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White Paper

RF heating, Force, Torque and Artifact of RFID tag

MR systems:
1.5 Tesla, Intera, Philips Healthcare
3 Tesla, Magnetom Trio, Siemens Healthcare
3 Tesla Achieva Philips Healthcare

Test objects: “FT301 & FT401”

Datamars textile ID, Switzerland
ImageFirst, United States of America

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Content:

1. Introduction

Implants and devices that are used in the Magnetic Resonance Imaging (“MR” or “MRI”) environment can pose possible risks to patients due to the interaction with the electromagnetic field. Therefore, objects that are present during MRI examination have to be labeled as “MR safe” or “MR conditional”. This labeling, the MR icon (TAB. 1) and the definitions are defined and referenced in the standards ASTM F2503 [1] and the equivalent IEC 62570 [2].

MR Safe		an item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and non-ferrous.
MR Conditional		an item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
MR Unsafe		an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

TAB. 1: Requirements for colored MR icons for device labeling for MR safety [1] [2].

Implants and devices are divided into two groups – active and ‘passive’ (non-active). An active device is defined having a source of energy / powered electronic components. Different testing procedures are defined for both groups.

For active implants, the new Technical Specification ISO/TS 10974:2018 [3] is mainly driven by pacemaker, neurostimulator and cochlear implant manufacturers. However this technical specification is requested by regulatory agencies, such as FDAs and Notified Bodies worldwide also for active and passive devices like ECG cables, which can interact with the switched gradient magnetic field and the RF field of the MR systems and can lead to high heating, and thus necrosis and burns of the human body tissue.

Determining MR safety and MR compatibility for uncritical common non-active devices four ASTM standard test methods have to be performed:

- Radiofrequency (RF) induced heating (ASTM F2182) [4]
- Magnetically induced displacement force (ASTM F2052) [5]
- Magnetically induced torque (ASTM F2213) [6] and
- MR image artifacts (ASTM F2119) [7]

Managing textiles in hospitals requires a very high level of control in order to guarantee the highest hygienic standards and to ensure that the correct supply is available when needed. To overcome these criticalities, UHF transponders are widely used in hospital and healthcare facilities to track and trace any type of textiles from patient gowns to linen or surgical textiles. The traceability of textiles helps to reduce losses, optimize logistics and ensure that hygienic and sterilization processes are correctly followed. The tag has no own source of energy and utilizes radio waves for data collection and transfer only on demand. Therefore, it counts as passive device which will be fully outside the human body.

The current state of technology provides additional standards and points of discussion for RF heating, e.g. electrical fields ("E-fields" in V/m) outside the human body are different to those inside the human body. The new guide of ASTM F04.15 – WK58852 for devices outside the human body is under development, but will concentrate on displacement force and malfunction. This new guide will not change the MR testing requirements or MR labeling used.

Since the RFID tag is a) fully outside the human body, b) electrically short compared to the wave length of the RF field and c) does not have any tissue contacting electrodes, thus a test according to ISO/TS 10974 is not necessary. The interaction of the tag with the electromagnetic field has to be examined with the mentioned ASTM standard tests.

This paper is based on the questions, which came up between the involved parties: RFID manufacturer, MR testing laboratory, clinical cloth manufacture and the clinical personnel. Therefore all four mentioned ASTM tests have been performed and can be reviewed (see chapter **9 MR:comp reports**). In order to validate the technical RF heating test results additional simulations are executed.

In the following always the worst-case situations are considered. We believe that in praxis, the device itself will nearly never be in direct contact with the human skin because of its surrounded material. A more detailed description of the single tests can be found in the referred test reports in chapter **9 MR:comp reports**.

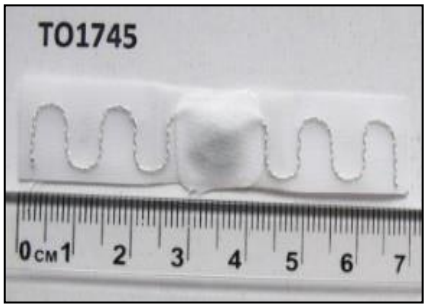
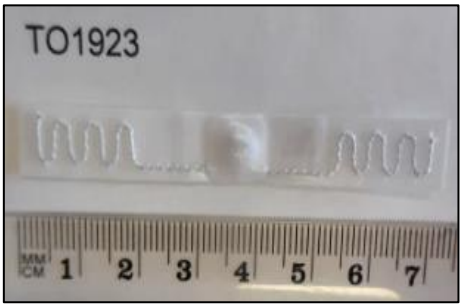
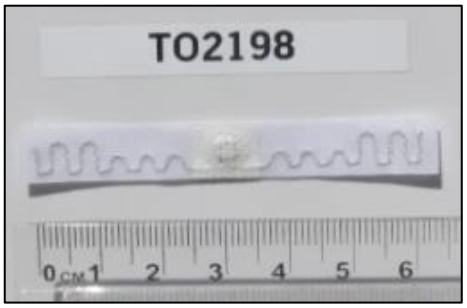
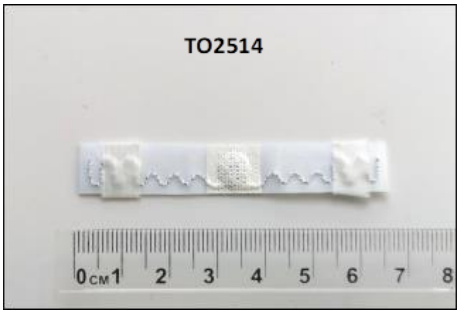
2. RFID Technology

UHF RFID tags used to identify textiles/patient gowns are similar in their functionality to the UHF tags that are for example used for logistic or anti-theft purposes in retail shops. When the tag is used for patient gowns it can be placed on the backside of the shirt or in the front in the hip area (see FIG. 1).

FIG. 1: Placement of the tag in a shirt (left). UHF LaundryChip (right).

Tags are made of an antenna and of a microchip but contain no battery or power source. They are a 'non-active (passive) device', which harvest electro-magnetic energy coming from a reader. As the electro-magnetic field emitted by the reader quickly fades away, a tag typically needs to be within 5 m of the reader to harvest enough energy and activate itself. When a tag receives enough energy to activate its internal circuitry, it replies back with a hexadecimal code that is unique to the tag and thus identifies the item that carries the tag (e. g. patient gowns). When not in proximity of a reader, the tags are basically a piece of passive hardware comparable to a paperclip. Since tags are electrical components, they are mostly made of conductive elements and as such cannot be considered as 'MR Safe' devices. While in the last years significant efforts have been made to reduce metal quantity or to decrease the magnetic impact of the metal contained in the tags, it is impossible to completely remove metal or conductive elements from an RFID tag. Therefore, it is necessary to perform accurate MR testing and validation before an RFID tag enters the MRI environment.

For the following MRI testing the RFID tags listed in table 2 are used. The tags differ in size, shape and material of the antenna.

RFID 1	RFID 2
	
RFID 3	**RFID 4**
	

TAB. 2: UHF RFID tags from Datamars textile ID for testing. For simplification the RFID tags are renamed in the following: RFID 1 = FT301 Novo, RFID 2 = FT401 ST, RFID 3 = FT401 (update version), RFID 4 = FT 401 V3 M.

The wire of RFID 1 has two large equal waves. The antenna of RFID 2 is completely straight coming from the chip and ends in three large equal waves. RFID 3 and 4 have the same, towards the ends increasing shape of the antenna. It is important to mention that RFID 4 contains a magnetic component compared to the other tags. All tags have approximately the same total length.

3. RF heating

The RF-induced temperature rise for a given electromagnetic field translated for description in power per exposed mass as specific absorption rate (SAR) depends of the RF frequency. Therefore, different static magnetic field strengths of MR systems lead to different temperature rises. RF heating is generated inside the human tissue due to the RF coil inside the MR system inducing an E-field inside the human body. MR safety testing is performed at 1.5 Tesla and 3 Tesla MRI systems (most common systems in clinical use) or an apparatus that reproduces the RF field of such an MR system. The ASTM tests are defined as worst-case test conditions. Therefore, MR safety testing does not have to be repeated on human patients or volunteers.

According to IEC 60601-1 [8] Clause 11 “Protection against excessive temperatures and other hazards” a temperature increase up to 43 °C for devices having contact with the patient is acceptable for the healthy skin of adults. Limits are determined for time periods greater than 10 minutes contact time. Temperature values are higher for a shorter “touch” time. Actually, the RFID tags are sewed in e.g. scrubs. A direct skin contact is not given. But if, however, a direct contact of chip or antenna appears, we will consider an acceptable temperature maximum of 43 °C.

The initial temperature of the tag may vary between 25°C (i.e. room temperature) and 37°C (when the tags adopt the skin temperature of the patient). Assuming these two different starting temperatures a temperature increase of 18 °C or 6 °C for devices with skin contact is tolerable. Since the paper considers the worst-case situation, in the following a temperature increase of 6°C will be assumed as limit.

3.1 Test Method

Three fiberoptic temperature probes were placed at the RFID tag where the highest RF heating is expected. The locations are based on long-term experience in RF-heating testing. Probes are placed at the ends of the antenna and in the middle of the RFID tag. The comparison with electromagnetic simulations showed that the sensor positioning was correctly executed at the hot spot regions of the RFID tag (see figure 2). One temperature probe was used as a reference probe to verify that the same RF exposure was used during all test runs positioned at the contra-lateral side of the phantom from the test object position.

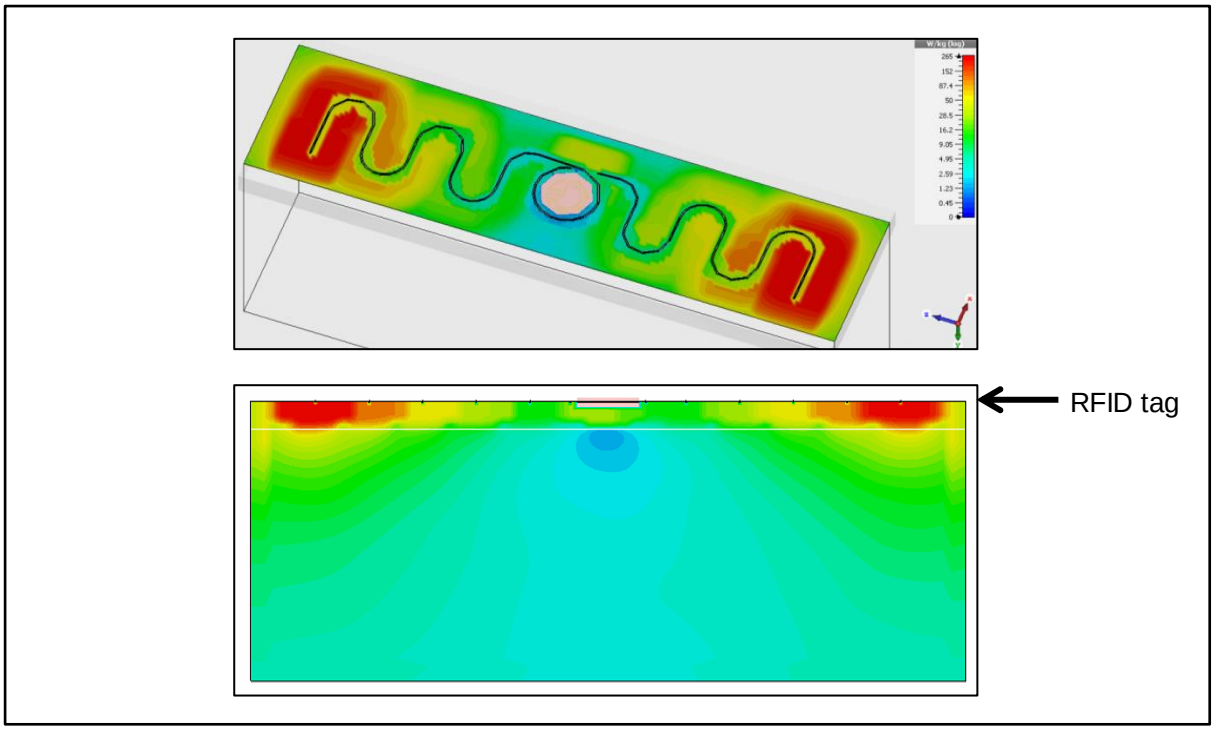


FIG. 2: Result of SAR simulation. Top: highest SAR (and therefore RF heating in a thermal stable phantom) at end of device (as expected). Bottom: transversal slice at x = 0 (along center of elongated tag). Tag on top of phantom. Dispersion of SAR inside the body phantom.

Afterwards the RFID tag, with the positioned temperature probes, is placed in a body phantom (according ASTM F2182 specification), which is filled with an electrically conductive gel material that simulates the electrical and thermal properties of the human body. The tag is placed at a location with well characterized exposure conditions.

Background SAR simulation at 64 MHz and 128 MHz are shown in FIG. 3. The whole body averaged (WBA) SAR of 2 W/kg was set for both frequencies. The SAR distribution plots without a test object for three cut planes: coronal, transversal and sagittal are illustrated.

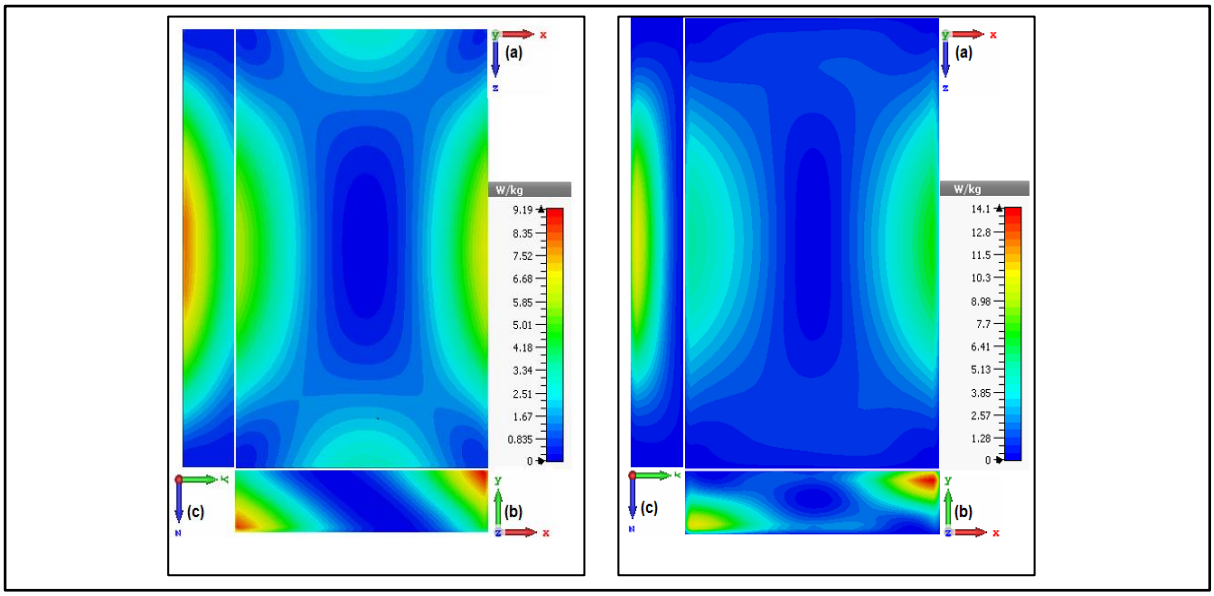


FIG. 3: left: 0.1 g averaged SAR distribution in the gel at 64 MHz, (a) coronal slice y=0, (b) transversal slice z=0, (c) sagittal slice x=-190 mm, right: 0.1 g averaged SAR distribution in the gel at 128 MHz, (a) coronal slice y=0, (b) transversal slice z=0, (c) sagittal slice x=-190 mm.

Actually, at the edge of the phantom local background SAR and the E-field have their maximum. To avoid edge effects the tag is placed in the plane with at a distance of 2 cm to the phantom edge (x = -190 mm).

According to the ASTM standard the RFID tags 1, 2, 3 and 4 (see TAB. 2) are first positioned in the center of the body phantom (in phantom material, y = 0 mm). To simulate a more similar position of the RFID tag in clinical practice, two more measurements of the tag at position “top” (y = 45 mm) and “bottom” (y = - 45 mm) have been performed. As shown in the table below 6 different test setups can be derived.

Measurement	1	2	3	4	5	6
RFID tag	RFID 1	RFID 2	RFID 3	RFID 4	RFID 1	
Position inside phantom	center				bottom	top
Argumentation for position	worst-case position according to ASTM test				relative to patients body	

TAB. 3: Different positions inside ASTM phantom.

The phantom with tag and temperature probes is placed in an MR system or an apparatus that reproduces the RF field of such an MR system (see FIG. 4). An RF field producing a whole body averaged (WBA) SAR of 2 W/kg (maximum SAR in IEC

defined normal operation mode) averaged over the volume of the phantom is applied for approximately 15 minutes.

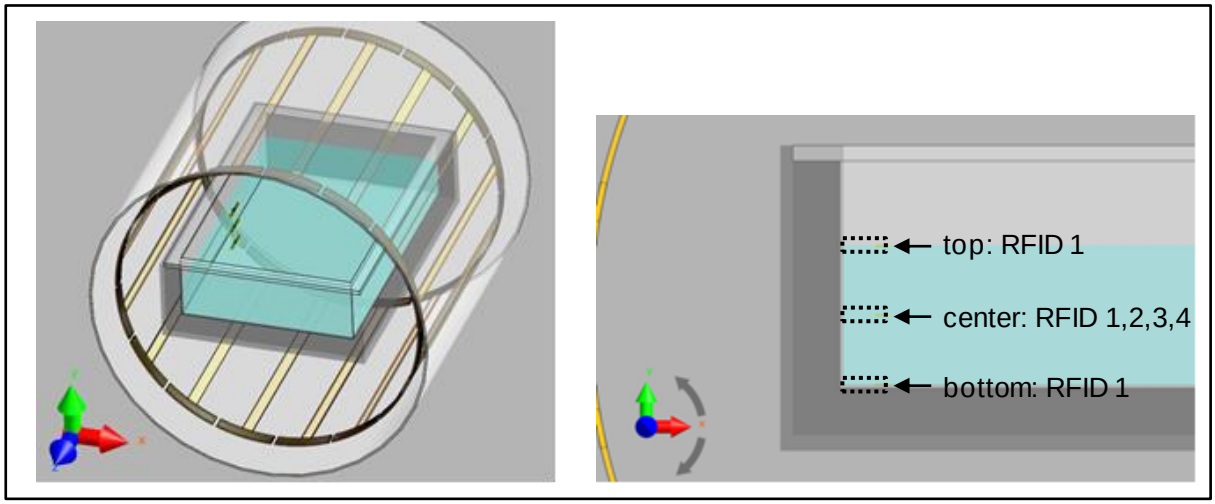


FIG. 4: ASTM body phantom with the three different positions of RFID tag positioned in the isocenter of the bore (left), enlarged view of RFID tag positions (right).

For a magnetic field of 1.5 Tesla (64 MHz) the Philips Intera MRI system and the RF test system (MITS (Medical Implant Test System), which is simulating the RF exposure of a 1.5 Tesla MR scanner were used. For testing at 3 Tesla (128 MHz) the Siemens system Magnetom Trio and the RF Test System with 128 MHz were used. According to TAB. 3, Measurements 1 – 4 (center position) are performed at MRI systems. Measurement 5 and 6 (bottom and top position) are performed at the MITS system.

3.2 Results & Discussion

The temperature rises of RFID tags in non-clinical testing showed values listed in TAB. 4. The background temperature means the temperature increase at the same positions when measuring without the device/tag.

Measurement		1	2	3	4	5	6
RFID tag		RFID 1	RFID 2	RFID 3	RFID 4	RFID 1	
Position		center				bottom	top
ΔT_{max} [°C]	**at 64 MHz**	3.9	3.4	4.0	3.1	2.8	2.7
	at 128 MHz	3.1	4.5	4.2	2.1	-	-
	background	min. 1.5 °C (conservative approximation)					

TAB. 4: Maximum temperature-rise at the different test objects and test object positions for RF frequency of 64 MHz and 128 MHz.

The RFID tag tested at 64 MHz experienced a temperature increase of maximum 4.0 °C for 2 W/kg whole body averaged (WBA) SAR within 15 minutes. A maximum

temperature increase of 4.5 °C for 15 minutes at 128 MHz was determined. Measurements at the bottom and the top showed slightly lower temperatures compared to center measurements, which are defined as worst-case position according to the ASTM test.

A maximum rise in temperature of about 4 °C is not harmful at the skin surface in normal operating mode. As mentioned in section 3 RF heating of a temperature increase of 6 °C (worst-case) for devices with skin contact is tolerable. Medical studies that already have been conducted show similar RF heating values for RFID tags from other manufactures [9]. Here, tags were not placed inside the liquid as recommended for implants. An agar-phantom, on which the tag was positioned, was used in order to mimic a patient's arm.

Measurements were executed for 15 minutes according to the ASTM standard. Considering a conservative temperature extrapolation (worst-case, actually temperature increase follows a saturation curve) it would be acceptable to measure continuously for 20 minutes in normal mode to reach the limit of 6 °C (worst-case scenario). Considering thermal conduction and convection the rise in temperature would even be reduced. Therefore, the measured background heating of at least 1.5 °C will change the maximum rise in temperature from 4.5 °C to 3 °C for 15 minutes.

Clinical MRI examinations can last for 10 minutes to 1 hour – depending on region of examination, patient movement, additional contrast medium, sequences, etc. For MRI examinations different protocols are saved on the system. They consist of several sequences, which are separated by short pauses (manual saved time break, local shim time, adjustment of system). A total MRI examination does not scan with continuous maximum SAR (normal mode, 2 W/kg) and single sequences in clinical examinations usually do not last much longer than 5 minutes. But if, however a continuous scanning with maximum SAR, over 20 minutes is desired (R&D), we suggest taking breaks in between.

We want to point out that this paper considers worst-case scenarios. As mentioned in section 3 RF heating, a common limit for temperature increase will be 18 °C assuming a room temperature of 25 °C. The temperature rise also follows a saturation curve and can't be extrapolated. As shown in the test reports the area of saturation is nearly reached after the 15 min. Therefore, no extremely high increase is expected. In addition, the RFID tag is normally surrounded by material and there will not be a direct skin contact. This would even lead to lower effective temperatures at the skin. Also, it has to be considered, that only regular whole-body RF transmit coils shall be used. Local RF transmit coils and multi-channel RF transmit coils must be avoided. This new design of RF coil architecture might lead to higher temperatures and was not subject of this test. Local receive coils can be used.

Further, the "adapted" ASTM measurements 5 & 6 (see TAB. 4), relative to the patients' body have to be considered. Even if they are not defined as worst-case position by the ASTM test, they are more authentic to the actual position and result in lower temperature rises.

4. Force & Torque

Accidental translocation of implants or devices used in the MRI environment, can lead to injuries or mortality. Therefore, MR safety testing, of possible induced displacement force and magnetically induced torque of devices to be used in the MRI environment must be considered. RFID tags are located outside of the human body and are sewn into patient's gowns. Only if the MRI field triggers a force in the tag, that an injury to the human body is caused, the device is considered as a risk. Hence it is recommended to perform ASTM tests according to F2052 (Force) [5] and F2213 (Torque) [6] also for external devices used in the MRI environment. In the following RFID 1, 2 and 4 are compared. As already mentioned in chapter 2, RFID 4 only differs in material in contrast to RFID 1 & 2. For RFID 3 no force and torque measurements were performed, due to the similar material and only very little shape changes compared to RFID 2.

The force measurement was performed at a 3 Tesla Magnetom Verio Siemens System. The medical device is suspended by a string in the MRI system at the location near the entrance to the bore and on the axis of the bore. The angular deflection of the string from the vertical is measured (see FIG. 5).

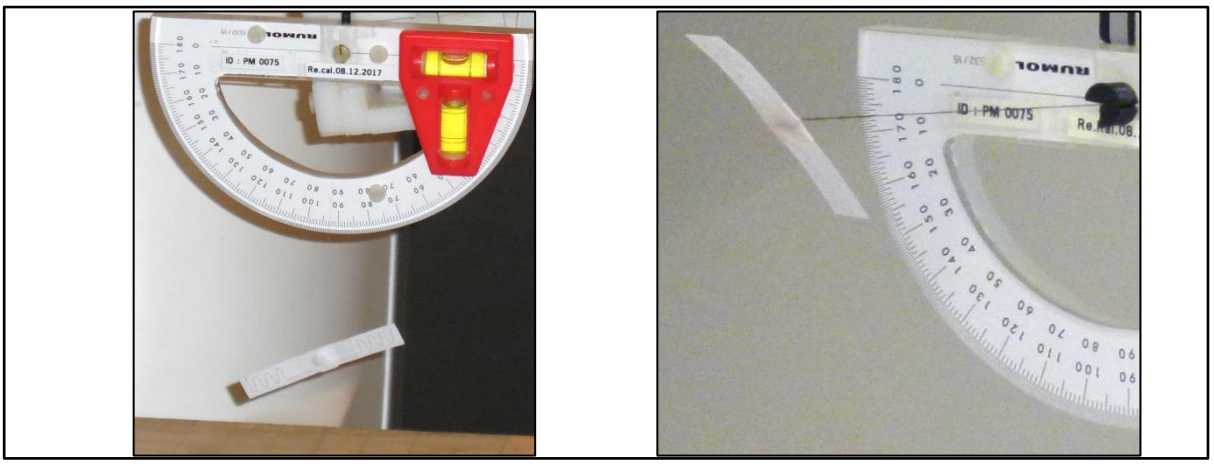


FIG. 5: Left: Configuration during the test of RFID 2 at the test location, Right: Configuration during the test of RFID 4 (magnetic component) at the test location.

The magnetically induced displacement force is calculated from the measured angular deflection. A more detailed description of the test procedure, positioning, etc. can be found in our test reports (see Chapter 9).

For RFID 4 torque was measured according to the ASTM standard by using a torsional spring at a 3 Tesla Magnetom Verio Siemens System. The test object is placed centrally on a holder, which is connected rigidly to the torsional spring (see FIG. 6).

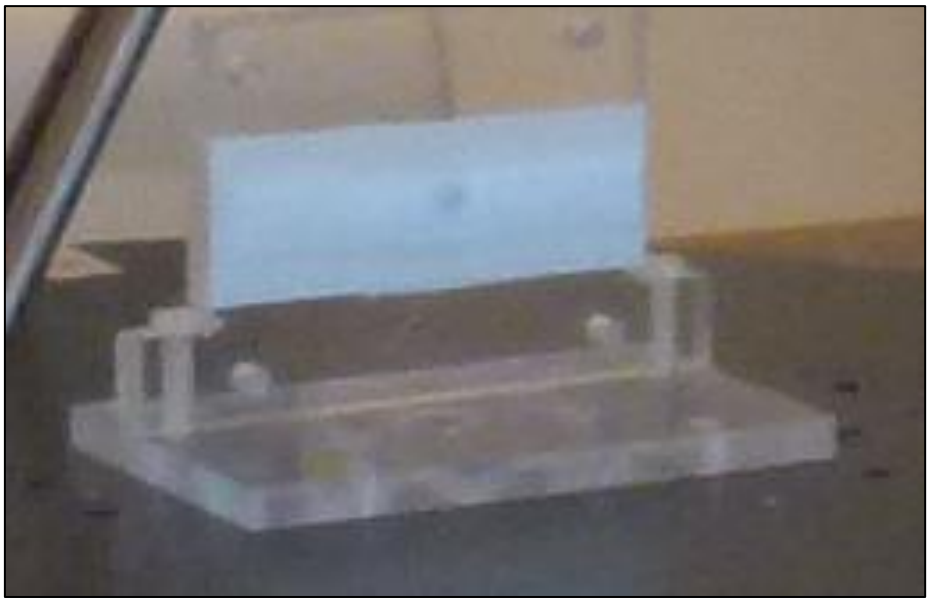


FIG. 6: Test set up with test apparatus, torsional spring

The apparatus is placed in the center of the MRI system where the magnetic field is uniform. The holding fixture of the spring and holder assembly is rotated through a turning rod, starting at 0° position to 360° with 10° increments. The torque is determined as a function of deflection angle. A more detailed description of this test procedure can also be found in our test reports, which numbering you will find in Chapter 9.

The results for the force and torque measurements for RFID 1, 2 and RFID 4 were shown in TAB. 5.

Measurement	1	2	3
RFID tag	RFID 1	RFID 2	RFID 4 (magnetic component)
	Force		
$F_{m\ mean}$ [mN]	0.19	0.07	28.6
$F_{due\ to\ gravity}$ [mN]	4.36	2.72	2.97
	Torque		
τ_{max} [mNm]	0.0232*	0.0085*	0.34
$\tau_{due\ to\ gravity}$ [mNm]	0.3045*	0.1902*	0.21

TAB. 5: Results of displacement force measurements and magnetically induced torque for RFID 1, 2 & 4. *Torque was only measured qualitatively; therefore the values were calculated from the force results (see Eq. 1 & Eq. 2)

RFID 1 & RFID 2 were investigated qualitatively for torque, which means, that 3 categories could be distinguished. “No self-acting alignment”, “slow self-acting alignment” or “fast self-acting alignment”. No deflection angles were measured.

Therefore, the torque values had to be calculated from the measured force values. The value was determined under the assumption of the tag consisting of iron (not reality + worst case).

*Torque calculation [6]:

$$\boldsymbol{\tau_{max}} = \frac{\boldsymbol{M_s \times F_m}}{\boldsymbol{4 \times \nabla B}} \qquad \text{Eq. 1}$$

M_s = conservative magnetic saturation value of iron [T] = 2.2 T
(M_s of implant was not available)
F_m = the measured magnetic force according to Test Method F2052 [N]
∇B = spatial gradient magnetic field at location of measurement [T/m]

$\tau_{max} = 0.0232\ mNm$ for RFID 1
$\tau_{max} = 0.0085\ mNm$ for RFID 2

The torque value due to gravity was calculated with the general formula.

$$\boldsymbol{\tau_{due\,to\,gravity}} = \boldsymbol{m \times L \times g} \qquad \text{Eq. 2}$$

m = mass of the device [kg] = 0.444 g for RFID 1 & 0.277 g for RFID 2
L = longest dimension of test device [m] = 70 mm
g = gravity [m/s^2] = 9.81 m/s^2

$\tau_{due\,to\,gravity} = 0.30\ mNm$ for RFID 1
$\tau_{due\,to\,gravity} = 0.19\ mNm$ for RFID 2

For the evaluation the measured magnetic force is compared with the force due to gravity and the measured maximal magnetic torque is compared to the worst-case gravity torque. In order to prevent movements, the device should experience a lower magnetic force/maximal magnetic torque than its force/torque due to gravity.

The deflection angles obtained from the measurements resulted in a significantly higher force value for RFID 4 than for RFID 1 & 2. Only for RFID 1 & 2 the measured force values are lower than the force due to gravity. The same results also apply to the torque values. Again, only the measured maximum magnetic torque values for RFID 1 & 2 are smaller than the torque due to gravity.

If the tag would be free to move in the MRI room, only RFID 1 & 2 can be brought into the vicinity of the scanner. RFID 4 (with magnetic component) would have a strong movement in the MRI environment and could pose a hazard to patients or employees. But still it has to be considered, that the RFID tags are sewn into the patients' gowns whereby a counterforce must be taken into account and will abet the results, especially for RFID 4. Therefore, from the point of view for force and torque, all RFID tags are not exposed to hazardous force.

5. MR image artifacts

In clinical MR imaging, the most challenging problem is to deal with a wide variety of artifacts because these artifacts may affect the diagnosis. In general, artifacts are more striking when using gradient echo sequences compared to spin echo pulse sequences. When using higher magnetic field strengths, the geometrical imaging distortion increases [10].

The most important issue with tags in MR imaging is the elimination of susceptibility artifacts that can result in geometric distortions. Such susceptibility artifacts are generated by the additional magnetization of the tag material, which interferes with not only the homogenous static magnetic field B_0, but also with the switched gradient magnetic fields. Due to the additional magnetization, the gradient magnetic field is altered, which results in signal loss or enhancement at different locations. Because of this non-linearity of the readout-gradient, the tissue pixels are incorrectly coded, resulting in more or less pixel shift. [11]

Since RFID tags are positioned close to the skin (see FIG. 1), the influence of possible artifacts should be reviewed when examinations are performed in the same area. Artifact measurements according to ASTM F2119-07 [7] were performed for RFID 1, RFID 2 and RFID 4 (see TAB. 2) on a 3 Tesla Achieva Philips System. The test set-up and MR image artifact on the received image for the GRE sequence is pictured in FIG. 7.

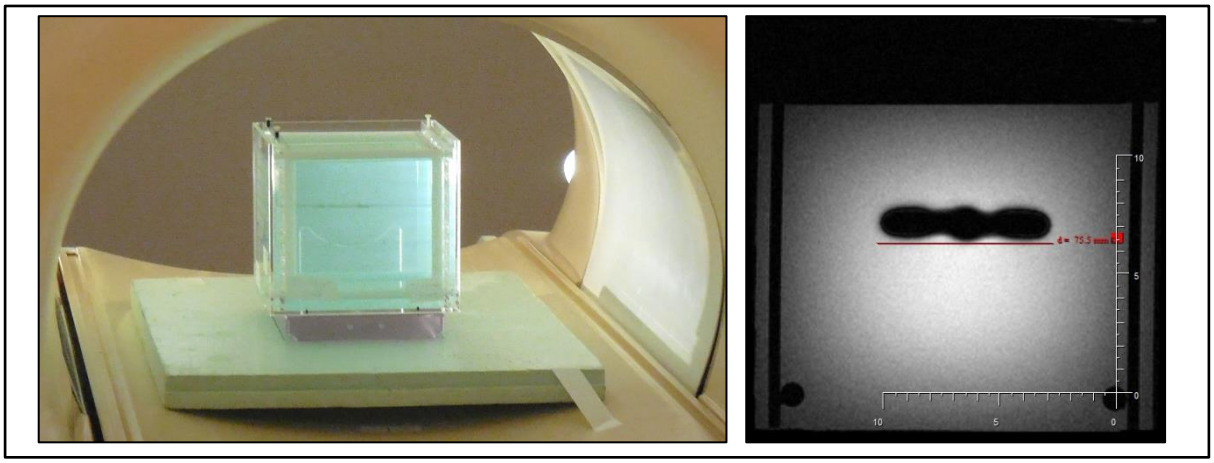


FIG. 7: Left: Test set-up for ASTM F2119 Artifact Measurement. Container filled with copper sulfate solution. RFID tag is positioned in the solution perpendicular to B_0. Right: Transversal MRI image from GRE sequence. Distance of artifact is measured.

The distance (in mm) from the device boundary to the fringe of the artifact is measured. For each image, the artifact must be characterized by the worst-case distance as the boundary of the device is completely circumscribed. The worst-case (maximum) distance found in the entire set of images acquired must be used to characterize the artifact. In addition to ASTM F2119-07 all longitudinal and cross sectional MR images are acquired for parallel & perpendicular orientations of the test

objects related to the main magnetic field B_0. Test object length and diameter are reported with calculation of geometric distortion. For all tested RFID tags the worst-case artifact was found by using gradient echo sequences. For the artifact analysis we focus on the comparison of RFID 2 & 4 (TAB. 6). As mentioned before, these two tags differ only in their material.

Measurement	1	2
RFID tag	RFID 2	RFID 4 (magnetic component)
Worst-case artifact [mm]	5.50	24.00

TAB. 6: Results of evaluation of MR image artifacts for RFID 2 & 4. Worst-case artifact values when measuring the diameter of the tag and by applying GRE-sequences.

The RFID tag is located on the skin whereby the effect of the artifact would only be interesting in this direction. Considering the surrounding material, the minimal distance between the tag and the skin is 1 mm. In addition, the thickness of the subcutaneous tissue must be considered, and is assumed to be at least 1 mm. Based on this consideration, we can assume that we would have remaining maximum artifacts of about **3.5 mm** in the region of interest looking at RFID 2. For RFID 4 the remaining maximum artifact will be about **22 mm**.

Another test was performed at an MRI facility in North Carolina. RFID 1 was directly positioned on the surface of a phantom consisting of 1900 ml H_20 distilled with 0.375 % $NiSO_4$ and 0.5 % NaCl. The experiment was performed on a 1.5 Tesla Siemens Avanto. Measuring the susceptibility artifact in the phantom generated by the tag shows a 3.9 mm signal void measured by the DICOM caliper function (FIG. 8).

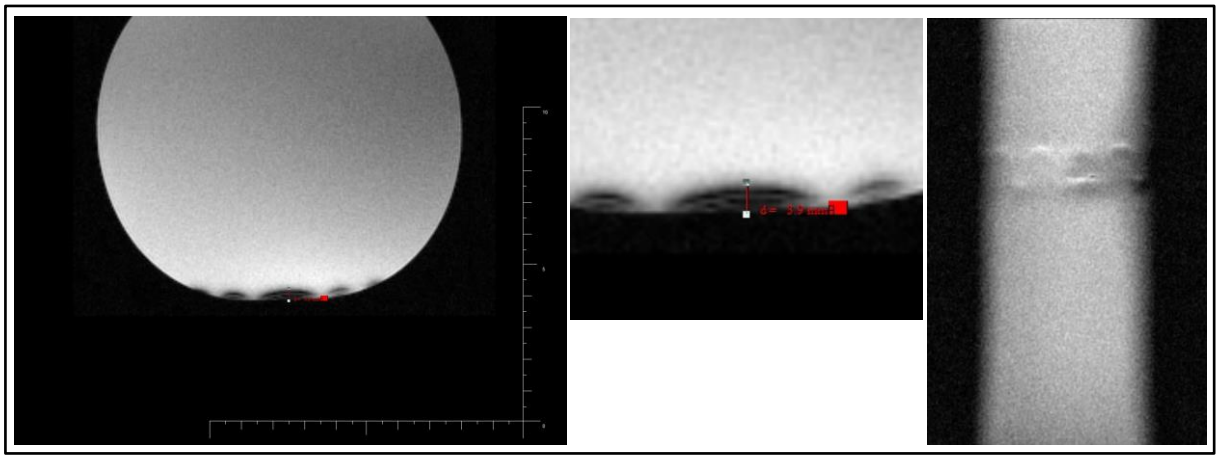


FIG. 8: Left: Transversal MRI image using a T1 weighted Flash2D GRE-sequence. Middle: Zoom of left image. Susceptibility artifacts show a signal void of 3.9 mm. Right: Coronal image on the level of RFID tag using a T1 weighted STIR sequence.

Former medical studies also analyzed RFID tags from other manufactures [9]. Here the measurements showed artifacts of 2 - 4 mm in size. The clinical images show a

minimally disturbance by the RFID tag which does not affect the image quality by using TSE sequences.

It is striking that RFID 4 shows artifacts of almost triple the size compared to RFID 2 (see TAB. 6). The remaining maximum artifact of 22 mm in GRE sequences in the region of interest can be explainable by the antenna wire made from a magnetic component compared to the non-magnetic wire from RFID 2. Therefore, medical assessments of the artifact impact of RFID 2 and RFID 4 were carried out separately.

The following anatomical structures may be at least partially influenced by the artifact of **RFID 2** positioned close to the skin:

- **The skin and subcutaneous structures** – however, these structures are rarely investigated by MR since skin disorders are usually examined by direct visual inspection and dermoscopy. One exception may be the skin infiltration in patients with breast cancer, but the affected area is larger than the size of the artifact. The subcutaneous tissue may be edematous or inflammatory, but this usually affects a larger area and is not restricted to the maximum of 5 mm diameter field. In the subcutaneous tissue, we can see inflammation of the bursae, such as the prepatellar bursa, which may be positioned within the artifact area, but again, cases of bursitis are usually larger than the 5 mm maximum artifact area and thus should be visible. Other abnormalities that may be seen in the subcutaneous tissue are superficially located lymph nodes, such as in the axillary and inguinal region, which can be increased in number as well as in size, but again, an increase in the number of lymph nodes can be easily seen despite a single artifact and even a single enlarged lymph node in the area of the artifact should be detectable because of the 10 mm or more size of pathologically enlarged lymph nodes. A rare referral for MRI may be a foreign body in the subcutaneous tissue, which are usually small and their characteristic artifacts on MR may be overlaid by the RFID tag artifact.
- **Tendons in superficial locations**, such as the Achilles tendon in the hindfoot, the triceps tendon in the insertion site of the elbow joint, as well as tendons in the foot, wrist, and hand area, may be affected by the artifact; however, this effect may be restricted to a partial area of the larger tendons, which will still allow a diagnosis.
- In the **smaller flexor/extensor tendons** of the ankle and foot, as well as in the wrist and fingers of the hand, focal lesions of these tendons, such as partial tears, may be masked locally by the artifact. The same is true for ligaments in the same areas, such as the collateral ligaments of the fingers, the pulleys for the fixation of the flexor tendon in the fingers of the hand and the plantar plates of the toes. Here, focal, partial, and complete tears may be masked by the artifact.
- **Superficial muscles**, such as those in the lower arm, and in the thigh and lower leg in slim patients, may show subtle injuries that are so superficial these injuries can be masked by the tag artifact. However, in all cases, muscle

injuries with edema and muscle fiber tears are larger than the 5 mm size of the tag artifact; therefore, the diagnosis of these injuries should still be possible.

- **Superficial joints**, such as the acromio-clavicular joint and the small joints in the hand and foot region. All of these joints are significantly larger than the measured maximum 5mm artifact, and therefore, a diagnosis of different joint disorders in these superficial joints should be unproblematic.
- **Hernias**, such as in the para-umbilical and inguinal region. All of these are significantly larger than 5 mm in diameter, and thus, would not affect the diagnosis of this entity.

The following anatomical structures may be at least partially influenced by the artifact of **RFID 4** positioned close to the skin:

- **The skin and subcutaneous structures** – These structures are, however, rarely investigated by MR since skin disorders are usually examined by direct visual inspection and dermoscopy. One exception may be the skin infiltration in patients with breast cancer. In these cases, the affected area may be at least partially be covered by the size of the artifact if the RFID tag is located exactly in the area of breast-skin infiltration and may prevent correct diagnosis.
  The subcutaneous tissue may be edematous or inflammatory, but this usually affects a larger area and is not restricted to the maximum of the 22 mm diameter field in fat-suppressed spin echo sequences, which are usually used for inflammatory diseases and edema. However, the frequency-selectve fat-saturation may be incomplete in this area, which negatively affects the diagnosis. In the subcutaneous tissue, we can see inflammation of the bursae, such as the prepatellar bursa, which may be positioned within the artifact area. Here the artifact may be larger than the extension of bursitis and may prevent a correct diagnosis.
  Other abnormalities that may be seen in the subcutaneous tissue are superficially located lymph nodes, such as in the axillary and inguinal region, which can be increased in number as well as in size, but, an increase in the number of lymph nodes can be easily seen despite a single artifact in this region. However, a single, enlarged lymph node in the area of the artifact may not be detectable. A rare referral for MRI may be a foreign body in the subcutaneous tissue; these bodies are usually small and their characteristic artifacts on MR may be overlaid by the RFID tag artifact.
- **Tendons in superficial locations,** such as the Achilles tendon in the hindfoot, the triceps tendon in the insertion site of the elbow joint, as well as tendons in the foot, wrist, and hand area—These tendons may be affected by the artifact. However, this effect may be restricted to a partial area of the larger tendons, but focal, partial, or complete tears without retraction may go undetected in the area of the tag artifact. In the smaller flexor/extensor tendons of the ankle and foot, as well as in the wrist and fingers of the hand, focal lesions of these tendons, such as partial tears, may be easily masked locally by the artifact. The same is true for ligaments in the same areas, such

as the collateral ligaments of the fingers, the pulleys for the fixation of the flexor tendons in the fingers of the hand, and the plantar plates of the toes. Here, focal, partial, and complete tears may be masked by the artifact.

- **Superficial muscles**, such as those in the lower arm, and in the thigh and lower leg in slim patients,—These may show subtle injuries and, if these injuries are superficially located, they may go undetected because of the tag artifact.
- **Superficial joints**, such as the acromio-clavicular joint and the small joints in the hand and foot region—These may be overlaid by the artifact and a diagnosis of different joint diseases, ganglia, cyts etc. may be problematic.
- **Superficial vessels,** such as veins may be affected in their visibility by the tag artifact, however this is only relevant for superficial veins and not for the more important deep veins and arteries, in which thrombosis, stenosis or occlusion have to be diagnosed
- **Hernias**, such as in the para-umbilical and inguinal region—Smaller hernias may pose a problem for diagnosis by the tag artifact in this area, if the hernias are significantly larger than 22 mm in diameter, respectively, this will not affect the diagnosis of this entity.

From the two medical assessments, it can be seen, that an artifact influences the diagnosis, if it exceeds the total size of medical diagnosis. Superficial inflammations/injuries etc. therefore depend on their size, if a diagnosis would be possible. For the artifact considerations the possibility to propose a correct diagnose for deeper structures may vary from patient to patient and tend to be affected by the larger artifact. Also, all of the listed locations in the human body require an exact positioning of the RFID tag in these areas, which is unlikely in regions such as the hand and foot, for example. If the tag is located posteriorly in the upper border of the shirt in the midline with the exception of the skin and subcutaneous tissue, and the most posterior nuchal muscles no other tissues listed above will be affected by the tag artifact. In this area of the tag in the midline of the distal posterior cervical spine, no diseases, other than subcutaneous edema, can be expected, and since edemas are usually diffuse, even an artifact here would not pose a problem for diagnosis.

If regions close to the skin need to be imaged, several MR image artifact reduction techniques are available. Even simple changes, such as increasing the bandwidth or optimizing repetition time in the scan protocol, can reduce MR image artifacts. Fast spin echo sequences are most robust to artifacts compared to other MR sequences. Furthermore, specialized sequences have been developed by the different manufacturers to minimize metallic artifacts. However, to be absolutely certain, the RFID tag preferably should not be placed directly on the region of interest during MRI examinations – especially for medical questions regarding the superficial area. If patient-related a simple movement of the tag in the scrub is not possible, it is recommended that the distance towards the skin be increased by placing, e.g., an MR Safe positioning aid or padding.

6. Summary & Conclusion

The RFID tag tested at 64 MHz experienced a temperature increase of maximum 4.0 °C for 2 W/kg whole body averaged (WBA) SAR within 15 minutes. A maximum temperature increase of 4.5 °C for 15 minutes at 128 MHz was determined.

Therefore we conclude, that for patient safety a maximum total continuous MR scan time with maximum SAR (2 W/Kg in normal mode) of 20 minutes by using whole-body RF transmit coils is suggested. If more time is necessary (R&D purposes), we advise to take breaks in between. For this statement it is important to consider, that in praxis, in general an MRI examination is never executed with a continuous maximum SAR. The protocol for different examinations is, especially for 3 Tesla, set up with pauses between the single sequences.

When comparing the RFID tags in terms of force and torque, only RFID 1 & 2 do not show large movement and are therefore MR Conditionally safe to use in the MRI environment. Due to the very little change of shape from RFID 2 to 3 and the use of same material, we can conclude, that also RFID 3 is MR Conditionally safe to use in the MRI environment. In contrast to all other tags, RFID 4 shows a significantly larger movement in the MR environment, which can be explained by the magnetic component. It must be taken into account, that the tags are sewn into patients' gowns, whereby a counterforce can be consulted and RFID 4 will not expose to hazardous force.

Regarding patient safety all tested RFID tags do not have to be removed for 1.5 Tesla and 3 Tesla MRI scanning using the tag manufacturer's MR Conditional labeling **up to normal operation mode** and considering the statements mentioned above.

In general, the remaining maximum artifacts will be about 5 mm in gradient echo (GRE) sequences in the region of interest considering surrounding material and the skin with subcutaneous tissue. By using RFID 4 (magnetic component) the remaining maximum artifact will increase up to 22 mm. If MR imaging of the skin or regions close to the skin is desired, it is suggested to simply remove the gown with the tag, if it is placed in the region of interest. If this is not possible, we recommend reducing MR image artifacts by changing the scan protocol with the common parameter changes. In general, it is improving to use turbo spin echo (TSE) sequences instead of GRE or EPI sequences to reduce artifacts.

7. Disclaimer

The above information of this White Paper is based on the current active standards and the best of one's knowledge. The manufacturer is responsible for its device marking and is liable for any damages involved in the device marking and its usage. The authors or MR:comp shall not be held liable for the marking or any damages, which can result from the marking usage of any kind.

8. References

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9. MR:comp reports

TR0411-301 Test report of displacement force for FT301 novo
TR0411-302 Test report for torque for FT301 novo
TR0411-303 Test report for RF heating at 1.5 Tesla for FT301 novo
TR0411-304 Test report for RF heating at 3 Tesla for FT301 novo
TR0441-306 Test report for MR Image Artifact for FT301 novo
TR0411-101 Marking Draft for FT301 novo

TR0480-301 Test report of displacement force for FT401ST
TR0480-302 Test report for torque for FT401ST
TR0480-303 Test report for RF heating at 1.5 Tesla for FT401ST
TR0480-304 Test report for RF heating at 3 Tesla for FT401ST
TR0480-305 Test report for MR Image Artifact for FT401ST
TR0480-101 Marking Draft for FT401ST

TR0592-303 Test report for RF heating at 1.5 Tesla for FT401 (updated version)
TR0592-304 Test report for RF heating at 3 Tesla for FT401 (updated version)

TR0580-202 Simulation report for RF heating at 1.5 Tesla for FT301

TR0809-301 Test report for displacement force for FT 401 V3 M
TR0809-302 Test report for torque for FT 401 V3 M
TR0756-301 Test report for RF heating at 1.5 Tesla for FT 401 V3 M
TR0756-302 Test report for RF heating at 3 Tesla for FT 401 V3 M
TR0776-301 Test report of MR Image Artifact for FT 401 V3 M
TR0791-101 Marking Draft for FT401 V3 M

10. Abbreviations

ASTM	American Society of Testing and Materials
B_0	Vector, magnetic flux density and direction of main magnetic field
ΔT	temperature increase
GRE	Gradient echo
IEC	International Electrotechnical Commission
ISO/TS	International Organization for Standardization / technical specification
Isocenter	Geometric center of a scanner with a cylindrical bore
MR	Magnetic resonance
MRI	Magnetic resonance imaging
RF	Radio frequency
RFID	Radio-frequency identification
SAR	Specific absorption rate
SE	Spin echo
T	Tesla, dimension of magnetic flux density
TE	Time of echo [ms]
TR	Time of repetition [ms]
TR0xxx	Test report with number xxx
VDE	German Association for Electrical, Electronic & Information Technologies
WBA SAR	whole body averaged SAR