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Magnetic resonance conditionality applications: EU requirements and supporting standards

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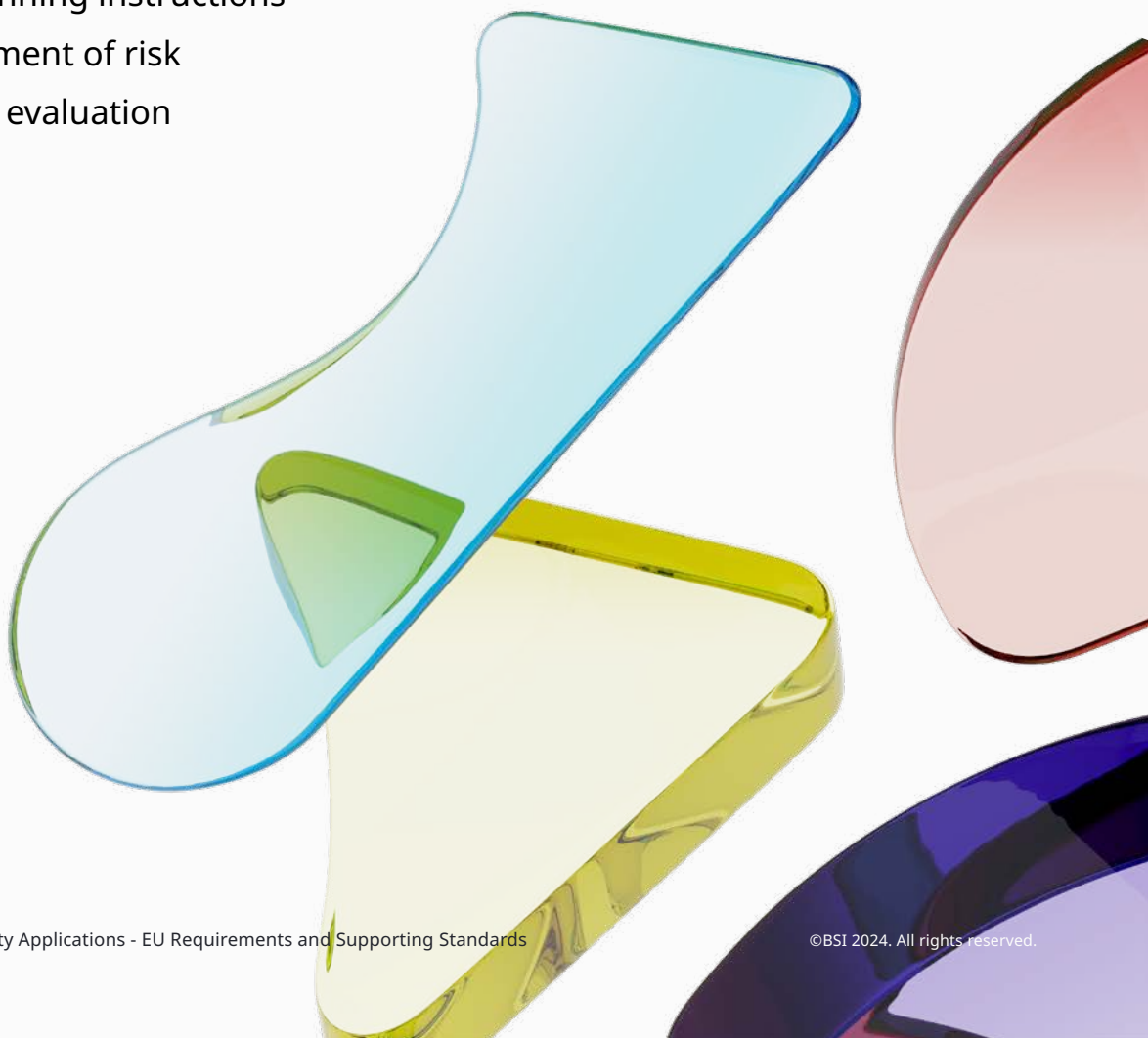
Contents



Overview

An application for Magnetic Resonance (MR) conditionality adds new features to the device, along with new clinical benefits, and the potential for new side effects and risks. Applications for MR conditionality shall be evaluated for impact to all General Safety and Performance Requirements (GSPRs) of the EU Medical Devices Regulation (MDR) and must evaluate all benefits and risks of the device being scanned in MR. Evaluations must be scientifically valid and be supported by sufficient preclinical and clinical analysis.

Devices that are MR Conditional are those for which the clinical safety and performance has been adequately demonstrated, in the MR environment, under specific conditions of scanning. Devices and MR Conditional information provided to the clinician, technician, and end-users, must have been evaluated through pre-clinical and clinical evaluation such that it is proven the clinical benefit of the device with MR Conditional labelling outweighs the additional risks, risks have been reduced as far as possible, and that performance and safety are in line with the generally acknowledged state-of-the-art.

Benefits and performances of the device will include:

- The ability to perform MR scans of target areas to acquire images of meaningful diagnostic quality
- Correct and safe behaviour of the device during and after an MR scan

Undesirable characteristics of the device present in the scanner may include:

- Heat, forces, torques, and voltages created by the device's presence within the scanner
- Unintended behaviour and/or malfunction of the device in the vicinity of the scanner
- Unintended interactions between the device and other present (including implanted) devices, causing unintended behaviour of either device
- Interference with the image acquisition, either because of the device or because of restrictions imposed on the scanning protocol, causing artefacts and/or images of insufficient diagnostic quality

Risks of scanning may consequently include:

- Risks of harm consequent of each of the undesirable characteristics exhibited during labelled scanning, i.e., seen even with proper preparation and under conditions specified within the IFU
- Risks of harm consequent of undesirable characteristics of the device in the scanner, if the device is unintentionally scanned without proper preparation, and/or under conditions outside of those specified in the IFU
- Risks of harm due to an incorrect or missed diagnosis of conditions consequent of artefacts or distortions to the image

As with all other aspects of the device, evaluations of risk should be supported by evidence, such as:

- Full characterization to applicable standards of the device within the scanner
- Technical evaluation validating usability of the scanning instructions, when used by the intended user
- Full, scientifically-backed, clinical evaluation to support the benefit of scanning and the acceptability of side effects and associated risks, including a full and ongoing comparison to state-of-the-art
- A plan to confirm benefits and risks of MR Conditional labelling in the clinical environment after certification

This paper provides an overview of these regulatory requirements and the standards that support them.

Requirements of the EU Medical Devices Regulation

Introduction

The European Medical Devices Regulation 2017/745 (MDR) dictates in Annex I general safety and performance requirements (GSPRs) to which the manufacturer shall demonstrate compliance. In particular, requirements to demonstrate the performance and safety of the device when subjected to specified external environmental conditions are included.

To achieve this the regulations specify that harmonised standards have a role in demonstrating conformity. Article 8 indicates that harmonised standards are those referenced in the Official Journal of the European Union. In the absence of a harmonised standard, or when the harmonised version of the standard is superseded by a later version, it is expected that the latest applicable standards are considered as part of the analysis against the state-of-the-art.

There are multiple relevant standards for medical device behaviour and safety in an MR environment that have not been harmonised to the MDR at the time of publication of this white paper.

In the absence of a harmonised standard, they may be used to evaluate the completeness of device characterization. In particular ISO/TS 10974:2018, which at this time is still a technical specification rather than a standard, and applicable only to 1.5T closed bore MR scanners and Active Implantable Medical Devices. With careful consideration however, it may act as a guide to help characterize the behaviourof a wide range of implantable and patient contacting medical devices, in 1.5T closed bore and other scanner types. Additionally, the next version of 10974, whilst still focussing on AIMD, is to be a full standard and is expected to expand its scope to include 3T closed bore scanners.

Some GSPRs, and their equivalent Essential Requirements (ER), that may be impacted by an MR Conditional application are listed below. This list should not be considered exhaustive. The manufacturer shall perform their own impact analysis to the GSPRs.

MDR GSPR

1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.

They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, considering the generally acknowledged state-of-the-art.

MDD ER: 1, 2, 3 | AIMDD ER: 1, 2, 3

Remarks

Benefits and performances of the device will include:

- The ability to perform MR scans of target areas, to acquire images of meaningful diagnostic quality
- Correct and safe behaviour of the device during and after an MR scan

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3. Manufacturers shall establish, implement, document, and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:

a Establish and document a risk management plan for each device.

b Identify and analyze the known and foreseeable hazards associated with each device.

c Estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse.

d Eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4.

e Evaluate the impact of information from the production phase and from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability.

f Based on the evaluation of the impact of the information referred to in point (e), if necessary, amend control measures in line with the requirements of Section 4.

MDD ER: – | AIMDD ER: –

Remarks

As covered by expected compliance to EN ISO 14971, the manufacturer shall establish a risk management system.

For this application, it is anticipated that there will be an impact to the risk analysis regarding:

b Known & foreseeable hazards

c Evaluations of risks occurring use, and foreseeable misuse

d Elimination and control of risks where possible

A plan is also expected to encompass an evaluation of impact (e,f) from Post Market Data.

4. Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state-of-the-art.

To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable.

In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:

a Eliminate or reduce risks asfar as possible through safe design and manufacture.

b Where appropriate, take adequate protection measures, including alarms, if necessary, in relation to risks that cannot be eliminated.

c Provide information for safety (warnings, precautions, contra-indications) and where appropriate, training to users.

Manufacturers shall inform users of any residual risks.

MDD ER: 2 | AIMDD ER: 6

Remarks

All appropriate risk control measures should be considered and where possible implemented.

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5. In eliminating or reducing risks related to use error, the manufacturer shall:

b Consider the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (i.e., design for lay, professional, disabled, or other users.)

MDD ER: 4 | AIMDD ER: –

Remarks

EN 62366
It is expected that any risks related to potential misuse of the device are minimized as far as possible. Evidence shall be presented, where possible to verify that risks have been minimized.

In cases where it is not self-explanatory or risk due to misuse is evaluated to be appreciable, it will be expected that an evaluation of usability shall be performed on any new features and the instructions provided.

Whilst AIMD does not explicitly call out usability in their ERs, safety in normal use (ER1) is dependent on the usability of the IFU.

6. The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

MDD ER: 4 | AIMDD ER: 3

Remarks

It shall be considered how the device will behave in the MR environment at different stages of its lifetime including after the device has stopped delivering clinical benefit to the patient and may be in an indetermined or faulty state. Consider conditions such as an IPG in a state of depletion, or a fractured lead which may not be able to be fully explanted.

Appropriate mitigations will be implemented to minimize risk as far as possible (AFAP).

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8. All known and foreseeable risks, and any undesirable side-effects, shall be minimized and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from achieved performance of the device during normal conditions of use.

MDD ER: 6 | AIMDD ER: 5

Remarks

"Normal conditions of use" now includes MR Conditional scanning. Device design is expected to minimize risks and side effects associated with this new condition of use. Residual risks shall be justified as acceptable, when weighed against the performance.

14.2 Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:

b Risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences.

f The risks of reciprocal interference with other devices normally used in the investigations or for the treatment given.

MDD ER: 9.2 | AIMDD ER: 8

Remarks

ASTM F2052, ASTM F2119, ASTM F2182, ASTM F2213

Listed standards provide testing information to determine device characteristics in the fields present in and generated by an MR scanner. It is expected that all characteristics are known and justified to be clinically acceptable as part of a clinical evaluation, including a comparison to the state of the art.

Image artefacts must be evaluated and well-characterised for a risk-benefit assessment of performing an MR scan.

17.2 For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state-of-the-art considering the principles of development life cycle, risk management, including information security, verification and validation.

MDD ER: 12.1a | **AIMDD ER: 9** (last indent)

Remarks

EN 62304 EN 60601-1

Devices may need to be put into a safety critical MR "safe mode" before scanning. It must be demonstrated that any software modifications are risk assessed, developed, verified, and validated in accordance to state-of-the-art.

23.1 General requirements regarding the information supplied by the manufacturer:

a The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the device, its intended purpose and the technical knowledge, experience, education, or training of the intended user(s). Instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.

f Instructions for use may be provided to the user in non-paper format (e.g., electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation.

h Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognized symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.

MDD ER: 13.1 and **13.2**
AIMDD ER: 13 and **15** (6th indent)

Remarks

EN 62366-1, EN 60601-1-6, ISO/TS 10974, ASTM F2503

The following shall be implemented and appropriately verified:

MRI scanning instructions shall be complete and clear, written for the intended user, for instance the clinician, technologist, and/or user, such that it is clear how conditions are implemented.

Residual risks, including those due to misuse (scanning outside of conditions), must be reported clearly, so it is understood what harms may occur if instructions are not followed.

The risk of interference of the device with imaging, in particular artefacts occurring consequent of the device being in place, shall be considered and clearly relayed via the IFU along with any precautionary measures that may be taken to reduce this interference.

MR Conditional and Unsafe symbols as per ASTM F2503 shall be displayed as appropriate on all parts of the device and accessories such as programmers and remote controls.

23. 4 Information in the instructions for use:

g Any residual risks, contra-indications undesirable side-effects, including information to be conveyed to the patient in this regard.

k The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer.

s Information that allows the user and/or patient to be informed of any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device.

The information shall cover, where appropriate:

Warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature.

Warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment.

MDD ER: 2, 13.6(d), 13.6(k-m)
AIMDD ER: 15 (Part 2)

Remarks

EN 62366-1, EN 60601-1-6, ISO/TS 10974, ASTM F2503

The following shall be implemented and appropriately verified:

MRI scanning instructions shall be complete and clear, written for the intended user, for instance the clinician, technologist, and/or user, such that it is clear how conditions are implemented.

Residual risks, including those due to misuse (scanning outside of conditions), must be reported clearly, so it is understood what harms may occur if instructions are not followed.

The risk of interference of the device with imaging, in particular artefacts occurring consequent of the device being in place, shall be considered and clearly relayed via the IFU along with any precautionary measures that may be taken to reduce this interference.

MR Conditional and Unsafe symbols as per ASTM F2503 shall be displayed as appropriate on all parts of the device and accessories such as programmers and remote controls.

Application of Medical Devices as MR Conditional

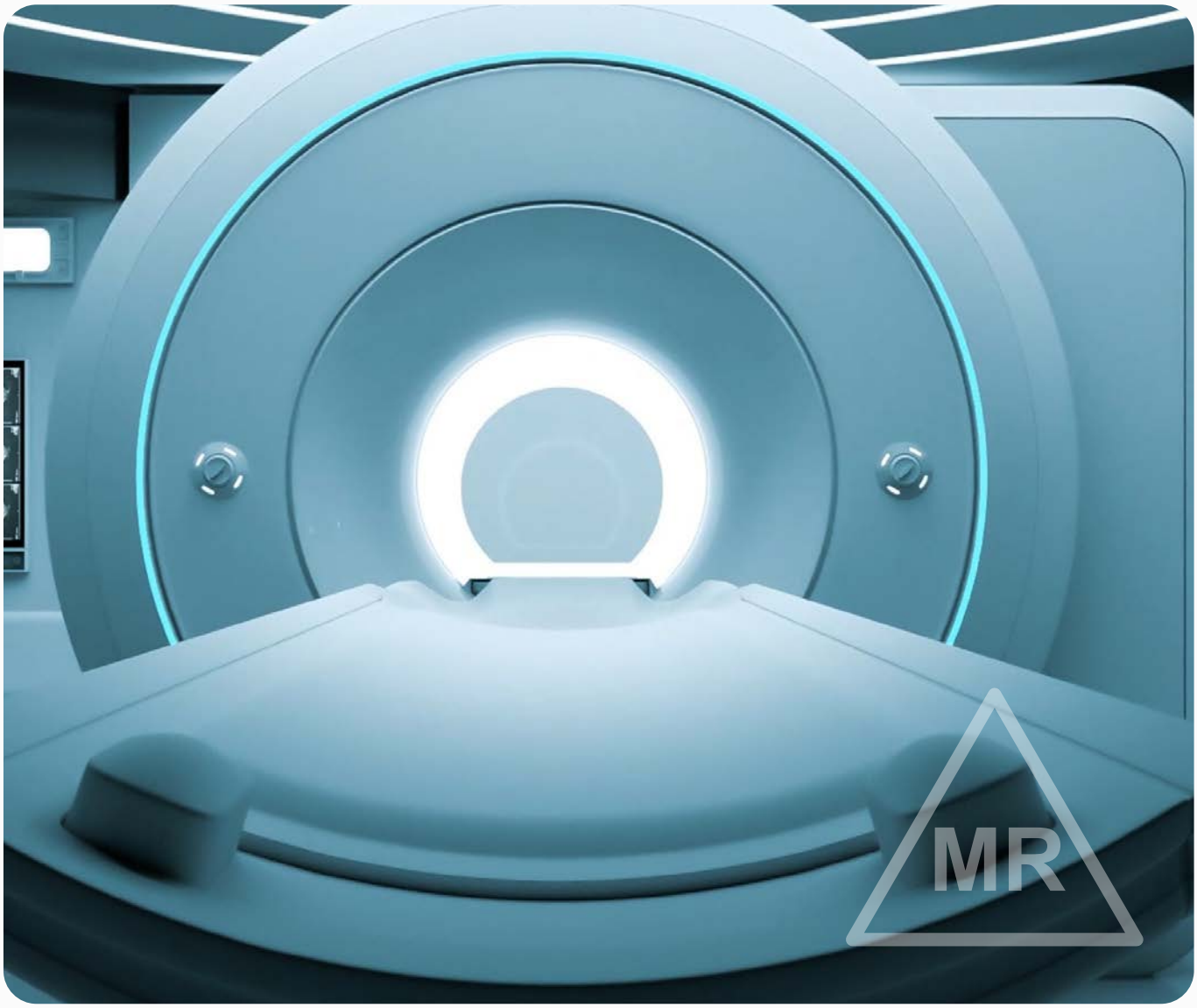
Introduction

The MR environment presents unique safety hazards for patients and people with medical devices near or inside an MR system. Ensuring safety and performance for implants and other devices intended to enter an MR environment should be an integral part of any application.

An application for MR conditionality shall therefore be considered a significant design change for a device, as MR conditionality is a new device feature with its own performances and risks.

MR conditionality has an impact on many areas of the technical documentation and will require ongoing evaluation in order to maintain expectations set by the state-of-the-art.

This section provides examples of considerations that may be made. It shall not be considered an exhaustive list. The manufacturer shall perform their own analyses.



Consideration of Standards and Guidelines

Below is an example of standards and other documents that may be considered during an application for MR conditionality. Please note that, at the time of publication, European standards listed are not yet harmonised to the MDR. The manufacturer must ensure that, at the time of submission, compliance to the current harmonised standards (or accepted state-of-the-art) and MDR is demonstrated.

ISO/TS 10974:2018[1]	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device.
ASTM F2052	Standard test method for measurement of magnetically iinduced displacement force on medical devices in the magnetic resonance environment.
ASTM F2119[2]	Standard test method for evaluation of MR image artefacts from passive implants.
ASTM F2182	Standard test method for measurement of radio frequency induced heating on or near passive implants during magnetic resonance imaging.
ASTM F2213	Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment.
ASTM F2503	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment.
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices.
EN 62366:2008 (EN 62366-1:2015)	Medical devices - Application of usability engineering to medical devices.
EN 60601-2-33:2010 +A12:2016	Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.
MEDDEV 2.7.1 Rev.4[3]	Clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42/eec and 90/385/eec.
FDA-2019-D-283[4]	Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, Guidance for Industry and Food and Drug Administration Staff, MAY 2021.

Note 1: As of the date of the issuance of this guidance, ISO/TS 10974 contained extensive information addressing the introduction of active implantable medical devices (AIMDs) into the 1.5T MR environment. While the scope is currently limited, it contains detailed information about hazards for medical devices in the MR environment and methods for assessing specific hazards that may be applicable for other types of medical devices.

Note 2: This standard has been withdrawn and there is no replacement at the time of publication of this white paper. It therefore no longer represents the state of the art in artefact characterisation. The manufacturer will need to carefully consider any replacement standard, and/or how to characterise image artefacts surrounding the medical device most effectively.

Note 3: The guidance MEDDEV 2.7.1 Rev. 4 is superseded in parts by the requirements of the MDR. Please refer to Appendix I of MDCG 2020-6 for guidance as to relevant parts.

Note 4: Whilst this is not a European standard or guidance, and may contain some irrelevant information, the FDA guidance on MR testing may still provide some additional valuable guidance on how to evaluate a medical device for safety in the MR environment.

Establishment of requirements

As with all design aspects, requirements should be set around clinical needs and safety and performance, and considering the state-of-the-art: i.e., establishment and consideration of the generally acknowledged state-of-the-art, MR Conditional parameters of other devices, accompanying guidance etc.

SAFETY	Heating, forces, torques, induced voltages, etc. that may be tolerated by the patient without discomfort or injury, in all conditions the patient may be scanned in, including the possibility of a raised temperature, impaired physiological state impacting safety thresholds or thermoregulation, or immediately after surgery.
PERFORMANCE	Modes and functionality required of the device during the scan. Diagnostic image requirements and acceptable limitations that will ensure that the benefit outweighs the risk.
CONDITIONS OF SCANNING	Types of scanners, tesla strengths, coil types, magnetic gradients, slew rates, SAR (and $B1_{+rms}$), patient positioning, scan times, pre and post conditioning conditions, and any other conditions required for the safe scanning with the device in situ, to get the diagnostic images required.

Characterization of device hazards in the scanner

Considering ISO/TS 10974:2018, ASTM F2052, ASTM F2119, ASTM F2182, ASTM F2213:

- Establishment of expected device behaviour within the scanner, and a clear analysis of which tests are required and which test method is most appropriate for the device (e.g., with RF heating, several different test methods are available)
- Testing of a device to the appropriate standards and establishing worst-case device behaviour in MR conditions in all relevant device states
- Establishment of conditions under which the device may be scanned, whilst still meeting safety requirements

The next section outlines the different hazards that may present themselves within a scanner.

Design and validation of MR scanning instructions

ISO/TS 10974:2018	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device, Clause 18, Markings and accompanying documentation.
EN 62366:2008 (EN 62366-1:2015)	Medical devices - Application of usability engineering to medical devices.

Considering the requirements of MDR and all relevant standards:

- Design of the IFU in compliance to applicable standards, providing clear information
- Clear reporting of all identified residual risks applicable to MR conditionality
- Clear conveyance of limitations of image quality/location that will be achieved consequent of the device in situ
- Validation of all steps required to perform a safe scan, for instance via a usability study compliant to ISO 62366, including:
  - Correct preparation of the device for scanning
  - Understanding conditions and taking all precautions necessary during scanning
  - Confirm availability of IFU to MR scanning centres and clinicians and how it is made available
- Confirm implant card, e.g., provides information to allow implanted device and accessories to be identified and scanned correctly
- Confirm MR Conditional labelling is correctly applied and MR Unsafe labelling applied where accessories to the device have not been shown to be safe under MR conditions

Assessment of risk

ISO 14971:2019	Medical devices - Application of usability engineering to medical devices.

Considering all evidence available, risks are mitigated AFAP via design, and ensuring residual risks are identified and appropriately reported:

- Risks associated with scanning according to conditions
- Risks associated with scanning off label, where certain aspects of the conditions of scanning are misinterpreted or ignored

Clinical evaluation

MDR ANNEX XIV	Clinical evaluation and post-market clinical follow-up
MEDDEV 2.7.1 Rev 4	Clinical evaluation: a guide for manufacturers and Notified Bodies under directives 93/42/EEC and 90/385/EEC
MDCG 2020-6	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC A guide for manufacturers and Notified Bodies

Clinical evaluation of clinical risks and benefits of scanning the device including:

- Evaluation of scanning conditions against current state-of-the-art
- Evaluation of device characteristics within the scanner, and potential risks to the patient
- Evaluation of quality of imaging achievable with device in situ
- Acceptability of residual risks given benefit of MR Conditional labelling

A plan to maintain current knowledge of the state-of-the-art in regard to MR, e.g., with an appropriate protocol to capture literature on state-of-the-art devices' behaviour in MR.

A plan to maintain current knowledge of the subject device, e.g., with an appropriate protocol to capture literature on the subject device and equivalents' behaviour in MR.

An appropriate PMCF plan to close gaps in clinical knowledge of the subject device, i.e., to collect sufficient clinical evidence to confirm device performance and safety in the MR environment.

Characterization of hazards for medical devices in the MR environment

Introduction

Standards considered may include ISO/TS 10974:2018, ASTM F2052, ASTM F2119, ASTM F2182, ASTM F2213.

The scanner "environment" includes three principal fields:

1. A high tesla "B0" static magnetic field, which for most scanners is always-on. This means that the hazards related to this field are always present. Typical horizontal closed bore scanners most commonly exhibit tesla strengths of 1.5 or 3 Tesla. As well as field strength, the maximum spatial field gradient (how quickly the magnetic field drops off with distance from the scanner) is an important factor and can be up to 20 T/m in a 1.5 Tesla scanner.
2. A high-speed time varying gradient magnetic field, switching in the order of 100's of Hz, present transiently during the scan. Maximum slew rate, measured in Tesla / Metre / Second, is an important variable, along with switching frequency. The maximum slew rate seen in modern scanners is around 200 T/m/s per axis. The slew rate is used along with the implant radial position, to calculate the worst-case rate of change of the magnetic field (dB/dt) at the implant location.
3. An RF electromagnetic field in the range of megahertz (frequency is proportional to the strength of the static magnetic field ~64MHz in a 1.5T scanner, ~128MHz in a 3T scanner). Historically RF field strength is normally measured in relation to average power absorption density in the body (Specific Absorption Rate: SAR) and is typically limited to 2W/kg whole-body SAR (wbSAR) and 3.2 W/kg head SAR (hSAR) in Normal operating mode, but can reach up to 4W/kg in First Level Controlled operating mode. $B1_{+rms}$ is a newer parameter used to characterize average RF field strength more directly.

This section summarizes the main ways the scanner environment can impact the device causing undesirable effects that consequently impact the patient the device is in contact with or implanted inside.

All aspects shall be considered, for all types of scanners intended to be included in the labelling. Results are not automatically transferrable between scanner types due to each scanner type presenting a unique combination of fields. Additionally, scanner properties vary between manufacturer and generation. It is important that any variations are taken into account when considering each aspect.

Multiple tests to characterize a property are available. One or other may be more, generally suitable for different types of medical devices or where the perceived risk is higher or lower. Some tests sacrifice accuracy for ease of implementation and overestimate the property. Some tests are more accurate, at a cost to complexity and the consequent possibility that incorrect implementation may invalidate the result.

Clear rationales for the selection and types of testing performed are required. Testing may not be required if an adequate scientific rationale is provided in the case where there will clearly be no impact.

It should be noted that testing provides a characterization of device behaviour but do not on their own provide proof of device safety in the scanner. The manufacturer is required to perform a full analysis, as exampled in the previous section to justify any claims of safety and performance.

Static field related hazards

The principal field of the MR scanner is a strong, magnetic field in the order of several Tesla. They can be permanent magnets or electromagnets with either standard, or superconducting coils. These can be in an open or closed bore configuration, i.e., the sides of the scanner may be open with the magnet above and below the patient or the patient may be inserted into the closed cylindrical bore of the magnet via a table. Except for the electromagnet with a standard coil, the static magnetic field is always present. It should be assumed with all systems that this is the case, as where it is possible with the standard coil electromagnet to switch the field off, it is not in practice done often as it can take ½ hour or longer to achieve a field stable enough to scan, when it is switched back on.

In general, open bore scanners are of lower Tesla strengths and closed bore scanners are of higher strengths. A higher Tesla, closed bore scanner can acquire higher quality images in equivalent scan time. Open bore scanners, on the other hand, may be preferable for particular scan types, may aid accessibility and may be suitable for some paediatric patients, or patients who suffer from claustrophobia. The most common scanner type that is considered for MR conditionality is the 1.5T, closed bore, superconducting coil scanners, with 3T closed bore scanners becoming more popular in clinics in recent years. High Tesla magnetic fields can impose significant torques on a medical device.

In addition to the strength of the static magnetic field, the spatial gradient of the static magnetic field is a key MR scanner characteristic that varies between scanner type, manufacturer and model and that principally determines the magnitude of the force exerted on a device. In modern scanners the spatial gradient is in the order of T/m, and typically is at a maximum near the scanner, just outside of the bore of the scanner.

Forces and torques imposed on a device may cause direct mechanical harm to the patient. Forces and torques on device components can cause medical devices to malfunction.

The manufacturer is expected to evaluate the effect of the static field on their device as follows.

Force

ISO/TS 10974:2018	**Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device,** Clause 11, protection from harm to the patient caused by B0-induced force. Clause 11 does not provide significantly more information and guides the reader to ASTM F2052.
ASTM F2052	**Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment** Provides a method by which the force exerted on a device due to the magnetic field can be measured. However, it is only useful for devices where the exerted force is in the same order of the device weight or less. If much greater forces are exerted, then the test may need to be modified. The manufacturer is responsible for justifying any changes to the test method. The manufacturer shall relate the measured force to the maximum likely experienced force in a scanner via an appropriate and justified method. Provides an assumption, not an acceptance criterion, that the risk imposed for a force less than the force of gravity, would not be any greater. For any maximum likely force predicted, the manufacturer must provide a scientifically and clinically backed justification of acceptability, considering all possible clinical conditions of the patient.

Impact

Both the magnetic field and its gradient induce forces on magnetic materials. This force may cause pressure on the patient's tissue, or cause displacement of the device itself, injuring the patient and/or affecting device function.

Torque

ISO/TS 10974:2018	**Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device**, Clause 12 Protection from harm to the patient caused by B0-induced torque. Clause 12 does not provide significantly more information and guides the reader to ASTM F2113.
ASTM F2213	**Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.** Provides methods by which torque may be measured. The Manufacturer is responsible for justifying the method chosen. Provides an assumption, not an acceptance criterion, that the risk for a torque less than that imposed by gravity, would not be any greater. For the maximum torque predicted, the manufacturer must provide a scientifically and clinically backed justification, considering all possible clinical conditions of the patient.

Impact

Torque occurs principally where the magnetic field is strongest, nominally at the centre of the bore of the magnet. Torque occurs as magnetic components attempt to align with field contours. This torque may cause pressure on the patient's tissue, or cause displacement of the device itself, injuring the patient and/or affecting device function. function.

Device malfunction

ISO/TS 10974:2018	**Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device.** Clause 14 Protection from harm to the patient caused by B0-induced malfunction.

Impact

Device malfunction due to interaction with magnetic fields is observed in both active and passive medical devices and is possible in cases where ferromagnetic, or magnetic, components make up part of the device, as well as any electronic components that are sensitive to magnetic fields. ISO/TS 10974:2018 provides some guidance for AIMDs which is of limited relevance to non-active devices. Manufacturers are expected to evaluate the possibility of device failure because of static magnetic field or provide a clear scientific justification why no failure can be expected.

Time-varying gradient magnetic field related hazards

During the scan, on top of the static magnetic field is generated a magnetic gradient that switches in the order of several hundred Hz to kHz. This time varying magnetic field can induce currents in wires, coils and metallic plates of significant surface area. These currents can cause heating of the device, vibrations, or unintended stimulation of the patient. In general, the magnetic field varies greatest and fastest towards the edges of the scanner. It may be possible to position the device to minimize the effect of the field on the device at the cost of more complex instructions, and the risk that they are not properly followed.

ISO/TS 10974:2018 considers the effects of the time-varying gradient magnetic field on AIMDs, but some aspects are also relevant to other devices. In the absence of a more relevant standard, the manufacturer should consider the tests in ISO/TS 10974:2018 to characterize the behaviour of devices due to the time-varying gradient magnetic field.

The manufacturer is expected to evaluate the effect of the time-varying gradient magnetic field on their device in the following areas.

Device heating

ISO/TS 10974:2018	**Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device.** Clause 9 Protection from harm to the patient caused by gradient-induced device heating. Provides formulae to estimate deposition of power in devices with a significant surface area, and estimations as to where the greatest heating may be observed within a scanner. This clause also provides tiered tests of varying complexity to establish likely heating observed within MR.

Impact

Switching gradient magnetic fields will induce eddy currents in conductive enclosures, coils or devices with a significant conductive surface area. Examples of this may be enclosures of a pacemaker or implanted drug infusion pump, metallic meshes and other orthopaedic implants. Eddy currents will in turn cause heating of the device. Excessive heating when in contact with sensitive tissues may cause patient injury.

The manufacturer is expected to consider device heating due to eddy currents in the overall evaluation of the device for MR conditionality. In cases where heating is likely, the manufacturer should perform analyses to establish the extent of any heating. If no testing is deemed necessary, justifications must be supplied.

Device vibration and malfunction

ISO/TS 10974:2018	**Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device.** Clause 10 Protection from harm to the patient caused by gradient-induced vibration. Provides two methods by which a device may be tested for vibration, via direct testing within the scanner, or via a shaker table mimicking vibrations observed within the scanner.

Impact

Devices prone to eddy currents, e.g., devices with large metallic surfaces, may also be prone to vibration in the scanner. This is due to an interaction with the magnetic field generated by eddy currents and the static magnetic field. This vibration will be in the order of 100's of Hz, at the same speed of the switching coil, and as such is different in nature to vibrations experienced in transportation.

Vibration may cause a patient injury if it causes the device to malfunction and/or if the device is in contact with sensitive membranes or organs of the patient.

The manufacturer is expected to consider Device vibration in the overall evaluation of the device for MR Conditionality.

Unintended stimulation

ISO/TS 10974:2018	**Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device**. Clause 13, Protection from harm to the patient caused by gradient-induced extrinsic electric potential. Clause 13 provides the theory and testing requirements for devices that may be prone to unintended stimulation.

Impact

Unintended stimulation is a phenomenon only likely to be seen in AIMDs or Active Devices in contact with the patient (and intended to provide electrical energy to the patient in normal operation). Unintended stimulation occurs typically with the combination of an electrode in contact with the patient and attached to a coil and/or nonlinear electric circuit.

The manufacturer is expected to consider unintended stimulation due to the Time Varying Gradient Magnetic Field in the overall evaluation of the device for MR conditionality. In cases where unintended stimulation is possible, the manufacturer should perform analyses to establish the extent, considering ISO/TS 10974:2018 in the absence of more relevant standards. If no testing is deemed necessary, a justification must be provided.

RF field hazards

The RF field is used to excite nuclei (typically hydrogen) during MR scans; the energy returned later in the form of a signal which is read to generate the MR image. The RF field is either generated and read via a Transmit/Receive (T/R) “body” coil which is surrounding the patient in the scanner itself, or it is delivered and/or read via various types of “local” coils designed to focus the RF signal onto the volume of interest. The frequency of the RF field is directly proportional to the strength of the static field. For 1.5T hydrogen imaging the frequency is nominally 64MHz, for 3T scanners around 128MHz.

There are several methods by which the device RF exposure may be limited, which includes the limitation of the SAR of the scan, usage of local T/R coils, or limiting scans to parts of the body. However, this comes at a cost of reduced performance (i.e., reduced quality of imaging), and areas where imaging is impossible (e.g., around the device itself) and increased risk, (i.e., increased complexity of instructions), and the risk that instructions may not be properly followed.

RF effects are particularly complex to evaluate. At every stage there must be careful review and justification of methods chosen and assumptions made.

To know more on testing methods refer to:

- ASTM F2182 - provides testing methods to evaluate RF heating for passive devices, however the methods are limited and may not be suitable for all devices
- ISO/TS 10974:2018 - Provides several types of tests for heating, unintended stimulation, and device malfunction, that may be used to evaluate both passive or active devices. Tests vary in complexity, required computational resource, and accuracy.

RF heating

ASTM F2182	**Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging.** Provides testing methods to evaluate RF heating for passive devices; however the methods are limited and are not suitable for all devices.
ISO/TS 10974:2018	**Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device**. Clause 8, Protection from harm to the patient caused by RF-induced heating. Clause 8 provides several types of test for heating that may be used to evaluate both passive or active devices. The test range in complexity, the intensity of resource, and accuracy.

Impact

Any conductive structure may act as an antenna and hence absorb or focus the RF energy in small volumes of tissue, causing excessive heating. This heating, which happens for instance around tips of leads or ends of metallic structures such as screws, vascular stents, or orthopaedic implants, may damage the surrounding tissue, especially if the device is in contact with sensitive structures. The consequence may be patient injury including mental or physical impairment, or the reduction of efficacy of therapy in the case of Active Implantable stimulation devices. The behaviour is dependent on RF frequency, and so characterizations performed at one frequency do not mean that assumptions of similar performance can be made at other frequencies. It, therefore, is not generally accepted that tests performed for one type of scanner are applicable to another.

Additionally, if devices are commonly implanted with other devices, or multiples of the same device used, then there may be interaction at the RF scale that increase the hazard.

The manufacturer is expected to consider the potential for RF heating with their device and to carefully evaluate any potential mitigations required to keep RF heating to an acceptable level. If mitigation is required, risk benefit and usability analyses shall be performed, and clinical follow-up proposed where it is necessary to confirm the efficacy of mitigations. If no testing is deemed necessary, justifications must be provided.

Unintended stimulation

ISO/TS 10974:2018	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device. Clause 15, Protection from harm to the patient caused by RF-induced malfunction and RF rectification Provides a table to identify situations where stimulation or malfunction are likely, and three different methods by which unintended stimulation and device malfunction may be evaluated, and provides detailed tests by which device behaviour under RF may be characterized.

Impact

RF unintended stimulation is only likely to be observed with active devices with electrodes and electronic systems. Unintended stimulation and device malfunction may lead to inappropriate or lack of therapy, which may have severe consequences for the patient's physical health.

RF Device Malfunction is only likely to be observed within active devices with electronic systems, or passive devices with parts that are sensitive to the temperature rise caused by RF heating.

The manufacturer is expected to consider the potential for RF unintended stimulation or malfunction with their device, evaluate under worst case conditions, and to carefully evaluate any potential mitigations required to keep risk to an acceptable level. In the case that mitigation is required, risk benefit and usability analyses shall be performed, and clinical follow-up is proposed where it is necessary to confirm the efficacy of mitigations. If no testing is deemed necessary, justifications must be provided.

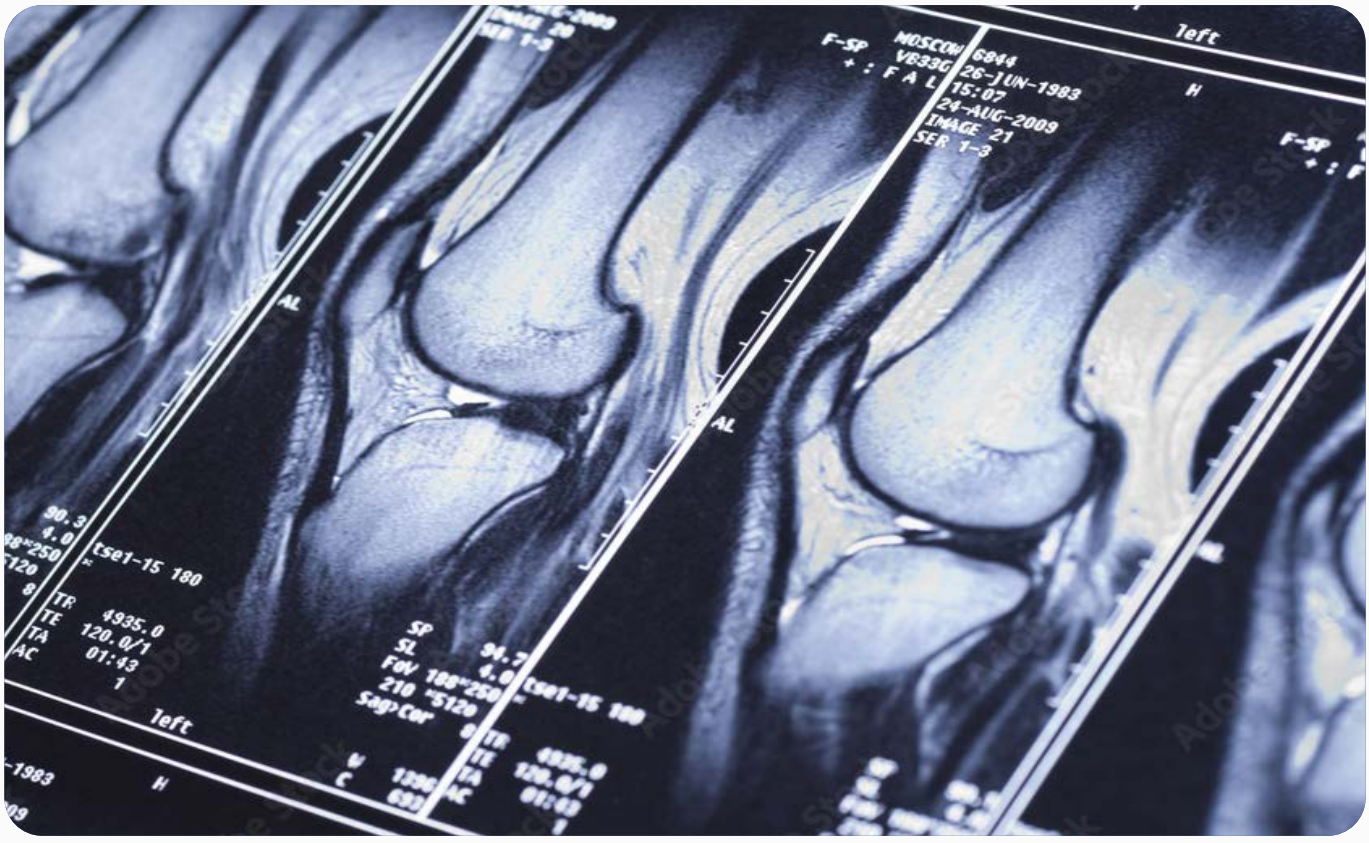


Image Artefacts

ASTM F2119	**Standard Test Method for Evaluation of MR Image Artefacts from Passive Implants.** Provides some methods by which the extent of artefacts may be quantified. Please note that this standard has now been withdrawn with no replacement at the time of publication of this white paper. It therefore cannot be considered a comprehensive guidance to evaluate artefacts, and additional considerations may need to be made to comprehensively characterise image artefacts caused by the device.
ISO/TS 10974:2018	**Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device.** Clause 18, Markings and accompanying documentation.

Impact

The performance of the scanner is affected by the presence of the device.

Devices in place when the patient is scanned may affect the quality of the captured image around the device. Artefacts in the image may hide or distort features of interest, and may affect the diagnostic quality of the image, in extreme cases to the point it becomes unusable.

It should be made clear within the IFU the geometric extent of artefacts, and under which conditions. For instance, if the electrodes of the spinal cord scanner generate artefacts that occlude the spinal column, this should be made clear within the IFU.

Device MR performance may be improved by providing methods by which the artefact may be minimized and a useful diagnostic image obtained.

Conclusion

Labelling a medical device as MR conditional is a change in conditions of use and, as such, has a wide-ranging impact to many aspects of the MDR Technical Documentation. The areas impacted will include Risk, V&V, Usability, Labelling, and Clinical Evaluation.

This position paper has attempted to highlight the breadth of the impact by providing an overview of aspects to consider prior to an application of MR conditionality for a medical device. It does not aim to be comprehensive. Additionally not all aspects discussed may be relevant to all medical devices on which MR conditional labelling may be applied.

No presumption of conformity can be made by following the considerations in this paper.

Further reading

The reader should refer to the regulations, standards, and guidance mentioned throughout this position paper for more information.

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Request a quote

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