DISPERSE

Electronics for spatially distributed sensors and transducers arrays

Labeled in PENTA, a EUREKA cluster, Call 1

PENTA Project Number 16012

D1.1 – Use-cases for healthcare, space and sound systems

Due date of deliverable: M12

Start date of project: 1 February 2017	**Duration:** 36 months
Organisation name of lead contractor for this deliverable:	Philips
Author(s):	Mark van Helvoort (Philips)
Status:	Approved
Version number:	1.0
Date:	February 19, 2018
Doc reference:	DISPERSE_Deliverable_D1.1._Use-cases_for_healthcare_space_and_sound_systems_V1.0.docx
Work Pack./ Task:	Work package 1, Task 1.2
Description: ***(max 5 lines)***	This document describes the use cases of the DISPERSE project

Nature:	<Use one of these codes: **R**=Report, **P**=Prototype, **D**=Demonstrator, **O**=Other>		
Dissemination Level:	**PU**	Public	**R**
	PP	Restricted to other programme participants	
	RE	Restricted to a group specified by the consortium	
	CO	Confidential, only for members of the consortium	

DOCUMENT HISTORY

Release	Date	Reason of change	Status	Distribution
V0.1	02/06/2017	First draft based on FPP and discussions during kick-off	Draft	All DISPERSE partners
V0.2	07/07/2017	Updated with hospital workflow	Draft	All DISPERSE partners
V0.3	07/08/2017	Updated with acoustics	Draft	All DISPERSE partners
V0.4	06/10/2017	Updated with review comments during consortium meeting.	Concept	All DISPERSE partners
V1.0	02/19/2018	Approved by PMT	Approved	PENTA Office

Table of Contents

Glossary

Abbreviation / acronym	Description
ASIC	Application Specific Integrated Circuit
GOF	Glass Optical Fibre
LNA	Low Noise Amplifier
MRI	Magnetic Resonance Imaging
POF	Plastic Optical Fibre

1. Executive Summary

DISPERSE focuses on Smart Health, but has cross-domain technology sharing with Smart Cities and Space. This documents describes the use cases of the technology developed in the DISPERSE project:

- Coexistence between MRI and Active Implantable Medical Devices
  - Improved MR Conditional Implants
  - Multi-implant coexistence
  - Optimal MRI workflow for implants
- Cross-domain synergies
  - Smart cities
  - Space

These use cases form the input for the derivation of the DISPERSE reference architecture and building block specifications.

2. Introduction

DISPERSE focuses on Smart Health, but has cross-domain technology sharing with Smart Cities and Space as shown in (Figure 1). In this document the use cases of the DISPERSE project are described. They form the input for the derivation of the DISPERSE reference architecture and building block specifications.

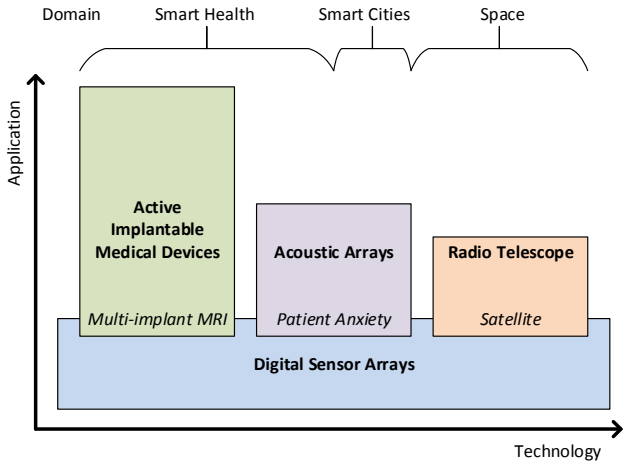

Figure 1: DISPERSE builds applications on a common technology. Focus is on healthcare with spin-off to smart cities and space.

3. Coexistence between MRI and AIMDs

For numerous identified medical conditions Magnetic Resonance Imaging (MRI) is required according to clinical consensus guidelines for diagnosis and treatment monitoring. As patients develop multiple medical conditions, many of those needing an MRI scan will have one or more implants.

Current medical practice excludes patients with an implant from access to MRI, because these scanners employ (electro-)magnetic fields which exceed regular emission limits by far. This causes serious health inequalities for a rapidly growing group of patients [3]. AIMD and MRI manufacturers are working together to resolve this issue. With state-of-the-art implants, called MR Conditional implants, scanning a patient with a single implant is allowed under strict limiting conditions of the MRI[2].

Unfortunately these limits extend the typical exam time from 20 minutes for a patient without implant to 1 hour for patients with one implant. The joint technical challenge in DISPERSE is to develop innovative electronic solutions to scan patients with multiple implants in a factor 3 shorter exam time with improved accuracy. This means that up to three times more patients can benefit from non-invasive diagnosis using MRI.

DISPERSE will optimize the workflow for MRI scanning of patients with multiple implants. Next to innovative building blocks for AIMDs and MRI, an acoustic observation system will be developed which on one hand can be used for detecting a calamity with the patient and on the hand for tracking operators throughout the room. The latter will help to optimize clinical routine and can also be used as basis for a dosimetry system which is currently under discussion by regulatory bodies.

3.1 Safety concerns for implants in MRI

Magnetic Resonance Imaging requires three powerful magnetic fields, a static field (**B0**), a gradient field (**G**) and a radiofrequency field (**B1**) [1]. See ***Figure 2*** for an illustration.

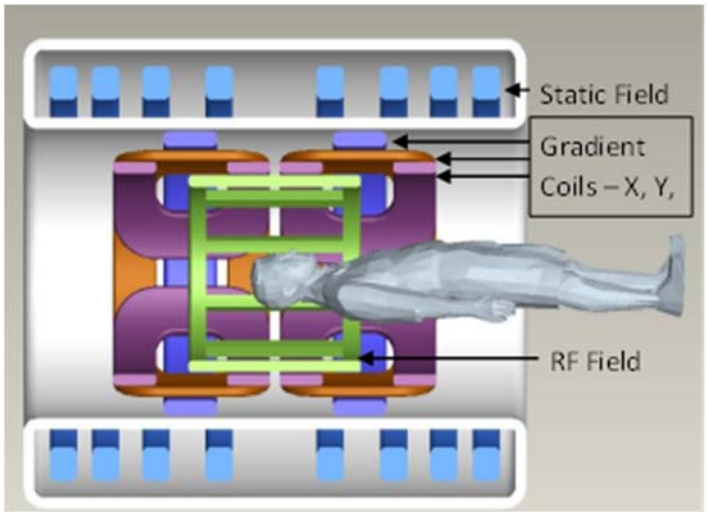

Figure 2 MRI scanner cross section, illustrating the coils that produce the required magnetic fields (static, gradient and RF) *Error! Reference source not found.*

These strong fields exceed those which are encountered in everyday life by far. This leads to potential hazards when electrically conductive, metallic and/or magnetic items are brought close or in to the MRI. Obviously this is in particular true for both passive and active devices which are implanted in the human body. The safety concerns related to implants can be divided in two categories (see also ***Figure 3***):

1. The always-present danger of the static magnetic field B0 with its risk of 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 or 5 Gauss. While EN 50527 specifies 1 mT or 10 Gauss, older implanted devices may still be affected at 5 Gauss, the value specified for delimiting the Controlled Access Area in IEC60601-2-33.
2. The risks associated with actual performance of the imaging procedure: emission of RF pulses and switching gradients that are needed to encode the MR image. These risks can be reduced by implementing and applying appropriate controls in the MR sequences.

A comprehensive overview of potential patient harm, hazards and their cause related to the MRI fields is given in Table 1.

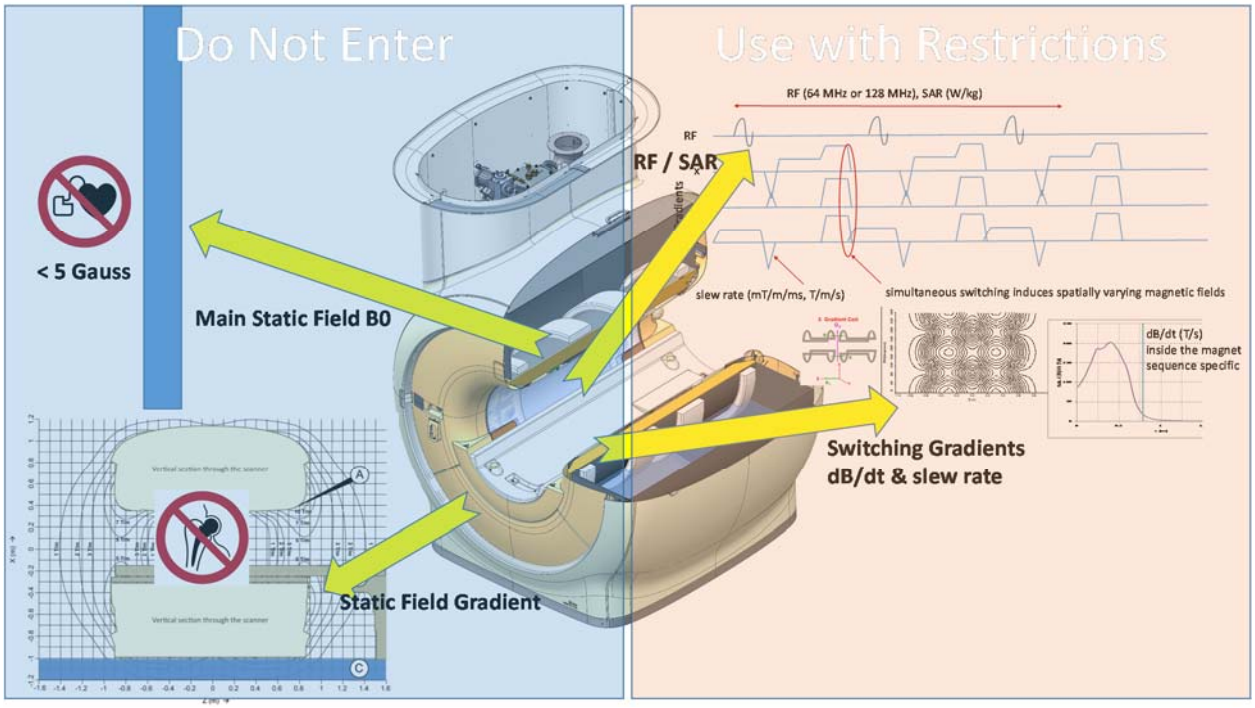

Figure 3 Safety concerns related to interactions between implants and MRI fields

Table 1 Causes for potential harm to patients with implants

Harm	**Hazard**	
Over- or under-treatment, or failure of life support	Device malfunction	1. B0 > 5 Gauss 2. Lead voltage (switching gradients' dB/dt) 3. Lead voltage: RF rectification (B1 peak) 4. Electromagnetic interference (EMI)
Tissue damage	Implant displacement	1. Magnetic Force (in Spatial Field Gradient) 2. Torque (in Spatial Field Gradient)
Tissue damage	Implant heating	1. Average RF power (SAR, B1+rms) 2. Gradient power (average dB/dt)
Tissue damage or implant breakdown	Vibration	Switching gradient amplitude (dB/dt)
No diagnosis		Image distortion 1. Magnetic materials distort B0 2. Gradient field distortion due to eddy currents RF shielded by implant

More details are provide in [1].

3.2 Hospital workflow

The current hospital workflow for scanning patients with implants is depicted in Figure 4 and described in detail in subsection 3.2.1. DISPERSE innovations facilitate optimization resulting in the future workflow shown in Figure 5 and detailed in subsection 3.2.2. Further optimization during scanning can be obtained with acoustic observation which is described in subsection 3.2.3.

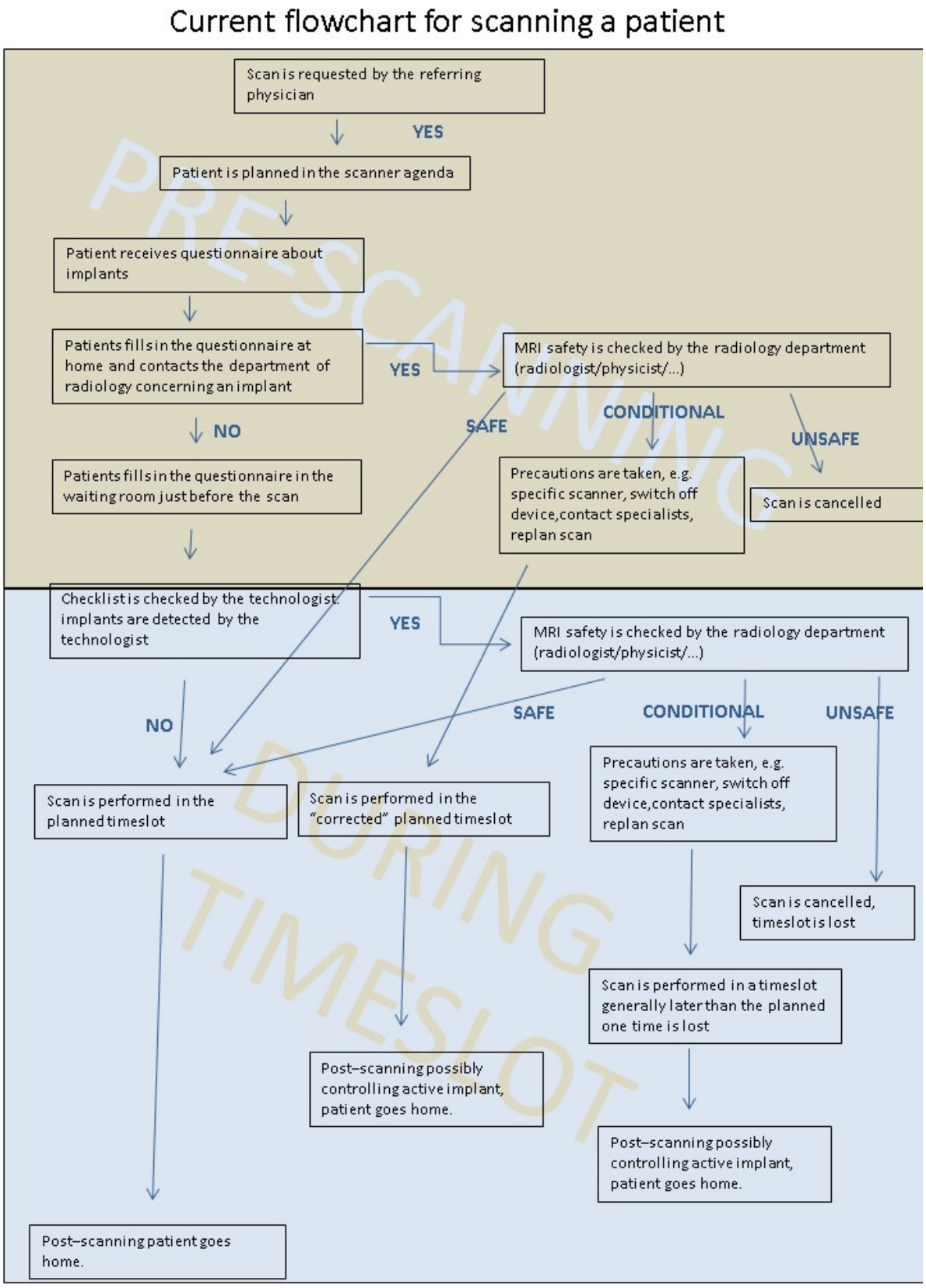

Figure 4 State-of-the-art hospital workflow for scanning patients with implants

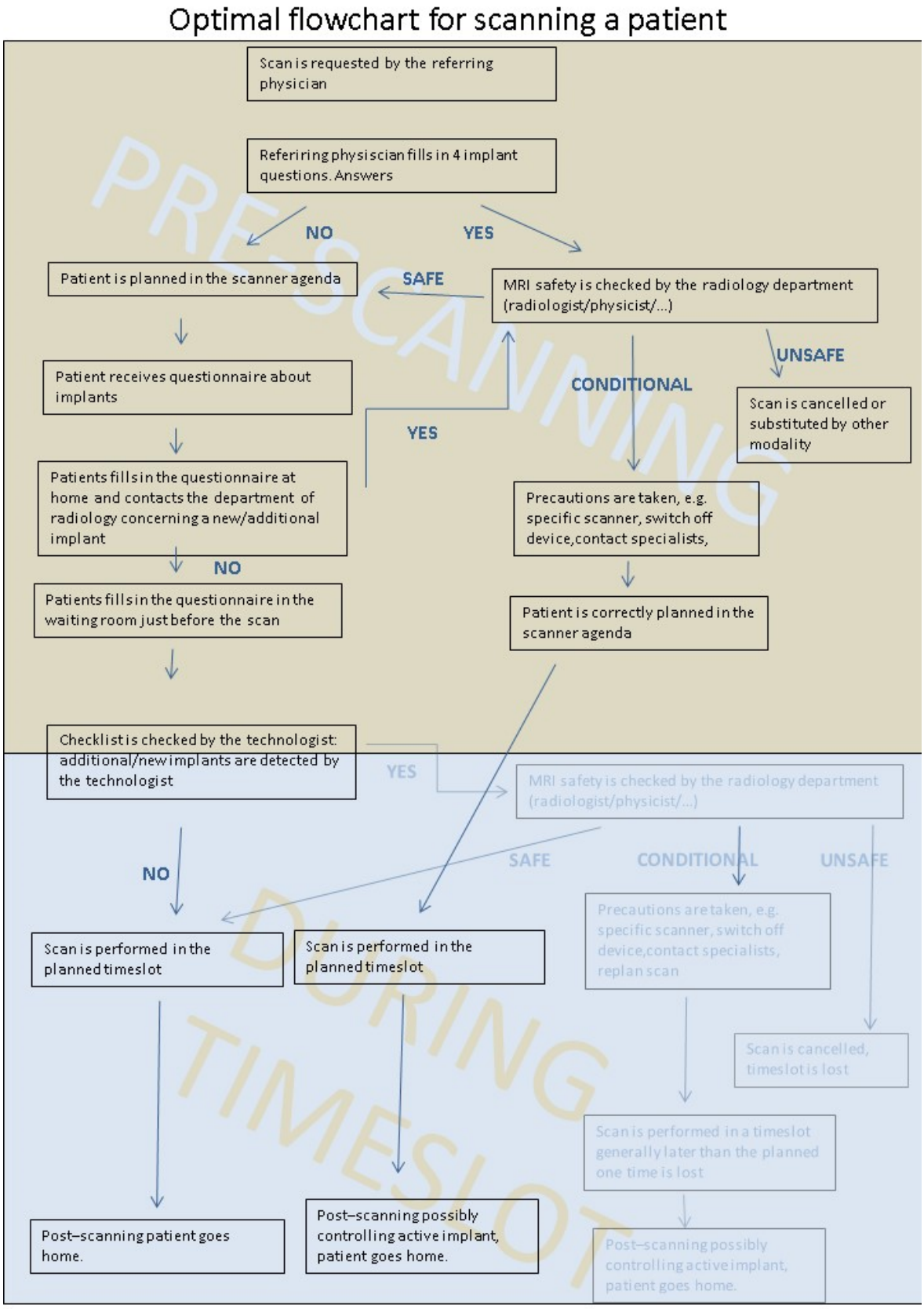

Figure 5 Future workflow optimized by DISPERSE innovations

3.2.1 Current situation:

In the current protocol for scanning patients with active/passive implants there are different flaws, which decrease the productivity and possibly increase the risk. An update of the clinical protocols is therefore urgently needed.

In the current protocol for scanning patients with implants the following steps are taken. (See also fig 1 current flowchart)

1) First a patient is planned for a scan on the request of a referring physician, the planning is done by the secretary of the referring department or the radiology department
2) When the patient is planned on a certain timeslot in the MR agenda, he/she receives letters of information about their scan date/time, possible preparations the patient has to do and also a patient questionnaire about implants and historical surgery (see Appendix 8.1 patient questionnaire)
3) On the day of the scan the patients brings with him this form, or if the patient does not have the form with him they still need to fill it in just before scan
4) The technologist checks the form and also repeats by asking several safety questions about implants as a double check
5) If a question about the implant was checked with “yes”, conditionality needs to be checked for the implant by the technologist/radiologist/MR physicist.
    a. When the implant is unsafe no scan is possible and the patient will be sent back home without a scan.
    b. If the implant is safe the scan can be performed without additional preparation.
    c. If the implant is MR conditional several different preparations have to be performed in order to be able to safely scan the patient. Depending on the type of conditionality preparations can be: switch off the active system or put it in a specific state, fixate the system, contact specialist (cardiologist/neurosurgeon) to change the device settings pre and post scan and/or monitor the patient during the scan.

This step by step algorithm has several drawbacks which ultimately results in lost scan time when it is needed to check the system just before the scan, or when the patient is not allowed under the scanner or when the patient has to be re-planned on another MRI system or at another timeslot when extra support is available.
All these issues will result in a lower throughput when patients with implants arrive at the hospital compared to non-implant patients. There is also a greater risk of possible safety issues when the patient doesn’t fill in the correct info or a correct search for the implant cannot be performed. Also for certain implants different scan settings need to be applied compared to the standard settings which also induces extra lost time.

3.2.2 Future optimized protocol

In the future optimized protocol for scanning patients with implants the following steps are taken. (See also fig 3 future flowchart)

1) When a scan for a patient is requested by the referring physician this physician needs to fill in several implant questions. (See fig 4)
2) If a question about the implants was checked with a yes by the referring physician, conditionality will be checked for the implant by an MR physicist before the patient can be planned in a time slot on the scanners.
3) After this check the result will dictate the actions to be taken.
    a. When the implant is unsafe no scan is possible and this will be communicated to the patient and the referring physician, a possible alternative will be looked for CT, echo,….
    b. If the implant is safe the scan can be planned and performed without any additional preparation.
    c. If the implant is MR conditional several different preparations have to be performed in order to safely scan the patient. All these preparations can be performed before the patient is in the hospital for the scan resulting in no loss of precious system time. Also the patient can be planned directly on the correct system dictated by the safety instructions of the implant. Specialists (Cardiologists/ Neurosurgeons) can be contacted beforehand for switching off/on the system before and after the scan and for monitoring the patient during the scan
4) If all these conditions are met the patient can be planned on the correct timeslot
5) For certain implants different scan settings need to be applied compared to the standard settings, these can be set in the system beforehand or automatically be selected by the system if a database is available in the system for the different implants.
6) On the day of the scan the patients still has to fill in a patient questionnaire about implants as possibly (in rare cases) things could have changed in the time between planning and the actual scan
7) The technologist checks the form and also asks several safety questions about implants as a double check

By following this step by step algorithm, there is generally no loss in time while scanning patients with implants compared to patients without implants. The triple checking also increases the safety of the entire process.

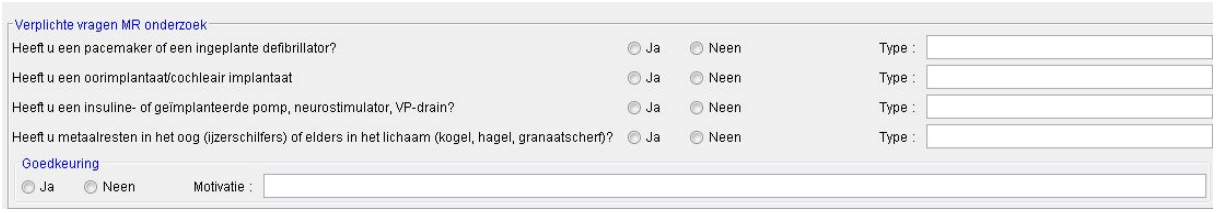

Figure 6 Safety questions (in Dutch) for referring physician during request for scan

3.2.3 Acoustic patient observation

Introduction

As part of optimizing hospital workflow an acoustic observation system will be developed which on one hand can be used for detecting a calamity with the patient and on the hand for tracking operators throughout

the room. The latter will help to optimize clinical routine and can also be used as basis for a dosimetry system which is currently under discussion by regulatory bodies.

In recognizing specific sounds, the environment where to recognise the sounds is very important. The more noise is present, the more difficult it will be to recognise anything at all. An MRI scanner is typically a device that is very challenging to operate with as it generates a lot of sound. This sound is so loud that normally a patient cannot be heard.

With the use of a microphone array system, it should be possible to detect the sounds of the patient although the surrounding noise is extremely high. This can generally be done using three methods: using specific directions of sound, specific frequency (ranges) and by using self-learning classification algorithms.

This way, it should be possible to analyse the sounds from the patient and furthermore, recognise if the patient stays calm or if the patient is starting to panic or lose patience. In case of panic or loss of patience, it should then be possible to send a trigger to the nearest operator (nurse or doctor). The operator can then react by speaking to the patient and going to live audio from the patient talking back.

Flow diagram

The flow diagram is given in the Figure 8. It starts with a person entering the MRI scanner. Using the microphone array with a specific 'beam' (listening direction) of the sound camera and when triggered do a classification of the sound. The beamformed data will be analysed and feedback will be given. From this feedback we will be able to give a trigger. This is used for the operator to act.

Steps planned to be able to support the flow diagram

In order to get to this result, the system needs to be tested, trained and validated. First of all, the data should be gathered by the microphone array system. The data should be annotated to make sure it is clear what data is present.

Microphone array

Before the system is operational, multiple tests will be done. For the microphone array, there is a continuous process of improvement, starting by measuring both the source and the background noise, as indicated in Figure 7. The goal is to find the right frequency range of interest which distinguishes between the speaking person and the background noise.

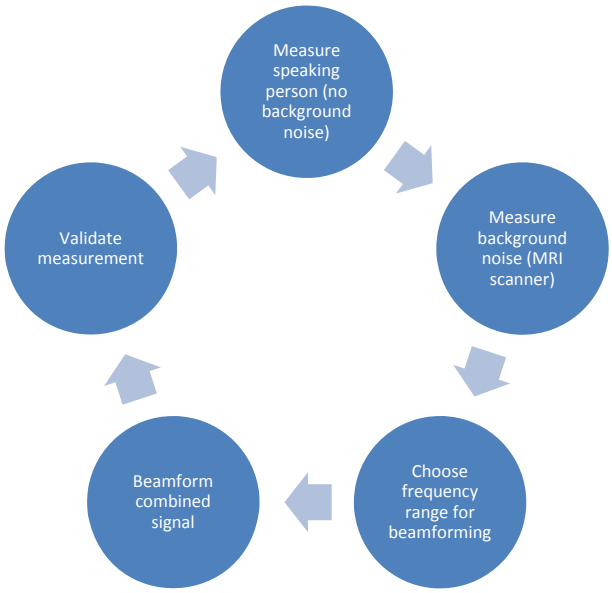

Figure 7 Continuous adjustment of microphone frequency range

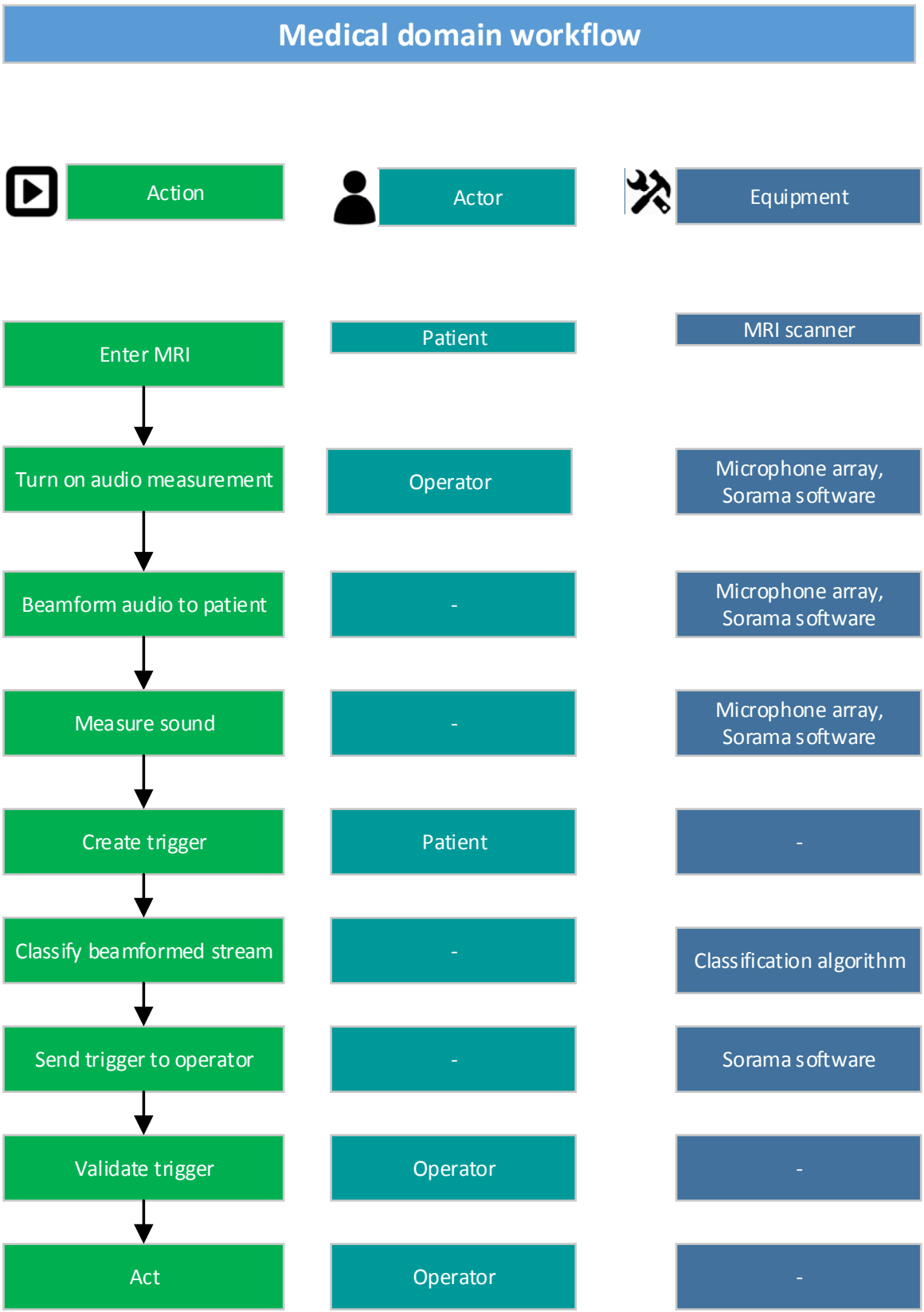

Figure 8 Flow diagram for acoustic patient observation

Classification algorithm

From that point on algorithms should be developed and trained to see if the differences in the patient situation on the base of sounds can be detected (see Figure 9).

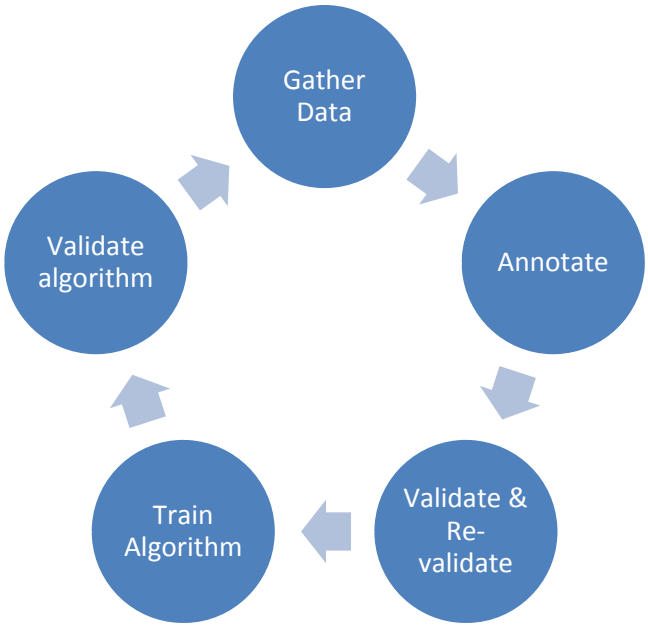

Figure 9 Development and training of smart sound recognition algorithms

Acting by the operator

After this process the algorithms should be made compatible to work on the microphone array system and in the case of an event be able to trigger an alarm. The alarm should possibly be going to the nearest Operator so the Operator can check and intervene appropriately.

The alarm should be made visible in an easy way. This means the operator can monitor the patient real-time looking at a monitor and seeing its status:

Patient making noise and classification of the noise of the patient (calm, losing patience, panicking).

4. Space

The space application concerns a future radio telescope system that will be maintained and operated according to the practises of present day radio telescopes. A good example of a present day radio telescope workflow is provided by ASTRON-Operations, the ASTRON department that handles the operation of the WSRT (Westerbork Synthesis Radio Telescope) and LOFAR (Low Frequency Array) radio telescopes.

The observations that are performed by both telescopes and the accompanying signal processing by the computer systems of both telescopes, are based on proposals from the global astronomy community. After sending a proposal to the observer portal, it is assessed by the radio observatory.

After acceptance and ranking of the proposal, the proposed observation is evaluated by the Science, Operations and Support (SOS) team who retrieves the telescope settings and configuration from the proposal. These settings and configuration items concern e.g. which set of the telescope antennas will be involved in the observation, the integration time, the settings of the beamformer system and the observation frequency band.

After configuring the telescope system according to the required settings the observation is scheduled and performed based on the ranking of the proposal. During this observation the hardware and software of the telescope will receive, transport and process the signals according to the settings that were provided in the proposal. The signal reception, transfer and processing is done in real time.

If the data products that result from the real time system need additional processing, the data are transferred to a temporary data storage system, where they wait for further offline processing. Once both the real time and the offline processing is performed, inspection plots are sent to the astronomer for verifying the quality of the data. If the data quality is sufficient, the data sets are transferred to an archive system. From there the data sets can be transferred to the local computer system of the involved astronomer via the Internet.

For further processing of the data by the astronomer, a library of software tools is available for the astronomer. These tools have been developed by ASTRON software engineers.

Both the hardware and software of radio telescope systems are continuously improved during the telescope lifetime. Small hardware upgrades and repairs are implemented every month during a “stop-day”. Large hardware upgrades take place approximately every 10 years.

Apart from the regular software maintenance, the software of both the real time and offline signal processing systems is frequently improved with software upgrades that focus on improved and more efficient observations.

5. Smart City

For the Smart City use case, a similar workflow can be used as for the MRI-scanner case, compare Figure 10 with Figure 8. Generally, an actor enters the area of interest, sets of a triggers and the operator is notified by the system. Both system do acoustic monitoring in harsh environments, but this time the environment is a Smart City area.

Training and improving the system is done in a similar way as for the MRI-scanner use case. Measurements are done with and without background noise and data is gathered for the classification algorithm. Now the difference is that the placement of the microphones and acoustic environment (including background noise) is different. For the classification algorithm, the acoustic triggers to be trained by the system are different. It now concerns aggressive voices, car alarms, breaking glass and gunshots.

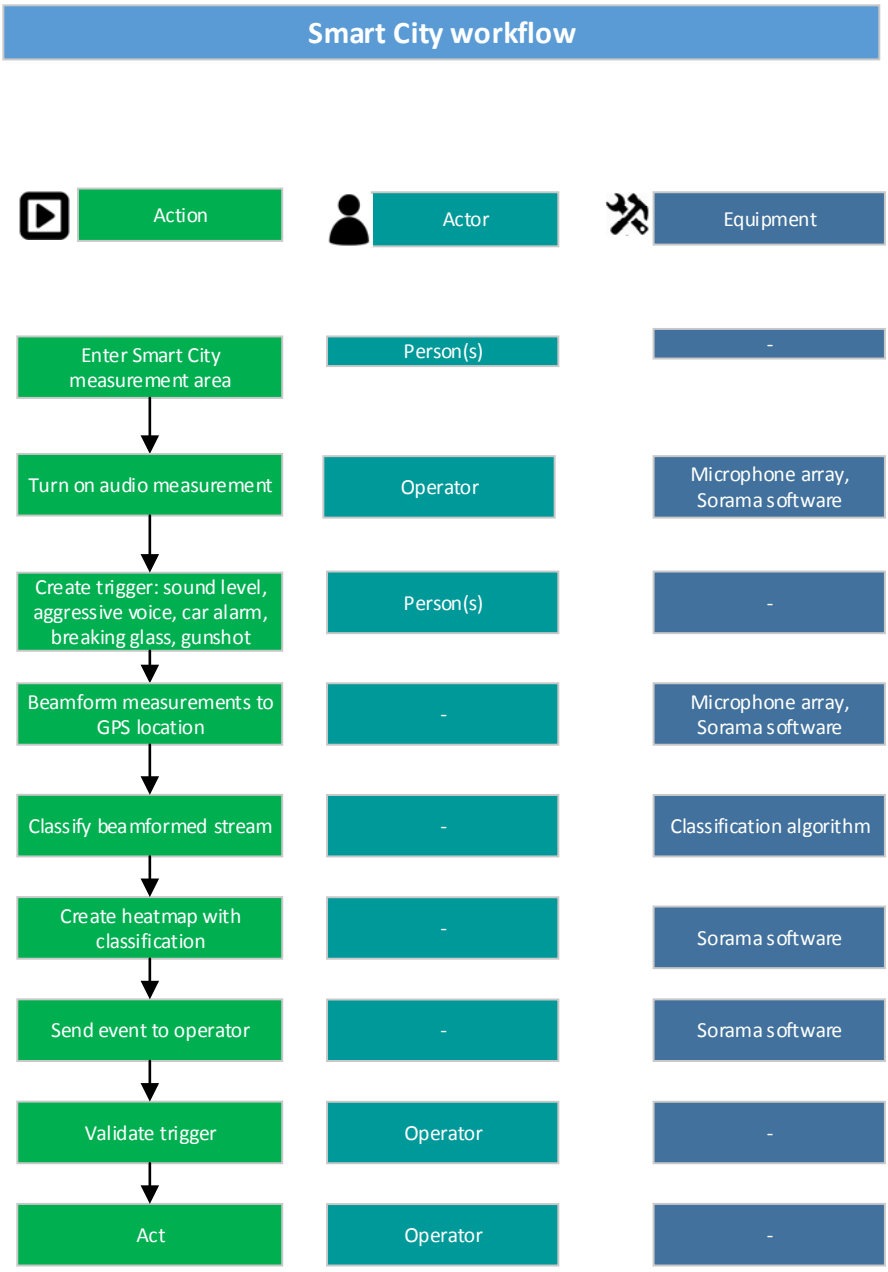

Figure 10 Flow diagram for acoustic city observation

6. Conclusions

Use cases have been described from which the DISPERSE reference architecture can be derived including relevant use case specifications.

7. References

[1] Vlaardingerbroek, M.T., den Boer, J.A.m Magnetic Resonance Imaging, Springer-Verlag, Heidelberg, 1999
[2] DeNeCoR Deliverable 3.6, Guidance for evaluating RF and Gradient Coil Concepts for MR Conditional Safety
[3] Ferreira AM et al., “MRI-conditional pacemakers: current perspectives” Medical Devices: Evidence and Research (2014) 7:115–124.

8. Appendices

8.1 Patient questionnaire

27 juni 2016

UZ LEUVEN | RADIOLOGIE

Patient questionnaire for MR examination

Your physician has requested an MR examination. For this procedure you will be exposed to a strong magnetic field.

In this regard and for your own safety we ask that you complete this questionnaire as correctly and completely as possible in order to trace any possible contraindicaton prior to the examination.

Please bring this form with you and give it to the person in charge of the examination. If this document is not properly filled out, the examination cannot take place for your own safety.

1. Do you have a pacemaker? Yes ☐ No ☐
2. Do you have an implanted defibrillator? Yes ☐ No ☐
3. Do you have an ear implant / a cochlear implant? Yes ☐ No ☐
4. Do you have an insulin or implanted pump, a neurostimulator or VP shunt? Yes ☐ No ☐
5. Do you have any metallic object in your eyes (metallic fragments)? Yes ☐ No ☐

IF YOUR ANSWER IS 'YES' TO AT LEAST ONE OF THE ABOVE MENTIONED QUESTIONS, PLEASE CONTACT THE DEPARTMENT OF RADIOLOGY AS QUICKLY AS POSSIBLE ON THE NUMBER 016/34 14 80 DURING OFFICE HOURS OR 016/34 05 22 AFTER OFFICE HOURS.

(For the following questions above remark does not apply:)

6. Do you have a hearing aid? Yes ☐ No ☐
7. Do you have an artificial valva? Yes ☐ No ☐
8. Do you have a joint replacement, dental prosthesis or dentures? Yes ☐ No ☐
9. Do you have a port catheter? Yes ☐ No ☐
10. Have you ever had brain surgery? Yes ☐ No ☐
11. Have you ever had a bloodvessel operation / bloodvessel catheter? Yes ☐ No ☐
12. Have you had an organ transplant? Yes ☐ No ☐
13. Do you have any medication or other patches on your body? Yes ☐ No ☐
14. Do you have a tattoo, (permanent) eyemake-up or piercing? Yes ☐ No ☐
15. Do you wear a wig/hair extensions or spray hairpaint on bold spots? Yes ☐ No ☐
16. Do you have metallic objects in your body (shotgun pellets, bullet, implant, pin, plate, orthodontics)? Yes ☐ No ☐

Please also read, complete and sign the back side/second page

Pagina 1 van 2