**Risk Management File Check List – RF617**

Before a test laboratory can use IEC 60601-1, there are many clauses that require information from the manufacturer’s Risk Management (RM) process. In this sense the manufacturer’s RM process feeds into the use of IEC 60601-1. The RM file should be generated in accordance with ISO 14971.

Once a manufacturer makes a decision to use IEC 60601-1, using its verifiable requirements allows the presumption of acceptable risk, provided there is no objective evidence to contrary. In this sense the manufacturer’s use of IEC 60601-1 feeds into manufacturer’s RM process.

**Key documentation required:**

* Risk Management File: This should include all of the records and documents that risk management process generated (risk management plan, records of risk analyses, risk

evaluations, risk control measures, and residual risk evaluations).

* RF617 Risk Management File Check List (this document): This document needs to be completed by the manufacturer. Once you have verified the core information including references back to clauses of ISO 14971 (i.e. those highlighted in red within the examples shown) Element will verify one of three things:
1. The relevant test of IEC 60601-1:2005 needs to be applied. However, to complete the test further information maybe be needed from you (Example 2 show where this might be required). Element will provide this advice once we have the RM file and the complete RF617 form.
2. Further information or clarification maybe required in regards to a specific point of risk analysis.
3. The risk analysis may need to be updated to take account of the tests performed by Element to verify the risk as acceptable (i.e. IEC 60601-1 is considered to provide a presumption of acceptance).

 Element appreciates there is a considerable amount of information to provide or complete however this is vital otherwise assessment against IEC 60601-1 3rd Edition is not possible.

If you have any questions about this form or require further assistance in completing this documentation please do not hesitate to contact a member of the Element safety team.

To try and help explain the process we have provided two examples of how the form is used including its interaction with IEC 60601-1 3rd Edition.

**Example 1:**

**Mapping from ISO 14971 into IEC 60601-1:**

**Clause 8.10.2 of IEC 60601-1:2006 (Fixing of wiring):**

4.3 Identification of hazards – **Potential sources of harm - loose wire**

4.4 Estimation of risks for each hazardous situation – **Electric shock**

5 Risk evaluation – **Is risk reduction required?**

6 Risk control

6.1 Risk reduction – **Required?**

6.2 Risk control option analysis - **Additional mechanical restraint**

6.3 Implementation of risk control measure(s) – **Done? Effective?**

6.4 Residual risk evaluation

6.5 Risk/benefit analysis

**Risk Management Process:**

| **8.10.2** | **RM RESULTS TABLE: Fixing of wiring** | **PASS** |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** | **ERP-14-0015 table headed “Risk Analysis”, item 3.2**  | **Element confirms the risk matrix identifies the hazard of a conductor breaking free** | **PASS** |
| **4.4** | **ERP-14-0015 table headed “Risk Estimation”, item 3.2** | **Element confirm that using the risk estimation, the manufacturer has determined the severity and probability of a conductor breaking free** | **PASS** |
| **5** | **ERP-14-0015….** | **Element confirm from the risk acceptability chart that the risk is unacceptable.**  | **PASS** |
| **6.2** | **ERP-14-0015….** | **Manufacturer has stated within the risk control that double crimp terminals will be used.**  | **PASS** |
| **6.3** | **ERP-14-0015….** | **Engineering change note ERP-23-0001 dated 1-1-2012 was used to verify the risk implementation was conducted** | **PASS** |
| **6.4** | **ERP-14-0015….** | **Element confirms that the risk estimation for the modification had been re-checked and documented.**  | **PASS** |
| **6.5** | **ERP-14-0015….** | **A risk benefit/analysis is not required in this case** | **N/A** |
| **Lab consideration:** Has the manufacturer identified in their risk management file the need to restrain by double securement any conductors and connectors where if they were to break free and touch circuit points this could result in a hazardous situation? If so, inspect the construction and restraint of these conductors and connectors to ensure that they are held in place by use of double securement. |

**Notes:**

Parts in red to be provided by the manufacturer

Parts in blue to be completed by Element

If your risk assessment process encompasses clause 4.3 through to 6.5 of ISO 14971 within one document, you will just need to reference the key document. Element will input the remaining information by way of review.

**Example 2:**

**Mapping from ISO 14971 into IEC 60601-1:**

**Clause 11.6.3 – Spillage on ME EQUIPMENT and ME SYSTEMS**

**ME EQUIPMENT and ME SYSTEM requiring the handling of liquids in NORMAL USE shall**

**be so constructed that spillage does not wet parts that could result in a HAZARDOUS**

**SITUATION.**

**Risk Management Process:**

| **11.6.3** | **RM RESULTS TABLE: Spillage on ME equipment and ME system** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2**  | **ERP-14-0015 Intended Use section** | **The Treadmill is provided with a cup holder. Spillage of liquids may occur.** | **PASS** |
| **4.3** | **ERP-14-0015 Table heading “Risk Analysis” “4.3 Identification of Hazards”** | **Hazard: Excessive Leakage Current or Access to Hazardous Voltage; Events: liquid spills onto device; Hazardous Situation: Liquid bridges safety insulation****causing conductive pathway from hazardous circuits to accessible parts** | **PASS** |
| **4.4** | **ERP-14-0015 Table heading “4.4 Risk Estimation”** | **Determined risk severity and probability based on the****manufacturer’s policy tables and previous device data****for probability** | **PASS** |
| **5** | **ERP-14-0015 Table heading “4.4 Risk Evaluation”** | **Determined risk acceptability based on the****manufacturers risk acceptability criteria table** | **PASS** |
| **6.2** | **ERP-14-0015 Table heading “6 Risk Control”, “6.2 Option Analysis”** | **Concern addressed by design of device enclosure including gasket** | **PASS** |
| **6.3** | **ERP-14-0015 Table heading “6 Risk Control” “6.3 Verify Implementation and Effectiveness”** | **Manufacturer Test Protocol DES-00503 and Element Safety Test Results Report 32547 dated 1/1/2012** | **PASS** |
| **6.4** | **ERP-14-0015 Table heading “6 Risk Control” “6.4 Residual Risk Estimation”****and “6.4 Residual Risk Evaluation”** | **Using the manufacturers risk estimation tables (FDA****based), and their risk acceptability criteria the manufacturer determined the severity and probability****of the residual risk and determined that with the risk control measures the risk is acceptable** | **PASS** |
| **6.5** | **ERP-14-0015 Table heading “6 Risk****Control” “6.5 Risk/Benefit Analysis”** | **A risk/benefit analysis was not required** | **PASS** |
| **Lab consideration:** 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? |

**Notes:**

Parts in red to be provided by the manufacturer

Parts in blue to be completed by Element

If your risk assessment process encompasses clause 4.3 through to 6.5 of ISO 14971 within one document, you will just need to reference the key document. Element will input the remaining information by way of review.

IEC 60601-1 states “Compliance with 11.6.3 is checked 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 application of the RISK MANAGEMENT PROCESS.***

***All test conditions are identified through inspection of 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 a HAZARDOUS SITUATION.***

Test parameters are not given in the IEC 60601-1 therefore this is derived by the Risk Management File:

***The possible hazard of electric shock to the patient caused by the insulation breakdown has been identified as a result of possible spillage of a drink place in cup-holder.***

***For the purpose of the test, the following test conditions have been identified:***

***Type of liquid: mineral water***

***Volume: 1 liter***

***Duration of spill: 15 s***

***Point of contact: at the end of the belt above the drum motor from a height not exceeding 5 cm.***

***Test result: With protective cover in place, no wetting of electrical parts***

Therefore in this particular case, the actual test is specified by the RM documentation and applied accordingly by the test laboratory.

**Application Information:**

|  |  |
| --- | --- |
| **RMF Reference No.** : |  |
| Complied by (applicant) : |  |
| Reviewed by Element (+ signature) : |  |
| Date of completion : |  |
| Total number of pages : |  |
| **Applicant name** : |  |
| Address : |  |
| **Manufacturer name (if different from above)** : |  |
| Address : |  |
| **Medical Product description** : |  |
| Trade Mark : |  |
| Manufacturer : |  |
| Address : |  |
| Equipment type : |  |
| Intended use : |  |
| Model/Type reference : |  |
| Ratings : |  |
| Classifications : |  |

**ISO 14971: 2000 Checklist**

|  Clause |  **Title** |  **Item** | **Comments and Location in the RMF**State page, section or other suitable ref. or N/A when not applicable plus a rationale |
| --- | --- | --- | --- |
| 3.3 | 3.2 \*) | Management Responsibilities | Policy for determining acceptable risk. |  |
| 3.5 | 3.4 \*) | Risk Management Plan | Evidence of risk acceptability criteria |  |
| 4.1 | Risk Analysis Procedure | Procedure for risk analysis |  |
| 4.2 | Intended use/intended purpose, etc. | Record of safety issue analysis |  |
| 4.3 | Hazard Identification | Record of hazard analysis |  |
| 4.4 | Risk estimation | - Definition of methods used for estimating risks- Description of method(s) used- Record of risk estimation activities |  |
| 5.0 | Risk evaluation | Record of risk evaluation activities |  |
| 6.1 | Risk reduction | Procedure for risk control activities |  |
| 6.2 | Option analysis | Record of risk control option analysis (including risk-benefit analysis, if appropriate) |  |
| 6.3 | Implementation of risk control measures | Inputs from risk management activities |  |
| 6.4 | Residual risk evaluation | Evidence e.g. from design verification activities |  |
| 6.5 | Risk-Benefit Analysis | Evidence as necessary…see 6.2 |  |
| 6.6 | Other generated hazards | Record of review of all risk controls for impact on new hazards |  |
| 7 | Overall risk evaluation | Records of related meetings, analysis, etc. |  |
| 8 | Risk management report | Summary of risk management activities |  |

\*) ISO 14971:2007

| **IEC 60601-1, ed 3, Requirements of which compliance is to be checked by review of the RMF** | **Location in the RMF**State page, section or other suitable ref. or N/A when not applicable plus a rationale |
| --- | --- |
| **4.2 Risk Management Process for ME Equipment and ME Systems**A Risk Management Process complying with ISO 14971 shall be performed.*Compliance is checked by inspection of the RMF. Minimum requirements:- established RISK MANAGEMENT PROCESS- established acceptable levels of RISK- demonstrated that the RESIDUAL RISK(S) is acceptable (in accordance with the policy for determining acceptable RISK).*  |  |
| **4.3**  **Essential performance** The manufacturer shall identify which functions of the ME EQUIPMENT and ME systems are essential performance. *Compliance is checked by inspection of the**RMF*. |  |
| **4.4 Expected service life**The manufacturer shall state the expected service life of the ME EQUIPMENT or ME system in the RISK MANAGEMENT FILE.*Compliance is checked by inspection of the RMF.* |  |
| **4.5 Equivalent safety for ME Equipment or ME Systems**Where this standard specifies requirements addressing particular RISKS, alternative means of addressing these RISKS are acceptable provided that the MANUFACTURER can justify that the RESIDUAL RISKS that result from applying the alternative means are equal to or less than the RESIDUAL RISKS that result from applying the requirements of this standard.*Compliance is checked by inspection of the RMF.* |  |
| **4.6 ME EQUIPMENT or ME system parts that contact the patient**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 shall be subject to the requirements for applied parts. *Compliance is checked by inspection of the RMF.* |  |
| **4.7 SINGLE FAULT CONDITION for ME EQUIPMENT**ME EQUIPMENT shall be so designed and manufactured that it remains SINGLE FAULT SAFE, orthe RISK remains acceptable as determined through application of4.2.Where a SINGLE FAULT CONDITION causes another SINGLE FAULT CONDITION, the two failures are considered as one SINGLE FAULT CONDITION.The results of the RISK ANALYSIS shall be used to determine which failures shall be tested. *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*.  |  |
| **4.8 COMPONENTS of ME EQUIPMENT**Any components used outside of their specified ratings shall be justified through risk management, that an unaccepted risk is not introduced. |  |
| **4.9 Use of components with high-integrity characteristics in ME EQUIPMENT****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 RMF and the selection criteria for the components with high-integrity characteristics.** |  |
| **5.4 a) OTHER CONDITIONS****ME equipment is to be tested in the least favourable working condition as specified in the risk analysis** |  |
| **5.7 Humidity preconditioning treatment****Where the RISK MANAGEMENT PROCESS suggests that the ME EQUIPMENT can be exposed to high humidity for extended periods (such as out-door use), the period is extended appropriately. Concluded preconditioning treatment: Per MIL810G and RTAC DO-160F** |  |

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| **5.9.2.3 Actuating mechanisms**Conductive parts of actuating mechanisms are not considered accessible parts if removal of handles, knobs, etc. requires the use of a tool and inspection of the RMF demonstrates that the relevant part is unlikely to become detached unintentionally during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. See also 15.4.6.1 |  |
| **7.1.1 Usability of the identification, marking and documents**The manufacturer shall address in a USABILITY ENGINEERING PROCESS the risk of poor usability associated with the design of the ME EQUIPMENT'S identification, marking and documents. See IEC 60601-1-6 and also see 1.3 and 12.2*Compliance is checked by inspection of the results of the USABILITY ENGINEERING PROCESS.* |  |
| **7.2.2 Identification**ME Equipment and its detachable components shall be marked with the name or trademark of the Manufacturer, and with a Model or Type Reference unless misidentification does not present an unacceptable risk |  |
| **7.2.5 ME EQUIPMENT intended to receive power from other equipment**If ME Equipment is intended to receive its power from other equipment including ME Equipment in an ME System and connection to another source could result in an unacceptable risk, the Model or Type Reference of the specified other equipment shall be marked adjacent to the relevant connection point |  |
| **7.2.13 Physiological effects (safety signs and warning statements)**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. |  |
| **7.2.17 Protective packaging**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).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). |  |

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| **7.3.3 Batteries**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. |  |
| **7.3.7 Supply terminals**Terminals for supply conductors shall be marked adjacent to the terminals unless it can be demonstrated that no HAZARDOUS SITUATION can result if connections are interchanged. |  |
| **7.4.2 Control devices**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. |  |
| **7.5 Safety signs**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. |  |
| **7.9.1 General (see also Table C.4)**Accompanying documents may be provided electronically, e.g. electronic file format on CD-ROM. If the accompanying documents are provided electronically, the RISK MANAGEMENT PROCESS shall include consideration of which information also needs to be provided as hard copy or as markings on the ME EQUIPMENT, e.g. to cover emergency operation. |  |
| **7.9.2.4 Electrical 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. |  |
| **7.9.2.4 Electrical power source**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. |  |
| **7.9.2.5 ME EQUIPMENT description**The instructions for use shall include information on the materials or ingredients to which the PATIENT or OPERATOR is exposed if such exposure can constitute an unacceptable RISK (see 11.7). |  |
| **7.9.3.2 Replacement of fuses, POWER SUPPLY CORDS and other parts**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. |  |
| **8.1 Fundamental rule of protection against electric shock**b) interruption of any one power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES, if the RISK ANALYSIS indicates that this condition might cause permitted limits to be exceeded |  |
| **8.1 Fundamental rule of protection against electric shock**b) unintended movement of a component; but only if the component is not mounted securely enough to ensure that such movement will be very unlikely to occur during the EXPECTED SERVICE LIFE of the ME EQUIPMENT, as determined by the RISK MANAGEMENT PROCESS (see also 8.10.1) |  |
| **8.2.2 Connection to an external d.c. power source**If ME EQUIPMENT is specified for power supplied from an external d.c. power source, no HAZARDOUS SITUATION, other than absence of its intended function, shall develop when a connection with the wrong polarity is made. The ME EQUIPMENT, when connection is subsequently made with the correct polarity, shall provide freedom from unacceptable RISK. Protective devices that can be reset by anyone without the use of a TOOL are acceptable provided that these restore correct operation on reset. |  |
| **8.3 Classification of applied parts**d) \*  For a part that is identified according to 4.6 as needing to be subject to the requirements for an applied part (except for marking), the requirements for a type B applied part shall apply unless the RISK MANAGEMENT PROCESS identifies a need for the requirements for a type BF applied part or type CF applied part to apply. |  |

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| --- | --- |
| **8.4.2 Accessible parts including applied parts**c) The limits specified in b) above do not apply to the following parts if the probability of a connection to a patient, either directly or through the body of the operator, through which a current exceeding the allowable touch current could flow, is negligible in normal use, and the instructions for use instruct the operator not to touch the relevant part and the patient simultaneously:– accessible contacts of connectors;– contacts of fuse-holders that are accessible during replacement of the fuse;– contacts of lamp-holders that are accessible after removal of the lamp;– parts inside an access cover that can be opened without the use of a tool, or where a tool is needed but the instructions for use instruct any operator other than service personnel to open the relevant access cover.*Compliance is checked by inspection of the RMF, by reference to the instructions for use and by measurement.* |  |
| **8.5.2.2 Type B applied parts****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 RMF.** |  |
| **8.5.2.3 PATIENT Leads****Any connector for electrical connections on a PATIENT lead that:****– is at the end of the lead 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).** |  |
| **8.6.3 Protective earthing of moving parts****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 RMF.** |  |
| **8.8.4.1**  **Mechanical strength and resistance to heat****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 RMF and, if necessary, in conjunction with the following tests:****– resistance to moisture, etc.** **– dielectric strength****– mechanical strength** |  |
| **8.10.1 Fixing of components****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 RMF.** |  |
| **8.10.2 Fixing of wiring****Conductors and connectors of ME EQUIPMENT shall be so secured or insulated that accidental detachment shall not result in a hazardous situation. They are not considered to be adequately secured if on breaking free at their joint and moving about their support point they are capable of touching circuit points resulting in a hazardous situation.****Breaking free of one means of mechanical restraint shall be considered a single fault condition.****Stranded conductors shall not be solder-coated if they are affixed by any clamping means and poor contact could result in a hazardous situation.****Compliance is checked by inspection of the ME EQUIPMENT and the RMF.** |  |
| **8.10.5 Mechanical protection of wiring****a) Internal cables and wiring shall be adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a hazardous situation.****b) ME EQUIPMENT shall be so designed that wiring, cord forms or components are not likely to be damaged during assembly or the opening or closing of access covers where such damage could result in a hazardous situation.****Compliance is checked by inspection and, where appropriate, by manual test or reference to the RMF.** |  |
| **8.11.5 Mains fuses and over-current releases****Justification for omission of fuses or over-current releases shall be included in the RISK MANAGEMENT FILE.****Compliance is checked by inspection of the ME EQUIPMENT and the RMF.** |  |
| **9.2 HAZARDs associated with moving parts****9.2.1 General****The residual risk associated with moving parts is considered acceptable if exposure is needed for the ME EQUIPMENT to perform its intended function. If after all reasonable protective measures have been implemented HAZARDs persist, warnings shall be marked on the ME EQUIPMENT or given in the instructions for use.** |  |
| **9.2.2.4.3 Movable guards****Movable guards that can be opened without the use of a tool:****– shall remain attached to the ME EQUIPMENT when the guard is open;****– shall be associated with an interlock device that prevents the relevant moving parts from starting to move while the trapping zone is accessible and stops movement when the guard is opened;****– shall be so designed that the absence or failure of one of their components prevents starting, and stops moving parts.****Compliance is checked by conducting any applicable tests and inspection of the ME EQUIPMENT and the RMF.** |  |
| **9.2.2.4.4 Protective measures****Protective measures shall be designed and incorporated into the control system so that:****– moving parts cannot start to move while they are in the reach of persons;****– once the ME EQUIPMENT has started to move, the trapping zone cannot be reached, or, if the trapping zone is reached, system movement must stop. In the later case, no HAZARD or damage shall result;****– if in a single fault condition of the protective measure, an unacceptable risk could arise, one or more emergency stopping device(s) in the ME EQUIPMENT shall be provided (see 9.2.4**0**).****Compliance is checked by inspection of the ME EQUIPMENT and the RMF.** |  |
| **9.2.2.5 Continuous activation** **Where it is impractical to make the trapping zone inaccessible, a trapping zone is not considered to present a mechanical HAZARD if:****c) in a single fault condition of the continuous activation system an unacceptable risk could arise, one or more emergency stopping device(s) are provided in the ME EQUIPMENT (see 9.2.4).****Compliance is checked by inspection of the ME EQUIPMENT and the RMF.** |  |
| **9.2.2.6 Speed of movement(s)****The speed of movement(s) that position parts of the ME EQUIPMENT or patient, where contact with the ME EQUIPMENT could result in a HAZARDous situation, shall be limited so that the operator will have adequate control of positioning without resulting in an unacceptable risk.****The overtravel (stopping distance) of such movement, occurring after operation of a control to stop the movement, shall not result in an unacceptable risk.****Compliance is checked by inspection of the ME EQUIPMENT and the RMF.** |  |
| **9.2.3.2 Overtravel** **The risk due to overtravel (past range limits) of ME EQUIPMENT parts shall be reduced to an acceptable level. End stops or other stopping means shall be provided to act as the ultimate travel limiting measure in both normal condition and single fault condition.****Such means shall have the mechanical strength to withstand the intended loading in normal use and reasonably foreseeable misuse.****Compliance is checked by inspection of the ME EQUIPMENT, the RMF, specifications of materials used and the processing specifications for these materials.** |  |
| **9.2.4 Emergency stopping devices****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. See standard.****Compliance is checked by inspection of the ME EQUIPMENT and the RMF.** |  |
| **9.2.5 Release of patient****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 protective measure or emergency stopping.** **Compliance is checked by inspection of the ME EQUIPMENT and the RMF.** |  |
| **9.3 Hazards associated with surfaces, corners and edges****Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in an unacceptable risk shall be avoided or covered.****Compliance is checked by inspection of the ME EQUIPMENT and the RMF.** |  |
| **9.4.2.4.3 Movement over a threshold****Mobile ME EQUIPMENT exceeding 45 kg shall be able to pass over a 20 mm threshold. Passing over a 20 mm threshold shall not result in an unacceptable risk.****Unacceptable risk is determined by inspection of the ME EQUIPMENT, its parts, and the RMF.** |  |
| **9.5.1 Protective means****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 RMF.** |  |
| **9.6.1 General****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 inspection of the RMF (taking into account the audibility of auditory alarm signals and patient sensitivity) and the tests indicated in 9.6.2 and 9.6.3.** |  |
| **9.6.2.2 Infrasound and ultrasound energy****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 RMF.** |  |
| **9.7.2 Pneumatic and hydraulic parts****Pneumatic and hydraulic parts of ME EQUIPMENT or accessories shall be so designed that: See standard.****– 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 RMF.** |  |
| **9.7.4 Pressure rating of ME EQUIPMENT parts****The maximum pressure to which a part of ME EQUIPMENT can be subjected in normal condition and single fault condition shall not exceed the maximum permissible working pressure for the part, except as allowed for pressure relief devices in 9.7.7****Compliance is checked by inspection of the manufacturer’s data for the component, inspection of the ME EQUIPMENT, inspection of the RMF, and where necessary, by functional test.** |  |
| **9.7.6 Pressure-control device****In ME EQUIPMENT for which 9.7.7 requires a pressure-relief device, any pressure-control device responsible for regulating the pressure shall be capable of performing under rated load for 100 000 cycles of operation and shall prevent the pressure from exceeding 90 % of the setting of the pressure-relief device under any condition of normal use.****Compliance is checked by inspection of the manufacturer’s data for the component, inspection of the ME EQUIPMENT, inspection of the RMF, and where necessary, by functional test.** |  |
| **9.7.7 Pressure-relief device****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: See standard.****Compliance is checked by inspection of the manufacturer’s data for the component, inspection of the ME EQUIPMENT, inspection of the RMF, and where necessary, by functional test.** |  |
| **9.8 Hazards associated with support systems****9.8.1 General** **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.****– 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 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.** |  |
| **9.8.2 Tensile safety factor****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 20 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).** **Compliance with 9.8.1 and 9.8.2 is checked by inspection of the ME EQUIPMENT, the RMF, the specifications of materials used and the processing specifications for these materials.** |  |
| **9.8.3 Strength of patient or operator support or suspension systems** **9.8.3.1 General****ME EQUIPMENT parts serving for support or immobilization of patients shall be designed and manufactured so as to minimize the risk of physical injuries and of accidental loosening of fixings.****Compliance is checked by inspection of markings, accompanying documents, and the RMF.** |  |
| **9.8.3.2 Static forces due to loading from persons****a) For a foot rest that is intended to temporarily support a standing patient or operator, the whole mass of the patient or operator is distributed over an area of 0,1 m2.****Compliance is checked by inspection of the ME EQUIPMENT, the RMF, the specifications of materials used and the processing specifications for these materials, and the following test:****b) For an area of support/suspension where a patient or operator can sit, deflection of a support surface from patient or operator loading shall not result in an unacceptable risk.****Compliance is checked by inspection of the ME EQUIPMENT, the RMF, the specifications of materials used and the processing specifications for these materials, and the following test:** |  |
| **9.8.4 Systems with mechanical protective devices****9.8.4.1 General** **b) The mechanical protective device shall:****– be designed on the basis of total load, which shall include the effects of the safe working load when applicable;****– have tensile safety factors for all parts not less than those in row 7 of Table 20** **– activate before travel (movement) produces an unacceptable risk;****– take into account 9.2.5 and 9.8.3.****Compliance is checked by inspection of the ME EQUIPMENT, the RMF, the specifications of materials used and the processing specifications for these materials.** |  |
| **9.8.4.3 Mechanical protective device intended for single activation****If a mechanical protective device is intended to function only once, the following requirements in this clause shall be fulfilled:****Compliance is checked as follows:****– by inspection of the ME EQUIPMENT, the accompanying documents, the RMF, specifications of materials used and the processing specifications for these materials;** |  |
| **9.8.5 Systems without mechanical protective devices****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 20; 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 20.****Compliance is checked by inspection of the ME EQUIPMENT and the RMF.** |  |
| **10.1.2 ME EQUIPMENT intended to produce diagnostic or therapeutic X-radiation****The manufacturer shall address in the RISK MANAGEMENT PROCESS the risk from unintended X-radiation from ME EQUIPMENT designed to produce X-radiation for diagnostic and therapeutic purposes. See IEC 60601-1-3 and also see 1.3****Compliance is checked by inspection of the RMF.** |  |
| **10.2 Alpha, beta, gamma, neutron and other particle radiation****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 RMF.** |  |
| **10.3 Microwave radiation****When applicable, the manufacturer shall address in the RISK MANAGEMENT PROCESS the risks associated with microwave radiation.****Compliance is checked by inspection of the RMF.** |  |
| **10.5 Other visible electromagnetic radiation****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 RMF.** |  |
| **10.6 Infrared radiation****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 RMF.** |  |
| **10.7 Ultraviolet radiation****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 RMF.** |  |
| **11.1.1 Maximum temperature during normal use****Table 23 – Allowable maximum temperatures for ME EQUIPMENT partsthat are likely to be touched. Appropriate limits shall be determined and documented in the RMF.** |  |
| **11.1.1 Maximum temperature during normal use****Table 24– Allowable maximum temperatures for ME EQUIPMENT partsthat are likely to be applied to the patient. Appropriate limits shall be determined and documented in the RMF** |  |
| **11.1.2.1 Applied parts intended to supply heat to a patient****The temperature (hot or cold surfaces) or (where appropriate) the clinical effects shall be determined and documented in the RMF. The temperatures and clinical effects shall be disclosed in the instructions for use.** |  |
| **11.1.2.2 Applied parts not intended to supply heat to a patient****The limits of Table 24 shall apply. If the surface temperature of an applied part exceeds 41 °C, the maximum temperature shall be disclosed in the instructions for use 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 RMF. Where 41°C is not exceeded, no justification is required.Surfaces of applied parts that are cooled below ambient temperatures can also result in HAZARD and shall be evaluated as part of the RISK MANAGEMENT PROCESS.** |  |
| **11.1.3 Measurements****Where engineering judgement by the manufacturer indicates that temperature limits cannot be exceeded, no measurement is required. 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 RMF.****Compliance with the requirements of 11.1 and11.2 is checked by inspection of the RMF and the instructions for use, operation of ME EQUIPMENT and temperature measurements as follows****e) Test criteria****The maximum temperature of a part is determined by measuring the temperature rise of the part under test and adding it to the maximum allowed ambient temperature specified in the technical description (see 7.9.3.1). Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RMF.** |  |
| **11.2.2.1 Risk of fire in an oxygen rich environment****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.****b) The configurations 1) to 4) in this clause, alone or in combination as appropriate (as determined by the application of the RISK MANAGEMENT PROCESS), are considered to provide an acceptable residual risk of fire in an oxygen rich environment.** |  |
| **11.3 Constructional requirements for fire enclosures of ME EQUIPMENT****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 RMF and if not met, specific justification shall also be given.** |  |
| **11.5 ME EQUIPMENT and ME systems intended for use in conjunction with flammable agents****The manufacturer’s RISK MANAGEMENT PROCESS shall address the possibility of fire and associated mitigations.****Compliance is determined by inspection of the RMF.** |  |
| **11.6.2 Overflow in ME EQUIPMENT****If ME EQUIPMENT incorporates a reservoir or liquid storage chamber that is liable to be overfilled or to overflow in NORMAL USE, liquid overflowing from the reservoir or chamber shall not wet any MEANS OF PROTECTION that is liable to be adversely affected by such a liquid, nor shall an unacceptable RISK be created. Unless restricted by a marking or by the instructions for use, no HAZARDOUS SITUATION (as specified herein) or unacceptable RISK due to overflow shall develop if TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 15.** |  |
| **11.6.3 Spillage on ME EQUIPMENT and ME system****ME EQUIPMENT and ME systems requiring the handling of liquids in normal use shall be so constructed that spillage does not wet parts that could result in a hazardous situation.****Compliance is checked 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 application of the RISK MANAGEMENT PROCESS. All test conditions are identified through inspection of the RMF.** |  |
| **11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS****ENCLOSURES of ME EQUIPMENT and ME SYSTEMS designed to give a specified degree of protection against harmful ingress of water or particulate matter shall provide this protection in accordance with the classification of IEC 60529. See also 7.2.9.** |  |
| **11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME systems****ME EQUIPMENT, ME systems and their parts, including applied parts and accessories, shall be capable of withstanding, without damage or deterioration of safety provisions, the cleaning or disinfection processes specified in the instructions for use. See also 7.9.2.12.****The manufacturer shall evaluate the effects of multiple cleanings/disinfections during the expected service life of the ME EQUIPMENT, ME system, their parts and accessories and assure that no unacceptable risk will occur. The results of the evaluation shall be documented in the RMF.** |  |
| **11.6.7 Sterilization of ME EQUIPMENT and ME systems****ME EQUIPMENT, ME systems and their parts or accessories intended to be sterilized shall be assessed and documented according to ISO 11134, ISO 11135 or ISO 11137 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 RMF.** |  |
| **11.6.8 Compatibility with substances used with the ME EQUIPMENT****When applicable, the manufacturer shall address in the RISK MANAGEMENT PROCESS the risks associated with compatibility with substances used with the ME EQUIPMENT.****Compliance is checked by inspection of the RMF.** |  |
| **12.1 Accuracy of controls and instruments****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 RMF.** |  |
| **12.2 Usability****The manufacturer shall address in a usability engineering process the risk of poor usability, including those associated with identification, marking and documents (see 7.1.1 and16.2). See IEC 60601-1-6 and also see 1.3****Compliance is checked by inspection of the results of the USABILITY ENGINEERING PROCESS.** |  |
| **12.3 Alarm systems****When applicable, the manufacturer shall address in the RISK MANAGEMENT PROCESS the need for alarm systems as a means of risk control and address any risks associated with the operation or failure of the alarm system. See IEC 60601-1-8 and also see 1.3****Compliance is checked by inspection of the RMF.** |  |
| **12.4.1 Intentional exceeding of safety limits****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 RMF.** |  |
| **12.4.2 Indication of parameters relevant to safety****When applicable, the manufacturer shall address in the RISK MANAGEMENT PROCESS the need for the indication of parameters that are associated with HAZARDOUS output.****Compliance is checked by inspection of the RMF.** |  |
| **12.4.3 Accidental selection of excessive output values****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 RMF.** |  |
| **12.4.4 Incorrect output****When applicable, the manufacturer shall address in the RISK MANAGEMENT PROCESS the risks associated with incorrect output.****Compliance is checked by inspection of the RMF.** |  |
| **12.4.5.2 Diagnostic X-ray equipment****When applicable, the manufacturer shall address in the RISK MANAGEMENT PROCESS the risks associated with diagnostic X-rays. See IEC 60601-1-3 and also see 1.3****Compliance is checked by inspection of the RMF.** |  |
| **12.4.5.3 Radiotherapy equipment****When applicable, the manufacturer shall address in the RISK MANAGEMENT PROCESS the risks associated with radiotherapy.****Compliance is checked by inspection of the RMF.** |  |
| **12.4.5.4 Other ME EQUIPMENT producing diagnostic or therapeutic radiation****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** **Compliance is checked by inspection of the RMF.** |  |
| **12.4.6 Diagnostic or therapeutic acoustic pressure****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 RMF.** |  |
| **13.2.6 Leakage of liquid** **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 RMF.** |  |
| **14 Programmable electrical medical systems****14.1 General****The requirements of this clause shall apply to pems unless:****– the PESS provides no basic safety or essential performance; or****– the application of ISO 14971 demonstrates that the failure of the PESS does not lead to an unacceptable risk.****Compliance is determined by application of the requirements in 14.2 to 14.13 (inclusive), by inspection of the RMF, and assessment of processes cited in this clause.** |  |
| **14.3 Risk management plan****The risk management plan required by 3.5 of ISO 14971 shall also include a reference to the pems validation plan (see 14.11).** |  |
| **14.4 PEMS development life-cycle****Each milestone shall identify the risk management activities that must be completed before that milestone.** |  |
| **14.6.1 Identification of known and foreseeable hazards****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 NETWORK/DATA COUPLING, components of third-party origin and legacy subsystems.** |  |
| **14.6.2 Risk Control****The following requirements for PEMS supplement Subclause 6.1 of ISO 14971.****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).** |  |
| **14.7 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.** |  |
| **14.8 Architecture****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 NETWORK/DATA COUPLING specification, if applicable.** |  |
| **14.9 Design and implementation****Descriptive data regarding the design environment shall be included in the RMF.** |  |
| **14.10 Verification****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;****– coverage criteria for VERIFICATION.** |  |
| **14.11**  **PEMS validation****A pems validation plan shall include the validation of basic safety and essential performance, and shall require checks for unintended functioning of the pems.****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 RMF.****A reference to the methods and results of the pems validation shall be included in the RMF.** |  |
| **14.13 Connection of PEMS by NETWORK/DATA COUPLING to other equipment**If the PEMS is intended to be connected by NETWORK/DATA COUPLING to other equipment that is outside the control of the PEMS MANUFACTURER, the technical description shall:b) list the HAZARDOUS SITUATIONS resulting from a failure of the NETWORK/DATA COUPLING to provide the specified characteristics; |  |
| **15.1 Arrangements of controls and indicators of ME EQUIPMENT**When applicable, the manufacturer shall address in the RISK MANAGEMENT PROCESS the risks associated with the arrangement of controls and indicators of ME EQUIPMENT.*Compliance is checked by inspection of the RMF.* |  |

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| **15.3.2 Push test**Enclosures of ME EQUIPMENT shall have sufficient rigidity to protect against unacceptablerisk.*Compliance is checked by the following test.**External parts of an enclosure are subject to a steady force of 250 N ± 10 N for a period of 5 s, applied by means of a suitable test tool providing contact over a circular plane surface 30 mm in diameter. However, this test is not applied to the bottom of an enclosure of ME EQUIPMENT having a mass of more than 18 kg.**After the test, any damage sustained that results in an unacceptable risk, as determined by inspection of the RMF, constitutes a failure.* |  |
| **15.3.3 Impact test**Enclosures of ME EQUIPMENT shall have sufficient resistance to impact to protect against unacceptable risk.*Compliance is checked by the following test. See standard.**After the test, any damage sustained that results in an unacceptable risk, as determined by inspection of the RMF, constitutes a failure.* |  |
| **15.3.4.2 Portable ME EQUIPMENT**Portable ME EQUIPMENT and ME EQUIPMENT parts that are portable shall withstand the stress caused by a free fall from the height indicated in Table 27 onto a hard surface.*After the test,* any damage sustained that results in a unacceptable risk, as determined *by inspection of the* RMF and inspection of the ME EQUIPMENT *or the ME EQUIPMENT parts that are* portable, constitutes a failure*.*  |  |
| **15.3.5 Rough handling test**Mobile ME EQUIPMENT and ME EQUIPMENT parts that are mobile shall withstand the stress caused by rough handling and movement and shall not result in an unacceptable risk.*After each test, any damage sustained that results in an unacceptable*risk, *as determined by inspection of the* RMF and inspection of the ME eqiupment *or the ME EQUIPMENT parts* that are mobile, constitutes a failure. |  |
| **15.4.1 Construction of connectors**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 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. b) Medical gas connections on ME EQUIPMENT for different gases to be operated in normal use shall not be interchangeable. See also ISO 407  *Compliance is checked by inspection of the RMF.* |  |

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| **15.4.2.1 a Application** Thermal cut-outs and over-current releases with automatic resetting shall not be used in ME EQUIPMENT if their use could result in a HAZARDous situation by such resetting.*Compliance is checked by inspection of the RMF*. |  |
| **15.4.2.1 b Application** Thermal cut-outs with a safety function that have to be reset by a soldering operation that can affect the operating value shall not be fitted in ME EQUIPMENT.*Compliance is checked by inspection of design documentation and the* *RMF* |  |
| **15.4.2.1 c Application** In ME EQUIPMENT, where a failure of a thermostat could constitute a HAZARD an independent non-self-resetting 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 but shall be within the safe temperature limit for its intended function.Compliance *is checked by inspection of design documentation and the* *RMF* |  |
| **15.4.2.1 d Application** Loss of function of the ME EQUIPMENT caused by operation of a thermal cut-out or over-current release shall not result in a hazardous situation.*Compliance is checked by inspection of design documentation and the**RMF.* |  |
| **15.4.2.1 h Application** 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 design documentation and the RMF.* |  |
| **15.4.3.1 Housing**In ME EQUIPMENT, housings containing batteries from which gases that are likely to result in a HAZARD can escape during charging or discharging shall be ventilated to minimize therisk of accumulation and ignition.Battery compartments of ME EQUIPMENT shall be designed to prevent accidental short circuiting of the battery where such short circuits could result in a HAZARDous situation.*Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.* |  |
| **15.4.3.2 Connection**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. |  |

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| **15.4.3.3 Protection against overcharging**Where overcharging of any battery of ME EQUIPMENT could result in an unacceptable RISK, the design shall prevent overcharging. |  |
| **15.4.3.4 Lithium Batteries**Lithium batteries used in ME EQUIPMENT that could become a HAZARD shall comply with the requirements of IEC 60086-4. See also 7.3.3. |  |
| **15.4.3.5 Excessive current and voltage protection**An internal electrical power source in ME EQUIPMENT shall be provided with an appropriately rated device for protection against fire caused by excessive currents if the cross-sectional area and layout of the internal wiring or the rating of connected components can give rise to a fire in case of a short circuit. Protective devices shall have adequate breaking capacity to interrupt the maximum fault current (including short-circuit current) which can flow. Justification for omission of fuses or over-current releases shall be included in the RMF.*Compliance is checked by inspection for the presence of protective means, and if necessary, by inspection of the design documentation and the RMF.* |  |
| **15.4.4 Indicators****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.** |  |
| **15.4.4 Indicators****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.** |  |
| **15.4.5 Pre-set controls****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 RMF.** |  |

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| **15.4.7.3 Entry of liquids**b) In ME EQUIPMENT, enclosures of foot operated control devices that contain electrical circuits shall be classified at least IPX6 according to IEC 60529 if they are intended for normal use in areas where liquids are likely to be found (such as emergency rooms and operating theatres). The probability of occurrence shall be estimated as part of the RISK MANAGEMENT PROCESS.*Compliance is determined by inspection of the accompanying documents, the design documentation, the RMF and by performing the appropriate tests of IEC 60529.* |  |

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| **16.1 General Requirements for ME Systems**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. |  |
| **16.9.1 Connection terminals and connectors**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 where a HAZARDOUS SITUATION could otherwise exist.– Connectors shall comply with 15.4.1.– Plugs for connection of PATIENT leads 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 HAZARDOUS SITUATION can result. |  |
| **17 Electromagnetic compatibility of ME EQUIPMENT and ME systems**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 RMF.* |  |

| **4.2** | **RM RESULTS TABLE: Risk Management Process for ME Equipment or ME Systems**  |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **3.3a** |  |  |  |
| **3.5e** |  |  |  |
| **4.1** |  |  |  |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.1** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |
| **6.6** |  |  |  |
| **6.7** |  |  |  |
| **7** |  |  |  |

| **4.3** | **TABLE: essential performance** | **P** |
| --- | --- | --- |
| **List of essential performance functions** | **Manufacturer’s document number reference or reference from this standard or collateral or particular standard(s)** | **Remarks** |
| **See Intended use** |  |  |
| **Supplementary Information:**Essential performance is performance, the absence or degradation of which, would result in an unacceptable risk. |

| **4.3** | **RM RESULTS TABLE: Essential Performance** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |

| **4.5** | **RM RESULTS TABLE: Equivalent Safety for ME Equipment of ME System** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** | **N/A** |  | **N/A** |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **4.6** | **RM RESULTS TABLE: ME Equipment or system parts contacting the patient** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **4.7** | **RM RESULTS TABLE: Single Fault Condition for ME Equipment** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |

| **4.8** | **RM RESULTS TABLE: Components of ME Equipment** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **4.9** | **RM RESULTS TABLE: Use of components with high-integrity characteristics** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **5.1** | **RM RESULTS TABLE: Type Tests** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |

| **5.4 a)** | **RM RESULTS TABLE: Other Conditions** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |

| **5.7** | **RM RESULTS TABLE: Humidity preconditioning treatment** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** | **ISO 14971 Risk Management Report Section 4.6** | **Requirement of ISO14971 is met within the RMF.** | **P** |

| **5.9.2.3** | **RM RESULTS TABLE: Actuating mechanisms** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **7.2.2** | **RM RESULTS TABLE: Identification** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.4** |  |  |  |

| **7.2.5** | **RM RESULTS TABLE: ME EQUIPMENT powered from other equipment** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.4** |  |  |  |

| **7.2.13** | **RM RESULTS TABLE: Physiological effects (safety signs and warning)** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.3** |  |  |  |

| **7.2.17** | **RM RESULTS TABLE: Protective packaging** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |

| **7.3.3** | **RM RESULTS TABLE: Batteries** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.3** |  |  |  |

| **7.3.7** | **RM RESULTS TABLE: Supply terminals** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |

| **7.4.2** | **RM RESULTS TABLE: Control devices** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |

| **7.5** | **RM RESULTS TABLE: Safety signs** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** | **ISO 14971 Risk Management Report Section 4.3** | **Requirement of ISO14971 is met within the RMF.** | **P** |
| **4.3** | **ISO 14971 Risk Management Report Section 4.4.4.6** | **Requirement of ISO14971 is met within the RMF.** | **P** |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.3** |  |  |  |

| **7.9.1** | **RM RESULTS TABLE: General accompanying documents (See Table C.4)** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |

| **7.9.2.4** | **RM RESULTS TABLE: Electrical power source** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.3** |  |  |  |

| **7.9.3.2** | **RM RESULTS TABLE: Replacement of fuses, power supply cords, other parts** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **8.1 b(1)** | **RM RESULTS TABLE: Fundamental rule of protection against electric shock- interruption of any one power-carrying conductor** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
| **4.4** |  |  |  |

| **8.1 b(2)** | **RM RESULTS TABLE: Fundamental rule of protection against electric shock- unintended movement of a component** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **8.1 b(3)** | **RM RESULTS TABLE: Fundamental rule of protection against electric shock- accidental detachment of conductors and connectors** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |

| **8.2.2** | **RM RESULTS TABLE: Connection to an external d.c. power sources** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |

| **8.3 d** | **RM RESULTS TABLE: Requirements of Type BF or CF Applied Parts** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **6.2** |  |  |  |

| **8.4.2 c** | **RM RESULTS TABLE: Accessible parts including applied parts** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |

| **8.5.2.2** | **RM RESULTS TABLE: Type B applied parts** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |

| **8.5.2.3** | **RM RESULTS TABLE: PATIENT Leads** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |

| **8.6.3** | **RM RESULTS TABLE: Protective earthing of moving parts** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **8.8.4.1** | **RM RESULTS TABLE: Mechanical strength and resistance to heat** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **8.10.1** | **RM RESULTS TABLE: Fixing of components** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **8.10.2** | **RM RESULTS TABLE: Fixing of wiring** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **8.10.5** | **RM RESULTS TABLE: Mechanical protection of wiring** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** | **ISO 14971 Risk Management Report Section 4.4.4.15** | **Requirement of ISO14971 is met within the RMF.** | **P** |
| **6.3** | **ISO 14971 Risk Management Report Section 4.4.4.15** | **Requirement of ISO14971 is met within the RMF.** | **P** |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **8.11.5** | **RM RESULTS TABLE: Mains fuses and over-current releases** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **9.2.1** | **RM RESULTS TABLE: HAZARDS associated with moving parts - General** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **9.2.2.4.3** | **RM RESULTS TABLE: Movable guards** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **9.2.2.4.4** | **RM RESULTS TABLE: Protective measures** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **9.2.2.5 c)** | **RM RESULTS TABLE: Continuous activation** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **9.2.2.6** | **RM RESULTS TABLE: Speed of movement(s)** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **9.2.3.2** | **RM RESULTS TABLE: Over travel** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **9.2.4** | **RM RESULTS TABLE: Emergency stopping devices** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |
| **6.6** |  |  |  |

| **9.2.5** | **RM RESULTS TABLE: Release of patient** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **9.3** | **RM RESULTS TABLE: Hazards associated with surfaces, corners and edges** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **9.4.2.4.3** | **RM RESULTS TABLE: Movement over a threshold** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **9.5.1** | **RM RESULTS TABLE: Protective means** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **9.6.1** | **RM RESULTS TABLE: Acoustic energy - General** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **9.6.2.2** | **RM RESULTS TABLE: Infrasound and ultrasound energy** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
| **5** |  |  |  |
| **6.2** |  |  |  |
| **6.3** |  |  |  |
| **6.4** |  |  |  |
| **6.5** |  |  |  |

| **9.7.2** | **RM RESULTS TABLE: Pneumatic and hydraulic parts** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
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| **9.7.4** | **RM RESULTS TABLE: Pressure rating of ME equipment parts** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
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| **9.7.6** | **RM RESULTS TABLE: Pressure-control device** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
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| **9.7.7** | **RM RESULTS TABLE: Pressure-relief device** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
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| **9.8.1** | **RM RESULTS TABLE: Hazards associated with support systems - General** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
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| **4.4** |  |  |  |
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| **9.8.2** | **RM RESULTS TABLE: Tensile safety factor** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
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| **9.8.3.1** | **RM RESULTS TABLE: Strength of patient or operator support or suspension systems - General** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
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| **6.5** |  |  |  |

| **9.8.3.2a, b** | **RM RESULTS TABLE: Static forces due to loading from persons** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
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| **6.3** |  |  |  |
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| **6.5** |  |  |  |

| **9.8.4.1** | **RM RESULTS TABLE: Systems with mechanical protective devices - General** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
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| **6.2** |  |  |  |
| **6.3** |  |  |  |
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| **6.5** |  |  |  |

| **9.8.4.3** | **RM RESULTS TABLE: Mechanical protective device for single activation** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
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| **6.5** |  |  |  |

| **9.8.5** | **RM RESULTS TABLE: Systems without mechanical protective devices** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |
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| **6.5** |  |  |  |

| **10.1.2** | **RM RESULTS TABLE: ME equipment intended to produce diagnostic or therapeutic X-radiation** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
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| **6.5** |  |  |  |

| **10.2** | **RM RESULTS TABLE: Alpha, beta, gamma, neutron & other particle radiation** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
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| **6.5** |  |  |  |

| **10.3** | **RM RESULTS TABLE: Microwave radiation** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
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| **6.5** |  |  |  |

| **10.5** | **RM RESULTS TABLE: Other visible electromagnetic radiation** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
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| **10.6** | **RM RESULTS TABLE: Risk associated with infrared radiation other than emitted by lasers and leds** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
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| **6.5** |  |  |  |

| **10.7** | **RM RESULTS TABLE: Risk associated with ultraviolet radiation other than emitted by lasers and leds** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
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| **11.1.1** | **RM RESULTS TABLE: Maximum temperature during normal use (Table 23 or 24)** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **11.1.2.1** | **RM RESULTS TABLE: Applied parts intended to supply heat to patient** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
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| **11.1.2.2** | **RM RESULTS TABLE: Applied parts not intended to supply heat to patient** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
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| **11.1.3** | **RM RESULTS TABLE: Measurements** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **11.2.2.1** | **RM RESULTS TABLE: Risk of fire in an oxygen rich environment** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **11.3** | **RM RESULTS TABLE: Constructional requirements for fire enclosures of ME equipment** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
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| **11.5** | **RM RESULTS TABLE: ME equipment and ME systems intended for use in conjunction with flammable agents** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **11.6.2** | **RM RESULTS TABLE: Overflow in ME equipment** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **11.6.3** | **RM RESULTS TABLE: Spillage on ME equipment and ME system** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
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| **6.5** |  |  |  |

| **11.6.5** | **RM RESULTS TABLE: Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **11.6.6** | **RM RESULTS TABLE: Cleaning and disinfection of ME equipment and ME systems** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **11.6.7** | **RM RESULTS TABLE: Sterilization of ME equipment and ME systems** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **11.6.8** | **RM RESULTS TABLE: Compatibility with substances used**  |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **12.1** | **RM RESULTS TABLE: Accuracy of controls and equipment** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
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| **12.3** | **RM RESULTS TABLE: Alarm systems** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **12.4.1** | **RM RESULTS TABLE: Intentional exceeding of safety limits** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **12.4.2** | **RM RESULTS TABLE: Indication of parameters relevant to safety** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **12.4.3** | **RM RESULTS TABLE: Accidental selection of excessive output values** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
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| **6.5** |  |  |  |

| **12.4.4** | **RM RESULTS TABLE: Incorrect output** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
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| **6.5** |  |  |  |

| **12.4.5.2** | **RM RESULTS TABLE: Diagnostic X-ray equipment** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
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| **12.4.5.3** | **RM RESULTS TABLE: Radiotherapy equipment** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
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| **12.4.5.4** | **RM RESULTS TABLE: Other ME equipment producing diagnostic or therapeutic radiation** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
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| **12.4.6** | **RM RESULTS TABLE: Diagnostic or therapeutic acoustic pressure** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
| **4.4** |  |  |  |
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| **13.2.6** | **RM RESULTS TABLE: Leakage of liquid** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **6.5** |  |  |  |

| **14.1** | **RM RESULTS TABLE: Programmable electrical medical systems - General** |  |
| --- | --- | --- |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
| **4.3** |  |  |  |
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| **14.6.1** | **RM RESULTS TABLE: Identification of known and foreseeable hazards** |  |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.3** |  |  |  |

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| **14.6.2** | **RM RESULTS TABLE: Risk control** |  |
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **6.1** |  |  |  |

| **14.7** | **RM RESULTS TABLE: Requirement specification** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **6.3** |  |  |  |

| **14.8** | **RM RESULTS TABLE: Architecture** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **6.3** |  |  |  |

| **14.9** | **RM RESULTS TABLE: Design and Implementation** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **14.10** | **RM RESULTS TABLE: Verification** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **6.3** |  |  |  |

| **14.11** | **RM RESULTS TABLE: PEMS validation** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **14.13** | **RM RESULTS TABLE: Connection of PEMS by NETWORK/DATA COUPLING to other equipment** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **15.1** | **RM RESULTS TABLE: Construction of ME equipment – Arrangements of controls and indicators of ME equipment** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **15.3.2** | **RM RESULTS TABLE: Push test** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **15.3.3** | **RM RESULTS TABLE: Impact test** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **15.3.4.2** | **RM RESULTS TABLE: Portable ME equipment** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **15.3.5** | **RM RESULTS TABLE: Rough handling test** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **15.4.1** | **RM RESULTS TABLE: Construction of connectors** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **15.4.2.1 a** | **RM RESULTS TABLE: thermal cut-outs and over-current releases**  |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **15.4.2.1 b** | **RM RESULTS TABLE: Thermal cut-outs with a safety function** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **15.4.2.1 c** | **RM RESULTS TABLE: Independent non-self-resetting thermal cut-out** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **15.4.2.1 d** | **RM RESULTS TABLE: Loss of function of me equipment**  |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
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| **15.4.2.1 h** | **RM RESULTS TABLE: Me equipment with tubular heating elements** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
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| **15.4.3.1** | **RM RESULTS TABLE: Housing** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **15.4.3.2** | **RM RESULTS TABLE: Connection**  |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
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| **15.4.3.3** | **RM RESULTS TABLE: Protection against overcharging** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **15.4.3.4** | **RM RESULTS TABLE: Lithium batteries** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
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| **15.4.3.5** | **RM RESULTS TABLE: Excessive current and voltage protection** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
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| **15.4.4** | **RM RESULTS TABLE: Indicators** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
| **4.2** |  |  |  |
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| **15.4.5** | **RM RESULTS TABLE: Pre-set controls** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **16.1** | **RM RESULTS TABLE: General requirements for ME Systems** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **16.9.1** | **RM RESULTS TABLE: Connection terminals and connectors** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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| **17** | **RM RESULTS TABLE: Electromagnetic compatibility of ME equipment and ME systems** |  |
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| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. & paragraph)** | **Result - Remarks** | **Verdict** |
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