DeNeCor

Devices for NeuroControl and NeuroRehabilitation

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D1.1.a – Recommendations for IEC/ISO 10974 version 2

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Work Pack./ Task:

Description: This task will consist of an in depth analysis of the safety requirements specified in IEC/ISO 10974

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1. Introduction

1.1 Objectives of Deliverable D1.1.a

1.1.1 Project Context

The DeNeCor project focuses on diagnosis and therapy systems for neurological diseases. In particular, the project addresses the coexistence of therapeutic devices and diagnostic systems, which is one of the major limitations for large scale introduction of nano-electronic neuromodulation devices. To achieve this objective, DeNeCor project will address the development and validation of several diagnosis and therapy systems shown in Figure 1.

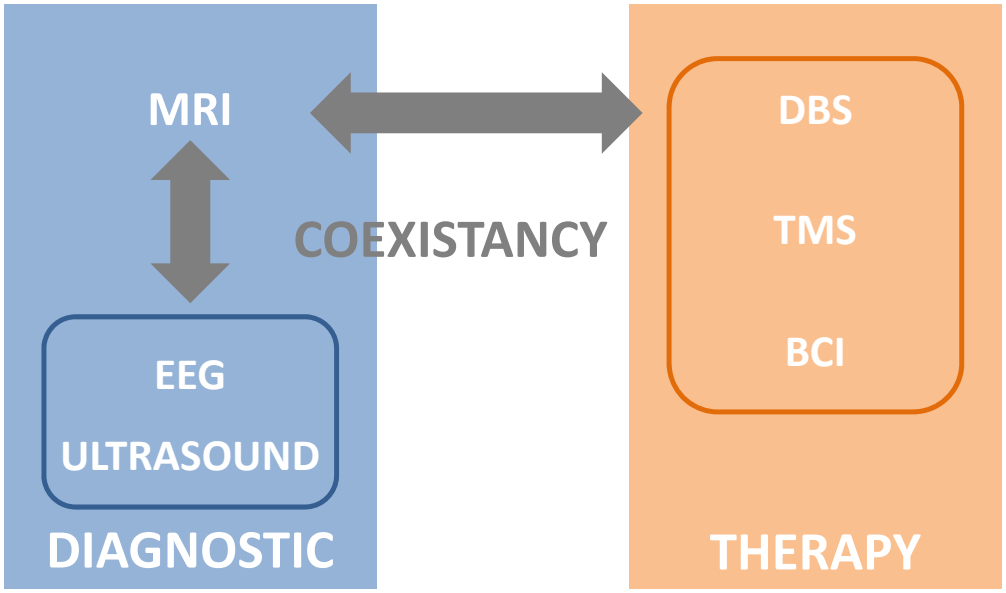

Figure 1. Diagnostic systems and therapy devices included in DeNeCor.

Therefore, one of the main objectives of DeNeCor, is to provide solutions for existing incompatibility issues between therapy devices and diagnostic systems to enable market acceptance. This objective is closely related to Technical Specification IEC/ISO 10974 which deals with safety issues for patients with an Active Implanted Medical Devices (AIMD) and Magnetic Resonance Imaging systems (MRI) and defines a set of technical challenges for AIMD (miniaturization, packaging and shielding) .

Another important objective in DeNeCor is to extrapolate recommendations for AIMD and MRI manufacturers to other diagnostic and therapy systems involved in the project, such as EEG and ultrasound imaging, and non-invasive neuromodulation devices. Although these topics are not addressed in IEC/ISO 10974, some tests and recommendations already included might be useful for future standards and technical specifications addressing those diagnostic and therapy systems. Finally, DeNeCor will develop stand-alone test methods to enable parallel development of diagnosis systems and therapy devices

As can be seen, some DeNeCor objectives are closely related to Technical Specification IEC/ISO 10974 while others go beyond current contents in IEC/ISO 10974. Therefore, research activities planned in DeNeCor have the potential to come up with useful results to improve the second edition of the Technical Specification IEC/ISO 10974 in the following areas:

- Validation of Technical Specification IEC/ISO 10974 by demonstrating the coexistence of AIMD and current 1.5T MRI scanners.
- Defining a set of recommendations to extend IEC/ISO 10974 to upcoming 3T MRI scanners.
- Extrapolating Technical Specification IEC/ISO 10974 agreements to other diagnostic systems and therapy devices included in the project.

- Defining stand-alone test methods currently missing in Technical Specification IEC/ISO 10974 to push forward its transformation towards international standard.

1.1.2 Deliverable objectives

This deliverable is included in DeNeCor's work package 1 "Requirement analysis and interface definition" which deals with the definition of technical requirements and interfaces to ensure coexistence between diagnostic systems and therapy devices. The first step in WP1 is the study of Technical Specification IEC/ISO 10974, included in task T1.1. This task addresses two main objectives: first, to determine existing technical limitations to meet IEC/ISO 10974 requirements and, secondly, to identify issues currently not covered in the Technical Specification to report a set of recommendations for the second edition of IEC/ISO 10974.

Then, the main objective in deliverable D1.1 is to report the results from IEC/ISO 10974 analysis including identified limitations and proposed recommendations focusing on the following topics: patient safety, therapy devices reliability, and the impact of therapy devices on imaging quality. Relation with other existing standards and norms, like the IEC 60601 series of safety standards will be also considered to improve the second edition of IEC/ISO 10974 and to extrapolate its contents to other type of imaging systems and therapy devices. Specially, the introduction of SPECIAL ENVIRONMENT for MR systems in IEC60601-1-2 Ed4 (FDIS Dec 2013) could affect formulation of tests and test conditions in IEC/ISO 10974.

As it is indicated in DeNeCor Technical Annex, deliverable D1.1 will consist in two versions: initial version scheduled for the sixth month (December 2013) and a final version scheduled for the eighteenth month (December 2014). The main objective of this first version (D1.1.a) is to identify main technological requirements for compliance with IEC/ISO 10974 and to propose a preliminary set of recommendations for the second edition of the Technical Specification IEC/ISO 10974 to be published early in 2015. It is questionable whether the final version of deliverable D1.1 will be in time to formulate requirements to be included in the second edition of the TS. In this situation it is realized that these additional requirements must be included in the International Standard for the safety of specific devices (if these exist) or in the first edition of the International Standard for the safety of MRI for patients with an AIMD when the technical committee responsible for the second edition of the TS decides to formulate such an International Standard. Irrespectively, several DeNeCor partners are involved in the development of the 2nd edition of IEC/ISO TS 10974, and will use findings in the drafting and review process of the standard, as indicated in D5.1.

1.2 Set-up of Deliverable D1.1.a

This document is organized into several sections according to defined objectives and information required in reference document template (see front page). Thus, first section is an executive summary containing a brief description of deliverable D1.1 aiming to provide a quick overview, while Section 2 (current section) introduces the context of deliverable D1.1 in DeNeCor and its main objectives and contents.

According to the first main objective of this document, Section 3 includes a summary of technical specification IEC/ISO 10974 including a description of its objectives and scope and a relation of its main technical requirements to ensure coexistence between diagnosis systems and therapy devices.

Then, Section 4 includes those aspects currently not covered by Technical Specification IEC/ISO 10974. This includes needed updates to meet existing equipment, relation with other standards dealing with EMC in medical devices, and the definition of proposed improvements and recommendations for the second edition of IEC/ISO 10974.

Finally, Section 5 includes document conclusions where the main results are highlighted as well as the guidelines for next actions. Relation to other work packages and deliverables is also explained in this section.

2. IEC/ISO 10974

2.1 Objectives of TS IEC/ISO 10974

International Standards are drafted in accordance with the rules given by the ISO/IEC organizations.

In specific circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish another type of normative document, e.g. a Technical Specification. An IEC/ISO Technical Specification (TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by the members of the committee casting a vote (the member countries of IEC/ISO).. A lower percentage of acceptance votes is required for a TS as opposed to an International Standard! A Technical Specification may be seen as an effort to capture the current understanding of relevant issues.

A TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn. As such TS is a normative document which can be seen as a predecessor of an International Standard. It may still include requirements which must be validated in practise.

Specifically for the IEC/ISO TS 10974 the first edition was reviewed and accepted for publication in 2012. Work on the second edition of the IEC/ISO 10974 is already started. Whether, after publication in 2015(?) and three years review it will result in a decision to formulate in International Standard for the safety of MRI for patients with an AIMD is currently being considered by the technical committee responsible for the publication of the second edition.

Following the rules of IEC/ISO also implies that new insights for requirements for specific devices for MR safety must be included in the safety standard for this specific device if such a standard exists.

2.2 Scope of TS IEC/ISO 10974

The Technical Specification IEC/ISO 10974 is applicable to Active Implantable Medical Devices (AIMDs) intended to be used in patients who undergo a Magnetic Resonance scan in 1,5T, cylindrical bore, whole body MR scanners for imaging the hydrogen nucleus. As such the TS is not applicable for non-implantable devices and auxiliary equipment to be used inside or outside (but close to) the bore of the MR scanner. It is good to realize however that many of the test methods formulated for AIMDs are also relevant for or can be transformed easily into test methods for non-implantable devices and auxiliary equipment to be used inside or outside (but close to) the bore of the MR scanner

The tests methods that are specified in the Technical Specification are type tests intended to be carried out on representative samples of a device to characterize interactions with the magnetic and electromagnetic fields associated with an MR scanner. They can be used to demonstrate device operation according to its MR Conditional labelling. The tests are not intended to be used for the routine testing of manufactured products.

The Technical Specification contains test methods that are applicable to a broad class of AIMDs for the purpose of evaluating device operation against several hazards (see Clause 7 of the TS). Tests methods for particular device types are not included.

2.3 Safety recommendations of TS IEC/ISO 10974

The IEC/ISO 10974 formulates test methods to assess the safety of magnetic resonance imaging for patients with an active implantable medical device.

Specific compliance criteria and the determination of risk resulting from device behavioral response during these tests are outside the scope of the Technical Specification.

Modification of these tests methods for particular device types is left to particular product committees, while other interested parties, such as device manufacturers, regulatory agencies, and particular product committees, are responsible for setting specific compliance criteria and determining risk.

During each type test the AIMD shall operate as intended according to its MR Conditional labelling. After each type test, the device shall operate as intended with no loss of function, have no degradation of

performance, and conform to all device specifications. All functionality (i.e. normal modes and MR modes) shall be checked after testing.

Instructions for the content of test reports are given in the TS extensively.

In principal test equipment should be designed independent of MRI systems. It is 'tempting' to use existing MRI scanners for the generation of the test fields, however new generations of MRI scanners will be present on the market with possibly new extreme values for the generated electromagnetic fields and it is virtually impossible to generate the required electromagnetic fields on commercial medical MRI scanners, since the user interface on these scanners is not designed for this purpose. Possible hazards to the patient as a result of the RF field, the gradient field and the static magnetic field that may result in harm to the patient are:

- Heat — RF and gradient
- Vibration — gradient in combination with the static magnetic field
- Force — static magnetic field
- Torque — static magnetic field
- Image artifacts — all fields
- Extrinsic electric potential — gradient
- Rectification — RF (induced rectified lead voltage)
- EMC related — all fields malfunction

It must be realized that all these hazards are also relevant for passive devices (apart from rectification and EMC malfunction) and auxiliary equipment close to the patient. They result in proposed test methods for

- RF induced heating
- Gradient induced heating and vibrations
- Static magnetic field, force and torque
- Image quality (artifact introduction)
- Gradient induced electric potential
- RF rectification (not for passive devices)
- EMC induced malfunction (B_0, RF and gradients) (not for passive devices)
- Combined field tests (not for passive devices)
- Overall RF and gradient sequence interaction (the Sequence Of Sequence test method). A basic test to secure that all intermediate (and thus not the extreme values) for the RF waveforms and gradient waveforms do not result in unsafe situations for the patients.

where no specific other test methods have to be added for these 'passive implanted device or for auxiliary equipment. An important question is whether additional tests are required for the innovative devices dealt with in the DeNeCor project (see section3.5). This will, in particular, be relevant since the MR system is operated in a Special Environment per the definition in the 4th Edition of IEC 60601-1-2. This implies that significantly higher EMC immunity (and potentially emission) requirements apply for all devices to be used in this environment.

3. Towards TS IEC/ISO 10974 Second Edition

Since the publication of the first edition, the Joint Working Group (ISO/IEC AIMR JWG) is working towards the second edition. In total 10 meetings are scheduled until February 2015 to work on the second edition. The draft 2nd version will be submitted for review and the feedback of all countries will be collected in meeting 11 (Q4 2015).

3.1 Goals and Scope for edition 2

The following goals are set for edition 2:

1. Simplify and streamline, e.g. by eliminating material or transferring to the vertical standards
2. Remove ambiguities, contradictions, clarify text
3. Evolve methods
    a. Replace descriptive statements with prescriptive statements such that the methods can be uniformly applied by all manufacturers to all AIMD types
    b. Prescriptive statements describe the necessary steps with the level of detail a senior engineer/scientist familiar with MRI theory and AIMD principles could understand and translate into practice
    c. Improve tier structures to better reflect current realities
4. Inclusion of Fixed Parameter Option (FPO) to standardize MRI output, enabling MR conditional devices to comply.

The following items are outside the scope of edition 2:

1. 3T
2. Non-implanted components and systems
3. Open MRI scanners
4. Automatic detection beacon, e.g. Unique Device Identification (UDI)
5. Round robin testing
6. Sensing devices
7. Specific performance and compliance criteria and the determination of risk resulting from device behavioural responses are left to the vertical standards
    a) All requirements for MR scanners are to be found in IEC 60601-2-33. Tests using clinical scanners do not imply any burden or obligation on the part of MR equipment manufacturers

The following items are within the scope for edition 2:

1. Horizontal standard for all active implantable medical device types
    a) Not specific to any single AIMD type
    b) But recognizing that the outcome depends on the expertise of those who participate
2. MR Scanner independent
    a) Cylindrical/elliptical bore
    b) 1.5T, proton (64MHz)
    c) (Open scanners are out of scope)
3. Is primarily a test method document
    a) Contains methods for characterizing device behavioural responses from exposure to the electromagnetic fields associated with an MR scanner
    b) Based on a set of known and foreseeable potential hazardous situations
    c) Methods should be written so they are applicable to all AIMD's within the scope of the TS

   d) (Details and test fixtures pertinent to a specific type of AIMD should be left to the vertical standards)
4. Contains AIMD labeling provisions that are applicable to all AIMD's within the scope of the TS

Note that unaddressed items of edition 2 might be part of the scope for edition 3, i.e. the first edition of a standard. Note further that TS IEC/ISO 10974 is a horizontal standard and that some of the items covered might be too product-specific and to be moved to vertical standards.

3.2 Progress of edition 2

The work is divided in mainly two sub-groups, i.e. RF and Gradient. Smaller sub-groups are EMC and labeling.

RF subgroup

- Various clauses are rewritten and currently being reviewed. There are ~12 RF related annexes, from which in early 2014 will be decided what should stay or move.
- Radio markers are most likely not suitable for positive system identification (PSID)
- Additional tissue simulants are proposed to cover a broader range of tissues at implant trajectories.
- Methods are being developed to validated AIMD/Lead model transfer functions and phase factors by both simulations and measurements. However, so far none of the methods have been shown reliable so far.
- Uncertainty evaluation: a working example for Clause 10 (RF heating) will be provided as informative annex. For other clauses, uncertainty analysis is required, but not methods are provided. The intention is that uncertainty evaluation will be normative for all clauses in the 3rd edition.
- The RF sequence of sequences (SOS) will be reduced to two sequences, covering either peak values, or maximum rms values.
- The RF injection network will be improved (i.e. 6db attenuators replaced by circulators), such that it can be used at high powers, enabling monitoring of reflections. Methods to characterize cross-coupling between ports are proposed. Phase differences (0/90/180/270) between ports have to be applied to address phase sensitivity.
- Test methods are proposed to measure induced lead voltages using representative DUT's enclosures including realistic input impedances and optically coupled measurements.

Gradient subgroup

- Various clauses are rewritten and currently being reviewed.
- The output of a large amount of generic gradient coils has been modeled as input for test methods. Little differences are experienced between 60/70cm bores. Results will be published i.e. in ISMRM abstracts.
- The Tier3 vector potential method will be dropped since it is not used.
- It is proposed to define rms slew rates based on realistic and conservative gradient intensities in clinical sequences.

3.3 Relevant IEC standards

All medical electrical equipment has to comply with the IEC60601-1 series of standards, prescribing requirements for Basic Safety and Essential Performance. This standard series covers electrical and mechanical safety, electromagnetic compatibility, biocompatibility, usability and requirements for home healthcare and emergency environments. These standards require extensive risk management related to electromagnetic compatibility of medical systems, in relation to essential performance, and require compatibility statements in the user documentation. The tests identified in TS can support such evaluations, but specific acceptance conditions to support compatibility statements are prescribed by the MR vendors.

The electromagnetic environment of the MR system is both aggressive (emission) and demanding (immunity). These requirements affect the device used inside and around the MR system, as being developed and evaluated in DeNeCor. The related special conditions are recognized in the new 4th Edition of the EMC collateral standard IEC 60601-1-2 (FDIS December 2013). This standard introduces the concept of SPECIAL ENVIRONMENT, which allows particular standards and manufacturers to define appropriate emission and immunity levels. The MR particular standard IEC60601-2-33 will need updates to specify the conditions valid inside the SPECIAL ENVIRONMENT, the requirements to its shielding effectiveness, and requirements to devices used inside the SPECIAL ENVIRONMENT. Such modifications are discussed in the standardization plan D5.1.

3.4 Relevant ASTM standards

Apart from the Technical specification IEC/ISO 10974, which specifically is formulated for the safety of Magnetic Resonance scanning of patients with an AIMD, there are also specific standards published by the ASTM standards organization, specifically for the safety of Magnetic Resonance scanning of patients with a passive implant. Some of these ASTM standards are formerly referred to in the first edition of the TS, because it is realized that they are directly valid also for AIMDs. The following ASTM standards are for the safety of MR scanning of patients with passive implants is published:

- ASTM F2052, Test methods to measure displacement force on ferromagnetic materials as a result of the static magnetic field
- ASTM F2213, Test methods to measure torque on ferromagnetic materials as a result of the static magnetic field
- ASTM F2119, Test methods to evaluate image artifacts
- ASTM F2503-8, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

In must be realized that specifically the ASTM standard for measuring RF heating of passive implants, ASTM F2182 is not referred to in the TS since the technical committee responsible for the TS decided that the formulation of the test methods for RF heating needed a complete rewording in the first edition of the TS.

4. Beyond IEC/ISO 10974

4.1 Need for TS IEC/ISO 10974 improvement.

As formulated in 2.2, the scope of the first edition of the TS is applicable to Active Implantable Medical Devices (AIMDs) intended to be used in patients who undergo a Magnetic Resonance scan in 1,5T, cylindrical bore, whole body MR scanners for imaging the hydrogen nucleus. The second edition reviews and improves all normative clauses and annexes. The focus is on replacing descriptive statements with prescriptive statements so the methods can be uniformly applied by all manufacturers to all AIMD types. Prescriptive statements describe the necessary steps with the level of detail a senior engineer/scientist familiar with MRI theory and AIMD principles could understand and translate into practice.

It must then be realized that the technical committee responsible for the second edition of the TS already limited the second edition still to 1.5T and quadrature RF transmit, which may make it necessary to develop new test methods for these technologies. Other elements that need to be addresses in the second edition of the TS:

- 3D SAR and T mapping techniques are proposed that use either SAR or fiber-optic T probes. No other options are discussed or explicitly excluded, i.e. MR Thermometry, IR thermometry, and thermistors. Such techniques can be used to detect where the maxima of RF heating will occur in the in-vitro phantoms. Then fiber-optic sensors can be placed in the -3dB regions to accurately characterize the worst-case energy deposition. Note that devising such tests should maintain the position that it recommended to prevent the use of a single commercial MR system for conformance tests.
- Calibrated magnetic field probes are proposed to monitor the field strength and polarization. I would suggest recommending electric field probes as well. Using electric field probes provides a better rationale for RF heating (T->SAR->E not B/H)
- It is not described how to translate temperature rise into application specific risk factors. It is suggested including a tissue-damage model to be used by manufacturers in their risk assessments.
- The advent of oval MR systems (Hitachi) requires consideration of compatibility of the proposed tests and acceptance criteria for systems other than cylindrical.
- 10.3.4: uncertainty in thermal tissue parameters (should be skipped here) are unnecessary for incident field uncertainty.
- L2 Recipes table L.1 p 112, liquid 99.71% H20 + 0.20% NaCl is not equal to 100%
- Percentages are used in recipes, of volume or of weight?, Reference i.e. Stochrijn and applicable Temperature is not mentioned i.e. room temp, or body temp?
- Recommend to include test methods to monitor B0 induced malfunctioning, as this difficult to monitor during B0 exposure. Before/After is easier. For DBS implants or any other non-life supporting implants, it is ok to switch off the device in a special MRI mode..
- RF induced malfunctioning. Determining the induced voltage using a bench-top RF birdcage is not feasible for everyone. Recommend to be able to use (validated) simulations or MRI scanners as well.
- Page 17, Table 8. Recommend to include phase weighting factors for more generic structures, such as helical wires
- Annex I: Measurement System Validation
    - It is recommended to improve or replace this section, as it is impossible to use the annex results to validate systems and simulation tools. It contains errors

and it is unclear how uncertainties are obtained (the used references are not published or do not contain the right information)

The DeNeCor project focuses on diagnosis and therapy systems for neurological diseases. It is well known that for these neurological systems the use of 3.0T cylindrical bore Magnetic Resonance Scanners is growing rapidly. In addition new MRI scanning techniques applying Multi Transmit RF coils and non-smooth multi-channel RF waveforms may introduce the need for new test methods. This will include inter-vendor discussions how to define RF system modes, and how to potentially control and limit RF outputs while maintaining the IQ gains of MultiTransmit RF technology. Labeling requirements for implants and devices must be aligned with those of MR systems. It is anticipated that this requires more research to define RF interactions, and to evaluate understanding of potential labeling for end users. The Standardization plan to accommodate these new developments is described in Deliverable D5.1.

4.2 Relation with IEC 60601-2-33

Possible new requirements for the MRI scanner, can only be included in the international safety standard for MR scanners, the IEC 60601-2-33.

The technical committee responsible for the TS however realized that for some devices the electromagnetic fields of the MRI scanner would be too high to guarantee safety without limitations for the MRI scanner. This would require the introduction of a specific scanning mode on the MRI scanner with limited performance for the RF and the gradient waveforms and thus an addition for the IEC 60601-2-33.

Such an operation mode with limited outputs is available since many years on every commercial clinical scanner and referred to as the normal operation mode (as opposed to first level controlled operation mode). This normal operation mode limits the RF and gradient waveforms during the MRI scan to values that will not result in physiological stress for the patient. Unfortunately, the parameters controlled in this normal operation mode scanning are not the relevant parameters for protection of active electronics of the AIMD or auxiliary equipment or possible hazardous passive HW interaction with the patient. The limitations in normal operation mode do reduce the RF (via SAR) and gradient power via avoidance of peripheral nerve stimulation), but not directly via maximum RF pulses (amplitude and time) and gradient waveforms (amplitude and time). This therefore required the introduction of a new operating mode. The MR manufacturers have accepted this proposal and are currently discussing the specification of the so-called Fixed Parameter Option. This FPO scanning option will be specified in a future amendment of the IEC 60601-2-33 and will allow the AIMD manufacturers to specify scanning in this operation mode as a ‘MR conditional safe’ way of scanning the patient in a MRI scanner.

In addition, FDA has requested clarifications for the multi transmit modes used in different commercial MR systems, to facilitate uniform testing and labelling of implants, as well as a definition of the formula used by MR vendors for Static Field Gradient reporting. These additions are also planned for Amendment 2 of IEC60601-2-33 Ed3.

4.3 Proposed recommendations set

DeNeCor project will develop research activities in diagnosis and therapy systems and devices for neurological diseases, with special emphasis on the coexistence of this systems and devices with MRI scanners. Therefore, methods for testing and validation to be defined during the project for planned demonstrators could be used during validation process for future medical products.

Within this section of the document, a series of recommendations to update the TS IEC/ISO 10974, or other upcoming technical specifications, for validation of electromagnetic compatibility of new devices and systems for neurological diagnosis and therapy, currently not covered by technical Specification IEC / ISO 10974, with MRI scanners are provided. These recommendations are based on two major lines: compatibility of AIMD with **3 Tesla MRI scanners**, and extension of the technical specification for **non-implantable medical devices** (NIMD).

As described in the Technical Annex, two versions of this document (D1.1.a and D1.1.b) will be delivered. In this first deliverable version a general description of the proposed recommendations is provided, while in the next release, scheduled for month 18, a detailed description of proposed test and measurement methods will be provided.

4.3.1 Coexistence of AIMD with 3T MRI systems.

The coexistence tests included in the current version of the technical specification IEC / ISO 10974 are limited to MRI systems up to 1.5T, but the current trend is to increase the power of these systems until 3T or even more in future. Therefore, one of the proposed recommendations is to extend the tests for AIMD coexistence included in the technical specification to 3T intensities.

In the case of AIMD, the current version of the technical specification is a reference document for the tests of coexistence with MRI systems, but there are other standards related with the validation of these devices. Specifically, the ISO 14708 (Parts 1 and 3) describe standard methods for validation of active implantable medical devices, especially implantable neurostimulators.

Therefore, the first recommendation is to extend coexistence tests of AIMD for neurological therapy to MRI systems up to 3T, using information contained in existing standards (ISO 14708) and the data that will be provided in the second version of this deliverable (D1.1.b) for the design on new tests.

4.3.2 Extension to non-implantable devices.

As mentioned before, TS 10974 focuses on active implantable medical devices (AIMD) but there are other types of systems which can be used for therapy and diagnostic in neurological diseases. In the case of passive implantable medical devices (PIMD) and non-implantable medical devices (NIMD), coexistence is not so critical because these devices can be removed of switched off during MR scanning. But, even in those cases, it could be useful to perform MR scanning simultaneously with other imaging or therapy systems to obtain information about the effects of those treatments. Then, it is recommended to modify coexistence test for AIMD included in TS 10974 to adapt them for PIMD and NIMD enabling simultaneous use of therapy devices and MRI systems.

Medical devices included in DeNeCor objectives are based on nanoelectronic technologies. One of the main requirements for any electronic device is the evaluation of electromagnetic compatibility and different standards have been developed for the evaluation of electromagnetic compatibility (EMC) for general purposes, but there is still a lack of specifications and methods to evaluate EMC during MRI processes. The next recommendation would be to extend coexistence methods included in TS 10974 to evaluate EM compatibility of nanoelectronic systems used in neurological treatments during MRI processes to ensure patient's safety and to avoid artefacts in imaging results.

In some cases, other factors in addition to electromagnetic interferences should be considered for imaging quality or patient safety. For instance, ultrasound imaging could complement the results obtained by MRI but there is a lack of coexistence requirements between both systems which difficult the implementation of this complementary diagnostic tools. It is recommended to consider the extrapolation of some tests detailed in TS 10974 to evaluate coexistence of Ultrasound imaging and MR imaging in terms of induced heating, imaging artefacts or any other possible malfunction due to acoustic pressure effects.

Finally, DeNeCor project will also develop a robotic based neurorehabilitation system including a BCI system based on EEG acquisition. Although the interaction of this type of systems with MRI processes seems not as relevant as for other devices, basic safety considerations will be addressed in DeNeCor. Existing safety standards for robotics, like ISO 10218, target industrial applications so there is a lack of reference documents and specific tests for medical applications. During this project, existing standards will be use as base to define additional specific tests for robotic medical applications related to neurological diseases.

5. Potential problems for DeNeCor innovations with the first edition of TS 10974

As mentioned before, most of DeNeCor project innovative products are currently out of TS 10974 scope so, the inclusion of these new products will require the definition of new coexistence test methods. Some of these methods might be included in future editions while some others might be completely out of TS 10974 scope.

The objective of this deliverable is to provide a set of recommendations based on the results obtained during project development. The potential inclusion of proposed recommendations, in future editions of TS 10974 or in other relevant documents, completely remains on existing working groups and their criteria.