The new ISO / IEC standard for active implants

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Scanning of patients with an AIMD (Active Implantable Medical Device) is currently contraindicated by the MRI and the implant manufacturers. It is however realized that MR scanning of patients with AIMD’s such as pacemakers, neurostimulators, cochlear implants, will become more and more frequently needed. As technical solutions to this problem become available, a new set of validation tests and labeling requirements accepted by both the AIMD and the MR manufacturers will be needed to ensure the global acceptance and safety of this important practice.

This issue is made more urgent because of anecdotal reports of off-label scanning and the possible perception that the risk is not as significant as is believed by AIMD and MR manufacturers and the regulatory bodies. The U.S. Food and Drug Administration MAUDE database [Ref 1] for adverse event reporting indicates several instances of device failures or patient injuries sustained during scanning, this despite the current contraindication. It is not clear from these reports whether the medical doctor adequately assessed the acceptability of the risk for the patient in these instances. It may be expected that in fact the medical doctor did not have enough information to be able to adequately assess the risk for the patient.

The need for international safety standards was obvious. Up till 2004 only a small number of ASTM (American Society for Testing and Materials) standards that covered non-active implants, were available, whereby certainly not all aspects of this safety were covered and in some standards also no clear criteria were formulated. In 2005, ISO (the International Standards Organization, responsible for safety standards for AIMD’s) recommended to form a liaison with IEC (the International Electrotechnical Commission, responsible for the safety standard for MR equipment, IEC 60601-2-33, Particular requirements for the safety of magnetic resonance equipment for medical diagnosis [Ref 2]) to consider recommendations that could be used to write MR related requirements for particular standards for AIMD’s.

In September 2006, the first informal meeting between representatives of ISO and IEC took place in Vienna where more than 50 experts from the implant and scanner industries and government regulatory agencies were present. This served an initial get-acquainted meeting and exchange of craft and problem identification. The outcome of the Vienna meeting was a proposal to formulate a New Work Item Proposal (NWIP) [Ref 3] with the intention of forming a Joint Working Group (JWG) with ISO TC150/SC6 and IEC SC/62B. Curt Sponberg, (Medtronic Minneapolis) representing TC150 and Hans Engels (Philips Healthcare Eindhoven) representing IEC, prepared the NWIP and were nominated as co-conveners.

The NWIP was being prepared and was circulated for comment and vote in February 2007, receiving a 93% approval vote. A JWG was formed with members from implant companies, MR companies, test houses, government, universities, and others. The JWG has held seven meetings so far. All these meetings were attended by a majority of different AIMD manufacturers, but we could establish sufficient input from the MR manufacturers. Fortunately (or may be unfortunately) the interest for every meeting was enormous (about 50 attendees!!), which however does not speed up the process to come to a common document.
The objective of the project is to produce a TS, Technical Specification (number ISO 10974) with requirements for AIMD’s and MR scanners so that safety can be validated and realized in practice. A TS is a "prospective standard for provisional application" in a particular field where there is an urgent need for guidance on how standards in this field should be used to meet an identified need [Ref 4]. At this time, publication seems most likely in late 2009.

Why a TS and not an IS (International Standard)? Because the subject matter is still under development and the engineering/science is still evolving/progressing. There is an urgent need for guidance in this area and a TS has fewer approval and comment cycles, which also speeds up the process to come to a published version of the document. In addition, information and experience of its use in practice may be gathered during the time between initial publication of the TS and the conversion into an IS. A TS is normative, it can contain requirements, and it can be used and applied as if it were an IS.

Due to the significance of MRI as a medical diagnostic and functional tool, the growing prevalence of active implantable medical devices, the high energy of MR electric and magnetic fields and extreme complexity of their interactions with implants, and the severe potential for harm, the continued need for a relevant standard will be as great as ever, so it is anticipated that this TS will be converted into an IS, whereby it is possible that the new requirements will be integrated into the existing safety standards for AIMD’s and MR or will become a standard in itself. Most probably the specific requirements for MR will be transferred eventually into the existing IEC 60601-2-33.

All implants are susceptible to force and torque from the static field, heating from the RF field, induced voltages from the gradient field which could cause unintended stimulation, and functional disturbances. In addition it must be realized that the electromagnetic fields generated by the MR scanner may influence the functioning of the AIMD. These EMC aspects are dealt with separately in the proposed TS. The proposed outline of the TS also includes requirements for markings and documentation for the AIMD’s.

The markings and documentation clauses are planned to include information concerning an AIMD mode for the MR scanner operation, an MR operating modes for the AIMD, patient risks, classification (MR safe, MR conditional, MR unsafe), operator risks, health care provider information about patient and operator safety, responsibilities for the AIMD and MR manufacturers and for the responsible organization (e.g. hospital), and information for the user. All this information should make it possible for the medical doctor to make a better founded risk/benefit decision when a patient carrying an AIMD is scheduled for an MR scan. For the marking requirements the TS refers to the existing ASTM standard [Ref 5].

The test method clauses will describe the test methods and related requirements for reporting of the results of these tests. It is attempted to include also test criteria for each test, although it is realized that for a number of the tests the exact criteria may be still open for further investigation. An additional clause for compatibility requirements will be concerned with the operational procedures related to MR mode of operation of the AIMD and AIMD mode of operation for the MR scanner (for example: limitations, boundary conditions, parameters of operation, lead placement, landmark position, and scanner user interface). The practical problem will be that the MR scanners already have specified safety related operation modes, whereby the RF and gradient related parameters are limited, but these modes do not always allow the operator to
specify the parameters which may be required to be limited for the safe MR scanning of a patient with an active implant.

Test details are still being formulated by the JWG. At the present time the draft methods are evolving towards a tiered approach with progressively more rigorous analysis and measurement techniques required. For example, a device with little susceptibility may be able to validate the ultimate requirements using one of the simpler, first tiers while devices having more complexity or reaction (less immunity) may need to use a third or fourth tier for validation.

For the first edition of the TS the following test methods are considered.

For the static magnetic field tests reference is made to the existing ASTM standards. Although these standards are designed for passive implants it is expected that the same tests and criteria can be used for the active implants [Ref 6, 7].

For the RF test method the objective of the assessment of RF induced $\Delta T$ or peak spatial SAR is to determine the maximum induced heating by the AIMD (all configurations) per $B_{1\text{rms}}$ in a uniform field with known uncertainty. The methodology is described to explain the relationship between the measured $\Delta T$ and peak spatial SAR and the statistical distribution of tissue damage that may occur in the entire patient population carrying the AIMD. At this moment the maximum allowed $\Delta T$ is still open for further validation. Criteria can and thus must be formulated in relation to the existing scanning modes of the MR scanner (normal and first level controlled operation mode as defined in the IEC60601-2-33). This implies that it must be clear to the medical doctor whether the proposed conditions for scanning of the patient with a specific AIMD are equivalent to the normal operation mode or to the first level controlled operation mode. A 4-tier approach is proposed to demonstrate the MR safety or MR conditional safety of AIMD’s with respect to RF heating. All assessments are conservative, but higher tiers result in smaller overestimation with respect to the maximum heating. For tier 1 no modeling is required, whereas for the higher tiers human modeling and ultimately also device modeling is required.

For the gradient test methods it is realized that the gradient field output of the MR scanner can produce induced voltages in the leads or other components of the AIMD. The induced voltages are a function of the dimension and shape of the AIMD (loop size), the position of the patient (and thus the AIMD) in the scanner patient bore and the scan protocol applied for the specific patient. Test methods are given for radiated field tests (applying either existing gradient coils of MR scanners or special designed coils) as well as for injected signal (voltage) tests. Additional testing is required to demonstrate the possible effects of eddy current heating for the case of the AIMD and possible vibration generated by the gradient field switching. The maximum allowed induced voltage by the gradient strength will be dependent on the AIMD tested. The performance requirement is therefore formulated for each AIMD separately. A secondary effect can be the unwanted stimulation of patient tissue by the induced voltages. The criterion for safety is therefore the combination of these two aspects.

For the EMC compatibility, for each different type of AIMD a standard MR mode, including specific operational parameter settings, shall be specified for the time that the AIMD is exposed to an MR scan. This MR mode shall be a minimum set of requirements for the AIMD and shall be defined in the AIMD device specific standard. An AIMD mode for the MR scanner, a minimal set of conditions for the MR scanner, can be identified. The EMC tests as specified in the AIMD’s device specific EMC standard or its product safety standard, shall be performed to establish that the device comes out of the MR environment fulfilling the compliance functionality criteria. The AIMD shall perform its intended functioning during and after the MR scanning.
Possible implications for the AIMD manufacturer include new test and labeling requirements, the formulation of boundary conditions and safety margins for safe scanning, aspects of training and education, and design changes. Possible implications for the MR manufacturer include making relevant specification values public so that implants can be designed optimally and changing the user interface to provide additional information (e.g. $B_{1\text{rms}}$) and to allow special scan modes for the implant.

**A preferred outcome is a set of test methods for the implants which are valid for all MR scanners so that individual testing of implants on all different types of scanners is not needed.**

Minimum expectations that have been established for the first edition of the TS are:

- Labeling (even a claim of "unsafe" requires proper labeling);
- Instructions for use (IFU) during scanning (e.g. conditions of use for the MR equipment and the active implant, patient safety related instructions, and information in order for the medical health practitioner to make a clear risk/benefit decision);
- Type of data and reports needed to substantiate the claims (including the type of tests or modeling necessary to produce the data).

An important activity for the JWG is self-validation of the eventual test methods and other requirements. This self-validation period will undoubtedly add to the overall development time of the TS and is an essential component of the project. Of course, since the nature and intent of producing a TS is to gain experience of its use in practice, some of the "proving" will occur in the real world laboratory. Being able to satisfy the objectives of the TS involves many parties. Its ultimate success depends upon the cooperation of regulators, and the implant and MR manufacturers.

**References:**

2. IEC 60601-2-33, Medical electrical equipment – Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis.
3. NWIP, ISO/TC 150/SC 6 N131, IEC 62B/647/NP, Requirements for the safety and compatibility of magnetic resonance imaging for patients with an active implantable medical device.