PHILIPS

ScanWise Implant

Simplify scanning of patients
with MR Conditional implants

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Patients with implants are not scanned routinely in MRI systems. Warning signs prohibit entrance to patients with a pacemaker, a hip implant, a clip or vascular coil, or any other device implanted in or worn on the body. Rigorous prescreening procedures apply, to identify patients with implants before they undergo an MRI examination.

In recent years, however, many MR Conditional implants have become available, and patients with such implants can now benefit from MR imaging. Nevertheless, scanning patients with MR Conditional implants remains challenging.

How confident are you that you can meet the MR Conditional requirements in your MRI practice? How do you explain to your neurologists, orthopedic, or vascular surgeons, and cardiologists that you can provide MRI services for patients with implants? How can you train your radiographers to apply the required limits to MR sequences if they cannot dial in the specified numbers? Furthermore, how do they prevent the MRI system from inserting pre-scans or system adjustments which exceed the constraints?

Philips has developed ScanWise Implant to simplify scanning of patients with MR Conditional implants. It provides you with the guidance and automatic features to easily meet the implant manufacturers MR Conditional specifications. It is as easy as entering patient demographics during the registration process. You can verify the static field strength and the Spatial Field Gradient in an interactive user interface, and copy the specific absorption rate (SAR) and other specifications from the implant label to the MRI scans on the patient registration screen. This sets the limits for the entire examination. No need to check each individual sequence; the system takes care of the constraints.

This publication provides an overview of our new ScanWise Implant technology that supports you in meeting current MR Conditional labeling requirements.

Why is it important to give patients with implants access to MRI?

As we get older many of us have an increased chance of experiencing musculoskeletal, cardiovascular, and neurological diseases, and diabetes. We also run a higher risk of developing more than one clinical condition, either chronic or acute. Access to diagnostic imaging will be required for many patients that already suffer from another disease. For example, studies of the prevalence of comorbidity show that at age 70, having three or four conditions is not uncommon.[1] While oncology was not included in this assessment, advances in treatment and medical care is expected to soon transform several cancers into chronic diseases.

Today, treatment of many chronic conditions involves the placement of implants or use of body-worn treatment-delivery devices. Millions of patients benefit from passive implants, like hip or knee replacements, spine stabilization devices, vascular stents, clips or coils. Many others depend on active implants or devices, requiring electrical power and logic components to operate, like pacemakers, neuro-stimulators, insulin pumps, spine pain-relief stimulators, and cochlear implants.

For numerous medical conditions, MRI is the modality of choice[2-6] recommended by consensus guidelines for diagnosis and treatment monitoring. Current medical practice, however, excludes patients with an implant from access to MRI, based on serious and valid safety concerns. This "clash of technologies"[7] results in unnecessary health inequalities for a rapidly growing group of patients.

Over the past decade, implant manufacturers have developed products that mitigate the safety concerns of scanning patients who have them. Implementing the necessary risk control measures requires applying restrictions on the MRI sequences and/or workflow. All mandatory limiting conditions are specified on the implant manufacturer's device label.[8,9] Such MR Safe or MR Conditional implanted Medical Devices are cleared by FDA for sales in the US, and are widely available in Europe and other regions.

Under these circumstances, access should no longer be denied to patients for an MRI if they present with an MR Safe or MR Conditional implant.[10] Enabling the MR radiographer to adhere to the conditions specified on implant labeling has therefore become a must-have for modern MRI systems.

To simplify the scanning process for patients with MR Conditional implants, Philips has developed ScanWise Implant. It allows MR radiographers to enter the MR Conditional restrictions in a simple manner. After the SAR and dB/dt values are entered on the ScanWise Implant user interface, the MRI system limits its outputs to these values throughout the entire examination. This paper explains the concept of MR Conditional labeling, the different parameters encountered on implant labels, and how ScanWise Implant is designed to control these parameters.

Why are conditions applied for implants in the MRI?

Implants must be strong for musculoskeletal applications or flexible, for instance when used as stents, and biocompatible. Active implants must sense or stimulate electrophysiological signals from the heart or the central nervous system.[11] Their microcontrollers and electronics must be protected against electromagnetic interferences in everyday life. All these requirements suggest the use of metallic structures, which can be problematic when brought near or inside an MRI system. This is particularly true because the strong electromagnetic fields required for MRI far exceed the electromagnetic fields encountered in urban environments.

Significant additional attention and care is prudent for all medical professionals when scanning patients with MR Conditional devices. Necessary precautions are:
- Having the treating physician select MR Conditional implants at the time of placement, document the implants in patient records, and provide clear information about the implant to the patient
- Making every physician aware that an MRI is often possible with an MR Conditional implant
- Having medical specialties consult with the radiologist to select the right MRI procedure
- Strict adherence to the MR Conditional parameters by the MR radiographer. This can be done in consultation with a medical physicist, if needed
- Having a cardiologist present during the MRI exam when active devices like pacemakers are being scanned
- Setting up a well-established emergency plan and training staff on its use

Physiological responses to RF exposure (SAR or tissue heating) and gradient switching (peripheral nerve stimulation) are well understood and regulated by the technical safety standard for MRI (IEC60601-2-33).[12] This provides the basis for widespread use of MRI to for diagnostic imaging of patients without implants.

When a patient with an implant is encountered, consider the following:

- Non-metallic implants generally do not raise additional MRI safety concerns. Such implants should have been labelled MR Safe.[13]
  Note: Carbon fiber may focus RF energy, and SAR may need to be limited.
- It is recommended that any implant without labeling be considered as MR Unsafe.
- Implant manufacturers are responsible for testing and releasing MR Safe and MR Conditional implants, and must provide the restrictions which must be applied when the implant is used inside the MRI. These conditions are specific for the (implanted) device.

Medical staff are responsible for cross-checking the scanning restrictions for an implanted device and for complying with the stipulated MR Conditions. Potential harm may arise to patients from hazards resulting from the placement of an implant in the MRI system. An overview of these hazards and their causes is given in Table 1 (adapted from ISO/TS 10974[14] and Circulation[11])

Figure 1 provides a pictorial overview of the identified risks of the use of implants near the MRI scanner.[11,14]
Note: Some of these risks occur even before scanning or image data acquisition starts, for example when the patient walks into the MRI suite or is moved inside the MRI system.

Table 1. Overview of effects and causes for implant-related hazards in the MRI environment.[11, 14]

| Harm	Hazard	Cause
Over- or under- treatment, or failure of life support	Device malfunction (active implants)	1. $B_0 > 0.5$ mT (5 Gauss) 2. Lead voltage (switching gradients' dB/dt) 3. Lead voltage: RF rectification (peak B_1) 4. Electromagnetic interference (EMI)
Tissue damage	Implant displacement	1. Magnetic Force (in Spatial Field Gradient) 2. Torque (in Spatial Field Gradient and B0)
Tissue damage	Implant heating	1. Average RF power (SAR, B_{1+rms}) 2. Gradient power (average dB/dt)
Tissue damage or implant breakdown	Vibration	Switching gradient amplitude (dB/dt)
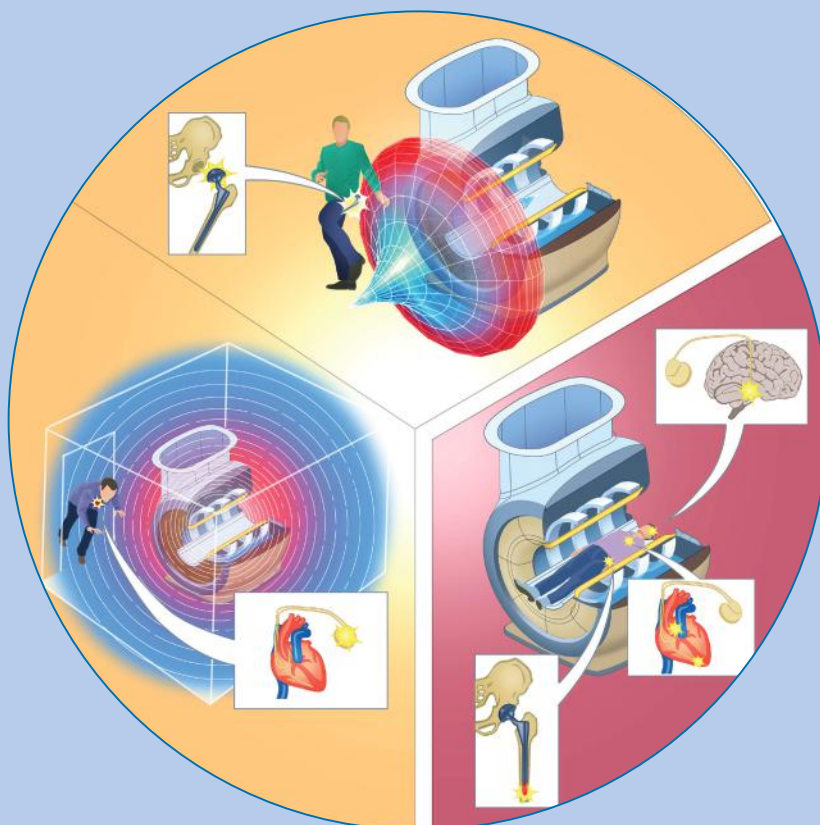
Figure 1. Overview of the risks associated with the use of implants near or inside an MRI system

Left side: The magnet is always on, and potentially endangers the patient by causing a malfunction in the implant. For example, a pacemaker may stop pulsing beyond a magnetic field of 0.5 mT (5 Gauss), or an implant may be dislodged when approaching the façade of the MRI magnet due to the local high spatial field gradient.

Right side: Strong time-varying electromagnetic fields are present when images are being acquired. These fields add risks related to heating (tissue burns), vibration, and implant malfunction.

How can you comply to requirements of MR Conditional implants?

Scanning patients with passive or active implants requires having significant additional organizational measures in place at the hospital. Retrieval and interpretation of MR Conditional implant labeling must be organized in a multi-disciplinary team. Cross-industry harmonization and standardization efforts by IEC and ISO[14] and FDA guidance[9] have improved the availability of information to support the clinical decision to scan in compliance with MR Conditional labeling.

Users should understand the possible interactions between implants and the MRI system, and should be able to identify related safety concerns. Figure 2 shows the identified risks in relation to the technical parameters of the MRI system.[11,14] These parameters can also be found on implant labels to specify MR Conditional use characteristics.

The required precautions related to implants can be divided into two categories:[12,15]
- The always-present static magnetic field B_0 can cause attraction and device malfunction. Pacemakers may reset to programming mode, and become non-functional, when the magnetic field exceeds the very small value of 0.5 mT (5 Gauss). While current standards[17] specify a safe limit of 1 mT (10 Gauss), older implanted devices may still be affected at 0.5 mT (5 Gauss), the value specified for delimiting the Controlled Access Area in IEC60601-2-33.
- RF pulses and switching gradients must be emitted to acquire the MR image. These outputs can be reduced by implementing and applying appropriate controls in the MRI sequences.

It is of paramount importance to perform all safety checks related to the static magnetic field before admitting a patient into the MRI suite. These checks should be done independently, and at every decision point in the workflow, by the referring physician, the radiologist, and the operator.

This leads to the following typical workflow steps:[15]
1. Check for the presence of an active implant. Ensure that the implant will not become dysfunctional when critical for life support. Keep the patient out of the 0.5 mT (5 Gauss) line.
2. Check for the Static Field Gradient condition, and verify the related exclusion zones around the magnet. Make sure that the implant does not enter these areas.
3. Check RF output (SAR or B_{1+rms}) and gradient (slew rate or dB/dt) limitations. When defining the examination protocol, make sure that each and every sequence complies with these restrictions.

Figure 2: Overview of the physical risk factors associated with scanning patients with implants.[15]

The superconducting MRI magnet is always on, and any person approaching the system must be screened. Even at very low magnetic fields (0.5 mT), pacemakers may default to programming mode and stop working. To minimize the size of the Controlled Access Area around the magnet, MRI systems are actively shielded.
The related magnetic fringe field (Spatial Field Gradient, T/m) is shown in the lower-right plot, with a steep gradient peaking near the bore entrance.
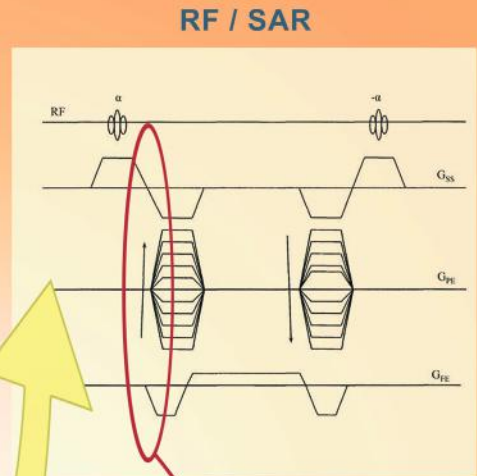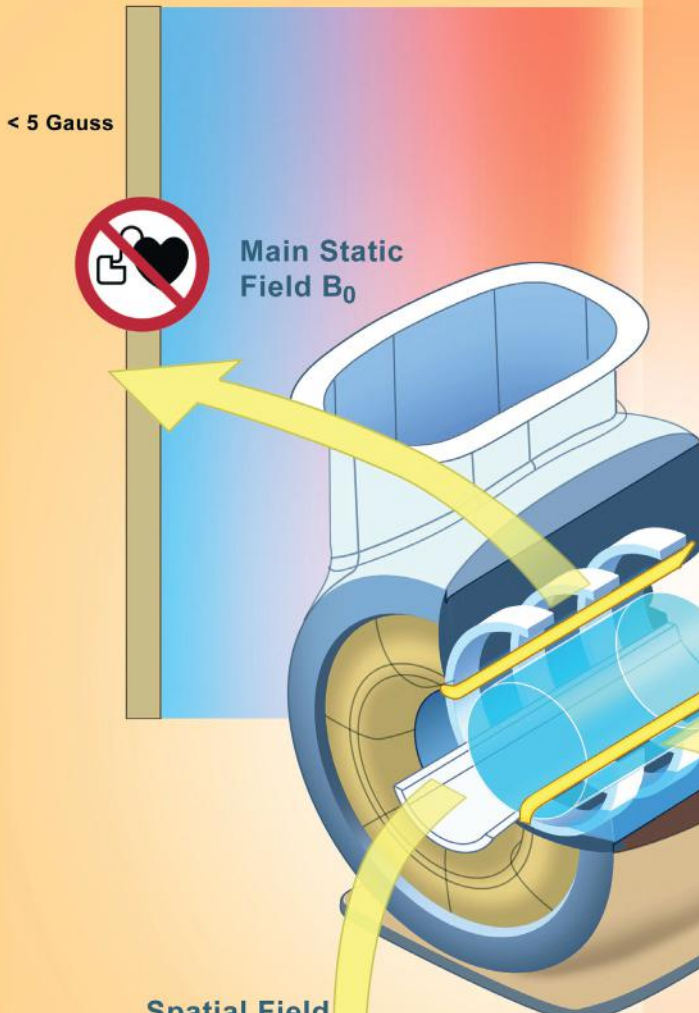To avoid risks, prevent unscreened patients and personnel from approaching the system.

Other risks are associated with the actual image acquisition:
The upper right graph is a schematic view of an MRI sequence, showing the RF excitation pulses (top row), causing heating by SAR, and the gradient pulses (lower rows), causing nerve stimulation or device malfunction by induced electric fields.
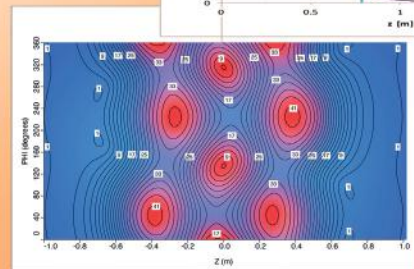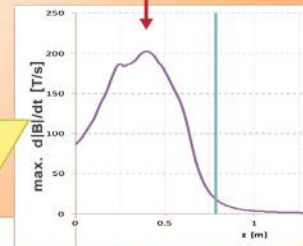
The plot on the lower right provides an overview of the locations near the bore wall where the gradient pulses induce the strongest time-varying magnetic fields (d|B|/dt). The speed of the time-varying gradients is called slew rate (T/m/s). The relation between slew rate and attained magnetic field is not trivial and depends on the design of the gradient coil. The graph shows that during scanning very high values can be encountered in locations near the bore wall, halfway to the center of the magnet. High dB/dt values can damage implant electronics or cause painful or harmful nerve stimulations.
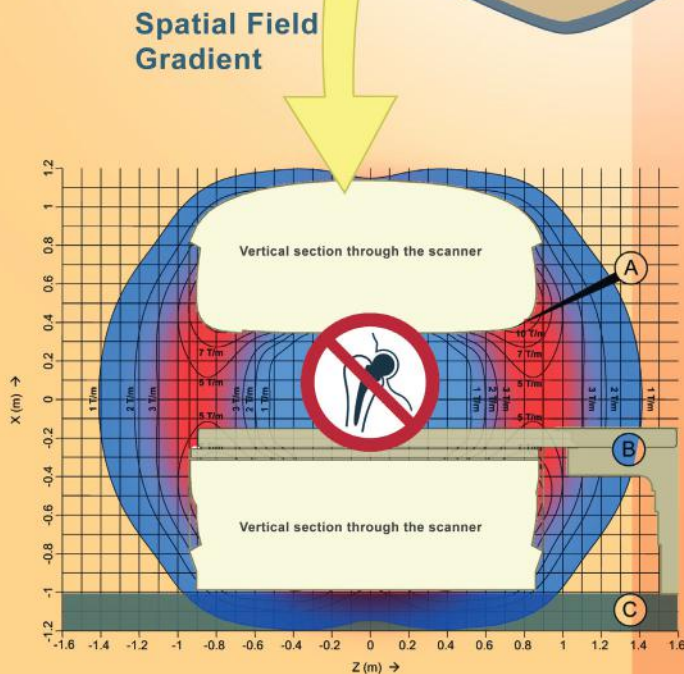
Do Not Enter

Use with Restrictions

< 5 Gauss

Main Static Field B_0

RF / SAR

Actual Gradient Output

Spatial Field Gradient

Vertical section through the scanner

Vertical section through the scanner

Switching Gradients dB/dt & slew rate

Which MRI system characteristics do MR Conditional limits address?

Static Magnetic Field (B_0)

Malfunction due to magnetic field exposure
Active implanted devices have a programming and an operational mode. A magnetic sensing device, which is sensitive at 0.5 mT (5 Gauss) or 1 mT (10 Gauss)[17] is commonly used to switch between these modes. When the implant is switched to programming mode it will not deliver treatment. This is the reason for the Controlled Access Area marked off around MRI systems. Staff should always check if a patient, worker, or an accompanying person has a pacemaker, ICD, or other active implant before approaching an MRI system.

Dislodgement effects
Besides pacemakers which should not enter the Controlled Access Area, i.e. > 0.5 mT (5 Gauss) because of device malfunction concerns, the first and primary concern before entering the MRI Suite is the risk of implant attraction or rotation.[15] The magnetic attraction force moves up and down in relation to the local static field gradient (SFG). The rotation or torque moves up and down in relation to the product of the SFG and B_0. Always check for the presence of implants, especially those containing any metal parts, and prevent them from being attracted by the magnet.

Implant labels specify two relevant parameters for the magnet:

- **Static Magnetic Field strength B_0.**
  The (SI) unit for the magnetic field is tesla (T). Implant labels often specify "up to 1.5T" or "equal or less than 3.0T".[9]
  Note: the Static Magnetic Field Strength is also relevant because the RF exposure-induced heating depends on the field strength.

*Note: An MR Conditional implant might be safe at higher field (3T) but not at lower field (1.5T) (Figure 3).[16] MR Conditional implants indicating "up to" 1.5T or 3.0T **shall not be used on open 1.0T or 1.2T systems**. The RF exposures on these systems are very different from cylindrical systems.*

- **Spatial gradient.**
  SFG (Spatial Field Gradient) is the spatial gradient of the static field, which characterizes how the magnetic field drops off around the magnet.[9] This so-called fringe field rapidly increases towards the magnet covers, and is proportional to the magnetic force exerted on an implant. Its location is shown in Figure 1 (top left) and Figure 2 (lower left). SFG (Spatial Field Gradient), also known as SGF (Spatial Gradient Field) or MSG (Magnetic Spatial Gradient), is often specified in gauss/cm or G/cm, or in SI units as tesla/m or T/m.

  Note: 1 T/m corresponds to 100 G/cm. Information on the SFG is usually provided as a plot in the Technical Description of the MRI system.

Implants are tested in or near the MRI magnet to ensure that the magnetic force will not exceed gravitational force.[9] A typical SFG value quoted for passive implants is 720 gauss/cm (or 7.2 T/m); however, lower and higher values are commonly specified as well. The specified SFG value might be exceeded in a small annulus of the patient-accessible bore of modern MRI systems.

Medical staff must make sure that the implant cannot enter the zone where the specified condition is exceeded.
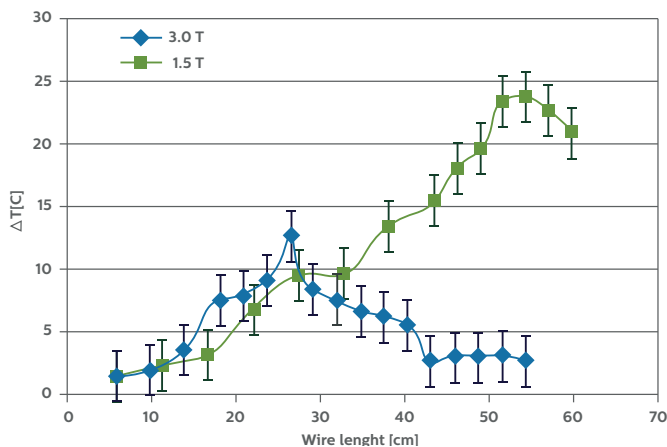
Dynamic electromagnetic fields: RF pulses and switching magnetic gradients

Once the patient has been positioned in the MRI system, the MR radiographer must exercise strict caution to implement MR Conditional limitations during scanning. The intense RF pulses and rapidly varying gradients may cause localized heating, vibration, or implant malfunction due to electromagnetic disturbances. Implant manufacturers have tested and released their MR Conditional devices with parameters that allow their use in MRI systems.

Rapid local heating near the implant

Radiofrequency (RF) pulses are necessary to select the signal used to create the image, and are shown in the sequence diagram in the top right of Figure 2. RF energy is deposited in the body and induces tissue heating, and heating of conducting structures like stents, orthopedic implants, or sensing or stimulating leads of active implants. These heating effects are magnetic field strength or frequency (and wavelength) dependent. Figure 3 shows that a structure that does not cause heating at 3T may cause significant heating at 1.5T, or vice versa. The implant manufacturer specifies SAR values to represent allowed MR Conditional RF exposures at the relevant RF frequency (64 MHz or 1.5T, and 128 MHz or 3.0T).

Note: *The presence of multiple implants such as stents may change these restrictions, and the user must contact the stent manufacturer for advice. In general, scanning under such conditions is contra-indicated.*

The following RF-related parameters are often encountered on MR Conditional labeling:[15]

- **SAR type** is explicitly specified as either "Head SAR" or "Whole Body SAR". It is extremely important to select the correct SAR type as specified by the implant manufacturer.
- **Maximum allowed SAR.**
  For the selected SAR type, the maximum SAR limit is specified by the manufacturer of the MR Conditional implant. This specification is often given for a 15 minute time interval, which reflects the total exposure time during the test by the implant manufacturer. Consult the implant manufacturer if it would be necessary to account for this specified duration. Sometimes, Normal Mode is specified as condition.[9] On Philips systems, the use of Normal Operating Mode or First Level Controlled Operating Mode always limits whole body SAR up to 2W/kg or 4W/kg, respectively.

- **Transmit coil.**
  It is also very important[15] to check if a dedicated transmit coil is specified on the instruction of the implant manufacturer. Never scan with a transmit coil that is different from the one specified. This information can be submitted in the user interface of Philips ScanWise Implant, in the additional constraints section, and will be displayed as reminder. Make sure that the specified coil is connected to the system, if required.

Malfunction of the implant or discomfort due to vibration

Image encoding gradients define the spatial location of the anatomy in the images, and are shown in the sequence diagram in the top right of Figure 2. Rapid switching of the magnetic field gradients causes acoustic noise by the varying Lorenz force. The varying magnetic field can also induce voltages, eddy currents, and/or vibrations in implanted devices.
Implant vendors specify the allowed gradient performance using two parameters.[15]

- **Gradient slew rate** (single axis), specified in **T/m/s** or mT/m/ms. Typical values encountered on implant labels are 200 T/m/s or 120 T/m/s, representative of the maximum performance of a state-of-the-art MRI system. The Technical Description and the SW About function specify the maximum slew rate for the MRI system configuration.
  Note: *Selecting "default" gradient mode in the sequence parameters will limit the slew rate to 100 T/m/s on Philips MRI systems.*
- **dB/dt (T/s)** is specified for certain active implants, especially deep brain stimulators. This is the maximum magnetic field change induced by switching the encoding gradients on all three axis simultaneously. The value of this parameter is expressed in tesla per second, T/s. Its value depends on the actual spatial position in the magnet bore. The Technical Description provides a graph with the maximum dB/dt that the MRI system can generate at the worst case z-axis off-center position, for different radii in the bore.
  This graph cannot be used to evaluate or control MR Conditional dB/dt values, if specified by the implant vendor. The Philips sequence software calculates dB/dt at a radius of 25 cm, and displays the value for each sequence to the user.

How does ScanWise Implant simplify scanning of patients with MR Conditional implants?

Scanning patients with MR Conditional implants requires significant expertise today. The implant and its MR Conditional parameters must be identified and the specified constraints must be controlled by the MR radiographer by manually consulting the Technical Description of the MRI system and by checking and adjusting the parameters displayed on the scanner, sequence by sequence. Relevant parameters specified for MR Conditional implants can be found on the MRI system, and judicious restriction of scan parameters can be performed using per-sequence information on SAR and dB/dt provided on the user interface. However, the current way of working on most MRI systems is time-consuming and requires a highly-skilled radiographer and/or physicist.

Based on user feedback, Philips has recognized the need to improve the usability of its MRI system in cases where MR Conditional implants must be scanned. Patient screening and the selection of MR Conditional parameters is the full responsibility of medical staff. Once the risk benefit analysis calls for scanning the patient with an MR Conditional implant, ScanWise Implant provides a simplified and guided workflow for MR Conditional scanning.

ScanWise Implant offers a key advantage by allowing the operator to enter the MR Conditional parameters – as defined by the implant vendor, and only once per examination. The MRI system then applies the specified constraints to all scans in the examination, including prescans and system adjustments.

Description of ScanWise Implant workflow
Patient registration
During the patient registration process, the radiographer can indicate several patient conditions, including the presence of an implant, on the ScanWise Implant user interface. This is illustrated in Figure 4a.

If the presence of an implant is indicated, ScanWise Implant launches automatically and guides the radiographer through the questions relevant to MR Conditional implant scanning.

Entering conditions
ScanWise Implant provides step-by-step guidance with supporting visuals, and background information, that allow the radiographer to specify the parameter values commonly found on the implant label, such as field strength (B_0), spatial gradient, SAR, and dB/dt, if needed. The first step is to confirm that the MR Conditional implant is labeled for use at the field strength of your MRI system (1.5T or 3.0T).

To prevent excessive attraction of implants, the implant must remain outside the area that has a higher Spatial Field Gradient value than specified on the implant label. When the Spatial Field Gradient value on the implant label is entered in the ScanWise Implant user interface, a red ring is overlaid on the front view of the MRI system to support the user in evaluating where the implant should be positioned in the magnet bore. This must be checked before the patient is guided to the MRI system. Besides the default front view, side and top views are also available. These can be printed out to store with patient records.

The Spatial Field Gradient screen is shown in Figures 4b and 4c.

Figure 4a. Overview of the Patient Registration screen, where demographics and patient conditions can be entered. This user interface also allows users to restrict SAR output to Normal Mode for the full examination.
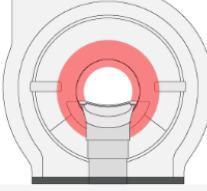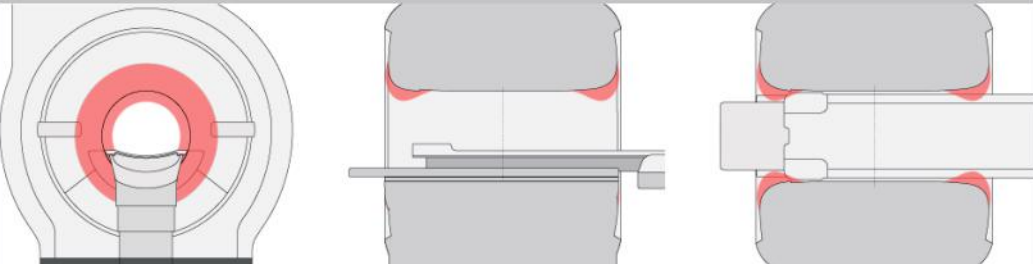
Figure 4b. The Spatial Field Gradient can be entered as specified on the implant label. A red ring is shown on the front view of the system to indicate the area where the specified value is exceeded when moving along the long axis of the magnet.

Figure 4c. Additional information on the area where the specified value of the Spatial Field Gradient is exceeded is provided as a side view and top view.
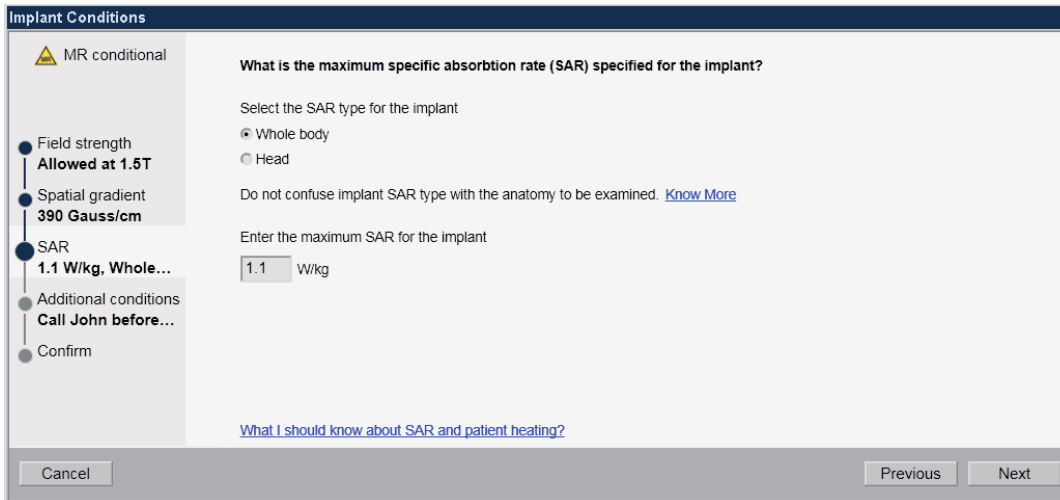
Figure 4d. Screen to select the specified SAR type and to enter the specified SAR value, with a resolution of 0.1 W/kg.
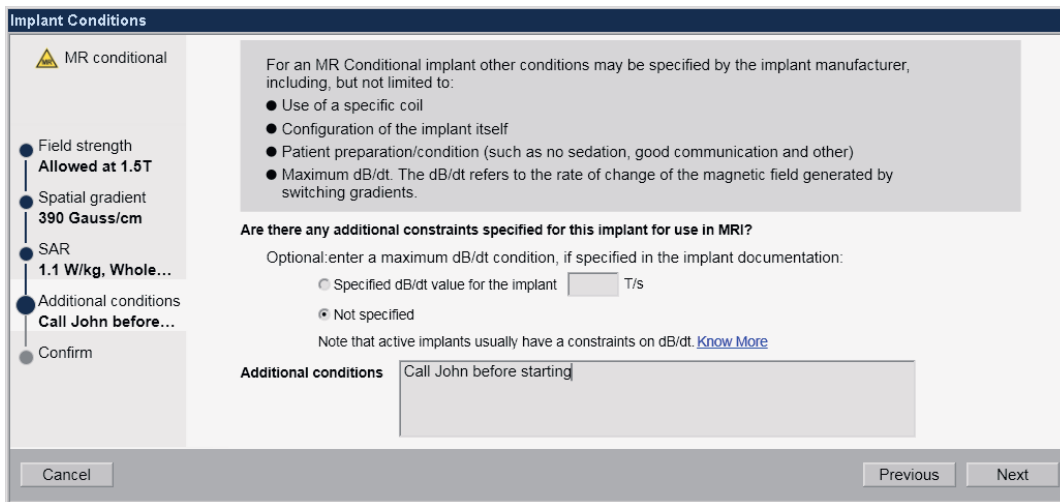

Figure 4e. Additional conditions can be specified, such as the need for a special transmit coil, a limit on dB/dt, or any other information that the user considers relevant for the MR Conditional examination.
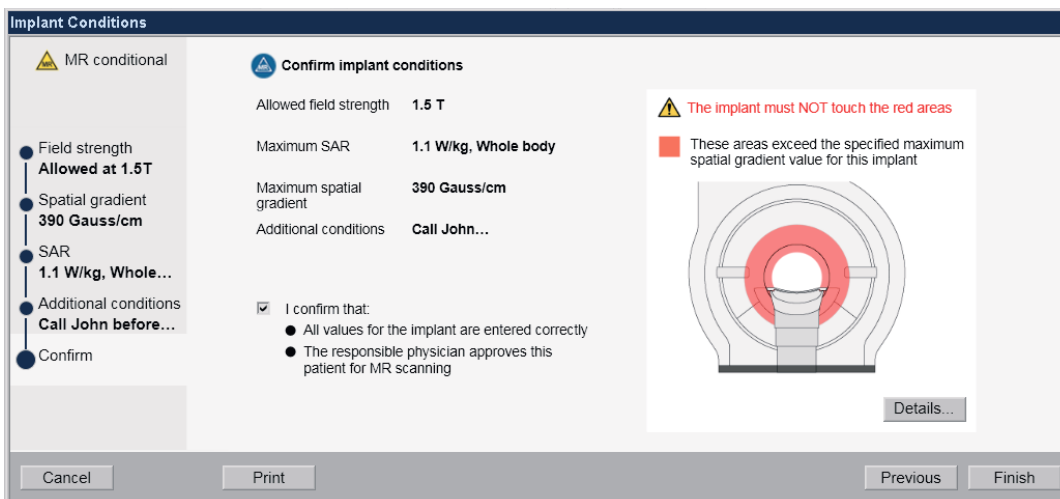

Figure 4f. As a last step, all entered conditions are summarized for a final check and approval.

The next screen (see Figure 4d) prompts the user to specify the SAR type (Head SAR or Whole Body SAR) and the limiting value defined by the implant manufacturer. Most active implants, and more than a few passive implants, specify maximum not-to-exceed SAR value of 2W/kg (i.e. less than the Normal Mode limit). ScanWise Implant allows users to specify the allowed maximum SAR with a resolution of 0.1 W/kg. *Note: if Normal Mode is selected on the Patient Registration screen, a specified value higher than 2 W/kg will not be used. The sequence definition software will always apply the lowest specified limiting value.*

Entering additional conditions
Finally, the user can specify additional conditions, like coils used, to be excluded landmarks, implant configuration, and dB/dt. See Figure 4e. The specified coils and landmarks are "free text" comments. The output of the image encoding gradients can be limited by entering dB/dt as specified on the implant label. The specified restriction will be applied by the sequence-definition software for any sequence, including pre-scans, just like a specified SAR value. If dB/dt is not specified on the implant label, this fact should be entered in the ScanWise Implant user interface.

All conditions entered are provided on a final overview screen (see Figure 4f) where the user is asked to review and confirm the conditions entered. The user thereby confirms that the responsible physician approves scanning for this patient.

When the examination is started, and is in progress, all selected conditions are continuously displayed in the workflow section of the user interface. See Figure 4g.
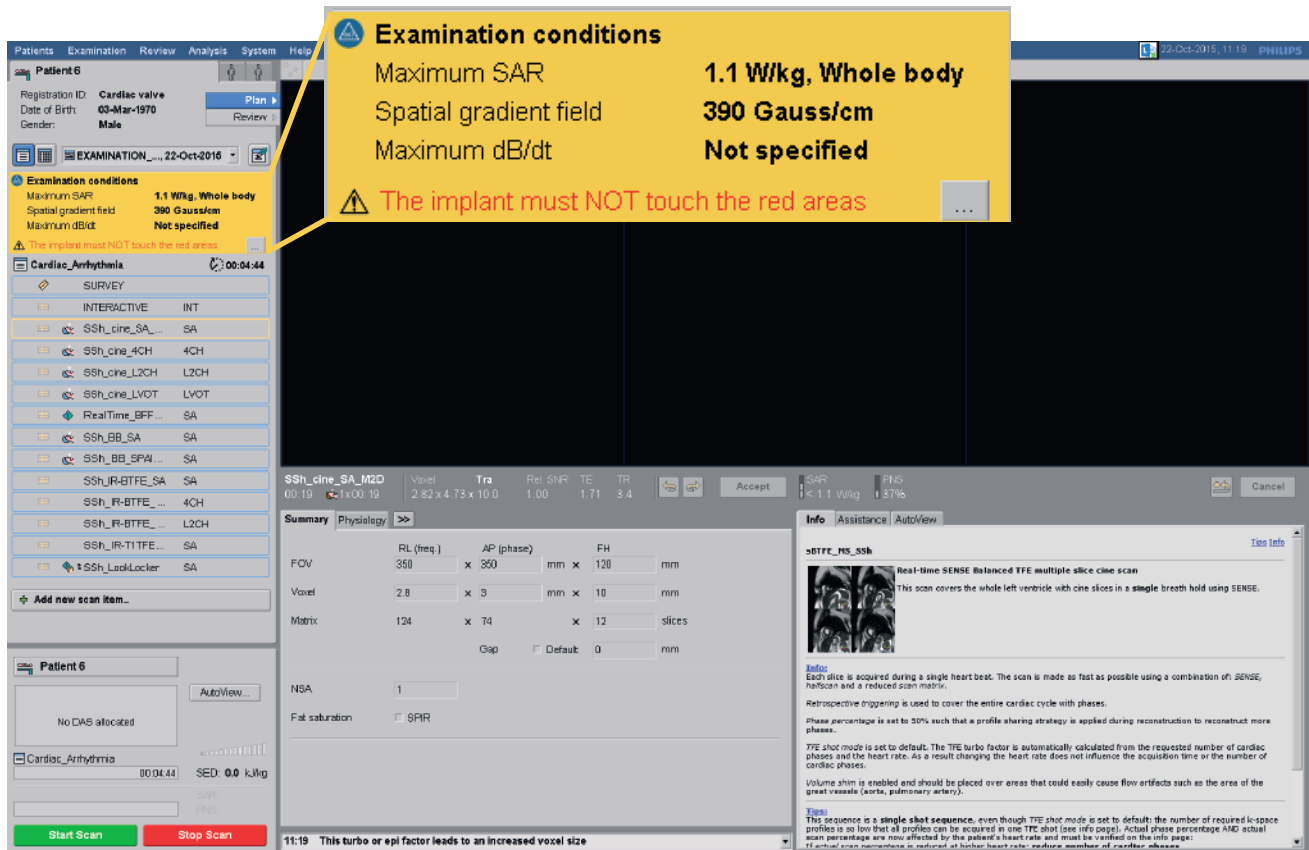

Figure 4g. Overview of the user interface during scanning. Whenever MR Conditional values are entered, the yellow area is displayed with current restrictions and additional information as entered by the user.

How do Philips MRI systems control MR Conditional restrictions?

Control of the RF and gradient outputs in MRI systems is an essential safety function. The required design elements for these controls have therefore been part of MRI systems since their initial market introduction.[12] Figure 5 provides an overview of the system design elements required to control these relevant parameters: Specific Absorption Rate (SAR) and Peripheral Nerve Stimulation (PNS). The associated user interface defines Normal Mode and First Level Operating Mode, where Normal Mode can be used for all patients and First Level Operating Mode requires medical supervision.

Implant vendors have often used the Normal Mode defined in IEC 60601-2-33 as a target to test and label their MR Conditional implants.[9] Specifically for whole body SAR, implant labels specify scanning in Normal Mode, i.e. SAR ≤ 2 W/kg. The IEC standard, however, allows for burst modes of higher SAR in Normal Mode, posing a risk for harm in the presence of implants. In addition, many implant labels call for fractional SAR values, like 0.4 W/kg or 1.3 W/kg. These cannot be controlled using the standard IEC Normal Mode requirements. Philips has recognized both needs, and ensures that Normal Mode never exceeds 2 W/kg, and that the fractional SAR values can be controlled for each sequence.

The SAR and dB/dt as specified by the user in ScanWise Implant take precedence over Normal Mode or First Level Operating Mode, or any other control parameter in the sequence. In all cases, the most
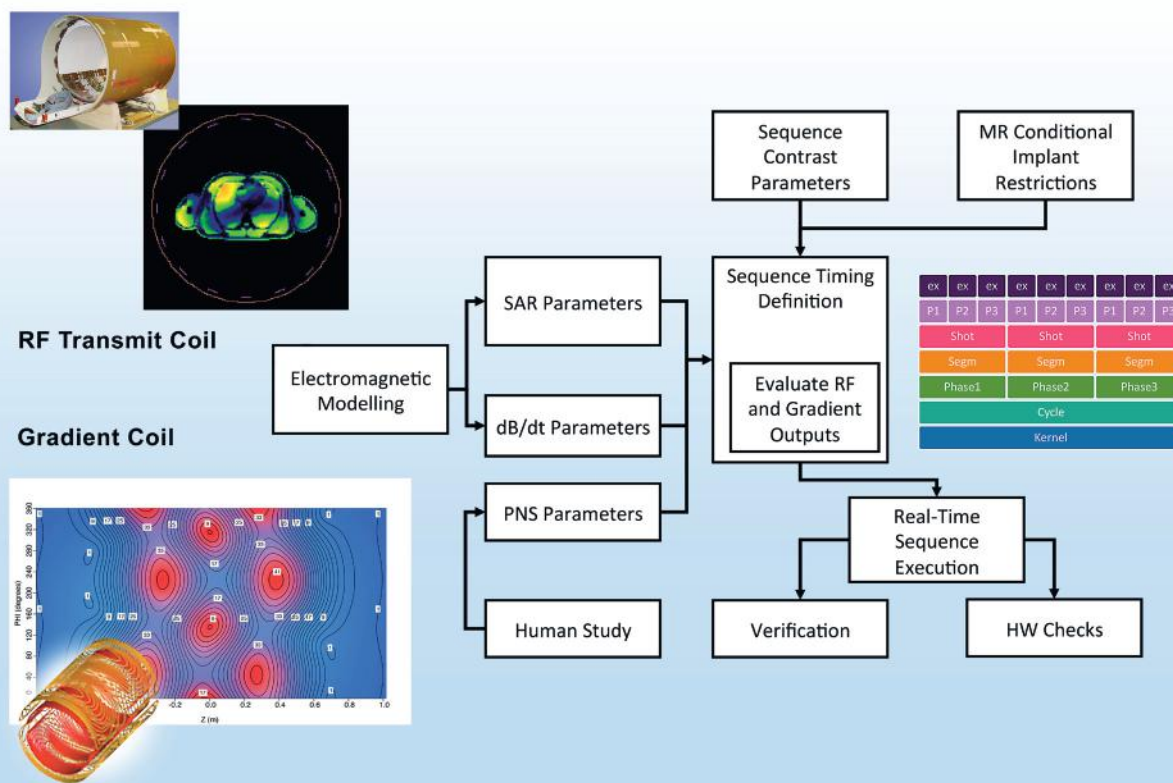

Figure 5. Overview of the system design elements required to control safety of the active electromagnetic fields in MRI (RF and switching gradients). The RF transmit coil and the gradient coils are modeled in detail to parameterize their performance characteristics (SAR and dB/dt). To protect patients from excessive peripheral nerve stimulation, a so called "direct determination" study has been conducted and used in a model to predict the Strength-Duration response for every sequence. The user-selected contrast parameters of the sequence are used to optimize the sequence timing to match constraints on SAR, PNS, and MR Conditional implant restrictions (new). The Philips-unique SOR (Sequence Order) object ensures compliance with all constraints at any time scales. The defined sequence is executed under real-time control where software and hardware perform checks on consistency of demand and output signals. At system release from the factory, the predicted electromagnetic outputs from the model parameters and generated by the real-time software are verified experimentally by temperature and magnetic field measurements. Additions specific to ScanWise Implant are control based on the MR Conditional restrictions as entered, and the calculation of the dB/dt for all sequences including pre-scans.

limiting restriction is applied when evaluating the sequence timing. For example, if the implant labeling allows 2.3 W/kg, but Normal Mode is also selected, the SAR will be limited to 2 W/kg. If the implant labeling requires 1.1 W/kg, this level will be imposed on the sequences.

The SAR value specified on the implant label must be explicitly controlled at each time interval of the sequence. With ScanWise Implant, Philips has adapted its dStream sequence control digital platform to specify and control allowed SAR levels to 0.1 W/kg resolution. Any sequence in the ExamCard will be evaluated against the user-prescribed limit, as an additional measure beyond the IEC safety mode checks. Either optimization algorithms resolve potential timing conflicts, or the user is prompted to address remaining issues in a guided workflow.

Well-established and proven methods to control RF and gradient outputs are used to secure compliance of sequence parameters to the user-defined constraints. This approach uses Philips-unique Sequence Order object models for MRI sequences to predictively evaluate actual scan execution and the resulting RF and gradient exposures. SAR is evaluated from B_{1+rms} of all RF pulses over multiple time intervals. A real-time monitor ensures that no excessive power can be deposited during scan execution.

Philips has also designed additional provisions to control the gradient outputs. Peripheral Nerve Stimulation is limited based on a human study, to prevent muscular twitching sensations in the majority of the population. For implants, direct control of d|B|/dt is required. |B| is the vector sum of the field components of the gradient coil, calculated by electromagnetic simulations and verified on the Philips system for separate and simultaneous switching gradient axes, using

$$|B| = \sqrt{(\Sigma_{i=X,Y,Z} B_{x,i})^2 + (\Sigma_{i=X,Y,Z} B_{x,i})^2 + (\Sigma_{i=X,Y,Z} B_{x,i})^2}$$

where the i=X,Y,Z denotes the axes of the gradient coil. The magnetic field is derived from full EM simulations, and a simplified approach using Biot-Savart is used to derive a conservative prediction.
In case of simultaneous switching of gradient axes, the fields cannot be simply added up since the maxima occur at different positions. Model parameters are derived to calculate |B| for each gradient slope in real-time during sequence definition using the following approximations:

for the maximum of Bz :

$$Bz, max = \sqrt{Bz_{max,X}^2 + Bz_{max,Y}^2 + Bz_{max,Z}^2}$$

and for the maximum of |B| :

$$|B|_{max} = \sqrt{\frac{|B|_{max,X}^2 + |B|_{max,Y}^2 + |B|_{max,Z}^2}{2\sqrt{Bz_{X,RMAX}^2 + Bz_{Y,RMAX}^2} \cdot |Bz_{Z,RMAX}|}}$$

The dStream digital platform evaluates d|B|/dt (magnitude of the full magnetic field vector, from simultaneous switching of all three gradient axes, for every slew in the sequence) for the relevant locations in the MRI system. Theoretical and experimental verification, based on full EM modelling of the gradient coil, and field measurements, show that the model-based d|B|/dt can be used as estimate for |dB/dt|. Control measures are then applied to limit d|B|/dt to the implant-specified restrictions, similar to those controlling and limiting PNS.

Which other MR Conditional parameters can be found in product standards?

ScanWise Implant is the solution to today's complex workflow which a user experiences when a patient with an implant must be scanned. It has emerged from active Philips engagement in IEC and ISO standardization activities with FDA, MRI manufacturers, and active implant manufacturers, to ensure harmonization of approaches, labeling, and implementations. Philips has been driving discussions and supporting proposals with technical feasibility studies and early implementations on our systems. Additional parameters as defined for MR Conditional implant scanning in IEC 60601-2-33 are B_{1+rms} and FPO:B.

Control of B_{1+rms}
It was recognized about a decade ago that reported (whole body) SAR varies significantly between MR systems, at the same expected performance level. There is an obvious and good reason for these variations: MRI manufacturers implement a safety margin to account for variability in SAR with body size and habitus.[18]

SAR is proportional to B_1^2, and industry agreed to report accurate B_{1+rms} values on the MR user interface. Philips started to report this parameter for every sequence far before it was required by IEC60601–2–33, and the value can be accessed on most systems of our installed base. Some implant manufacturers have recently started to (also) specify B_{1+rms} as a limitation for the RF output. Currently, the SAR limitations specified on implant labeling are generally more conservative (i.e. safer). B_{1+rms} is displayed in the sequence–definition user interface for each sequence.

FPO:B

The medical industry and the FDA agreed in 2009 to develop an option on MR systems to restrict the RF and gradient outputs to mutually–agreed limitations, which should resemble "Normal Mode" operation. This restriction, called FPO:B, would be activated with a single 'yes/no' action. FPO:B is the acronym for Fixed Parameter Option – Basic, and has been specified in full detail in IEC 60601–2–33, Edition 3 Amendment 2, published in 2015.[12] Currently, FPO:B is a voluntary option, only defined for 1.5T systems. Philips has been the pioneer in the evaluation of the technical feasibility of FPO:B with a fully functional software implementation to identify reasonable limit values for B_{1+rms} and d|B|/dt.[19] This study provided the foundation for the implementation of ScanWise Implant, which addresses current MR Conditional labeling practice. Today, no implants are available on the market with FPO:B labeling.

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