPANYING DOCUMENTS. Compliance is checked by inspection of the ME EQUIPMENT (including markings), the ACCOMPANYING DOCUMENTS, the MANUFACTURER'S data for the component, the RISK MANAGEMENT FILE, and, where necessary, functional test.
Guidance	**Only applicable to equipment supporting/suspending the PATIENT or OPERATOR** The mechanical system should be design taking these requirements into account. The information required here should be included in the DHF. Have the risks caused by mechanical hazards associated with the support or suspension of the patient (including particular applications) been addressed?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**9.8.5 Systems without mechanical protective devices**	Verdict
Requirement Summary	A MECHANICAL PROTECTIVE DEVICE is not required if: — the support system parts are not impaired by wear and have TENSILE SAFETY FACTORS greater than or equal to the values specified in rows 1 and 2 of Table 21; or — the support system parts are impaired by wear but have TENSILE SAFETY FACTORS greater than or equal to the values specified in rows 3 and 4 of Table 21. Compliance is checked by inspection of the ME EQUIPMENT, the design documentation and the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment with support systems that do not have a mechanical protective device** The mechanical system should be design taking these requirements into account. The information required here should be included in the DHF. Has the manufacturer determined that the use of mechanical protective devices in the MEE is not required? Has the manufacturer justified the reasons not to use mechanical protective devices?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**10.1.2 ME equipment intended to produce diagnostic or therapeutic X-radiation**	Verdict
Requirement Summary	Unintended X-radiation from ME EQUIPMENT designed to produce diagnostic or therapeutic Xradiation shall be reduced as far as possible by application of applicable particular and collateral standards, or in the absence of these standards by application of the RISK MANAGEMENT PROCESS. For intended X-radiation, also see 12.4.5.2 and 12.4.5.3. Compliance is checked by application of applicable particular and collateral standards or inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment intentionally producing X-radiation for diagnostic or therapeutic purposes** For devices with sources of radiation, there should be corresponding information in the RMF. Additionally the design should take these requirements into account. The information required here should be included in the DHF and/or RMF. Additionally, there are particular (-2-x) standards for radiation emitting equipment that should be considered as needed. When applicable, has the manufacturer identified hazards and hazardous situations associated with production of x-radiation in the risk management file?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**10.2 Alpha, beta, gamma, neutron & other particle radiation**	Verdict
Requirement Summary	When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with alpha, beta, gamma, neutron, and other particle radiation. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment producing Alpha, beta, gamma, neutron or other particle radiation** For devices with sources of radiation, there should be corresponding information in the RMF. Additionally the design should take these requirements into account. The information required here should be included in the DHF and/or RMF. Additionally, there are particular (-2-x) standards for radiation emitting equipment that should be considered as needed. 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**10.5 Other visible electromagnetic radiation**	Verdict
Requirement Summary	When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with visible electromagnetic radiation, other than that produced by lasers and light emitting diodes (see 10.4). Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment producing visible electromagnetic radiation (excluding lasers & LEDs) where hazards exist associated with the visible electromagnetic radiation** For devices with sources of radiation, there should be corresponding information in the RMF. Additionally the design should take these requirements into account. The information required here should be included in the DHF and/or RMF. Additionally, there are standards for visible (IEC 60825-x) radiation emitting equipment that should be considered as needed. When applicable, has the manufacturer identified hazards and hazardous situations associated with production of visible electromagnetic radiation in the risk management file?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**10.6 RISK associated with infrared radiation other than emitted by lasers and LEDS**	Verdict
Requirement Summary	When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with infrared radiation, other than that produced by lasers and light emitting diodes (see 10.4). Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment emitting infrared radiation (excluding emissions from Lasers & LEDs)** For devices with sources of radiation, there should be corresponding information in the RMF. Additionally the design should take these requirements into account. The information required here should be included in the DHF and/or RMF. When applicable, has the manufacturer identified hazards and hazardous situations associated with production of infrared radiation in the risk management file?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**10.7 RISK associated with ultraviolet radiation other than emitted by lasers and LEDS**	Verdict

Requirement Summary	When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with ultraviolet radiation, other than that produced by lasers and light emitting diodes (see 10.4). Compliance is checked by inspection of the RISK MANAGEMENT FILE.
Guidance	**Only applicable to equipment emitting ultraviolet radiation (excluding emissions from Lasers & LEDs)** For devices with sources of radiation, there should be corresponding information in the RMF. Additionally the design should take these requirements into account. The information required here should be included in the DHF and/or RMF. When applicable, has the manufacturer identified hazards associated with production of ultraviolet radiation in the risk management file?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**11.1.1 Maximum temperature during normal use (Table 23 or 24)**	Verdict
Requirement Summary	Table 23: These temperature limit values are applicable for touching the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. This also applies in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE. Table 24: a These temperature limit values are applicable for the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. They are not applicable in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE. b) Where it is necessary for APPLIED PARTS to exceed the temperature limits of Table 24 in order to provide clinical benefit, the RISK MANAGEMENT FILE shall contain documentation showing that the resulting benefit exceeds any associated increase in RISK.	
Guidance	**Only applicable where the APPLIED PART is in contact with 10% of the head or body; or where the temperatures for applied and accessible parts exceed the limits for the maximum duration based on the material and contact times defined in Tables 23 & 24** Table 23: For devices which fall under this clause (contact with 10% of the head of body), the temperature limits should be assessed with clinical input and the final limits (if different from those listed here) shall be documented in the DHF. Has the manufacturer identified parts of the ME Equipment that are likely to be touched in normal or foreseeable misuse that can contact more than 10% of the surface area operator or patient's body or 10% of the surface area of the patient's or operator's head? Has the manufacturer identified the duration of continuous or aggregate contact? Has the manufacturer identified and addressed such risks?	

	Has the RM process determined suitable limits for temperature based on the risk acceptability criteria and risk benefit analysis in association with patient state of health and whether adult, pediatric or neonate? Table 24: For devices which fall under this clause (contact with 10% of the head of body), the temperature limits should be assessed with clinical input and the final limits (if different from those listed here) shall be documented in the DHF. Has the manufacturer identified applied parts of the ME Equipment that can contact more than 10% of the surface area operator or patient's body or 10% of the surface area of the patient's or operator's head during normal or foreseeable misuse? Has the manufacturer identified the duration of continuous or aggregate contact of these applied parts? Has the manufacturer identified and addressed such risks? Has the RM process determined suitable limits for temperature based on the risk acceptability criteria? If the temperature limits exceed the values in table 24 has a favorable risk benefit analysis in association with patient state of health and whether adult, pediatric or neonate been documented?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**11.1.2.1 Applied parts intended to supply heat to patient**	Verdict
Requirement Summary	The temperature (hot or cold surfaces) or (where appropriate) the clinical effects shall be determined and documented in the RISK MANAGEMENT FILE. The temperatures and clinical effects shall be disclosed in the instructions for use.	
Guidance	**Only applicable to equipment with APPLIED PARTS intended to supply heat to the patient as part of the intended use** The clinical effects should be reviewed and documented in the DHF. 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**11.1.2.2 Applied parts not intended to supply heat to patient**	Verdict

Requirement Summary	The limits of Table 24 shall apply in both NORMAL CONDITION and SINGLE FAULT CONDITION. If the surface temperature of an APPLIED PART exceeds 41 °C: – the maximum temperature shall be disclosed in the instructions for use; – the conditions for safe contact, e.g. duration or condition of the PATIENT, shall be disclosed; and – the clinical effects with respect to characteristics such as body surface, maturity of PATIENTS, medications being taken or surface pressure shall be determined and documented in the RISK MANAGEMENT FILE. Where 41°C is not exceeded, no justification is required. If analyses documented in the RISK MANAGEMENT FILE demonstrate that APPLIED PART temperatures cannot be affected by operation of the ME EQUIPMENT including in SINGLE FAULT CONDITIONS, measurement of APPLIED PART temperature according to 11.1.3 is not required. Surfaces of APPLIED PARTS that are cooled below ambient temperatures can also result in an unacceptable RISK and shall be evaluated as part of the RISK MANAGEMENT PROCESS.	
Guidance	**Applicable to equipment with applied parts not intended to supply heat to the patient as part of the intended use** The clinical effects should be reviewed and documented in the DHF. Does the ME equipment have any applied parts that are not intended to heat or cool the patient that could in normal or foreseeable misuse exceed 41 °C or cool below ambient temperature?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**11.1.3 Measurements**	Verdict
Requirement Summary	Where engineering judgement by the MANUFACTURER indicates that temperature limits cannot be exceeded, no measurement is required. Where such judgements indicate that the test corner will not impact the measurements, it may be omitted. However, the rationale for such judgement shall be documented in the RISK MANAGEMENT FILE. If the test corner is used, its surfaces shall not exceed 90 C. For ME EQUIPMENT parts that are likely to be touched and for APPLIED PARTS, the probability of occurrence of contact and of the duration of contact is determined and documented in the RISK MANAGEMENT FILE. Compliance with the requirements of 11.1.1 and 11.1.2 is checked by inspection of the RISK MANAGEMENT FILE and the instructions for use, operation of ME EQUIPMENT, and temperature measurements as follows:	
Guidance	**Only applicable where temperature measurements are not taken based on documentation in the risk management file** The data required here should be developed based on scientific review of the design. This review and its conclusion should be documented in the DHF.	

	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? 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?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**11.2.2.1 Risk of fire in an oxygen rich environment**	Verdict
Requirement Summary	In ME EQUIPMENT and ME SYSTEMS, the RISK of fire in an OXYGEN RICH ENVIRONMENT shall be reduced as far as possible under NORMAL CONDITION or SINGLE FAULT CONDITIONS (as identified in 11.2.3). An unacceptable RISK of fire is considered to exist in an OXYGEN RICH ENVIRONMENT when a source of ignition is in contact with ignitable material and there is no means that would limit the spread of a fire.	
Guidance	**Only applicable to equipment intended for use in an oxygen rich environment (>25% O_2 concentration)** This requirement only applies to devices intended for use in OXYGEN RICH ENVIRONMENTS. These devices should be designed with these requirements taken into account. This requirement does not make specific reference to the RMF. Has the manufacturer identified that there is a risk of fire from an oxygen rich environment? Where scenario number 3 is applicable, has the manufacturer conducted a risk assessment to determine hazards associated with leaks or component failures causing a source of ignition been conducted?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**11.3 Constructional requirements for fire enclosures of ME equipment**	Verdict
Requirement Summary	This subclause provides an alternative means of compliance with selected HAZARDOUS SITUATIONS and fault conditions as identified in 13.1.2. In doing so, the following constructional requirements shall be met or specifically analyzed in the RISK MANAGEMENT FILE, and if not met, specific justification shall also be given	
Guidance	**Only applicable to equipment where there is >15 W or 900 J of energy and no fire enclosure is provided** For devices that will follow this exception to compliance with Clause 13.1.2, all parts of this clause shall be reviewed and the appropriate design input requirements should be developed related to the design of the enclosure. Other than the standard flammability items on the RMF, there should not need to be any additional items specified. The RMF should reference the testing required by this	

	clause as evidence the risk of fire from the device have been mitigated to an acceptable level. The evidence should be located in the DHF. 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?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**11.5 ME equipment and ME systems intended for use in conjunction of flammable agents**	Verdict
Requirement Summary	The MANUFACTURER's RISK MANAGEMENT PROCESS shall address the possibility of fire and associated mitigations. Compliance is determined by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment intended for use in conjunction with flammable agents** Possibility of fire and any associated mitigations must be covered in the Risk Management Process. Is the ME Equipment intended to (or can it through foreseeable misuse) come into contact with flammable agents?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**11.6.3 Spillage on ME equipment and ME systems**	Verdict
Requirement Summary	ME EQUIPMENT and ME SYSTEMS requiring the handling of liquids in NORMAL USE, including ME EQUIPMENT or ME SYSTEMS used in an enviornment where the PROCESS has determined that spillage on the ME EQUIPMENT is likely to occur, shall be so constructed that spillage does not wet parts that are likely to result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE. Compliance is checked by inspection of the RISK MANAGEMENT FILE and by the following test. The ME EQUIPMENT is positioned according to 5.4 (a). A quantity of liquid is poured steadily on a point on the top of the ME EQUIPMENT. The type of liquid, volume, duration of the spill, and location (point) are determined through RISK ANALYSIS. Terst conditions that simulate the worst case for spillage shall be documented in the RISK MANAGEMENT FILE. After these PROCEDURES, the ME EQUIPMENT is to pass the appropriate dielectric strength and LEAKAGE CURRENT tests and is to show no signs of wetting of uninsulated electrical parts or electrical insulation of parts that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on visual inspection).	
Guidance	**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)**	

	This requirement applies to equipment which require liquids based on their intended use/intended use environment. This should be identified during the design input phase. For equipment falling under this requirement, the intended use/intended use environment should be 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 This should be listed as a design input requirement, with the verification test specified as stated in the standard using items 1-6 to write the test requirements. The evidence should be located in the DHF. 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 spill? (should be - for the equipment to be spilled on)
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**11.6.6 Effects of Cleaning on ME equipment and ME systems**	Verdict
Requirement Summary	The MANUFACTURER shall evaluate the effects of multiple cleanings/disinfections as indicated in the instructions for use during the EXPECTED SERVICE LIFE of the ME EQUIPMENT, ME SYSTEM, their parts and ACCESSORIES and assure that these PROCESSES do not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE. The RISK MANAGEMENT FILE is inspected to verify that the MANUFACTURER has evaluated the affects of multiple cleanings.	
Guidance	Are there hazards associated with degradation of materials or labels from cleaning chemicals? The device should be designed to withstand the effects of multiple cleaning cycles as identified in the instructions for use based on the EXPECTED SERVICE LIFE, verification tests should be performed as stated here. The evidence should be located in the DHF.	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**11.6.7 Sterilization of ME equipment and ME systems**	Verdict

Requirement Summary	ME EQUIPMENT, ME SYSTEMS, and their parts or ACCESSORIES intended to be sterilized shall be assessed and documented according to ISO 11135-1, ISO 11137-1 or ISO 17665-1 as appropriate. See also 7.9.2.12. After these PROCEDURES, the ME EQUIPMENT, ME SYSTEM, and their parts or ACCESSORIES are to show no signs of deterioration that could result in an unacceptable RISK (visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests and by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to sterile equipment or equipment parts** This requirement applies only to devices/components which are intended to be sterilized. These devices should be designed to withstand the sterilization procedures based on the EXPECTED SERVICE LIFE, verification tests should be performed as stated here. The evidence should be located in the DHF. 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**11.6.8 Compatibility with substances used**	Verdict
Requirement Summary	**Applicable when substances are used with the equipment** When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with compatibility with substances used with the ME EQUIPMENT. Such RISKS may be addressed through the application of appropriate ISO or IEC standards (giving the presumption of acceptable RISK according to 4.2) such as ISO 15001 [70] for components that contain oxygen at pressures greater than 50 kPa or through the MANUFACTURER'S own testing and RISK CONTROL measures. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	Devices should be designed so that substances intended to be used with the devices do not have a detrimental impact on the safety and/or function of the device. Evidence should be located in the DHF. NOTE: any additional hazards related to substances should be also captured in the RMF. Has the manufacturer identified all substances to which the ME Equipment may come into contact with in normal or foreseeable misuse?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**12.1 Accuracy of controls and equipment**	Verdict

Requirement Summary	When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with accuracy of controls and instruments. Compliance is checked by inspection of the RISK MANAGEMENT FILE.
Guidance	**Only applicable to equipment where inaccurate controls could lead to RISK** See also particular standards (IEC 60601-2-xx) for additional guidance/requirements. Accuracy that is important to clinical function or safety should be identified as a design input requirement. The evidence should be located in the DHF. NOTE: any additional hazards related to accuracy should be also captured in the RMF. 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?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**12.4.1 Intentional exceeding of safety limits**	Verdict
Requirement Summary	When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with hazardous output arising from the intentional exceeding of safety limits. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable where equipment intentionally exceeds safety limits (e.g. leakage current) as part of the intended use. NOTE: where the exceeding of limits is NORMAL USE…not a fault condition** This requirement applies where the device allows the identified safe limits to be exceeded intentionally by the OPERATOR or by the EQUIPMENT (e.g.; entering a mode on an imaging device where the radiation exposure can exceed the generally recognized safe limits for a specific treatment/patient). Where applicable these items shall be identified and the risks associated with exceeding the limits should be included on the RMF. 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**12.4.2 Indication relevant to safety**	Verdict
Requirement Summary	When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the need to indicate any parameters that are associated with hazardous output.	

	Compliance is checked by inspection of the RISK MANAGEMENT FILE.
Guidance	**Only applicable to equipment where the indication of any hazardous output is required as a risk mitigation** During the deign input phase, all parameters which will be indicated to the OPERATOR shall be identified (including those indicated as a risk mitigation). Evidence should be included in the DHF. Those items which are indicated specifically as a risk mitigation shall be included in the RMF. 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?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**12.4.3 Accidental selection of excessive output values**	Verdict
Requirement Summary	Where ME EQUIPMENT is a multi-purpose unit designed for providing both low-intensity and high-intensity outputs for different treatments, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with accidental selection of excessive output values. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment where an excessive output is possible (e.g. where both high and low output modes are possible)** Where a device has both high & low intensity output the design shall include the requirements related to selection of high/low intensity outputs. Any risks associated with incorrect selection should be evaluated as part of the USABILITY ENGINEERING PROCESS where appropriate the evidence should be included in the RMF or the Usability Engineering 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**12.4.4 Incorrect output**	Verdict

Requirement Summary	When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with incorrect output. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment where an incorrect output (e.g. energy or substance) can be applied to the patient** During the deign input phase, all parameters which will be indicated to the OPERATOR shall be identified (including those indicated as a risk mitigation). Evidence should be included in the Usability Engineering File. Those items which are indicated specifically as a risk mitigation shall be included in the RMF. Has the manufacturer identified all features of the ME Equipment that provide an output? Has the manufacturer identified hazards associated with incorrect output?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**12.4.5.3 Radiotherapy equipment**	Verdict
Requirement Summary	When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with radiotherapy. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to radiotherapy equipment** Compliance with this requirements is through application of the appropriate radiotherapy standards (e.g., IEC 61217, IEC 61852, IEC 62274). Additionally, for radiotherapy devices, specific risks should be covered by the product RMF. 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**12.4.5.4 Other ME equipment producing diagnostic or therapeutic radiation**	Verdict
Requirement Summary	When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than for diagnostic X-rays and radiotherapy (see 12.4.5.2 and 12.4.5.3). Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment producing diagnostic or therapeutic radition**	

	Compliance with this requirements is through application the relevant IEC standards based on the device type – where no standards exist, IEC 60601-1-3 and/or IEC 60601-2-54 can be utilized as guidance. Additionally, for devices which utilize diagnostic X-Rays, there should be specific risks associated with x-rays covered by the product RMF. 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?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**12.4.6 Diagnostic or therapeutic acoustic pressure**	Verdict
Requirement Summary	When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with diagnostic or therapeutic acoustic pressure. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment producing diagnostic or therapeutic acoustic pressure** Compliance with this requirement is through application of the relevant IEC standards for the device type (e.g., IEC 60601-2-37). Additionally, any risks specific to acoustic pressure should be listed in the RMF. 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**13.2.6 Leakage of liquid**	Verdict
Requirement Summary	ME EQUIPMENT shall be so constructed that liquid that might escape in a SINGLE FAULT CONDITION does not result in an unacceptable RISK. Since only small amounts of liquid will escape when they leak, sealed rechargeable batteries are exempted from this requirement. A RISK MANAGEMENT PROCESS shall be used to determine the appropriate test conditions for the ME EQUIPMENT. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment that utilizes liquid (internally or externally)**	

	The design input and verification requirements should be developed taking this requirement into account. The evidence required should be located in the DHF. Has the manufacturer determined the appropriate test conditions for the evaluation of liquid leakage?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**14.1 Programmable electrical medical systems - General**	Verdict
Requirement Summary	The requirements in 14.2 to 14.12 (inclusive) shall apply to PEMS unless: – none of the PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS) provides functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE; or – the application of RISK MANAGEMENT as described in 4.2 demonstrates that the failure of any PESS does not lead to an unacceptable RISK. The requirements in 14.13 are applicable to any PEMS intended to be incorporated into an ITNETWORK whether or not the requirements in 14.2 to 14.12 apply. Compliance is determined by inspection of all documentation required, and when necessary, assessment of the requirements in 14.2 to 14.13 (inclusive). When the requirements in 14.2 to 14.13 apply, the requirements in subclause 4.3, Clause 5, Clause 7, Clause 8 and Clause 9 of IEC 62304:2006 shall also apply to the development or modification of software for each PESS. Compliance is determined by inspection and assessment as required by subclause 1.4 of IEC 62304:2006.	
Guidance	The risk assessment is always required unless there is no software/firmware (PEMS, PESS) in the equipment. Based on the assessment of BASIC SAFETY, ESSENTIAL PERFORMANCE and a review of the risks associated with software failures if this exemption to all the requirements in Clause 14 is taken, justification shall be included in the DHF and (where appropriate) the RMF. Does the application of ISO 14971 demonstrate that the failure of the PEMS does not lead to an unacceptable risk?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**14.6.1 Identification of known and foreseeable hazards**	Verdict

Requirement Summary	When compiling the list of known or foreseeable HAZARDS, the MANUFACTURER shall consider those HAZARDS associated with software and hardware aspects of the PEMS including those associated with the incorporation of the PEMS into an IT-NETWORK, components of third-party origin and legacy subsystems.
Guidance	**Only applicable where software (PEMS) provides BASIC SAFETY or ESSENTIAL PERFORMANCE or where the failure of the PESS leads to an unacceptable risk** Compliance with this requirements is though application of the Risk Management Process. 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?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**14.6.2 Risk control**	Verdict
Requirement Summary	The following requirements for PEMS supplement 4.2.2. Suitably validated TOOLS and PROCEDURES shall be selected and identified to implement each RISK CONTROL measure. These TOOLS and PROCEDURES shall be appropriate to assure that each RISK CONTROL measure satisfactorily reduces the identified RISK(s).	
Guidance	**Only applicable where software (PEMS) provides BASIC SAFETY or ESSENTIAL PERFORMANCE or where the failure of the PESS leads to an unacceptable risk** Compliance with this requirement is through application of IEC 62304 incorporated with the Risk Management Process. 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?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**14.7 Requirement specification**	Verdict
Requirement Summary	For the PEMS and each of its subsystems (e.g., for a PESS) there shall be a documented requirement specification. The requirement specification for a system or subsystem shall include and distinguish any ESSENTIAL PERFORMANCE and any RISK CONTROL measures implemented by that system or subsystem.	
Guidance	**Only applicable where software (PEMS) provides BASIC SAFETY or ESSENTIAL PERFORMANCE or where the failure of the PESS leads to an unacceptable risk**	

	Compliance with this requirement may be achieved through application of IEC 62304. Does the requirement specification include and distinguish any risk control measures?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**14.8 Architecture**	Verdict
Requirement Summary	For the PEMS and each of its subsystems, an architecture shall be specified that shall satisfy the requirement specification. Where appropriate, to reduce the RISK to an acceptable level, 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, e.g., limits on potentially hazardous effects by restricting the available output power or by introducing means to limit the travel of actuators. The architecture specification shall take into consideration: g) * allocation of RISK CONTROL measures to subsystems and components of the PEMS; NOTE—Subsystems and components include sensors, actuators, PESS, and interfaces. h) failure modes of components and their effects; i) common cause failures; j) systematic failures; k) test interval duration and diagnostic coverage; l) maintainability; m) protection from reasonably foreseeable misuse; n) the IT-NETWORK specification, if applicable.	
Guidance	**Only applicable where software (PEMS) provides BASIC SAFETY or ESSENTIAL PERFORMANCE or where the failure of the PESS leads to an unacceptable risk** Compliance with this requirement may be achieved through application of IEC 62304 taking into account the specific items listed here. Does the architecture specification reduce the risk to an acceptable level, where appropriate, using levels a) - f)? Does the architecture specification take into consideration allocation of risk control measures?	

Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**14.10 Verification**	Verdict
Requirement Summary	VERIFICATION is required for all functions that implement BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures. A VERIFICATION plan shall be produced to show how these functions shall be verified. The plan shall include: — at which milestone(s) VERIFICATION is to be performed for each function; — the selection and documentation of VERIFICATION strategies, activities, techniques, and the appropriate level of independence of the personnel performing the VERIFICATION; — the selection and utilization of VERIFICATION TOOLS; and — coverage criteria for VERIFICATION. The VERIFICATION shall be performed according to the VERIFICATION plan. The results of the VERIFICATION activities shall be documented.	
Guidance	**Only applicable where software (PEMS) provides BASIC SAFETY or ESSENTIAL PERFORMANCE or where the failure of the PESS leads to an unacceptable risk** VERIFICATION information should be located in the DHF. Is the result of the verification activity documented? Have all functions that implement risk control measures been verified?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**14.11 PEMS validation**	Verdict
Requirement Summary	A PEMS VALIDATION plan shall include the validation of BASIC SAFETY and ESSENTIAL PERFORMANCE. Methods used for PEMS VALIDATION shall be documented. The PEMS VALIDATION shall be performed according to the PEMS VALIDATION plan. The results of PEMS VALIDATION activities shall be documented. The person having the overall responsibility for the PEMS VALIDATION shall be independent of the design team. The MANUFACTURER shall document the rationale for the level of independence.	

	No member of a design team shall be responsible for the PEMS VALIDATION of their own design. All professional relationships of the members of the PEMS VALIDATION team with members of the design team shall be documented in the RISK MANAGEMENT FILE.
Guidance	**Only applicable where software (PEMS) provides BASIC SAFETY or ESSENTIAL PERFORMANCE or where the failure of the PESS leads to an unacceptable risk** Information regarding VALIDATION should be located in the DHF. 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?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**14.13 PEMS intended to be incorporated into an IT-NETWORK**	Verdict
Requirement Summary	If the PEMS is intended to be incorporated into an IT-NETWORK that is not validated by the PEMS MANUFACTURER, the MANUFACTURER shall make available instructions for implementing such connection including the following: a) the purpose of the PEMS's connection to an IT-NETWORK; b) the required characteristics of the IT-NETWORK incorporating the PEMS; c) the required configuration of the IT-NETWORK incorporating the PEMS; d) the technical specifications of the network connection of the PEMS including security specifications; e) the intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK; and f) a list of the HAZARDOUS SITUATIONS resulting from a failure of the IT-NETWORK to provide the characteristics required to meet the purpose of the PEMS connection to the ITNETWORK. Compliance is checked by inspection of the instructions. In the ACCOMPANYING DOCUMENTS, the MANUFACTURER shall instruct the RESPONSIBLE ORGANIZATION that: – connection of the PEMS to an IT-NETWORK that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties; – the RESPONSIBLE ORGANIZATION should identify, analyze, evaluate and control these RISKS; – subsequent changes to the IT-NETWORK could introduce new RISKS and require additional analysis; and – changes to the IT-NETWORK include: • changes in the IT-network configuration;	

	• connection of additional items to the IT-NETWORK; • disconnecting items from the IT-NETWORK; • update of equipment connected to the IT-NETWORK; and • upgrade of equipment connected to the IT-NETWORK. Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.
Guidance	**Only applicable where software (PEMS) provides BASIC SAFETY or ESSENTIAL PERFORMANCE or where the failure of the PESS leads to an unacceptable risk AND THE PEMS is intended to be connected to an IT-NETWORK (WIRED OR WIRELESS)** There is no direct reference to the RMF in this requirement. Compliance with this clause may be satisfied by application of IEC/ISO 80001-1. 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.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**15.4.1 Construction of connectors**	Verdict
Requirement Summary	Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors of ME EQUIPMENT shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented where an unacceptable RISK would otherwise exist. In particular: a) Plugs for connection of PATIENT leads or PATIENT cables shall be so designed that they cannot be connected to other outlets on the same ME EQUIPMENT intended for other functions, unless it can be proven that no unacceptable RISK can result. Compliance is checked by inspection of PATIENT leads, PATIENT cables, connectors and outlets and, if interchange of the leads, cables, connectors or outlets is possible, by inspection of the RISK MANAGEMENT FILE.	
Guidance	**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** The requirements of this clause should be identified as design input requirements with reference to Table 28 to determine which sections of this clause are applicable to specific devices. 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).
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**15.4.2.1 a THERMAL CUT-OUTS and OVER-CURRENT RELEASES**	Verdict
Requirement Summary	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting shall not be used in ME EQUIPMENT if their use could lead to a HAZARDOUS SITUATION as described in 13.1 by such resetting. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment with automatic resetting thermal cut-outs or over-current releases where resetting could result in a hazardous situation** During the design input phase, the requirements listed here should be identified as design inputs. Where appropriate, information regarding risks associated with fire or burns can be found in the RMF. Specific information related to the design in accordance with this clause should be located in the DHF. 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.	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**15.4.2.1 c Independent non-SELF-RESETTING THERMAL CUT-OUT**	Verdict
Requirement Summary	c) In ME EQUIPMENT, where a failure of a THERMOSTAT could lead to a HAZARDOUS SITUATION described in 13.1, an independent non-SELFRESETTING THERMAL CUT-OUT shall additionally be provided. The temperature of operation of the additional device shall be outside that attainable at the extreme setting of the normal control device (THERMOSTAT) but shall be within the safe temperature limit for the intended function of the ME EQUIPMENT. Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment with a thermostat where the failure of the thermostat constitutes a hazard** During the design input phase, the requirements listed here should be identified as design inputs. Where appropriate, information regarding risks associated with fire or burns can be found in the RMF. Specific information related to the design in accordance with this clause should be located in the DHF. 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.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**15.4.2.1 d Loss of function of ME EQUIPMENT**	Verdict
Requirement Summary	d) Loss of function of the ME EQUIPMENT caused by operation of a THERMAL CUT-OUT or OVER-CURRENT RELEASE shall not result in the loss of ESSENTIAL PERFORMANCE or any of the HAZARDOUS SITUATIONS described in 13.1. Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment with a thermal cut-out or over-current release** During the design input phase, the requirements listed here should be identified as design inputs. Where appropriate, information regarding risks associated with fire or burns can be found in the RMF. Specific information related to the design in accordance with this clause should be located in the DHF. 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.	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**15.4.2.1 h ME EQUIPMENT with tubular heating elements**	Verdict
Requirement Summary	h) ME EQUIPMENT that incorporates tubular heating elements shall have protection against overheating in both leads where a conductive connection to earth could result in overheating. Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment with tubular heating elements where a conductive connection to earth from the leads results in overheating** During the design input phase, the requirements listed here should be identified as design inputs. Where appropriate, information regarding risks associated with fire or burns can be found in the RMF. Specific information related to the design in accordance with this clause should be located in the DHF. 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.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**15.4.3.1 Housing**	Verdict
Requirement Summary	In ME EQUIPMENT, housings containing batteries from which gases can escape during charging or discharging shall be ventilated so that there is no unacceptable RISK from the accumulation of gasses and possible ignition is prevented. Battery compartments of ME EQUIPMENT shall be designed to prevent accidental short circuiting of the battery where such short circuits could result in the HAZARDOUS SITUATIONS described in 13.1. Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment with batteries (and housings)** Devices with batteries should be designed taking this requirement into account. General RISKS associated with the use of batteries should be included in the RMF. 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.	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**15.4.3.2 Connection**	Verdict
Requirement Summary	If a HAZARDOUS SITUATION might develop by the incorrect connection or replacement of a battery, ME EQUIPMENT shall be fitted with a means of preventing incorrect polarity of connection. See also 7.3.3 and 8.2.2. *Compliance is checked by inspection.*	
Guidance	**Only applicable to equipment with batteries** Battery connections shall not be reversible unless it can be shown that no hazardous situation results from the incorrect connection.	

	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.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**15.4.3.3 Protection against overcharging**	Verdict
Requirement Summary	Where overcharging of any battery of ME EQUIPMENT could result in an unacceptable RISK, the design shall prevent overcharging. Compliance is checked by inspection of the design documentation.	
Guidance	**Only applicable to equipment with rechargeable batteries where overcharging could result in an unacceptable risk** Devices with batteries should be designed taking this requirement into account. Does overcharging of any battery of equipment result in an unacceptable risk, the design shall prevent overcharging? Review the manufacturers risk management file for any risk analysis.	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**15.4.4 Indicators**	Verdict
Requirement Summary	Unless it is otherwise apparent to the OPERATOR from the normal operating position, indicator lights shall be provided to indicate that ME EQUIPMENT is ready for NORMAL USE. The marking of 7.4.1 is not sufficient for this purpose. If equipped with a stand-by state or a warm-up state whose duration exceeds 15 s, the ME EQUIPMENT shall be provided with an additional indicator light unless it is otherwise apparent to the OPERATOR from the normal operating position. Indicator lights shall be 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. Indicator lights shall be 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. Colors of indicator lights are described in 7.8.1.	

	In ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE, the charging mode shall be visibly indicated to the OPERATOR. *Compliance is checked by inspection of the presence and function of indicating means visible from the position of NORMAL USE.*
Guidance	Indicator lights, indicating that non-luminous heaters are operational shall be provided unless it is apparent to the operator from the normal operating position or no hazardous situation exists without the indication. This does not apply to heated stylus-pens. Indicator lights indicating an equipment output exists when accidental or prolonged use of the output could constitute a hazardous situation. 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.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**15.4.5 Pre-set controls**	Verdict
Requirement Summary	When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with pre-set controls. Compliance is checked by inspection of the RISK MANAGEMENT FILE.	
Guidance	**Only applicable to equipment with pre-set controls (e.g. power cycle sets controls to a specific setting)** If the device will have any pre-set controls they should be designed taking the risks into account. Any risks associated with preset controls (and their accidental resetting e.g., due to power loss) should be captured in the RMF. Where applicable, has the manufacturer addressed the risk associated with pre-set controls?	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**16.1 General requirements for ME Systems**	Verdict
Requirement Summary	After installation or subsequent modification, an ME SYSTEM shall not result in an unacceptable RISK.	

	Only HAZARDS arising from combining various equipment to constitute an ME SYSTEM shall be considered. An ME SYSTEM shall provide: — within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and — outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective IEC or ISO safety standards. Tests shall be performed: — in NORMAL CONDITION unless otherwise specified, and — under the operating conditions specified by the MANUFACTURER of the ME SYSTEM. Safety tests that have already been performed on individual equipment of the ME SYSTEM according to relevant standards shall not be repeated. The MANUFACTURER of an ME SYSTEM that is (re)configurable by the RESPONSIBLE ORGANIZATION or OPERATOR may use RISK MANAGEMENT methods to determine which configurations constitute the highest RISKS and which measures are needed to ensure that the ME SYSTEM in any possible configuration does not present an unacceptable RISK. Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with IEC or ISO safety standards that are relevant to that equipment. Equipment in which protection against electric shock relies only on BASIC INSULATION shall not be used in an ME SYSTEM. Compliance is checked by inspection of appropriate documents or certificates.
Guidance	**Only applicable to equipment intended to be part of a system** There is no reference to the RMF in this requirement. For evaluation of ME SYSTEMS, the verification requirements should specify the “worst case” system configurations which need to be evaluated for compliance with the requirements of this standard. 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? If the ME System is reconfigurable, have risk management methods been used to determine which configurations constitute the highest risks and which measures are needed to ensure that the reconfiguration does not constitute an unacceptable risk?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**16.9.1 Connection terminals and connectors**	Verdict
Requirement Summary	Design and construction of electrical, hydraulic, pneumatic, and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented unless it can be proven that no unacceptable RISK can result. In particular: — Plugs for connection of PATIENT leads or PATIENT cables shall be so designed that they cannot be connected to other outlets of the same ME SYSTEM that are likely to be located in the PATIENT ENVIRONMENT unless it can be proved that no unacceptable RISK can result. *Compliance is checked by inspection of PATIENT leads, PATIENT cables, connectors and outlets and, if interchange of the leads, cables or connectors or outlets is possible, by inspection of the RISK MANAGEMENT FILE.*	
Guidance	**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** Accessible connectors shall not be removable without the use of a tool unless it can be shown that no hazardous situation exists. Connectors for patient leads shall be designed so that they cannot connect to other outlets on the ME or MES located in the patient environment unless it can be shown that no hazardous situation can result. 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.	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1:2012 Requirement		
IEC 60601-1 Clause	**17 Electromagnetic compatibility of ME equipment and ME systems**	Verdict
Requirement Summary	The MANUFACTURER shall address In the RISK MANAGEMENT PROCESS 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; and — 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.	

	See IEC 60601-1-2 and also see 1.3. Compliance is checked by inspection of the RISK MANAGEMENT FILE.
Guidance	Compliance with this clause is through application of IEC 60601-1-2. Prior to testing to this standard, the pass/fail criteria should be determined. Any results that arise that are not expected should be reviewed to determine if they are acceptable. Evidence should be located in the DHF. 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?
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1-8:2012 Requirement		
Clause	**IEC 60601-1-8, 4 Alarm System – General requirements**	Verdict
Requirement Summary	If the MANUFACTURER chooses as a means of RISK CONTROL to have the ME EQUIPMENT or ME SYSTEM notify the OPERATOR that a HAZARDOUS SITUATION can exist, then the ME EQUIPMENT or ME SYSTEM shall include an ALARM SYSTEM complying with this collateral standard for that purpose. See also 12.3 of the general standard. The RISK ASSESSMENT shall also consider HAZARDS to PATIENTS, OPERATORS, and other persons arising from the ALARM SYSTEM (see 6.8.3).	
Guidance	As a means of risk control, has the manufacturer provided an alarm system that is used to notify the operator that a hazardous situation can exist? • If so, then an alarm system complying with this standard is used for this purpose. • If not, continue with other risk management requirements. Does the manufacturer's risk assessment identify hazards to patients, operators and other persons arising from the alarm system? • If so, verify that the resulting risk is an acceptable level before or after risk control measures are implemented as applicable based on the manufacturer's criteria for acceptable risks. • If not, and the medical electrical equipment has an alarm system, then this is an unacceptable result.	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1-8:2012 Requirement		
Clause	**IEC 60601-1-8, 6.1.2 Alarm Condition Priority**	Verdict
Requirement Summary	ALARM CONDITIONS shall be assigned to one or more of the following priorities: HIGH PRIORITY, MEDIUM PRIORITY, or LOW PRIORITY. Unless a particular ALARM CONDITION priority is specified in a relevant particular standard, the assignment of priorities is part of the RISK MANAGEMENT PROCESS and shall be based on Table 1. The priority of each ALARM CONDITION shall be disclosed in the instructions for use. Priorities may be identified in groups. *Compliance is checked by inspection* of *the instructions for use and RISK MANAGEMENT FILE.*	
Guidance	Compliance is checked by inspection of the risk management file. Does the manufacturer's risk management file include the assignment of alarm priorities based on Table 1 or in accordance with relevant particular standards? • If so, then verify by testing them accordingly. • If not, then this is an unacceptable result. Review the manufacturer's risk management file in regards to the assignment of alarm condition priorities	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1-8:2012 Requirement		
Clause	**IEC 60601-1-8, 6.8.3 Global indefinite Alarm Signal inactivation states**	Verdict
Requirement Summary	If deemed acceptable by RISK ASSESSMENT with regard to the intended environment of use of the ALARM SYSTEM, a global ALARM OFF or AUDIO OFF may be provided. If an ALARM SYSTEM is provided with a global ALARM OFF or AUDIO OFF, the ALARM SYSTEM shall be provided with: a) a REMINDER SIGNAL; and b) means to configure (enable or disable) any global ALARM OFF or AUDIO OFF. Such means shall be restricted to the RESPONSIBLE ORGANIZATION and shall prevent the clinical OPERATOR from changing the configuration in NORMAL USE (see 6.7). NOTE 1 A global ALARM OFF or AUDIO OFF ALARM SIGNAL inactivation state affects all PHYSIOLOGICAL ALARM CONDITIONS in an ALARM SYSTEM with multiple PHYSIOLOGICAL ALARM CONDITIONS. NOTE 2 See also 6.8.2 for requirements for REMINDER SIGNALS.	
Guidance	The application specification, user profile, frequently used functions are all used as inputs into the risk analysis according to ISO 14971. Compliance is checked by inspection of the risk management file. Has the manufacturer's risk management file, risk assessment, considered the intended environment of use, and accepted the Alarm System function of global Alarm Off or global Audio Off? • If so, follow the requirements of the standard. • If not, then this is an unacceptable result.	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1-11:2015 Requirement		
Clause	**IEC 60601-1-11, 4.2.2 Environmental conditions of transport and storage between uses**	Verdict
Requirement Summary	The instructions for use shall indicate the permissible environmental conditions of transport and storage of ME EQUIPMENT after the ME EQUIPMENT has been removed from its protective packaging and subsequently between uses. Unless otherwise indicated in the instructions for use or if the ME EQUIPMENT is STATIONARY, the ME EQUIPMENT shall remain operational in NORMAL USE within its specification and the requirements of this standard after transport or storage in the following environmental range: – – 25 °C to + 5 °C, and – + 5 °C to + 35 °C at a relative humidity up to 90 %, non-condensing; – > 35 °C to 70 °C at a water vapour pressure up to 50 hPa after having been removed from its protective packaging and subsequently between uses. If the instructions for use state a more restricted range of environmental transport and storage conditions between uses, these environmental conditions shall be: – justified in the RISK MANAGEMENT FILE; – marked on the ME EQUIPMENT, unless such marking is not practicable, in which case the more restricted range need only be disclosed in the instructions for use; and – marked on the carrying case, if the instructions for use indicate that the ME EQUIPMENT is intended to be transported or stored in a carrying case between uses. Symbols 5.3.5 (ISO 7000-0534 (2004-01)), 5.3.6 (ISO 7000-0533 (2004-01)) or 5.3.7 (ISO 7000-0632 (2004-01)) of ISO 15223-1:2012 may be used to mark the temperature range (see Table C.1, symbols 2, 3 and 4). Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2012 may be used to mark the humidity range (see Table C.1, symbol 5) and symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2012 may be used to mark the atmospheric pressure range (see Table C.1, symbol 6). Where ME EQUIPMENT has different markings for conditions of transport and storage between uses, continuous operating conditions (see 4.2.3.1) and transient operating conditions (see 4.2.3.2), those markings shall be accompanied by supplementary marking (e.g. appropriate wording) except where the respective applicability would be obvious (e.g. limits for transport and storage between uses on the carrying case and limits for operation on the ME EQUIPMENT itself).	
Guidance	Where the environments are more restricted than specified in this clause, there must be a justification in the risk management file for the more restricted range. This justification should take into account the intended use of the equipment as well as reasonably foreseeable misuse. Do the instructions for use state a more restricted range of environmental transport and storage conditions between uses? If yes, the range of environmental conditions shall be justified in the Risk Management file.	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1-11:2015 Requirement		
Clause	**IEC 60601-1-11, 4.2.3.1 Continuous environmental operating conditions**	Verdict
Requirement Summary	The instructions for use shall indicate the permissible environmental operating conditions of the ME EQUIPMENT.	

	NOTE 1 The environmental operating conditions should be marked on TRANSIT-OPERABLE ME EQUIPMENT, unless such marking is not practicable, in which case the environmental operating conditions need only be disclosed in the instructions for use. Unless otherwise indicated in the instructions for use, the ME EQUIPMENT shall comply with its specifications and all the requirements of this standard when operated in NORMAL USE under the following environmental operating conditions: – a temperature range of + 5 °C to + 40 °C; – a relative humidity range of 15 % to 90 %, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa; and – an atmospheric pressure range of 700 hPa to 1 060 hPa. *NOTE 2 This represents class 7K1 as described in IEC TR 60721-4-7:2001 [7].* If the instructions for use state a more restricted range of environmental operating conditions, these conditions shall be: – justified in the RISK MANAGEMENT FILE; – marked on the ME EQUIPMENT, unless such marking is not practicable, in which case the more restricted range need only be disclosed in the instructions for use; and – marked on the carrying case if the instructions for use indicate that the ME EQUIPMENT is intended to be operated in a carrying case. Symbols 5.3.5 (ISO 7000-0534 (2004-01)), 5.3.6 (ISO 7000-0533 (2004-01)) or 5.3.7 (ISO 7000-0632 (2004-01)) of ISO 15223-1:2012 may be used to mark the temperature range (see Table C.1, symbols 2, 3 and 4). Symbol 5.3.8 (ISO 7000-2620 (2004-01)) of ISO 15223-1:2012 may be used to mark the humidity range (see Table C.1, symbol 5) and symbol 5.3.9 (ISO 7000-2621 (2004-01)) of ISO 15223-1:2012 may be used to mark the atmospheric pressure range (see Table C.1, symbol 6). Where ME EQUIPMENT has different markings for continuous operating conditions and transient operating conditions (4.2.3.2), those markings shall be accompanied by supplementary marking (e.g. appropriate wording). The ME EQUIPMENT shall comply with its specifications and all the requirements of this standard when operated in NORMAL USE under the specified environmental operating conditions.
Guidance	Where the environments are more restricted than specified in this clause, there must be a justification in the risk management file for the more restricted range. This justification should take into account the intended use of the equipment as well as reasonably foreseeable misuse. Do the instructions for use state a more restricted range of environmental operating conditions of the ME Equipment? If yes, the range of environmental conditions shall be justified in the Risk Management file
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1-11:2015 Requirement		
Clause	**IEC 60601-1-11, 7.4.1 Additional requirements for warning and safety notices**	Verdict
Requirement Summary	In addition to the requirements of 7.9.2.2 and 16.2 c) of the general standard for each warning and safety sign, the instructions for use shall describe the nature of the HAZARD, likely consequences that could occur if the advice is not followed, and the precautions for reducing the RISK. If applicable, the instructions for use shall address the issues of: – strangulation due to cables and hoses, particularly due to excessive length; EXAMPLE 1 Strangulation resulting from baby or child entanglement in monitoring cables. EXAMPLE 2 Strangulation resulting from breathing system hoses.	

	– small parts being inhaled or swallowed; EXAMPLE 3 Choking resulting from a child swallowing a small part that has become detached from the ME EQUIPMENT. – potential allergic reactions to accessible materials used in the ME EQUIPMENT; EXAMPLE 4 Natural rubber latex sensitivity. – contact injuries. EXAMPLE 5 Skin irritation due to prolonged exposure to APPLIED PARTS or other ACCESSORIES. If applicable, the instructions for use shall include warnings to the effect that it can be unsafe to: – use ACCESSORIES, detachable parts and materials not described in the instructions for use (see 7.9.2.14 of the general standard); – interconnect this equipment with other equipment not described in the instructions for use (see 16.2 c) indent 9) of the general standard); – modify the equipment; – use the ME EQUIPMENT outside its carrying case if some part of the protection required by this standard is provided by that carrying case (see 8.3.1 and 10.1).
Guidance	The risk management file should contain (as appropriate) an assessment of unique risks related to this use environment and the users within the home healthcare environment. When necessary, advice on reducing these risks should be included in the instructions for use. For each warning and safety sign, the instructions for use shall describe the nature of the HAZARD, likely consequences that could occur if the advice is not followed, and the precautions for reducing the RISK. Review the manufacturers risk management file for risk analysis, risk evaluation and where necessary implementation of risk control.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1-11:2015 Requirement		
Clause	**IEC 60601-1-11, 7.4.5 Additional requirements for operating instructions**	Verdict
Requirement Summary	In addition to the requirements of 7.9.2.9 of the general standard, the instructions for use for ME EQUIPMENT that is intended for use by a LAY OPERATOR shall include a description of generally known conditions in the HOME HEALTHCARE ENVIRONMENT that can unacceptably affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT and the steps that can be taken by the LAY OPERATOR to identify and resolve these conditions, and shall include, where applicable, at least the following issues: – the effects of lint, dust, light (including sunlight), etc.; – a list of known devices or other sources that can potentially cause interference problems; EXAMPLE 1 Heat from a fireplace or radiant heater. EXAMPLE 2 Moisture from a nebuliser or steam kettle. – the effects of degraded sensors and electrodes, or loosened electrodes, which can degrade performance or cause other problems; – the effects caused by pets, pests or children. The instructions for use shall explain the meaning of the IP classification marked on the ME EQUIPMENT and, if applicable, on any carrying case provided with the ME EQUIPMENT.	
Guidance	Based on the risk analysis (hazard identification), any risks than can be caused by the use environment must be identified and mitigated, where appropriate information must be included in the instructions for use to aid in minimizing the risks. Where the instructions for use include a description of generally known conditions in the HOME HEALTHCARE ENVIRONMENT that can unacceptably affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT and the steps that can be taken by the LAY OPERATOR to identify and resolve these conditions, review the manufacturers risk management file for risk analysis, risk evaluation and implementation of risk control.	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1-11:2015 Requirement		
Clause	**IEC 60601-1-11, 8.4 Additional requirements for interruption of the power supply/supply mains to ME Equipment and ME System**	Verdict
Requirement Summary	In addition to the requirements of 11.8 and 16.8 of the general standard, ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall maintain its ESSENTIAL PERFORMANCE for a sufficient time or for a sufficient number of PROCEDURES, when loss or failure of the SUPPLY MAINS or near depletion of the INTERNAL ELECTRICAL POWER SOURCE occurs. The time or number of PROCEDURES remaining shall allow alternative life-supporting methods to be employed. *NOTE 1 Requirements for loss or failure of SUPPLY MAINS for very short periods are found in IEC 60601-1-2.* An INTERNAL ELECTRICAL POWER SOURCE may be utilized to maintain ESSENTIAL PERFORMANCE. Independent means may also be utilized to provide ESSENTIAL PERFORMANCE. *EXAMPLE 1 Manually-driven pump or resuscitator.* The instructions for use shall disclose the time or number of PROCEDURES available following a loss or failure of the SUPPLY MAINS or near depletion of the INTERNAL ELECTRICAL POWER SOURCE. The instructions for use shall describe the alternative life-supporting methods to be employed. The technical description shall describe methods that can be employed for longer periods. *NOTE 2 Electrical power supply failure includes failure of the SUPPLY MAINS or any near depletion of INTERNAL ELECTRICAL POWER SOURCES.*	

	If an INTERNAL ELECTRICAL POWER SOURCE is not used, ME EQUIPMENT or ME SYSTEMS with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY ALARM CONDITION that indicates a power supply failure. *EXAMPLE 2 The SUPPLY MAINS voltage falls below the minimum value required for normal operation.* If an INTERNAL ELECTRICAL POWER SOURCE is used, ME EQUIPMENT or ME SYSTEMS with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall be equipped with an automatic switchover to the INTERNAL ELECTRICAL POWER SOURCE. *NOTE 3 A visual indication of this charging mode is required in 15.4.4 of the general standard.* If an INTERNAL ELECTRICAL POWER SOURCE is used, ME EQUIPMENT or ME SYSTEMS with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION that indicates that the INTERNAL ELECTRICAL POWER SOURCE is nearing insufficient remaining power for ME EQUIPMENT operation. This TECHNICAL ALARM CONDITION shall provide for a sufficient time or for a sufficient number of PROCEDURES for a LAY OPERATOR to act. A TECHNICAL ALARM CONDITION of at least LOW PRIORITY shall remain active until the INTERNAL ELECTRICAL POWER SOURCE is returned to a level that is above the ALARM LIMIT or until it is depleted. It shall not be possible to inactivate the visual ALARM SIGNAL of this TECHNICAL ALARM CONDITION.
Guidance	The risk management file should contain an assessment of the risk(s) related to loss of power. For life supporting equipment, this risk must be mitigated for a specified period of time according to the requirements of this clause. When loss or failure of the SUPPLY MAINS or INTERNAL ELECTRICAL POWER SOURCE would result in an unacceptable risk, do the time or number of PROCEDURES remaining allow for alternative life-supporting methods to be employed? If so, review the manufacturers risk management file for risk analysis, risk evaluation and where necessary implementation of risk control, as well as whether an acceptable residual risk results.
Comment	
RMF Reference(s) (Document Name, Revision Number and Section Reference)	

IEC 60601-1-11:2015 Requirement		
Clause	**IEC 60601-1-11, 9 Accuracy of controls and instruments and protection against hazardous outputs**	Verdict
Requirement Summary	In addition to the requirements of 12.2 of the general standard, when performing the USABILITY ENGINEERING PROCESS, the RISKS associated with USABILITY in the HOME HEALTHCARE ENVIRONMENT for OPERATOR PROFILES including a LAY OPERATOR shall include consideration of at least: – changes of controls; – unexpected movement; – potential for misconnection; – potential for improper operation, or unsafe use; – potential for confusion as to current operational mode; – change in the transfer of energy or substance; – exposure to environmental conditions specified in this standard; – exposure to biological materials; and – small parts being inhaled or swallowed. Particular emphasis shall be placed on the limited training of a LAY OPERATOR with respect to the ability to intervene and maintain BASIC SAFETY and ESSENTIAL PERFORMANCE. The MANUFACTURER shall include the least capable intended LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION in the USABILITY ENGINEERING PROCESS. EXAMPLES LAY OPERATORS with sensory, cognitive, physical limitations or comorbidities.	
Guidance	Have the RISKS associated with USABILITY in the HOME HEALTHCARE ENVIRONMENT included consideration of all factors identified by the Standard, placing particular emphasis on the limited training of a LAY OPERATOR with respect to the ability to intervene and maintain BASIC SAFETY and ESSENTIAL PERFORMANCE? If so, review the manufacturer's USABILITY ENGINEERING FILE for risk analysis, risk evaluation and where necessary implementation of risk control, as well as whether an acceptable residual risk results. See USABILITY ENGINEERING FILE Assessment per IEC 60601-1-6/IEC 62366	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

IEC 60601-1-11:2015 Requirement		
Clause	**IEC 60601-1-11, 11 Protection against strangulation or asphyxiation**	Verdict
Requirement Summary	Means shall be provided to control the RISK of strangulation and asphyxiation of the PATIENT and others to an acceptable level. *EXAMPLE 1 By routing wires or tubing.* *EXAMPLE 2 Using retention devices.* *EXAMPLE 3 Providing the option of multiple length ACCESSORIES.* *EXAMPLE 4 Not providing removable small parts for ME EQUIPMENT.*	
Guidance	Risks associated with strangulation must be identified in the risk management file. These risks must be controlled to an acceptable level through the design of the equipment. Have means been provided to control the RISK of strangulation and asphyxiation of the PATIENT and others to an acceptable level? If so, review the manufacturers risk management file for risk analysis, risk evaluation and where necessary implementation of risk control, including whether other hazards may have been generated.	
Comment		
RMF Reference(s) (Document Name, Revision Number and Section Reference)		

Revision History

Revision	Reason for Change or Change Control Number	Document Author	Date
0.0	Initial Release	Alex Grob	2014-07-21
0.1	Updated document title (Quality System Record update only)	Alex Grob	2014-09-16
0.2	Clarified risk tables to include document references information and removed assessment section of tables	Justin Martineau	2018-07-25
1.0	Revision 1.0 (2019-07-11) Added collateral standard risk requirements to checklist (i.e. -1-8, -1-11), changed title, updated logos and corrected title of clause 8.6.3 earthling to earthing	Jeremi Peck	2019-07-11