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D 6.5 - Modelled and Model-based Analysis of the Health AdCoS and HF-RTP Requirements Definition Feedback

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1. Glossary

7T
Seven Tesla (magnetic field strength).

C-arm
A C-shaped rotating arm carrying equipment needed to create images of the patient from different angles.

DICOM
Digital Imaging and Communications in Medicine, a standard for the storage and exchange of medical imaging.

ECG
Electrocardiogram.

EHR
Electronic Hospital Record.

EM
Electromagnetic.

Dependent variable
A variable that is being measured in an experiment, as opposed to the independent variable (see below) that represents the independent input to the process under investigation.

Independent variable
An independent input to an experiment, i.e., a variable fully under the experimenter's control.

MR
Magnetic resonance.

MRI
Magnetic resonance imaging.

PACS
Picture archiving and communication system.

PHR
Patient hospital record.

RF
Radio frequency.

TSO
Table side operated.

TSM
Table side mounted.

UI
User interface.

VCG
Vector electrocardiogram.

WADO
Web Access to DICOM Objects.

ZMT
Zürich MedTech AG.

2. Introduction

This document contains the results of the modelling effort for the AdCoS being developed in WP6, the health application domain.

2.1. Objective of the document

The objective of this document is to provide a report on the current state of the modelling effort, with definitions of the operator role, the environment of the AdCoS and the functionality of the AdCoS itself, in a format that is shared across other application domains to enhance the potential for sharing of methods and general experience.

The intention is to increase the insight into the AdCoS, the workflow around it and the tasks of the operator in such a way as to allow the development of the AdCoS to a higher standard of human-machine interaction than what would have been possible without the modelling contained in the present document.

2.2. Relation to the work done in other domains in HoliDes

The notion of an AdCoS is defined in the common annex, but each application domain has different specific needs for the functionality of the AdCoS, leading to different needs regarding the modelling of the AdCoS.

Several AdCoS modelled in this document address the problem of supporting an operator in organising the workflow (and performing it correctly) for a specific procedure (e.g., lab tests, positioning of a patient for an MRI exam or positioning ECG sensors correctly), which is not a problem that is directly addressed in other domains.

Similarly, two development use cases are concerned with designing a user interface to ensure that the staff can use the advanced features of modern equipment correctly and safely (the 3D acquisition and Safe parallel transmit scan cases).

Lastly, two development use cases deal with improving the design of AdCoS to access and use clinical data or imaging data over web connections.

These healthcare-related problem fields do not have any direct parallels in the AdCoS development use cases of the other application domains, but a common trait shared across most AdCoS in WP6 and many AdCoS in other domains is the use of task analysis and modelling in some form to create a more formalised insight into the design problems.

Many of the task analysis methods employed originate from other domains and are used in other application work packages in HoliDes as well. There is therefore a direct, if implicit, exchange of tools, methods and experience between the application domains through this informal channel.

3. AdCoS modelling

In this section, the modelling of each AdCoS is discussed.

The AdCoS cover a very broad range of situations in a hospital, ranging from the workflow of a laboratory to the operator having to identify the correct, specific settings of an MRI scanner.

Therefore, the discussion will follow a common format, but there will also be deviations from this format when the specific aspects of the AdCoS warrant a slightly different presentation.

The descriptions are focused on the needs of the operator, and begin by describing what the AdCoS does for the user to help them perform their task satisfactorily, for instance:

- Which user goals does it help to achieve?
- What types of input and output does it handle?

The term "user goal" means a goal that the operator tries to (or should try to) achieve when performing the task.

The aim of the AdCoS is to help the operator achieve this goal, based on input from its environment and by providing output to the operator and, depending on the nature of the AdCoS, the controlled entity.

The environment
Another important aspect to delineate in order to define a model of an AdCoS is the environment in which the AdCoS will be operated. For the

purpose of this document, the environment is seen as the various entities that provide input to and receive output from the AdCoS, such as:

1) The controlled entity
The AdCoS can be seen as a system that helps the operator control an external process or system, called the controlled entity. This view fits very well in cases where the AdCoS has a role of a control system, but can also be useful for AdCoS with broader roles, or roles better described as supporting of the operator.

A definition of the controlled entity provides a useful background to understand the model of the AdCoS, and most AdCoS models in this work package include a definition of the controlled entity.

In the case of an AdCoS with a broader role, the notion of the controlled entity is also broadened, to reflect this view on the system.

2) The operator of the AdCoS
The same way as it is important to define the controlled entity, it is also important to define the role of the operator(s) and their relationship with the AdCoS. To this end, most AdCoS models in the following contain an explicit definition of the operator role. Since a few of the AdCoS discussed in this document use standard software design practices, the operator is also at times referred to as a "user", especially when the role is comparable to a normal user role in interactive software development.

3) External environment
What is outside of the operator(s) and controlled entity makes up the external environment.

Relevant elements of the external environment are for instance which disturbing events it provides on the controlled entity, the operator and their working environment.

Whether this is relevant for a given AdCoS depends on the situation in which it is applied, and the definition of the external environment varies accordingly across different AdCoS.

4) Communication between AdCoS and environment
Since all the AdCoS discussed in this document employ some form of interaction with the environment (be it the operator, the controlled entity or something external), the nature of this information exchange – or

communication – is important for the creation of useful models and the understanding of them.

The AdCoS models discussed in this document include a description of this communication at some level of detail.

Modelling techniques employed
This subsection will discuss which modelling techniques have been chosen to model the AdCoS – and its environment, if included in the modelling.

The focus is on the modelling techniques, but in some cases these are so closely connected with an associated tool that the tool will be included in the discussion.

In the following, the modelling of each AdCoS is discussed.

3.1. Guided patient positioning

3.1.1. Description of the AdCoS

The AdCoS is the system that provides guidance to the operators during preparing and positioning patient for MRI examinations.

Correct positioning of the patient for the MRI examination and using the right coils and other devices is important to get good diagnostic quality images, but also important to avoid safety issues. Currently, operators are trained for this. The on-line guidance system intends to improve usability and to reduce risks, also in case of novice, less experienced users.

Most operators position the patient on their experience, however the operator still makes mistakes in positioning the patient correctly. This will be noted during the survey scan but will still result in a loss of time, because the patient has to be repositioned again and a new survey scan has to be taken in order to proceed.

Research (previously conducted research, internal Philips Healthcare) has shown that some operators are not confident when selecting the coil and had problems in positioning it. This problem is to a large degree dependent on the training level of the staff, which again depends on regional regulations and procedures of the organization employing the equipment.

However, it is important that all operators are able to perform an MRI exam properly to safeguard the patient safety.

As hospitals are under a lot of time pressure during the day and want to help as many patients as possible, they do not have the margin for errors. Philips Healthcare wants to improve the usability of the MRI, to increase the efficiency and reduce the amount of errors during a MRI scan.

A series of observations (performed as internal research by Philips), at hospitals in the Netherlands were carried out, and it became clear that the operators already clearly know what coils they need to select and how to position them and the patients, from their experience. However the operators could still benefit from a small memory support on the following things.

- Earplugs
- Patients weight question, as it most of the time being guessed
- Exam card, to help explain to the patient what is going to happen. When is the contrast liquid injected, does it require breath holding etc.
- Coil connection status

To support the operator, a display could be added to the gantry of the MRI-system. The gantry display should give the user a dedicated guide in positioning the patient, and selecting and positioning the coil.

The gantry display will be developed by first doing a paper prototyping test. Creating a basic wireframe that should indicate which widgets are required to meet the operator needs (requirements), and in what order the operator wants to walk-through the dedicated guide on the gantry display. This also creates a flowchart of how the user operates the MRI.

3.1.1.1. Operational definition

It is important that the patient and the coil are positioned correctly during an MRI exam, for a high quality image from the MRI and to ensure the safety from the patient. Currently most operators position the patient based on their experience, however the operator still makes mistakes in positioning the patient correctly. This could create a hazardous environment and/or a loss of time.

In the countries with lower required education to be an operator, the users were not confident in selecting a coil and had problems positioning them.

The AdCoS should support the operator by guiding them in positioning the patient and coils. In this way, the amount of errors that occur during the patient positioning will be reduced.

The aim is that less experienced users are supported by the AdCoS by providing a clear guideline, while for experienced operators the AdCoS can function more as a checklist.

3.1.1.2. The environment of the AdCoS

The Guided patient positioning AdCoS interacts with its controlled entity, the operator and the external environment as outlined in the following.

Controlled entity

The controlled entity in the case of the Guided patient positioning AdCoS is an MRI scanning scene – the scanner and the patient. In this view, the scanner and the patient are equally important in the creation of the necessary imaging.

The aim is to create a situation (a state) which is functional to capture the right image and safe and comfortable for the patient.

In this architecture, the operator works to manage the scene and the AdCoS follows this work, giving advice along the way.

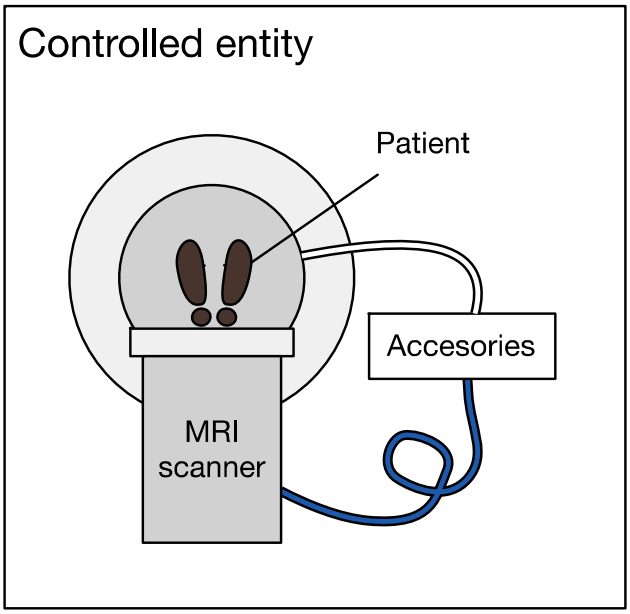


Figure 1 The elements making up the controlled entity of the Guided patient positioning AdCoS

Operator of the AdCoS

The user is the MRI operator, he wants to be sure that the examination he selects and performs for a patient is the examination that radiologist ordered. The operator has to be confident that the image quality for the radiologist is up to standards, within the time available and with high patient comfort. The operator often works together with another operator; one positions the patient while the other is in the control room. The operator that positions the patient is operator of the AdCoS. Here the operator is responsible that the patient and coil are positioned correctly and the patient is comfortable.

External environment

The most important element of the external environment is the control system of the scanner, which is coincidentally an AdCoS itself. On this control system the operator imports the *patient data* from the central information management system and enters additional data that are specific for the MRI examination. The operator also selects the examination (the so-called **ExamCard**) from the ExamCard database, based on the clinical request. The ExamCard specifies the series of scans and patient positioning details, for instance:

- Head-first or feet-first

- Supine or prone (on the back or belly)
- Required physiology sensors (to detect heart-rate, respiratory cycle)
- Required MRI coils to receive the MRI signals, etc.

The external environment provides the information that makes up the external context of the scanning and the starting point of the guidance for the positioning procedure.

Communication between AdCoS and environment
The communication (data exchange, interactions, etc.) between the environment and the scanner is listed in Table 1.

Data item	Data format	Comment
Patient Name	Free text	Imported patient data at the control system
Patient Birthdate	Date	Imported patient data at the control system
Patient Weight	Number	Comes with patient data or is weighted or guessed by operator
Patient Positioning	Position encoding	Extracted from the selected ExamCard at the control system
Exam (name)	Text	Exam ordered by radiologist
Exam duration	Time	Extracted from the selected ExamCard at the control system control system
Earplugs		Operator training
Headset		Operator training
Nurse call balloon		Operator training
Contrast liquid (connecting to the cannula)	Icon	Extracted from the selected ExamCard at the control system
Contrast liquid (already injected during patient preparation)		Operator training
SAR Indication (induced heat in the patient per scan)	Number	Extracted from the selected ExamCard at the control system
SED Indication (induced heat in the patient for the complete examination)	Number	Extracted from the selected ExamCard at the control system

Data item	Data format	Comment
Breath holding	Icon	Extracted from the selected ExamCard at the control system
Respiratory gating required	Icon	Extracted from the selected ExamCard at the control system
Respiratory sensor connection status	Graph	On AdCoS display
Respiratory sensor signal status	Graph	On AdCoS display
Respiratory sensor low battery indication	Icon	On AdCoS display
Respiratory sensor positioning		Operator training
Cardiac synchronization with VCG	Icon	Extracted from the selected ExamCard at the control system
VCG connection status	Graph	On AdCoS display
VCG signal status	Graph	On AdCoS display
VCG low battery indication	Icon	On AdCoS display
VCG positioning		Operator training/Additional guidance on AdCoS display
Coil selection (head/body/etc.)	Text	Extracted from the selected ExamCard at the control system
Coil connection status	Icon/graphics	On AdCoS display
Coil positioning		Operator training/On AdCoS display
Medicine infusion pump		Additional patient information, observed by operator

Table 1 Data exchanged between environment and Guided patient positioning AdCoS

3.1.1.3. Modelling techniques employed

Two modelling methods are being employed to describe the Guided patient positioning AdCoS with two complementary areas of focus.

The first area covers workflow, seen mainly as a sequential series of actions and is modelled as a flowchart of actions, based on observations of hospital staff using MRI scanners without a Guided patient positioning AdCoS.

The second focuses on modelling the means-end relations in the workflow and the equipment and uses the means-end modelling method developed in WP5 to identify goals for the use case and functions and means available in AdCoS and environment.

The workflow analysis provides a non-hierarchical task model with a focus on sequencing and branching in case of optional actions or configurations of the scanner. This provides a basis for the memory support that the AdCoS should provide for the operator in cases where a specific step of the procedure has been omitted.

The means-end model identifies functions, with a description that is independent on the architecture or procedure design used to ensure that the functionality is provided. The independence of the functional layer in the model allows for flexible assignment of tasks and dynamic re-sequencing of tasks based on the goal structure and not a pre-determined action sequence.

This flexibility encapsulated in the means-end model can also be used to identify areas where the AdCoS can adapt the guidance in response to disturbances or deviations in the execution of the positioning procedure.

3.1.1.4. Input to the modelling process from other work packages

The means-end analysis method is developed in WP5 and provides the input to the modelling process.

The workflow analysis is based on standard techniques in the field and is not developed in any specific work package of HoliDes.

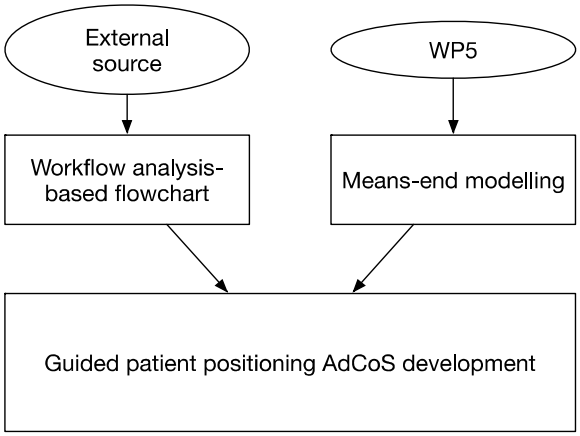


Figure 2 Flow of modelling MTTs related to Guided patient positioning

The Means-end modelling method is described in more detail in deliverable 5.4.

3.1.2. The model

The Guided patient positioning AdCoS is modelled in two different ways, one describing the typical workflow as determined by observations of hospital staff, and the other as a means-ends model of the workflow as defined originally for hazard analysis purposes.

The workflow analysis can be classified as a descriptive model/analysis, while the means-ends model is normative.

3.1.2.1. The workflow analysis

The flowchart (see figure 4 – Operator workflow part A to and inclusive figure 9 – Operator workflow part F) is based on the observations of the MRI operators in the Dutch hospitals (previously mentioned internal research by Philips). The operators worked in pairs, they will be referred to as operator A and operator B. Operator A, mainly focuses on the actions in the control room, where operator B focuses on the tasks in the MRI room. After each patient the operators swap from roles, so operator A becomes operator B and operator B becomes operator A. The operators have to move between five different locations these are:

- Patient waiting area, here the patients wait till they get picked up.
- Changing room, here the patient can change his/her cloths

- Preparation area, this area connects the examination-, control- and changing room. Here the cannula will be placed or other preparations will be done when required. With curtains the patient can be separated from the rest for privacy concerns.
- Control room, where the consoles are
- MRI room, here is the MRI located.

See Figure 3, for the location of the different areas. All the locations have been marked with a colour; the steps in the flowchart have been marked with these colours to indicate their location.

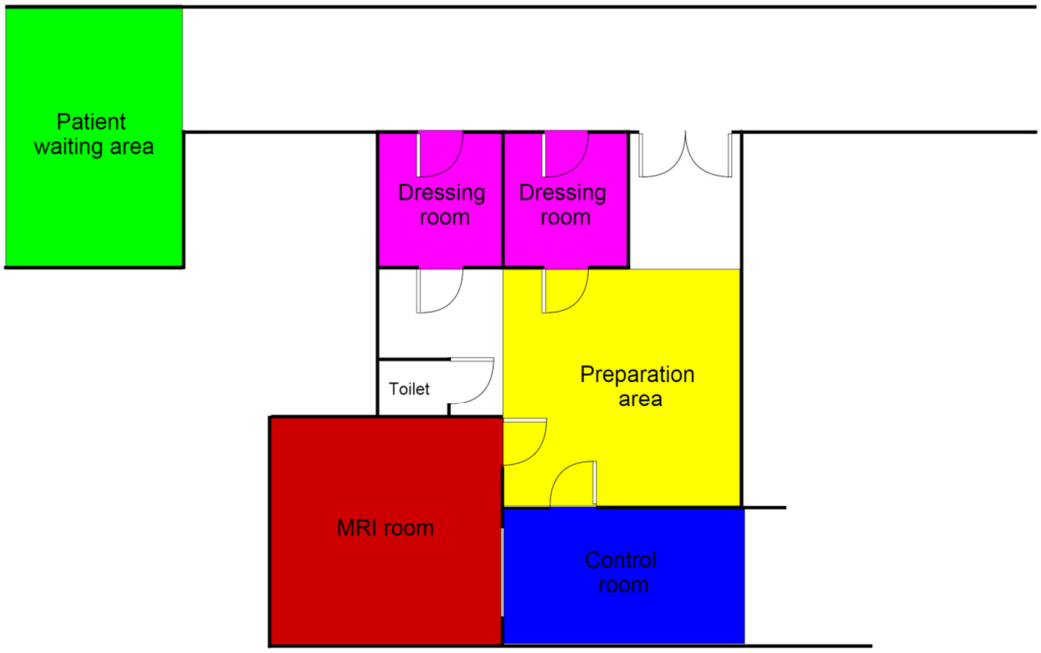


Figure 3 Map of MRI scanner room and adjacent locations

All the steps are described and numbered, for further detail. Where some steps also have been redone, in a more detailed flowchart. For readability, the flowchart is broken up and shown from Figure 4 to Figure 9 below. The complete flowchart is available as Annex III to this document.

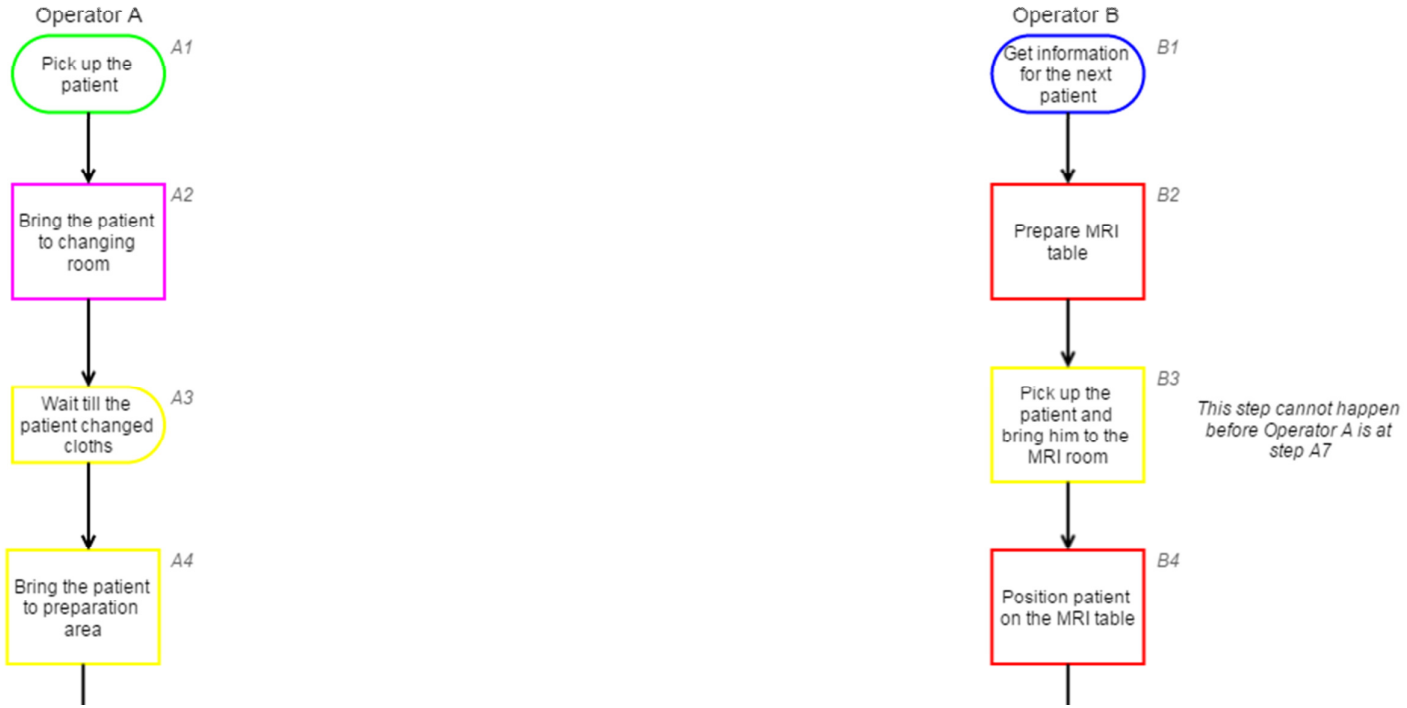


Figure 4 Operator workflow part A

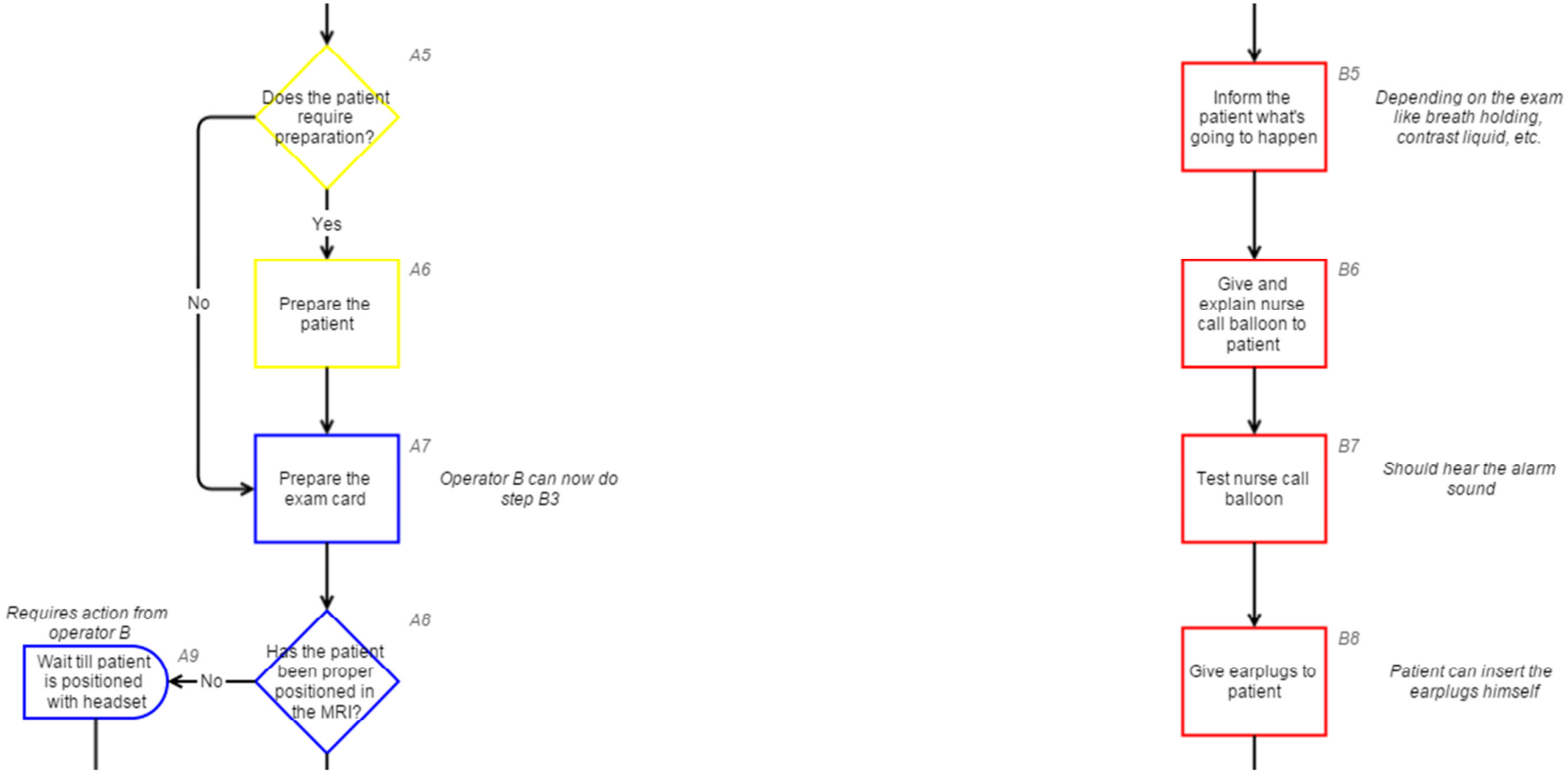


Figure 5 Operator workflow part B

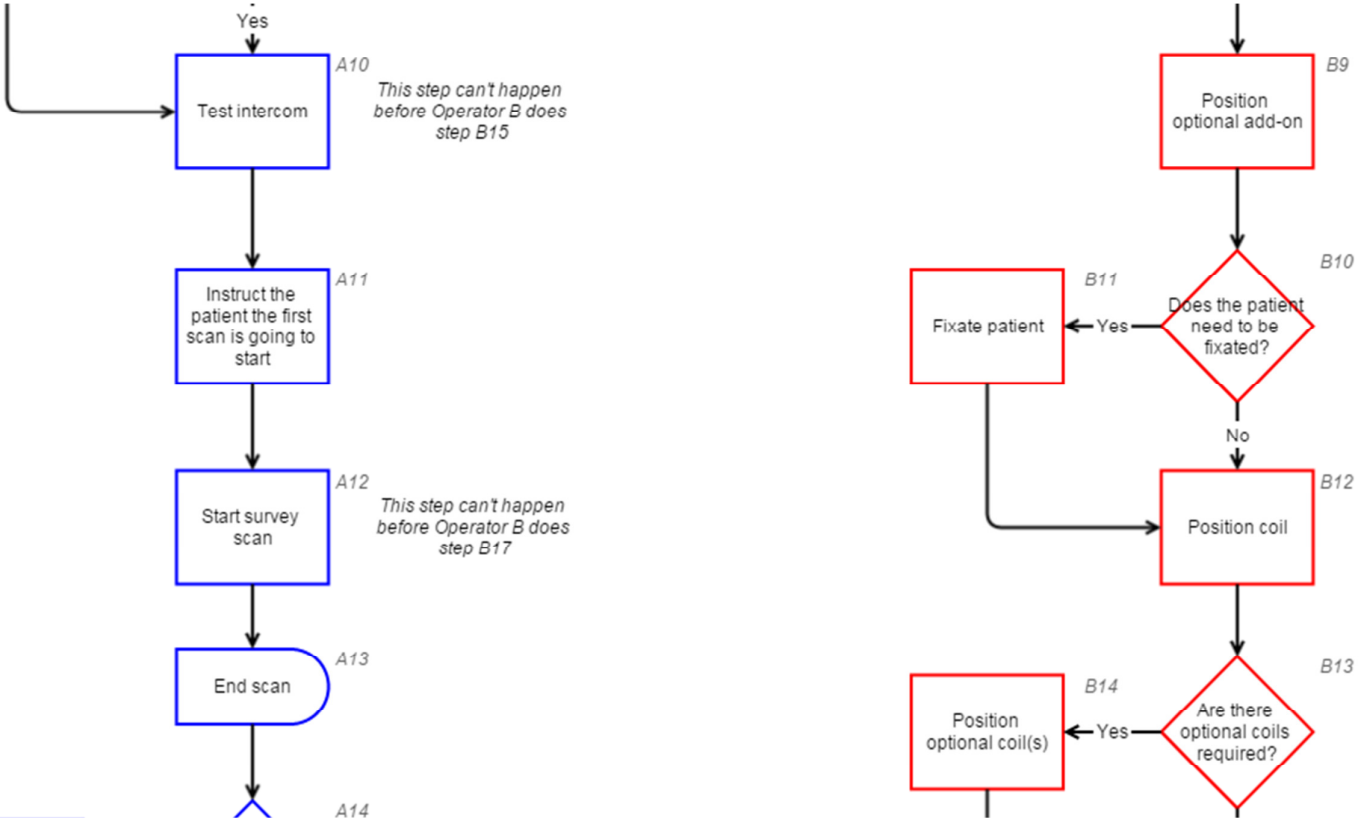


Figure 6 Operator workflow part C

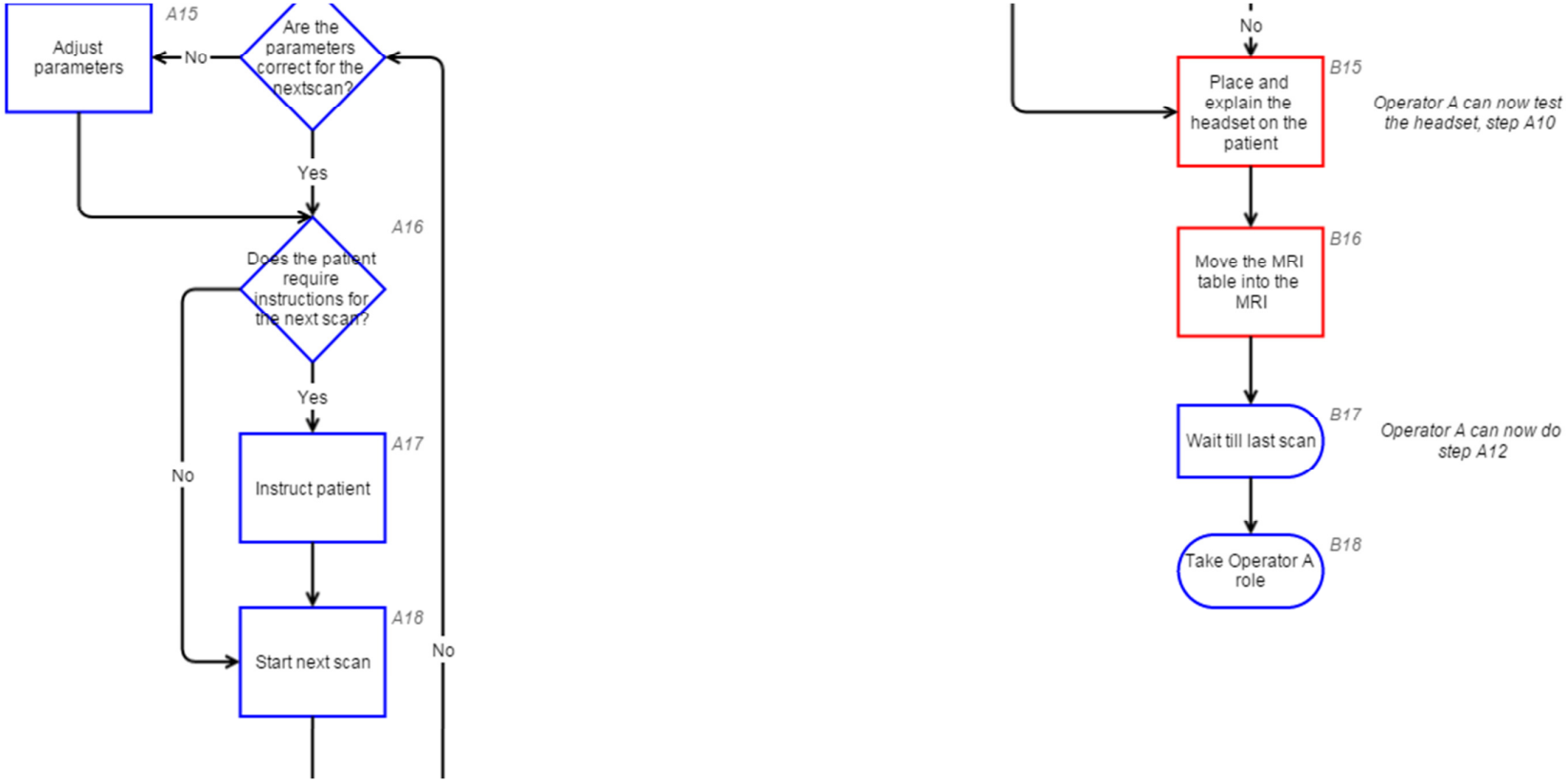


Figure 7 Operator workflow part D

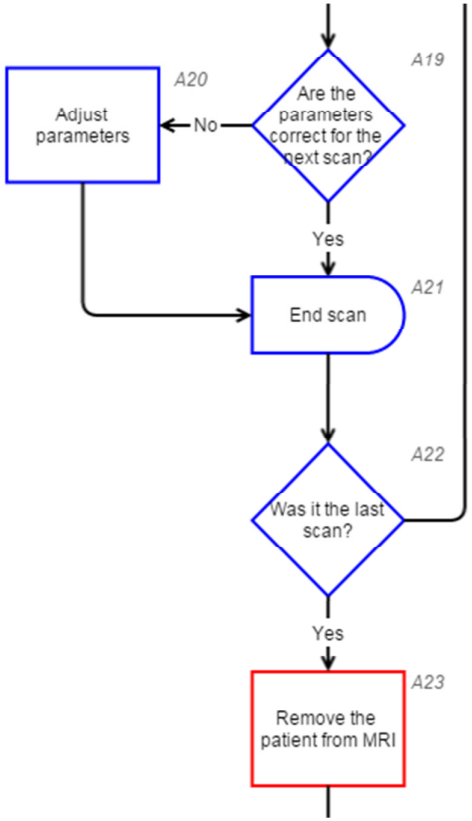


Figure 8 Operator workflow part E

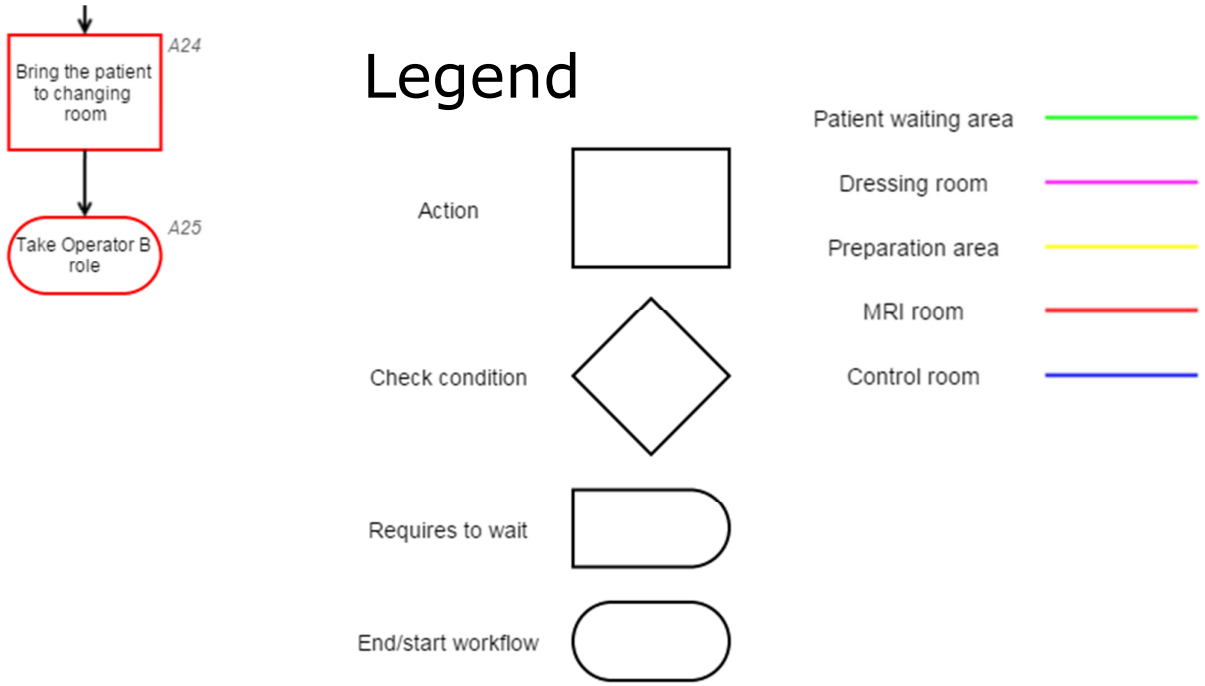


Figure 9 Operator workflow part F

A1 – Pick up the patient:
Operators A gets the next patient from the waiting area, here the operator also confirms the patient's identity.

A2 – Bring the patient to the changing room
Operator A guides the patient from the waiting area to the changing room.

A3 – Wait till the patient changed cloths
In most hospitals the patient is required to change cloths to reduce metal and avoid artefacts in the image. While the patient is changing the operator A goes to the preparation area.

A4 – Bring the patient to the preparation area
When the patient signals that he is ready the patient will be brought to the preparation area.

A5 – Does the patient require preparation? & A6 – Prepare the patient
Depending on the exam the patient sometimes needs a cannula, contrast liquid, VCG patches on his chest, etc. These preparations happen here.

A7 – Prepare the exam
After step A5 (and A6) the patient will be left in the patient in the preparation area to wait. While operator A proceeds to the control room, where the operator starts preparing the exam card. Operators A selects the exam that has been requested by the radiologist.

A8 – Has the patient been proper positioned in the MRI? & A9 – Wait till the patient is positioned with the headset
Check if the patient has been positioned on the MRI by operator B, and if the patient is ready to talk

A10 – Test intercom
Test the sounds for the intercom, to make sure the patient can hear the operator and the operator the patient.

A11 – Instruct the patient the first scan is going to start
Operator A explains the patient the first scan is about to start and that the patient has to lay still.

A12 – Start survey scan
Operator A stars the survey scan from the exam card

A13 – End scan
Operator A waits till the survey scan is finished, if the resulting image is good enough for a diagnosis the operator can proceed to the next step. If the image isn't good enough for a diagnosis the survey scan has to be redone. See Figure 10. Where operator A first has to identify the problem.

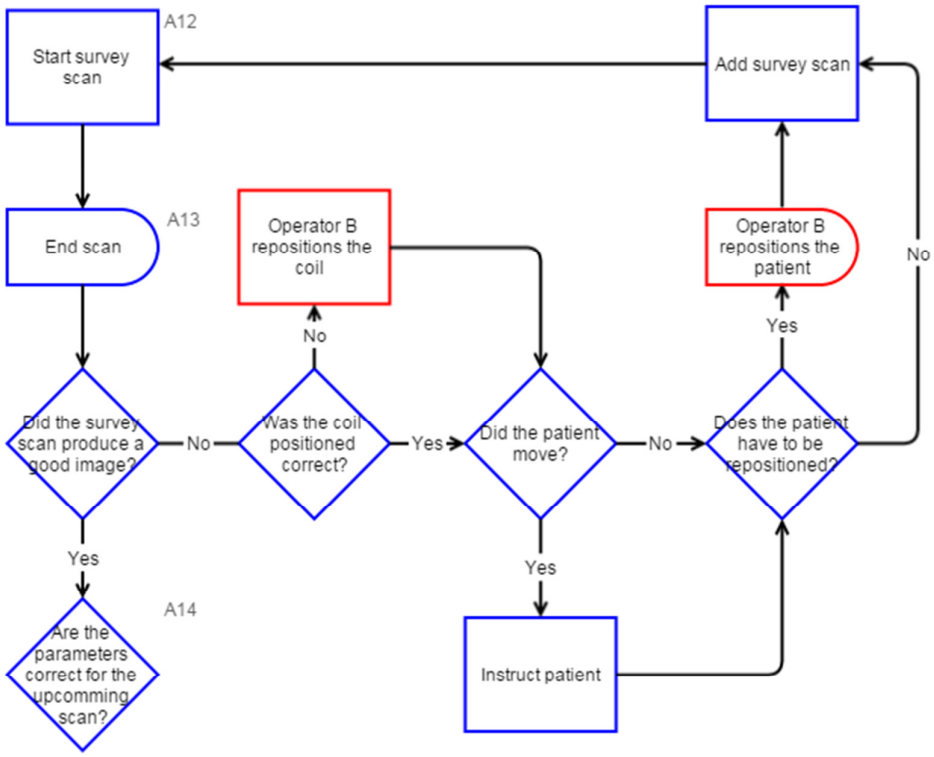


Figure 10 Survey scan

A14 – Are the parameters correct for the next scan? & A15 – Adjust parameters
Depending on the scan and the operator or radiologist preference, the operator want to adjust some parameters get a better image for the diagnosis.

A16 – Does the patient require instructions for the next scan? & A17 – Instruct patient
Depending on the scan, the patient has to hold his breath, will be injected with the contrast liquid, a scan will start with a high SAR or something else special. Operator A has to inform the patient on what's going to happen next and what the patient can expect or has to do.

A18 – Start next scan
Operator A tells the patient the next scan is to start and starts the next scan (starting of the next scan goes automatically however the operator can start and stop them manual).

A19 – Are the parameters correct for the next scan? & A20 – Adjust parameters
During the scan that is running some changes can be made for the next scan, see A14 & A15.

A21 – End scan
Operator A waits till the scan is finished, if the resulting image is good enough for a diagnosis the operator can proceed to the next step. If the image isn't good enough for a diagnosis the scan has to be redone. Assuming operator A doesn't make a mistake in the parameters, the patient has moved during the scan if the image quality isn't good enough. Were operator A has to add the last scan to be redone and goes back to step A14.

A22 – Was it the last scan?
When it wasn't the last scan, operator A goes back to step A14, and keeps looping these steps until all the scans are done. If it was the last scan operator A will tell the patient they are finished and will get him out of the MRI.

A23 – Remove the patient from the MRI
Operator A goes to the exam room and removes the patient from the MRI, here the operator will also remove any attachments on the patient like a cannula or VCG patches.

A24 – Bring the patient to the changing room
Operator A escorts the patient to the changing room, where the patient will be told he can change back to his own cloths and can leave through the other door, and the radiologist will contact him with results.

A25 – Take operator B role
Operator A switches from role with operator B, and they start all over again.

B1 – Get information for the next patient
Operator B has to get information for the next exam that will occur, from the exam card in the control room. Where the following information has to be gained:

- What will be scanned
- What is the required coil
- Does the patient have to hold his breath any moment during the exam
- Will the patient get any contrast liquid, already injected or will it be done later during the scan
- How will the patient be positioned

B2 – Prepare the MRI table
Operator B is in the MRI room, here he has to prepare the MRI table first. Where he has to get correct coil and prepare the MRI table accordingly if the patient goes head or feet in first, see figure 3 – MRI table preparation.

B3 – Pick up the patient and bring him to the MRI room
Operator B gets the prepared patient from the preparation area, and escorts the patient to the MRI room.

B4 – Position the patient on the MRI table.
Operator B positions the patient on the MRI table, here the operator makes sure the patient is lying comfortable.

B5 – Inform the patient what's going to happen
Depending on the exam, operator B tells the patient what to expect and what the patient has to do during the exam. This can vary between, explaining the patient he has to hold his breath during scans, how to position his hands or he could get a cold feeling when the contrast liquid is injected. This step occurs while performing the next steps.

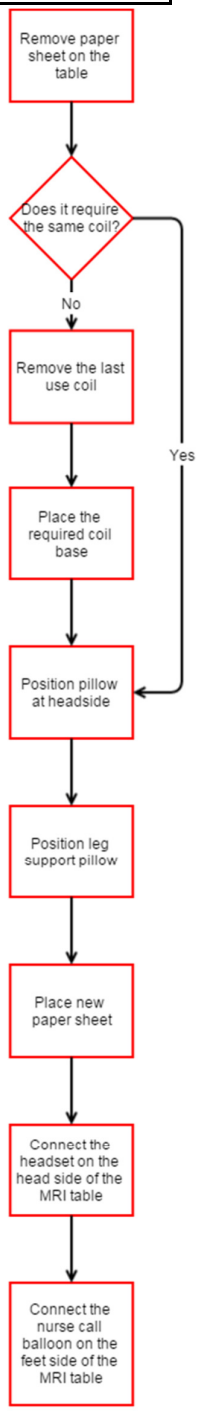


Figure 11 MRI table preparation

B6 – Give and explain the nurse call balloon to the patient
Operator B gives the nurse call balloon to the patient and explains when the patient should use the nurse call balloon.

B7 – Test nurse call balloon
The patient tests the nurse call balloon and should hear the alarm sound that goes off in the control room. In case if there is no sound check if the nurse call balloon is connected properly, or check in the control room if the battery is low.

B8 – Give earplugs to the patient
Operator B gives a set of earplugs to the patient, in the case of an elderly or handicapped person assist the patient in positioning the earplugs. Or the patient positions the earplugs himself.

B9 – Position optional add-on
Operator B attaches any optional add-on that is required during the exam. See Figure 12.

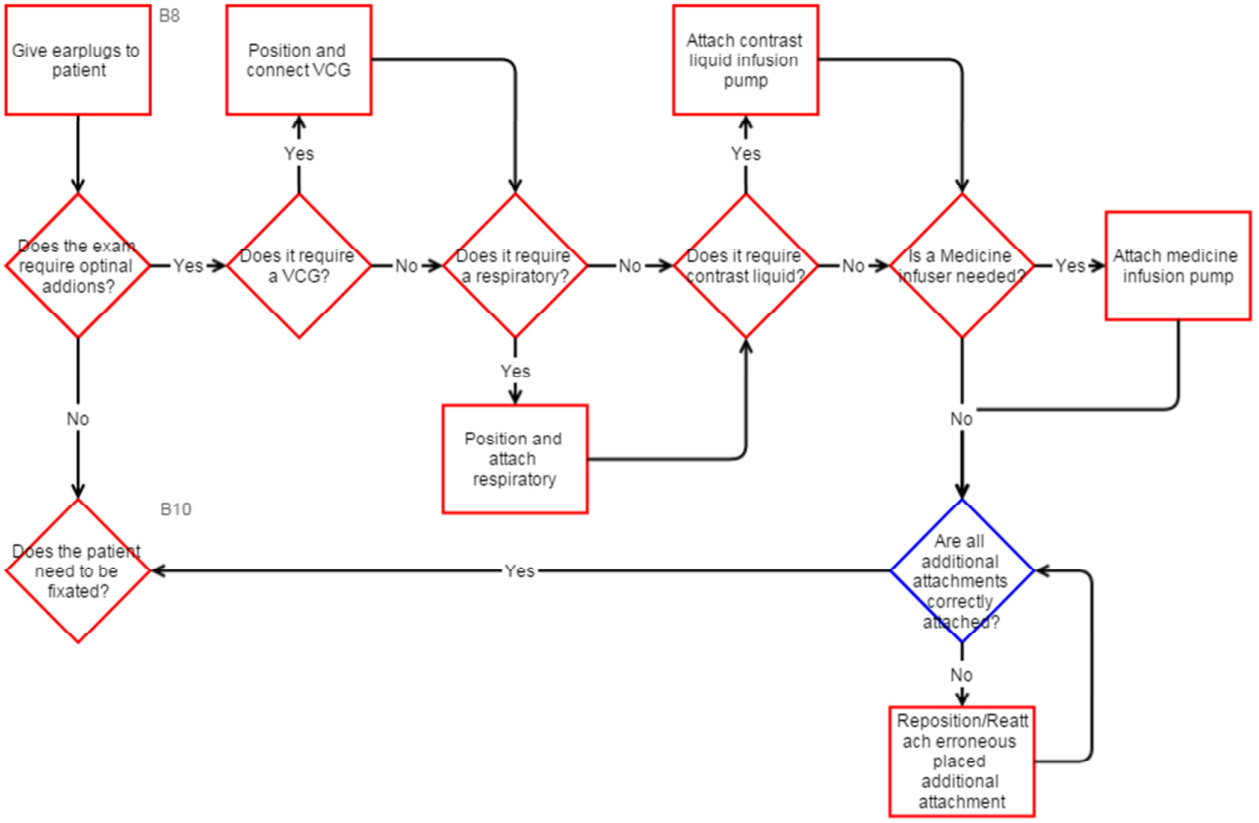


Figure 12 Optional add-on

B10 – Does the patient need to be fixated? & B11 – Fixate patient
Operator B has to fixate, some infant patients or a patient with a spasm, with straps to make sure the patient lies still to make sure the quality of the images is high enough.

B12 – Position coil
Operator B positions the coil on the patient and connects it to the MRI.
B13 – Are there additional coils required & B14 – Position additional coil(s)
Operator B positions and connects the additional coils, like flex coils or second body coil.

B15 – Place and explain the headset on the patient
Operator B positions the headset on the patient, now operator A can test the intercom.

B16 – Move the MRI table into the MRI
Operator B turns on the light visor, and tells the patient not to look into it, and focus the reference point on the area to be scanned by moving the table. Operator B then presses the, travel to scan plane button, to move the patient reference point into the centre of the magnet. The operator has to make sure the table moves smoothly without getting stuck between cables or the patient.

B17 – Wait till the last scan
Operator B moves from the MRI room to the control room, where closing the MRI room door. Here the operator will wait for the survey scan, if the survey scan by operator A gave a good image operator B, can go do other tasks in the vicinity. In case something went wrong survey scan operator B has to reposition the patient or coil see Figure 13.

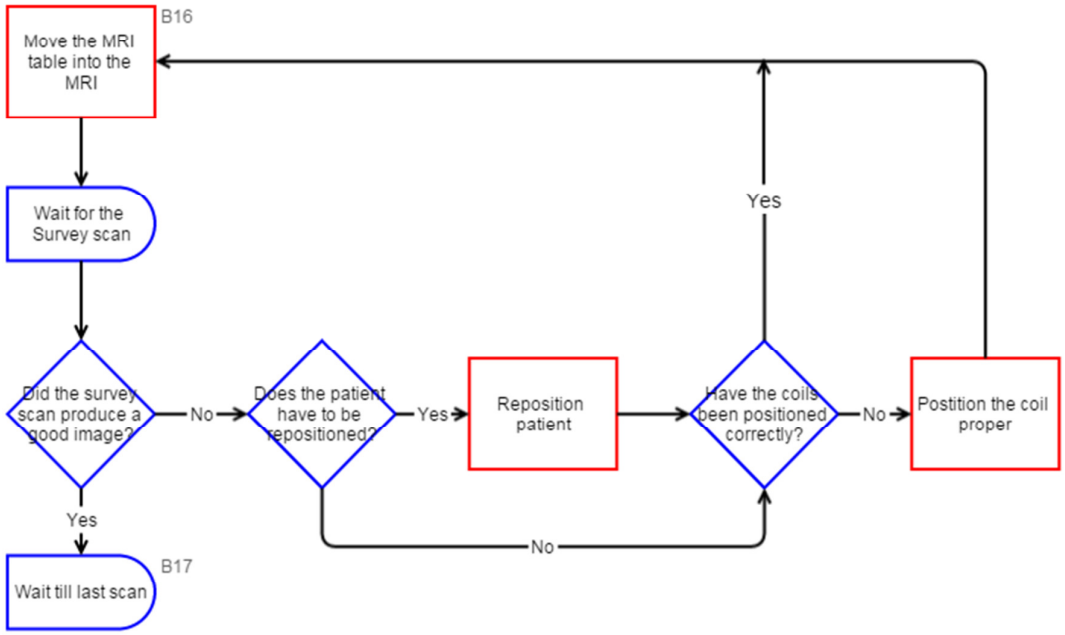


Figure 13 Waiting for survey scan

B18 – Take operator A role
Operator B takes the role from operator A, and they start all over again.

3.1.2.2. Use of the workflow analysis to structure the AdCoS

The workflow diagram reflects the results of the observations made in a hospital department. In particular, it shows:

- In which parts of the workflow the operator needs to use information available from the exam card
- Which steps the operator has to take
- Which instructions the operator has to give to the patient
- Which external equipment has to be attached to the scanner
- Where the user guidance system can support the operator

With this information, the design of the AdCoS can be targeted to the most important parts or the workflow and the interaction with the operator can be focused on the parts of the workflow identified in the analysis.

3.1.2.3. The means-ends model

The mean-ends model differs from the workflow analysis by organising the goals, functions and behaviour on 5 levels, in a relatively flat hierarchy.

The top and second level (Goal and objectives in the model produced here) consist of the elements listed in Table 2 below.

Goal
Provide safe, functional and comfortable situation for MRI scanning
Objectives
Provide patient in correct physical situation for scanning
Provide safe transmission channels for radio frequency signals
Provide physical environment to acquire image
Provide passive safety for patient
Provide means of communication
Provide a comfortable environment

Table 2 Elements of the model at the goal and objectives levels

Due to the flat hierarchy, the diagram will have to be split up for the purpose of the presentation in this document. In the following figures

(Figure 14 to Figure 17), the objectives listed in Table 2 are further divided into functions and the associated behaviours are identified. The complete diagram of the Guided patient positioning means-end model is available in Annex IV.

The lowest level (on a grey background) contains the mapping to the actions identified as a part of hazard analysis outside of the scope of HoliDes.

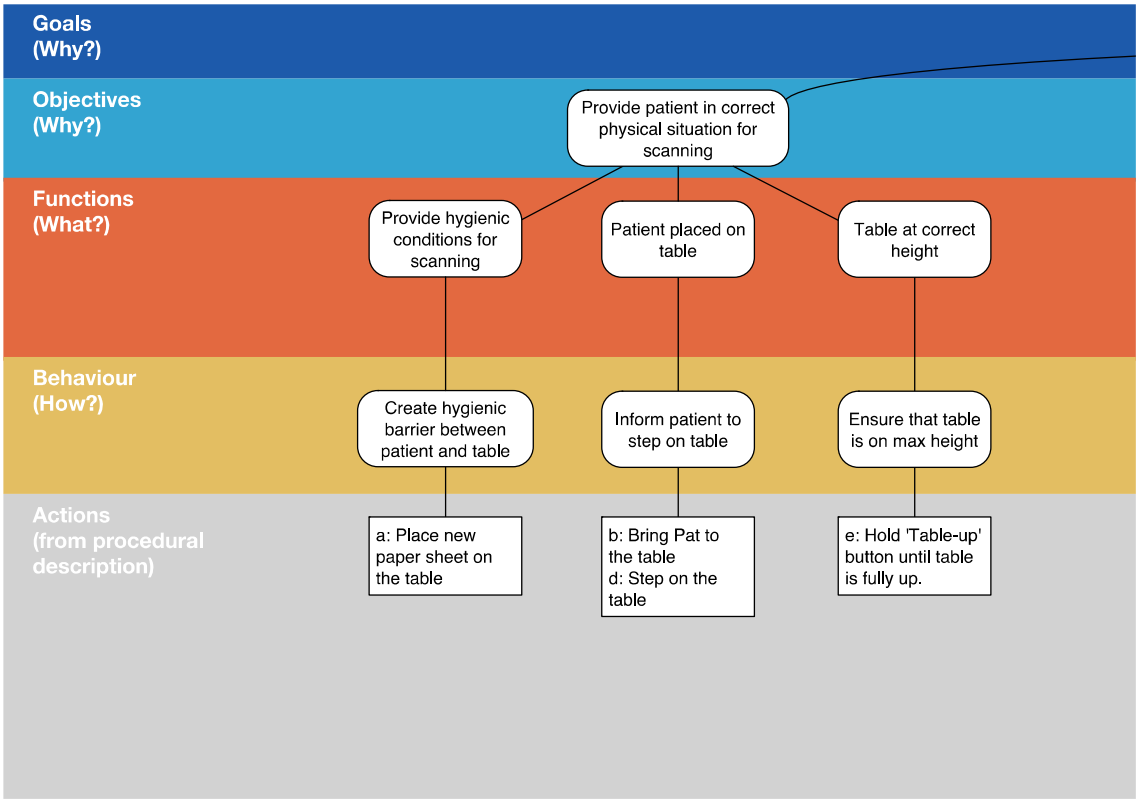


Figure 14 Expansion of the objective "Provide patient in correct physical situation for scanning"

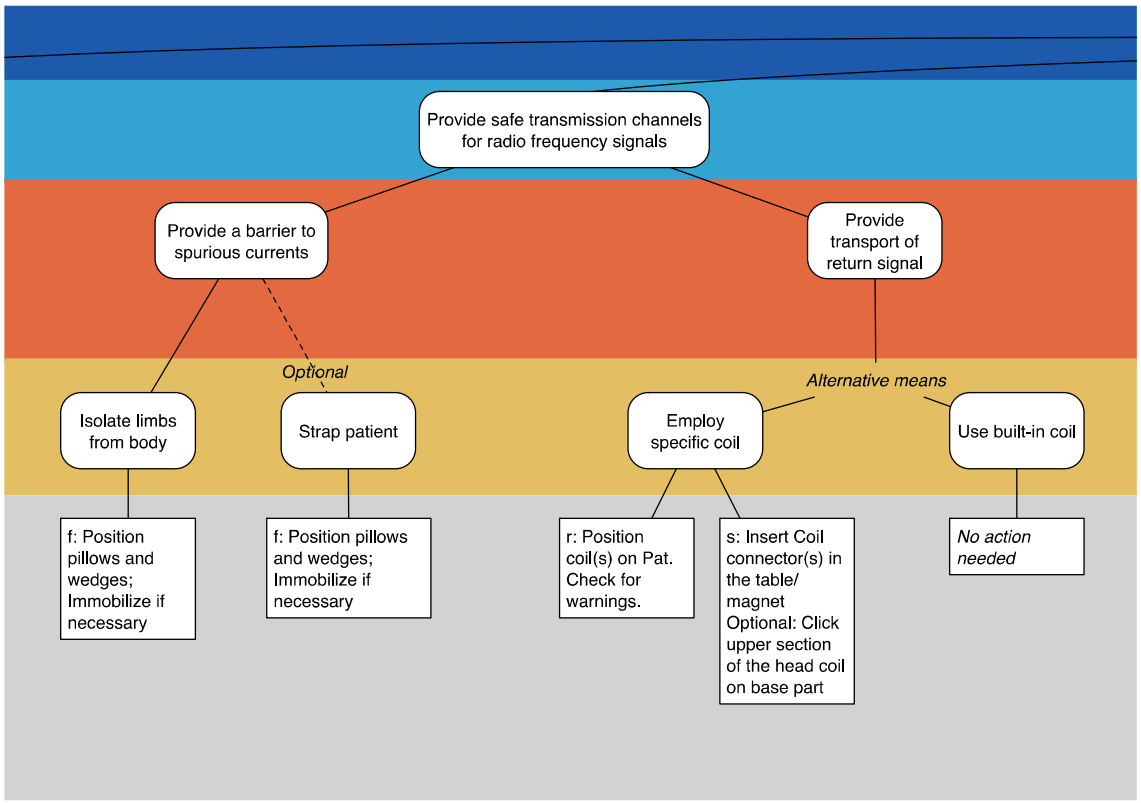


Figure 15 Expansion of the objective "Provide safe transmission channels for radio frequency signals"

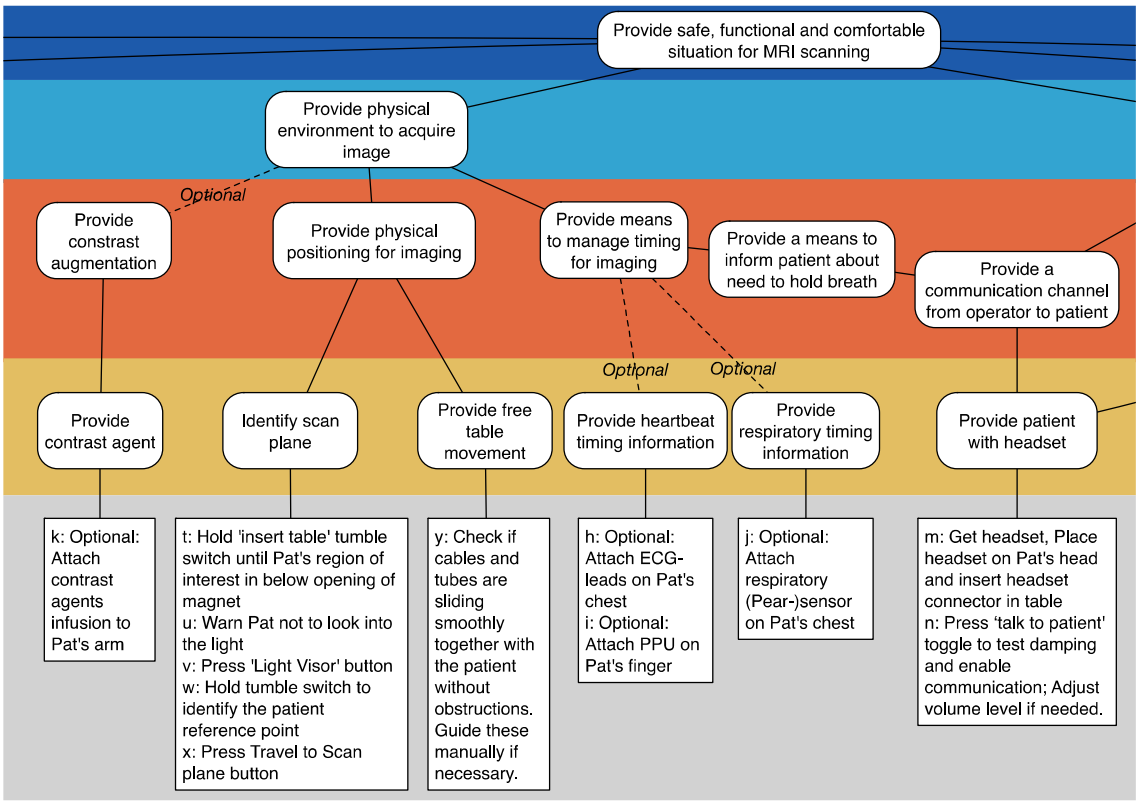


Figure 16 Expansion of the objective "Provide physical environment to acquire image"

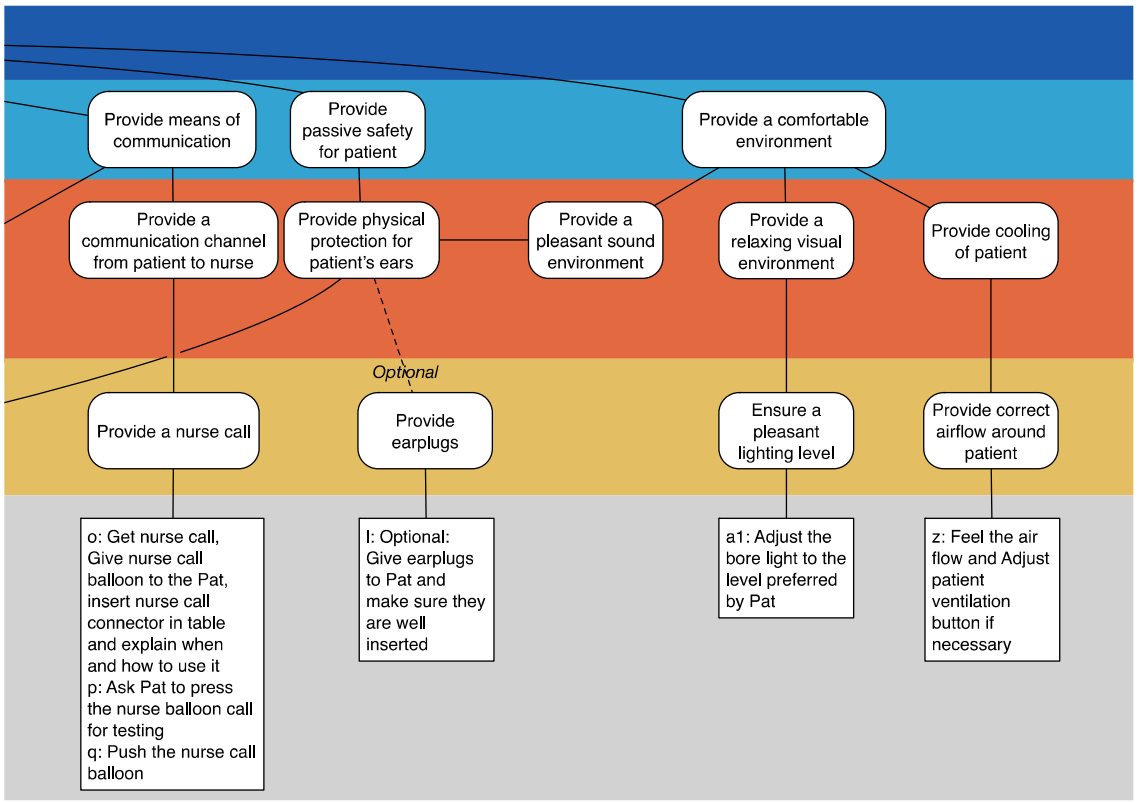


Figure 17 Expansion of the remaining objectives

3.1.2.4. Use of the means-end model to structure the AdCoS

The means-end model can help structure the AdCoS, both the knowledge base used to guide the operator and the user interface presenting the guidance.

As discussed earlier, the model focuses on objectives and functions of the controlled entity. This allows the organisation of an architecture of the AdCoS where the functionality of the each part of the AdCoS reflect the purpose of a group of actions and the subsystems or components that they act on.

In the means-end model discussed in section 3.1.2.3 oben, an example of this approach is seen in the function hierarchy associated with the objective "Provide physical environment to acquire image". In that part of the model, several different actions on several different subsystems are involved, but since they all serve to ensure or improve the quality of the

image produced, the system architecture could be designed to take this into account.

In the case of the user interface, the means-end analysis will be used in two ways.

The first is to help non-experienced users to fulfil all the needs of a safe and correct procedure by allowing the system to dynamically adapt the guidance to provide the functions and achieve the goals, even if the operator executes some actions out of the normal order. In order for the model to support this, it must be further augmented with pre- and postconditions in the behaviour elements.

The second way the model can be used to improve the UI is for more experienced operators, for whom the state of the patient positioning can be summarised in terms of functions that are correctly provided or subgoals that have been reached, without having to explicitly acknowledge which single actions have been carried out.

Only when a step of the procedure has been forgotten, should the system expand to a level of detail to highlight the missing step.

3.1.3. Feedback on MTTs and HF-RTP regarding Guided patient positioning

See annex II.

3.2. Safe parallel transmit scanning

3.2.1. Description of the AdCoS

To optimise the MR image quality for certain anatomical regions, a so-called phased antenna array is used in 7T MR imaging. A set of (e.g. 8) RF amplifiers each connected to a coil element (antenna) provides the transmit field to generate MR signal. Each channel is independently modulated: phase and amplitude modulation should lead to the required excitation of part of the patient, e.g. homogeneous (same signal from all parts of the brain), or spatially focussed (e.g. only signal from the spinal cord).

However, this temporal modulation of the RF signals alters also the spatial interference of the concomitant electric fields resulting potentially in

unsafe RF induced tissue heating (microwave heating effect) at certain body location. The electric fields and heating cannot be detected directly with MRI and their spatial patterns are highly patient specific due to the complex electromagnetic interaction of RF signals with the human body. The RF power absorption can only be determined by means of electromagnetic simulations employing dielectric models of the scanned subject.

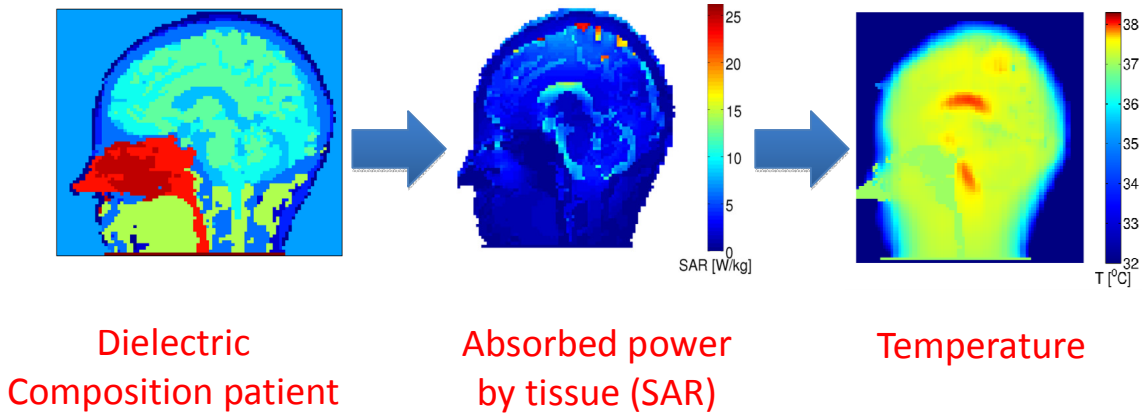


Figure 18 Relation between various calculated maps of fields in the patient

The AdCoS consists of the following parts:

- RF safety assessment technology to estimate safe RF power settings for a given patient prior to scanning and monitor heating during scanning.
- An operator workflow that enables non-scientific staff to be able to perform safe parallel transmit scanning.
- UI elements to communicate the status and required actions to the operator

The AdCoS makes use of the general capabilities of the MRI system to calibrate average RF power and to scan a series of scans and real-time generate images.

3.2.1.1. Operational definition

The AdCoS should enable non-scientific operators to do parallel transmit MR scan that is optimal in terms of image quality and patient safety. Therefore the complete workflow of a parallel transmit experiment should

be facilitated by a clear workflow description/instruction for the operator and a safety monitoring systems with optimal UI design that provides:

- Clear and timely feedback to the operator on the status
- Clear dialogues if intervention of the operator is required
- Assist/help the operator in making corrections if necessary.

Input/output channels:

Input:

- All data and settings available at the MRI system
- Operator control via the console

Output:

- Images, text, pop-ups, dialogues, graphics on the console and transmit field settings for the scanner (e.g. channel phases).

3.2.1.2. The environment of the AdCoS

Controlled entity
An MRI scan is acquired by a complex and accurately timed interplay of magnetic field variations, high power RF pulses with predefined shapes and periods of signal detection. These patterns of interplay are highly repetitive and are called 'MRI sequence'. This is, effectively, the controlled entity.

In its simplest form, an MRI sequence consists of a RF pulse, a waiting time, a detection period and another waiting time before the next RF pulse is fired. The RF pulse and the repetition time (time after which the whole process repeats itself) are the parameters that need to be adjusted by the AdCoS. They have to be chosen such that 1) the RF field distribution within the patient has the required shape for the desired imaging target and 2) the temperature of the patient remains below safe limits in spite of the RF power being deposited in the patient (microwave oven effect).

Operator of the AdCoS
The operator is a non-scientific, trained MR operator that is not per se familiar with the physics and exact principles of RF safety of MRI.

External environment
The most important external environment in this AdCoS is the patient to be scanned. The operator has to deal with patient specific issues like claustrophobia, unwell-being during scanning, the presence of implants and tattoos. Some of these aspects will change in a non-deterministic fashion.

Communication between AdCoS and environment
The operator will perform prior to the MRI exam a screening of the patient including an interview, patient files inspection. The operator console of the MRI scanner will load the patient characteristic from the patient database (birth date, name, weight) just prior to the first patient contact.
Before entering the scanner room, the operator will instruct the patient. Prior to the actual scanning, various calibration measurements are performed characterising the RF response of the patient. During the exams, the RF signals reflected of the RF antennas are monitoring. Furthermore, the patient can press an alarm button during the exam.

3.2.1.3. Modelling techniques employed

As a start of the modelling process, video recordings were taken during actual parallel transmit experiment using volunteers of the complete workflow (preparations and actual MR scanning). This footage has been analysed by SNV using empirical analysis techniques.

The starting point of the empirical investigation aims at collecting as much information as possible on the interaction that operators have with the display and, as a consequence, with the attentional and decision making process.

The analysis demonstrated that the critical part in this AdCoS occurs when the operator is at the console. Based on the findings SNV has advised to employ the following steps in the modelling process.

1st step: A questionnaire will be developed for the operator. This questionnaire will be designed according to the elements that are displayed in the UI. In this way, information is obtained on the decisions that have to be made by operator. Twenty questions will be created on a seven-point scale in order to have a quantitative measure to evaluate the interaction. In addition, for some of the questions, a few lines of explanation about the "why" of a given answer will be used to collect also qualitative measures. This questionnaire will be drafted by SNV.

2nd step: A focus group of operators will be formed. This group will consist of users/researchers that want to apply parallel transmit technology in their MRI exams for certain applications, but are not familiar with the technology.

Eye tracking technology will be used based on the results of the questionnaire and of the focus group. This way independent variables will be selected to observe the operators interacting with a first prototype UI, and complex and difficult tasks in the workflow will be identified. This information will be used in an iterative design loop for the UI.

The last part of the questionnaire from the 1st step will also serve as control to test the consistency of the answers given in the focus group.

The focus group will be divided into three separate sets: The first set will be formed by six to seven experts, on the topic of the safe parallel scanner transmission; the second set will be formed by non-experts of the specific tool but general experts of the fMRI; the third group will be a mixed group of experts/non experts. The focus group will be guided to collect information on the interaction with the display. Given the results of this first part of the empirical investigation, quantitative experiments on attention will be implemented to evaluate the interaction with the display under different attentional conditions.

By means of observations of the operators interacting with a first prototype UI, complex and difficult tasks in the workflow will be identified. This information will be used in an iterative design loop for the UI.

Figure 19 Screenshots of video footage. The footage describes the entire process of welcoming a patient, acquisition of information by means of a survey, setup of the patient and all scanning procedures

The AdCoS needs to ascertain that the temperature rise of the patient remains below safe limits. Since the temperature cannot be measured directly, the AdCoS will rely on pre-calculated simulations. Therefore, this project also comprises the physical modelling of RF safety for patients. The outcome of these simulations will become underlying data for the AdCoS. The simulations will be performed by the EM modelling package Sim4Life (ZMT, Zurich, CH). The distributions of energy deposition for a wide range of varying subjects will be studied to establish a method to accurately calculate safe power limits while scanning. A procedure will be developed that uses atlas-matching to identify for a certain patient the best RF safety predictive pre-simulated model.

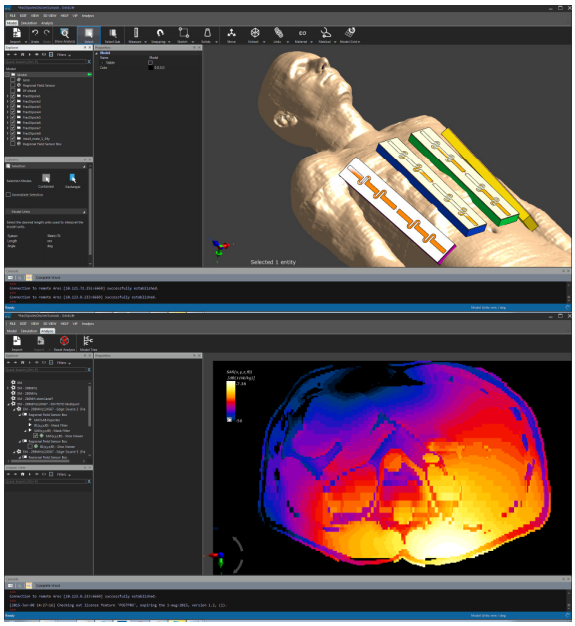


Figure 20 Screenshots of EM simulation software Sim4Life. The screenshots show calculation of RF safety Q-matrices (becomes underlying data for RF safety assessment GUI).

3.2.1.4. Input to the modelling process from other work packages

On this AdCoS WP5 (SNV) is involved in the task modelling and UI design using techniques such as questionnaires, eye tracking experiments on a pre-selected focus group.

The flow of modelling MTTs is illustrated in Figure 21 below.

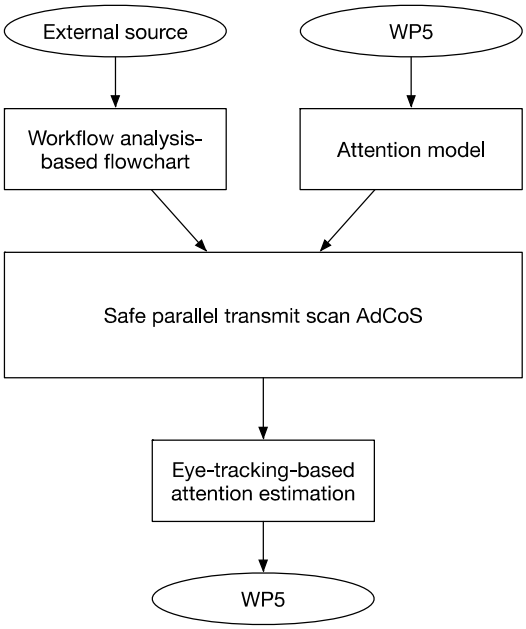


Figure 21 Flow of modelling MTTs related to Safe parallel transmit scan AdCoS

3.2.2. The model

In preparation of the empirical investigation discussed above, a workflow analysis has been carried out. This will allow mapping the empirical observations to specific steps of the workflow in order to identify potential areas of improvement in the system and workflow.

Figure 22 below shows a high-level workflow analysis, with the part relevant to the HMI studies highlighted as block "B".

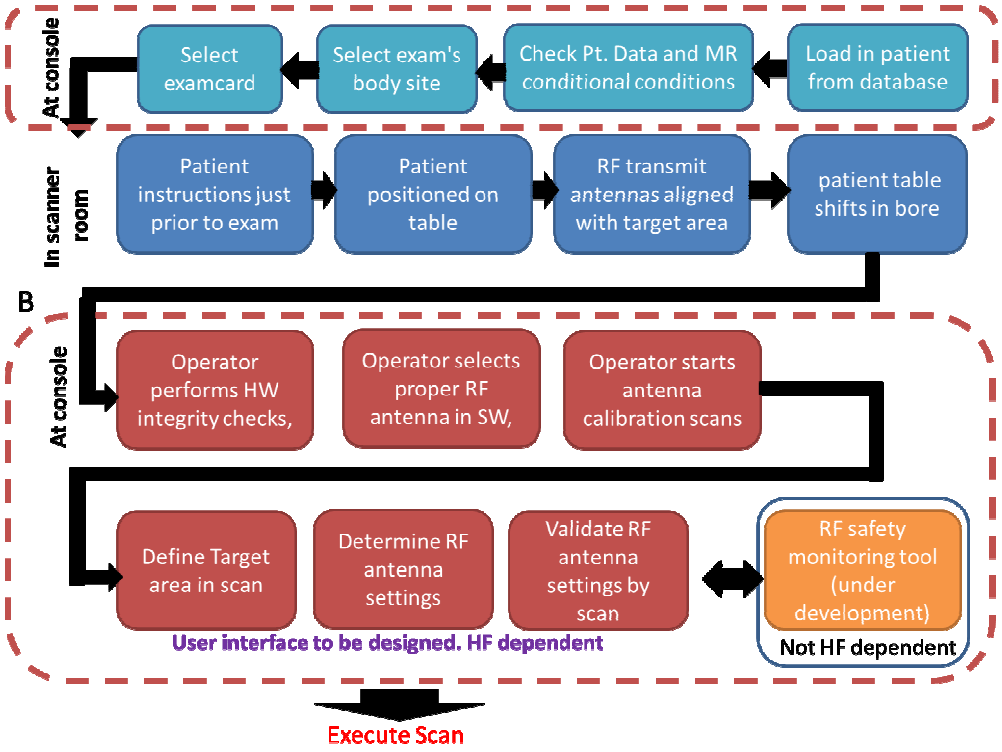


Figure 22 The overall workflow for a safe parallel transmit scan

As can be seen in Figure 22, the workflow is divided in three distinct parts, given by the physical location of the work – either at the console or in the scanner room.

Figure 23 below shows the more detailed analysis of the last part of the workflow, the determination of parameters for the scan, after the patient has been prepared in the scanner room.

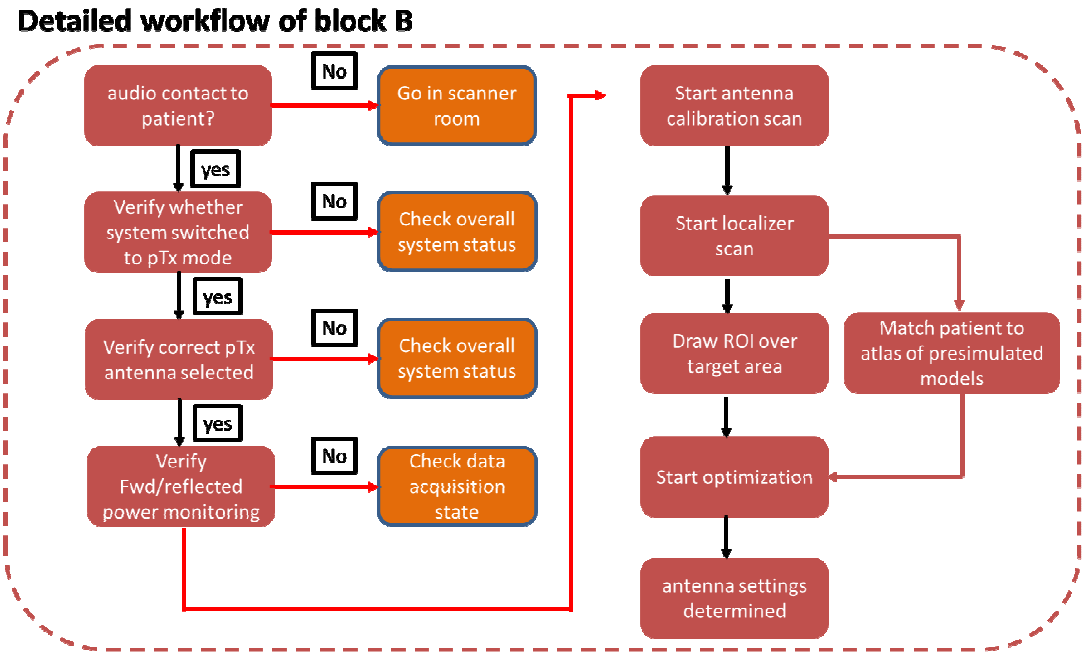


Figure 23 Detailed task workflow for MRI operator for a parallel transmit experiment.

The workflow in block B is further specified as it contains the critical interaction in terms of tasks and decisions of the operator at the scanner console.

3.2.3. Feedback on MTTs and HF-RTP regarding Safe parallel transmit scanning

See annex II.

3.3. Robust ECG Triggering System

3.3.1. Description of the AdCoS

One of the elements in the AdCoS Guided Patient positioning, described in section 3.1, is the attachment of ECG sensors to obtain trigger signals from patient's heartbeats.

The AdCoS Robust ECG Triggering System is connected the Guided Patient Positioning AdCoS.

For robust ECG triggering two traces are acquired simultaneously, the Vector-ECG (VCG), which can be pictured in a two-dimensional diagram that represents the ECG vector. The system analyses the signals, determines calibration setting for the trigger detection algorithm, display the trigger signals and provide triggers to the MR system during scanning for real-time synchronization. The system also displays the signals, allowing the operator to judge the quality, and all data are logged for off-line analysis.

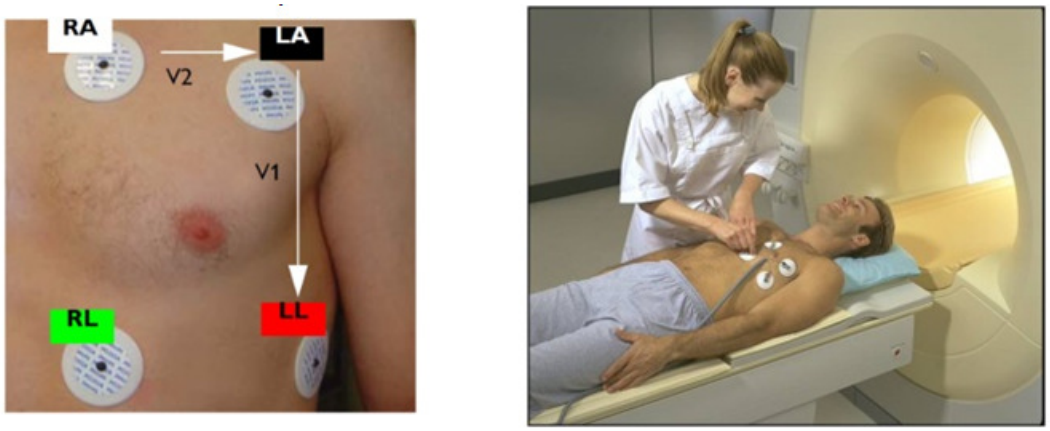


Figure 24 Placement of the ECG electodes.

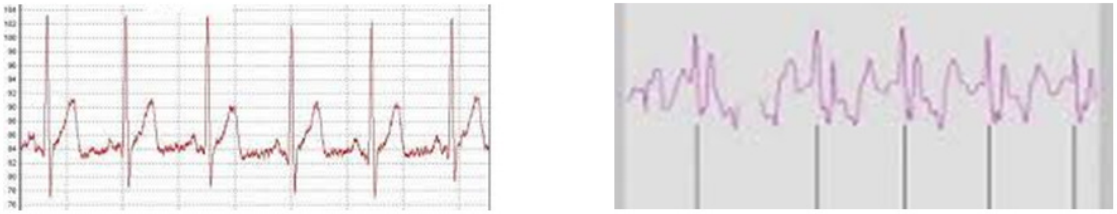


Figure 25 Example ECG signals. Left: Clean ECG signal outside the magnet, right distorted ECG signal in the magnet due to MHD effect in combination with blood flow.

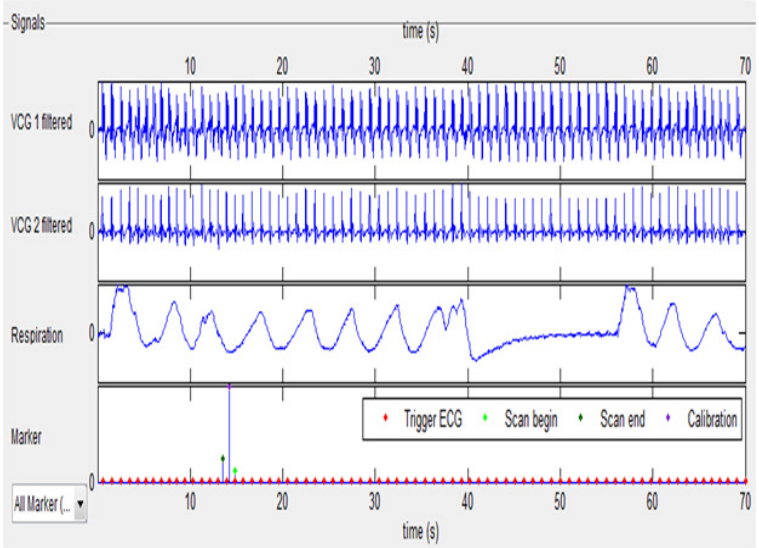


Figure 26 Example physiology display. The display shows from top to bottom: two ECG traces, one respiratory trace, and the red trace with trigger signals. Note that this was a breath hold scan, as can be seen from the respiratory signal.

3.3.1.1. Operational definition

In order to perform cardiac triggering, calibration of the acquired VCG signal is required. VCG calibration is currently performed as a continuous process throughout a cardiac examination and is automatically executed prior to a cardiac triggered scan. It is known that cardiac triggering may be negatively affected if the VCG calibration is distorted, e.g. by patient motion or by flow-induced artefacts. To prevent these types of distortion of the VCG calibration, the operator is offered an option to control the moment at which VCG calibration is performed.

The users of the system are the operators of the MRI scanner. Their user needs are specified following a generic workflow:

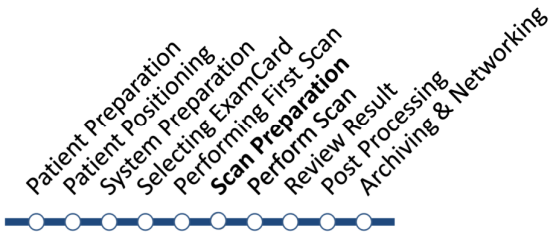


Figure 27 Generic workflow to operate an MRI scanner

Looking at the generic MR workflow, two steps in the workflow may be impacted by the use of cardiac triggering, being "prepare patient" and "perform scan". In fact, the users (the operators) want to be able to prepare the examination and to perform the scan without interruptions. The two tables below present the related Clinical User Needs (CUN), which are used as input for the system requirements:

Name	**CUN.Workflow.ScanPreparation**
Description	The user shall be able to adapt the scans to the patient and to specific diagnostic needs (geometry, contrast, coil selection, physiology etc.) in parallel while scanning.
Rationale	User wants to adapt the scan features to the patient's anatomy in order to produce relevant images that will support the clinical diagnosis

Table 3 Scan preparation system requirements

Name	**CUN.Workflow.PerformScan**
Description	The user shall be able to execute the scans without unexpected delay, while receiving clear feedback if user interaction is required
Rationale	User wants to perform scans without delay to ensure that examinations can be completed on time. Clear instructions are required to support the user to do the right things to ensure that the images for clinical diagnosis can be acquired

Table 4 Perform scan system requirements

3.3.1.2. The environment of the AdCoS

The environment

The workflow for VCG manual calibration is described for a mainstream hospital where a mix of clinical procedures is executed (although the workflow is also applicable to e.g. research hospital or cardiac centre).

The workflow for VCG manual calibration occurs in the Examination room (or Preparation room), and at the operator's console.

Controlled entity
In the examination room the guided patient position environment is available, including a monitor to display the physiology signals. In the Examination room the operator console of the MRI scanner is used to control and inspect the VCG triggering related settings. The AdCoS controls the physiology part of the both the monitor and the console to interact with the operator, and controls gain settings and internal calibrations and filters for the physiology signals.

Operator of the AdCoS
The user role associated with the use of this AdCoS is the Operator. The MR operator can have various level of education, e.g. he/she can be a technologist, a lead technologist, or even a radiologist/cardiologist. He/she has the skills to apply the VCG electrodes in a safe and correct manner, if needed with guidance from user documentation

3.3.1.3. User role description

The MR operator is the person who actually conducts the MR examination. In the context of an MR examination in which cardiac triggering is used, he/she is responsible for setting up the VCG electrodes.

For certain examinations it is required to synchronise the acquisition of data to the cardiac cycle of the patient. This is done in order to:

1. Minimise effects of cardiac motion on the images
2. Capture data at the desired moment in the cardiac cycle (e.g. to obtain functional data)

MR-compatible VCG electrodes are applied on the patient's chest for this purpose, and the VCG signal is measured during the examination.

3.3.1.4. Modelling techniques employed

Task analysis modelling is used to structure the design process for this AdCoS.

3.3.2. The model

This chapter describes an MR-workflow for a cardiac triggered exam, in order to identify new or affected tasks for a user that performs a manual VCG calibration.

The below flow chart indicates all involved steps (represented by ellipse) of 4 sequential tasks in the workflow. Steps of the next task are generally not performed before completion of all steps in the previous task.

Note that the steps in task 4 may be repeated several times in an arbitrary order during the examination.

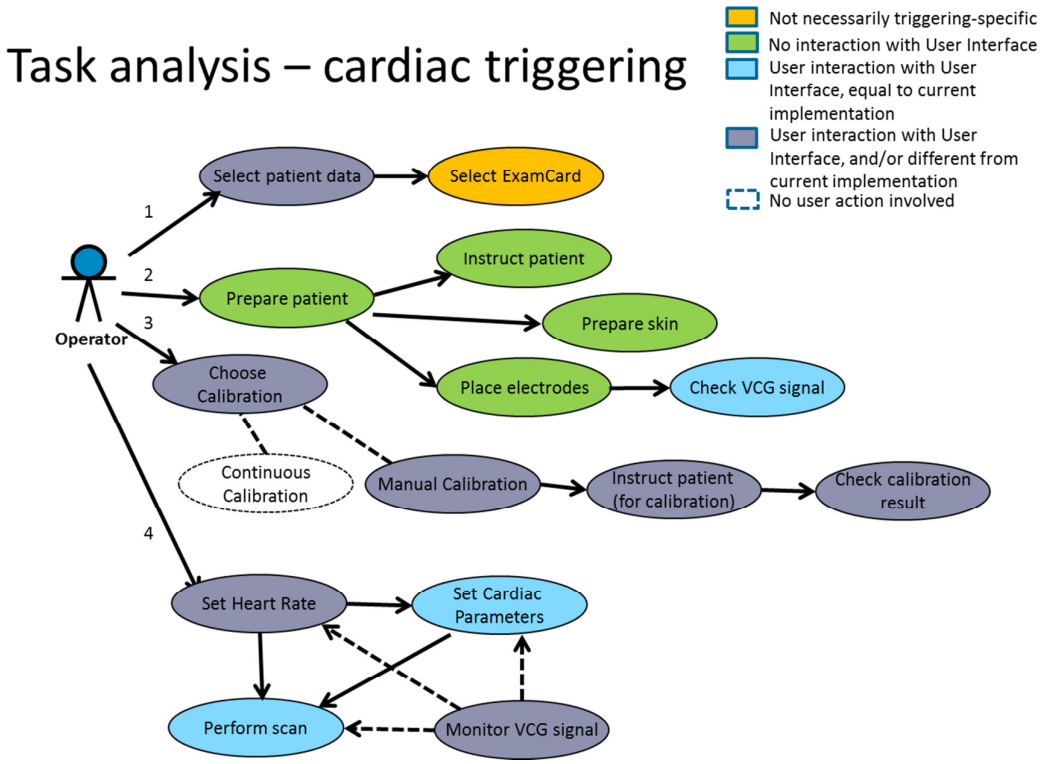


Figure 28 Task analysis for the Robust ECG triggering AdCoS

Select patient data	
Environment: operator's console	Frequency: once / exam
User role: operator	Saftety [N/Y]: N

User goal:
Enter New Exam details to start exam of (the next) patient

Description:
Operator wants to enter New Exam details in order to start the examination of the next patient. By doing so, the operator expects that all information (including VCG calibration data) of the previous patient is cleared from the acquisition context

Not critical:
Task does not involve safety, and is not frequently used during examination.
Workflow and user interface are not affected with respect to current way-of-working.: "existing UI of unknown provenance". (although this task induces a reset of VCG manual calibration results, which is different from current implementation)

Table 5 Select patient data step

Select ExamCard	
Environment: operator's console	Frequency: once / exam
User role: operator	Safety [N/Y]: N

User goal:
Select the right procedure for the scheduled examination

Description:
Once New exam details are entered, the user wants to select the right clinical procedure for the examination that is requested for this patient. Imaging strategy might be different depending on patient condition etc.

Not critical:
Task does not involve safety, and is not frequently used during examination.
Workflow and user interface are not affected with respect to current way-of-working.: "existing UI of unknown provenance"

Table 6 Select ExamCard step

Prepare patient

Environment: Exam (prep) room | Frequency: once / exam
User role: operator | Safety [N/Y]: N

User goal:
Ensure that the patient is ready to undergo the MR-exam

Description:
The operator wants to ensure that the exam can run smoothly and will therefore check if the patient is ready for the exam: check for contra-indications

Not critical:
Task does not involve safety, and is not frequently used during examination.
Workflow and user interface are not affected with respect to current way-of-working.:
"existing UI of unknown provenance"

Table 7 Prepare patient step

Instruct patient

Environment: Exam (prep) room | Frequency: once / exam
User role: operator | Safety [N/Y]: N

User goal:
Ensure that the patient has a good understanding of what will happen during the exam

Description:
The operator wants to explain the steps of the examination. A good understanding will ensure that the patient can be more cooperative. Usually, operator will explain about the need for breath-holding, if contrast injection is required etc.

Not critical:
Task does not involve safety, and is not frequently used during examination.
Workflow and user interface are not affected with respect to current way-of-working.:
"existing UI of unknown provenance"

Table 8 Instruct patient step

Prepare skin

Environment: Exam (prep) room
User role: operator
Frequency: once / exam
Safety [N/Y]:

User goal:
Skin preparation is required to reduce skin impedance and to ensure good contact between electrodes and skin

Description:
The operator wants to ensure that the electrodes can be properly placed on the patient's skin as loose electrodes may lead to loss of VCG signal.
The steps required for proper skin preparation:

- Shave if (excessive) chest hair is present in the areas where the electrodes are going to be applied
- Abrade the skin with a gauze pad. This may result in slight skin reddening.
- Clean the skin with a special abrasive skin prep gel (such as NuPrep). Do NOT use alcohol as this will dry the skin.
- Dry the area thoroughly, ensuring that excessive gel is wiped off.

The operator will be able to find information about these steps in the user manuals

Not critical:
Task does not involve safety, and is not frequently used during examination.
Workflow and user interface are not affected with respect to current way-of-working.: "existing UI of unknown provenance"

Table 9 Prepare skin step

Place electrodes

Environment: Exam (prep) room
User role: operator
Frequency: once / exam
Safety [N/Y]: N

User goal:
Electrodes are optimally and correctly placed in order to measure the VCG signal during the examination

Description:
The user wants to place the electrodes as optimally as possible to ensure the best possible VCG signal. He/she might want to refer to Instructions for Use to find information about recommended leads, guidance concerning lead placement
The operator will be able to find information about lead placement in the user manuals.
Note: recommended lead placement will be changed from 'squared' to 'L-shape'

Not critical:
Task does not involve safety, and is not frequently used during examination.
Workflow and user interface are not affected with respect to current way-of-working.: "existing UI of unknown provenance"

Table 10 Place electrodes step

Check VCG signal

Environment: operator's console | Frequency: once / exam
User role: operator | Safety [N/Y]: N

User goal:
Verify that the VCG signal that is detected, is good enough to start the examination

Description:
Once the electrodes are placed, the operator wants to verify (by visual inspection) that the VCG trace is clean, to get the confidence that reliable R-top detection can be obtained throughout the exam. Based on the visual inspection, the operator may decide to change the electrode set-up if he/she thinks this is necessary.
Depending on selected calibration method, trigger markers are displayed in the user interface as soon as VCG calibration is performed.
The operator will be able to find information about these steps in the user manuals

Not critical:
Task does not involve safety, and is not frequently used during examination.
Workflow and user interface are not affected with respect to current way-of-working.: "existing UI of unknown provenance"

Table 11 Check VCG signal step

Choose calibration

Environment: operator's console | Frequency: once (/ exam)
User role: operator | Safety [N/Y]: N

User goal:
Ensure that VCG data is calibrated in order to get reliable R-top detection throughout the exam.

Description:
VCG calibration is a process that analyses the VCG data in order to determine which of the waveforms in the signal is the R-top. The operator wants to ensure that VCG calibration is done correctly in order to get reliable R-top detection throughout the exam. This task is used by the operator to make a deliberate choice between continuous calibration and manual calibration.

Design proposal:
Initially, the current continuous calibration method is activated. An option is offered to the user to enable the manual calibration process

Not critical:
Task does not involve safety, and is not frequently used during examination.
This step is an optional process. Current implementation ("UI of existing provenance") remains default setting, hence current Way-of-working is not changed

Table 12 Choose calibration step

Manual Calibration

Environment: operator's console | Frequency: once / exam
User role: operator | Safety [N/Y]: N

User goal:
Ensure that VCG data is calibrated in order to get reliable R-top detection throughout the exam.

Description:
Instead of continuous calibration, the operator may want to perform a manual VCG calibration in order to initiate this process at the moment that he/she thinks it is most appropriate. Since the operator has chosen the most appropriate moment for calibration, he/she will want to keep the calibration data to apply for each subsequent cardiac triggered scan (instead of repeating a new calibration for each scan).

Design proposal: UI attracts operator's attention as soon as a usable VCG signal is detected for which VCG calibration is still required. It must be clear to the operator how or where to initiate the VCG calibration. If operator attempts to start cardiac triggered scan without calibration, the UI will make clear to the operator why the scan cannot be started

Not critical:
Task does not involve safety, and is not frequently used during examination.
This is an optional process. Current implementation ("UI of existing provenance") remains default setting, hence current Way-of-working is not changed

Table 13 Manual calibration step

Instruct patient (for calibration)

Environment: operator's console | Frequency: once / exam
User role: operator | Safety [N/Y]: N

User goal:
Optimize patient-related circumstances under which VCG calibration is performed

Description:
VCG calibration can be disturbed by patient motion or by heavy/irregular breathing. It can also be disturbed by e.g flow-induced artifacts on the ECG-signal. The operator wants to initiate the VCG calibration under optimal circumstances (when patient is instructed to lay still, to breathe regularly), preferably outside the bore to ensure that the calibration results are as optimal as possible. (This step is not relevant if continuous calibration is selected)

Design proposal: the UI will present clear instructions to the operator concerning these instructions, and it must be clear to the operator how to continue with the VCG calibration process

Not critical:
Task does not involve safety, and is not frequently used during examination.
Not a primary operating function. Instruction is not required to continue (similar to continuous calibration), but foreseen as a way to enhance the outcome of the calibration process.

Table 14 Instruct patient (for calibration) step

Check calibration result

Environment: operator's console	Frequency: once / exam
User role: operator	Safety [N/Y]: N

User goal:
Verify that the VCG calibration is completed successfully. In case not successful, operator wants to intervene and repeat the process

Description:
The operator wants to be informed by the UI about the progress of calibration, and wants to see the results of the calibration, expressed in a clear and understandable measure. The operator wants to understand from this measure how he/she shall proceed with the examination. (Calibration result is indirectly presented to the user if continuous calibration is selected: calibration completed if trigger markers appear.)

Design proposal: : the UI will present clear feedback to the operator concerning the calibration results (signal strength, rhythm-indicator), and it must be clear to the operator how to proceed with the exam, or, in case of unsuccessful calibration, it must be clear to the operator how to repeat the calibration process.

Not critical:
Task does not involve safety, and is not frequently used during examination.
Not a primary operating function. Instruction is not required to continue (similar to continuous calibration), but foreseen as a way to enhance the outcome of the calibration process.

Table 15 Check calibration result step

Set Heart Rate

Environment: operator's console
User role: operator
Frequency: multiple times / exam
Safety [N/Y]: N

User goal:
At ExamCard level, operator specifies the patient's heart rate (as well as other properties such as laterality, anatomic region etc)

Description:
The patient's heart rate (in bpm) is displayed on the UI after completion of VCG calibration. The operator wants to enter this value in the ExamCard to ensure that the cardiac-triggered scans can be synchronized with the heart rhythm of the current patient.

Design proposal:
HR in bpm is a patient-characteristic and not so much an ExamCard property, and the field should be more visible to the operator. UI should allow for a single-click update of the entered heart rate, taking over the measured heart rate.

Not critical:
Task does not involve safety. Way of working is not is affected (current location to set Heart Rate remains available on the ExamCard properties tab). Workflow may be enhanced if the function is made more visible to the operator, but not using this function will not lead to risk

Table 16 Set heart rate step

Prepare scan: set cardiac parameters

Environment: operator's console	Frequency: multiple times / exam
User role: operator	Safety [N/Y]:

User goal:
Fine-tune the scans as saved in the selected ExamCard for the specifics of the current patient

Description:
Scan properties may need modification, based on the patient's heart rhythm (eg lower or higher heart rate than average, arrhythmia). The operator wants to make sure that the scans are fine-tuned, based on the patient's actual heart rate, as entered in the previous step of the workflow.

This step is not affected by the implementation of manual calibration, but is added in the task analysis, since it expresses the importance of setting the correct heart rate.

Not critical:
Task does not involve safety. Workflow and user interface are not affected with respect to current way-of-working.: "existing UI of unknown provenance"

Table 17 Prepare scan: set cardiac parameters step

Perform scan

Environment: operator's console
User role: operator
Frequency: multiple times / exam
Safety [N/Y]: N

User goal:
Acquire cardiac triggered scan with reliable R-top detection

Description:
Once VCG calibration is completed, the operator wants to acquire the cardiac triggered scans. He/she expects that R-top detection happens reliably during the scan, such that scans are completed and resulting images are free from cardiac motion artifacts. He/she also expects that actual scan time is close to the indicated scan time (minor difference accepted if HR changes during the scan)

This step is not affected by the implementation of manual calibration, but is added in the task analysis, since it expresses the importance of reliable R-top detection during a scan such that motion artifacts, or scan aborts, will not occur.

Not critical:
Task does not involve safety. Workflow and user interface are not affected with respect to current way-of-working.: "existing UI of unknown provenance"

Table 18 Perform scan step

Monitor VCG signal	
Environment: operator's console	Frequency: multiple times / exam
User role: operator	Safety [N/Y]: N

User goal:
Verify the quality of the VCG signal, in order to intervene if needed

Description:
The operator wants to continuously monitor the VCG signal on the UI. He/she might want to change the imaging strategy if VCG signal changes during the scan (rhythm, strength): change entered heart rate, set different scan parameters, acquire new VCG calibration, modify sensitivity of trigger detection etc.

Design proposal: The UI shall provide clear information about signal strength (e.g. mV indicator in physiology display). If operator chooses to acquire a new VCG calibration, the operator gets clear feedback about which calibration is active. If operator chooses to change the sensitivity of the trigger detection, the operator gets clear feedback about with sensitivity-setting is active.

Not critical:
Task does not involve safety. Way of working is not is affected. Workflow may be enhanced if the additional feedback is provided to the operator, but not using acting on this feedback will not lead to risk

Table 19 Monitor VCG signal step

3.3.3. Feedback on MTTs and HF-RTP regarding Robust ECG Triggering System

See annex II.

3.4. iXR 3D Acquisition

3.4.1. Description of the AdCoS

The 3D Acquisition AdCoS is about the use of an X-ray angiography system during minimally interventional treatments. X-ray image guidance is used and to allow better visualization of the anatomy and planning of

the treatment, a 3D rotational scan is made. Performing such a 3D scan is very complex and requires highly skilled personnel.
It is the aim of this use case to develop an AdCoS that eases the 3D scan procedure by developing an improved HMI that greatly simplifies the workflow.

3.4.1.1. Operational definition

The main tasks in the 3D Acquisition AdCoS are the preparation of the patient and system followed by the actual execution of the 3D scan. An elaborate description of the 3D acquisition workflow has been made in deliverable D6.4.

Failing to do the correct preparation leads to non-optimal scan results, possible collision between C-arm and other equipment leading to unsafe situations and eventually a re-take of the 3D scan.

User goal

It is very important that the patient and system preparation are done correctly, such that the 3D scan can be done safely. Therefore the user goal of the AdCoS is to help the user perform all the necessary preparations by providing him with an HMI that shows the adequate information in an intuitive way.

Information flow

The information flow has been described in a hierarchical task analysis (abbreviated as "HTA" in the following) in which all relevant UI components are included. As part of the HTA an overview of the UI elements is shown in Figure 29.

Inputs:

- TSO: A table side operated module with hardware buttons to control the movements of the patient table and the C-arm
- TSM: A table side mounted touch screen that is used for clinical procedure selection and protocol parameters
- Foot switch: Pedal on the ground that is used by the doctor to start X-ray generation
- Hand switch: A hand switch with the same function as the foot switch is located in the Control Room.

Outputs:

- Exam room monitor: This monitor shows the X-ray images and several system settings. The monitor is not a touch screen and thus will not be used as input device.

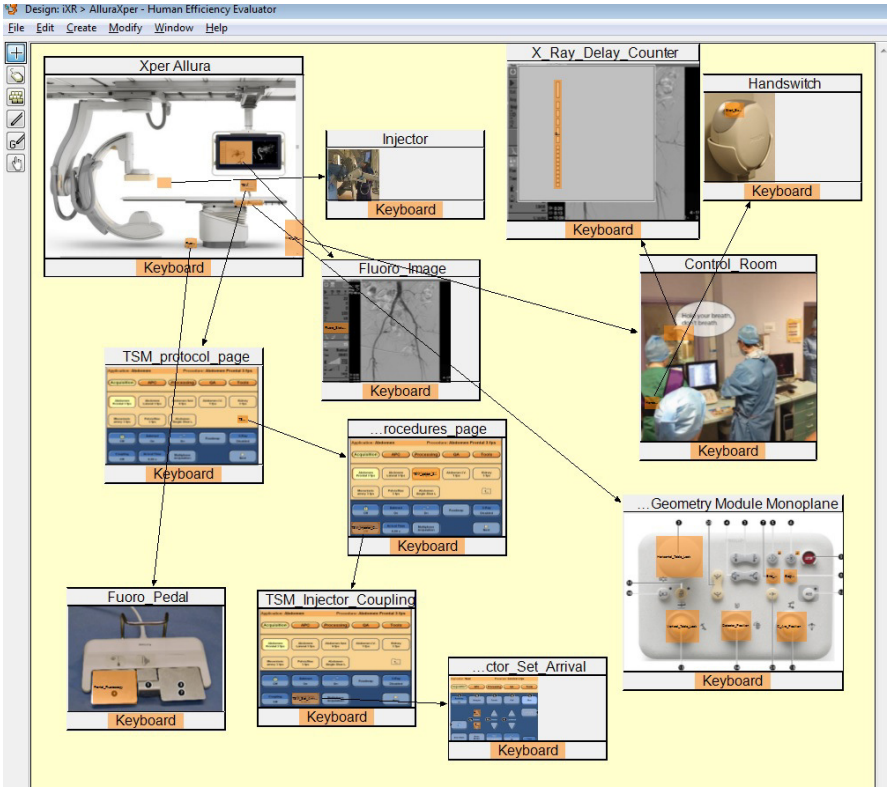


Figure 29 UI elements in the 3D Acquisition AdCoS

3.4.1.2. The environment of the AdCoS

Controlled entity

As can be derived from the user goal description (system and patient preparation), the controlled entity in this AdCoS consists of the X-ray system and the patient. On the one hand the X-ray system needs to be brought into the correct state and position, on the other hand the patient needs to be positioned correctly in order to guarantee a correct and safe 3D scan procedure.

Operator of the AdCoS
Within the interventional X-ray lab there can be two different operators of the AdCoS present:

- Clinical specialist (cardiologist, neurologist)

The clinical specialist usually has an expertise in the treatment of the patient's disease and is not a technical expert in using the X-ray system. As a result the clinical specialist sometimes is not confident in making a 3D scan and needs a more intuitive HMI to help him do the preparations.

- Radiographer

A radiographer is a professional who specialises in the use of medical imaging equipment. He is not specialised in patient's diagnosis and treatment but is usually well educated in the use of the X-ray system.

External environment
The external environment consists of other equipment and staff in the room which are needed for the overall interventional treatment but are not essential in performing the 3D scan. The AdCoS operator needs to take the presence of the equipment and staff into account during the preparation and execution of the 3D scan. Equipment should not be placed in the scan area and wires should be fixed to prevent collision or unwanted removal of wires. Furthermore, the team members also need to make sure they are out of the way for the rotational scan, to clear the area and to prevent any unnecessary X-ray radiation.

Communication between AdCoS and environment
In section 3.4.1.1 the main UI elements are mentioned.

3.4.1.3. Modelling techniques employed

A very important aspect in the 3D Acquisition AdCoS is having a correct understanding of the current workflow and the use of the existing HMI. From this understanding, the bottlenecks and improvement points in both the overall workflow as well as in the HMI can be identified.

Hierarchical Task Analysis
In this AdCoS we have used Human Factors – Hierarchical Task Analysis (HTA) to understand the workflow and the interaction between the various inputs and outputs. The process started with decomposing the existing 3D rotational scan task into lower level tasks and eventually further detailing into atomic tasks. Figure 30 depicts an overview about the entire 3D Acquisition procedure.

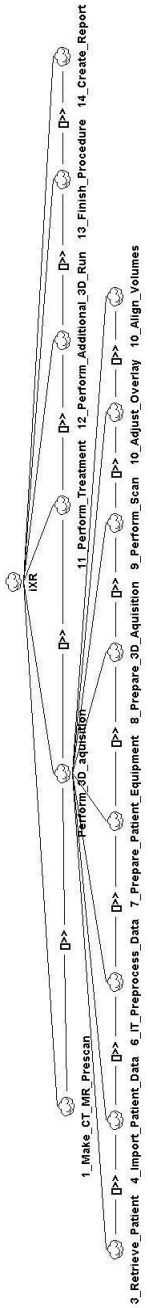


Figure 30 Snapshot of the HTA. Figure rotated to improve readability.

Cognitive Task Analysis
Since the 3D acquisition task is very complex, an important improvement in the AdCoS will be gained by developing an improved HMI. Therefore the cognitive aspects in the interaction between the user and the system HMI have been modelled, leading to an operator model and an environment model. From these models and an early HMI prototype, the prediction of the operator's workload and reaction times can be made.

3.4.1.4. Input to the modelling process from other work packages

As mentioned above the 3D acquisition AdCoS applies hierarchical task analysis to understand, structure and improve the workflow. Furthermore cognitive task analysis and modelling is used to capture the interaction between the user and the HMI. The information from these modelling activities is used in a feedback loop to learn from and to improve the workflow and HMI design.

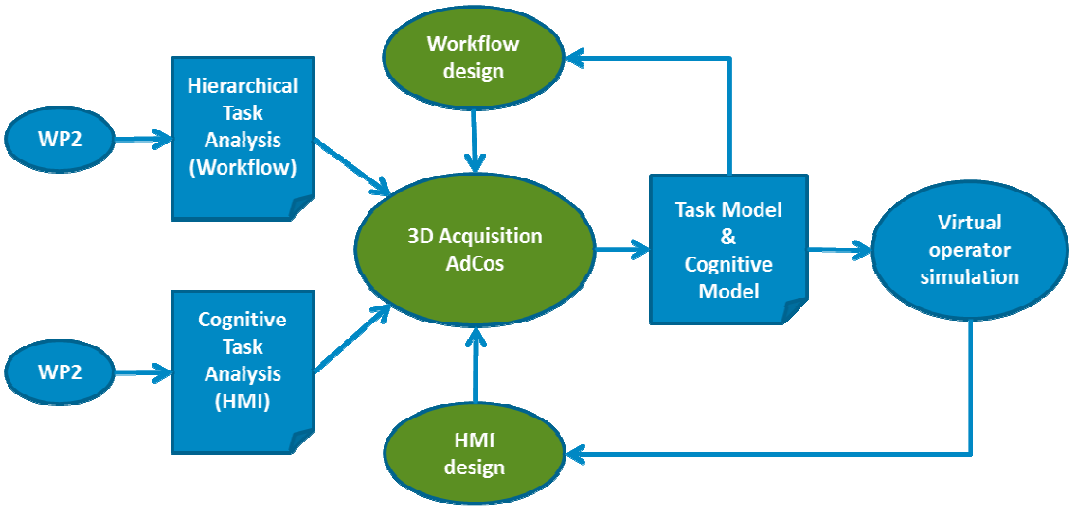


Figure 31 Flow of modelling MTTs related to iXR 3D Acquisition

3.4.2. The model

The focus of the modelling was on improving specific aspects of the current procedure: the patient and system preparation that happens before the actual scan is performed. We therefore concentrated on a further task decomposition especially on those two aspects and ended up with around 120 basic cognitive tasks.

Figure 32 depicts an excerpt of the entire task tree, which describes how the user has to confirm the start position of the C-arc.

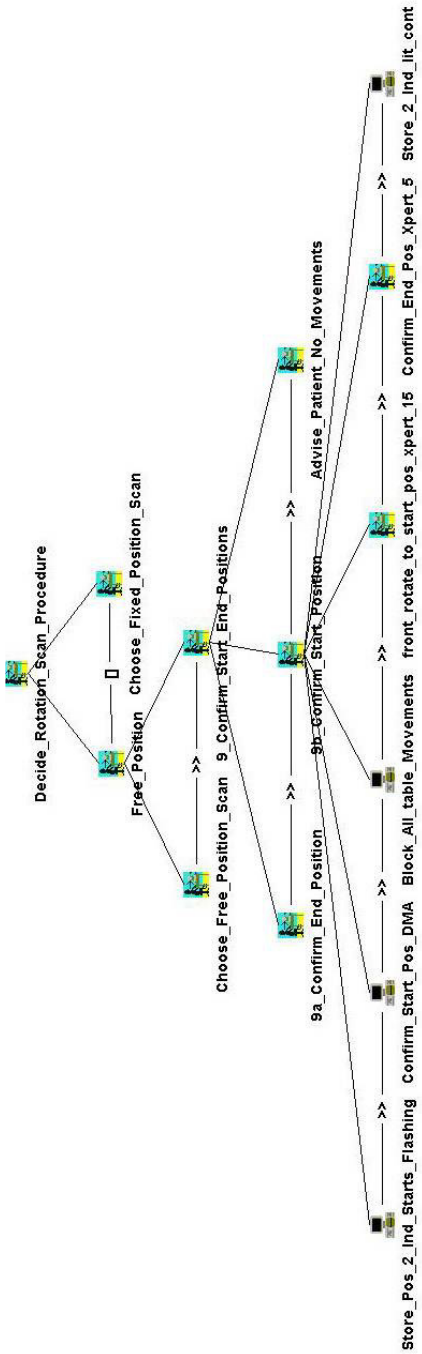


Figure 32 A sub task model describing how to conform the start position of the C-arc. Figure rotated to improve readability.

Figure 33 depicts how the actual scan is performed: The physician first gives breathing instructions to the patient, then presses the exposure button, which disables a safety function (the bodyguard) of the X-ray system. Thereafter the scan is performed and ended by the physician by releasing the exposure button and the C-arc moving back to its initial position.

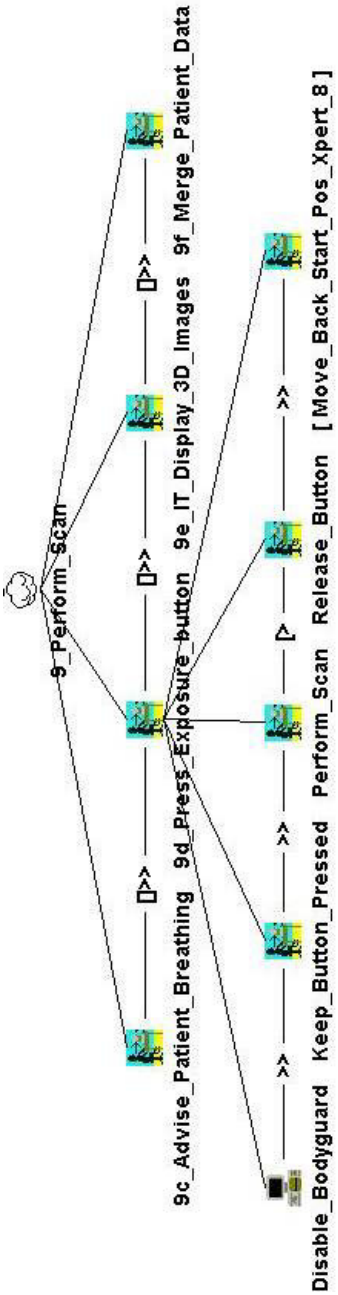


Figure 33 A sub task model of the scan. Figure rotated to improve readability.

The entire task model for the 3D Acquisition procedure is attached as an annex to this document.

3.4.3. Feedback on MTTs and HF-RTP regarding iXR 3D Acquisition

See annex II.

3.5. Querying openEHR data

3.5.1. Description of the AdCoS

This AdCoS has two different approaches:

1. From professional perspective: This AdCoS provides effective access to patient clinical data, EHR (Electronic Health Record), by any authorised physician at any location for fast and full documented medical support.
2. From patient perspective: This AdCoS provides effective remote access for the patient to his or her EHR. In addition, the patients are allowed to modify some data like demographic, habits or personal details in order to keep their information as updated as possible.

3.5.1.1. Operational definition

One main objective is to **improve diagnostic process and treatment** of the patient. For that purpose, the system keeps patient EHR updated and complete, due to, the system joins information from different sources:

1) Clinical details provided by the patient (PHR – Patient Health Records) like demographic details, Habit patterns, family history, etc. and
2) Several patient studies provided by the hospital environment (HIS - Hospital Information Systems) like Radiological studies.

In addition, the system:

1) Encourages a **closer communication between professional and patient** due to a system of messages and alerts and
2) Facilitates the process of requesting **second medical opinions** by sharing clinical reports and radiological studies between professionals.

From the patient point of view, the AdCoS encourages:

1) **Patient motivation**: The patients take a more active and important role in monitoring their own health. Being more aware of their role may make them feel more motivated to maintain a good health.
2) **Patient mobility:** The person may access his or her clinical information from anywhere at any time (with internet access).
3) **Patient satisfaction:** Avoiding patient's unnecessary timeouts and visits to the hospital or care environment, duplicating information, etc.

3.5.1.2. The environment of the AdCoS

One of the requirements which can be found in D6.3, section 3.9.3 Requirements Update, is to provide secure remote access. This means that the operator may access the AdCoS securely at any time from anywhere (with internet connection). It implies that the operator (professional or patient) has to interact with the AdCoS through a web platform, graphical user interfaces (GUI).

Controlled entity

The controlled entity in the case of the Querying openEHR data AdCoS is a web platform which helps professional and patients to perform their task satisfactorily.
This controlled entity ensures a secure and private access, collects data from heterogeneous sources (PACs, PHR, etc.) and displays them in a very simple and easy way taking into account particularities like language, ability to adapt to new technologies or procedures, etc.

Operator of the AdCoS

This AdCoS needs the operator to work; the operator provides continuous inputs through GUIs. This interface allows operator to interact with the AdCoS, once again it is found the importance of enhance the efficiency and ease of use.

It may be important to emphasise the difference between users (operators) in order to make the AdCoS easier to understand; (1) health professional, who provides some type of health care services (diagnosis, advise, curative, rehabilitative, etc.) and (2) patients, who is any recipient of health care services, both interact with the AdCoS, although rather different.

To help health professionals to perform their task the Human Efficiency Evaluator tool from OFFIS has been applied in the most critical part of the workflow, "Display patient Studies". It has enabled us to identify critical points and modify them, for example, it does not make sense to download a study that has not been previously selected, so this option will not visible until one study (DICOM) is selected by the professional.

To help patient users to perform their task satisfactorily this Querying openEHR data AdCoS, takes into account patient characteristics like language, disabilities and their ability to adapt to new technologies, using the keyboard or mouse may not be easy for some older patients.

One advantage is that the interface is independent to the architecture, so the GUI can be easily customised depending on operator, patient age, preferences, etc. design a different "skin" at will, changing the interface as the user needs evolve.

External environment
Since it is possible to connect this AdCoS from anywhere with internet connection and one device like PC or tablet the external environment may significantly change, it makes difficult to identify those elements that may provide disturbing events on the controlled entity.

It should be emphasised that in those cases where the connection is made from the medical consultation or specialist, the environment is very controlled.

For these reasons it is considered that there are not relevant elements of the external environment which may be mentioned related to this AdCoS.

Communication between AdCoS and environment
We must remember that this AdCoS joins DICOM images with patient´s EHR using WADO (Web Access to DICOM Persistent Objects). WADO will connect to the PACs (Picture Archiving and Communication System, as an image server) Therefore, internet access is required, and devices like PC or tablet.

The information will flow from Hospital PACs to the operator, whatever the environment. The communication (data exchange, interactions, etc.) is listed in Table 20.

Data item	Data format	Comment
Patient username	Free text	AdCoS secure access
Patient password	Free text	AdCoS secure access
Display patient main details	Plain text (name, surname, age, etc.)	Main patient details collected from PCAs
Display patient radiological studies	Dicom images	Radiological studies collected from PACs
Display patient clinical report	PDF	Patient clinical reports previously generated in Internal analysis and reporting.
Display clinical details	Plain text	
Display prescriptions	Plain text	Patient prescriptions previously generated by doctor role.

Table 20: Data exchanged in Querying openEHR data AdCoS

3.5.1.3. Modelling techniques employed

In process modelling, the following techniques have been used:

- HEE tool to improve "Display patient Studies" interface,
- Several UML diagrams to visualise and identify components and how they interact with others, etc.
- Scenario description: Free text describing the way that the AdCoS system is envisaged to be used, different roles and their interactions, functionalities and scenarios working in concert with end users and developers.
- Mock-ups: Several mock-ups are provided in order to enable testing the design and acquire feedback from users.

- Modelling of AdCoS from a means end perspective: We are considering using this methodology to model the AdCoS for retrieving the data from the electronic health record taken into account the human factors related to the user.

3.5.1.4. Input to the modelling process from other work packages

As it is described along the sections for the Querying openEHR data AdCoS we are using different techniques for modelling and tools in the interaction between the modules. We used the HEE for the workflow and task modelling and the Data Healer to find inconsistencies in the java source code. To exchange the information between the components we are planning to use AEON. Finally modelling from a means end perspective and the HF Filer will allow us to ease the validation process.

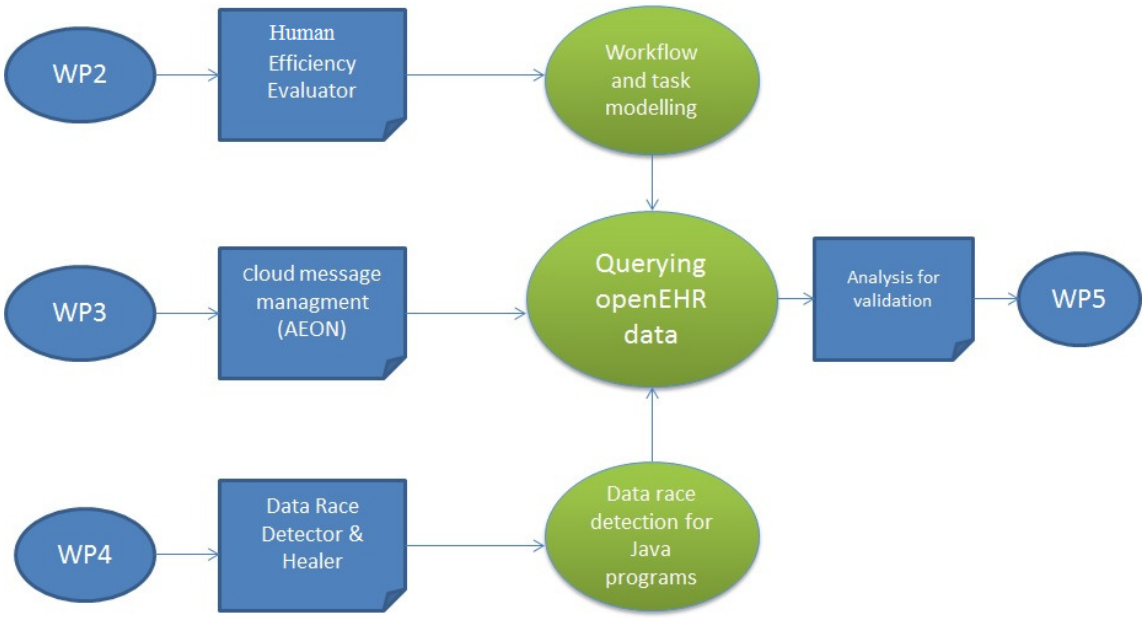


Figure 34 Flow of modelling MTTs related to Querying openEHR data

3.5.2. The model

To describe the model several diagrams are included in this document to show the relevant aspects of the AdCoS, starting with a general overview and going deeper to more specific and relevant aspects.

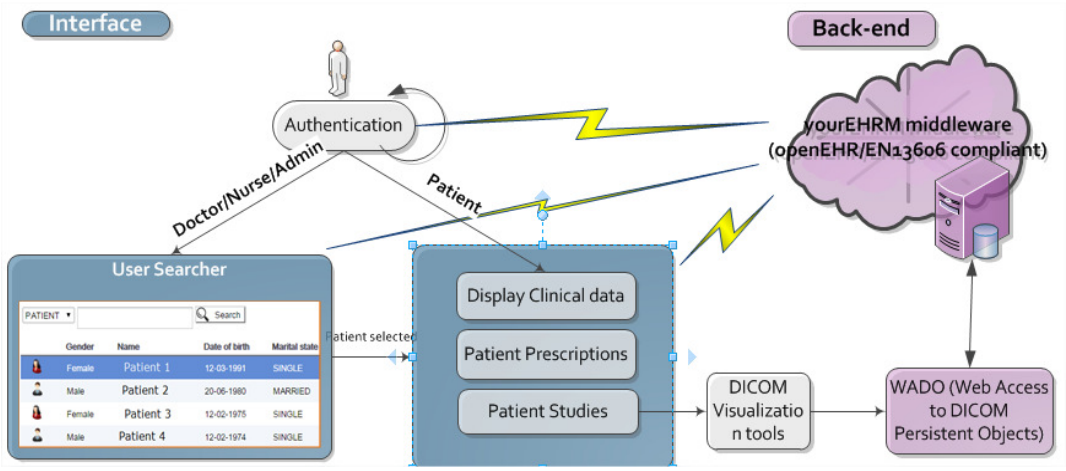


Figure 35: UML diagram; general overview

Now, each module is outlined, focusing on most critical part and those updated from D6.3:

- ✓ Secure Access,
- ✓ Display Clinical Date,
- ✓ Patient studies and
- ✓ Display Patient prescriptions

Secure Access

While the user is not properly identified, the access to the system is not allowed, one secure module has been included: :When the AdCoS receives a username and password from an operator, it performs the hashing operation on the password and compares the resulting hashed value with the password hash stored in the database for the particular user. If the two hashes are an exact match, the user provided a valid username and password. The AdCoS will never store the clear text password. It stores only the hashed value. The number of attempt will be also restricted.

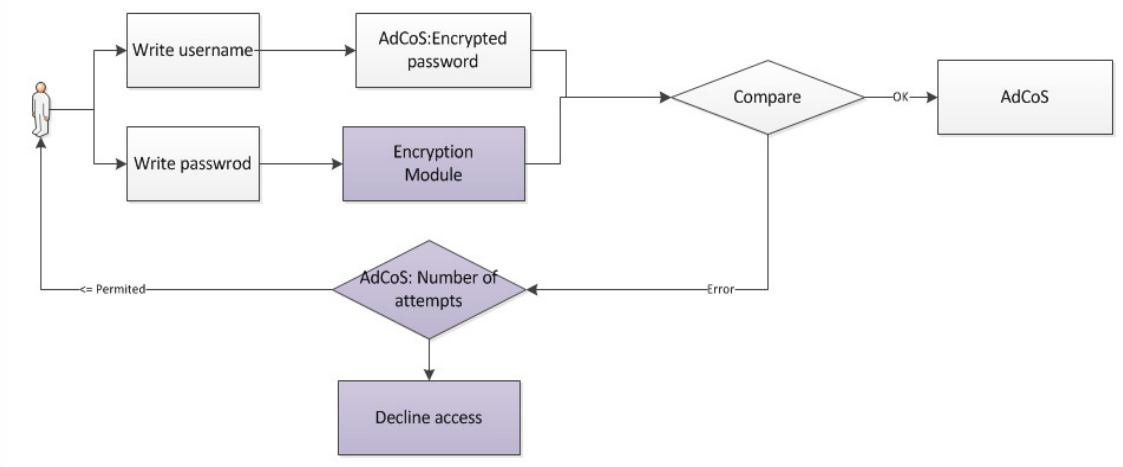


Figure 36: Diagram of use case "Secure access"

Display Clinical data

Once (1) the doctor selects a patient to work with or (2) a patient is logged into the system, it displays all patient (selected/logged) clinical details.

Doctors and patients are allowed to update any information on it as you can see on Figure 37.

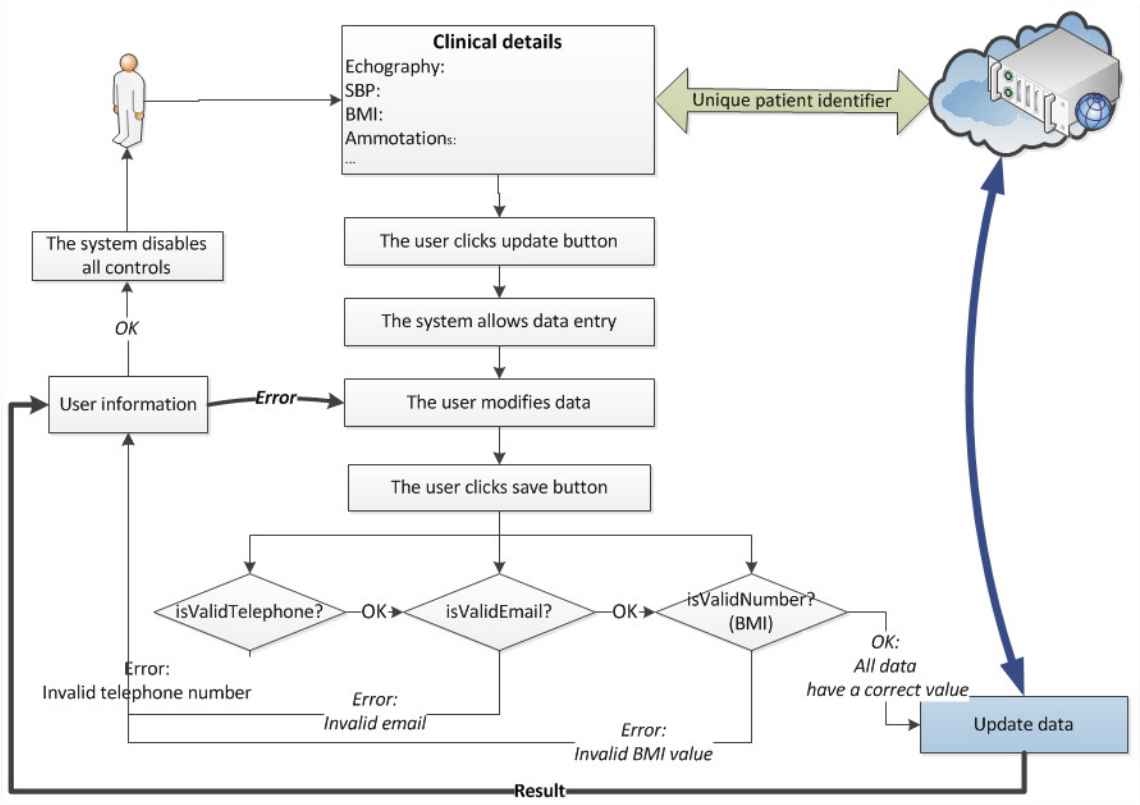


Figure 37: Diagram of use case "Display clinical data"

Display Patient studies

The user (doctor, nurse or patient) is allowed to access to patient studies (DICOM images).

As a reminder, a specific patient´s study contains series of related DICOM images, each of them with certain information associated (name, date, type, etc.).

It provides a GUI which is capable to deploy these studies, apply filters, zoom the image, scroll through the whole series, etc.

It is also possible to create a preview image (PNG format). These images can be attached to any clinical patient as you can see on Figure 38.

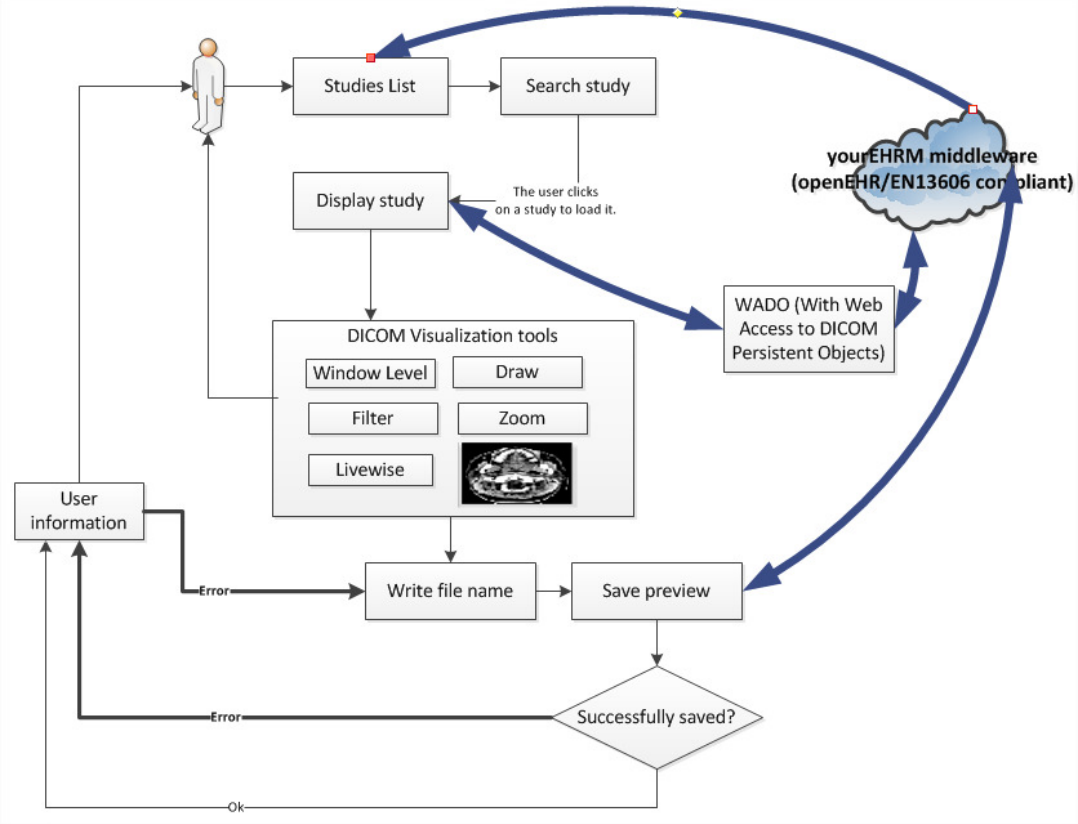


Figure 38: Diagram of use case "Patients studies (DCM images) display"

Display Patient studies use case has been identified as the most critical part of the whole workflow, therefore, the HEE has be applied in this use case.

The idea is to use HEE in order to choose and design the most appropriate interface. In order to improve the model, it would have been interesting to know HEE customised statics by age, gender, profession, etc. It is important in order to enhance the efficiency and ease of use keeping in mind that patients with many different characteristics may connect to this AdCoS.

In the following, an example is used to explain the use of HEE in Display Patient studies use case, the Figure 39 shows the first mock-up designed.

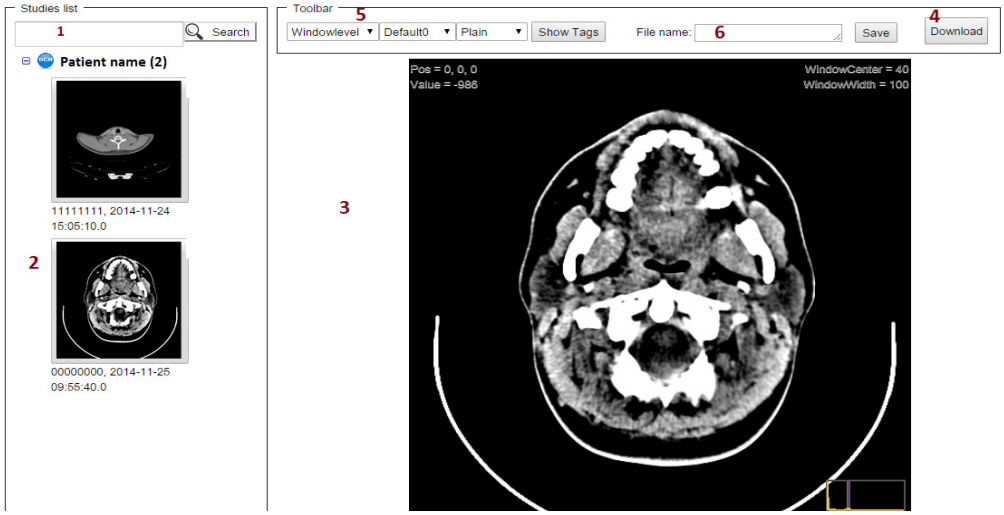
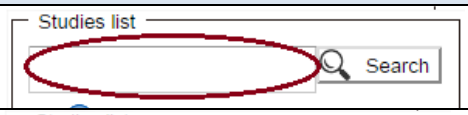
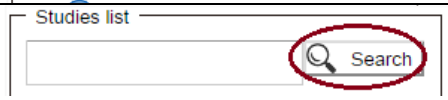
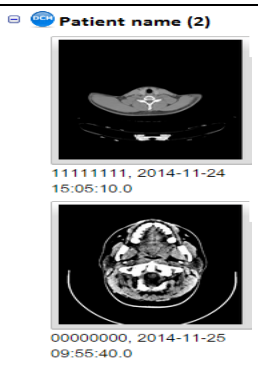


Figure 39: Patient studies GUI, option one.

The approach can be described as comprised of the steps outlined below.

1. Mock up the UI: See Figure 39.
2. Identify the tasks: The red numbers in Figure 39 represents the logical linear sequence of tasks, deeply described in Table 21.
3. Create a table with the task sequence: See Table 21.

Task	Interaction Screen or panel 1	Interaction Screen or panel 1	Comment
Enter user search criteria			
Click on "Search"			The system get result and display them

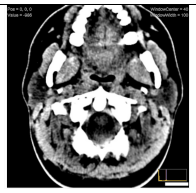
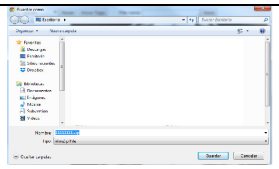
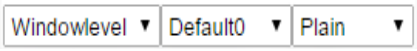
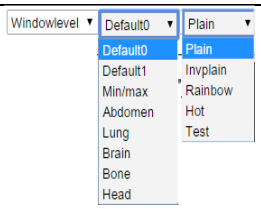
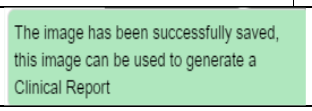
Click on an image preview			The system gets the series of related DICOM images and displays them
Click on "Download"			The system (after creating a zip file) ask the user Where to save the full study
DICOM options			The system changes the Window and Level of the image depending on options automaticall y.
Enter file name			
Click on "Save"			

Table 21: Patient Studies, sequential task breakdown and associated UI parts.

The most complicated issue we have found is that it is not a linear sequence of tasks, even if there is a logical sequence, the user may use any alternative path at any moment. Seems to be more useful to analyse the whole GUI and not go so deeply through atomic tasks.

This procedure is the previous necessary steps before applying HEE tool.

Display Patient prescriptions

In this section we are allowed to display patient prescriptions. The plan of care consists of name, beginning and end date, frequency, dose and units and also information on which doctor made the prescription as you can see on Figure 40.

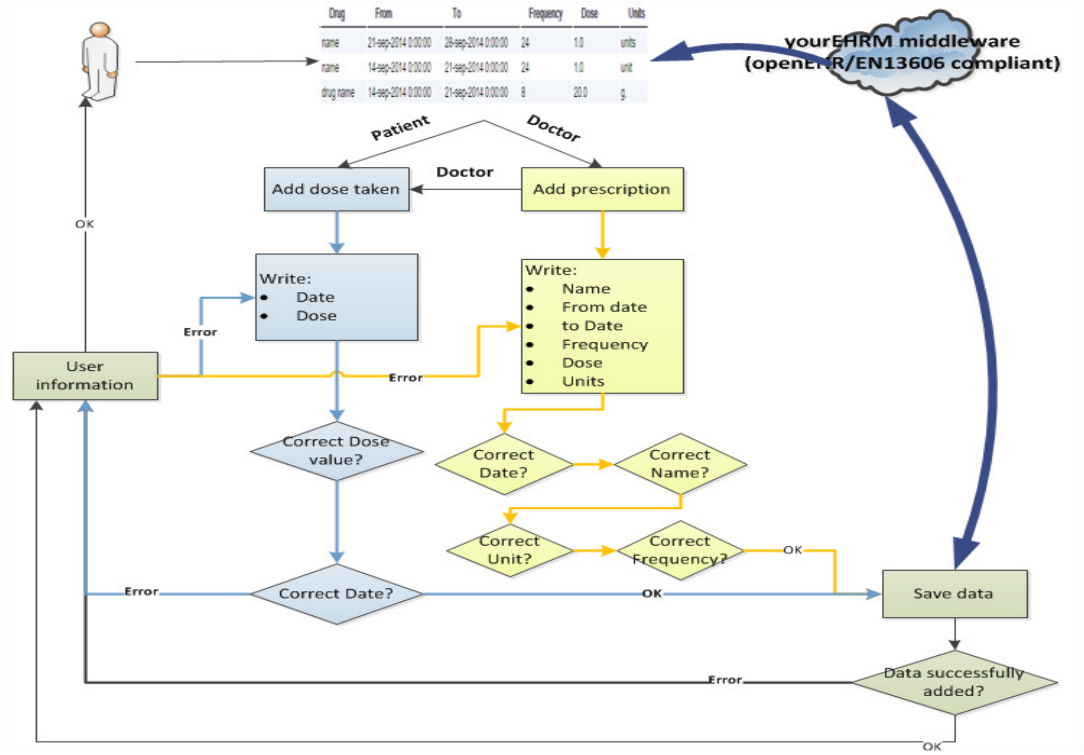


Figure 40: Diagram of use case "Patient´s prescription".

A qualified practitioner is allowed to add a prescription (yellow) to a selected patient and the patient is allowed to add his/her dose taken (date and time –blue).

Regarding the tools:

- AEON will be used to exchange information between the systems we will use the cloud message capability of AEON.
- Data Race Detector & Healer. We are considering using this tool to detect and heal data races and atomicity violations in the use of the GUI (same doctor accessing the same EHR or image).

3.5.3. Feedback on MTTs and HF-RTP regarding Querying openEHR data

See annex II.

3.6. Internal analysis and reporting

3.6.1. Description of the AdCoS

Internal analysis and reporting AdCoS provides professional access to the patient data for statistical analysis of pathologies and generates clinical reports based on data coming from heterogeneous and fragmented healthcare information systems.

3.6.1.1. Operational definition

From D6.3 had been defined the main objective of this AdCoS:

1. **Generate internal clinical report**: This report allows analysing possible causes that has brought a certain patient to the hospital by comparing and analysing data with other patients in order to avoid possible future illness. This report is internal to the hospital and includes risk analysis, predictions, etc.

2. **Generate patient clinical report**: The system allows generating patient clinical reports in order to provide a general overview of his/her health status. This report includes clinical patient data. MRI, Lab Tests, prescriptions, etc., any EHR data that the professional considered desirable.

Internal clinical reports help the professional to get a **better understanding of patient behaviour** (risk, predictions, etc.). The AdCoS allows the professional to select a group of patients with similar diseases or characteristic. Once the group of patients is selected by the professional, the AdCoS, making use of predictive analytics tools, automatically generates an internal clinical report with risks factors, predictions and hidden patterns. It is from this time that the report is accessible for any authorised physicians.

Patient clinical reports help the user to avoid or **reduce unnecessary patient visits to the hospital** in order to collect his/her medical results the AdCoS provides:

- Secure patient access; the authorised patient get into the system.
- Patient clinical report list; the system displays patient clinical reports order by date, the last generated first, report name and date of generation.
- Patient clinical report displayed: by just clicking on the report name it is automatically displayed.

In addition, **it removes external devices** such DVD or CD to store medical result or paper, clinical patient reports may contain medical images (DICOM).

It is important to highlight that all clinical reports are generated following requirement specified on D6.3, section 3.9.3 Requirements Update, with special importance given to those related to customization.

The biggest challenge is to generate statistical reports where predictions and machine learning are involved. Initially, tools like rapid-miner or Weka (free software tools for developing data mining models) were studied. At this moment, and after acquiring a deeper understanding, tools like **Supervised learning LEA** and **Data mining APA** are better decisions.

3.6.1.2. The environment of the AdCoS

Ono of the requirements which can be found on D6.3, section 3.9.3 "Requirements Update" is related to secure remote access; the system MUST allow a remote consultation (out from hospital environment).It means, that the operator may access to the AdCoS at anytime from anywhere (with internet connection). The operator will interact with the AdCoS through a web platform, graphical user interfaces (GUI).

Controlled entity

The controlled entity in the case of the Internal analysis and reporting AdCoS is a web platform which helps professionals to generate smart and customised reports satisfactorily.

This controlled entity ensures a secure and private access, collects data from heterogeneous sources (PACs, PHR, etc.) and generates a clinical report following doctor's needs.

Operator of the AdCoS
The main users (operators) in this AdCoS are the health professionals, who generate statistical report. To help the health professional to perform their task this AdCoS take into account usability concepts. Usability is the ease of use, learnability and usefulness.

Usability is about designing products to be effective, efficient, and satisfying. Usability is part of the human-computer interaction (HCI) research and design field. A key aspect of usability is following a user-centred design (UCD) process to create positive user experiences. User-centred design (UCD) focuses on usability goals, user characteristics, environment, tasks, and workflow in designing a user interface to meet user requirements.[i]

To generate statistical report the operator has to:

- ✓ Get into the system
- ✓ Select a group of patients with similar diseases or characteristic
- ✓ Click to generate statistical report

To generate Patient report the operator has to:

- ✓ *Get into the system*
- ✓ *Select one patient*
- ✓ *Click to generate clinical report*
- ✓ *Select data to be included*

External environment
Since it is possible to connect this AdCoS through several GUI, the external environment may be anywhere with internet connection and one equipment like PC or tablet. Although, we can assume that in many cases the connection will be made from the medical consultation or specialist, it means in a very controlled environment.

In this AdCoS the external environment is not relevant.

Communication between AdCoS and environment
Internet access is required, and devices like PC or tablet in order to connect to the web Side.

The information will flow from Hospital PACs to the operator, whatever the environment. The communication (data exchange, interactions, etc.) is listed in Table 22.

Data item	Data format	Comment
Patient username	Free text	AdCoS secure access
Patient password	Free text	AdCoS secure access
Display patient main details	Plain text (name, surname, age, etc.)	Main patient details collected from PCAs
Display patient radiological studies	Dicom images	Radiological studies collected from PACs
Display patient clinical report	PDF	Patient clinical reports previously generated in Internal analysis and reporting.
Display clinical details	Plain text	
Display prescriptions	Plain text	Patient prescriptions previously generated by doctor role.
Generate Patient clinical report	PDF	The doctor selects all information to be included into the report
Generate Statistical report.	PDF	

Table 22: Data exchanged in internal analysis and reporting AdCoS

3.6.1.3. Modelling techniques employed

In process modelling, the following techniques have been used:

- Several UML diagrams to visualise and identify components and how they interact with others, etc.
- Scenario description: Free text describing the way that the AdCoS system is envisaged to be used, different roles and their interactions, functionalities and scenarios working in concert with end users and developers.
- Mock-ups: Several mock-ups are provided in order to enable testing the design and acquire feedback from users.
- Modelling of AdCoS from a means end perspective: We are considering using this methodology to model the AdCoS for retrieving the data from the electronic health record taken into account the human factors related to the user.

3.6.1.4. Input to the modelling process from other work packages

To model Internal analysis and reporting AdCoS different techniques and tools had been used.

We used the HEE for the workflow and task modelling and the Data Healer to find inconsistencies in the java source code. **APA** and **LEA** will be included to generate internal clinical reports.

To exchange information between the components we are planning to use **AEON**. Finally modelling from a means end perspective and the HF Filer will allow us the validation process.

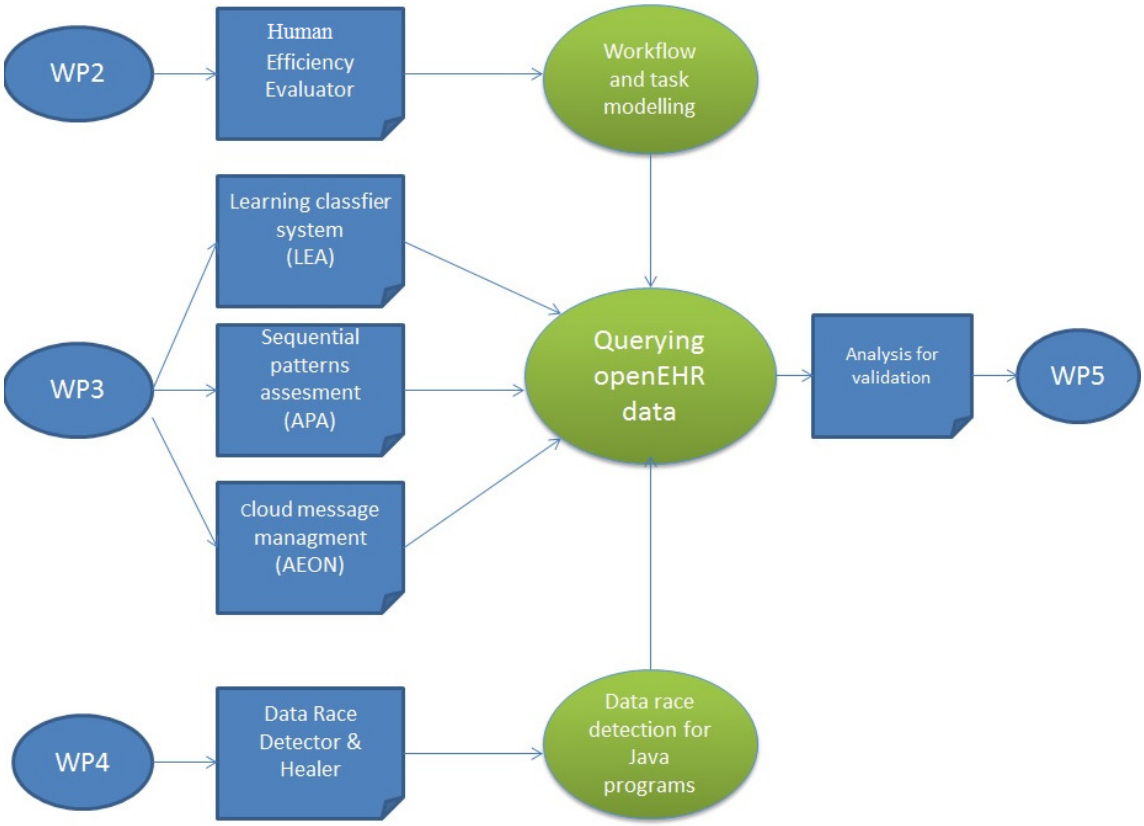


Figure 41 Flow of modelling MTTs related to Internal analysis and reporting

3.6.2. The model

To describe the model several diagrams are included in this document to show the relevant aspects of the AdCoS, starting with a general overview and going deeper to more specific and relevant aspects as you can see on Figure 42.

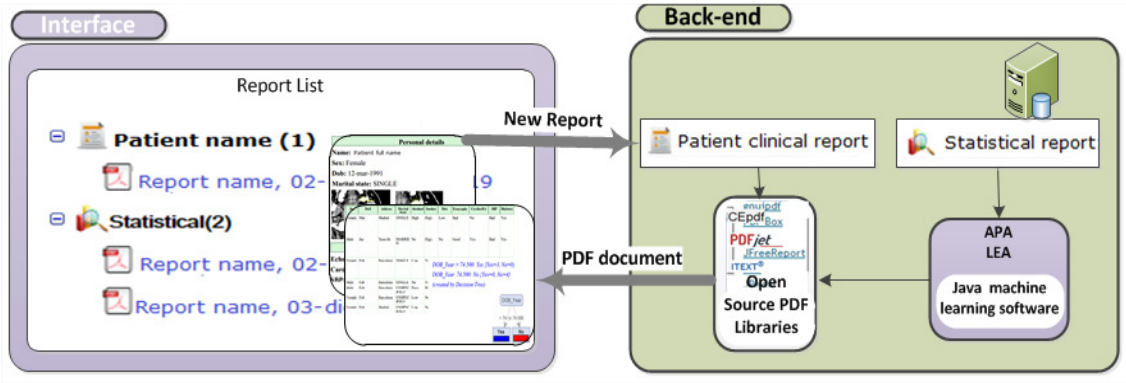


Figure 42: General diagram of Analysis and reporting AdCoS.

UML diagram in Figure 43 gives details of the process:

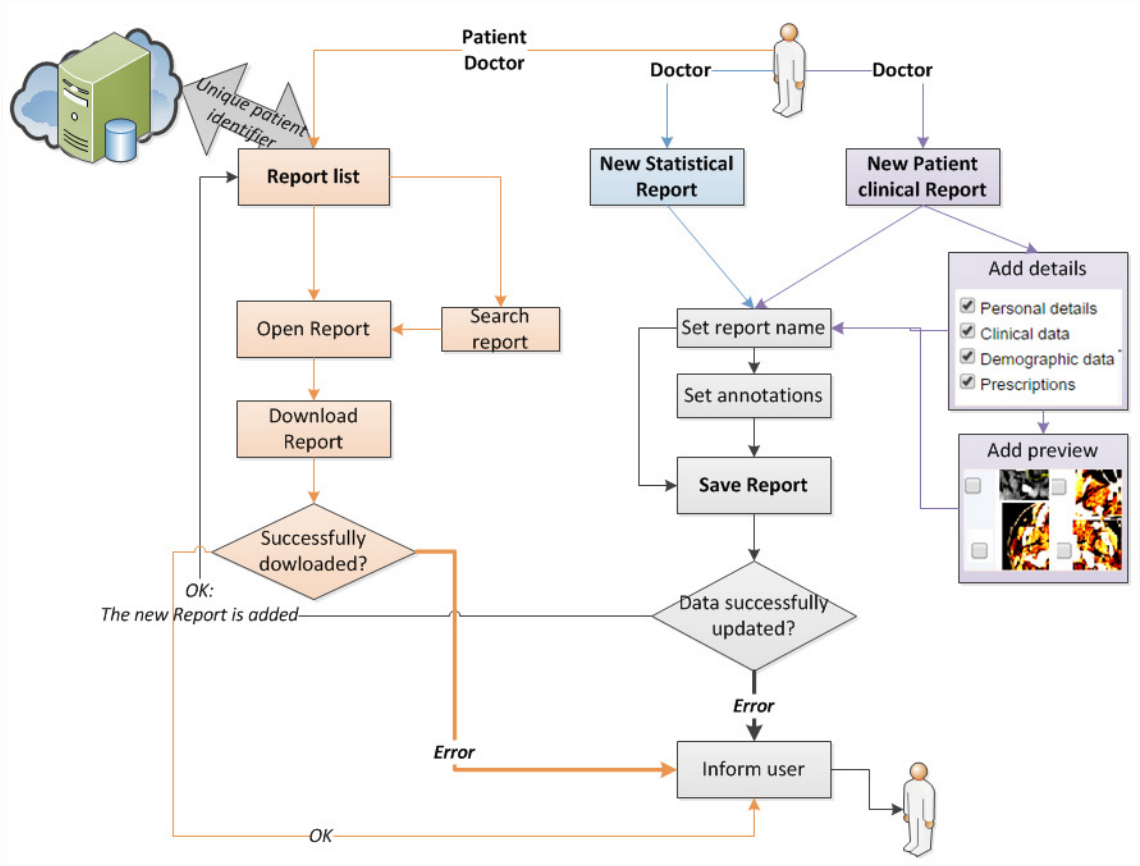


Figure 43: UML Diagram of use case "Analysis and reporting".

3.6.3. Feedback on MTTs and HF-RTP regarding Internal analysis and reporting

See annex II.

3.7. Operator task schedule and guidance

3.7.1. Description of the AdCoS

The workflow for operators in medical environment (nurses, physicians…) comprises very complex procedures with many factors that influence the execution of tasks, such as unexpected events that make it difficult to accomplish a pre-organised plan. Informal process at hospital is very

common. For instance, short disruptions of daily tasks of nurses are usual in hospital. When the number of small interruptions outweighs the amount of planned work done in a given hour, that impact is felt as slower progress, lower job satisfaction, and potentially lower quality of care.

3.7.1.1. Operational definition

The main objective of this AdCoS had been defined from D6.3, and basically, it aims to ease the development of workflow solution for hospital focused on the following aspect:

- To support the proper assignment of task in a clinical laboratory environment to the operators
- To provide real time instructions – trigger alarms – reminders and check points
- To optimise the workflow and cooperation with rest of operators
- To provide feedback to our AdCoS system for further refinement of decision algorithms

Given the broad scope of workflows, we will focus on a subset of functionalities: Our application focused on a **prototype implementation** of a dynamic system that helps hospital operators to carry out their daily tasks.

Our intention is to implement a simulation tool that helps us to pre-validate the implementation of an AdCoS, before the full implementation on real hospital is carried out.

The basic functionalities are:

- To help to assign/re-assign tasks to operators
- To give context-aware instructions to operators

For those functionalities, different user interfaces are foreseen: Tablet, smartphone, smart-watch.

The high level objectives are:

- To improve the efficiency of activity management in Hospital
- To ensure the usability of the system: satisfaction of operators, instructors and patient.
- To accomplish strict requirement of hospitals procedure in terms of patient safety.

In D6.3, section 3.1.2, there is a detailed description of the application we propose in this use case. It specified the interaction between operators and the application. In addition, the following use cases describe the operational perspective of this AdCoS from end user perspective:

Use case name	User Login
Primary actor	Laboratory technician
Scope	The access based on authentication by credential for each user to the application workspace.
Level	Subfunction use case
Goal/ Description	The goal is to get access to the application workspace. This access must ensure privacy, be unique and secure for each user registered in the application. The workspace will be independent for each user so that the information provided for the application will be specifically addressed to the registered user.
Trigger	The beginning of workday of the user. The user clicks on the icon of the application in the tablet.
Assumptions/ preconditions	Previously, user has to be registered in database correctly
Minimal guarantees	The user gets access for the application workspace.
Success guarantee	The user gets access for the application workspace.
Steps/Main success scenario	1. The user starts the application in the tablet. 2. The user introduces their username. 3. The user introduces their password. 4. The user clicks the button to check the application
Extensions	1. If the application fails during the boot, the user will force the closure and restart the application. If it fails again, the user will phone the application technician for the reparation. 2. If the credentials are not correct, the user will contact the administrator of the application for the request of new credentials.

Table 23 *User Login* use case from Operator task schedule and guidance

Figure 44: Mock-up of Login screen.

Use case name	Main Menu
Primary actor	Laboratory technician
Scope	The main menu of the application
Level	Subfunction use case
Goal/ Description	The main goal is to provide a menu that allows user to access all functionalities of the application.
Trigger	The user completes the login process
Assumptions/ preconditions	User is registered and logged in the system Previously, tasks and its associated content are assigned to operators in the database. Mobile application bound to smartphone
Minimal guarantees	The menu is shown to user
Success guarantee	The menu is shown to user

Table 24 *Main Menu* use case from Operator task schedule and guidance

Figure 45: Mock-up of *Main Menu* screen.

Use case name	Task Menu
Primary actor	Laboratory technician
Scope	The task menu for associated content for a task
Level	Subfunction use case
Goal/ Description	The main goal is to provide a menu to provide access to the associated content for a task like the subtask list or detailed information about the task (methods).
Trigger	The user clicks on a task.
Assumptions/ preconditions	User is registered and logged in the system Previously, tasks and its associated content are assigned to operators in the database. Associated content to the task is in the database
Minimal guarantees	The task menu is shown to user
Success guarantee	The task menu is shown to user

Table 25 *Task Menu* use case from Operator task schedule and guidance

Figure 46: Mock-up of *Task Menu* screen.

Use case name	Subtask List
Primary actor	Laboratory technician
Scope	Visualization of the subtask list for a task.
Level	Subfunction use case
Goal/ Description	The goal is to visualise the subtask list associated to a task. The elements of the list can be marked as completed.
Trigger	The user selects a task in the menu and click on subtask list.
Assumptions/ preconditions	User is registered and logged in the system Task has associated subtasks.
Minimal guarantees	The user shall be able to access to the subtask list.
Success guarantee	The user shall be able to access to the subtask list.
Steps/Main success scenario	1. The user clicks on the task to mark it as completed.

Table 26 Subtask List use case from Operator task schedule and guidance

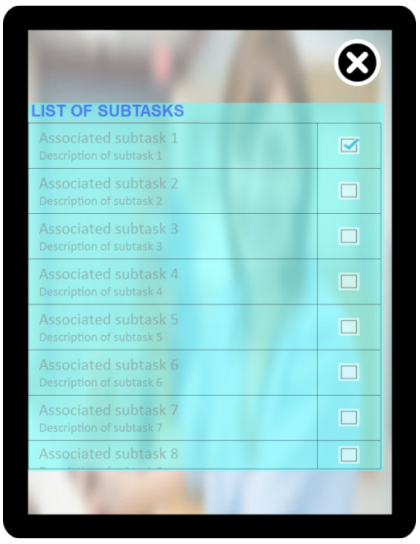


Figure 47: Mock-up of *Subtask List* screen.

Use case name	Modification of the state of a task
Primary actor	Laboratory technician
Scope	The modification of the state of a task assigned
Level	User goal use case
Goal/ Description	The user shall be able to modify the state of each task assigned by the workspace throughout the workday
Trigger	The user starts, finish or pause the activity related with a task. The user touches the clickable icon that indicates the status of the task from the main screen menu. Selecting this icon will open the "confirmed task" screen.
Assumptions/ preconditions	User is registered and logged in the system User is assigned to tasks Task are assigned to operators
Minimal guarantees	The user changes the state of a task.
Success guarantee	The user changes the state of a task.
Steps/Main success scenario	The user selects the new state of the task in order to save the value in the server.
Extensions	If there is no wireless connection available, it would not be possible to modify the status of a task in the server.
Variations	It is possible for the user to choose one status: started, suspended, resumed or completed.

Table 27 *Modification state* use case from Operator task schedule and guidance

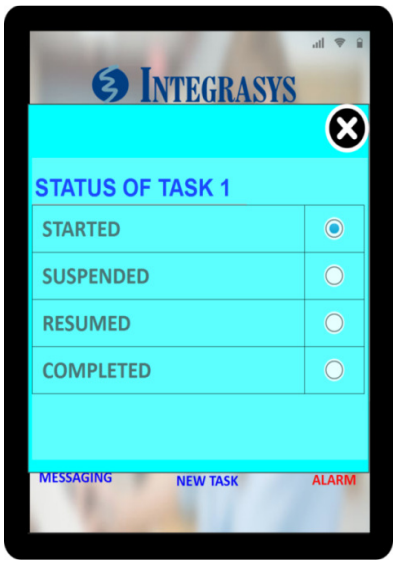


Figure 48: Mock-up of *Modification of the state of a task screen*.

Use case	Insert of new task
Primary actor	Laboratory technician
Scope	The insertion of a new task in the database
Level	Subfunction use case
Goal/ Description	The user shall be able to add new tasks, and add it to the task list in the correct position. This functionality is flexible enough. The user will select from a predefined list of tasks, or insert a new task, which is not registered previously in the database.
Trigger	A not planned event needs to be added. The user touches the clickable icon to create a new task in the main menu.
Assumptions	User is registered and logged in the system
Minimal	The user creates a new task in the database.
Success	The user creates a new task in the database.
Main success scenario	1. The user chooses one from the predefined list of task. 2. The user saves the task clicking in the button.
Extensions	N/A
Variations	1. The user chooses that the task is not registered. 2. The user inserts the name of the task 3. The user inserts a brief description of the task. 4. The user sets the estimated duration of the task. 5. The user defines the patient for who needs the task (if it has a patient associated) 6. The user inserts the department assigned to the task (if it is applicable).The user defines if the task is planned or not.The user saves the task clicking in the button.

Table 28 *New task* use case from Operator task schedule and guidance

Figure 49: Mock-up of *Insert New Task* screen.

Use case name	Send alarm
Primary actor	Laboratory technician
Scope	The sending of an alarm in emergency cases to different actors.
Level	Subfunction use case
Goal/ Description	The operator is able to send an alarm to: - Instructor/managers - All the team - Operator in the nearby - Individual colleagues
Trigger	It is an emergency case and the user needs to send an alarm to get help. The user clicks on alarm button in the main menu.
Assumptions/ preconditions	Prioritization of this message with respect to other ones User is registered and logged in the system
Minimal guarantees	The user sends an alarm.
Success guarantee	The user sends an alarm.
Steps/Main success scenario	1. The user selects the person or group who will receive the alarm. 2. The user writes the information about the alarm (brief description, text or voice)

	3. The user clicks on the button for send it
Extensions	N/A
Variations	N/A

Table 29 *Sending alarm* use case from Operator task schedule and guidance

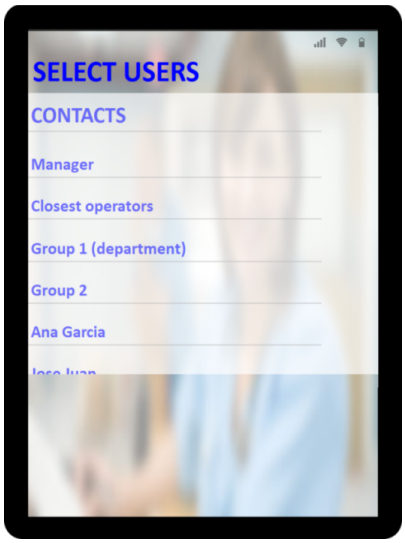


Figure 50: Mock-up of *Send Alarm* screen.

Use case name	Sending a message
Primary actor	Laboratory technician
Scope	The sending of a message to a colleague.
Level	Subfunction use case
Goal/ Description	The objective is to perform a secure messaging application that helps medical staff to coordinate care and collaborate on cases and efficiently manage communication over the continuum of care. It would allow to connect to other colleagues, asking for support or providing information. The application would support text/voice/images. Users are retrieved from the database. It allows individual and group communication.
Trigger	The user needs to communicate something to a colleague. The user clicks on the messaging button from the main menu.
Assumptions/ preconditions	User is registered and logged in the system
Minimal guarantees	The user sends a message correctly.

Success guarantee	The user sends a message correctly

Table 30 *Sending message* use case from Operator task schedule and guidance

Use case name	Reception of an alarm
Primary actor	Laboratory technician
Scope	The reception of an alarm created by a colleague in emergency cases and redistributed by the system. Also, includes the reply of the user.
Level	Subfunction use case
Goal/ Description	The main goal is to allow users to receive and answer to alarms. The basic information is the position of the operators that generates the alarm, and the text/voice message. The operator will be able to indicate whether he is available to assist the alarm, and in the same interface also is shown the colleagues that already confirmed that can help.
Trigger	This interface is triggered by an alarm sent by other colleagues.
Assumptions/ preconditions	The user is logged and the application is running.
Minimal guarantees	The user shall be able to receive an alarm and to reply it.
Success guarantee	The user shall be able to receive an alarm and to reply it.
Steps/Main success scenario	1. The application informs users that an alarm has been generated producing sound and vibration. 2. The user opens the application and reads the alarms. 3. The user replies the alarm.

Table 31 *Alarm reception* use case from Operator task schedule and guidance

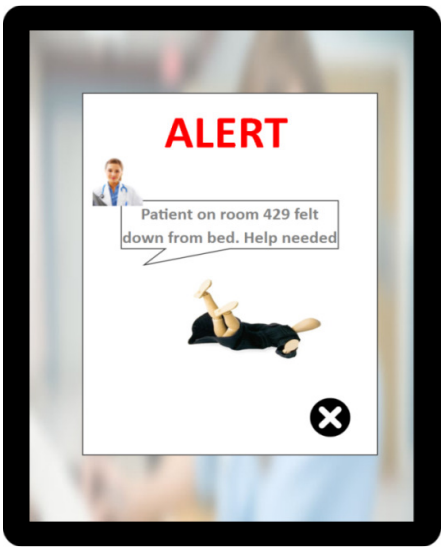


Figure 51: Mock-up of *Reception of an alarm* screen.

Use case name	Reception of a message
Primary actor	Laboratory technician
Scope	The reception of a message from a colleague.
Level	Subfunction use case
Goal/ Description	The objective is to perform a secure messaging application that helps medical staff to coordinate care and collaborate on cases and efficiently manage communication over the continuum of care. It would allow to connect to other colleagues, asking for support or providing information. The application would support text/voice/images. Users are retrieved from the database. It allows individual and group communication
Trigger	The messaging application receives a
Assumptions/ preconditions	User is registered and logged in the system. The application is running.
Minimal guarantees	The user shall be able to read the message received.
Success guarantee	The user shall be able to read the message received
Steps/Main success scenario	1. The messaging application informs the user of the new message received using the vibration (no sound). 2. The user uses the scroll access for display the message and read it.

Table 32 *Message reception* use case from Operator task schedule and guidance

The mock-up is similar to the one presented for alarm reception

Use case name	Workflow management
Primary actor	Laboratory supervisor
Scope	The management of the workflow in the server side
Level	Overall management functionalities for the supervisor.
Goal/ Description	This use case includes several sub-use cases that will be detailed in next stage, since we need to defined the information model. It encloses registration /modification/removal of tasks, users, validation of assigned workflow, visualization of task status, and access to information for further analysis
Trigger	The supervisor logs in to the system with their credentials
Assumptions/ preconditions	The user must have access to the management tool.
Minimal guarantees	At least validations of assigned workflow and access to task status is mandatory
Success guarantee	All functionality should be available for the supervisor.
Steps/Main success scenario	The user gets into the management system and access to the graphical interface with all the functionalities.

Table 33 *Workflow use case* from Operator task schedule and guidance

There is no still mock-up for this workflow use case.

3.7.1.2. The environment of the AdCoS

Controlled entity
The controlled entity if this AdCoS are the operators of the laboratory. In our case we collaborate with the automatised and robotised laboratory in the Hospital Macarena of Seville.

Operator of the AdCoS
In our use case, the AdCoS helps operators to control an automatised and robotised laboratory in the Hospital Macarena of Seville. The Automated

Laboratory of Biochemistry General (SAR) processes daily about 2,000 serum samples, 200 urine and 400 samples of glycated haemoglobin. In the laboratory work: 6 laboratory technicians (TEL) in the morning shift and 3 in the afternoon shift.

There are two sample managers that feed and get out the samples from the chain, three analysers for serum samples and urine (called ADVIA) and 3 analysers for glycated haemoglobin (called HbA1c).

The following figure depicts the infrastructure of the laboratory that we consider in HoliDes:

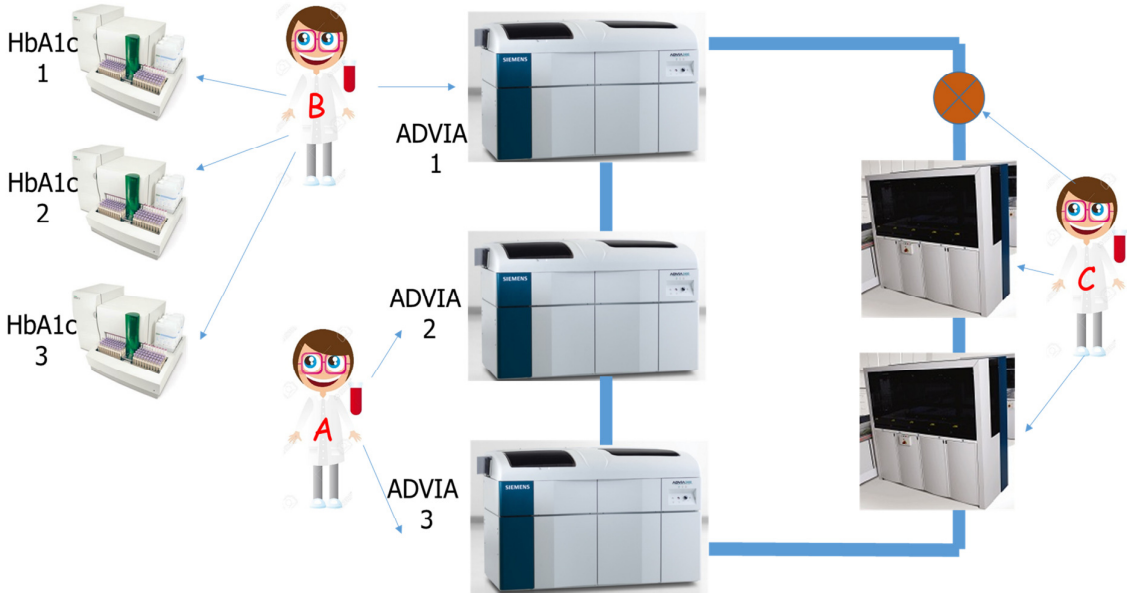


Figure 52 The entities of the AdCoS *Operator task schedule and guidance*

Communication between AdCoS and environment

In subsection *3.6.1.1* Operational definition, we describe how the operator interacts with the application. The application allows the communication among operators, and the tasks that compose the workflow are store in a database. Wireless communication is foreseen for the distributed communication between operators and systems.

The mock-ups we already displayed in the description of the use cases (see section *3.6.1.1* Operational definition), are also part of the specification of the *communication between AdCoS and environment*.

In section 3.7.2 *The model*, we include sequence diagrams that specify the interaction between the user, the application, server and database.

3.7.1.3. Modelling techniques employed

Up to now we have used the following techniques to model the application:

- Scenario description: Free text where we tell a story about a work day of operators
- Use cases: Use case specifications, to describe the interaction between end users and the application
- Mock-ups: We provide pictures and explain the interaction with the user interfaces.
- High level architecture, where we enumerate the different entities that take part of the scenario(reported in D6.3).

Moreover, we use questionnaires to capture the requirements of the end users.

In addition, we are also working in other techniques such as:

- sequence diagram, since it help you discover architectural, interface and logic)
- task modelling and workflow diagrams, to express the relations between the different task, its constrained and its time dimension, and
- Information Model, to identify and model all entities and ease the implementation of the prototype.

3.7.1.4. Input to the modelling process from other work packages

At the current stage we have assessed tools mainly from WP2. The initially assessed tools were GreatSPN, HEE and the task modelling approach proposed in WP2, with the MagicDraw tool and MagicPED plugin. We also explore the use of RTMAPS as potential simulation engine.

We gave first feedback. The results were reported in D6.4. In next section, we make a more conscious usage of the task modelling process and GreatSPN tools.

3.7.2. The model

For this use case, we propose modelling and development process explained in deliverable D6.4 and summarise in Figure 53:

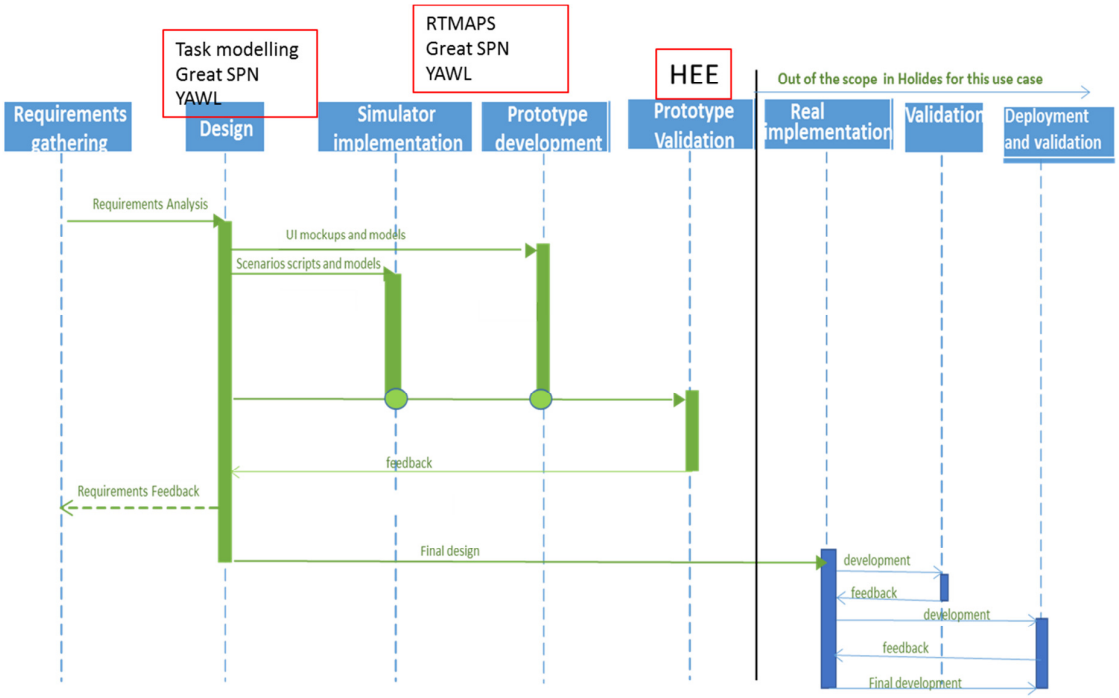


Figure 53 Flow of modelling MTTs for Operator task schedule and guidance

From previous deliverable, we provide feedback:

- RTMAPS: It is an interesting tool, but its application in this use case is not so easy as desired. RTMAPS accelerate the simulation and development for soft real-time scenarios with multiple sensors and information flow. Despite we analysed in D6.3 the features that lead this tool to be good candidate for simulation engine, real time is not a real requirement, nor is acquiring intensive sensor information. As commented, RTMAPS could be used in the context of a reasoning engine in the simulator, but the tailoring to our application requires the development of new components and do not bring benefits to our use case..

- GreatSPN: It is tested and the results reported in this document
- Task modelling: It is tested and the results reported in this document
- YAWL: This tool is out of HOLIDES. It offers comprehensive support for the control-flow patterns and is based on a modelling language that allows the handling of complex data transformations and full integration with organisational resources and external Web Services. Although it is our of this project, its features are very interesting for workflow modelling and simulation, and we tested it.
- Human Efficiency Evaluator: The HEE could be applied to compare the task performance of the current design with the context-based guidance adaptations for different user profiles. This tool will be tested in next stage, when we develop the advanced version of the prototype.

3.7.2.1. Workflow of the scenarios

In order to better understand the workflow, we describe different scenes of a hypothetical workday of a laboratory technician:

Scene 1: Starting the day - quality controls

Mary arrives at the hospital at 7:55. In the locker room, she gets her uniform, takes the electronic identity card and is about to begin an intense day of work.

She registers in the AdCoS application with her credentials. Hereafter we name HOLIAPP.

The HOLIAPP reminds her that she must first check the levels of different reagents needed for the day.

She starts autoanalysers, checks the levels of different ancillary reagents and liquids of the system. Also, she begins to review the different reagents needed for today.

At the end of the previous day, their colleagues left one of these reagents with low level so she is forced to fill it. This issue may delay her workday, but Mary today is in good spirits.

The HOLIAPP is beginning to remind her to take out the controls of the refrigerator.

She goes to the cold room to take the reagent needed for today. While the

reagent is taking the right temperature (in 10 minutes), she reviews the rest of reagents: everyone else is OK.

She also takes the controls from the refrigerator needed to monitor the analytical techniques today.

She marks in HOLIAPP that she has reviewed the levels and has taken the controls. Then, she introduces the reagent in the autoanalyser and proceeds to apply all the necessary controls for the analytical techniques of the day.

She applies the controls on the monitor, enters them manually into the sample carousel of autoanalyser and boots the machine and starts working normally.

She marks on the HOLIAPP that controls are requested and it reminds her that the labelling of urine samples is the next task, so, while the controls are performed in the autoanalyser, she has to label the urine samples of the day before in order to analyse them.

In the autoanalyser, the results of controls are already available so she checks that they are like almost every day. Today, the creatinine levels are again out of the usual range. In recent weeks it has happened too often so that she suspects that the analytical technique is failing. Today also the cholesterol has slightly moved out of range. So she decides to repeat cholesterol control and decides not to repeat the creatinine control and instead of this, calibrate directly the creatinine. The reason for this decision is that her experience tells her that it is better to waste more time to calibrate due to the repetition of control would be in vain and the calibration would be inevitable with this far values so different from the reference. She talks with the manager about the results of the quality control checks and both agree that this is the best decision.

She marks in the HOLIAPP that she has verified the controls and adds an alarm that informs about the controls that have failed. The system gives her the option to repeat control or calibrate. So, she indicates in the HOLIAPP that she is going to repeat cholesterol control and calibrate the creatinine.

She gets the calibrator of the creatinine and she also decides to take some new controls to recheck the technique and no accumulate more delay today.
She introduces the calibrators in the machine and programs the new calibration and control of the analytical technique that failed. Meanwhile, she introduces the urine samples of the day before in the analyser.

When she ends this task, she checks with joy that the scheduled cholesterol control is now within the expected values.

So, she re-checks in the HOLIAPP that the cholesterol control is successful at the second time.

After 5 minutes she verifies that the creatinine calibration has been successful. The analyser is ready to work.

She marks in the HOLIAPP that the creatinine has been calibrated, which passed the test and controls as well.

She marks in the HOLIAPP that all controls are finally in order.
Once she checks this, she marks in the HOLIAPP that the autoanalyser is prepared to analyse the samples of the day.

The workflow of this scene can be modelled as follows:

Scene 2: Sample processing and review of results

Once the chain of robotic laboratory is started, the tubes begin to enter for their analysis by different analysers depending on the test that they have requested and the work list.

Mary takes a coffee break at 11:30 when the tubes have been successfully analysed by the analysers and they begin to pass the data results to the computer system middleware to be reviewed by Mary.

The HOLIAPP begins to warn that the first results need to be revised following the estimated schedule.

Mary begins reviewing the results of the computer system and she realises that Calcium has altered values generally far from normal. Therefore Mary suspects that the reagent is in bad conditions despite the early morning control came out correctly.

She registers the problem in the HOLIAPP in order to transmit this incident to other partners throughout the day. Mary tells this problem to the manager to agree if they should replace the reagent. Finally both agree that this is the best solution

Mary is forced to stop the analyser and pull the automated chain for a while.
Once the work scheduled for the analyser has terminated, Mary extracts the Calcium reagent and verifies that it is in bad conditions so she must replace it.

Following the procedure, first, she must perform a calibration of the analyser for calcium technique and then, places calibrators and new controls. The calibration and control checks if it is correct. If the calibration is correct, the analyser will connect to the chain to continue processing patient samples. If not correct, it

would be possible to continue working with this analyser but without this technique neither to work in the chain with the two other analysers. This decision depends on the workload of the day.

So she goes to the cold camera and takes a new reagent. When this reagent gets the correct temperature, she introduces it in the analyser.

She registers in the HOLIAPP that she has introduced a new reagent Calcium in the analyser A, so this action will be reflected in the stock of laboratory reagents.

She applies for the calibration and control of Calcium to verify that this reagent is in perfect condition, and after 10 minutes the result shows that finally everything is in order so the analyser is reconnected to the chain and everything returns to normal.

She marks in the HOLIAPP that the new reagent has been given the OK to the first control and the analyser has been reconnected.

While the chain is processing chain tubes, Mary is still reviewing the results of different samples that are being processed.

Then, a result of glucose and other of calcium with high pathological levels are detected in several patients. Therefore she decides to repeat samples in order to check them. Then she verifies that the glucose result is not wrong but the calcium result is due to a mistake of the analyser.

She registers in the HOLIAPP that she has repeated the sample 15897 and 16587 so, the supervisor will be able to check easily that these samples have been repeated and one of the results is true while the other was due to a mistake of the analyser.

At mid-morning Mary detects an alarm from the analyser B indicating that there is a problem in it. She goes to monitor the analyser and verifies that there is an error in the analytical module. Mary remembers that this error occurs sometimes, so she decides to call the technician. The first thing to do is disconnect the analyser from chain. In order that no more work would be delayed, she disconnects it and calls the technician. As always Mary reports this failure to the manager to discuss the problem with him. The technician

Within thirty minutes the technician comes to laboratory and solves the fault in just 15 minutes so Mary can reconnect the autoanalyser to the chain one hour later since the detection of the problem.
She marks in the HOLIAPP that the fault has been resolved and she is now able to continue working normally.

Workflow diagrams from previous scenes
From previous scenes, we extract the following relevant workflow diagrams.

The first one (*workflow#1*), is about the process for start-up and preparing the auto-analysers

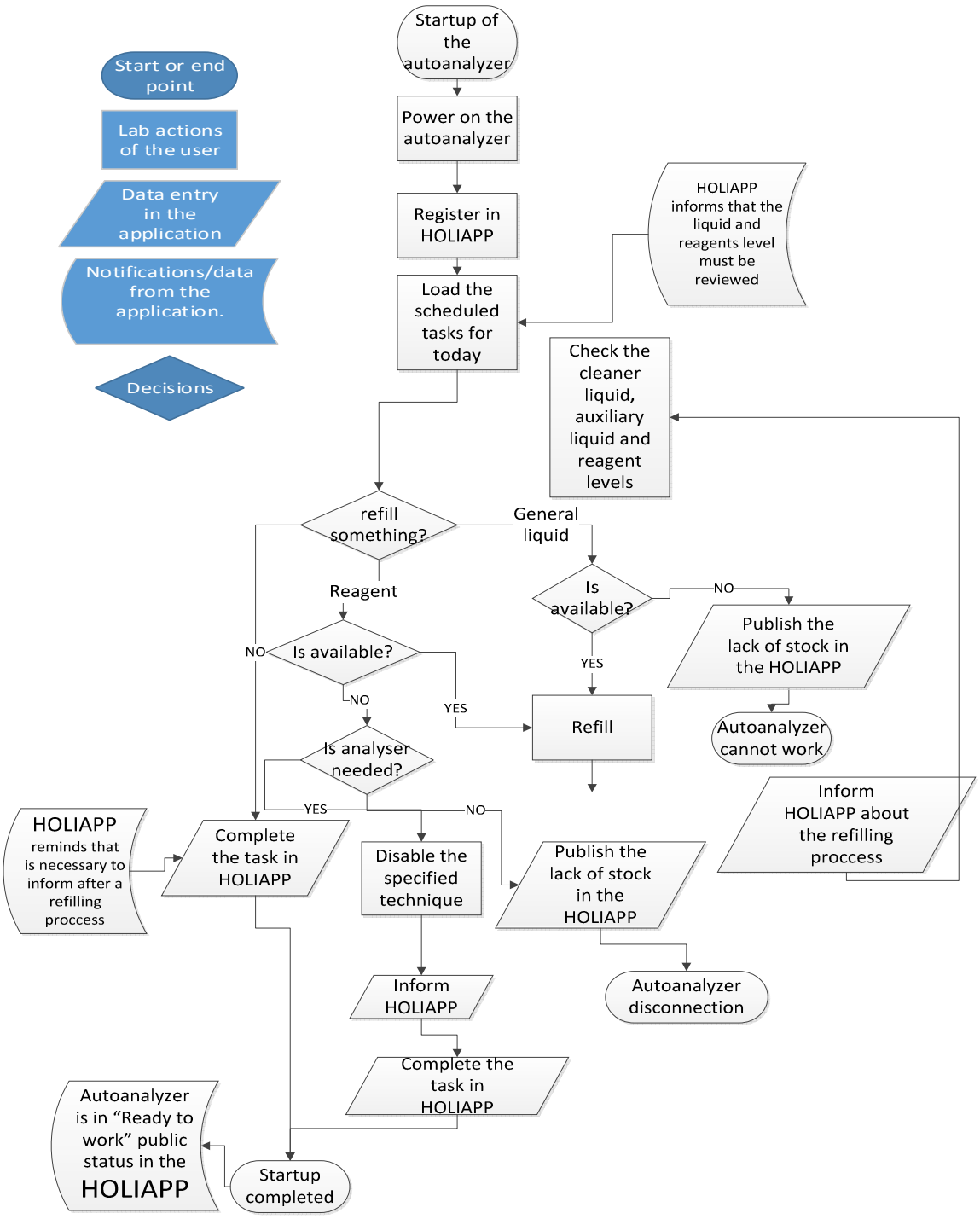


Figure 54: Workflow#1 Preparing autoanalysers

The second one (*workflow#2*), is about the preparation of reagents and quality controls of liquids.

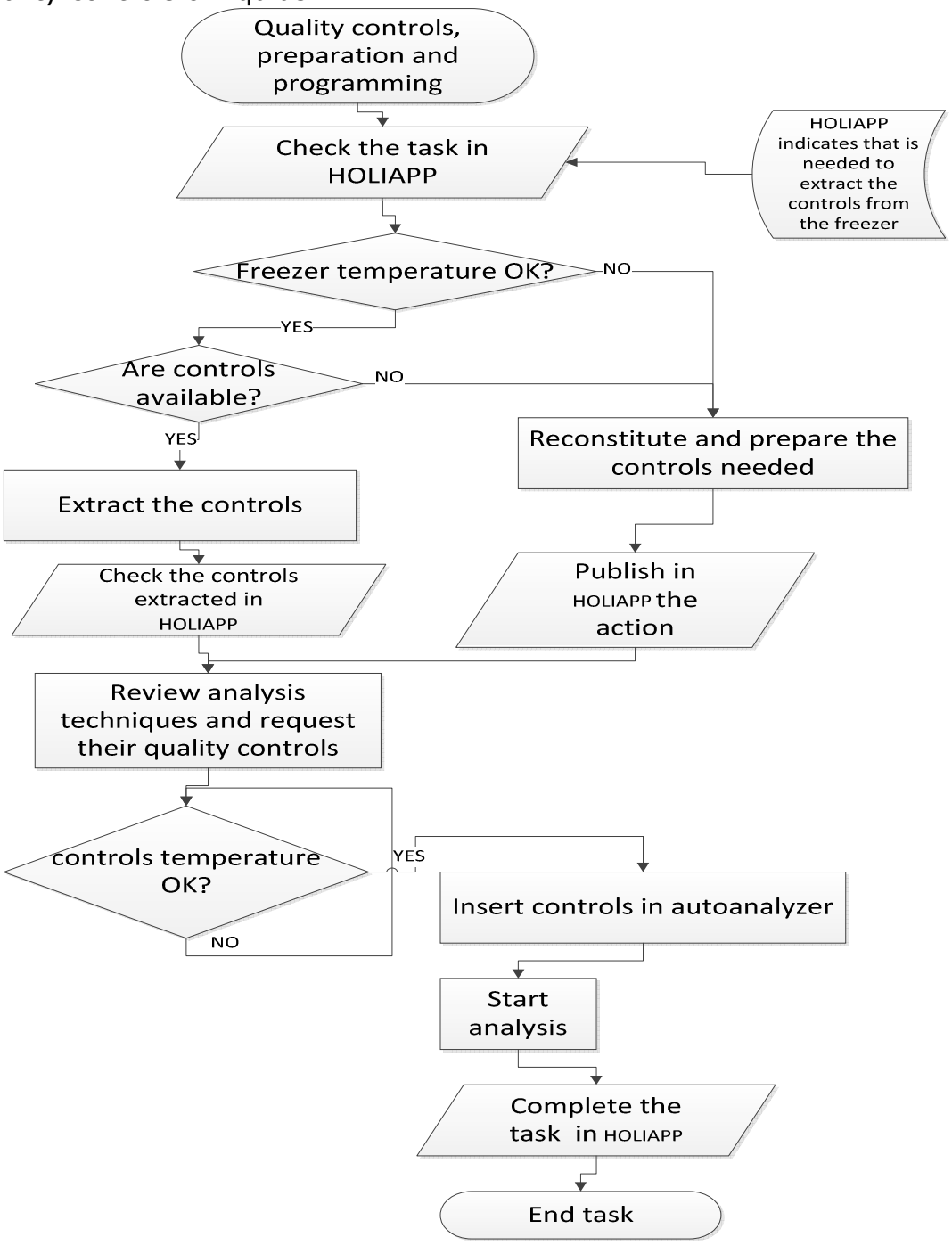


Figure 55 Workflow#2, preparation of reagents and QC liquids

The third one (*workflow#3*) depicts the workflow for the review the results of the Quality Controls

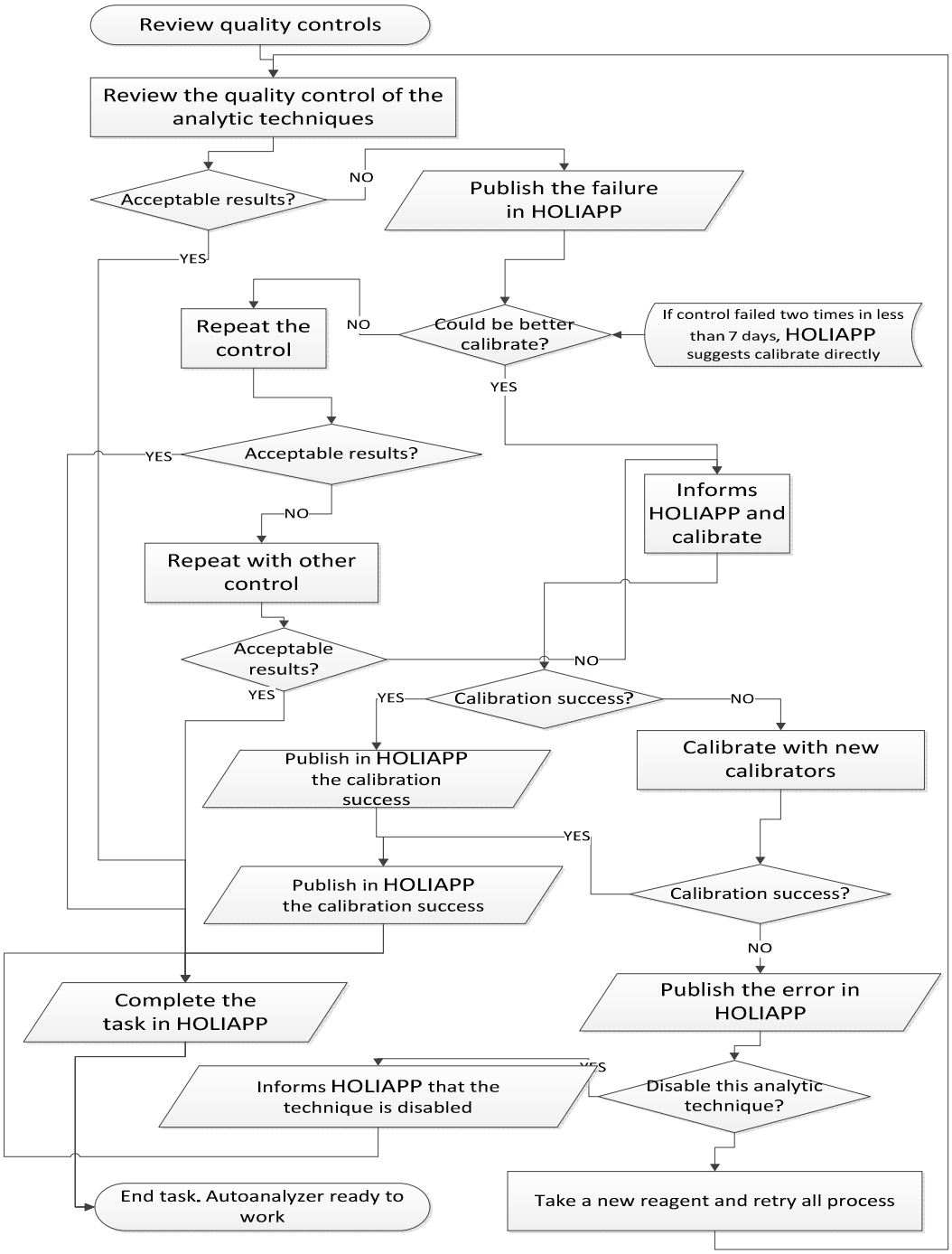


Figure 56 Workflow#3, review of QC controls

The fourth one (*workflow#4*) depicts the replenishment of liquids in the auto-analysers:

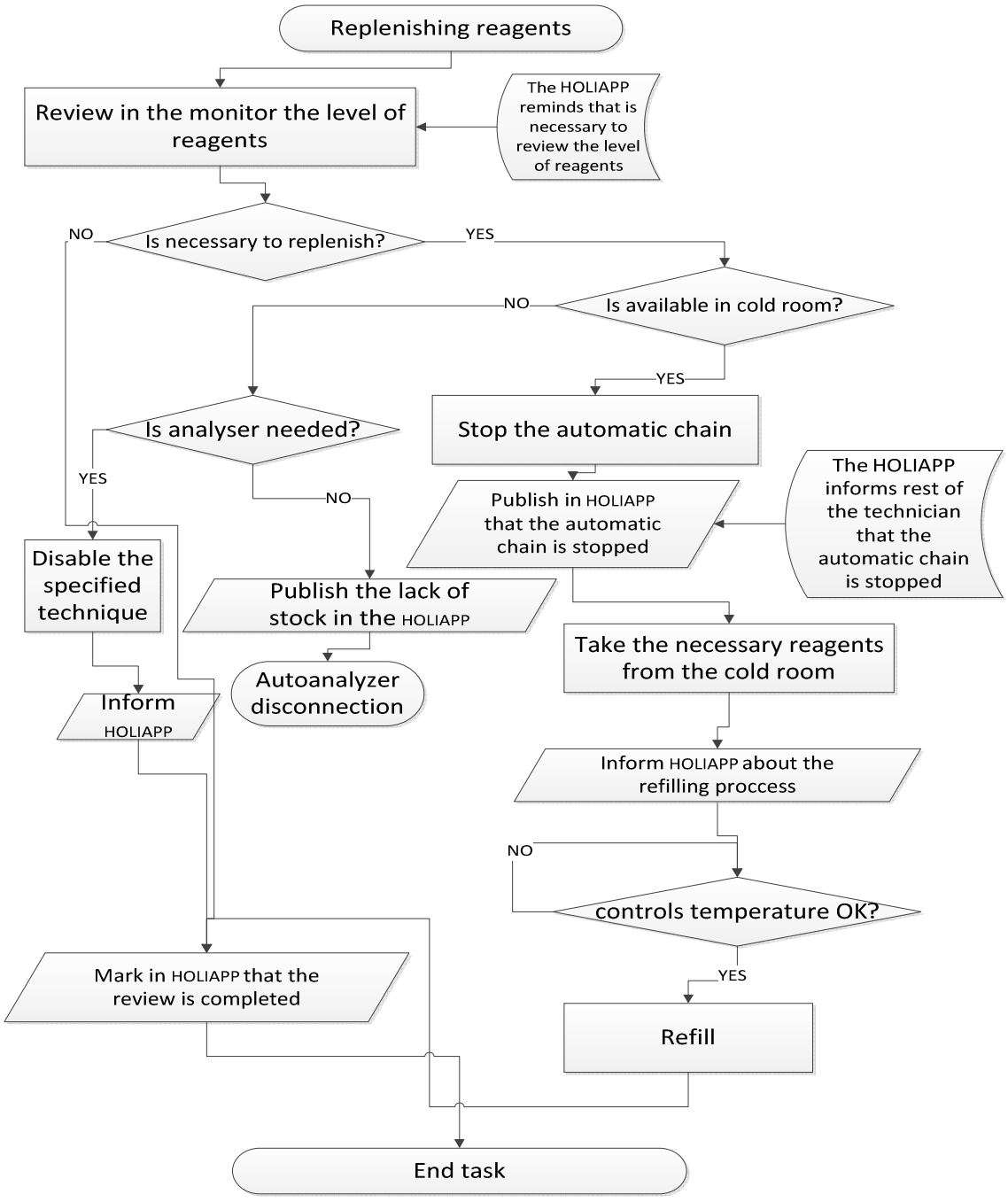


Figure 57 Workflow#4, Refilling http://www.highflyer.airbus-group.com/04_2013_efan_and_ethrust.htmlof liquids in the auto-analysers

Task modelling using HoliDes approach

An initial version of the task modelling of the previous workflow is shown in Figure 58:

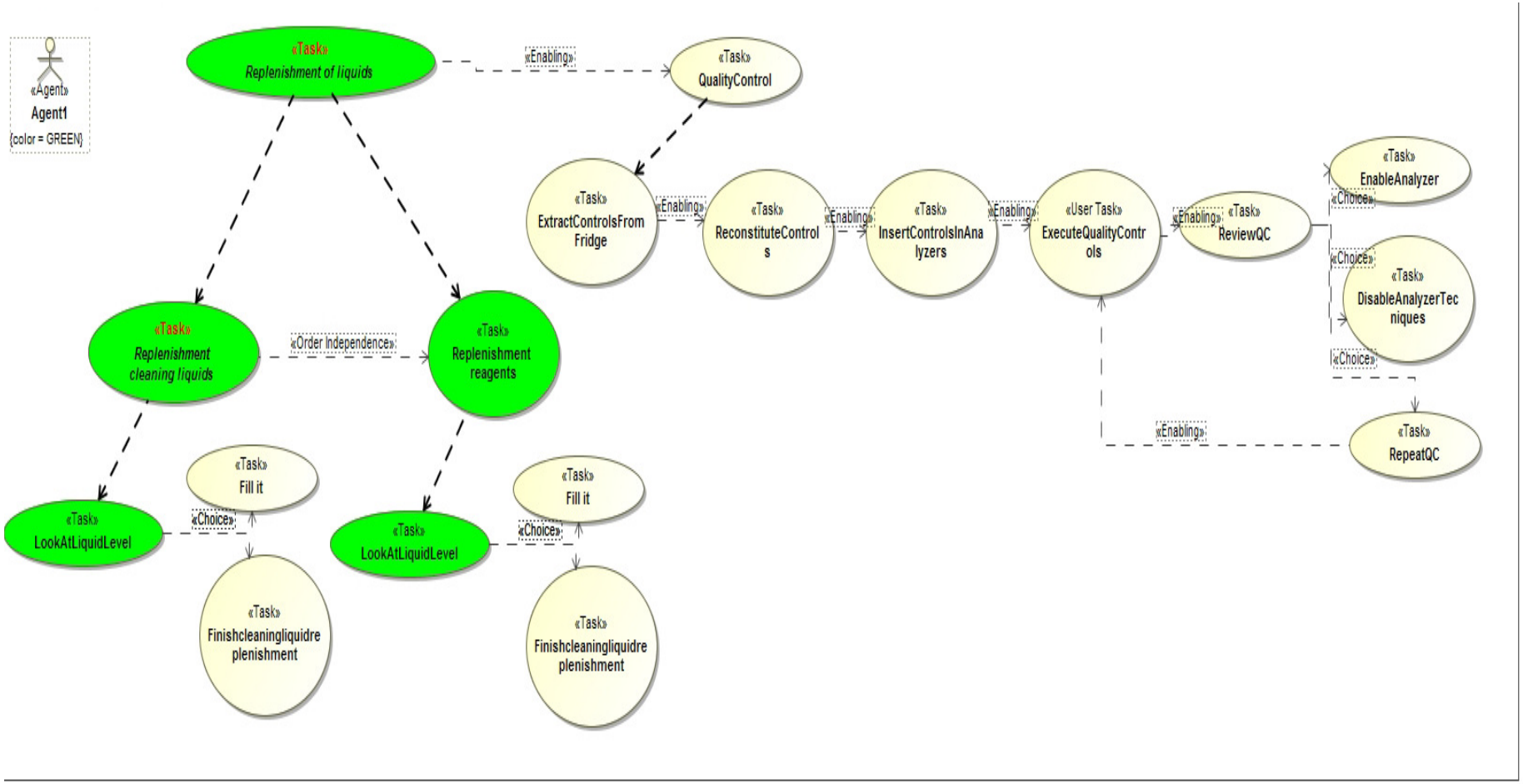


Figure 58 Task modelling of QC with HoliDes Task Hierarchy approach

In the Figure 58, we represent a sample of the model following the Task Hierarchy Model proposed in HoliDes WP2. For this purpose, we utilise MagicDraw and MagicPED tools, as proposed in WP2. The illustration depicts the first part of the scenario, which encloses the replenishment of liquids, and the quality control execution tasks. With this diagram, we are only able to estimate simple execution times for higher task level. For more detailed and precise estimation of time and simulation, Rule Diagram should be added. It is a work in progress.

The GreatSPN model

Another technique and tool to model the workflow is based of the GreatSPN tool, provided by UNITO. In D6.3 we explained and justify the selection of this tool. In such document, we describe our objective to use this tool: For task modelling, to simulate execution time of a workflow, and change configurations to simulate how it affect.

Figure 59 represents the diagram that just models the reconstitution of reagents and preparation of Quality Control in the laboratory (workflow#2, the simplest workflow):

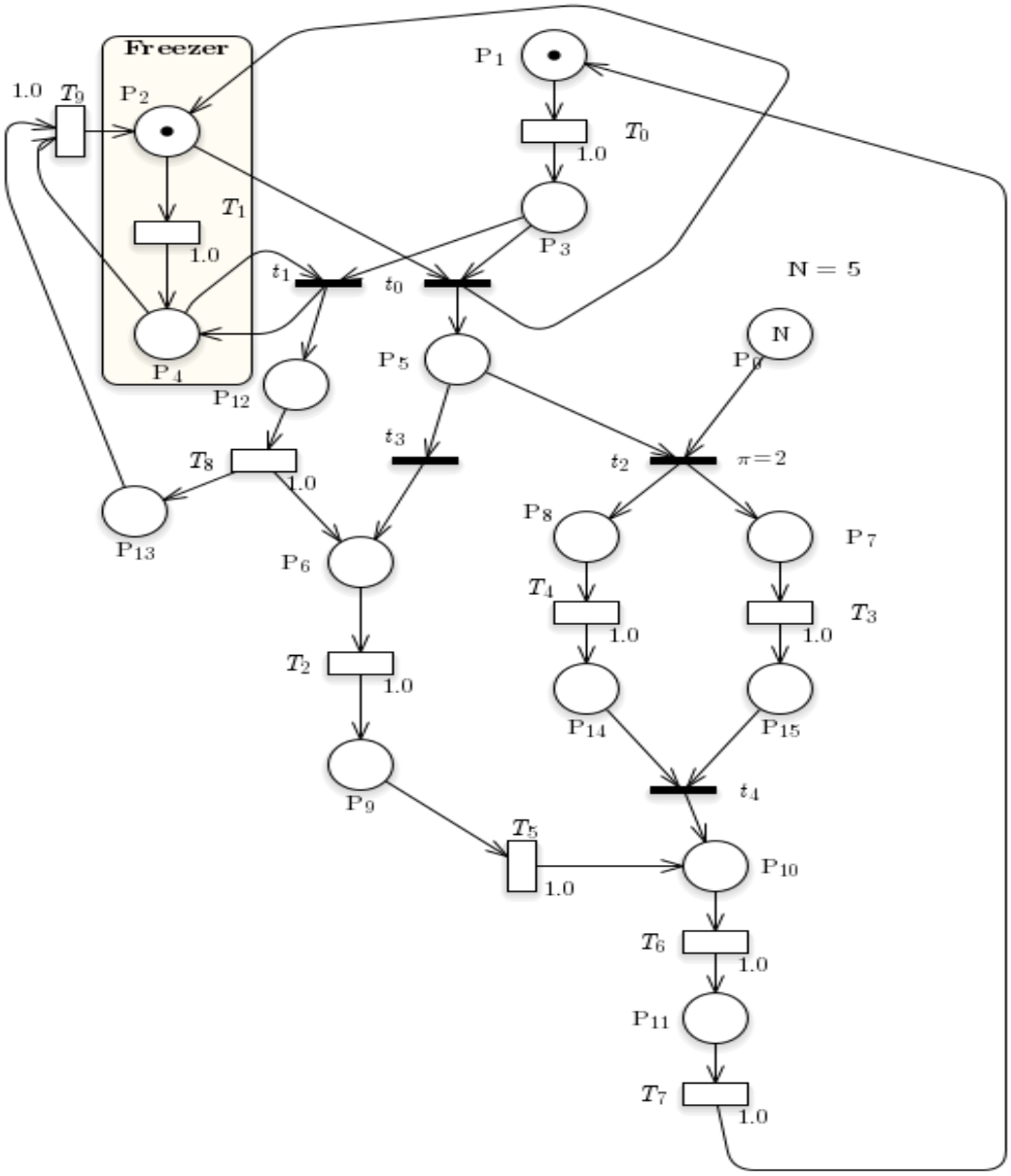


Figure 59 GreatSPN diagram of workflow#2

The different entities that composed the GreatSPN diagram are described in Table 34:

Label	Phase	Description
P0	Quality controls	This phase include tokens for the quality controls

	available	available inside freezer. This number is defined at beginning of the simulation (N parameter).
P1	Initial Phase	Technician is initiating the task of preparation and programming quality controls
P2	Freezer OK	The freezer is working properly.
P3	Technician ready	Technician ready to perform the quality controls.
P4	Freezer failure	The freezer does not work.
P5	Intermediate	The freezer is working so technician performs the quality controls if they are available or start preparing new controls if they aren't.
P6	Preparation of new controls	The technician is preparing new quality controls because they were consumed or spoiled due to the fact that freezer had a problem.
P7	Waiting for correct temperature of controls	The controls extracted from the fridge are getting ambient temperature. This step is before the introduction of these in the analyser.
P8,P9	Reviewing techniques & programming quality controls.	Technician is reviewing analysis techniques and requesting their quality controls in the analyser graphical interface.
P10	Inserting controls and starting the analysis	Technician inserts the controls in the analyser and then starts the analysis.
P11	Task completed	The task is completed. This phase include a waiting loop to repeat the task when it will be needed again.
P12	Calling operator	The freezer is not working so the technician calls someone to repair it.
P13	Repairing of the freezer	This phase includes the wait until the arrival of the operator and the time necessary to solve the problem.

Table 34 Entities of the GreatSPN diagram

Figure 60 models the workflow#3. With the graphical visualization of this workflow, we can get an idea of the complexity of PetriNets for this domain.

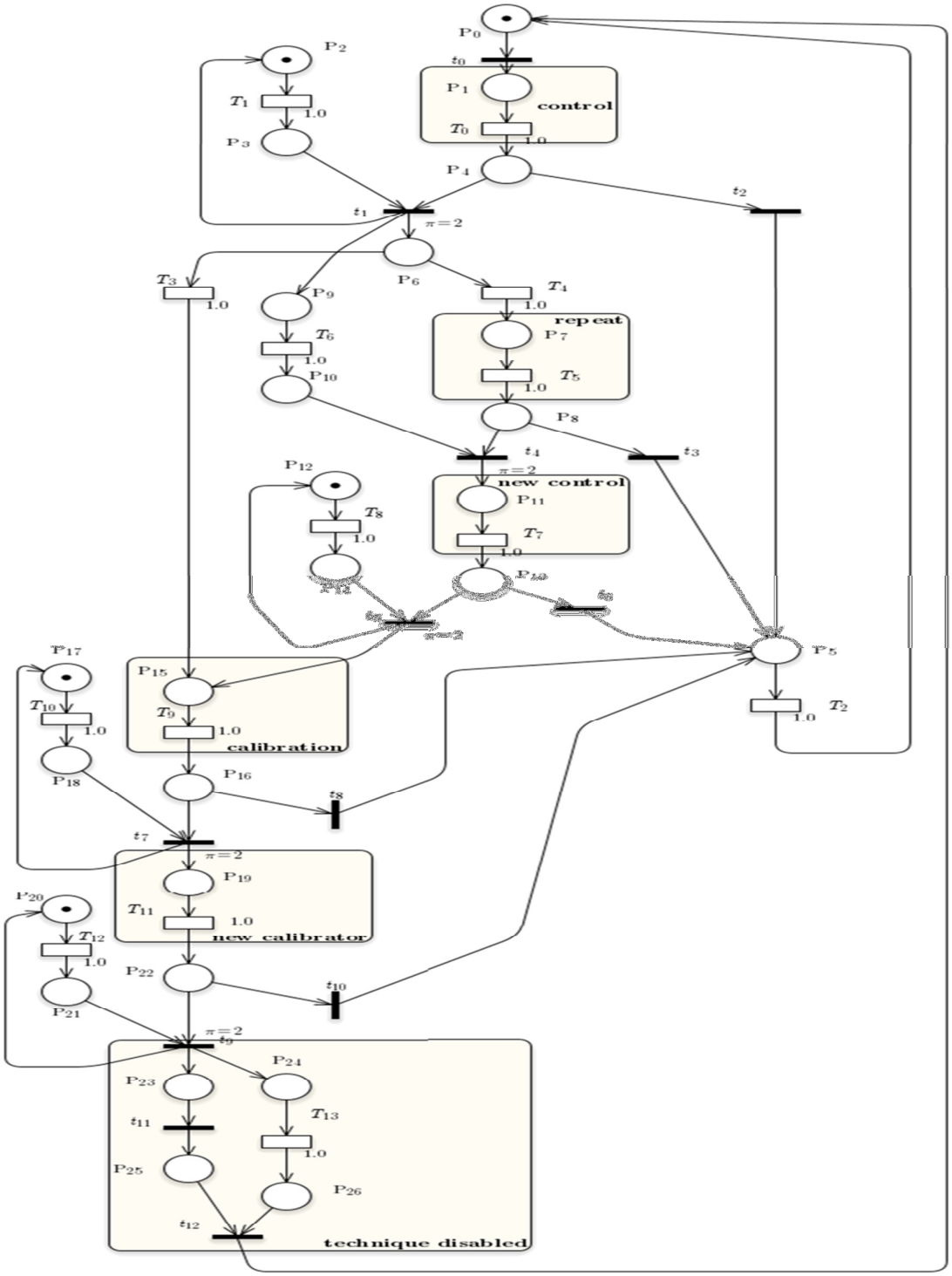


Figure 60 GreatSPN diagram of workflow#3

Label	Phase	Description
P0	Starting	Starting the review of the quality controls
P1	Review quality control	Technician reviews that the results are inside the correct range.
P2&P3	Event probabilistic of quality control failed	This status simulates the fail of the quality control modelled as a probabilistic event. P3 indicates that the next review of quality controls produces bad results. The T1 transition tries to model this kind of probabilistic error.
P4	Quality controls reviewed	Technician finishes the review. If the results are correct the review process ends but, if not, the technician must take a decision between calibrate directly or retry the control.
P5	End	The procedure has ended. This phase simulates the wait until the procedure starts again.
P6	Taking a decision	The technician must take a decision using his experience. The first option is to retry the quality control if the error is a false positive or to calibrate directly (this operation takes too much time).
P7	Repeating control	Technician is repeating the control.
P8	Second quality controls reviewed	If the results are good, the process ends but, if not, the technician will take a new control and retry the review with it.
P9&10	Event probabilistic of the quality control failed again	This status simulates the repetition of the fail of the quality control modelled as a probabilistic event. P10 indicates that the next review of quality controls produces bad results. The T6 transition tries to model this kind of probabilistic error. This error depends of the fail of the first review so, the P9 phase is dependent on the P3 phase.
P11	Repeating with new control	Technician is repeating the review with a new control
P12&P14	Event probabilistic of quality control failed	This status simulates the fail of the quality control modelled as a probabilistic event. P14 indicates that the next review of quality controls produces bad results. The T8 transition tries to model this kind of probabilistic error.
P13	Quality controls reviewed	Technician finishes the review. If the results are correct the review process ends but, if not, the technician must calibrate because the error could be a problem with the calibration.

P15	Calibration	The technician is calibrating the specified technique
P16	Calibration finished	The technician verifies the results of the new calibration. If the results are correct the process ends but, if not, the calibration must be repeated with a new calibrator.
P17&P18	Event probabilistic of calibration failed	This status simulates the fail of the calibration modelled as a probabilistic event. P18 indicates that the next calibration produces bad results. The T10 transition tries to model this kind of probabilistic error.
P19	Calibration with new calibrator	The technician is calibrating the specified technique with the new calibrator.
P20&P21	Event probabilistic of calibration failed	This status simulates the fail of the calibration modelled as a probabilistic event. P21 indicates that the next calibration produces bad results. The T12 transition tries to model this kind of probabilistic error.
P22	Calibration finished	The technician verifies the results of the new calibration. If the results are correct the process ends but, if not, the analytic technique must be disabled until an operator fixes the equipment.
P23&P25	Technique disabled	The analyser is working with the specified technique disabled
P24	Waiting for the reparation	This state simulates the waiting of the arrival of operator, the verification and reparation of the equipment.
P26	Reparation completed	The equipment has been repaired and can work normally.

Our first conclusions, is that, although we have model simple cases, GreatSPN could be very complex for our use case. Moreover, the huge variability of the tasks execution times in this use case, has a negative effect on the reliability of the simulation.

Sequence diagrams of Holiapp application

In the previous section we model the workflow of the operators. Our proposed solution to improve, optimise and make error-free this workflow is based on a mobile application that guides the user in their daily tasks. This application is described in D6.3. Now, we present the sequence diagrams of the different interface and functionality provide to the user.

User login

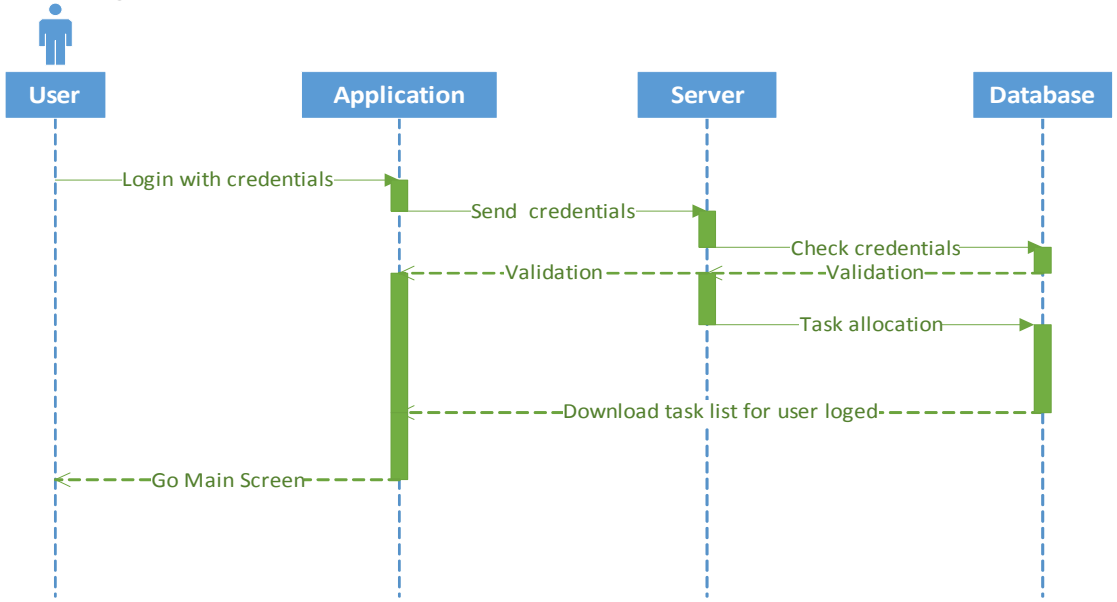


Figure 61 *User Login* sequence diagram

Modification of status of tasks

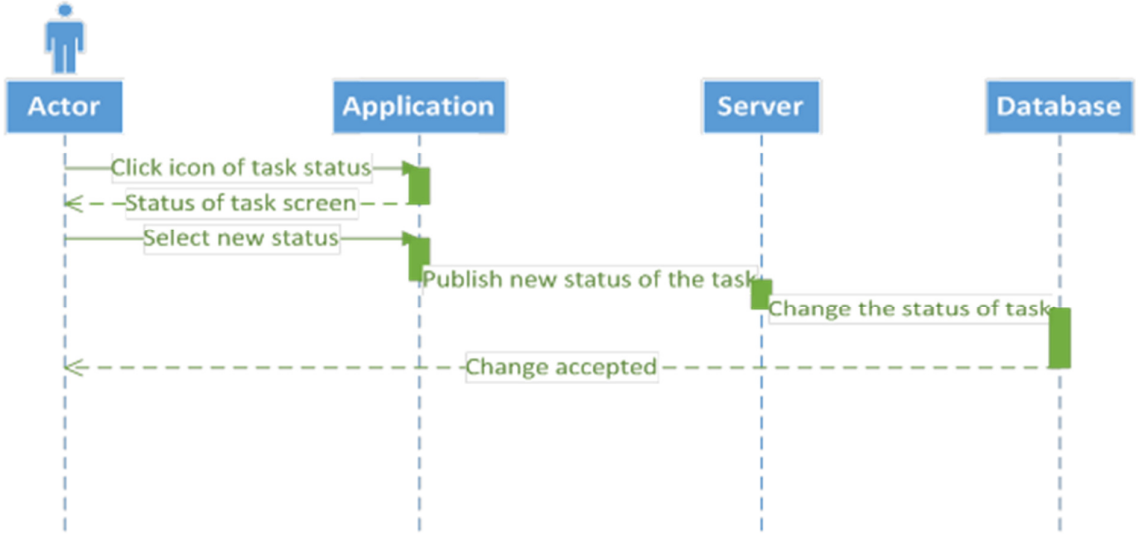


Figure 62 *Modification of status of tasks* sequence diagram

Messaging sending

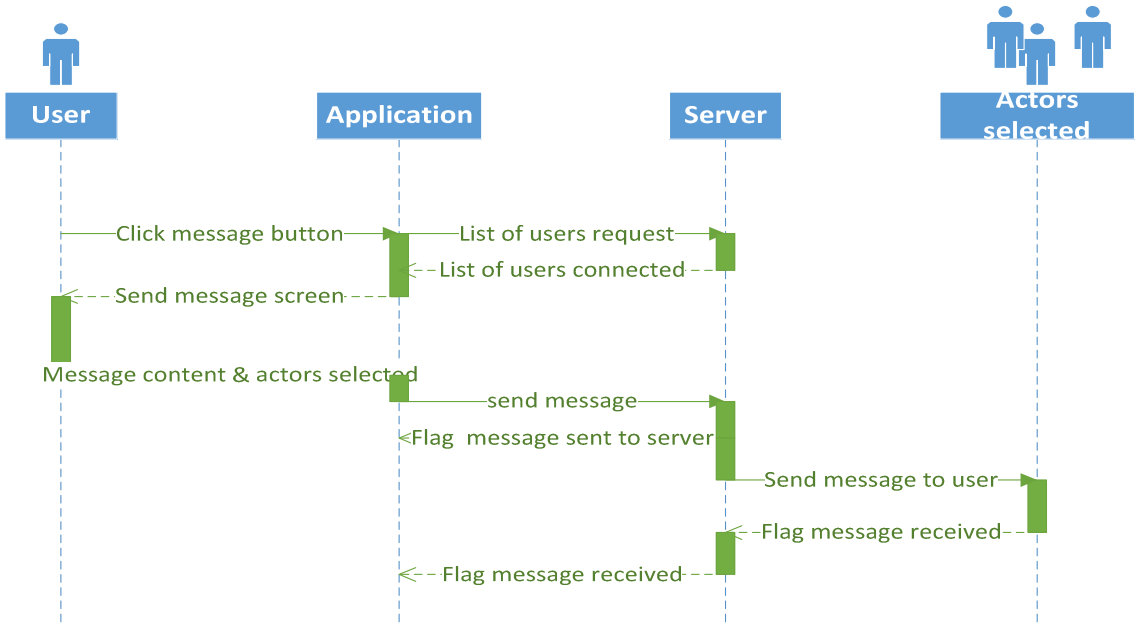


Figure 63 *Messaging sending* sequence diagram

Create new task

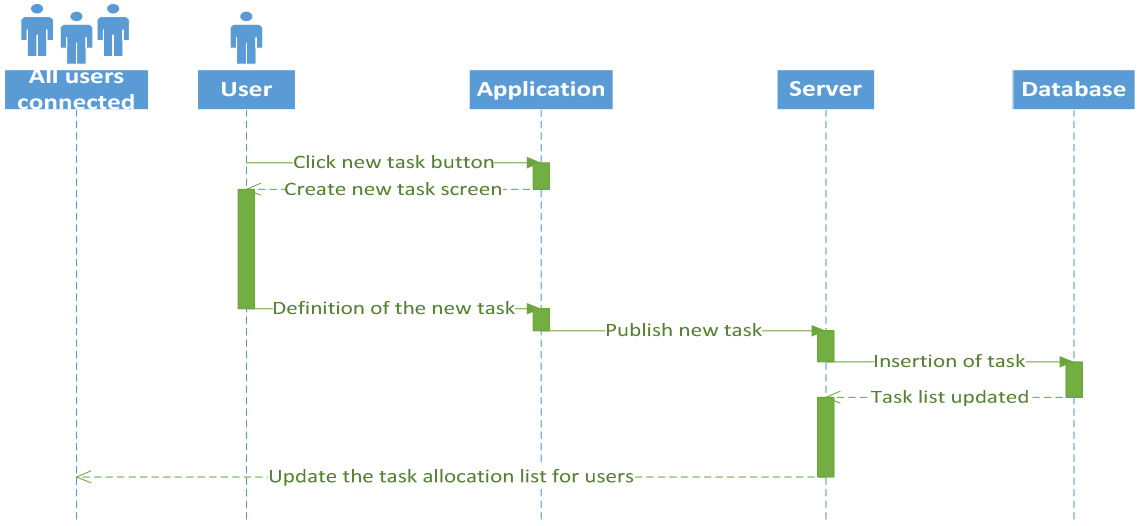


Figure 64 *Create new task* sequence diagram

Sending alarm

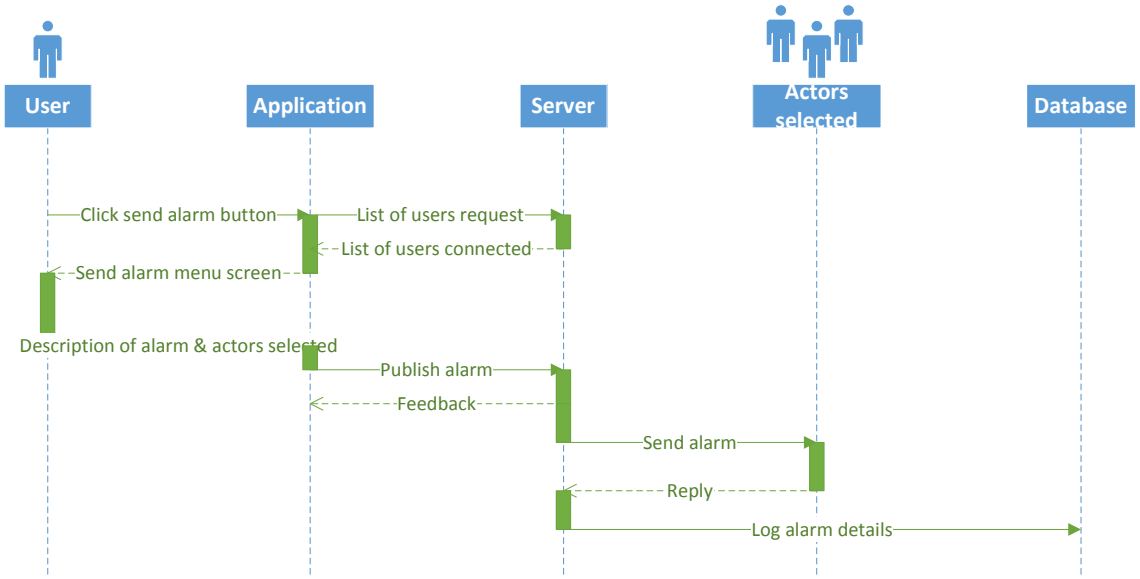


Figure 65 *Sending alarm* sequence diagram

3.7.3. Feedback on MTTs and HF-RTP regarding Operator task schedule and guidance

See annex II.

3.8. Safe patient transfer

3.8.1. Description of the AdCoS

As described in D6.3 the AdCoS is the system intended to enable the design and validation of the Safe Patient Transfer System, also called the MRI Trolley.

This Trolley needs to be safe and easy to use for a broad range of operators and patients.

This AdCoS has only limited connection to the other AdCoS and related use cases defined for HoliDes, since the trolley is only a mechanical device without system interaction and the HoliDes HF-RTP does not contain tools to facilitate efficient mechanical designs. The requirements from this AdCoS for HoliDes are therefore only focusing on the validation process and archiving of results, which also can be exercised with other AdCoS in WP6.

So this AdCoS will not be continued in HoliDes.

4. General feedback on MTTs and the HF-RTP regarding modelling of AdCoS in the health domain

The general feedback is available in Annex II.

4.1. Requirements update

In the course of the modelling process, some requirements have been updated, relating to models developed in WP2 and tooling developed in WP1. Two requirements have been retracted, two added and two have been modified, as shown in Table 35 below.

ID	Change	Name	Description
WP6_AWI_HEA_REQ01	Retracted	Follow regulatory and standards training requirements	The RTP must support adapting to changes to regulations regarding training for new versions of training material.
WP6_AWI_HEA_REQ03	Modified	Compare observations or simulations of operators conducting procedures with medical guidelines	The human factors models should allow observations or a simulation of an operator conducting an MRI scan with the relevant guidelines, such as procedure archetypes.

ID	Change	Name	Description
WP6_PHI_HEA_REQ13	Retracted	AdCoS sensing	Techniques for sensing context as input for adaptive behaviour of the product agent in the AdCoS (e.g. video camera input, user agent input, event timestamps)
WP6_PHI_HEA_REQ14	Modified	Product usability validation methods and tools for trolley	Methods + tools shall be provided for formal product usability validation
WP1_HFRTP_REQ34_v3	New	Creation and storage of evaluation plans	The HF-RTP shall include MTTs to set up and store itemised evaluation plans for AdCoS. The evaluation plans must refer to a unique AdCoS project within the same RTP instance. The plans must be incrementally modifiable as new versions of the AdCoS design are defined.
WP1_HFRTP_REQ35_v3	New	Storage of textual evaluation reports	The HF-RTP shall provide MTTs for a storage of textual evaluation reports based on itemised evaluation plans. The evaluation reports must be traceable to design versions.

Table 35 Updates to requirements as a result of the modelling effort.

Colour coding: Red: Text that has been deleted. Blue: Text that has been added.

5. Conclusions

This document contains the results of the modelling effort for the AdCoS developed in the health application domain, with definitions of the operator role, the environment of the AdCoS and the functionality of the AdCoS itself.

The modelling has increased the insight into the AdCoS, the workflow required to operate them and the tasks of the operator to improve on the design in the next phases and in preparation of the implementation phase.

The AdCoS developed in WP6 address several different working situations, but the modelling can nevertheless be divided into three main categories:

1. Models of AdCoS to support an operator in organising the workflow for a specific procedure and performing it correctly
2. Models to support designing a user interface to ensure that the staff can use the advanced features of modern equipment correctly and safely
3. Models to help improving the design of AdCoS to access and use clinical data or imaging data over web connections

The first two categories, while being quite different from one another, have in common that the favoured modelling technique for each of the AdCoS in both categories is task analysis in some form.

The last category contains two AdCoS, which are both modelled using UML-based methods.

Both of these modelling techniques, or classes of modelling techniques, have been used in other application domains in HoliDes as well.

There are therefore good opportunities for development of methods, tools and techniques that can be applied in several domains, along with training and exchange of know-how for interested partners.

5.1. Next steps

To continue the work on modelling of the AdCoS and the use of the models in the design and development process, the next steps regarding each AdCoS are listed in the following.

5.1.1. Modelling plan for 2015 for Guided patient positioning and robust ECG triggering

Q3:

- Build HEE models of new HMI
- HMI performance comparisons using HEE

Q3+4:

- User evaluations/questionnaires and clinical feedback of new HMI

5.1.2. Modelling plan for 2015 for 3D Acquisition

Q3:

- Build HEE models of new HMI
- HMI performance comparisons using HEE

Q3+4:

- User evaluations/questionnaires and clinical feedback of new HMI

5.1.3. Modelling plan for 2015 for Querying openEHR data

Q3:

- Analyse the **AEON** cloud message platform to be integrated in the tool.
- Study the application of **Data Race Detector & Healer** to the software.
- Study the methodology to model the AdCoS from a means end perspective and **HF Filer**
- HMI performance comparisons using HEE
- AEON integration if suitable
- Application of the modelling the AdCoS as the means end perspective.
- Integration of Data Race Detector & Healer and HF File if suitable

Q3+4:

- User evaluations/questionnaires and clinical feedback of new HMI
- Validation and testing

5.1.4. Modelling plan for 2015 for Internal analysis and reporting

Q3:

- Analyse the **AEON** cloud message platform to be integrated in the tool.

- Study the application of **Data Race Detector & Healer** to the software.
- Study the methodology to model the AdCoS from a means end perspective and **HF Filer**
- Analyse **LEA** and **APA** pros and cons to be used in the reporting tool.
- AEON integration if suitable
- Application of the modelling the AdCoS as the means end perspective.
- Integration of Data Race Detector & Healer and HF File if suitable
- Integration LEA and APA if it is statistically relevant.

Q3+4:

- User evaluations/questionnaires and clinical feedback of new HMI
- Validation and testing

5.1.5. Modelling plan for 2015 Operator task schedule and guidance

Q3:

- Make more complex models with GreatSPN
- Initial Information Model and detailed definition of infrastructure

Q3+4:

- Start the prototype implementation (to be continued during 2016)

[i] http://www.w3.org/WAI/intro/usable