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AAPM Task Group 334: A Guidance Document to using Radiotherapy Immobilization Devices and Accessories in an MR Environment

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Abstract

Use of magnetic resonance (MR) imaging in radiation therapy has increased substantially in recent years as more radiotherapy centers are having MR simulators installed, requesting more time on clinical diagnostic MR systems, or even treating with combination MR linear accelerator (MR-linac) systems. With this increased use, to ensure the most accurate integration of images into radiotherapy (RT), RT immobilization devices and accessories must be able to be used safely in the MR environment and produce minimal perturbations. The determination of the safety profile and considerations often falls to the medical physicist or other support staff members who at a minimum should be a Level 2 personnel as per the ACR. The purpose of this guidance document will be to help guide the user in making determinations on MR Safety labeling (i.e., MR Safe, Conditional, or Unsafe) including standard testing, and verification of image quality, when using RT immobilization devices and accessories in an MR environment.

Keywords

magnetic resonance; immobilization devices; radiotherapy; MR Safety

2. Introduction

2.1 Preface

Magnetic resonance (MR) is one of the major modalities in diagnostic imaging today, especially for soft tissue visualization. MR imaging (MRI) uses the principle of nuclear magnetic resonance (NMR) to generate images or to obtain chemical and physical information about tissues. In radiation therapy, the soft tissue contrast of MR is of primary interest to enable highly accurate treatment planning and to guide treatment. The main source of the *in vivo* MR signals is the nuclear proton of the hydrogen atom, which is abundant in the human body primarily in water and lipid molecules. MR can produce images of human body with a variety of soft tissue contrasts, which can be used to characterize internal anatomy, bodily functions, and metabolism.

2.2. Purpose and Scope of this report

The purpose of this document is to provide guidance on the safe use and integration of RT immobilization devices and accessories in the MR environment. It will help medical physicists and other health professionals practicing in MR-guided radiation therapy (MRgRT), whether via diagnostic MRI in the treatment position, MR-based treatment simulation, or MR-linear accelerators (MR-linacs), to address safety concerns and safe integration into this hybrid environment. The charges of this task group are as follow:

1. To provide guidance on safety and image quality using RT immobilization devices and accessories in an MR environment.

2. To recommend standard measures for vendors to test and communicate MR status of radiotherapy immobilization devices and accessories in an MR environment.

Intended Audience—This report is primarily intended for medical physicists, MRI technologists, and radiation therapists involved in MR-based RT treatment simulation and MR-guided RT. Other healthcare professionals including nurses and physicians may also find this resource useful in their practice. Even though it is not intended to provide specific guidance to the medical device industry, this document may provide insight for industry professionals to address issues raised by clinical MRgRT practice.

Expected outcome—This report provides guidance about the safe and effective use of RT immobilization devices and accessories in the MR environment, including MR Safety labeling, testing, and evaluation of these devices for clinical use.

Disclaimer—The authors of TG334 recognize that MR Safety is a field of expertise, clinical practice, and active area of research, all on its own. This document is intended to serve as a source of information and a reference but cannot replace adequate training and relevant experience in MR Safety. The reader is strongly encouraged to seek training and information related to all aspects of MR Safety, and to seek certification from appropriate bodies during professional development. While certification is not always possible or practical, the reader should seek guidance from a qualified medical physicist (QMP) who is as defined by the AAPM[1] certified and trained in MR. The tasks described in TG334 should always be performed under the supervision of a QMP with the appropriate training.

2.3 Technical information about MR systems

MR systems are usually composed of four subsystems: the main magnet subsystem, the radio frequency (RF) transmit and receive subsystems, and the gradient subsystem. These subsystems generate the magnetic fields that combine to collect data that can be reconstructed into images or spectra. These are summarized in Table 1. In addition to these subsystems, the MR system features a patient support subsystem that includes the patient table, ventilation, lighting, a patient intercom, and devices for optional monitoring of the cardiac and respiratory cycles. These subsystems are controlled and synchronized by computers. Further details can be found in the literature[2].

2.4 Implications of RT accessories for MR Safety and image quality

Safety considerations arise around MRI systems due to the use of static and time-varying magnetic fields generated by the subsystems. Each component gives rise to unique risks regarding to patient safety that have been well documented in the literature[3], and these are summarized in Table 2. The static field of the main magnet is tens of thousands of times stronger than the magnetic fields at the surface of the Earth, leading to complex attractive forces on ferromagnetic objects that are typically maximal at the opening of the MR bore. Contour maps of the main magnetic field and of the spatial gradient of the main field are typically provided by the manufacturer and can be used to identify areas of concern for static magnetic field safety. Effects on active devices may exclude certain active devices from the

MR environment. In the context of the present work, the exclusion of active devices might notably apply to accessories used to position or inform the patient during simulation in the MR environment such as displays for breath-hold coaching or external patient monitoring devices.

Safety testing and labeling of devices—MR Safety is a topic of paramount importance, and guidance comes in the form of internationally recognized guidelines[22–30]. Most discussion around MR Safety focuses on patient safety when there is an implanted medical device i.e., concerns due to magnetic field exposure, heating, etc. Standards for safety in the design and construction of MR systems are encapsulated in standards for MR systems from the IEC[31]. Guidelines exist for safety testing and for labeling of devices to be used in the MR environment[32]. These include documents from the FDA providing guidance on all medical devices that might be used in the MR environment[3], a set of testing standards from ASTM International for passive implants[33–36], and finally, ISO standards for active implants[37]. Device testing is required to address magnetic forces on metallic objects and potential for heating when exposed to RF magnetic fields[3]. Testing for potential gradient-induced heating is currently not standardized by the ASTM, but guidance is provided in Technical Specification ISO 10974[37]. Table 3 gives the relevant MRI system specifications that should be considered for a complete safety assessment for RT immobilization devices and accessories in an MR environment.

Device safety is communicated through appropriate labeling, which has been expanded and standardized over the years as the MR safety labeling continues to evolve[38,39]. Devices, whether external or implanted, passive or active, are usually labeled using one of three categories: MR Safe, MR Unsafe, or MR Conditional[40]. A device labeled MR Safe is non-metallic and non-conductive and is safe in all MR environments. A device labeled MR Unsafe is deemed unsafe in all MR environments (or to indicate absence of testing, for potentially unsafe devices) and use is to be prohibited. The third and possibly most oft-discussed label is MR Conditional, which applies to devices that have been tested and shown to pose minimal hazard in a specific MR environment, usually defined according to specifications related to field strength, spatial gradient, radio-frequency electromagnetic energy deposition, and device settings or configuration.

Most of the attention in MR Safety of devices has been concentrated on patient implants, for instance implanted cardiac devices[21], orthopedic devices[41], and other devices commonly encountered in radiological imaging. Much less attention has been given specifically to devices used in the context of MR-guided radiation therapy, though some reports have been published about RT-specific accessories[42,43].

Impact on image quality—The introduction of devices in the MR environment can interfere with any of the three magnetic fields involved in the imaging process. Variations in magnetic susceptibility on the order of a few parts-per-million can disrupt the static (main) magnetic field, leading to image distortion and/or signal loss, akin to those observed in patient-induced disruptions[44]. While MR systems are equipped with active shimming systems that can compensate for these effects, their capacity may be limited, and residual effects may be observed.

The impact of RT immobilization devices or accessories on image quality is also related to RF transmit and receive performance, often encapsulated in image uniformity. The current standard of practice in many clinics suggests that immobilization may be unnecessary for imaging of the brain, where image co-registration can overcome positioning variations[45,46]. Others have demonstrated that specific RT setups, which are essential or at least beneficial for many other treatment sites[47,48], have minimal effect on SNR[49–52]. Accessories such as coil bridges or breast boards, may introduce a gap between the patient and the coil, which is desirable for unobstructed contour of the patient but may reduce image quality due to less-than-optimal coil loading, thereby reducing the SNR. Some studies have shown that this impact may be surmountable[53], especially when consideration is given to coil placement[54] and setup position[55]. In head and neck cancer, alternate surface RF coil combinations and holders are often used to accommodate the thermoplastic mask to match neck flexion and patient pose, where wrapping coils close to the patient surface improves SNR and image intensity uniformity[46]. Recommendations for use of RT immobilization devices and accessories has received attention in the context of clinical trials in relation to image quality and patient positioning[56], and these recommendations certainly extend to standard clinical practice.

In addition to immobilization devices, additional accessories and MR equipment also need to be considered. For example, flat-top couch inserts increase the distance between the patient and receiver coil elements embedded in the table which will reduce SNR. Furthermore, materials such as carbon fiber are electrically conductive and may potentially burn patients while adversely affecting image quality, most notably with SNR and image uniformity[42,57]. Solutions have been proposed by adapting the receive-coil setup to alternative coil configurations to accommodate immobilization devices and maintain sufficient image quality[46,58].

Additional considerations due to MR system design also need to be considered. Gradient switching in the presence of metallic implants can cause artifacts[59], which may carry over to devices used in MR-guided RT if these contain conductive materials. The effect of MR system design on image quality in the RT context have been studied, in particular wide-bore systems that may bring patient positioning and clearance advantages for the RT context[60].

2.5 Current gaps in knowledge and clinical needs

The availability of efficient high resolution anatomical MRI in the treatment position (with adequate volumetric coverage), the developing availability of synthetic CT generation from MRI data, and the added value of functional MRI all combine to make MRI a viable solution for simulation imaging and image guidance in the RT treatment planning and guidance process[57,58,61–65]. As a result, the deployment and use of MR systems dedicated to radiation therapy[61,64], including diagnostic MR systems for simulation[57] and integrated MR-guided radiation therapy systems[66], is growing at a rapid pace. This leads to specific needs to be addressed with respect to the introduction of devices specific to the radiation therapy workflow in the MR environment for a particular treatment site. These include positioning and other devices that are routinely used in the radiation therapy environment and are now desirable in the MR environment. In RT, immobilization devices are often

made of carbon fiber which may cause thermal injuries in MRI due to their electrically conductive nature[42,46]. Thus, it is recommended that immobilization devices are fabricated by MR-optimal material, such as melamine[61], that is not conductive and does not introduce image artifacts.

The use of MRI in the RT process for simulation, planning, and guidance introduces MRI systems to an entirely new environment, where it is possible that professionals with limited experience and/or training in the use of MRI are now tasked with employing this technology safely[63,67]. The desire to image the patient in the treatment position using RT immobilization devices and accessories, as is done conventionally during CT simulation, means that an entirely new set of RT immobilization devices and accessories, foreign to radiology practice, are introduced to the MR environment. In certain jurisdictions, quality guidelines have been proposed[68]. Finally, while recommendations exist for the use of MRI in RT for clinical trials, these do not specifically address safety issues related to RT immobilization devices or accessories[46,56].

This report identifies two specific gaps in knowledge to be addressed:

1. External devices, such as positioning devices, pose a variety of safety and image quality concerns, and some have not been addressed in the radiation therapy workflow.
2. There is a need for consensus on the use of radiation therapy immobilization devices and accessories in the MR environment that extend outside of the existing documentation and recommendations specific for implanted devices.

3. Review of Testing Methods used by United States and Canada Regulatory Requirements for Manufacturers

The MR Safety status of a RT Immobilization device or accessory needs to be determined before it is brought into an MR environment. A device is deemed MR Safe, MR Conditional, or MR Unsafe based on criteria defined in the American Society of Testing and Materials (ASTM) International guidelines 2503[40]. Regulatory requirements for RT immobilization device and accessories used in an MR environment in the United States go through Food and Drug Administration (FDA) clearance documents[3,69] which provide their own information following the ASTM International guidelines for MR Safety testing[33–36]. In Canada, licensing of Class II, III, and IV medical devices by Health Canada requires a detailed technical assessment based primarily on combination of ASTM testing standards and ISO 10974 testing[70].

In this section, we summarize the ASTM recommendations and how they can be applied to RT immobilization devices and accessories. Please note that these do not include all the details in the ASTM documents – the readers should thoroughly read the FDA and ASTM documents before proceeding with any testing and ensure that all the points are followed. We also recommend reading the International Electrotechnical Commission (IEC) standards for safety of MR[31]. The recommendations per this task group are based on the regulatory

documents from the time of publication of this task group report. As the regulations change, the latest versions of the documents should be referred to before proceeding with testing.

This task group urges that RT immobilization devices or accessories to be used in an MR environment to be purchased from vendors with MR Safety status already determined. The MR Safety status of a RT immobilization device or accessory is determined using the testing methods discussed in the following sections. The user should be familiar with what should be included in the MR Safety documentation of the RT immobilization devices and accessories. We encourage the reader to review the following sections to ensure that the documentation that they receive from the vendor is sufficient. If the documentation is insufficient, the user should reach out to the vendor to ensure that they have the most up to date MR Safety information for the RT immobilization device or accessory.

If a RT immobilization device or accessory does not come with specific MR Safety documentation, per ASTM recommendation[40], scientific rationale with appropriate clearance criteria can be used to establish that a device is MR Safe, *i.e.* without safety concern in any MR environment, obviating the need for device testing. This rationale can be applied to RT immobilization accessories and devices composed entirely of electrically nonconductive, nonmetallic, and nonmagnetic materials. In a device containing no ferromagnetic material, magnetic force and torque are no longer a safety concern when the device is used in an MR environment[3]. The absence of metallic components reduces the risk of heating caused by gradient and/or RF field interactions.

Before testing a new device in an MR environment, the absence of metallic components should be ascertained by taking an x-ray or CT of the device. Conductive non-metallic materials, such as carbon fiber, must also be excluded to eliminate the risk of RF heating[42,46]. The manufacturer can be contacted to determine the specific materials used in the device as well. All evidence to show that scientific rationale deems a RT immobilization device or accessory as MR Safe must be documented. Tests for image artifacts as laid out in Section 3.4 should be performed in all cases.

If scientific rationale cannot be used to determine that the RT immobilization device or accessory is MR Safe before bringing it into the MR environment, it should be considered MR Unsafe until testing can be performed per ASTM testing procedures if applicable. An MR Unsafe characterization can be confirmed using a hand-held magnet with a strength of > 0.1 T (>1000 G) as per the ACR Manual on MR Safety[22] and should be used on any RT immobilization device or accessory before entering Zone III. Testing with a handheld magnet does not replace the ASTM testing procedures, as the handheld magnet does not produce a comparable magnetic field strength as the MRI system. These testing methods, discussed in Sections 3.1–4, require specific equipment, some of which may not readily be available in all institutions or vendor facilities. Therefore, if the institution or vendor does not have the required testing equipment or expertise to perform the appropriate tests, it is recommended to send out the device for testing to a site that has the required equipment and has International Organization for Standardization (ISO) accreditation for MR Safety testing[71]. These test results provide the conditions under which the RT immobilization

device or accessory are MR Conditional and should be listed in the vendor documentation or report from an external testing facility.

If a device is marked as MR Conditional and the device is to be used outside of the MR system specifications that it was deemed MR Conditional, the RT immobilization device or accessory must be assessed for off label use with the testing methods provided in Sections 3.1–3.4. These assessments for the MR Conditional status must be well documented in the acceptance documents of the RT immobilization device or accessory and MUST state that the device is being used off label of the vendor's recommendations. Off label use is discussed in more detail in Section 6.

An institution can perform the MR Safety tests as laid out in Sections 3.1–3.4. We would like to stress that this is not an easy task, and as discussed in the Disclaimer section of the Introduction section, requires certain expertise and equipment not readily available in every institution. Thus, it should only be performed if adequate expertise in MR Safety testing AND the appropriate equipment are available at the institution.

Thus, as a summary of what has just been discussed, we are proposing the workflow in Figure 1 for when one needs to ascertain the MR Safety of a RT immobilization device or accessory. The user should combine the results from all required ASTM and ISO MR Safety tests before determining that a device is MR Conditional. As recommended by the ACR, each institution shall have an MR medical director (MRMD), MR Safety officer (MRSO), and MR Safety expert (MRSE)[22]. Regardless of whether the device is tested on site or in an accredited facility, the final MR Safety designation of a RT immobilization device or accessory should be reviewed by the MRSO in consultation with the MRMD and MRSE before it is used on a patient.

3.1 ASTM F2052 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

The general principle of ASTM F2052[33] is to measure the magnetically induced displacement force produced by static magnetic field gradients on a device or accessory and determine how it compares to the weight of the device. While not specifically stated in the documentation, this testing method is general enough to be applied to RT immobilization devices or accessories.

The testing method in ASTM F2052 involves hanging the RT immobilization device or accessory from a string near the entrance to and on the axis of an MR system with a horizontal bore and a horizontally oriented static magnetic field. The reason that the test is performed at the entrance to the scanner bore entrance is because the dB/dz is at the maximum close to this area. The string should be hung from a place that can support enough force. The weight of the string must be less than 1% of the weight of the tested immobilization device or accessory. To maintain measurement sensitivity, the testing position where the RT immobilization device or accessory is hung is determined to be where "the spatial gradient of the field strength, dB/dz, is within 20 percent of the maximum value of the spatial gradient on the axis of the bore"[33]. Detailed distribution of spatial gradient around the MRI scanner may be obtained from the vendor. The bulk of the RT

immobilization device or accessory should be placed at the testing position and care should be taken that the device is not touching the tabletop and skewing the results. Once the device is placed and the movement has settled, the angular deflection of the string from the vertical is measured[33]. The testing setup as recommended is depicted in Figure 2. RT immobilization devices or accessories may be too large or bulky to be tested using the methods described in ASTM F2052 due to their size and bulk, for example a long vacuum cushion bag or a wingboard. Practically, devices are considered as bulky when it can't be fit into the scanner bore, or when the testing procedure can't be reliably followed due to collision with the table or scanner bore. This limitation is discussed in Section 8.1. It is recommended that devices too large to be tested should not be used in the MR environment if they contain any ferromagnetic materials. The presence of ferromagnetic components may be assessed using a powerful hand-held magnet (> 0.1 T) or a ferromagnetic detector.

If the angle of deflection of the string is less than 45°, the magnetically induced deflection force is less than the force on the RT immobilization device or accessory due to gravity. If this is the result when testing an RT immobilization device or accessory, one can conclude that it is not a risk to the patient in terms of the magnetic force. If the angle is more than 45°, the RT immobilization device or accessory should not be considered safe with respected to the magnetically induced deflection force.

3.2 Applying ASTM F2182 Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging to RT Immobilization Devices and Accessories

The methods in ASTM F2182[36] can be used with some modification to determine the amount of RF induced heating on or near a passive medical RT immobilization device or accessory and its surroundings during an MRI. This test method is essential in establishing if the presence of the RT immobilization device or accessory may cause thermal injury to the patient during an MRI acquisition. Test results for RF heating depends highly on the test configuration[72,73], so these tests require careful design. In ASTM F2182, RF heating tests of passive implants require that these devices be submerged in a test solution to mimic *in vivo* implantation. This submerged approach for testing can be extended to RT devices intended for use inside the body, *e.g.* intra-cavitary or interstitially. However, RT accessories that are used externally in the vicinity of patients, such as immobilization accessories, should undergo RF heating testing that mimics this situation using a phantom placed beside it.

RF induced heating test requires at least two pieces of equipment, a phantom and a thermometry probe. The phantom should be MR Safe, and composed of non-magnetic, non-metallic and electrically insulated materials that mimics the electrical and thermal properties of the human body. ASTM F2182 provides two phantom formulations in Section 8.3 and X1.3 with detailed ingredients and preparation steps to create phantoms that mimic human tissue. It is reasonable to use the same formulations to create phantoms for this modified test. If a different material is used, it should have electrical and thermal properties similar to those suggested in ASTM F2182 to sufficiently mimic the properties of the human body. During RF exposure, an MR Safe fiberoptic or fluoroptic thermometry probe[74] should be used to measure temperature as a function of time on or in the vicinity of the

RT immobilization device or accessory. The probe should have a temperature resolution of at most 0.1°C, a spatial resolution less than or equal to ≤ 1 mm in any direction along the specific axis of measurement, and a temporal resolution ≤ 4 s. It should also not substantially perturb the applied RF field or local electric field. The most common thermometry probes used in MR environment are relatively fragile. It is important to make sure that the probes have good thermal contact while avoiding excessive pressure/weight from the phantom.

For this RF heating test, the RT immobilization device or accessory should be placed with the phantom in an MR system. An MR protocol that produces RF power to achieve a whole-body average SAR of about 2 W/kg over the volume of the phantom for at least 15 minutes should be used, matching the guidance of ASTM F2182. In general, the fast spin echo (FSE) sequence tends to have high SAR, especially when it is combined with high echo train length. Therefore, it is a good candidate for this specific test. This test provides information about potential heating under normal conditions. Testing can also be performed under a higher SAR level to characterize RF induced heating under a variety of conditions. While the SAR value reported by the MR system, known as the scanner SAR, is the most directly accessible information available and is used as the *de facto* indicator of RF power in testing standards, it is nonetheless noted that there can be a difference between the scanner SAR (which is calculated from a model and usually includes a conservative margin for safety) and the measured SAR[75]. Therefore, a report of this test result obtained based on the *scanner* SAR should be very clearly stated as such. Alternatively, a test result based on the maximum allowed root-mean-square transmit field ($B^{+}_{1,rms}$) can be accepted[17]. The use of $B^{+}_{1,rms}$ is sporadic, and not all MRI systems report this value to the user; therefore, care should be taken to ensure that the test result should be expressed in units that can be compared with information reported by the scanner console.

The temperature increases on or near the device or accessory at several locations should be measured in real-time using the thermometry probe during the RF application. It is important to know that the RF induced heating may not be uniform based on the material that is involved. The number of simultaneous measurement points is also limited by the thermal instrument, e.g., the number of available probes and the number of channels on the readout device. It is a reasonable practice to initially space out locations that have close contact to the phantom. Once thermal hot spots are identified, repeat the measurements around these areas to find the hottest spots. Once the position of greatest heating is determined, the temperature increase should be measured for at least 15 minutes at that position and a reference position that is not in close proximity to the RT immobilization device or accessory. Next, the RT immobilization device or accessory should be taken out, and the measurements should be repeated at both the maximal RF heating and reference positions. The purpose of temperature measurements at the reference position is to ensure equivalent RF exposure settings are used with and without the RT immobilization device or accessory[36]. A maximum surface temperature of 40°C is tolerated for the inner surface of the MR system bore during RF exposure[31], and the same limit can reasonably be applied in the context of RT accessories.

If there are multiple arrangements for the RT immobilization device or accessory, testing should be performed for each arrangement. This includes arrangements where the device is placed in proximity to the RF transmit coil, which might exacerbate heating due to proximity effects. The arrangement and orientation of the RT immobilization device or accessory that induces the highest heating in the phantom should be identified, and the evidence used to determine the clinically relevant worst-case scenario should be documented thoroughly. Alternatively, numerical simulations based on SAR models can be used to identify the worst-case scenarios for RF heating, followed by physical testing of these arrangements. Typically, the measurement results in conjunction with the simulation results based on SAR models are used in determining the conditions under which an RT immobilization device or accessory can be labeled MR Conditional[36,69].

Given the availability of measurement devices and complexity of SAR computation, it may be difficult for this type of test to be performed in every institution for RT immobilization devices and accessories that have not already received FDA clearance. Therefore, it is recommended that the user should reach out to appropriate testing facilities for RF heating tests. Testing conditions including usage conditions and prescribed SAR levels should be conveyed to the testing facility so the results correspond to the institution's clinical practice. The parameters required for FDA clearance are listed in the FDA document "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment from FDA"[3]. It is recommended that the testing facilities should include this information in their MR Conditional statement.

The reader should be aware that the version of ASTM F2182[36] cited in this TG report specifically states that "the test method assumes that testing is done on devices that will be entirely inside the body". The FDA also specifically states that for external devices such as those discussed in this TG report that the user should "seek feedback through the Q-submission process on the proposed testing plan for assessing heating and the corresponding MRI safety labeling for these devices"[3].

3.3 ASTM F2213 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

The magneto-static torque considered here is due to the interaction of the static magnetic field of the MRI system with the magnetization in the RT immobilization device or accessory. The main issue for this test method is that it was initially written for implants[35] which are significantly smaller than some of the RT immobilization devices or accessories under consideration in this task group report. Even more so than the testing of magnetically induced force, which is conducted outside the scanner bore, the proposed testing of the torque is conducted inside of the scanner bore. This poses more restrictions on the size of the testing setup and should also be a consideration for any RT immobilization device or accessory one wants to use in an MR environment. Again, it may be difficult for an individual institution to perform this test given the necessary equipment required. Therefore, the recommendation for the torque test is the same as for the heating test – that an outside testing facility performs the test under the conditions to be used in the institution and provides detailed testing results.

The torque is evaluated using a torsional pendulum method, which can detect a torque measurement that is “greater than 1⁄10 the “gravity torque,” the product of the device’s maximum linear dimension and its weight”[35]. The RT immobilization device or accessory is placed on the testing platform suspended by a torsional spring, as depicted in Figure 3. The testing platform is allowed to come to equilibrium before the whole testing apparatus is placed in the uniform magnetic field at the center of the MRI system. The RT immobilization device or accessory’s torque in the MR environment is evaluated by the deflection angle of the testing platform from its equilibrium position. The deflection angle is measured at different orientations of the RT immobilization device or accessory to determine the worst-case scenario for the magnetically induced torque. The maximal magnetic torque is compared to the gravity torque, defined as the product of the maximum linear dimension of the device and the RT immobilization device or accessory’s weight.

If the maximal torque is less than the gravity torque, then the magnetically induced deflection torque is less than the worst-case torque on the device due to gravity. Thus, in these cases and conditions, the device can be taken as MR Conditional up to the B_0 used for testing with respect to magnetically induced torque. FDA guidance[3] suggests that a device that exhibits magnetically induced torque that exceeds this limit may be accepted as MR conditional if the device is restrained when within the MR environment. This approach may be applied conservatively for devices are firmly affixed throughout the MR procedure, for example to the patient table.

3.4 Applying ASTM F2119 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants to RT Immobilization Devices and Accessories

Based on the materials used in the typical RT immobilization devices and accessories, image artifacts may appear near the interface between the human body and the RT immobilization device or accessory. The severity of artifacts depends on many things, including the materials used in construction of the RT immobilization device or accessory, magnetic field strength, and imaging protocol. These artifacts may interfere with delineation of the target, external body contour, and organs-at-risk and thus require additional characterization.

ASTM F2119[34] provides guidelines to evaluate image artifacts for passive implants used in an MR environment. With slight modifications, the method can be used to assess image artifacts for RT immobilization devices and accessories as well. Before starting this test, the device should already be labeled as MR Safe or Conditional after performing the ASTM tests previously reviewed in this section[33,35,36].

To quantify image artifacts, ASTM F2119[34] requires first using a spin echo sequence to identify the worst-case configuration and then using the gradient echo sequence to quantify the extent of image artifacts. In general, image artifacts are more severe on the gradient echo sequence compared to the spin echo sequence.[76] ASTM 2119 recommends that the testing of the RT immobilization device/accessory should be performed by immersing the device into a container filled with non-toxic gelatin-based or aqueous solution of gadolinium-based contrast agent with at least 4 cm clearance to each side of the container from the investigated device. A copper sulfate solution is recommended by ASTM 2119, but other solutions may also be used with appropriate justifications. This approach for testing can nominally be

extended to devices intended for use inside the body, *e.g.* intra-cavitary or interstitially. In this case, the largest RT device or accessory that can be tested using this method must be able to fit within the test container. There are implications related to the potential toxicity of the proposed solution in the case where the RT devices or accessory subjected to immersive testing needs to be used with patients afterwards. Care should be taken to ensure that a non-toxic test solution be used and that appropriate cleaning and sterilization of the device can be ensured.

Most RT immobilization devices or accessories will not be used within the body, and instead will be placed as a patient support, so immersive testing may not be appropriate. In this case, an appropriate MR imaging phantom, possibly constructed using with the solutions used for immersive testing, can be placed onto or next to the RT immobilization device or accessory to assess the artifacts. Following ASTM 2119[34], image artifacts can be quantified by acquiring images with and without a reference object such as a nylon rod immersed in a solution including a combination of object orientations and acquisition conditions available in a table in ASTM 2119 to accurately assess the position of the RT immobilization device or accessory and quantifying potential distortions. Morris et al (2023)[77] provided examples of using the ACR phantom, which most institutions have to show examples of artifacts in RT immobilization devices and accessories. One example was a metal artifact from the metal spring in the valve in a vacuum cushion bag while the other example was the shading artifact that could occur if a a carbon fiber head a neck board is used instead of a MR-safe head a neck board[77].

Object-induced distortions arising from B_0 inhomogeneities due to differences in magnetic susceptibility of materials should also be characterized. Well-defined methodologies are summarized in TG-284 for characterization using phase difference maps to characterize the local distortion. One such extreme example is the Leksell stereotactic system where an aluminum frame is attached to a patient's head using four pins. In addition to eddy currents arising from closed loops within the aluminum frame, local distortions of ~5 mm have been quantified within a few centimeters from the frame and decay with increased distance from the base when imaged at 1.5 T[78]. In addition to selecting MR-optimal material for devices, B_0 distortions may be further reduced by increasing the readout bandwidth (at a tradeoff of lower SNR with a method outlined in TG-284), optimizing the B_0 shimming, using vendor-provided mitigation[79] techniques, or implementing an image correction strategy[46,80]. Another image artifact that may be produced by immobilization devices is the introduction of aliasing or "wrap around" artifacts within the clinical image arising from signal generated by the device placed outside the prescribed field of view. This can be evaluated by acquiring a short echo time or proton density image to characterize the latent signal arising from the immobilization device. This phasewrap could also be eliminated by using a larger FOV or phase frequency swapping.

To determine the worst-case configuration, a pair of spin echo images with and without the RT immobilization device or accessory are acquired for multiple configurations, including positioning the RT immobilization device or accessory in the orientation it will be used clinically with respect to the static field and switching the readout/phase-encode

designations[34]. The condition that creates the largest artifact size in 3-D is deemed as the worst-case configuration for further evaluation.

For the worst-case configuration, a pair of gradient echo images should be acquired with and without the RT immobilization device or accessory, and any artifacts visualized should be investigated[34]. If the signal intensity in a pixel is modified by at least 30% with the introduction of the RT immobilization device or accessory, this pixel is considered as part of the image artifact. The distance in millimeters from the RT immobilization device or accessory boundary to the furthest end of the image artifact is measured, which is used to characterize the image artifact. The reference object or phantom placed onto or beside the RT immobilization device or accessory can be used for assessing both artifacts and any possible geometric distortions caused by the presence of the RT immobilization device or accessory. A detailed record of the testing conditions and results should be kept for future use of the RT immobilization device or accessory so that the conditions and locations under which these artifacts are seen in MR images are known. If there is a sizable artifact affecting target or OAR delineation, the RT immobilization device or accessory should not be used in an MR environment or specific use considerations should be specified, i.e. an artifact on the edge of the MR field of view may clinically acceptable for lesions located midline (i.e., pancreas) but may not be appropriate for a lateral lesion such as liver or breast.

The importance of testing for image artifacts cannot be overstated – distortion in target or OAR delineation could result in suboptimal treatment plans and treatment outcomes. Also, if MR-only radiotherapy treatment planning is being used, the external body contour location could be compromised, which would adversely affect the dose distribution calculation accuracy[61,80–85]. Once these artifacts are characterized for each device, training should be provided to all team members who are responsible for using the RT immobilization device or accessory in practice or handle/review images in their practice such as for contouring organ at risk and gross tumor volume contours in the presence of these artifacts and quantifying the impact of these artifacts on dose calculation accuracy. It is also recommended that this training should be included in the on-boarding training for new staff as described in Section 4.

4. Clinical recommendations

4.1. Departmental Policies and Procedures

Each organization’s MR Safety Committee is responsible for the development of an MR Safety training program and overseeing the implementation of the safety training. The recommendations for the composition of the committee members are given in the ACR Manual on MR Safety[22] and AAPM TG 284[46]. The MR Safety committee should provide training competencies, policies and procedures on the safety checks, acceptance, and handling of MR simulation with RT immobilization devices and accessories. The departmental competencies, policies, and procedures should be reviewed and updated as necessary and at least annually by the MR Safety committee. The recommended training for any personnel who will work in an MR environment is provided in TG284[46].

The assumption of this TG report is that any radiotherapy institution that has an MR simulator or MR-linac available is also treating patients with radiotherapy techniques without MR guidance (conventional linear accelerators, tomotherapy, Gamma Knife, Cyberknife, proton therapy etc) whilst the RT immobilization devices and accessories may have very similar appearances (i.e. indexing bars, breast boards, and equipment such as levels) between the MR and non-MR environments. Thus, it is strongly recommended for safety reasons to implement a policy that only devices with MR Safe or MR Conditional labels are permissible to enter and be used in the MR environment. Devices with no labels shall be assumed to be MR Unsafe and shall not be used in the MR environment.

Emergency response and evacuation procedures in the context of MR simulation will be referred to the emergency response guidelines from the hospital/radiology MR Safety committee and are detailed in TG284[46] and ACR guidelines[22].

All the records regarding MR Safety training, MR Safety documentation, screening, consent forms, incidents/injury record, safety and inventory checks for RT immobilization device or accessory should be maintained by MRSO appointed by the departmental MRMD. Our recommendation for which Level II MR personnel shall be responsible for the different aspects of MR Safety testing in regard to RT immobilization devices and accessories is laid out in Table 4. By AAPM's definition, a qualified medical physicist (QMP) is someone who can independently perform the necessary tasks in one of the subspecialties of medical physics[1]. An example of an MR Safety program in a radiation oncology department is detailed in a recent paper by Gach et al [86].

4.2 Education of staff members

The training recommendations of staff that will work in an MR environment are well defined in the ACR MR Safety Manual[22] and recently summarized in TG-284[46]. An inventory of RT immobilization devices and accessories should be reviewed during education sessions. All information related to RT immobilization devices should be included in this education, including positioning and measures for artifact avoidance. Any updated MR Safety related information should be immediately released to all relevant staff members, and additional competencies should be provided as any new RT immobilization device or accessory are incorporated into the inventory and before use on any patient.

4.3 Safety and image artifact evaluation of a RT Immobilization Device or Accessory to be used in an MR Environment

The standard process for the safety check of a RT immobilization device or accessory to be used in the MR environment must include a step-by-step process as laid out in Figure 1 to evaluate whether it is MR Safe, MR Conditional or MR Unsafe. Use of an MR Conditional RT immobilization device or accessory outside of the specified conditions (e.g. different field strength) is considered off label use and is discussed in further detail in Section 6.

When in-house developed devices are used in the department, their MR Safety status must be assessed through testing as described previously in Section 3. Development of in-house devices should pay careful attention to materials and design to increase the likelihood of an MR Safe or MR Conditional designation. Since in-house developed devices are likely

to undergo frequent modifications, it is necessary to keep track of all modifications and corresponding MR Safety status. Additional considerations for these are covered in detail in Section 6.

After the MR Safe or Conditional status of a RT immobilization device or accessory has been ascertained by the testing methods described in Section 3, it is recommended on acceptance of a RT immobilization device or accessory to first take a CT of the device for records and to repeat the testing for image artifacts with RT-specific MR protocols of the institution, developed as mentioned in TG-284[46]. This is because if the RT immobilization device or accessory is sent to an outside testing site for MR Safety testing and includes MR image quality testing, the imaging artifacts might be different since some are highly dependent on the field strength and MR protocols used. Thus, these tests should be performed with the RF coils to be used with the RT immobilization device or accessory and with proper coil filling with a phantom. Optimal coil positioning and evaluating bore clearance are important with bulky RT immobilization devices or accessories. Patient setups should be mimicked for appropriate clinical use cases using positioning of the devices or accessories with respect to a patient in the bore to provide an accurate depiction of imaging artifacts and to quantify the potential impact in image quality that may occur when in the presence of the RT immobilization device or accessory. Depending on institutional practices, this may require the development of an IRB-approved protocol for imaging healthy volunteers to test appropriate configurations. The QMP should determine if RT specific protocols need to be modified when a specific RT immobilization device or accessory is used with them, for example to increase the SNR or adjust the FOV[61,80,81]. All results of these tests should be well documented in the acceptance documentation of every device.

During the commissioning of the device, it is recommended to identify and address other safety aspects that may be introduced by the device, e.g. interference with patient communication, compromising hearing protection, potential skin contact, or clearance concerns within the bore. Any of these additional safety aspects should be incorporated into the MR Safety checklists for the RT immobilization devices or accessories.

As part of routine quality assurance, RT immobilization devices should be checked periodically to ensure the continued safe use of the devices. A hand-held magnet or ferromagnetic detection system should be used to check every RT immobilization device or accessory each time before it enters the MR suite (Zone III). It is recommended that other periodic safety checks include at least a visual inspection which checks MR labelling, integrity of the device, and any possible modifications to the device differing from the acceptance and inventory documentation. The visual inspection for any modifications is a quick check which should be integrated into at least an annual QA. If any of these routine quality assurances do not pass, the RT immobilization device or accessory should not be brought into Zone III before a thorough investigation has been performed.

4.4 Inventory List

Before initiating the use of RT immobilization devices and accessories in an MR environment, it is strongly recommended that an inventory of MR Safe and MR Conditional

RT immobilization devices and accessories be generated. This inventory list must be easily accessible for all departmental staff for ease of reference. RT immobilization devices or accessories not on the list shall be considered MR Unsafe and shall not be used in an MR environment until the labeling of MR Safe or MR Conditional has been ascertained. This list shall include (but not be limited to) objects and devices listed in Sections 5–7 of this TG report. Appendix A and Appendix B lay out example checklists to be used for in the departmental inventory of MR RT Immobilization Device/Accessory and Records of Modification or Part Replacement of MR RT Immobilization Device/Accessory. This inventory list should also be reviewed during annual QA to ensure it is up to date.

4.5 TG100 FMEA for the integration of RT immobilization devices and accessories in an MR environment

In the hybrid MRI and radiation therapy environment, the safety profile of mixed staffing not familiar with the risks of MRI may require added safety measures. Given that the risks of bringing in an MR Unsafe device into Zone IV (e.g., magnet room) are potentially fatal, failure mode and effects analysis (FMEA) as detailed in AAPM Task Group 100[87] is highly recommended to be performed before the integration of RT immobilization devices and accessories in an MR environment. An interdisciplinary team should include at a minimum medical physicist, radiation oncologists, radiation therapists (ideally with additional MR certification), and nurses. Input from a diagnostic department's MR Safety officer, medical physicists, and MR technologists would also be beneficial in assessing the thoroughness of the FMEA. FMEA can be used to identify areas where a high failure mode could occur in the integration of these devices and risk reductions can be introduced based on three major aspects: (1) severity (S) of the effects from FMs, (2) frequency of occurrence (O), and (3) detectability (D) of their occurrence[87–90]. One example of where technical failure mode could occur is when an institution has an MR Safe or Conditional RT immobilization device or accessory that appears visually similar to one that is MR Unsafe which could lead to patient injury or damage the MR equipment. Another possible technical failure mode is that an MR Conditional RT immobilization device or accessory could be used outside of the conditions that it has been tested for. As discussed previously, this can be addressed by having site specific MR scanning protocols that are also specific for the RT immobilization devices. Anytime a deviation from these scanning parameters for the MR Conditional status of the RT immobilization device or accessory needs to occur, this is considered off label use which is discussed in further detail in Section 6. Thorough documentation and liability from all clinical staff of all equipment characteristics, locations of storage and use of equipment, and noting any modifications to equipment (additions or removal of components) are especially important in a hybrid MRI and radiation therapy environment in order to reduce the frequency of failure occurrences. A detailed FMEA has also been conducted for general MR Safety and contraindications to MRI outside of the radiation therapy workflow[91].

5. Vendor devices

5.1 Specification for MR Safety of vendor RT Immobilization devices and accessories

The introduction of MR simulation and MR-linacs necessitates the evaluation of radiation therapy devices and accessories to be used in the MR environment. The method for addressing MR Safety with RT immobilization devices recommended by this task group is that dedicated MR Safe or MR Conditional RT immobilization devices and accessories should be commissioned for these programs. This method should prevent visually similar MR Unsafe RT immobilization devices or accessories from entering an MR environment and ensure optimal image quality is maintained. In general, the basic guiding principles that apply to RT immobilization devices or accessories used in radiation oncology remain relevant when considering deployment in an MRI environment. These include the need to reliably accommodate patients of various shapes and sizes, withstand frequent use, be rigid enough to prevent significant sag, and ensure reproducible set-up, to be light enough so that therapist can easily interchange them between patients, to be made of medically safe materials, and, finally, they should not support bacterial growth and be easy to clean and disinfect. However, additional considerations apply for use of RT immobilization and devices in an MR environment that require the use of new materials and designs. For example, the device must have a low attenuation for radiation in the therapeutic range to maximize skin sparing, minimize the reduction in useable beam angles. For this reason, most RT immobilization devices, such as breastboards, couch tops, wingboards, head-and-neck overlays/attachments, are traditionally made of carbon fiber[92]. Yet, as mentioned earlier, carbon fiber RT immobilization devices are not to be used in an MR environment since they are electrically conductive[42,46] and thus many of these devices have now been made with a more MR Safe or Conditional material.

Other than imaging artifacts and the possibility of thermal injuries, some of the RT immobilization devices traditionally used in radiation therapy were just too large for the smaller bores of MR systems, resulting in the need for MR-specific RT immobilization devices and accessories. Based on this need, vendors have adapted their materials to produce MR Safe or MR Conditional RT immobilization devices and accessories. Examples include SBRT devices, where bridges and paddles are used for abdominal compression, inclined breast boards, or large wingboards. It is thus encouraged that the radiation oncology team ensure that these devices will fit through the MR simulator or MR-linac bore before purchase and use, even if they are deemed to be MR Safe or MR Conditional. The small bore size of many MRIs may limit the size of patients that can be imaged, particularly in the treatment position. One should also recognize that the use of such RT immobilization devices, may further restrict this limitation.

With the advent of 70-cm-bore MR systems, the increased flexibility in patient positioning has resulted in broader adoption of dedicated MR systems for simulation[61]. Some models also offer flat tabletops that make the use of RT immobilization devices easier, as well as external lasers, dedicated software features, and coil setups. When researching possible devices for purchase for the institution, the couch tabletop indexing available for RT

immobilization devices or accessories should ensure reproducible positioning between MR simulation and treatment.

5.2 Types of devices and considerations with relation to MR

Vendors are required to clearly mark their devices as MR Unsafe, Safe or Conditional as per ASTM 2503[40], and the documentation for the labeling should be part of the instructions for use (IFU) as required by the FDA in the United States[3]. A suggested workflow to determine if vendor RT immobilization device and accessories are MR Safe or Conditional is given in Figure 1. It is recommended to develop an institutional workflow like this when accepting vendor devices into the MR Safe/Conditional inventory.

As mentioned in Section 3, a device can be deemed MR Safe if it is non-metallic, non-magnetic, and non-conductive. Some equipment where an MR Safety label is not given might thus be easy to identify as MR Safe. However, for some devices this might not be obvious, *e.g.* vacloc bags, if the valve contains a spring mechanism, or wingboards, which might be made of carbon fiber or contain hidden metal hardware. Thus, all devices should be tested for MR Conditional status. As mentioned previously before any device is used in an MR environment and with a patient, it is advised to take a radiograph or CT scan of the device with a field of view sufficient to encompass the entire device to determine if there is any potential metal present. Some positioning devices may act as thermal insulators reducing the patient's natural cooling ability and effectiveness of ventilation in the MR bore. In such cases, it is not enough to designate a device MR Unsafe; care should be taken in monitoring patient comfort throughout the procedure. RT immobilization devices like overlays for SRS frames, SBRT or head and neck boards are traditionally made of carbon fiber are not considered MR Safe due to heating concerns[42,46], and additionally might cause severe shadowing in MR images. Devices that are not designated as MR Safe should be evaluated, and the conditions for their use verified with the vendor. If these devices that do not already have MR safety designation from the vendor come in batches, we recommend that each batch be retested to ensure continued safety. Examples of such devices include prone breast devices that incorporate metallic components in the indexing systems, abdominal compression belts, Foley catheters, and rectal balloons. The specifications of single use RT immobilization devices or accessories may change with each new lot as manufacturer conditions may change. Thus, the MR Safety documentation should be verified to ensure the MR Safety status has not changed before accepting the device into inventory.

If the treatment is not delivered by an MR-linac, then superficial accessories (e.g. bolus, plastic wrap, custom bolus material or 3D printing material that will be placed superficially on top of the patient) can be excluded for the purpose of MR simulation if it will not affect patient positioning or change the deformation of their anatomy compared to the CT simulation used for RT planning. Additional consideration must be given to allowing thermoplastic devices formed via water baths to completely dry before placement on the patient to reduce the risk of heating and potential patient burns[46].

Some of the RT immobilization devices discussed in this report may also be used in brachytherapy or pediatric applications. While the recommendations made and safety

practices described herein apply to immobilization of brachytherapy or pediatric patients during MRI as well, some additional caveats are noteworthy. For brachytherapy applications additional equipment is often used, for example: devices for fixation of the applicator in the patient or patient monitoring and anesthesia support units and related accessories. The reader is referred to AAPM TG-303[93], which details safety considerations for gynecological and prostate brachytherapy in the MRI setting. Finally, patients undergoing MRI are normally instructed to alert staff to heating/burning sensations, yet brachytherapy and pediatric patients are often imaged under local or general anesthesia, and recommended practices are described elsewhere[94,95].

6. Legacy Devices, In-house Patient Specific Devices, and Off label use of Devices

Often in the radiotherapy clinic, improvisations are made, and the RT immobilization devices or accessories used are not limited to solely vendor made devices that have gone through the rigorous testing discussed in Section 3. These include legacy devices and in-house patient specific devices that may lack proper MR Safety documentation. Both categories of devices have become an integral part of the clinical workflow. With the addition of MR simulators and MR-linacs in radiation oncology departments, some of the materials used to manufacture these devices may not be suitable for use in an MR environment, and they may need to be replaced or modified prior to use in an MR environment[61,96]. However, in some cases, when such devices would appear to qualify for use in an MR environment, if they can be ascertained to have no metallic, magnetic, or conductive components, they can be deemed MR Safe by scientific rationale. If scientific rationale cannot be used, the devices should undergo MR Safety testing following the standard acceptance and testing procedures discussed in Sections 3 and 4 for both the impact on MR Safety and imaging artifact concerns. The MRMD and/or MRSO must approve the use of any of these device categories.

Examples of legacy devices outside of the normal RT immobilization categorization are pool noodles, towels, or pillows often used to suspend surface coils from the patient external anatomy[61]. In-house patient-specific devices are often used for a particular use case[47,50,97]. These devices could include 3D printed devices[98–101] or common thermoset and thermoplastic materials[61]. In the construction of in-house devices, the use of bonding agents may be required[102]. Figure 4 is an example of how choosing the correct bonding agent is important when constructing in-house devices to be used in an MR environment. Another example is shown in Figure 5 is an in-house constructed 3D printed holder for the commonly used ACR phantom along with the use of another bonding agent that did not result in any demonstrable MRI artifacts.

A third category of devices is the off label use of other materials or devices that are not specifically made for patient setup but can aide in the immobilization and setup in the MR environment. This includes the off label use of MR Conditional vendor devices outside of the range of conditions for which it was approved at by the vendor in their IFU (also referred to as labeling) for its MR Conditional labeling, for example, at a field strength of 0.35 T

for an MR-linac. Another off label use includes modifications to RT immobilization devices such as replacing metallic fixation with MR Safe components or adding risers or holders to accommodate RF coils.

This report does not condone off label use, yet the authors acknowledge it is part of the clinical practice in many institutions. Before being used on a patient, the RT immobilization device or accessory should undergo MR Safety clearance following the standard acceptance and testing procedures in Sections 3 and 4. It should be stressed that in these cases of using a device off label the burden of liability will rest with the institution. Table 3 gives the relevant MRI system specifications for MRI safety assessment of devices. While not all the parameters in Table 3 are relevant to every device safety assessment, a complete assessment when considering off label use of a device should at least consider each of these values. In addition, when assessing and documenting the off label use of an MR Conditional immobilization device or accessory, consideration should be given at a minimum[3] to 1) magnetic forces and torques on ferromagnetic components, 2) Lenz forces on all metallic components, 3) potential for malfunction of the device (passive or active), 4) device heating from RF and/or gradient fields in consideration of potential thermal injury to the patient, 5) gradient induced vibration, and 6) unintended stimulation from gradient induced electrical potential and from rectified RF pulses. The authors also strongly recommend that the reader refer to AAPM TG 121, where the responsibilities of the medical physicists when using medical products off label is discussed[103]. Modifications made to FDA approved devices may alter the performance of the device in unexpected ways and the users should, here too, be cognizant that the burden of liability will rest with them. Vendors may not provide support or service for a modified device and warranty will likely be voided. If modifications are deemed necessary, users should consider the mechanical integrity, general safety, as well as the MR Safety status of the device. And if status is determined to remain or become MR Conditional, the user must establish and document the updated conditions for safe use of the modified device (see sections 3 and 4 above) prior to clinical use.

When making new in-house devices or modifications to vendor devices, it is recommended to maintain records of what materials were used to create devices in-house or modifications to vendor devices. Any new in-house device constructed shall be evaluated for bore clearance (including patient size considerations) and shall not possess any additional MR Safety or imaging artifact concerns. We strongly recommend that any new in-house device should be composed of parts that have been deemed MR Safe (preferably by scientific rationale). Any devices that are assembled of multiple components with MR Conditional labeling should be tested as a complete combination before MR Conditional labeling can be applied to the combination. If any new in-house device has parts that can be removed or assembled, each component should be labeled with the appropriate MR Safety sticker as well as an inventory sticker.

Routine QA procedures of the in-house/legacy devices in general can follow the same protocol as other devices as outlined in Section 4. However, extra caution and documentation for those devices shall be shouldered by the institution’s physicists. Particularly, the labeling of device for MR usage clearance should be included in the QA procedures and checks should also include the list of components each time.

7. MR-guided radiotherapy additional considerations

7.1 Rationale

The integration of on-board MRI with compact linear accelerators has paved the way for a new era of MR-guided radiotherapy (MRgRT), the use of which is currently evolving and expanding[104–106]. MR Safety considerations are similar to those needed for conventional MR systems. Yet, in this hybrid environment, additional considerations are required for immobilization devices and accessories that include factors such as the dosimetric impact of the presence of the device, compatibility with treatment planning, need for MRgRT specialty equipment, patient setup and patient safety considerations. Further, the personnel involved in the daily operations for an MRgRT program often differs from a traditional MRI as well as RT staffing, thus developing tailored recommendations to address critical safety challenges in this hybrid environment is essential.

7.2 Integrated MR-guided Radiotherapy Systems

At the time of writing this report, MRgRT systems that are commercially available for clinical have field strengths that range from 0.35T-1.5T[106–112]. The different MRgRT systems orient the magnetic field either perpendicular or parallel to the radiation beam direction, and all use a flat table top[106–112].

7.3 Equipment Setup Considerations

In addition to the differences in configuration of the different integrated MRgRT systems, new practical considerations regarding equipment setup are necessary when transitioning from a conventional RT system to an MRgRT environment. MR Safety considerations must be made for equipment specific to MRI-guidance including indexing bars, hearing protection, surface coils, and a coil bridge/frame, along with typical RT immobilization devices such as cradles and vacuum bags.

Primary considerations in the use of indexing bars in an MRgRT setting include the compatibility of indexing positions and spacing between simulation and treatment tabletops, ensuring an MR Safe or Conditional status of an indexing device, and the potential degradation of image quality. A higher field strength MRgRT system has a treatment tabletop indexing that matches the one to be placed on top of the CT simulator tabletop and is secured by pins on indexing bars at designated locations[113,114]. Existing CT tabletops can be used at the time of CT simulation if the indexing positions and spacing allow for a direct conversion to the higher field strength MRgRT system’s tabletop indexing. This interchangeability should be validated prior to use with patients to ensure the correct indexing is applied for planning and setup purposes such that unexpected, longitudinal shifts into any beam path do not occur prior to treatment. The tabletop of a lower field strength MRgRT system is equipped with indexing notches compatible with available indexing devices to secure RT immobilization devices for conventional radiotherapy systems[115,116]. Indexing bars provided by vendors for CT and MR use are generally distinguished by 2 pins (for conventional CT) versus 3 pins (for MRI use) or different shaped pins to prevent the use of MR Unsafe devices in the MR environment. For example, at the time of this publication, CIVCO Radiotherapy has Three-Pin Lok-Bars for indexing of MR Safe and MR Conditional

devices. As another example, a higher field strength MRgRT system uses a 2 pin index bar but with the use of non-cylindrical dowels[117].

The positioning of hearing protection in the form of ear plugs and/or headphones must also be considered during daily patient setup on the MR-linac. Whether the hearing protection is placed underneath or around any other RT immobilization devices such as thermoplastic masks and vacuum bags shaped around the patient's head, patient comfort, acceptable communication, and the reproducibility of the setup must be considered as shown in Figure 6.

Another consideration for MR-linac patient setup includes surface coils and bridge/frames. The higher field strength MRgRT system currently has a single anterior / posterior coil design that is already included in the TPS to account for attenuation differences between the anterior and posterior coils of 0.4% and 2.2%, respectively[107]. Given the variability in attenuation, the coil placement relative to the treatment beam is vitally important with >2% reduction if coils are incorrectly placed relative to the beam[107]. The lower field strength MRgRT system, on the other hand, currently provides two RF receive coil designs: a head and neck coil and a torso coil constructed of flexible foam. The coils are placed on the anterior of the patient with the posterior coil positioned between the patient and the couch top with attenuation accounted for in the treatment planning system[115,116]. Due to the current limitations on the availability of coils for all MRgRT systems, the positioning of the coils should be placed to maximize signal-to-noise ratio. Patients should also be oriented so that the treatment area is near the magnet isocenter to improve the overall geometric distortion, which has been shown to increase with increased distance from magnet isocenter[118].

Bore clearance is also important, especially for bulkier setups such as those utilizing breast or wing boards. To ensure the setup used during the CT simulation process (bore sizes typically 70–85 cm) is reproducible at treatment in the smaller bore of the MRgRT system (60–70 cm for the current commercial systems), in-house solutions such as using a bore template, hula hoop with 60–70 cm diameter to check for clearance, or the vendor-provided clearance evaluation tools may be used[117]. The use of coil bridges and frames may be necessary to prevent deformation of the patient anatomical surface, which may result in poor setup reproducibility. With these considerations of coil placement and spacing, the goal of centering target volumes within the bore may not always be feasible. In such cases, the potential for insufficient field of view or scan extent and resulting poor image quality must be considered during adaptive treatment planning.

7.4 Patient Safety Considerations

Prior to patient imaging in the MRgRT environment, contraindications to MRI must be confirmed with screening to confirm all noted MR Safe and MR Conditional devices. Direct contact between any transmit coils or other conductive materials and a patient's bare skin must be avoided in order to reduce the risk of burns and the induction of imaging artifacts[119]. The ACR recommends the placement of vendor-specified padding between a patient's skin and transmit RF coils as well as other points of skin-to-skin contact[22]. An example of a patient setup with the use of a patient support immobilization cushion for coil

placement to reduce the distance between the patient and coil and increase the SNR is shown in Figure 7. A summary of MRgRT-related considerations and potential clinical impacts for the pieces of equipment discussed here is included in Table 5[120,121].

7.5 RT Immobilization Device or Accessory Suitability for MRgRT environment

The flowchart included in Figure 8 describes a general approach to determining the MR Safety of a RT immobilization device or accessory intended for use in an MRgRT environment. It is important to note that the following discussion deals with the suitability with the MRgRT environment. Manufacturer recommendations shall be reviewed to confirm the current MR Safety status of a device as discussed in Sections 3–5.

For those devices labeled as MR Safe or Conditional, the next consideration is the availability of electron density information as required for accurate dose calculation, which may be provided by the manufacturer or derived from an in-house CT scan. Tertiary considerations for RT immobilization devices and accessories are their visibility in an MRI scan and their rigidity. Even if an object is not visible in an MRI scan, the position may be indexed and composition known well enough to enable manual electron density overrides. In some clinical workflows, electron density information for these devices could be introduced through a rigid or deformable registration process between the MRI and an accompanying treatment planning CT. Similarly, a device's rigidity is an important consideration in regards to setup reproducibility and the accuracy of any manual electron density overrides that may need to be performed for the device. This is because the location or placement is extremely important in ensuring consistency between the initial dose calculation and the received daily dose. In the case that either of these conditions is not met and manual electron density overrides are not feasible, the device requires physics QA and dosimetric evaluation to determine if the device can be consistently accommodated in the MRgRT workflow.

As the primary workflow for MRgRT systems still requires electron density for dose calculation, a CT simulation data set may be needed for treatment planning, which may necessitate RT immobilization devices and other equipment to leave and re-enter the MR designated Zone IV. If cost is not prohibitive and to align with recommendations from this TG regarding MR Safety, we recommend that the same RT immobilization device accessory be available both in and outside of the MR environment. If this is not possible, such as when a patient specific mold, mask etc, all equipment exiting and re-entering Zone IV should be tested using a handheld magnet or ferromagnetic detector. Ultimately, as discussed in Sections 3–5, comprehensive testing needs to be performed at the initial adoption stage to ensure the device is MR Safe or Conditional and functional inside Zone IV.

8. Unmet needs and future directions

8.1 Detailed MR Safety testing for external devices

As discussed in Section 3, the current testing standards and documentation are mainly for implanted devices[3,31,33–36,40,69]. These procedures can be extended to RT devices that are small and/or light enough to be tested using the standard methods. The creation of new detailed testing standards and documentation for external RT immobilization devices and

accessories is outside of the scope of this task group report. Given the advent of MRgRT, it would be useful to have such testing methods documented and approved by governing bodies such as the FDA, the ASTM, and IEC, so that there is no ambiguity when a RT immobilization device or accessory is received, especially when the device or accessory is too bulky or heavy to be tested using existing procedures.

8.2 Detailed design of MR Safe or Conditional RT Immobilization devices and accessories

Detailed design principles of MR Safe or Conditional RT immobilization devices or accessories have not been discussed in this task group report. As discussed in Section 6, there is sometimes a need for a specific RT immobilization device or accessory to be made for a certain patient, patient population or treatment method that is not commercially available. When such a device is necessary for use in an MR environment, and the treatment is not emergent, consultations with a vendor or a fabrication laboratory will be necessary. When a treatment is non-emergent but a long timeline for these consultations is not possible, several publications have detailed their in-house devices and fabrication methods [47,50,61,97–102]. However, to ensure adequate and consistent MR Safety for patients in these situations, it would be beneficial for the MRgRT and RT communities for a consensus document to provide and share the details for different treatment sites and diseases so that these patient communities can be served faster.

8.3 Detailed RF coil or bridge positioning or construction for new RT immobilization devices/accessories

This task group report has not discussed the most optimal positioning of RF coil or bridges with RT immobilization devices or accessories. However, it is well discussed in TG284[46]. Also, recent review papers by Cuccia et al (2021)[122] and Hu et al (2020)[123] both discuss the positioning of RT immobilization devices or accessories and RF coils for different disease sites and the associated caveats. Some of the current RF coils available on the market from the vendors also may not be optimal for all patient setups, especially with more bulky RT immobilization devices. Thus, the development of RF coils for these instances could be investigated so that image quality could be improved in these instances. As the adoption of MRgRT accelerates, more development of RF coil, bridge designs that are tailored to imaging in the RT position including immobilization device and accessories will also emerge.

9. Conclusions

To summarize, this task group report provides structured guidance on the safe integration of RT immobilization devices and accessories in the MR environment, including a review of testing methodologies and management of legacy, in-house, and off label use devices. Appendix C summarizes the tests and steps recommended on initial acceptance of a RT immobilization device or accessory as well as the routine quality assurance tests to be performed. The recommendations set forth in this report are made to provide practical and attainable clinical recommendations and actions that medical physicists and other qualified health professionals practicing in MRgRT environments (e.g., diagnostic MRI in the treatment position, MR-based treatment simulation, or MR-linac end users) can take

to support and safely integrate into this hybrid environment. Guidance on recommended staffing involvement, training, and responsibilities are provided along with specific MRgRT considerations. This task group report is expected to function as the basis of future development in MR safe or conditional RT immobilization devices and accessories as the field of MRgRT continues to rapidly expand.

10. Disclosure Statement

The chair of AAPM Task Group 334 has reviewed the required Conflict of Interest statement on file for each member of Task Group 334 and determined that disclosure of potential conflicts is an adequate management plan. The members of Task Group 334 listed below attest that they have no potential conflicts of interest related to the subject matter or materials presented in this document: Dr. Barrett Caldwell, Gil'ad Cohen, Dr. Yanle Hu, Dr. Sunyong Jang, Dr. Ulrich Langner, Dr. Ives Levesque, Dr. Sreeram Narayanan, Dr. Justin C. Park, Dr. Jackie Wu, and Dr. Yong Zhou. The members of Task Group 334 listed below disclose the following potential Conflicts of Interest related to subject matter or materials presented in this document. Dr. Carri Glide-Hurst discloses research agreements with Modus Medical, Inc and GE Healthcare. Dr. Maritza Hobson and Dr. Hannah Lee disclose that their previous employer GenesisCare USA has strategic research partnerships with Elekta AB and ViewRay Technologies Inc. Paul Jackson discloses that his previous employer Henry Ford Health System has a master research agreement ViewRay Technologies Inc. Work reported in this publication was supported in part by the National Cancer Institute of the National Institutes of Health under award numbers: R01CA204189 and R01HL153720 (Carri Glide-Hurst). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. John Steffen discloses that he is the Senior Director of Product Management at CIVCO Radiotherapy and has financial interest in CIVCO Radiotherapy.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Glossary and Abbreviations

ACR	American College of Radiology
ASTM	American Society of Testing and Materials
CT	computed tomography
FDA	Food and Drug Administration

FOV	field of view
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
Linac	linear accelerator
MRgRT	magnetic resonance guided radiation therapy
MRI	magnetic resonance imaging
MRMD	MR medical director
MRS	magnetic resonance spectroscopy
MRSE	MR Safety expert
MRSO	MR Safety officer
NMR	nuclear magnetic resonance
OAR	organ at risk
RF	radiofrequency
RT	radiotherapy
SAR	specific absorption rate
T	tesla

References

1. AAPM. Definition of A Qualified Medical Physicist. AAPM; 2018. https://www.aapm.org/org/policies/details.asp?id=2551
2. McRobbie DW, Moore EA, Graves MJ, Prince MR. Let's talk technical: MR equipment. In: MRI From Picture to Proton. 2nd ed. Cambridge University Press; 2006:167–191. doi:10.1017/CBO9780511545405
3. U.S. Food and Drug Administration Center for Devices and Radiological. Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment. U.S. Food and Drug Administration; 2021. Accessed October 7, 2021. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/testing-and-labeling-medical-devices-safety-magnetic-resonance-mr-environment
4. Panych LP, Madore B. The physics of MRI safety: Physics of MRI Safety. J Magn Reson Imaging. 2018;47(1):28–43. doi:10.1002/jmri.25761 [PubMed: 28543948]
5. Schenck JF. Safety of Strong, Static Magnetic Fields. J Magn Reson Imaging. 2000;12(1):2–19. doi:10.1002/1522-2586(200007)12:1<2::AID-JMRI2>3.0.CO;2-V [PubMed: 10931560]
6. Woods TO, Delfino JG, Rajan S. Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices. J Test Eval. 2021;49(2):20190096. doi:10.1520/JTE20190096
7. Kalin R, Stanton MS. Current Clinical Issues for MRI Scanning of Pacemaker and Defibrillator Patients. Pacing Clin Electrophysiol. 2005;28(4):326–328. doi:10.1111/j.1540-8159.2005.50024.x [PubMed: 15826268]

8. De Andres J, Valía JC, Cerda-Olmedo G, et al. Magnetic Resonance Imaging in Patients with Spinal Neurostimulation Systems. Anesthesiology. 2007;106(4):779–786. doi:10.1097/01.anes.0000264776.17533.06 [PubMed: 17413916]

9. Sayed D, Chakravarthy K, Amirdelfan K, et al. A Comprehensive Practice Guideline for Magnetic Resonance Imaging Compatibility in Implanted Neuromodulation Devices. Neuromodulation Technol Neural Interface. 2020;23(7):893–911. doi:10.1111/ner.13233

10. Neufeld E, Kühn S, Szekely G, Kuster N. Measurement, simulation and uncertainty assessment of implant heating during MRI. Phys Med Biol. 2009;54(13):4151–4169. doi:10.1088/0031-9155/54/13/012 [PubMed: 19521007]

11. Bottomley PA, Andrew ER. RF magnetic field penetration, phase shift and power dissipation in biological tissue: implications for NMR imaging. Phys Med Biol. 1978;23(4):630–643. doi:10.1088/0031-9155/23/4/006 [PubMed: 704667]

12. Collins CM, Wang Z. Calculation of radiofrequency electromagnetic fields and their effects in MRI of human subjects: RF Field Calculations in MRI. Magn Reson Med. 2011;65(5):1470–1482. doi:10.1002/mrm.22845 [PubMed: 21381106]

13. Schaefer DJ. Safety aspects of radiofrequency power deposition in magnetic resonance. Magn Reson Imaging Clin N Am. 1998;6(4):775–789. [PubMed: 9799855]

14. Bennett MC, Wiant DB, Gersh JA, et al. Mechanisms and prevention of thermal injury from gamma radiosurgery headframes during 3T MR imaging. J Appl Clin Med Phys. 2012;13(4):54–70. doi:10.1120/jacmp.v13i4.3613

15. Dempsey MF, Condon B, Hadley DM. Investigation of the factors responsible for burns during MRI. J Magn Reson Imaging. 2001;13(4):627–631. doi:10.1002/jmri.1088 [PubMed: 11276109]

16. Yeung CJ, Susil RC, Atalar E. RF safety of wires in interventional MRI: Using a safety index. Magn Reson Med. 2002;47(1):187–193. doi:10.1002/mrm.10037 [PubMed: 11754458]

17. Winter L, Seifert F, Zilberti L, Murbach M, Ittermann B. MRI-Related Heating of Implants and Devices: A Review. J Magn Reson Imaging. 2021;53(6):1646–1665. doi:10.1002/jmri.27194 [PubMed: 32458559]

18. Graf H, Lauer UA, Schick F. Eddy-current induction in extended metallic parts as a source of considerable torsional moment. J Magn Reson Imaging. 2006;23(4):585–590. doi:10.1002/jmri.20539 [PubMed: 16534754]

19. Graf H, Steidle G, Schick F. Heating of metallic implants and instruments induced by gradient switching in a 1.5-Tesla whole-body unit. J Magn Reson Imaging. 2007;26(5):1328–1333. doi:10.1002/jmri.21157 [PubMed: 17969167]

20. El Bannan K, Handler W, Chronik B, Salisbury SP. Heating of metallic rods induced by time-varying gradient fields in MRI: Heating of Metal Rods by Gradient Fields. J Magn Reson Imaging. 2013;38(2):411–416. doi:10.1002/jmri.23984 [PubMed: 23293032]

21. Jung W, Zvereva V, Hajredini B, Jäckle S. Initial experience with magnetic resonance imaging-safe pacemakers: A review. J Interv Card Electrophysiol. 2011;32(3):213–219. doi:10.1007/s10840-011-9610-0 [PubMed: 21993594]

22. ACR Committee on MR Safety. ACR Manual on MR Safety. American College of Radiology; 2020. https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf

23. Canadian Association of Radiologists. CAR Standard for Magnetic Resonance Imaging (2011). Canadian Association of Radiologists; 2021. Accessed January 13, 2023. https://car.ca/wp-content/uploads/Magnetic-Resonance-Imaging-2011.pdf

24. Medicines and Healthcare products Regulatory Agency (UK). Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use (2021). Medicines and Healthcare products Regulatory Agency (UK); 2021. Accessed January 13, 2023. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/958486/MRI_guidance_2021-4-03c.pdf

25. MRI Working Group (Netherlands). Using MRI Safely – Practical Rules for Employees (2008). MRI Working Group (Netherlands); 2008. Accessed January 13, 2023. https://www.ismrm.org/smrt/files/20081210_Dutch_Guidelines_on_MR_Safety.pdf

26. Safety in magnetic image resonance imaging. Society and College of Radiographers and the British Association of MR Radiographers; 2019. Accessed January 13, 2023. https://www.sor.org/getmedia/07f3f6a9-9c32-43f1-af07-6a9934c21e6c/final_safety_in_magnetic_resonance_imaging_2018_final_word_copy.pdf
27. European Society of Radiology (ESR), European Federation of Radiographer Societies (EFRS). Patient Safety in Medical Imaging: a joint paper of the European Society of Radiology (ESR) and the European Federation of Radiographer Societies (EFRS). Insights Imaging. 2019;10(1):45. doi:10.1186/s13244-019-0721-y [PubMed: 30949870]
28. Ministero della salute. Decreto 10 Agosto 2018 - Determinazione Degli Standard Di Sicurezza e Impiego per Le Apparecchiature a Risonanza Magnetica (2018). Ministero della salute; 2018. Accessed January 19, 2023. https://www.ismrm.org/smrt/safety_page/Determinazione_degli_standard_Ministero_della_salute.pdf
29. European Union. DIRECTIVE 2013/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Minimum Health and Safety Requirements Regarding the Exposure of Workers to the Risks Arising from Physical Agents (Electromagnetic Fields). European Union; 2013. Accessed January 13, 2023. DIRECTIVE 2013/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)
30. The Royal Australian and New Zealand College of Radiologists. MRI Safety Guidelines (Version 3.0) (2021). The Royal Australian and New Zealand College of Radiologists; 2021. Accessed January 13, 2023. https://www.ranzcr.com/college/document-library/ranzcr-mri-safety-guidelines
31. International Electrotechnical Commission. IEC 60601–2-33, Ed. 4.0: Particular Requirements for the Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis. International Electrotechnical Commission; 2022.
32. Delfino JG, Woods TO. New Developments in Standards for MRI Safety Testing of Medical Devices. Curr Radiol Rep. 2016;4(6):28. doi:10.1007/s40134-016-0155-y
33. American Society for Testing and Materials International. ASTM F2052–21: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment. ASTM International; 2022. doi:10.1520/F2052-21
34. American Society for Testing and Materials International. ASTM F2119–07: Test Method for Evaluation of MR Image Artifacts from Passive Implants. ASTM International; 2013. doi:10.1520/F2119-07R13
35. American Society for Testing and Materials International. ASTM F2213–17: Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment. ASTM International; 2017. doi:10.1520/F2213-17
36. American Society for Testing and Materials International. ASTM F2182–19e2: Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging. ASTM International; 2020. doi:10.1520/F2182-19E02
37. International Organization for Standardization (ISO). ISO/TS 10974: Assessment of the Safety of Magnetic Resonance Imaging for Patients with an Active Implantable Medical Device. International Organization for Standardization (ISO); 2018.
38. Kanal E, Froelich J, Barkovich AJ, et al. Standardized MR Terminology and Reporting of Implants and Devices as Recommended by the American College of Radiology Subcommittee on MR Safety. Radiology. 2015;274(3):866–870. doi:10.1148/radiol.14141645 [PubMed: 25329683]
39. Shellock FG, Woods TO, Crues JV. MR Labeling Information for Implants and Devices: Explanation of Terminology. Radiology. 2009;253(1):26–30. doi:10.1148/radiol.2531091030 [PubMed: 19789253]
40. American Society for Testing and Materials International. ASTM F2503–23e1: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International; 2023. doi:10.1520/F2503-23E01
41. Xia M, Zheng J, Yang R, et al. Effects of patient orientations, landmark positions, and device positions on the MRI RF-induced heating for modular external fixation devices. Magn Reson Med. 2021;85(3):1669–1680. doi:10.1002/mrm.28514 [PubMed: 32970911]

42. Jafar MM, Reeves J, Ruthven MA, et al. Assessment of a carbon fibre MRI flatbed insert for radiotherapy treatment planning. Br J Radiol. 2016;89(1062):20160108. doi:10.1259/bjr.20160108 [PubMed: 27033180]
43. Juresic E, Liney GP, Rai R, et al. An assessment of set up position for MRI scanning for the purposes of rectal cancer radiotherapy treatment planning. J Med Radiat Sci. 2018;65(1):22–30. doi:10.1002/jmrs.266 [PubMed: 29528199]
44. Lundman JA, Bylund M, Garpebring A, Thellenberg Karlsson C, Nyholm T. Patient-induced susceptibility effects simulation in magnetic resonance imaging. Phys Imaging Radiat Oncol. 2017;1:41–45. doi:10.1016/j.phro.2017.02.004
45. Nagtegaal SHJ, van Lier ALHMW, den Boer AA, et al. Does an immobilization mask have added value during planning magnetic resonance imaging for stereotactic radiotherapy of brain tumours? Phys Imaging Radiat Oncol. 2020;13:7–13. doi:10.1016/j.phro.2020.02.003 [PubMed: 33458301]
46. Glide-Hurst CK, Paulson ES, McGee K, et al. Task group 284 report: magnetic resonance imaging simulation in radiotherapy: considerations for clinical implementation, optimization, and quality assurance. Med Phys. 2021;48(7):e636–e670. doi:10.1002/mp.14695 [PubMed: 33386620]
47. Hanvey S, Sadozye AH, McJury M, Glegg M, Foster J. The influence of MRI scan position on image registration accuracy, target delineation and calculated dose in prostatic radiotherapy. Br J Radiol. 2012;85(1020):e1256–e1262. doi:10.1259/bjr/26802977 [PubMed: 23175491]
48. Zhou Y, Yuan J, Wong OL, et al. Assessment of positional reproducibility in the head and neck on a 1.5-T MR simulator for an offline MR-guided radiotherapy solution. Quant Imaging Med Surg. 2018;8(9):925–935. doi:10.21037/qims.2018.10.03 [PubMed: 30505721]
49. Hanvey S, Glegg M, Foster J. Magnetic resonance imaging for radiotherapy planning of brain cancer patients using immobilization and surface coils. Phys Med Biol. 2009;54(18):5381–5394. doi:10.1088/0031-9155/54/18/002 [PubMed: 19687561]
50. Mandija S, D'Agata F, Navest RJM, et al. Brain and Head-and-Neck MRI in Immobilization Mask: A Practical Solution for MR-Only Radiotherapy. Front Oncol. 2019;9:647. doi:10.3389/fonc.2019.00647 [PubMed: 31380283]
51. Wong OL, Yuan J, Yu SK, Cheung KY. Image quality assessment of a 1.5T dedicated magnetic resonance-simulator for radiotherapy with a flexible radio frequency coil setting using the standard American College of Radiology magnetic resonance imaging phantom test. Quant Imaging Med Surg. 2017;7(2):205–214. doi:10.21037/qims.2017.02.08 [PubMed: 28516046]
52. Webster GJ, Kilgallon JE, Ho KF, Rowbottom CG, Slevin NJ, Mackay RI. A novel imaging technique for fusion of high-quality immobilised MR images of the head and neck with CT scans for radiotherapy target delineation. Br J Radiol. 2009;82(978):497–503. doi:10.1259/bjr/50709041 [PubMed: 19221183]
53. Groot Koerkamp ML, Vasmel JE, Russell NS, et al. Optimizing MR-Guided Radiotherapy for Breast Cancer Patients. Front Oncol. 2020;10:1107. doi:10.3389/fonc.2020.01107 [PubMed: 32850318]
54. Ahn KH, Hargreaves BA, Alley MT, et al. MRI Guidance for Accelerated Partial Breast Irradiation in Prone Position: Imaging Protocol Design and Evaluation. Int J Radiat Oncol. 2009;75(1):285–293. doi:10.1016/j.ijrobp.2009.03.063
55. Batumalai V, Liney G, Delaney GP, et al. Assessment of MRI image quality for various setup positions used in breast radiotherapy planning. Radiother Oncol. 2016;119(1):57–60. doi:10.1016/j.radonc.2016.02.024 [PubMed: 26970675]
56. Johnstone RI, Guerrero-Urbano T, Michaelidou A, et al. Guidance on the use of MRI for treatment planning in radiotherapy clinical trials. Br J Radiol. 2020;93(1105):20190161. doi:10.1259/bjr.20190161 [PubMed: 31724876]
57. Xing A, Holloway L, Arumugam S. Commissioning and quality control of a dedicated wide bore 3T MRI simulator for radiotherapy planning. Int J Cancer Ther Oncol. 2016;4(2):421. doi:10.14319/ijcto.42.1
58. Liney GP, Owen SC, Beaumont AKE, Lazar VR, Manton DJ, Beavis AW. Commissioning of a new wide-bore MRI scanner for radiotherapy planning of head and neck cancer. Br J Radiol. 2013;86(1027):20130150. doi:10.1259/bjr.20130150 [PubMed: 23690434]

59. Graf H, Steidle G, Martirosian P, Lauer UA, Schick F. Metal artifacts caused by gradient switching. Magn Reson Med. 2005;54(1):231–234. doi:10.1002/mrm.20524 [PubMed: 15968663]
60. Nakazawa H, Komori M, Shibamoto Y, Takikawa Y, Mori Y, Tsugawa T. Geometric accuracy in three-dimensional coordinates of Leksell stereotactic skull frame with wide-bore 1.5-T MRI compared with conventional 1.5-T MRI: Localization accuracy of wide-bore MRI. J Med Imaging Radiat Oncol. 2014;58(5):595–600. doi:10.1111/1754-9485.12225 [PubMed: 25124316]
61. Paulson ES, Erickson B, Schultz C, Allen Li X. Comprehensive MRI simulation methodology using a dedicated MRI scanner in radiation oncology for external beam radiation treatment planning. Med Phys. 2014;42(1):28–39. doi:10.1118/1.4896096
62. Devic S MRI simulation for radiotherapy treatment planning: MRI-simulation for RTP. Med Phys. 2012;39(11):6701–6711. doi:10.1118/1.4758068 [PubMed: 23127064]
63. Rai R, Kumar S, Batumalai V, et al. The integration of MRI in radiation therapy: collaboration of radiographers and radiation therapists. J Med Radiat Sci. 2017;64(1):61–68. doi:10.1002/jmrs.225 [PubMed: 28211218]
64. Buszek SM, Ikner S, Wiedemann L, et al. Safety and Feasibility of Magnetic Resonance Imaging Simulation for Radiation Treatment Planning in Pediatric Patients: A Single Institution Experience. Adv Radiat Oncol. 2019;4(2):362–366. doi:10.1016/j.adro.2018.12.002 [PubMed: 31011682]
65. Das IJ, McGee KP, Tyagi N, Wang H. Role and future of MRI in radiation oncology. Br J Radiol. 2019;92(1094):20180505. doi:10.1259/bjr.20180505 [PubMed: 30383454]
66. Lagendijk JJW, Raaymakers BW, Van den Berg CAT, Moerland MA, Philippens ME, van Vulpen M. MR guidance in radiotherapy. Phys Med Biol. 2014;59(21):R349–R369. doi:10.1088/0031-9155/59/21/R349 [PubMed: 25322150]
67. Cao M, Padgett KR, Rong Y. Are in-house diagnostic MR physicists necessary for clinical implementation of MRI guided radiotherapy? J Appl Clin Med Phys. 2017;18(5):6–9. doi:10.1002/acm2.12171
68. Canadian Partnership for Quality Radiotherapy. MRI.2020.09.01: Canadian Partnership for Quality Radiotherapy Technical Quality Control Guidelines for Magnetic Resonance Imaging for Radiation Treatment Planning; 2020. Accessed October 8, 2021. http://www.cpqr.ca/wp-content/uploads/2020/09/MRI-2020-05-01.pdf
69. U.S. Food and Drug Administration Center for Devices and Radiological. Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices.; 2016. Accessed October 14, 2021. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessment-radiofrequency-induced-heating-magnetic-resonance-mr-environment-multi-configuration
70. Lamoureux M Personal e-mail communication regarding ASTM standards/device approval, Medical Devices Evaluation Bureau, Health Canada. Published online April 30, 2021.
71. ISO/IEC. ISO/IEC 17025:2017: General Requirements for the Competence of Testing and Calibration Laboratories. International Organization for Standardization; 2017. https://www.iso.org
72. Kainz W MR heating tests of MR critical implants. J Magn Reson Imaging. 2007;26(3):450–451. doi:10.1002/jmri.21020 [PubMed: 17729357]
73. Shellock FG. Comments on MR heating tests of critical implants. J Magn Reson Imaging. 2007;26(5):1182–1185. doi:10.1002/jmri.21176 [PubMed: 17969159]
74. Schena E, Tosi D, Saccomandi P, Lewis E, Kim T. Fiber Optic Sensors for Temperature Monitoring during Thermal Treatments: An Overview. Sensors. 2016;16(7):1144. doi:10.3390/s16071144 [PubMed: 27455273]
75. Bottomley PA. Turning Up the Heat on MRI. J Am Coll Radiol. 2008;5(7):853–855. doi:10.1016/j.jacr.2008.04.003 [PubMed: 18585665]
76. Cortes ARG, Abdala-Junior R, Weber M, Arita ES, Ackerman JL. Influence of pulse sequence parameters at 1.5 T and 3.0 T on MRI artefacts produced by metal–ceramic restorations. Dentomaxillofacial Radiol. 2015;44(8):20150136. doi:10.1259/dmfr.20150136

77. Morris ED, O'Connell DP, Gao Y, Cao M. MR safety considerations for MRI-guided radiotherapy. In: Advances in Magnetic Resonance Technology and Applications. Vol 8. Elsevier; 2023:81–100. doi:10.1016/B978-0-323-91689-9.00005-4

78. Pappas EP, Seimenis I, Moutsatsos A, Georgiou E, Nomikos P, Karaiskos P. Characterization of system-related geometric distortions in MR images employed in Gamma Knife radiosurgery applications. Phys Med Biol. 2016;61(19):6993–7011. doi:10.1088/0031-9155/61/19/6993 [PubMed: 27648985]

79. Weiss S, Nejad-Davarani S, Eggers H, Orasanu E, Renisch S, Glide-Hurst C. A novel and rapid approach to estimate patient-specific distortions based on mDIXON MRI. Phys Med Biol. 2019;64(15):155002. doi:10.1088/1361-6560/ab2b0a [PubMed: 31216529]

80. Paulson ES, Crijns SPM, Keller BM, et al. Consensus opinion on MRI simulation for external beam radiation treatment planning. Radiother Oncol. 2016;121(2):187–192. doi:10.1016/j.radonc.2016.09.018 [PubMed: 27838146]

81. Liney GP, Moerland MA. Magnetic Resonance Imaging Acquisition Techniques for Radiotherapy Planning. Semin Radiat Oncol. 2014;24(3):160–168. doi:10.1016/j.semradonc.2014.02.014 [PubMed: 24931086]

82. Fortunati V, Verhaart RF, Verduijn GM, et al. MRI integration into treatment planning of head and neck tumors: Can patient immobilization be avoided? Radiother Oncol. 2015;115(2):191–194. doi:10.1016/j.radonc.2015.03.021 [PubMed: 25866029]

83. Glide-Hurst CK, Wen N, Hearshen D, et al. Initial clinical experience with a radiation oncology dedicated open 1.0T MR-simulation. J Appl Clin Med Phys. 2015;16(2):218–240. doi:10.1120/jacmp.v16i2.5201

84. Walker A, Metcalfe P, Liney G, et al. MRI geometric distortion: Impact on tangential whole-breast IMRT. J Appl Clin Med Phys. 2016;17(5):7–19. doi:10.1120/jacmp.v17i5.6242 [PubMed: 28297426]

85. Mcjury M, O'Neill A, Lawson M, et al. Assessing the image quality of pelvic MR images acquired with a flat couch for radiotherapy treatment planning. Br J Radiol. 2011;84(1004):750–755. doi:10.1259/bjr/27295679 [PubMed: 21750138]

86. Gach HM, Green OL, Mackey SL, et al. Implementation of Magnetic Resonance Safety Program for Radiation Oncology. Pract Radiat Oncol. Published online August 2021:S1879850021002241. doi:10.1016/j.prro.2021.08.008

87. Huq MS, Fraass BA, Dunscombe PB, et al. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management: TG 100 report. Med Phys. 2016;43(7):4209–4262. doi:10.1118/1.4947547 [PubMed: 27370140]

88. Teng S(Gary), Ho S (Michael). Failure mode and effects analysis: An integrated approach for product design and process control. Int J Qual Reliab Manag. 1996;13(5):8–26. doi:10.1108/02656719610118151

89. Teoh PC, Case K. Failure modes and effects analysis through knowledge modelling. J Mater Process Technol. 2004;153–154:253–260. doi:10.1016/j.jmatprotec.2004.04.298

90. Kim J, Miller B, Siddiqui MS, Movsas B, Glide-Hurst C. FMEA of MR-Only Treatment Planning in the Pelvis. Adv Radiat Oncol. 2019;4(1):168–176. doi:10.1016/j.adro.2018.08.024 [PubMed: 30706025]

91. Thornton E, Brook OR, Mendiratta-Lala M, Hallett DT, Kruskal JB. Application of Failure Mode and Effect Analysis in a Radiology Department. RadioGraphics. 2011;31(1):281–293. doi:10.1148/rg.311105018 [PubMed: 20980666]

92. de Mooy LG. The use of carbon fibres in radiotherapy. Radiother Oncol. 1991;22(2):140–142. doi:10.1016/0167-8140(91)90010-E [PubMed: 1957004]

93. Prisciandaro J, Zoberi J (Esthappan), Cohen G, et al. AAPM task group report 303 endorsed by the ABS: MRI implementation in HDR brachytherapy—Considerations from simulation to treatment. Med Phys Published online June 20, 2022:mp.15713. doi:10.1002/mp.15713

94. American College of Radiology, Society of Interventional Radiology. ACR–SIR Practice Parameter for Adult Sedation/Analgesia.; 2020. Accessed February 24, 2020. https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Sed-Analgesia.pdf?la=en

95. Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging. Anesthesiology. 2015;122(3):495–520. doi:10.1097/ALN.0000000000000458 [PubMed: 25383571]

96. Ding Y, Mohamed ASR, Yang J, et al. Prospective observer and software-based assessment of magnetic resonance imaging quality in head and neck cancer: Should standard positioning and immobilization be required for radiation therapy applications? Pract Radiat Oncol. 2015;5(4):e299–e308. doi:10.1016/j.prro.2014.11.003 [PubMed: 25544553]

97. Botman R, Tetar SU, Palacios MA, Slotman BJ, Lagerwaard FJ, Bruynzeel AME. The clinical introduction of MR-guided radiation therapy from a RTT perspective. Clin Transl Radiat Oncol. 2019;18:140–145. doi:10.1016/j.ctro.2019.04.019 [PubMed: 31341990]

98. Herrmann KH, Gärtner C, Güllmar D, Krämer M, Reichenbach JR. 3D printing of MRI compatible components: Why every MRI research group should have a low-budget 3D printer. Med Eng Phys. 2014;36(10):1373–1380. doi:10.1016/j.medengphy.2014.06.008 [PubMed: 25092622]

99. Haefner MF, Giesel FL, Mattke M, et al. 3D-Printed masks as a new approach for immobilization in radiotherapy - a study of positioning accuracy. Oncotarget. 2018;9(5):6490–6498. doi:10.18632/oncotarget.24032 [PubMed: 29464087]

100. Mitsouras D, Lee TC, Liacouras P, et al. Three-dimensional printing of MRI-visible phantoms and MR image-guided therapy simulation. Magn Reson Med. 2017;77(2):613–622. doi:10.1002/mrm.26136 [PubMed: 26864335]

101. Glide-Hurst CK, Myers E, Du D, et al. Development of 3D printed immobilization for the MR-linac: Toward high precision brain treatments. Med Phys. 2018;45(6):e481–e482.

102. Lee HJ. Volumetric, Magnetic Resonance-Visible, and Radiation-Sensitive Detectors for Magnetic Resonance Image-Guided Radiation Therapy. Ph.D. The University of Texas MD Anderson Cancer Center, UTHealth Graduate School of Biomedical Sciences; 2017.

103. Thomadsen BR, Heaton HT, Jani SK, et al. Off-label use of medical products in radiation therapy: Summary of the Report of AAPM Task Group No. 121a): Off-label use of medical products. Med Phys. 2010;37(5):2300–2311. doi:10.1118/1.3392286 [PubMed: 20527564]

104. Hall WA, Paulson ES, van der Heide UA, et al. The transformation of radiation oncology using real-time magnetic resonance guidance: A review. Eur J Cancer. 2019;122:42–52. doi:10.1016/j.ejca.2019.07.021 [PubMed: 31614288]

105. Kerkmeijer LGW, Fuller CD, Verkooijen HM, et al. The MRI-Linear Accelerator Consortium: Evidence-Based Clinical Introduction of an Innovation in Radiation Oncology Connecting Researchers, Methodology, Data Collection, Quality Assurance, and Technical Development. Front Oncol. 2016;6. doi:10.3389/fonc.2016.00215

106. Liney GP, Whelan B, Oborn B, Barton M, Keall P. MRI-Linear Accelerator Radiotherapy Systems. Clin Oncol. 2018;30(11):686–691. doi:10.1016/j.clon.2018.08.003

107. Hoogcarspel SJ, Zijlema SE, Tijssen RHN, et al. Characterization of the first RF coil dedicated to 1.5 T MR guided radiotherapy. Phys Med Biol. 2018;63(2):025014. doi:10.1088/1361-6560/aaa303 [PubMed: 29260729]

108. Mutic S, Dempsey JF. The ViewRay System: Magnetic Resonance–Guided and Controlled Radiotherapy. Semin Radiat Oncol. 2014;24(3):196–199. doi:10.1016/j.semradonc.2014.02.008 [PubMed: 24931092]

109. Mittauer KE, Dunkerley DAP, Yadav P, Bayouth JE. Characterization and longitudinal assessment of daily quality assurance for an MR-guided radiotherapy (MRgRT) linac. J Appl Clin Med Phys. 2019;20(11):27–36. doi:10.1002/acm2.12735

110. Elter A, Dorsch S, Mann P, et al. End-to-end test of an online adaptive treatment procedure in MR-guided radiotherapy using a phantom with anthropomorphic structures. Phys Med Biol. 2019;64(22):225003. doi:10.1088/1361-6560/ab4d8e [PubMed: 31610529]

111. Tadic T, Fallone BG. Design and Optimization of a Novel Bored Biplanar Permanent-Magnet Assembly for Hybrid Magnetic Resonance Imaging Systems. IEEE Trans Magn. 2010;46(12):4052–4058. doi:10.1109/TMAG.2010.2074208

112. Fallone BG. The Rotating Biplanar Linac–Magnetic Resonance Imaging System. Semin Radiat Oncol. 2014;24(3):200–202. doi:10.1016/j.semradonc.2014.02.011 [PubMed: 24931093]

113. Winkel D, Bol GH, Kroon PS, et al. Adaptive radiotherapy: The Elekta Unity MR-linac concept. Clin Transl Radiat Oncol. 2019;18:54–59. doi:10.1016/j.ctro.2019.04.001 [PubMed: 31341976]

114. Snyder JE, St-Aubin J, Yaddanapudi S, et al. Commissioning of a 1.5T Elekta Unity MR-linac: A single institution experience. J Appl Clin Med Phys. 2020;21(7):160–172. doi:10.1002/acm2.12902 [PubMed: 32432405]
115. ViewRay, Inc. Operator's Manual for the MRIdian Linac System Version 5 Document No. L-0086 Rev D. ViewRay, Inc.; 2019.
116. ViewRay, Inc. Physics Essential Guide: Technical Manual for the MRIdian Linac System Document No. L-0092. ViewRay, Inc.; 2019.
117. Elekta. Elekta Unity Instructions for Use - Clinical Mode Document ID 1530128_07. Elekta; 2020.
118. Nejad-Davarani SP, Kim JP, Du D, Glide-Hurst C. Large field of view distortion assessment in a low-field MR -linac. Med Phys. 2019;46(5):2347–2355. doi:10.1002/mp.13467 [PubMed: 30838680]
119. Shellock FG, Crues JV. MR Procedures: Biologic Effects, Safety, and Patient Care. Radiology. 2004;232(3):635–652. doi:10.1148/radiol.2323030830 [PubMed: 15284433]
120. Salvi R, Sheppard A. Is Noise in the MR Imager a Significant Risk Factor for Hearing Loss? Radiology. 2018;286(2):609–610. doi:10.1148/radiol.2017172221 [PubMed: 29356640]
121. Jin C, Li H, Li X, et al. Temporary Hearing Threshold Shift in Healthy Volunteers with Hearing Protection Caused by Acoustic Noise Exposure during 3-T Multisequence MR Neuroimaging. Radiology. 2018;286(2):602–608. doi:10.1148/radiol.2017161622 [PubMed: 28813235]
122. Cuccia F, Alongi F, Belka C, et al. Patient positioning and immobilization procedures for hybrid MR-Linac systems. Radiat Oncol. 2021;16(1):183. doi:10.1186/s13014-021-01910-6 [PubMed: 34544481]
123. Hu Q, Yu VY, Yang Y, et al. Practical Safety Considerations for Integration of Magnetic Resonance Imaging in Radiation Therapy. Pract Radiat Oncol. 2020;10(6):443–453. doi:10.1016/j.prro.2020.07.008 [PubMed: 32781246]

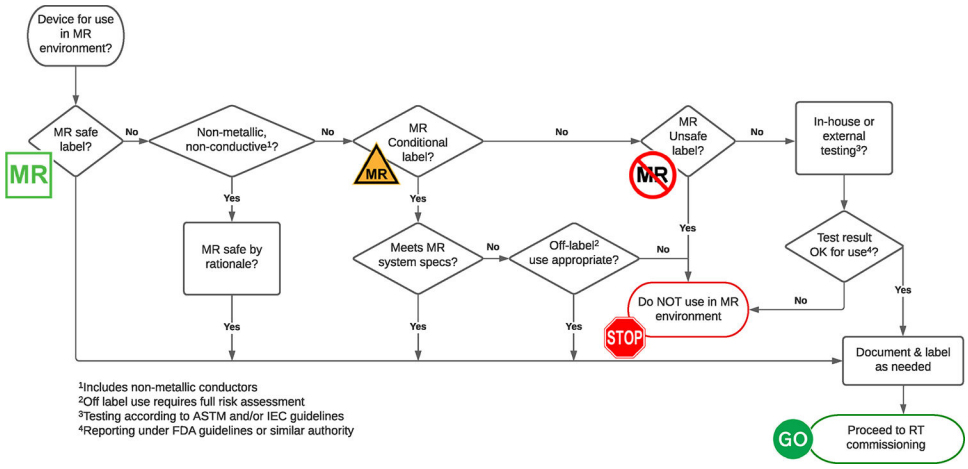

Figure 1.

A suggested workflow diagram of how to determine the MR safety status of a RT immobilization device and accessory.

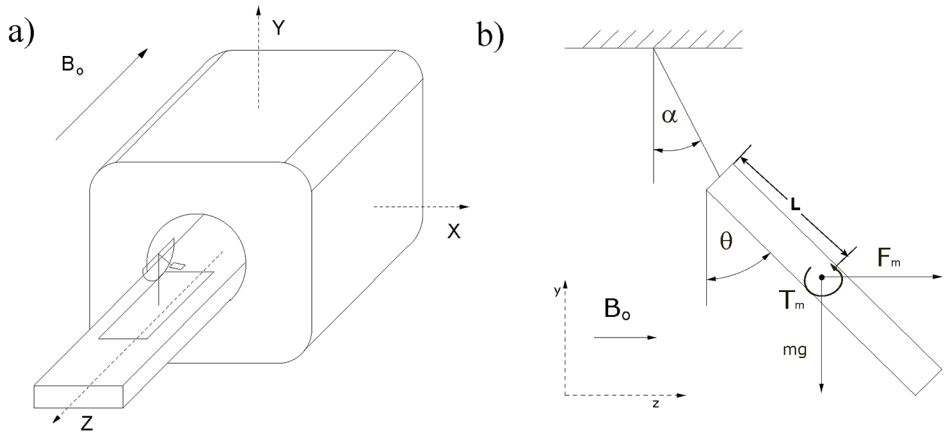

Figure 2.

(a) Proposed setup from ASTM document F2052 for determining the magnetically induced displacement force. Setup involves hanging the immobilization device or accessory from a string near the entrance to a horizontal bore MR system on the axis of the horizontally oriented static magnetic field. (b) The angle of deflection, α, is used to determine whether the device or accessory is safe to be used with regards to the magnetically induced displacement force. Reprinted, with permission, from ASTM F2052–21, Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment, copyright ASTM International. A copy of the complete standard may be obtained from www.astm.org.

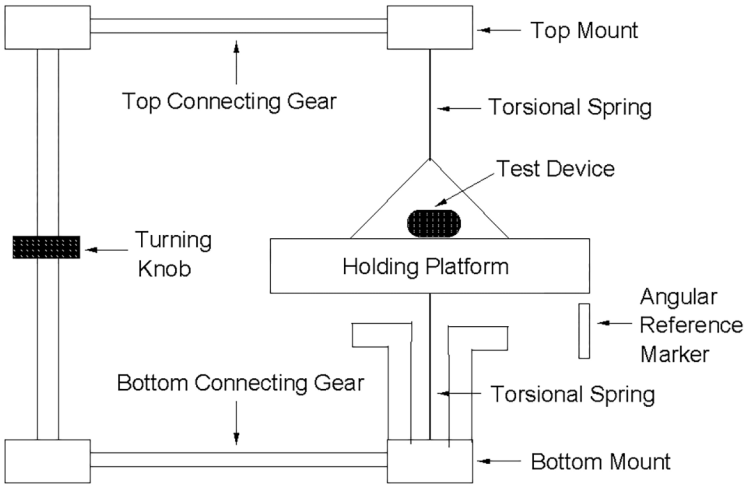

Figure 3.

Proposed setup from ASTM document F2213 for determining the magnetically induced torque. Setup involves placing the immobilization device or accessory on a holding platform with torsional spring. The amount of torque is calculated using the measured amount of angular deflection and the spring constant. The reader can refer to the ASTM F2213 documentation for the details of the method. Reprinted, with permission, from ASTM F2213–17, Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment., copyright ASTM International. A copy of the complete standard may be obtained from www.astm.org.

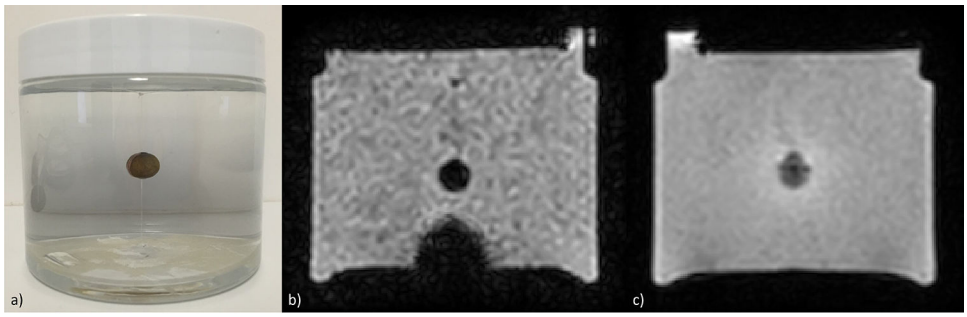

Figure 4.

(a) Setup of rFOX dosimeter gel container demonstrated with water and brass ball bearing (BB) attached to PET plastic container using fishing line to initially suspend the ball at the desired location inside the container with adhesive. (b) MR image with Loctite super glue used to adhere BB setup. The glue is at the bottom of the container where the dark void in signal is. The initial setup was in water to test out the BB. The glue was used so that the BB could be fixed before adding in the initially liquid gel before it solidifies. (c) MR image with hot glue used to adhere BB setup. For b) and c), the following sequence parameters were used: T1 3D, TR/TE = 13/4.5 ms, and 27° flip angle. The slice thickness for b) was 3 mm and the slice thickness for c) was 10 mm, resulting in the difference in image noise. Adapted from Figure 47 in Lee, HJ (2017).

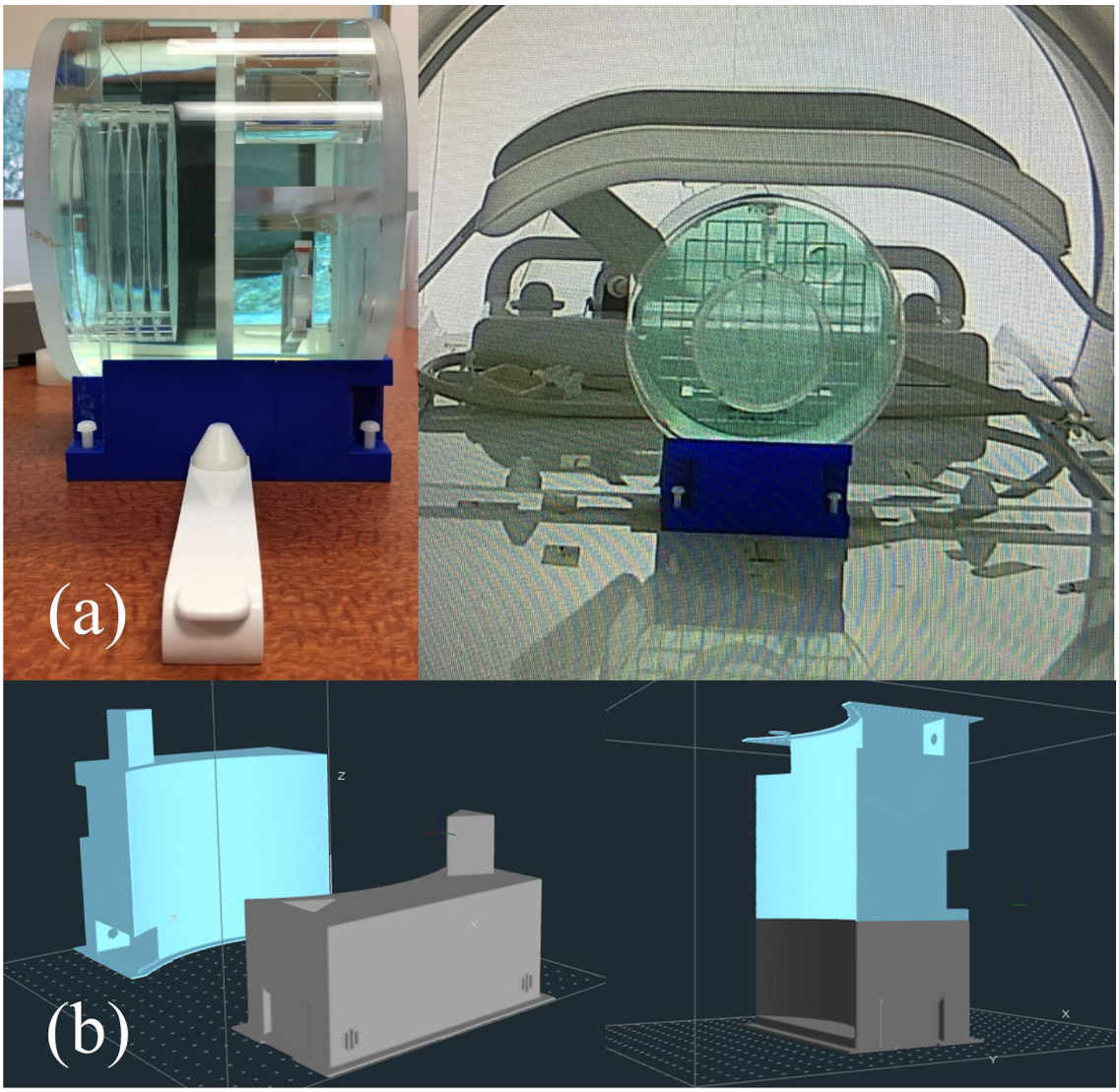

Figure 5.

(a) Due to the lack of an ACR phantom cradle available for a higher field strength MRgRT system, an in-house solution was created using 3D printed Polyactic acid (PLA) (blue pieces in the subfigure (a) underneath the ACR phantom). When using scan parameters designated by the ACR, no imaging artifacts resulted from using 3D printing PLA filament and the incorporated bonding agent, Weld-On #16 Clear (Medium Bodied Solvent Cement), to combine the printed pieces. (b) The ACR phantom cradle was 3D printed as 2 separate pieces as shown in this figure and then combined due to physical printing limitations of the specific 3D printer used (Ender 3 Pro).

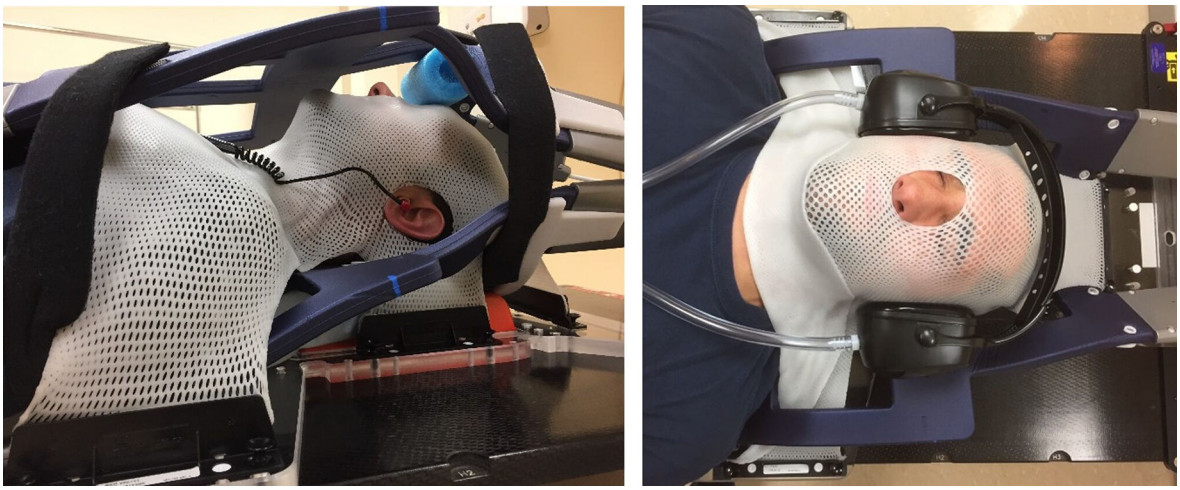

Figure 6.
Two example coil configurations with immobilization devices and required hearing protection for head and neck cancer radiation therapy with a MR-linac.

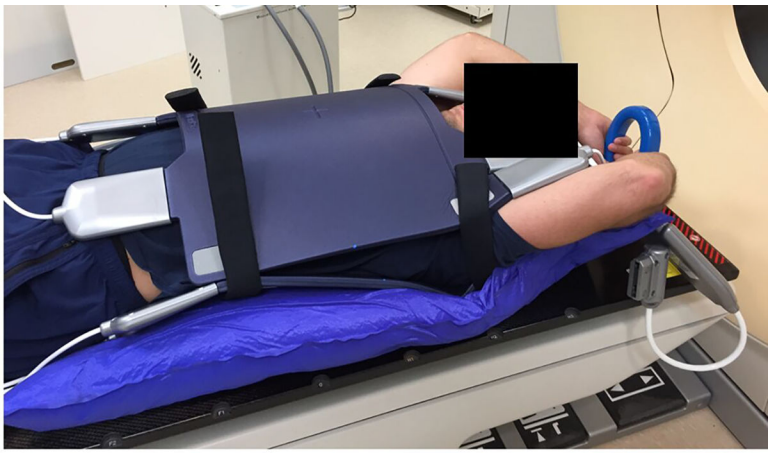

Figure 7.

An example of patient setup for thoracic radiation therapy with an MR-linac. Patient is setup with Posterior MRI receive coil built into a patient support immobilization cushion with Anterior MRI receive coil placed directly on patient to reduce distance between patient and coil to increase signal-to-noise ratio.

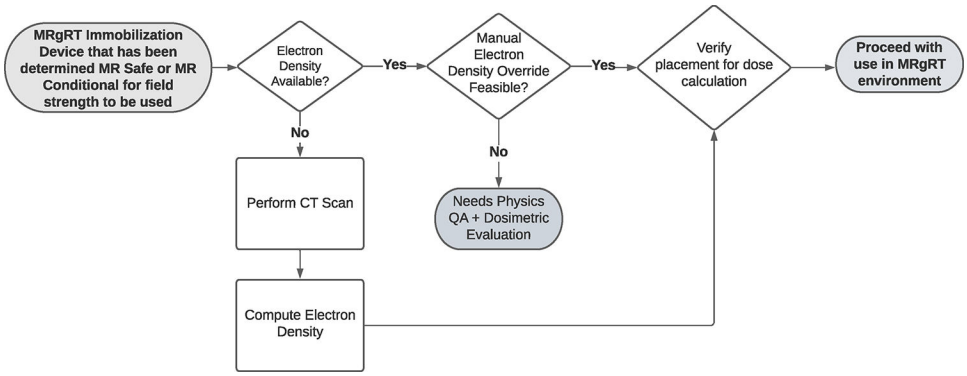

Figure 8.

Flow chart to assess the suitability of a RT immobilization device or accessory for a MRgRT environment.

Table 1.

Subsystems of a typical MRI system with superconducting magnet. The components and role of each subsystem are listed, along with typical values. Related safety implications are listed in Table 2.

Subsystem	Components	Role	Typical values
Main field	Main magnet, shim subsystem, cryostat	Generate highly uniform static $\mathbf{B_0}$ field	$\lvert\mathbf{B_0}\rvert$ = 0.25–7 T (^{1}H f_0 = 10–298 MHz)
RF transmit	Transmitter, power amplifier, transmit coil	Generate time-varying $\mathbf{B_1}$ field to induce NMR signal	peak $\lvert\mathbf{B_1}\rvert$ ~50 μT, depending on $\lvert B_0\rvert$ Circular polarization or multi-channel
RF receive	Receive coil, preamplifier, digitizer, digital signal processing	Signal detection	–
Gradient	Pulse generator, amplifiers, coils	Generate pulsed gradient fields **G** for spatial encoding and contrast modulation	Max. $\lvert\mathbf{G}\rvert$ ~ 30–80 mT/m Max. $d\lvert\mathbf{G}\rvert/dt$ ~ 150 – 200 T/m/s

Table 2.

Subsystems of a typical MRI system with superconducting magnet. Each subsystem is listed with specific considerations and related safety risks. Descriptions of subsystems and roles can be found in Table 1.

Subsystem	Considerations	Safety risks
Main field	Strong superconducting magnet Fringe field extends well outside the bore Field is on at all times	Risks always present Powerful magnetic displacement force and torque on ferromagnetic objects[4–6] Force on conductive objects due to Lenz's Law Disruption of active devices [7–9]
	Presence of cryogen	Patient and/or staff exposure to cryogen
RF transmit	Pulsed radiofrequency magnetic field On during imaging only Field largely contained within the bore	Risks present during imaging, inside the bore
	RF power deposition[10] Quantified using Specific Absorption Rate (SAR) [11,12], specific Energy Dose (SED), or root-mean-square transmit field (B_{1+rms})	Heating[4,13–17] of patient Heating of implants and/or devices possibly leading to patient heating Potential for burns
	Considerations for MR Conditional status of conductive implants and devices	Mis-use may lead to heating of implants and/or devices leading to patient discomfort and/or injury, and/or equipment damage
	Rectification of RF pulses[3]	Electrical stimulation in the body Disruption of active devices[7–9]
RF receive	Must be plugged in and recognized by system Actively detuned during transmission	Improperly connected coils may lead to coil heating resulting in patient heating, implant heating, and/or equipment damage
Gradient	Magnetic field components parallel to main field On during imaging only Field largely contained withing the bore	Risks present during imaging, inside the bore
	Acoustic noise	Patient discomfort, potential for hearing damage
	Time-varying magnetic fields and/or mechanical vibrations[18]	Gradient induced electrical potential in patient (peripheral nerve stimulation)[3] Gradient induced vibration of devices[3] Gradient induced heating of devices[19,20] Disruption of active devices[21]
Patient subsystem	Moving parts Ventilation, lighting, communication	Mis-use leading to injury Ventilation used to reducing patient heating

Table 3.

Relevant MRI system specifications for MRI safety assessment of devices. Information aligns with FDA guidance for medical device safety in the MR Environment[2] and ISO Technical Specification 10974[37]. Not all parameters listed are relevant to every device safety assessment. A complete assessment should at least consider all these specifications.

Subsystem	Specification	Description	Symbol; units
MR System	Nucleus of interest *	Nucleus or nuclei being imaged or used for spectroscopy (*e.g.* ^{1}H, ^{31}P, ^{23}Na, ^{13}C)	n/a
	Scanner type	Design of the MRI system (cylindrical bore, vertical bore, etc.)	n/a
Main field	Static magnetic field B_0	Magnetic flux density at center of MRI system	T
	Maximum spatial field gradient ∇B_0	Maximum value of spatial gradient of static magnetic field, identifiable on spatial gradient field maps	T/m (or G/cm)
Gradient field	Maximum gradient amplitude per axis G_{max}	Maximum value of pulsed gradient fields for each axis	T/m
	Maximum gradient slew rate per axis	Maximum temporal rate of change of the pulsed gradient fields for each axis	T/m/s
	Maximum rate of change of field $\lvert dB/dt \rvert$ †	Maximum temporal rate of change of the magnetic field due to the pulsed gradient fields	T/s
	Root-mean-square rate of change of field $\lvert dB/dt \rvert_{rms}$ †	Root-mean square temporal rate of change of the magnetic field due to the pulsed gradient fields	T/s
RF transmit and receive	RF excitation mode	Choice of RF excitation mode (circular polarization, multi-channel etc.); include the number of channels in multi-channel	n/a
	RF transmit coil	Choice of coil for RF excitation (body coil, head transmit coil, etc.)	n/a
	RF receive coil type	Choice of coil for RF signal reception (body coil, head receive-only, surface coil, etc.)	n/a
	Maximum achievable SAR	Maximum specific absorption rate for RF power deposition (1.5 T and 3 T systems limited by operating modes); SAR is patient, sequence, and protocol dependent	W/kg
	Maximum B_{1+} amplitude or root-mean-square (rms) B_{1+} amplitude31 †	Maximum transmit field amplitude; in practical circumstances, the root-mean-square value of B_{1+}, B_{1+rms}, can be used in lieu of SAR and is sequence and protocol dependent.	μT

* Nucleus of interest is relevant as it impacts center frequency selection and system design. Assumed to be ^{1}H throughout this document when not specified.

† Parameters sometimes used in device safety description but not required by FDA guidance and not always reported by system manufacturers.

Table 4.

Recommendations for staffing roles when determining the MR Safety status of a RT immobilization device or accessory. Roles may be adjusted based on internal credentialing processes.

Action	MRI QMP	Non-MRI, Non-Diagnostic QMP with sufficient training per internal credentialing	Trained MPA/RTT/MP resident under supervision of QMP	Test Engineer
Reading labels on new devices and ascertaining that the device can be used safely	●	●	●	●
Verifying MR Safe labeling consistent with product	●	●	●	●
Dedicated device testing as per Section 3 to meet ASTM standards when no labeling is available	✓	✓		●
Dedicated device testing as per Section 3 to meet ASTM standards when want to use device labeled as MR Conditional outside of conditions	●✓	✓		●
Checking cleared device clearance with hand-held magnet or ferromagnetic detection system before entering MR suite (Zone III)	●	●	●	●

● Performed by

✓ Reviewed by

Table 5

Major equipment and related considerations and potential impact for use in MRgRT systems.

Major Equipment	MRgRT immobilization considerations	Potential clinical impact
Indexing Bar	Verify MRI Safe if used between CT and MR-Linac couches	Ferromagnetic interaction with the main magnet [Critical]
	Verify consistent dimensions and indexing between MR-Linac and CT couch	Device incompatibility Inaccurate electron density mapping
Hearing protection	Hearing protection required (attenuate to < 105 dBA)[120,121]	Patient Discomfort
	Build into immobilization devices	Proper fitting of masks and other immobilization devices may be compromised if hearing protection is not taken into account during the simulation setup process
	Electron Density Modeled with CT or bulk density override	Treatment site underdosed in case the device overlaps with the beam path
Surface coils and coil bridge/frame	Direct contact between the surface coil and patient's bare skin must be avoided	Burn risk and image artifacts
	Prevent the coil weight from deforming patient anatomy	Poor setup reproducibility
	Position of coil relative to radiation beam entry	Incorrect dose calculation from expected radiation attenuation and damage to electrical components of the coil
	Clearance of immobilization devices inside bore and coil setup	Patient injury due to lack of clearance and inability to perform couch corrections as needed Improper coil setup may lead to insufficient field of view/ scan extent and poor image quality due to lack of coil coverage