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D3.1.1 - User Interface for MR imaging with MR Conditional Implants and Devices

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1 Executive summary

MR imaging vendors, collaborating on magnetic resonance (MR) safety through IEC MT40 (maintenance team for international safety standard IEC 60601-2-33), and AIMD vendors, collaborating on safety of Active Implantable Medical Devices through ISO, have joined forces through JWG1 to produce a technical specification for safety of MR Conditional implants. One open issue from the JWG1 is the question to implement controls at the MR scanners to guarantee fixed limits for physical parameter outputs to facilitate design and compliance validation for the AIMDs. This report describes the rationale for this so-called fixed parameter option (FPO), reports on the current state of investigations related to the consequences of the proposed limitations, and describes a demonstrator that integrates the proposed behavior into MR System SW. The FPO is limited to 1.5T systems, since implant manufacturers have (until now) focused their design and clinical validation efforts to 1.5T.

2 Introduction

1. Aim of activity

Provide UI controls in regular SW release for reduced dose scanning (SAR, dB/dt) as implementation of request by implant manufacturers.
Conformance to MR Conditional parameters as required by implant manufacturers is difficult to guarantee in current MR systems. Improved UI concepts will be developed and evaluated that allow direct control of relevant parameters (such as SAR, peak B1, and slew rate).

2. Background

High quality MR imaging requires high-performance switched gradients (kHz range) and pulsed RF fields (MHz range). These intense, time-varying electromagnetic fields (EMF) generate physiological responses in humans, viz. nerve stimulation and (local) tissue heating. To prevent adverse effects, patient safety during MR operation is controlled by the international standard IEC 60601-2-33:2010, using the concept of ***operating modes*** to limit the outputs of the switched gradients and the pulsed RF fields. For reference, the definitions of the modes are copied from the 3rd edition of the standard:

201.3.224
normal operating mode
mode of operation of the mr equipment in which none of the outputs have a value that can cause physiological stress to patients

201.3.208
first level controlled operating mode
mode of operation of the mr equipment in which one or more outputs reach a value that can cause physiological stress to patients which needs to be controlled by medical supervision

201.3.231
second level controlled operating mode
mode of operation of the mr equipment in which one or more outputs reach a value that can produce significant risk for patients, for which explicit ethical approval is required (i.e. a human studies protocol approved to local requirements)

Control of MR system performance and outputs for patient safety relates to *physiological responses* or biophysical effects. The interaction of the physical fields with human physiology is complex, and depends on e.g. patient orientation and directionality of the switching magnetic field, anatomical landmark position relative to the MRI scanner, thermoregulatory capabilities, and other factors. To ensure maximum MR system performance, defined limits for patient protection are expressed relative to the physiological response or their surrogates: PNS – peripheral nerve stimulation for the gradient fields, or SAR – specific absorption rate for the RF fields. These quantities are only indirectly correlated to the physical quantities causing the effect (dB/dt or B1rms) by modeling of biophysical parameters.

AIMD manufacturers have requested MR manufacturers to provide a mode of MR system operation where the physical outputs from the gradients and RF are limited to well-defined and unique values. Appendix A includes these documented requests for reference. Focus is on 1.5T MR Systems (for now), since these are most widely

available, and implant manufacturers are focusing design and validation efforts to this field strength. The requested mode of MR system operation is intended to protect the implants from malfunction, and to control adverse effects of the implant on patient safety. Intention of the limit values are to be as close as possible to what is perceived as the operating space of Normal Mode, where clinical performance is expected to be adequate for primary MR diagnostic quality. The actual limit values are currently still under discussion, with the intention to consolidate them in Amendment 1 of the 60601-2-33 3rd edition per end 2012, as Normative Annex. Implementation by MR vendors remains voluntary, but if implemented, strict regulations from the standard will apply.
The MR manufacturers participating in IEC MT40 have decided to denote this mode of operation as FPO (Fixed Parameter Option), to distinguish the notion of Modes from the IEC 60601-2-33 from the new physical-output controls. FPO will enable designs of MR Conditional devices (implants) to comply with dB/dt and B1 values (far) below MRI system (bidspec) capabilities, and is intended to allow easier and more transparent implant labeling.

This report provides information how existing modes and information are used in device labeling, why the existing patient safety modes from IEC 60601-2-33 are not suitable for this purpose, provides an impact assessment of fixed physical parameters, and describes Use Cases for system use when implementing the additional mode of operation, including a review of findings from implementation of FPO as SW demonstrator.

3. Examples of Device Labeling

Existing labeling of MR Conditional implants does not offer a unified approach in identifying limiting parameters such as main field strength (1.5T or 3T), fringe field (static field gradient or magnetic force product), allowed SAR and examination duration, dB/dt or slew rate. For sake of illustration, some examples of existing labeling are added in Appendix B. Note that some labeling also indicates that scanning is considered safe when using Normal Operation Mode, i.e. assuming limits for SAR cq B1rms, and PNS cq dB/dt. The usefulness of this approach must be scrutinized, and will be discussed in the next sections. Extensive information on MR Conditional devices can be found at www.mrisafety.com and www.mrcomp.com.

4. Peripheral Nerve Stimulation and d|B|/dt

Protection against pain due to peripheral nerve stimulation (PNS) during MRI scanning is implemented based on “direct determination studies” of volunteers reporting sensations ranging from tinkling to real pain. Limit values for gradient switching (amplitude and frequency) are selected to prevent occurrence of adverse effects in the patient population. Transition from Normal Mode to 1st level controlled mode occurs at 80% PNS (percentage of 1st level controlled mode upper threshold), which implies a level of 80% of the gradient output where the median of the population reports a tinkling sensation.
We modeled the induced rate of change of the magnetic field (d|B|/dt) due to gradient switching for the Philips Achieva XR (1.5T, 60 cm bore diameter) and the Philips Ingenia (1.5T, 70 cm bore diameter). The model parameters have been added to the MR System SW to evaluate impact of FPO on clinical sequences by deriving the actual parameter values d|B|/dt and slew time percentage (per sequence), and compare these values to PNS percentages as calculated from the direct-determination model. The d|B|/dt values are evaluated at a cylinder with radius “bore liner minus 5

cm", conform IEC 60601-2-33: 2010, section 201.7.9.3.101 b.[1] Figure 1 shows the resulting d|B|/dt profiles for simultaneous switching gradients on the three physical axes, at different radii around the bore center line, as a function of z-offcentre.
Slew time percentage is defined as the fraction of the time that the gradients are changing in amplitude, i.e. generate a time-varying magnetic field d|B|/dt. This is evaluated as part of the parameterized sequence design and optimization software, and adds another constraint to the multiple other constraints used to evaluate whether the sequence will run on the available hardware configuration. Slew time percentage provides an estimate of the deposited power in implanted devices, which can be used to predict or evaluate (local) heating due to eddy currents in the device.

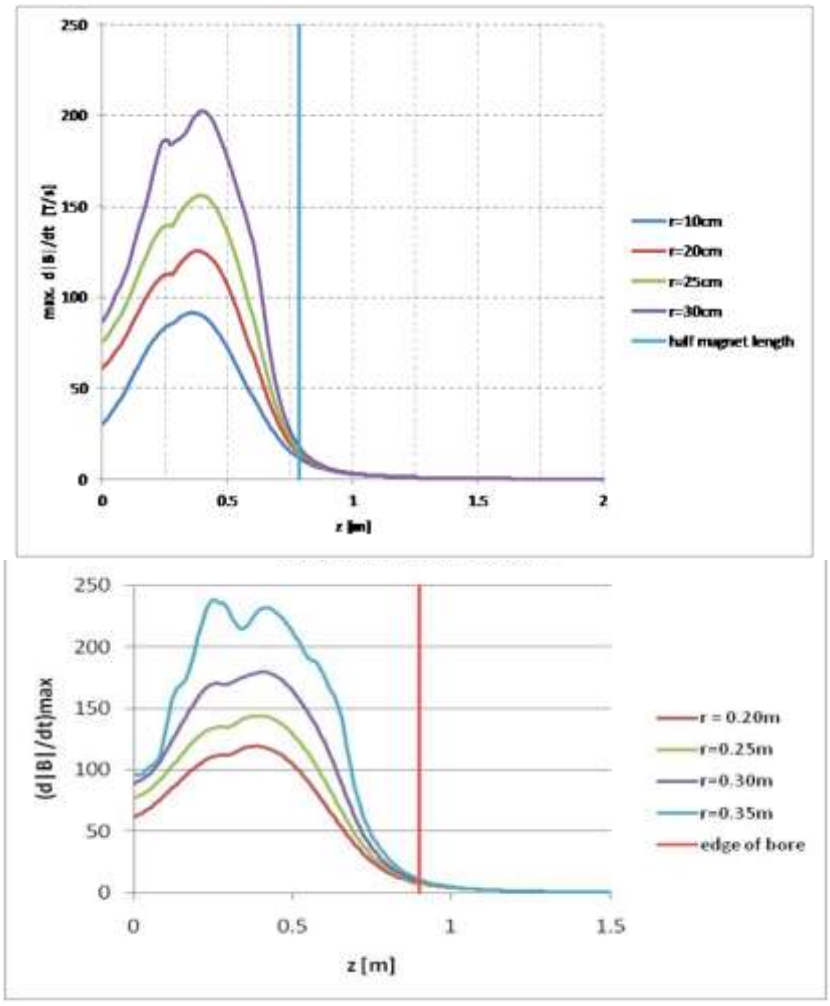

Figure 1. Graphs showing the maximum d|B|/dt at different radii around the central line of the bore of the MR system, for 60 cm, 40 mT/m, 200 T/m/s (top), and for 70 cm, 33 mT/m, 200 T/m/s (bottom).

Figure 2a illustrates the fact that sequences with the same PNS% (derived from direct-determination assessment) have multiple d|B|/dt(peak) values. The reason is that

[1] For 70 cm bore systems, the cylinder size from IEC 60601-2-33 is inconsistent with the fixed radius of 25 cm for the defined "implant volume" in ISO/TS 10974. The FPO proposal uses the IEC 60601-2-33 definition. This inconsistency must be resolved in the process of acceptance of the FPO proposal. Note that d|B|/dt includes Bx and By, which are field components that do not influence the MR imaging process.

single, or low frequency gradient slopes may induce a large d|B|/dt, while not inducing PNS (which largely depends on the frequency content of the gradient waveform). In addition, Figure 2b shows that rotation (relative to the physical gradient axes) of the scan plane for a selected protocol does not change the PNS percentage while the d|B|/dt value is varying.

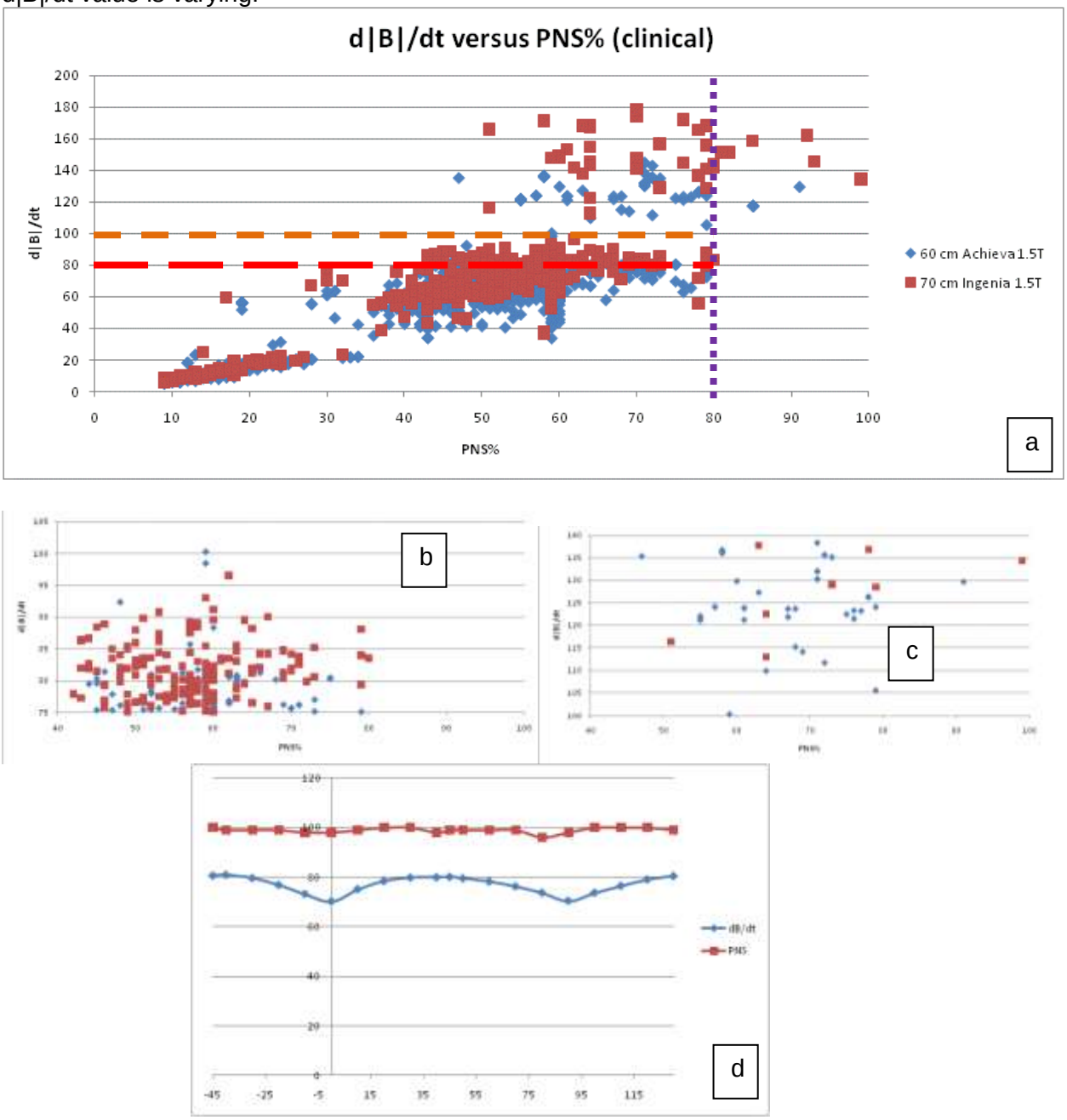

Figure 2 (a) scatter plot of calculated d|B|/dt values versus peripheral nerve stimulation (PNS) thresholds (percentage of upper limit for 1st level controlled mode) for factory clinical sequences delivered with 60 cm and 70 cm MR systems. The purple vertical line is the transition from Normal Mode to 1st Level Controlled Operating mode. Most Philips factory sequences are designed for Normal Mode with respect to PNS. The horizontal lines indicate the propose limit values from AIMD manufacturers (red) and MR manufacturers (orange). Figure 2 (b) and (c) show zoomed plots from (a) to indicate that several sequences, both at 60 cm and 70 cm systems are hit by the 80

T/s proposal from AIMD manufacturers (b), and that modern sequences truly use the gradient system performance beyond 100 T/s (c). Finally, Figure 2 (d) illustrates that d|B|/dt varies with scan plane orientation for the same PNS level, and that a SW validation is required to reflect actual sequence parameters.
AIMD manufacturers proposed a value of 80 T/s for d|B|/dt at "bore liner minus 5 cm" radius. Figure 2 shows that a set of protocols operating in Normal Mode will not be possible under these constraints *for 60 cm systems*. *70 cm systems*, however, lead to an increase of d|B|/dt inside the bore for similar protocols. MT40 therefore proposes a value of 100 T/s for d|B|/dt based on the reasoning that the d|B|/dt level at the compliance volume (20 cm radius) will be comparable for both system types, while the ratio of d|B|/dt(r=25)/ d|B|/dt(r=20) $\cong$ 1.25 for 60 cm gradient coil designs and d|B|/dt(r=30)/ d|B|/dt(r=20) $\cong$ 1.45 for 70 cm gradient coil designs. Thus, similar protocol behavior as accepted for 80 T/s on 60 cm systems will occur at 100 T/s on 70 cm systems.

Note 1 : A consequence of implementing 100 T/s at 60 cm systems will be that more protocols are possible at 60 cm systems than at 70 cm systems. This is illustrated by the scatter plot in Figure 1a, showing that the proposed limit of 100 T/s is exceeded for a only a few out of 100 typical scans operating in Normal Mode at the 60 cm system. The limit of 100 T/s also allows protocols to operate in the 1st level controlled mode (PNS >80%, while d|B|/dt <100 T/s, orange circle). The 100 T/s limit will be imposed on the AIMD manufacturers to demonstrate compliance of implants labeled as FPO compatible devices. MRI system manufacturers can decide to use 80 T/s as limit for 60 cm systems, and 100 T/s for 70 cm systems, if commercial or business reasons require comparable clinical performance of both systems types.

Note 2: The potential use of 100 T/s at 60 cm systems and the somewhat complex relation between d|B|/dt and PNS implies that protocols limited by FPO can still invoke the 1st Level Controlled Mode for gradient output. This behavior is acknowledged by MT40 members, and will be implemented by means of independent control mechanisms at MRI systems.

The limit to d|B|/dt(peak) is important for AIMD manufacturers to design devices for electromagnetic compatibility (avoid interferences). In addition, the time-varying magnetic field induces eddy currents in the enclosures of the AIMDs. To prevent excessive heating, a limit for d|B|/dt(rms) has been requested. To avoid evaluations of the magnetic field vector over time, which some MR vendors consider too cumbersome, MT40 proposes to implement a slew-time percentage.

Figure 3 shows a scatter plot of slew time percentage versus d|B|/dt(peak), including two proposed limit values for d|B|/dt(rms), viz. 56 and 65 T/s. The trend line shows the allowed d|B|/dt(peak) as a function of slew-time percentage for the d|B|/dt(rms) limit values. We propose a two-step approach to guarantee d|B|/dt(rms) < 65 T/s: allow dB/dt(peak) = 100 T/s for slew-time percentage < 40%, and dB/dt(peak) = 80 T/s for 40% < slew-time percentage < 65%. This is indicated in the graph by the orange dashed line. Further discussions between MR vendors and AIMD vendors are required to address this issue.

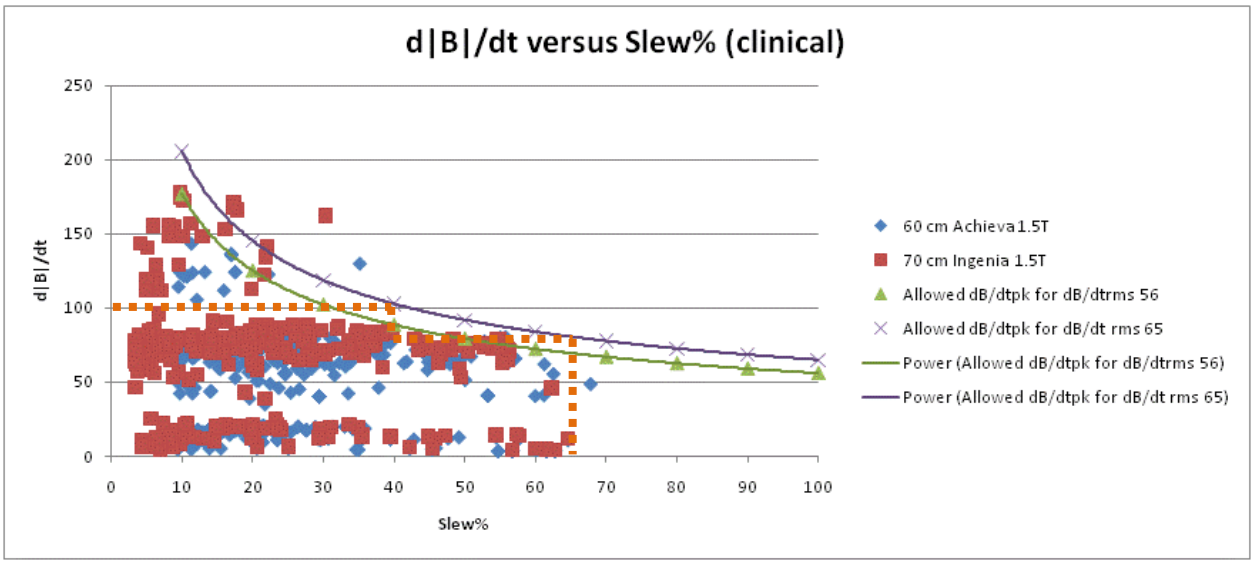

Figure 3. Scatter plot of calculated d|B|/dt values versus sequence slew-time percentages for factory clinical sequences delivered with 60 cm and 70 cm MR systems. Trend lines show the allowed d|B|/dt(peak) for two proposed limit values for d|B|/dt(rms), viz. 56 and 65 T/s. The orange dashed line indicates the proposed limits for clinical sequences in FPO.

Figure 2 and 3 shows that several clinical sequences cannot be operated when the Fixed Parameter Option is applied. Analysis of the sequence classes that are affected reveals the following impact

80 < dB/dt < 100

- *CE angio, dynamic perfusion*
- *2D TSE (body, MSK, brain)*
- *non-CE angio & flow (cardiac, brain, extr.)*
- *perfusion, diffusion*

dB/dt > 100

- *bFFE / true FISP (cardiac / abdomen)*
- *high-res (3D) TSE (brain, MSK)*
- *fMRI, perfusion, diffusion (brain)*
- *multi-echo FFE (spine)*
- *dyn. FFE, DIXON FFE (CE abdomen)*

Evaluation of the impact of clinical efficacy of these limitations will be required by e.g. FDA when MR vendors will introduce FPO to market.

In summary, controlling a fixed, constrained upper limit for dB/dt requires additional measures in MR system software beyond controlling 1st Level Controlled Mode. These controls must be patient specific, and may correlate to the presence of implants. The constraining parameter values must be carefully chosen to prevent significant impact on clinical capabilities. A SW demonstrator to evaluate these consequences has been built, and can now be used for further evaluations.

5. WB SAR and B1rms

Protection against (systemic) heating is provided in IEC 60601-2-33 by controlling whole-body (WB) and Head SAR. WB SAR obviously correlates with the power deposited into the patient, which depends on patient size, composition, and posture. MR systems control the effective average flip angle (determining the MR contrasts) by adjusting B_1^+ and the power delivered to the patient. The SAR is derived from $(B_1^+{}_{RMS})^2$

via a proportionality constant c_{SAR} with units $W \cdot kg^{-1} \cdot \mu T^{-2}$. This constant c_{SAR} is known to vary per patient and per landmark position, but a conservative estimate is derived using RF coupling studies or FDTD RF simulations. MR vendors ensure that reported WB SAR never exceeds regulatory guidelines, but do not ensure that reported SAR is accurate for every patient. As a result, reported SAR (given $B_1^+{}_{RMS}$) is known to vary between MR systems of different vendors. This is schematically represented in Figure 4. It illustrates that a B_{1rms} limit of will drive most systems into reported WB SAR >2W/kg, i.e. 1st Level Controlled Mode.
An additional factor for which c_{SAR} may account is the degree of elliptical polarization induced by the human body inside the RF coil. IEC 60601-2-33:2010 states that this factor may be ignored at 1.5T, i.e. that true quadrature polarization may be assumed, or $B_1 = B_1^+$. Small deviations (up to 10%) may occur at 1.5T, while at 3.0T nominal quadrature drive may result in almost linear polarization ($B_1^- = B_1^+$, i.e. SAR doubles for a given flip angle).

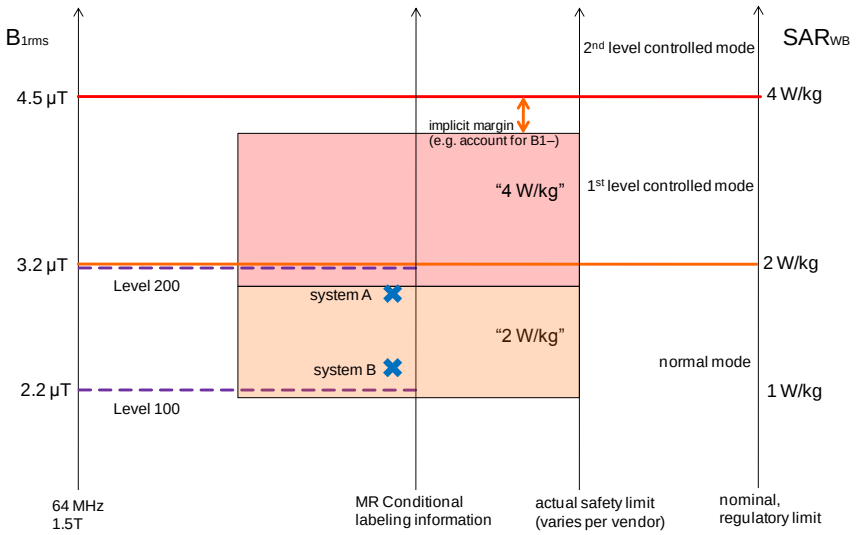

Figure 4. Schematic representation of (1.5T) B_{1rms} values and corresponding WB SAR values for typical body coil designs. Reported 2W/kg may results in significantly different actual deposited powers for different systems. Further margins may be applied by MR manufacturers to account for e.g. B_1^- contributions. Body Coil designs affect the conversion between B_{1rms} and WB SAR.

The AIMD manufacturers' FPO proposal contains a value of 3.2 µT for B_{1rms} limit. MR manufacturers have responded that they prefer to explicitly control $B_1^+{}_{RMS}$ *only*. As mentioned before, the difference becomes most relevant at 3.0T, while at 1.5T both values are sufficiently similar to expect AIMD manufacturers to adjust the safety margins in their testing procedures to ensure compliance. This issue still needs to be settled to satisfaction of all involved parties. For the time being, MR manufacturers will report $B_1^+{}_{RMS}$, and assume a value of 3.2 µT.

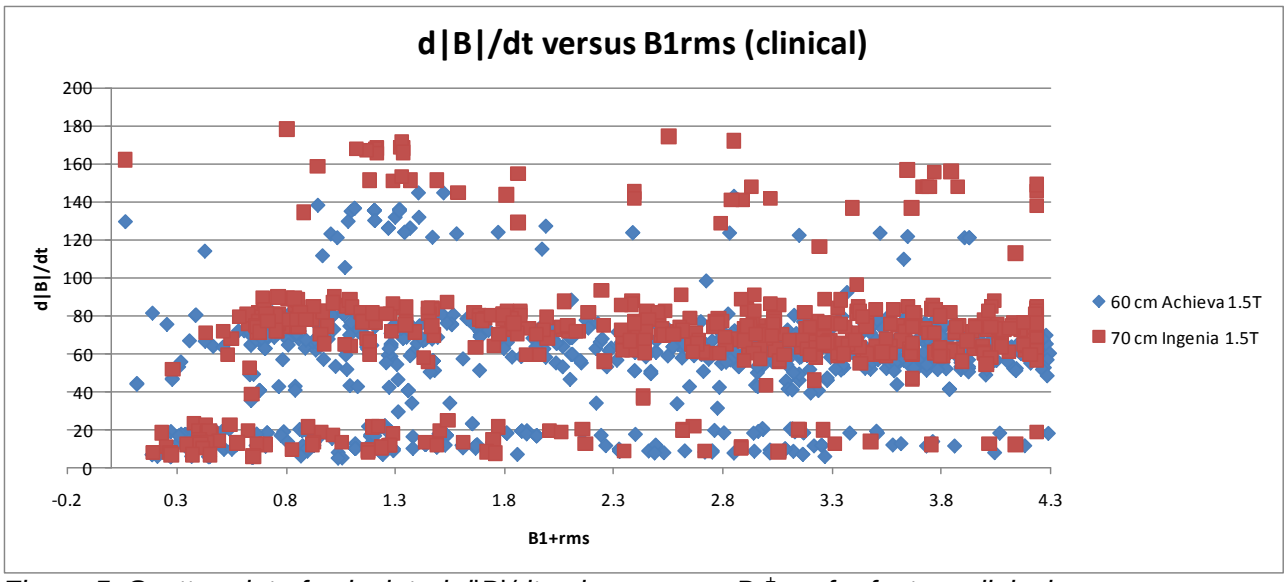

Figure 5. Scatter plot of calculated d|B|/dt values versus $B_1^+{}_{RMS}$ for factory clinical sequences delivered with 60 cm and 70 cm MR systems. The orange dotted line indicates the allowed range of sequence parameters. A significant number of protocols (esp. TSE and bFFE), running in 1st level controlled mode, are (obviously) excluded by FPO, and need re-evaluation.

Figure 5 shows the scatter plot of d|B|/dt versus $B_1^+{}_{RMS}$ for all factory protocols. A significant class of sequences is affected by the 3.2 μT limit, viz. nearly all TSE and bFFE sequences. Reducing the number of slices per unit time may resolve this issue, but it will require significant clinical application effort to optimize sequences for the required limit values.

6. Use Case Scenario description for FPO

The tables below describe current and future workflows using the FPO. In addition, the flow contains a description of the anticipated registration of the presence of implants. The future flow shows that

- FPO is selected at patient administration (New Examination selection at MR system)
- Scans operating under FPO may or may not enter 1st Level Controlled Mode (both for SAR and/or PNS)

Current Workflow	
Alternative System 1	Alternative System 2
Patient presents at referring physician or Radiology registration with Implant information	
Implant information is supplied with and/or attached to Imaging request (paper or RIS)	
Patient demographics is entered at RIS	
MR tech retrieves Patient demographics from RIS into MR system	
Patient presents at MR system; MR tech checks for contra-indications or MR Conditional conditions	
MR tech activates new study for this patient and verifies demographics	
MR Tech selects system to operate in 1st level controlled mode	
MR Tech selects study protocols and puts them in sequences worklist	
MR Tech activates sequences worklist	
MR System starts scanner calibration sequences	
MR System starts clinical scan, evaluates Normal / 1st level controlled mode condition, and identifies it as Normal Mode	
MR System executes clinical scan	
MR Tech reviews scan outcomes and selects additional scan, and places it in sequence worklist	
MR System starts clinical scan and evaluate Normal / 1st level controlled mode condition, and identifies it as 1st level controlled mode	
	System prompts MR Tech for attention and approval of 1st level controlled mode scanning
	MR Tech approves 1st level contr olled mode

Proposed Workflow	
Alternative System 1	Alternative System 2
Patient presents at referring physician or Radiology registration with Implant information	
Implant information is supplied with and/or attached to Imaging request (paper or RIS)	
Patient demographics is entered at RIS	
MR tech retrieves Patient demographics from RIS into MR system	
Patient presents at MR system; MR tech checks for contra-indications or MR Conditional conditions	
MR tech activates new study for this patient and verifies demographics	
MR Tech checks button that MR Conditional implant is present	
System responds that scanning with implants is contra-indicated, and that responsibility for procedure is transferred to medical professional	
MR Tech selects system to operate in 1st level controlled mode	
MR Tech selects system to operate in Constrained Active Fields Option	
MR Tech selects study protocols and puts them in sequences worklist	
MR Tech activates sequences worklist	
MR System starts scanner calibration sequences within Constrained Active Fields limits	
MR System evaluates selected sequences against Constrained Active Field limits, and prompts at the sequence UI if limits are exceeded	
MR Tech adjusts sequence parameters to comply with Constrained Active Field limits (or select a pre-adjusted sequence with appropriate characteristics)	
MR System starts clinical scan, evaluates Normal / 1st level controlled mode condition, and identifies it as Normal Mode	
MR System executes clinical scan	
MR Tech reviews scan outcomes and selects additional scan, and places it in sequence worklist	
MR System evaluates selected sequences against Constrained Active Field limits, and prompts at the sequence	
MR Tech adjusts sequence parameters to comply with Constrained Active Field limits (or select a pre-adjusted	
MR System starts clinical scan and evaluate Normal / 1st level controlled mode condition, and identifies it as 1st level controlled mode	
	System prompts MR Tech for attention and approval of 1st level controlled mode scanning
	MR Tech approves 1st level contr olled mode

7. FPO user interface proposal

The selection of FPO is related to patient characteristics and demographics. This selection has been added to the “New Examination” user interface, see Figure 6. A simple check box is chosen, without further parameter indications or selection options. It is anticipated that AIMD MR Conditional device labeling will also contain the simple message FPO (y/n).

8. Outlook: flexibility & additional parameters to control

The implementation of FPO has been discussed between MT40, AIMD manufacturers and FDA. Implementation of the labeling practice will (likely) be a single indicator “MR Conditional when selecting FPO”. No further parameter names or values (like dB/dt or B1rms) will be exposed to end users.
In the FPO concept, limits in dB/dt and B_{1rms} cq SAR get a hard coupling (i.e. are both applied simultaneously), which may reduce applicability in the use of the concept for head implants (e.g. DBS) or knee implants, where local transmit/receive coils may be used. Further developments of devices and procedures may require additional flexibility in selecting parameter values, either below or above the introduced FPO values. In addition, certain procedures (pregnancy or paediatrics, compromised patients like diabetics) may also require controlling the physiological outputs, esp. SAR, at or below 1st Level Controlled Mode.
It is the intent to provide additional controls to (independently) set outputs of the identified physical parameters (dB/dt, percentage slew duty cycle, B_{1rms}, B1pk, WB SAR, Head SAR) at patient registration. Esp. the SAR controls may need evaluation and introduction as product options. Figure 7 shows the additional user interface developed for research and evaluation purposes. When defining and executing an ExamCard (set of diagnostically related MR sequences), the research or expert user can assess the values of the parameter limits applied in the FPO. Lower values can be selected at ExamCard level to support evaluation of new sequences and new devices. In addition to the requested physical parameters, also limits to whole-body and head SAR are provided. This has been requested by clinicians to support existing MR Conditional labeling practice, and for other purpose like scanning compromised patients (elderly, diabetics, pregnant women).

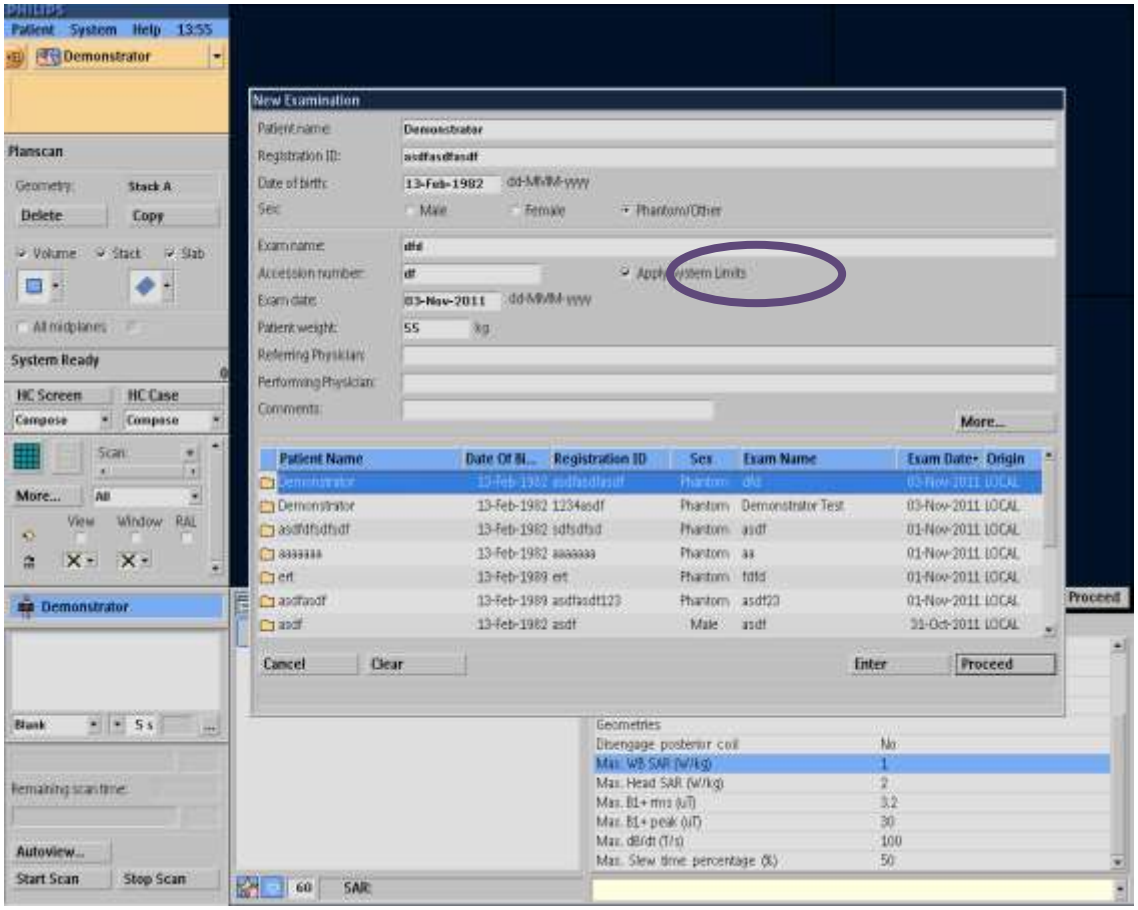

Figure 6. User Interface screenshot of the Philips MR system, to illustrate the check box where the FPO is selected at New Examination registration, in relation to other patient demographic information.

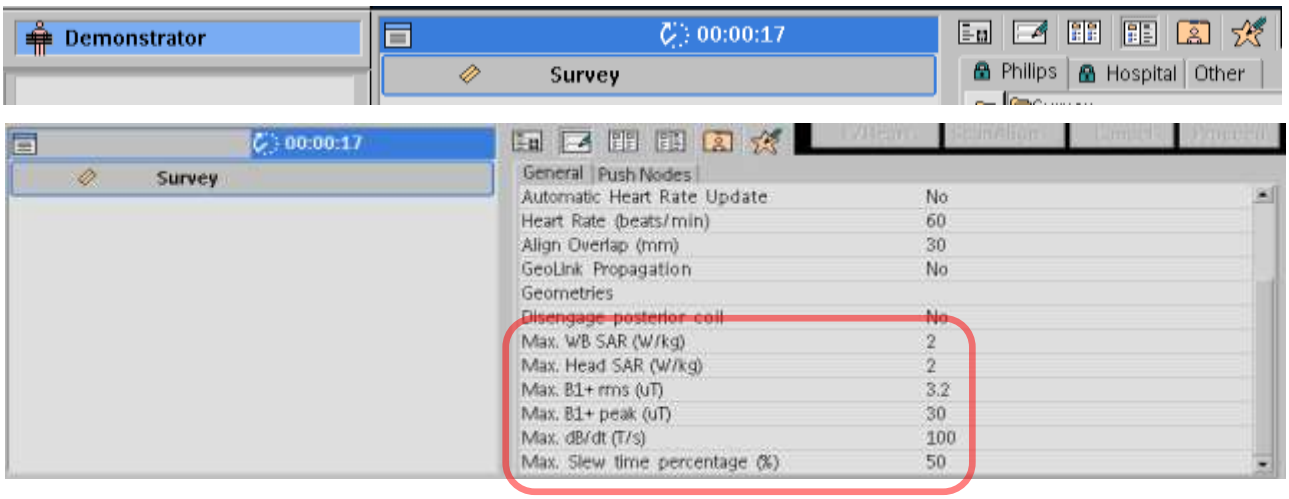

Figure 7. ExamCards User Interface screenshot of the Philips MR system, to illustrate the controls for the parameters defined in FPO. The user can define lower limit values for research and evaluation purposes.

Appendix A: AIMD manufacturer request for Fixed Parameter Mode

AIMD members of
IEC- ISO JWG on
MRI Compatibility
April 18, 2011

Dear members of MT40,
The AIMD community has come to consensus on the attached fixed parameter proposal documents, and we hope that your review will find them to be clear, thorough, and to represent the best interests of our shared patients. We are requesting the fixed parameter mode concept to limit the RF and gradient field levels to defined levels to facilitate safety testing and labeling of active implantable medical devices (AIMD) in an MRI environment. Provision and widespread use of these modes can help ensure patient safety when scanning patients with and without implanted devices.
What we originally submitted as a single proposal—with two fixed modes—we now submit as two separate recommendations: one to clarify the AIMD community's top choice of limit values for a single fixed parameter mode scenario, and one to communicate our broader vision that includes multiple fixed modes and preliminary limit values relevant to 3T systems.
The first attached document to this letter, titled *"Response to MT40 from the AIMD community for a single fixed parameter mode,"* includes the consensus definitions and limits from the AIMD community if there is to be a single fixed parameter mode. We intend that this response can directly fulfill the request from MT40 during the September 2010 meeting in Washington DC, and we expect that this document—along with the continued support of the AIMD community—will enable significant progress towards implementation by MT40 and MR manufacturers. We formally request that the proposed definitions and limits be included as a normative amendment or in the next edition of IEC 60601-2-33.
The AIMD community agrees that our top priority is to make progress on achieving at least one fixed parameter mode around which we can build, test, and label devices effectively. However, we also agree on the importance of clearly communicating to MT40 our interest and the potential value in building a more comprehensive set of fixed parameter modes.
The second attached document to this letter, titled *"Revised recommendation to MT40 for establishment of Limited Exposure Safety Settings for MRI scanners"* proposes a set of three fixed parameter modes ('Limited Exposure Safety Settings'), at both 1.5T and 3T. As implementation of the consensus single fixed parameter mode as proposed in the first attached document (identical to the LESS-2 limit in the second document) could represent a strong first step along this path, we formally request that MT40 consider adoption of this broader 'roadmap' as a separate issue from implementation of the single fixed parameter mode proposal.

In closing, the AIMD community is overwhelmingly agreed on the significant value of having fixed parameter modes in MRI scanners, and we look forward to helping MT40 and MR manufacturers continue to move toward implementation in the near future.
Sincerely,
AIMD members of IEC/ISO JWG

The following AIMD members of the JWG reviewed these recommendations/proposals for approval: **Name**	**Company**	**Approve**	**Disapprove**
Curt Sponberg	Medtronic		X
Jim Olsen	Medtronic		X
John Welter	Medtronic		X
Ingmar Viohl	St. Jude Medical		X
Bob Stevenson	Greatbatch		X
Steve Wedan	IMRICOR		X
Mark Conroy	Medtronic		X
Sandy Wixon	Medtronic		X
Joe Bocek	Boston Scientific		X
Ross Venook	Boston Scientific		X
Ingo Weiss	Biotronik		X

Appendix B: Examples of existing labeling for MR Conditional implants

The examples below show the information provided for some typical MR Conditional implants. Note the incompleteness and the different parameters characterized in the labels.

1. Medtronic Neuro Stimulation Device

MRI exposure requirements

Prior to an MRI examination, determine whether the patient has multiple active medical device implants (such as deep-brain stimulation systems, implantable cardiac defibrillators, and others). The most restrictive MRI exposure requirements must be used if the patient has multiple active medical device implants. Contact the appropriate manufacturers of the devices if you have questions.

If the following requirements cannot be met, do not proceed with the MRI examination.

- Use only an RF transmit/receive head coil.*
- Use only a 1.5-Tesla horizontal bore MRI (do not use open-sided or other field strength MRI systems).
- Enter the correct patient weight into the MRI console to ensure the head SAR is estimated correctly.

The MRI scan sequences must meet the following requirements. If they do not, the pulse parameters must be adjusted so that they comply with these requirements.

- Use MRI examination parameters that limit the head SAR to 1.5 W/kg or less for all RF pulse sequences.
- Limit the gradient dB/dt field to 20 Tesla per second or less.

*Important: If you are unsure if your MRI has RF transmit/receive head coil capability or if it displays "head SAR", check with your MRI manufacturer.

2. Philips Innercool (stent)

WARNINGS:

- Disconnect the InnerCool Catheter from the InnerCool RTx Console or the Celsius Control Console completely prior to entering the MRI environment. Failure to do so may result in serious injury to the patient. It is not possible to continue therapy with the system during an MRI procedure.
- This labeling information applies to "head-only" MRI procedures conducted using a 1.5 Tesla transmit/receive RF head coil or a transmit RF body/receive-only head coil ONLY. MRI examinations of other parts of the body are strictly prohibited with the InnerCool Catheter in situ, as this may result in serious injury to the patient.
- Testing has not been performed using non-1.5 Tesla MRI systems operating at other static magnetic field strengths and, therefore, other scanners should not be used to perform an MRI examination on a patient who has an indwelling InnerCool Catheter.
- The InnerCool Catheter must be properly positioned per these instructions for use with the catheter introduced through the femoral vein of either the left or right groin of the patient and advanced into the IVC such that the catheter is parallel to the bore of the MRI system. Do not perform the MRI examination with the InnerCool Catheter placed in any other configuration. Failure to follow this guideline may result in serious injury to the patient.
- Using the transmit/receive RF head coil, do not exceed an MRI system reported whole body averaged specific absorption rate (SAR) greater than 0.4 W/kg.
- Using the transmit RF body coil/receive-only head coil, do not exceed an MRI system reported whole body averaged SAR of greater than 3.5 W/kg.