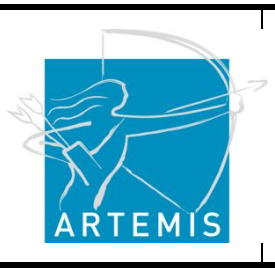

HoliDes

Holistic Human Factors **Des**ign of Adaptive Cooperative Human-Machine Systems

D6.10 Final version of the Health AdCoS

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25.07.2016	Draft structure of deliverable	Robert Hofsink
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06.09.2016	Review comments incorporated	Robert Hofsink

Table of Contents

1 Introduction

This document describes the final implementation of the Health AdCoS and feedback to the HF-RTP. Since there are multiple AdCoS's for the Health domain, each chapter covers a separate AdCoS. Each chapter starts with a short AdCoS introduction, followed by a description how the MTT's from the HF-RTP have been integrated. The benefits of the HoliDes approach for qualification and certification is described. Furthermore, an impression of the HMI is given. Finally, each chapter concludes with feedback and recommendations.

The order in which the AdCoS's are described in this document is derived from the overall health application scenario, which describes the flow of a patient through the hospital.

AdCoS

1. Medical consult
   - Operator task schedule
   - Querying open EHR Data
2. MRI examination
   - Guided patient positioning
   - Robust VCG triggering
   - Safe parallel transmit scanning
3. iXR treatment
   - 3D Acquisition
4. Data analysis, reporting
   - Internal analysis and reporting

2 Operator task schedule and guidance

2.1 AdCoS description

The objective of this AdCoS is to ease the collaboration between the different actors and systems that compose a laboratory in a medical environment (i.e. Automated Laboratory of Biochemistry General at the Hospital Macarena of Seville). More specifically, the AdCoS is focused on aspects related with the proper assignment of tasks in a clinical laboratory and the ability to manage real time instructions (alarms, checkpoints, reminders) and to optimize the workflow and cooperation among operators.

One of the main problems that older adults and newcomers face at work is the adaptation to a changeable working environment, which comes from many factors: new computer and machine interfaces, new devices, new procedures and workflow, new business line and markets, etc. An incorrect entering of changes in the working environment can cause a wrong understanding of concepts, and it could also cause demotivation and low productivity, especially in older employees. Furthermore, it can lead to user errors, which can put patients at risk.

The intention of our AdCoS system is to ease the development of a workflow solution for hospitals focusing on the following aspects:

- Helping to the proper staff assignment to tasks.
- Providing real time instructions – trigger alarms – reminders and check points.
- Optimizing of the workflow and cooperation with the rest of operators.

To that end, we have implemented a prototype of a dynamic workflow system that helps to help personnel (specifically nurses) to carry out their daily tasks and that the prototype helps us to pre-validate the implementation of an AdCoS System, before the full implementation on a real hospital is carried out. Next figure shows the interaction between different actors and agents involved in this use case.

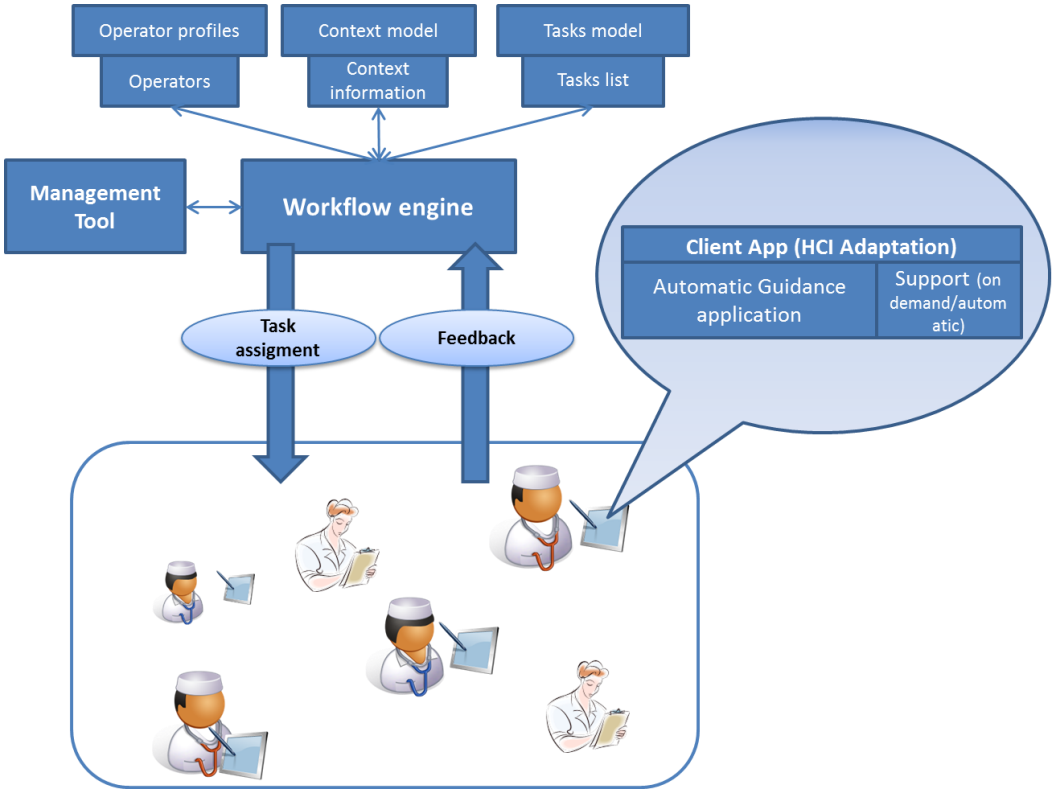


Figure 1 Operator Task Schedule and Guidance AdCos Use Case

2.2 Final HMI

The interaction between the operator and the system has been carried out through an infrastructure composed by a server side (workflow engine and editor + workflow management tool), network communication and a client side using a PC or tablet. This PC or tablets allow the operators to interact by using Graphical User Interfaces (GUI).

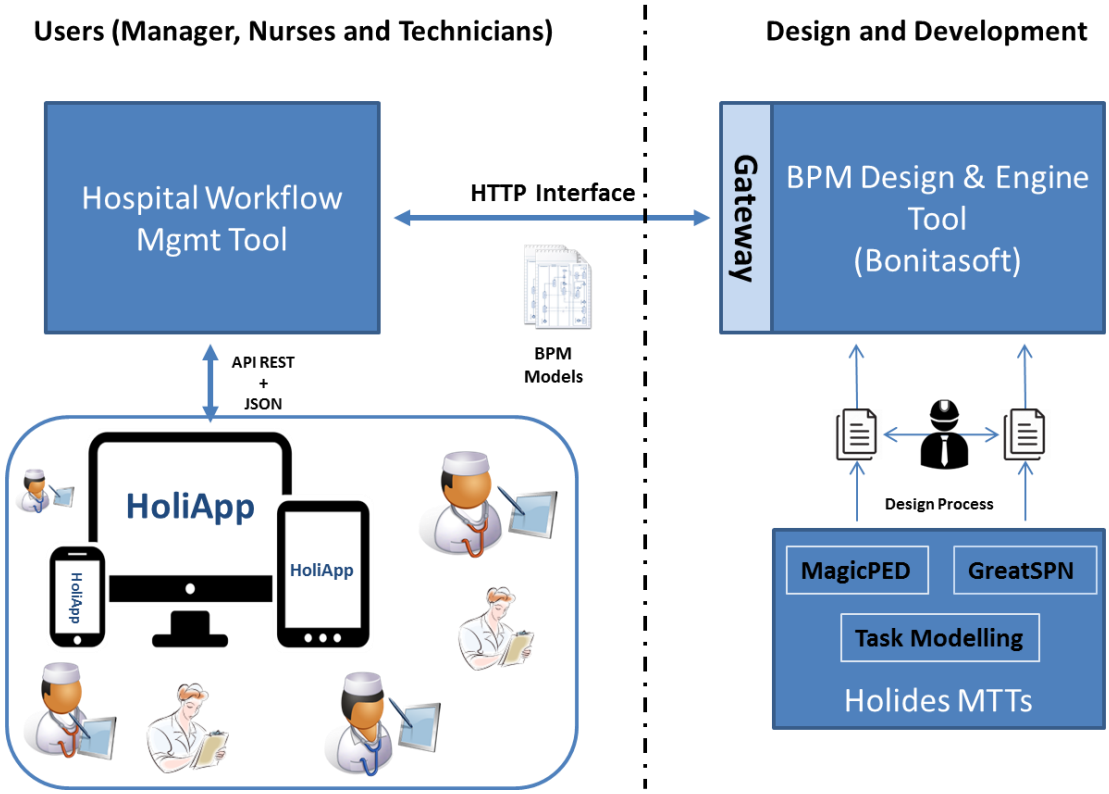


Figure 2 Software Architecture and actors involved

As you can see in the previous figure of software architecture, the Operator Task Schedule and Guidance AdCoS use case is made up of three parts:

- **Workflow Engine & Editor**: This tool is in charge of edition of workflow diagrams and processing the instructions, decision making and interacting with the real device that implements the prototype mobile application. BonitaSoft has been used to carry out this functionality.
- **Hospital Workflow Management Tool**: This tool has been implemented to manage the workflows (business processes) and the user activity.
- **Client application (HoliApp)**: application where the workflow and alarm information is shown in real time to the operators, e.g. available tasks to be performed, alert about new task available, assigned tasks, etc.

2.2.1 AdCoS design – before and after

The AdCoS use case was initiated from zero at the time the project started, so the logic and the GUIs have been developed during the project. At present, the traditional 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-organized plan, anyway informal processes at hospitals are very common such as meetings, hearings, notetaking, etc.

The final HMI is mainly composed of a PC based interface for the laboratory manager (management tool) and a tablet/smartphone based interface for the operators (client application). Next, several screenshots have been taken for both parts.

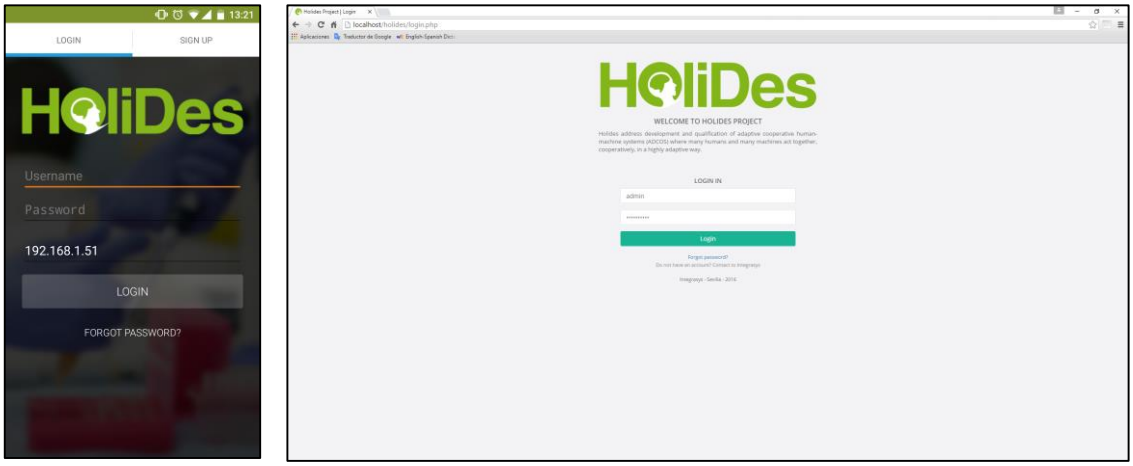


Figure 3 Operator task schedule and guidance use case: Login Interfaces for Manager and Operator.

The next figure represents the main page of the workflow engine HMI simulating a dashboard, which is only accessed by the manager or administrator of the laboratory. In this page, the manager visualizes a general summarize about the status of the system.

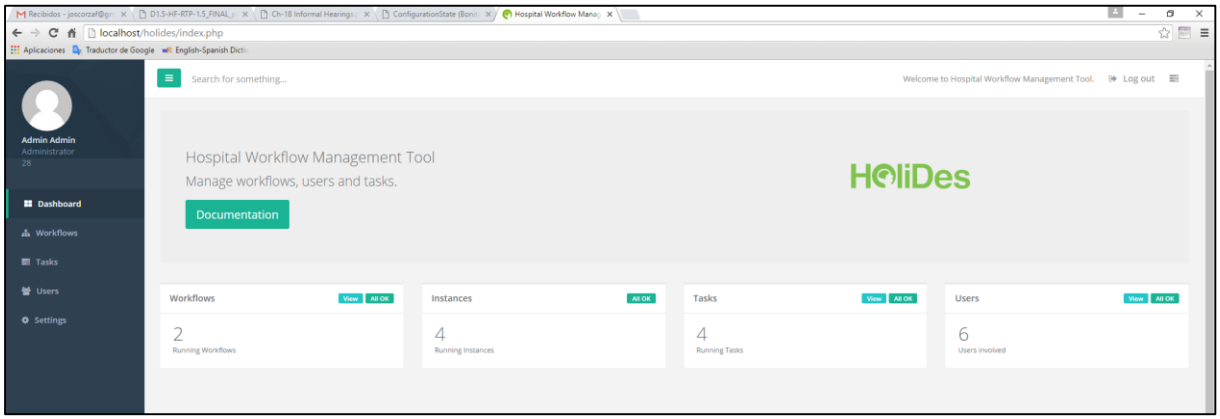


Figure 4 Operator task schedule and guidance use case: Hospital Workflow Management Tool (dashboard)

By using this HMI, the manager is able to visualise the workflows deployed in the workflow engine, modify some of their properties (e.g. user assignment, time schedules, task properties, etc.), visualise the tasks and the users assigned to those tasks, or manage the users. All these features are represented in the next figures.

This following figure shows a list of diagrams deployed in the workflow engine, indicating two parameters: the configuration state (resolved or unresolved) and the status (enable or disabled). The configuration state determines if a process can be started or not. The reasons are related to the definition of the workflow diagram (i.e. not all the actors of the process have mappings to users, some business data are not available, etc.)

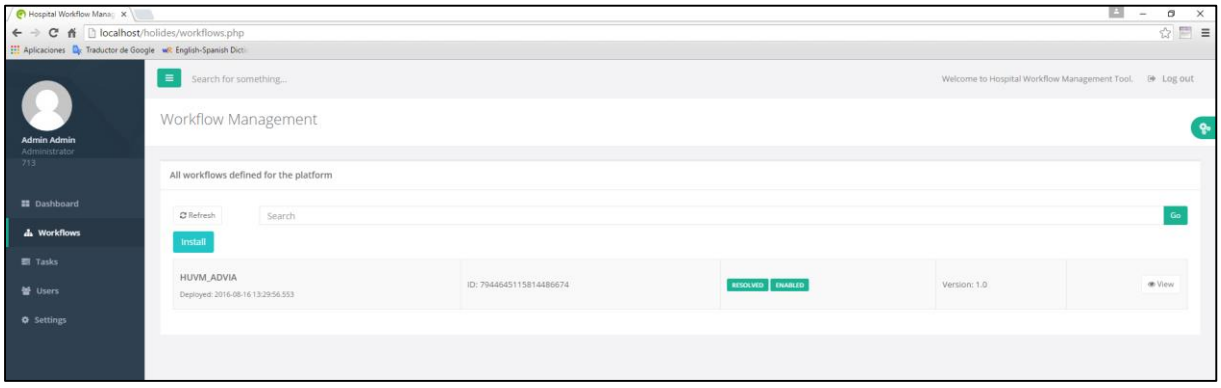


Figure 5 Operator task schedule and guidance use case: Hospital Workflow Management Tool (list workflows)

Each workflow can be clicked to get more information and perform some actions on the workflow: description, involved actors, workflow diagram

(BPMN format), modify the status, remove the workflow in the system, know the different instances and the management of them, etc.

Figure 6 Operator task schedule and guidance use case: Hospital Workflow Management Tool (visualise workflows)

The manager can carry out changes in the workflow diagram, for later to be reloaded in the workflow engine manually. This feature will be improved in next versions, to allow to the manager the possibility of updating in real time the workflows. The only restriction is that the previous running instances of the workflows are deleted with the new deployment. Next figure shows the BPMN diagram for a particular workflow.

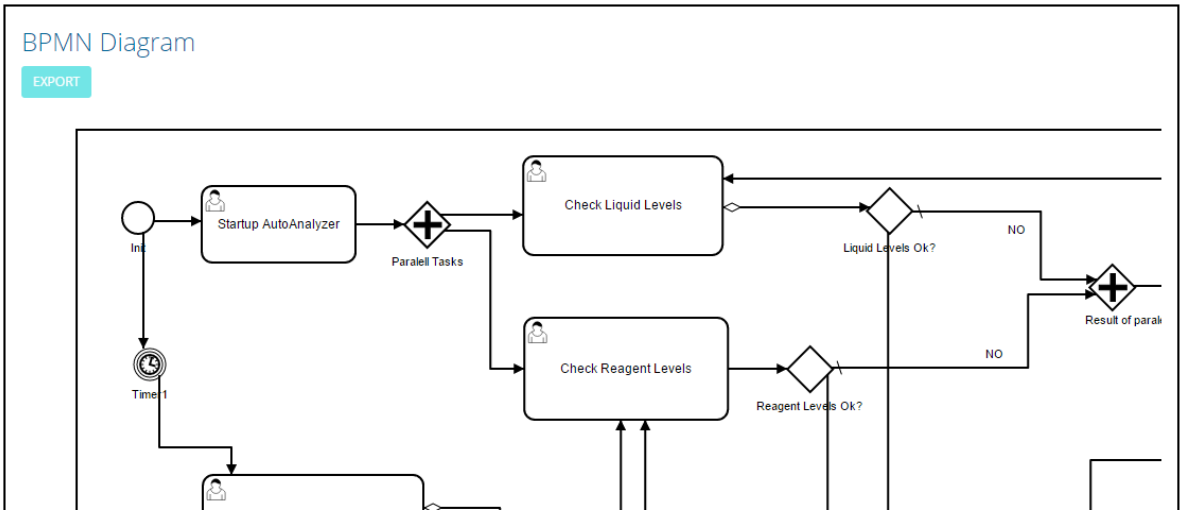


Figure 7 Operator task schedule and guidance use case: Hospital Workflow Management Tool (edit workflow properties)

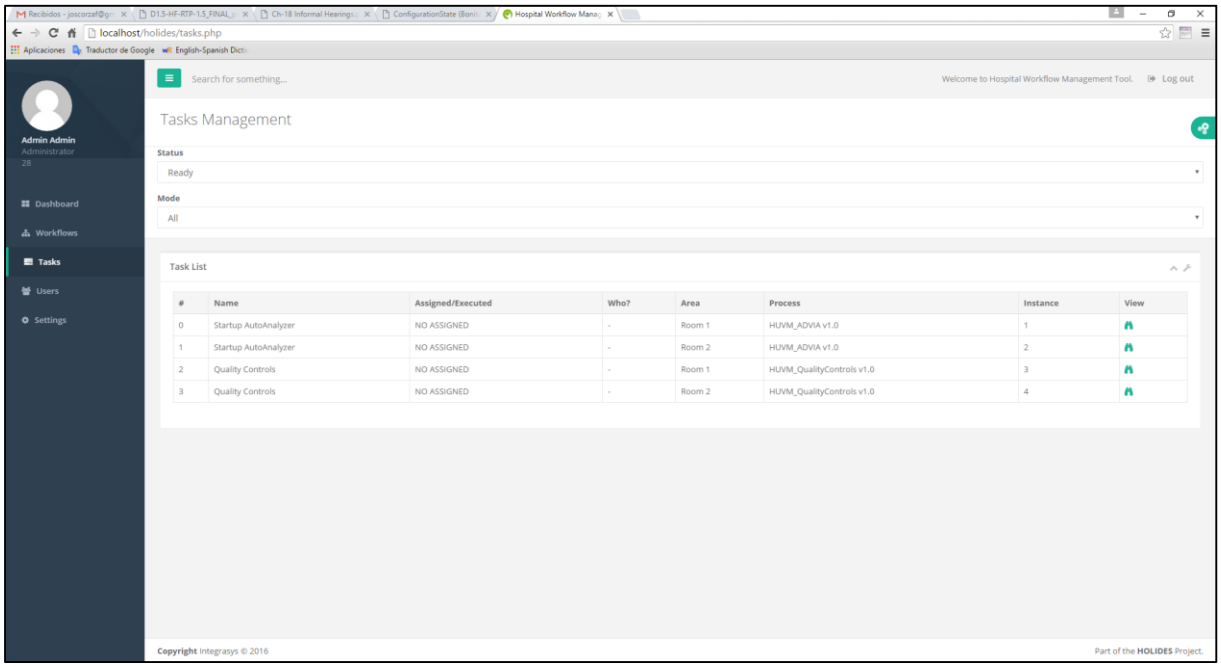


Figure 8 Operator task schedule and guidance use case: Hospital Workflow Management Tool (visualise tasks)

Another feature is the management of users and actors, which are involved in the business processes or workflows. This information about actors and filters can be defined for each workflow in particular. When you define a business process, you need to define who will carry out a task or step in the process by specifying an actor. An actor can be defined for a particular task, lane or global process. An actor is a placeholder that defines the theoretical user or group of user who will perform the task.

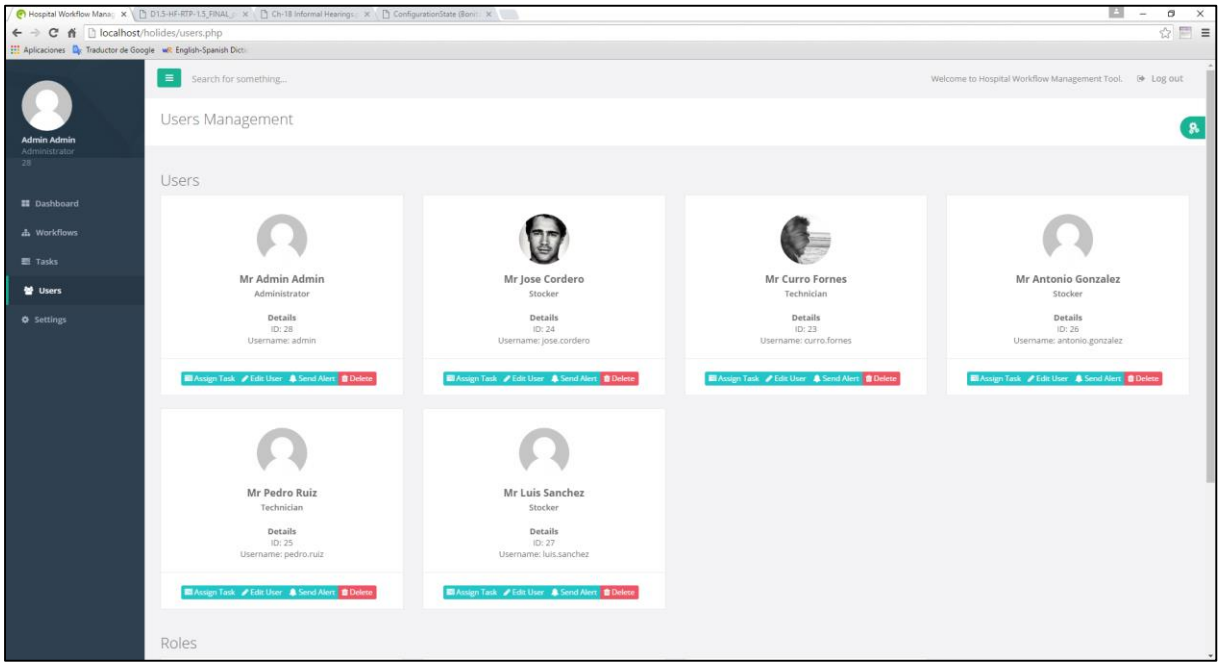


Figure 9 Operator task schedule and guidance use case: Hospital Workflow Management Tool (manage users)

Regarding the client application (HoliApp), next we show several screenshots of the main windows of the application: login, profile, task list, task info, etc.

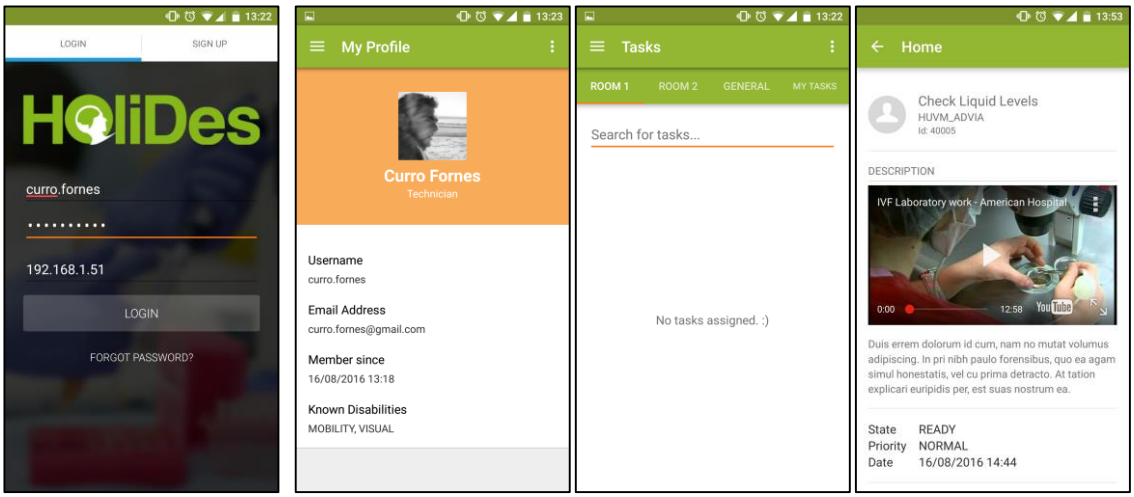


Figure 10 Operator task schedule and guidance use case: HoliApp - main windows of HoliApp

The application allows to the operator to check the tasks available to be taken. The tasks can be associated to a particular area (“Room 1”, “Room 2”) or not (“General”) where this information is indicated when the workflow is instantiated.

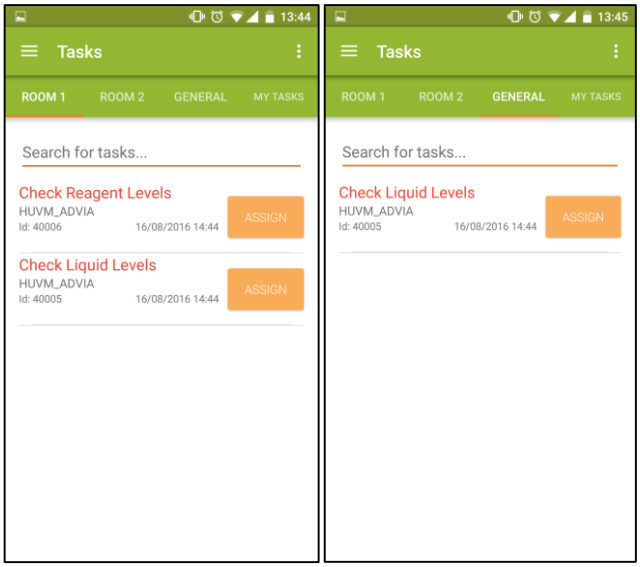


Figure 11 Operator task schedule and guidance use case: HoliApp - task list associated to particular area (“ROOM 1”) and task list for general tasks (“GENERAL”).

Other aspect to take into account is the adapted design of the disabilities. Different design guidelines have served as a relevant reference on a range of topics that are crucial for the design and development of more age-friendly human-computer interfaces, considering aspects such as vision and hearing, motor skills, cognitive fluency and memory, familiarity and prior experience with other technologies. The profile of the users includes the disability information and such information could be managed from management tool by the manager.

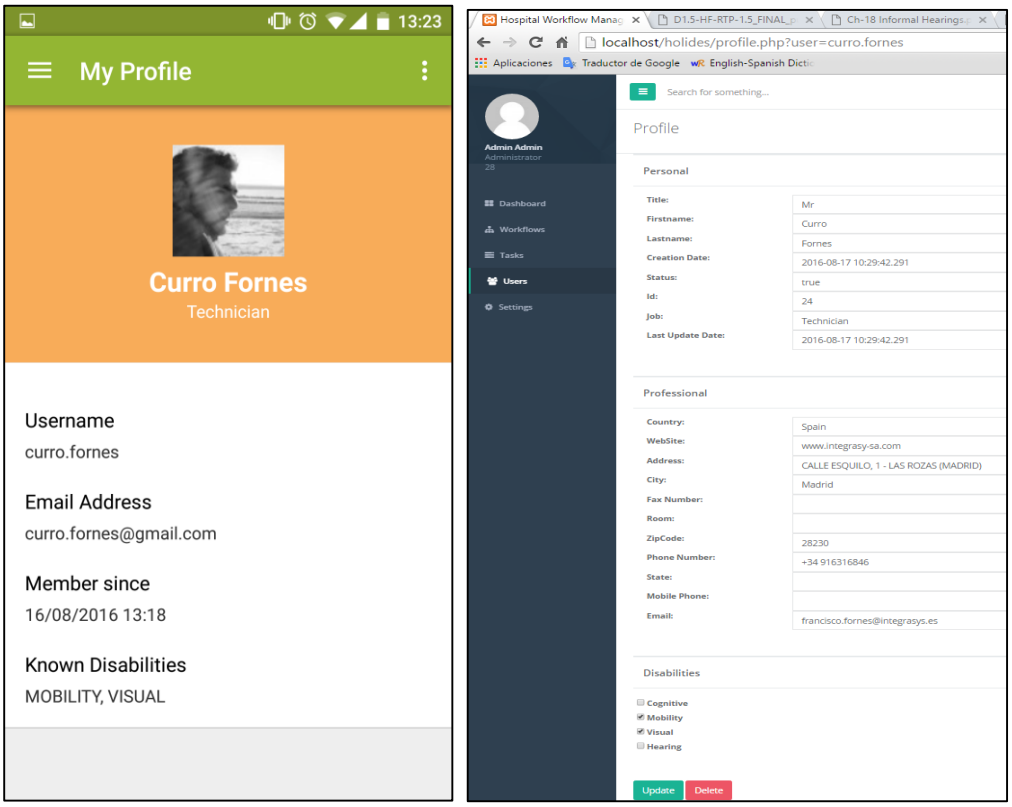


Figure 12 Operator task schedule and guidance use case: HoliApp - user profile and known disabilities.

The disabilities taken into account have been:

- Mobility. Some tasks require high physical effort and some operators can present temporal back problems, physical disability, etc. The tasks with this feature cannot be selected for this type of operators.
- Visual Impairment. Operators with a limitation of actions and functions due an eyesight problem in the vision such as Short sight, long sight and astigmatism, etc. The interface will be enriched with text-to-speech and augmented text.
- Hearing Impairment. Operators with hearing problems. For this disability, all the elements that require audio will be removed from the interface.
- Cognitive Impairment. Operators with learning problems when facing new procedures or work with new technologies. The interface will be enriched with how-to videos to facilitate the introduction to the new procedure or system.

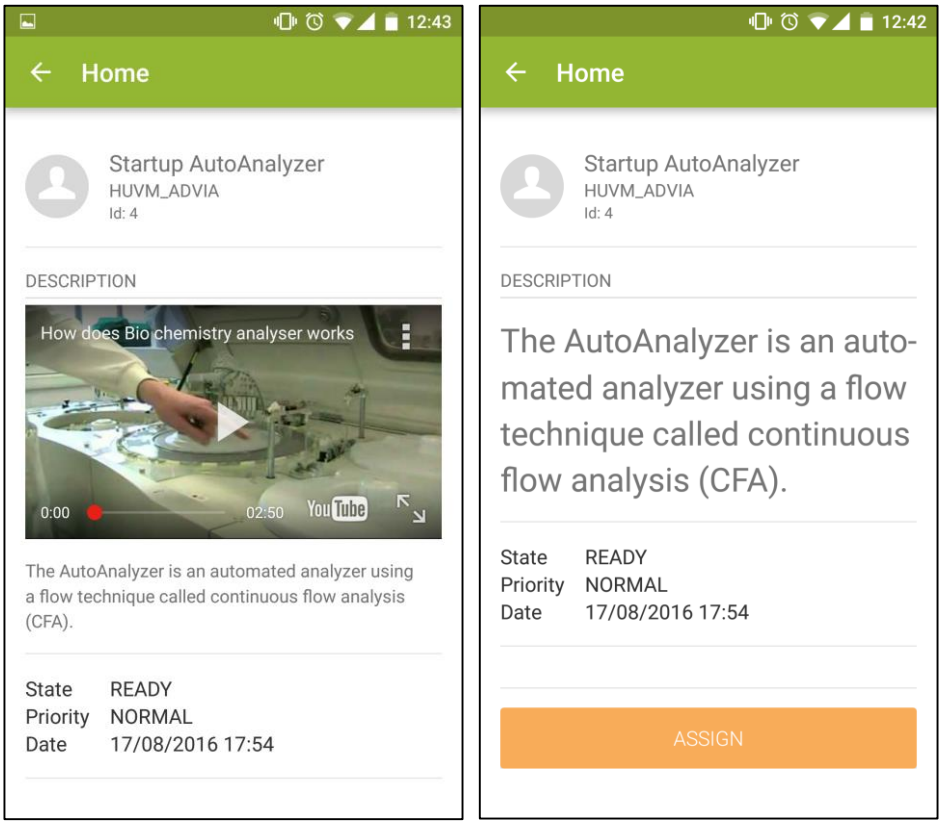


Figure 13 Operator task schedule and guidance use case: HoliApp - adapted interfaces depending on user disabilities (left – cognitive impairment, visual problems).

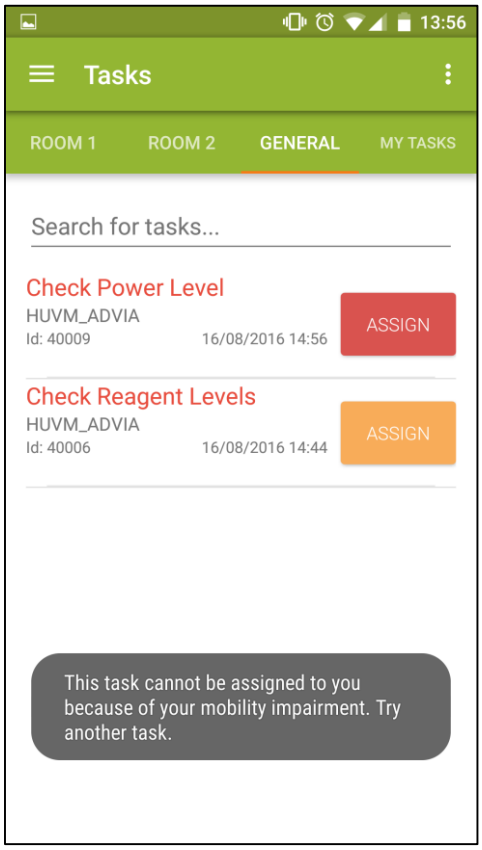


Figure 14 Operator task schedule and guidance use case: alert message indicating that this task cannot be assigned to the operator due to mobility impairment.

2.2.2 Qualification and certification

The developed software and designed GUI have been carried out for a use in a research environment, so qualification and certification have not been taken in mind although we consider it a fundamental factor in this area. The next steps after the ending of the project, in addition to improve the functional and maturity aspects because we consider that the results are not mature enough to concretize a final product, one of the points to be improved is the robust error (e.g. bugs) and certification issues of the system in Hospital domains.

2.3 HF-RTP assessment and recommendations

This use case requires a strong interaction between machine and operator, which make adaptive human factor design very important. MTTs that support the design process by simulating and modelling the AdCoS and user interaction are important to optimize the design. In the context of the Operator task schedule and guidance AdCoS, several HF-RTP tools have been involved for modelling and designing the processes that compose the use case.

In deliverable D6.3, several HoliDes methods and tools (RTMAPS, GreatSPN, HEE, task modelling approach…), initially selected as the candidates for accomplishing the use case, were analysed indicating which of them covered most of our requirements based on the steps of the AdCoS design and development process (requirements, design, simulator and prototype development and prototype validation).

After comprehensive analysis, GreatSPN was selected for the design stage where basic Petri nets were used to create models for the proposed clinical guidelines in this use case. GreatSPN tool presents complete features for modelling and simulate the workflow of the targeted scenarios but we can find two main drawbacks:

- It is not possible to perform simulation in real time, with external events that triggers certain actions.
- The large variability of human action in this environment is difficult to model. The non-deterministic nature of the scenario makes it difficult to model such scenario.

Finally, the previous drawbacks causes to consider other workflow tools like BonitaSoft or YAWL to cover the all required requirements in this use case. Anyhow, GreatSPN was employed to model and simulate the different clinical guidelines, and this information was used as input to validate the workflows in BonitaSoft.

Regarding the assessment, the AdCoS assessment has been performed on the GUIs and logic achieving an estimation of maturity of use case of TRL 4, where the different components are checked at laboratory environment that they will work together, providing an estimation of how software test results differ from the expected system goals.

We note that evaluation has been carried out in a laboratory environment by a group of non-expert users (neither technical users nor users involved in the development of the use case), due to the difficulty to deploy the system in a real hospital. Different profile or physical states of users have been simulated such as disabilities, workload or tiredness.

The results indicate that the tools comply with the set of requirements defined at the beginning of the project, the quantitative objectives set in this evaluation and the expectations by users that they only gave feedback some minor changes suggested in the interface. They will propose changes in the smartphone mobile interface to increase the adaptability to the user state, improving the efficiency and interactivity. These proposed changes will be performed in future versions. From this evaluation, we can conclude that the objective of this AdCos use case has been achieved in terms of usability and interactivity with the user.

3 Querying open EHR data

3.1 AdCoS description

Querying open EHR data AdCoS provides effective and secure remote access for patients and authorized professionals to EHR (Electronic Health Records). EHR contains the medical and treatment histories of patients, diagnoses, medications, radiological studies, etc.

The patient may access to his or her own EHR and may modify some data like demographic, habits or personal details in order to keep his or her information as updated as possible.

In addition, all clinicians involved in a patient's care may access to his/her EHR. With Querying open EHR data AdCoS, information is available whenever and wherever it is needed for fast and full documented medical support.

The users, patient or professional, may access from wherever outside the hospital (Web development), so, this information needs to be safely accessible anytime anywhere.

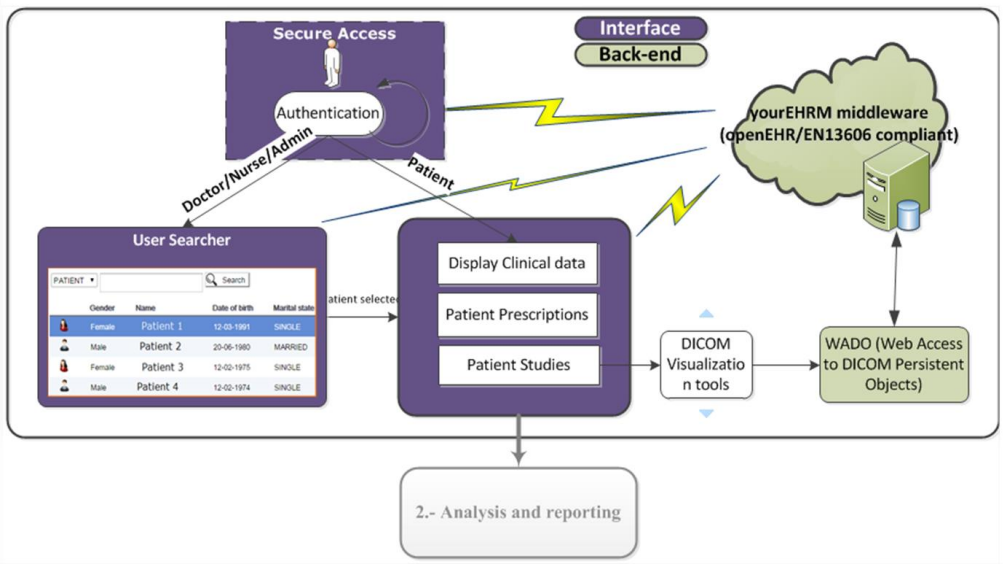


Figure 15: Querying open EHR data AdCoS.

The final version of this AdCos is a prototype in order to become a product aiming at:

- Gathering information from heterogeneous sources (DICOM images[2], EHR data, etc.) to show the data to the medical specialists in a common way
- Extracting new useful knowledge from the aforementioned information

3.2 Final HMI

The interaction between the operator and the system has carried out through a technical structure; server, network communication and a device like PC or tablet. This PC or tablets allow the users (patient and/or professional) to interact by using Graphical User Interfaces (GUI).

In the context of the Querying open EHR data AdCoS several tools have been considered in the development process for the new HMI; HEE, AEON, Data race detector & healer and HF-filer. Finally, HEE and AEON are integrated.

HEE
The Human Efficiency Evaluator from OFFIS has been integrated in "Display Patient Studies" use case. In following figure, you can see the user graphical interface developed fulfilling the HEE recommendations.

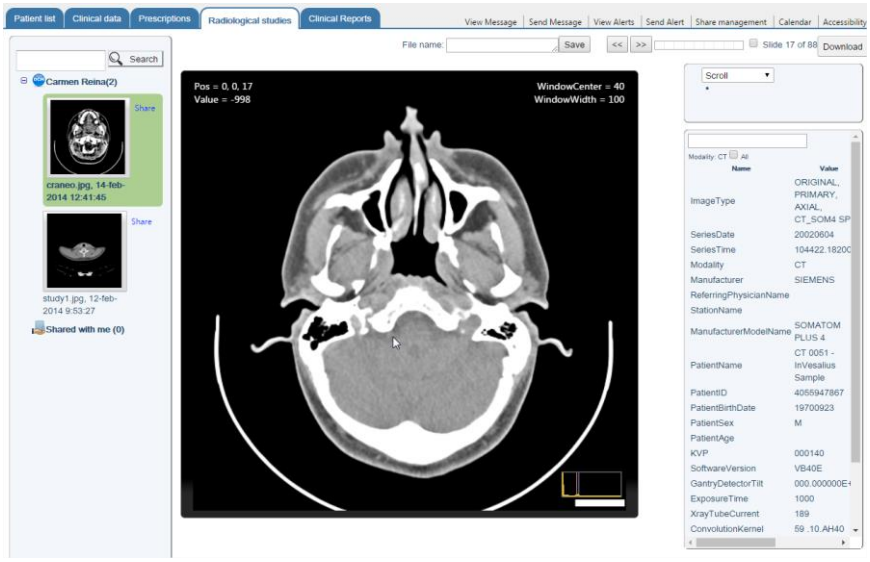


Figure 16: Display Patient Studies Graphical User Interface

[2] Digital Imaging and Communications in medicine, http://dicom.nema.org/

Once we change "Display Patient Studies Graphical" User Interface, we change, in cascade, all AdCoS GUI keeping a common design in all of them, like "Clinical Reports":

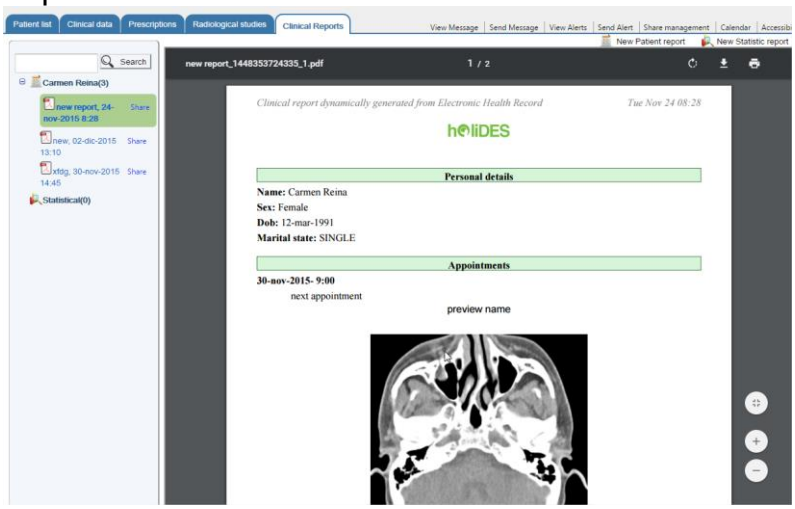
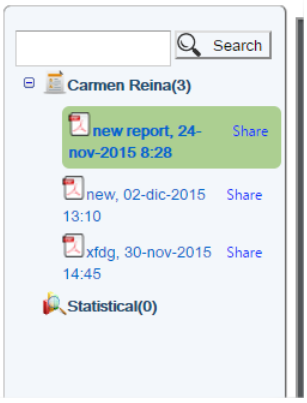


Figure 17: Display Clinical Reports Graphical User Interface

Keeping a common design is a way to enforce usability and consequently user satisfaction.

Querying open EHR data AdCoS has been developed taking several actions to facilitate access to patients and professionals. All recommendation described in D6.7 have been developed:

• **Standard GUI Controls**: All GUIs keep a basic and similar appearance and behavior. Following figure shows Clinical images and Clinical Reports searcher, where the users use it in a similar way to look for details (clinical images or reports) and select them.



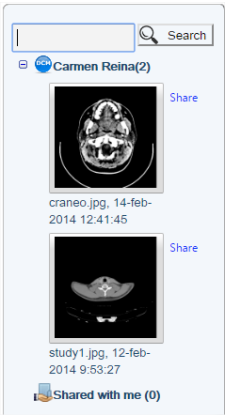


Figure 18: Clinical report searcher

Figure 19: Clinical images searcher

• **Simple interfaces:** It is necessary to avoid unnecessary elements and be clear in the language used on labels and texts. All texts have been carefully reviewed to ensure their understanding and clarity. However, it has been developed in such a way that if a wrong text is detected, it is very easy to replace it.

• **Common design:** One common design through the AdCoS to facilitate efficiency (colours, light, contrast, progress bar, etc.). Careful placement of items can help draw attention to the most important pieces of information and can aid scanning and readability. This figure shows two different interfaces "Send Message" and "Send Alerts" with a common design. Therefore, once the user becomes familiar with "Sending message" will be familiar with "Send Alerts" and vice versa.

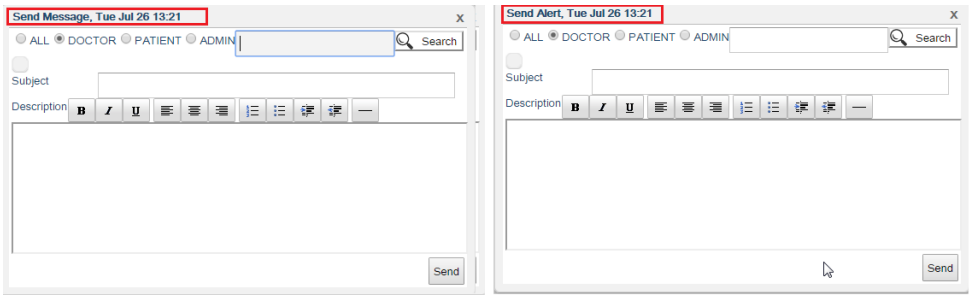


Figure 20: Send Message (left) and Alerts (right) comparison

• **Keep the user informed (at any time):** The AdCoS informs the users of actions. It reduces frustration for the user. Throughout the entire design, the AdCoS shows information about action ("Click here to send one message", "Click Here to save details", etc.) and results ("The message has been sent", "You have a new message", etc.). These figures show some examples:

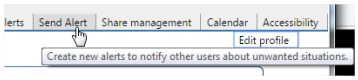


Figure 21: Tooltip label to know what "Send Alert" does

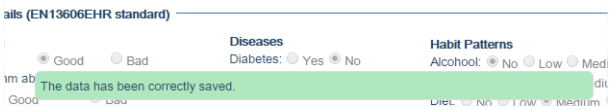


Figure 22: Information displayed on the screen about action

• **Defaults values:** The AdCoS displays clinical data in logical and coherent default values as much as possible. It reduces the user actions and speeds up the interaction.

• **Personalization options:** Personalization can help make users feel more comfortable. The users have the option to change language (English, Spanish, etc.) and text size (at any time). These tow functionalities are developed in Querying open EHR data AdCoS.

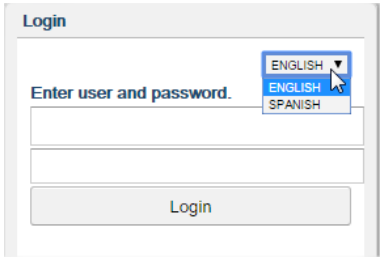


Figure 23: Language selection.

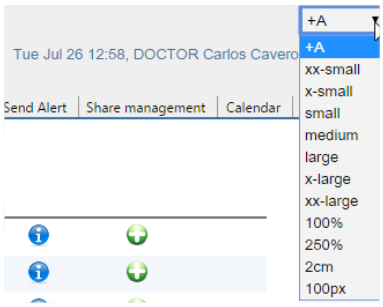


Figure 24: Set text size.

• **Response time limits**: Response times must be as fast as possible; the AdCoS displays a "Busy" cursor if a command takes more than 8 seconds, an explicit progress if longer.

• **Display error messages:** If something is wrong, like empty username, the AdCoS displays an error message explaining clearly, why and how the user can fix the problem, see following figure:

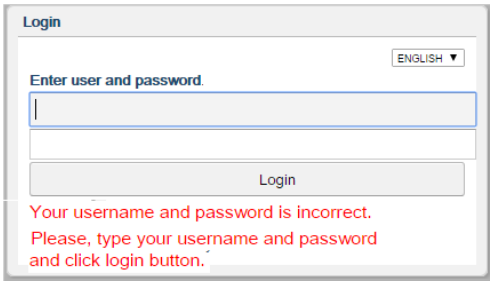


Figure 25: Incorrect username and password information

• **Required fields:** Any obligatory fields (lists, input boxes, etc.), which must be filled out by the user must be highlighted. This allows us to ensure that the user knows and provides all data needed. See following figure:

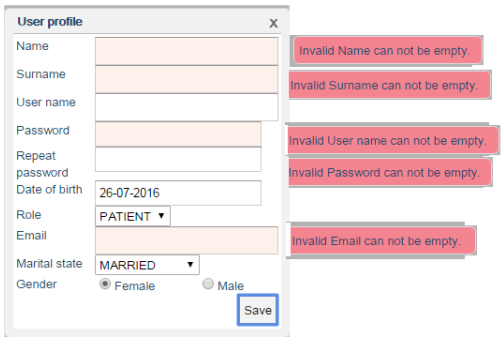


Figure 26: New User Interface; Errors messages.

During all development and improvements, it has taken into account Evaluation methodology applied and described in D6.9 and its results.

Improvement compared to baseline
The new HMI has simplified the way of access clinical information data and patient HER by (1) collecting information from heterogeneous sources and (2) displaying it in a fast and simple way.

	DESCRIPTION OF DEPENDENT VARIABLE	MEASURE BEFORE (1-10)	MEASURE AFTER (1-10)
Adaptability	How the GUI adapt to the user needs	5	6
USABILITY	Usability of the AdCoS	5	8

Figure 27 Evaluation methodology applied

Two performance indicators to key words have been selected:

- **Adaptability**: this indicator measures how the GUI is adapted to the user needs in order to highlight the relevant parts of the GUI (the image in our case).
- **Usability**: this indicator gives the improvement in the GUI management gathered from the users (avoiding user frustration, keeping user informed, etc.).

For the evaluations users have been tested the GUI before and after the changes providing feedback using surveys.

This improvement related to user satisfaction (see Figure 27 Evaluation methodology applied

) is due to several changes in the Interfaces design. All this changes are described above.

Qualification and certification

In this AdCoS, the use of the HEE tool was clearly beneficial because it forced the designers to explicitly think about every individual step in the workflow and describe it in the task analysis step. In addition, the change of the focus, from the developer to the end user, to increase usability and adaptability, as well as working in close collaboration with heath care professionals. All this leads to improve functionality, usability, safety, and, consequently, the quality of the certification process.

3.3 HF-RTP assessment and recommendations

As we mentioned in D6.7 we highly recommend that the HEE tool is able to simulate different situations and user profiles, for example:

- One user patient elder may have more difficulties to interact with a GUI than a professional may.
- Experienced user in using technologies will have less difficulties that a person with not experience.

4 Guided patient positioning

4.1 AdCoS description

The Guided patient positioning system provides guidance to operators of MRI scanner during preparing and positioning patients 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.

Figure 28 Pictures of several actions during patient positioning

4.2 Final HMI

The UI Designs on the gantry display to guide the user to prepare the patient has been iteratively improved based on user test feedback.

4.2.1 AdCoS design – before and after

At the start of the project on Guided Patient Positioning the initial UI design is depicted below. Based on this design feedback was gathered from users by (1) hospital observations to learn about the current way of working, (2) a card sorting exercise to discover what users find important in the workflow, and finally (3) a user test based on an iterated version of the UI design as depicted in figure 2.

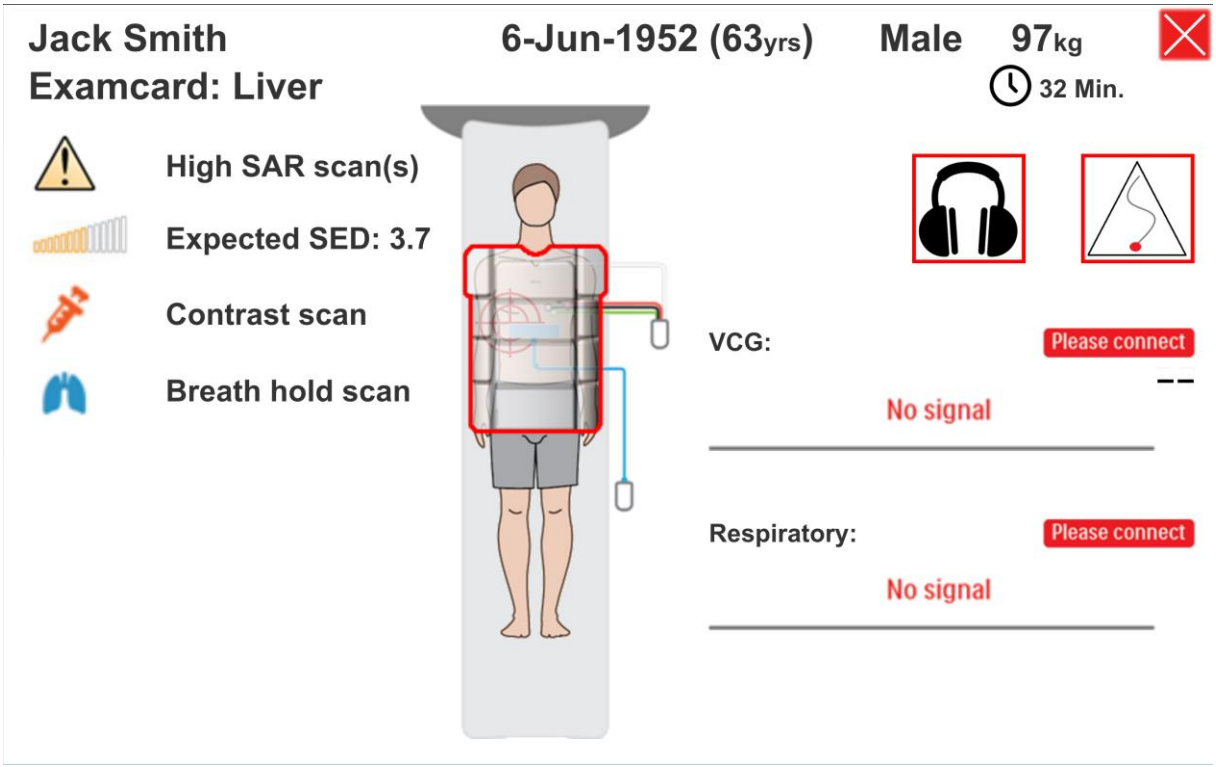


Figure 29 Initial UI Design

The final design has shown improvements on several aspects:

- Information clustering to easier find important information on-screen
- Improved layout of information that fits the workflow. Actions for the user are laid out from top-left to bottom-right
- Progressive disclosure has been applied to show relevant information at the time required.

More details on the performance indicators can be found in deliverable D1.7 on the final baseline assessment.

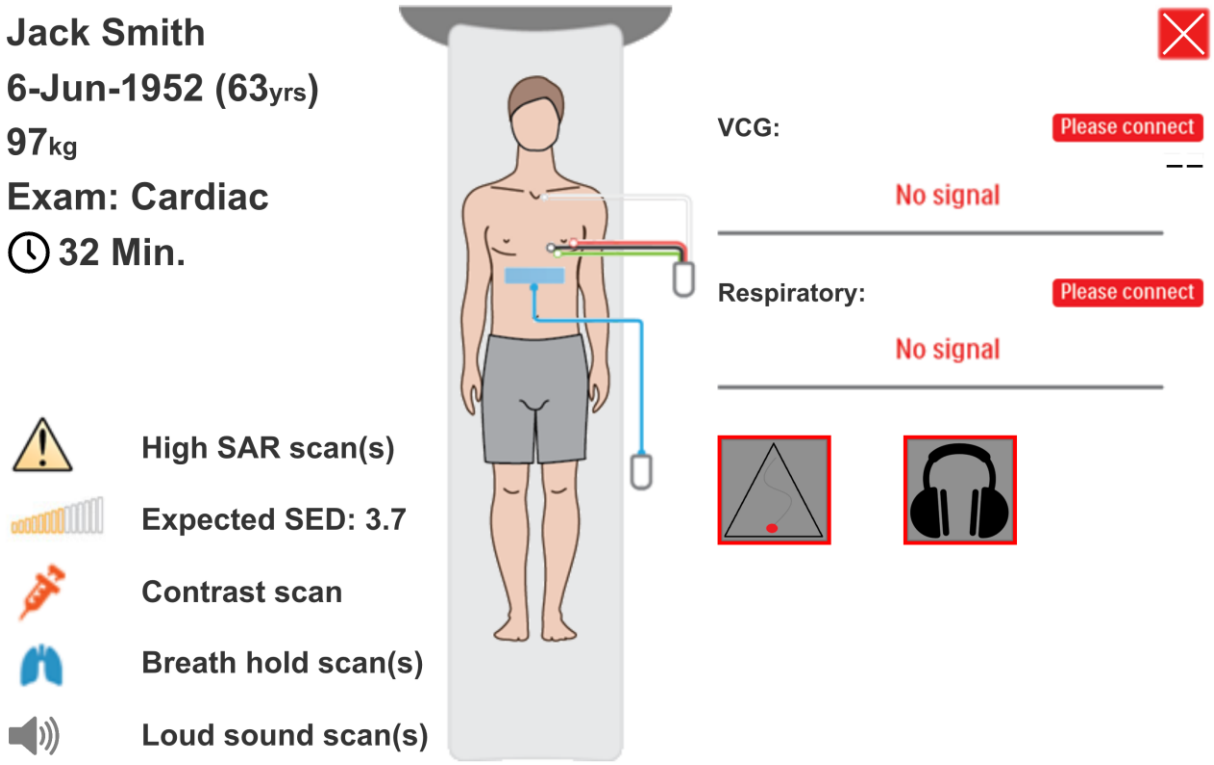


Figure 30 final UI Design

4.2.2 Qualification and certification

Most AdCoS in the Health domain, like this one, are products in a regulated industry. This means that we have to adhere to specific quality and process guidelines and standards to acquire for example CE certification. CE certification is needed to be able to sell the product in the European market. Similarly, a health product of a certain class needs FDA certification to be sold in the USA.

These standards require a documented and consistent way of working throughout the whole product realization process (PRP). Already at the start of a project you need to also plan all usability related activities and perform them to quality standards. Evidence on the way of working and quality standard results must be documented throughout the PRP.

Having tools that support in a consistent way of working and anticipating the clauses from standards that have to be adhered to are obviously of great value.

- The standardization of information formats increases the consistency of results.
- Tools anticipating the needs and requirements from standards, like task analysis tools (means-end modelling, HF-TA, U-DAT), facilitate documentation of the necessary artefacts needed as evidence to particular standards. For example, a built-in module to gather and document possible use-errors is provided by both U-DAT and HF-TA. Use-error assessment is an important part of safety standards.
- Automation saves a lot of time. Gaining time helps to focus more on things that really matter. Even more, automation improves consistency in results. Consequently, the quality of results will improve as well.
- Eventually, documentation of process and results must be documented properly and be easily accessible. HF-Filer anticipates such needs in providing a means to archive relevant documents and results.

4.3 HF-RTP assessment and recommendations

For concept validation we provide preliminary embodiments of the proposed solutions and assess these with real user representatives in various geographical regions (e.g. Europe, India, US).
The WP5 MTT U-DAT, in combination with HF-task analysis and HF-filer, have been used in different stages, which allows for a more systematic concept validation and capturing of the results. See figure 3.

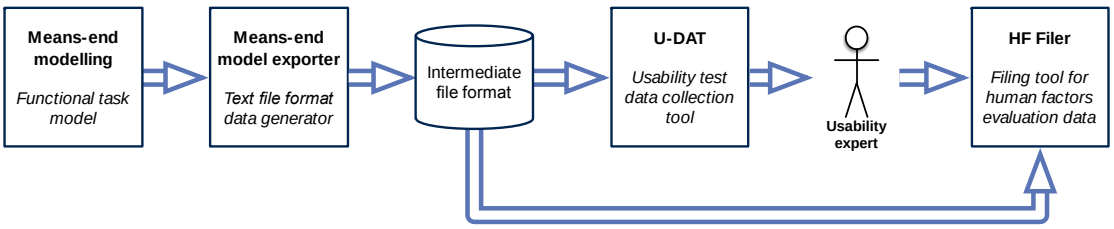


Figure 31 Chain of lifecycle tools for usability evaluations of the Guided patient positioning AdCoS

The systematic approach going from a task analysis in one tool – Means-end analysis - then using another tool – U-DAT – to perform user evaluations, and finally using HF Filer to capture the main results, helps to streamline the complete workflow and optimize and connect information flow between different stages. This was not the case before using this chained approach. Consequently, the chained tooling approach with agreed upon information interfaces saves significant time as the format of different results are consistent. Even more, automation of information flowing from one workflow step to the next saves significant time where previously a lot of manual-work was involved.
For the future, more automation in subsequent steps are possible. Also, extending the common information format and providing general interfaces from different tools, preferably in the HF-RTP, could be of great value.

5 Robust VCG Triggering

5.1 AdCoS description

ECG triggering is often required during MRI scans to avoid image artefacts due to motion of the heart or blood flow. However, it is not very easy to obtain reliable trigger signals, since both the magnetic field and the scanning techniques distort these signals. A new technique measures the voltages between different leads indicated as V1 and V2 in figure 1. A smart algorithm based on this cross-referential information can detect the ECG triggers in a different and better way. However, this technique requires some user interaction to get the system properly calibrated.

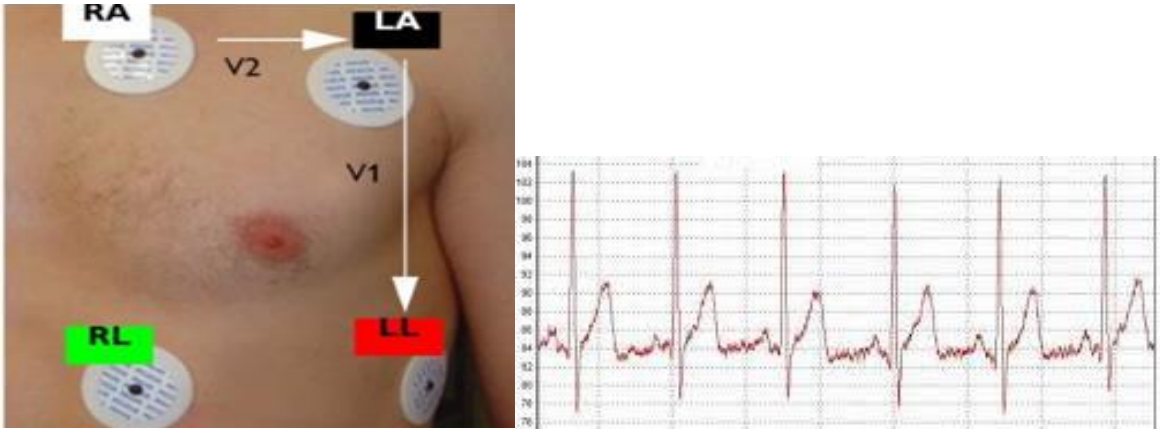


Figure 32: Pictures of the positioning of the ECG electrodes and an example of an ECG trace

Additional guidance for the operator is required during patient preparation and scanning to improve the reliability of these newly measured ECG triggers.

5.2 Final HMI

The UI Designs on the console for VCG Triggering to guide the user to prepare for manual VCG triggering has been iteratively improved based on user test feedback.

5.2.1 AdCoS design – before and after

At the start of the project on Guided Patient Positioning the initial UI design is depicted below. Based on this design feedback was gathered from users by (1) hospital observations to learn about the current way of working, (2) a card sorting exercise to discover what users find important in the workflow, and finally (3) a user test based on an iterated version of the UI design as depicted in figure 2.

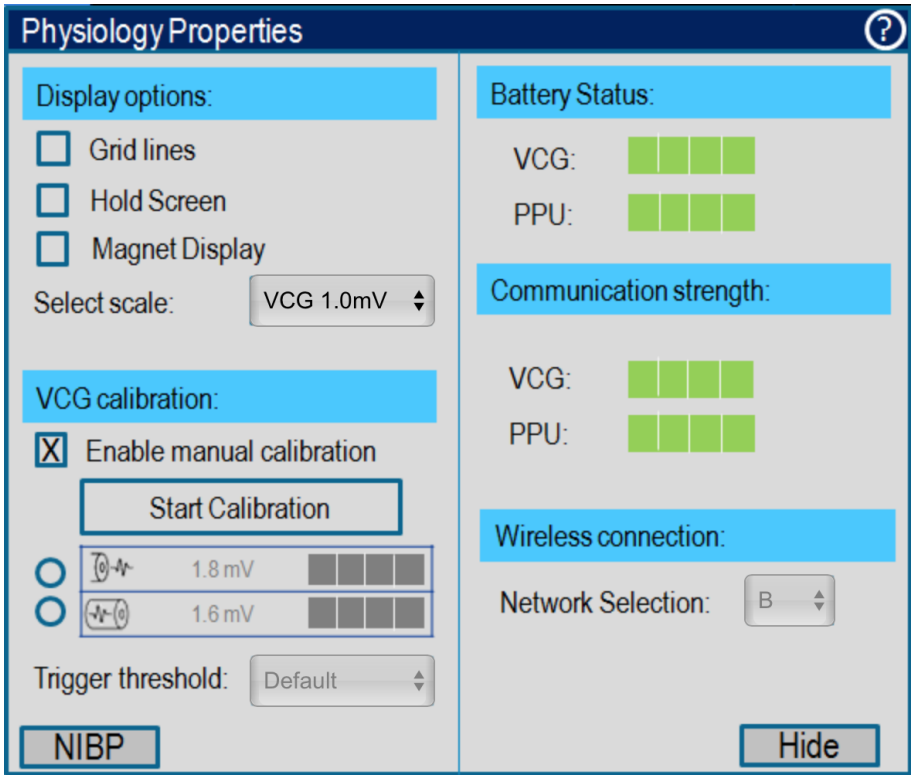


Figure 33 Initial UI Design of the main screen for manual VCG Triggering

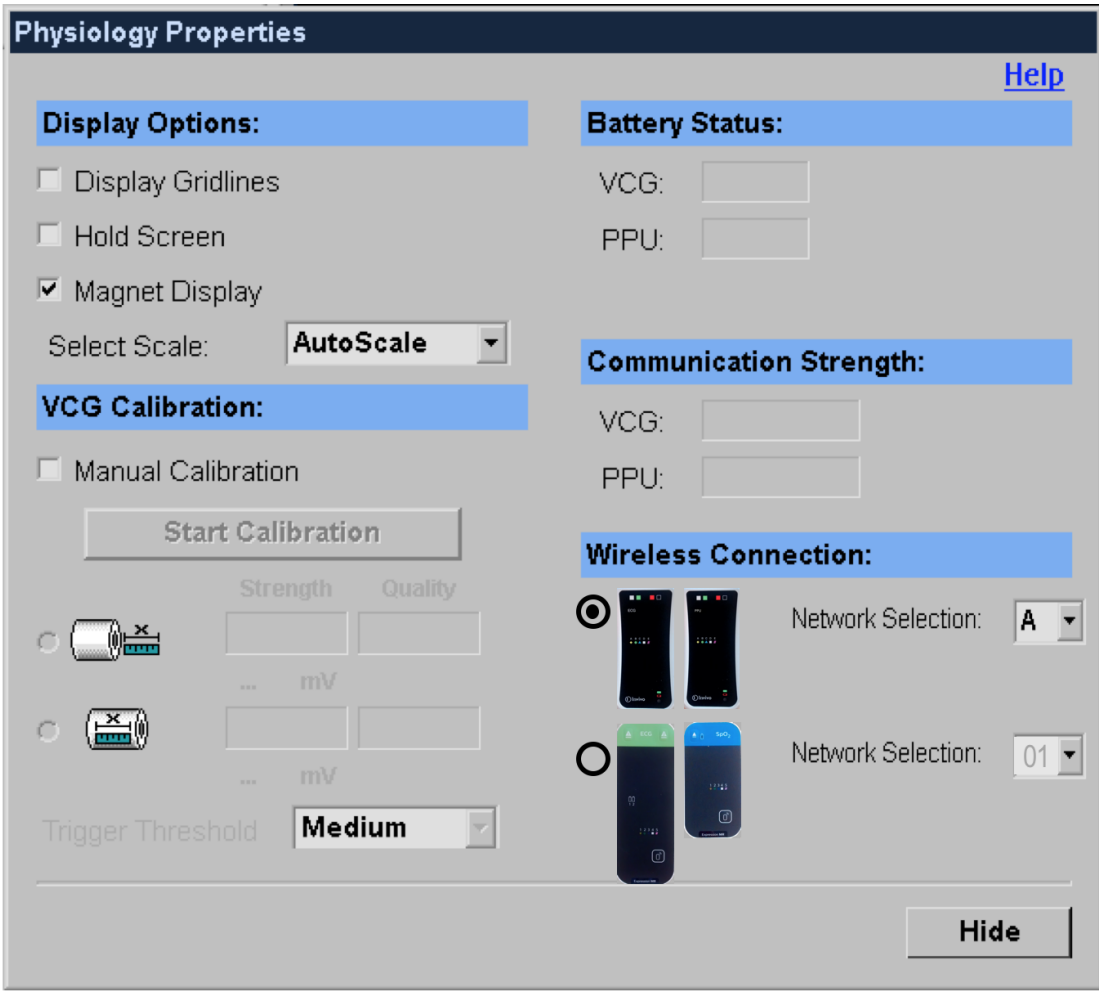


Figure 34 final UI Design of the main screen for manual VCG Triggering

The formative user test revealed 23 usability issues. All feedback has been taken into account, which has led to the final UI Design from figure 2. The fact that these usability issues were highlighted using the U-DAT based user test has resulted in an improved usability in terms of possible use error and efficiency.

The manual ECG triggering feature has been released as part of the Philips MR scanner software. Feedback from actual customers shows very satisfying results.

More details on the performance indicators can be found in deliverable D1.7 on the final baseline assessment.

5.2.2 Qualification and certification

Most AdCoS in the Health domain, like this one, are products in a regulated industry. This means that we have to adhere to specific quality and process guidelines and standards to acquire for example CE certification. CE certification is needed to be able to sell the product in the European market. Similarly, a health product of a certain class needs FDA certification to be sold in the USA.

These standards require a documented and consistent way of working throughout the whole product realization process (PRP). Already at the start of a project you need to also plan all usability related activities and perform them to quality standards. Evidence on the way of working and quality standard results must be documented throughout the PRP.

Having tools that support in a consistent way of working and anticipating the clauses from standards that have to be adhered to are obviously of great value.

- The standardization of information formats increases the consistency of results.
- Tools anticipating the needs and requirements from standards, like task analysis tools (means-end modelling, HF-TA, U-DAT), facilitate documentation of the necessary artefacts needed as evidence to particular standards. For example, a built-in module to gather and document possible use-errors is provided by both U-DAT and HF-TA. Use-error assessment is an important part of safety standards.
- Automation saves a lot of time. Gaining time helps to focus more on things that really matter. Even more, automation improves consistency in results. Consequently, the quality of results will improve as well.
- Eventually, documentation of process and results must be documented properly and be easily accessible. HF-Filer anticipates such needs in providing a means to archive relevant documents and results.

5.3 HF-RTP assessment and recommendations

For concept validation we provide preliminary embodiments of the proposed solutions and assess these with user representatives in various geographical regions (e.g. Europe, India, US).

The WP5 MTT U-DAT, in combination with HF-TA task analysis and observations function, have been used in different stages of the evaluation.

The systematic approach going from a task analysis in one tool – HF-TA - then using another tool – U-DAT – to perform user evaluations, and finally using HF Filer to capture the main results, helps to streamline the complete workflow and optimize and connect information flow between different stages. This was not the case before using this chained approach. Consequently, the chained tooling approach with agreed upon information interfaces saves significant time as the format of different results are consistent. Even more, automation of information flowing from one workflow step to the next saves significant time where previously a lot of manual-work was involved.

For the future, more automation in subsequent steps are possible. Also, extending the common information format and providing general interfaces from different tools, preferably in the HF-RTP, could be of great value.

6 Safe parallel transmit scanning

6.1 AdCoS description

To optimise the MR image quality for certain anatomical regions, a so-called phased antenna array is used in 7T head 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: optimal phase, frequency 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.

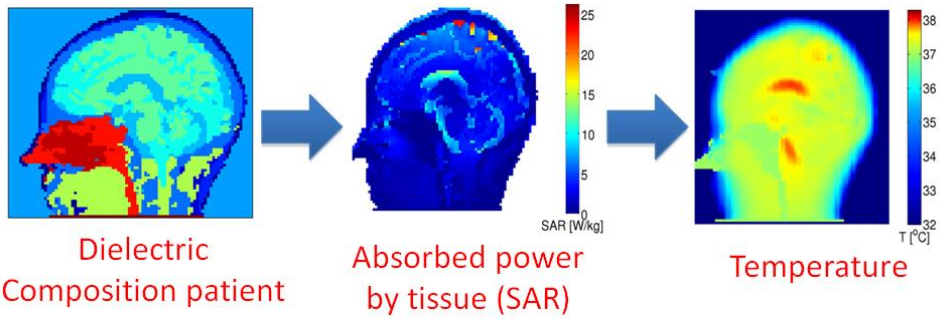


Figure 35 Relation between various calculated maps of field in the patient

The AdCoS consists of the following parts:

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

6.2 Final HMI

The AdCos has been realized by means of a matlab-based software tool that allows the MRI-operator to perform all required actions. This software tool has been installed at the scanner console, i.e. the computer that controls the MRI scanner.

The software tool has been designed to realize an intuitive work flow that can be used with very limited training efforts (by operators that are trained to used traditional scanners without parallel transmit capabilities). For use by scientists and senior operators, an extended 'expert mode' has been implemented that allows for extra functionality.

To ensure safe parallel transmit scanning, the potential heating pattern within the patient needs to be calculated beforehand. Such a calculation takes too much time to perform real-time with the patient on the table. Therefore the tool contains an atlas of pre-calculated heating patterns for a wide range of potential imaging subjects. For demonstration and testing purposes, this atlas has been realized for prostate imaging only. For an extension towards other imaging targets, new atlases would have to be realized for these alternative setups.

After the patient is positioned on the scanning table and the table has been moved into the scanner, low intensity survey scans and single-channel images will be acquired. The user will then load this data into the software tool and select the imaging target (region of interest, ROI). After that, the workflow follows a two or three stage process (depending on standard or expert user). The horizontal bar on top of the GUI indicates the progress.

For standard users, the stages are as follows:

1. **Model selection.** Based on low-intensity survey scans, select the best corresponding model within the database (this is aided by an automatic selection algorithm; the user only needs to confirm the suggested selection or select an alternative model). Figure 6.2a
2. **Pulse Design.** The software tool calculates the optimal phase-amplitude settings and displays the expected signal distribution within the body (figure 6.3). The maximum SAR (limiting factor for safe scan settings) is depicted on the right. Below that is an indicator that indicates the agreement between the calculated signal intensity distribution and the expected signal intensity distribution based on the individual channel measurements. If the user presses 'Accept' the safety threshold is sent to the scanner. Alternatively, the use may

choose to select a different model or operate the scanner using worst case expectations (conservative scanning mode).

For expert users, 'Model selection' is identical. The two subsequent stages are as follows:

2. **Pulse Design.** The user can choose from various pulse design options and the expected signal intensity distribution and the expected heating pattern (SAR distribution) are shown. The use may choose to accept these distributions and proceed to 'Validation' or change pulse sequence parameters/adjust ROI. Figure 6.5.
3. **Validation.** The user is presented with the expected signal distribution based on single-channel measurements and the expected signal distribution based on model calculations. The user can choose to accept/change the model or to scan with worst-case heating expectations (conservative scanning mode). Figure 6.6.

After the data has been sent to the scanner, new limitations are calculated by the scanner software based on the calculated heating values. All subsequent diagnostic scans are subject to these new more accurate limitations.

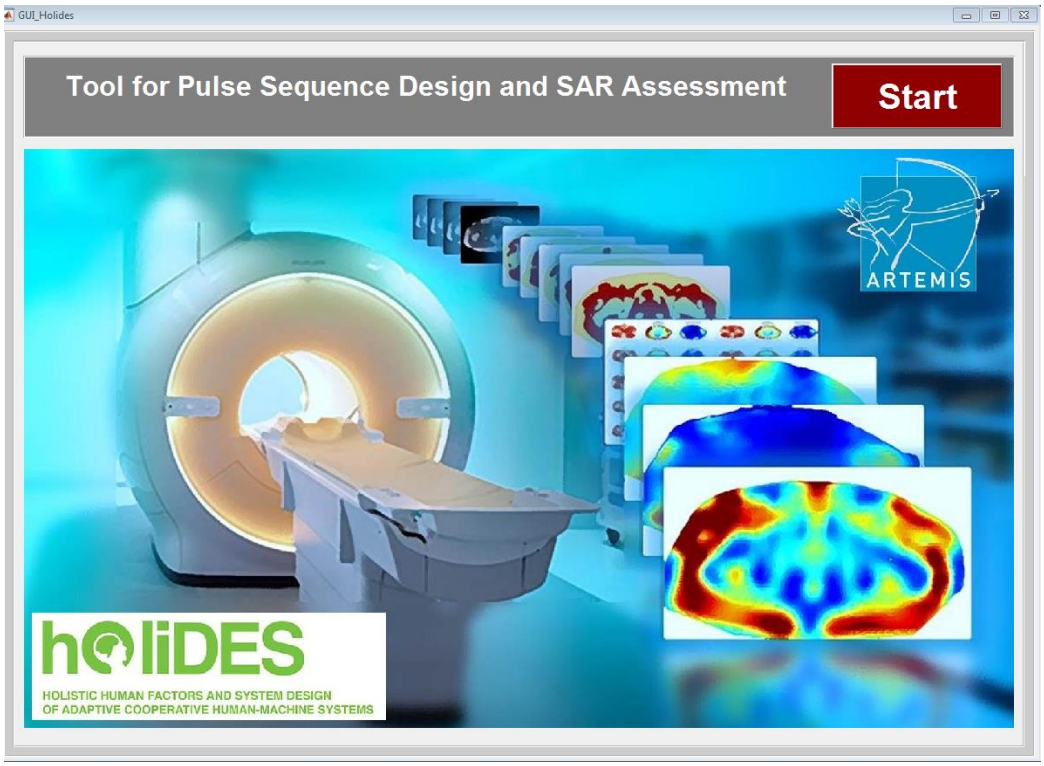


Figure 36 Front page' of the software tool for safe parallel transmit MRI

Figure 37 Selection of the best corresponding model from the database

(left: patient image; right: image from database). The indicator shows the level of agreement. To the left of that the model properties are depicted.

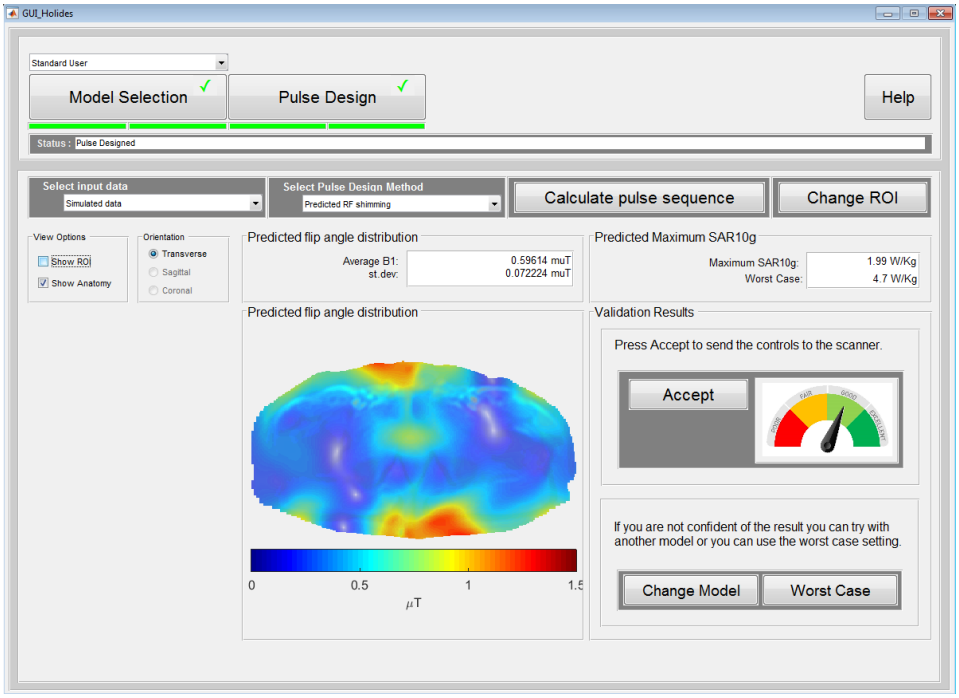


Figure 38 The resulting expected signal intensity pattern.

The maximum SAR level (=limiting factor for safe scan settings) is depicted on the right.

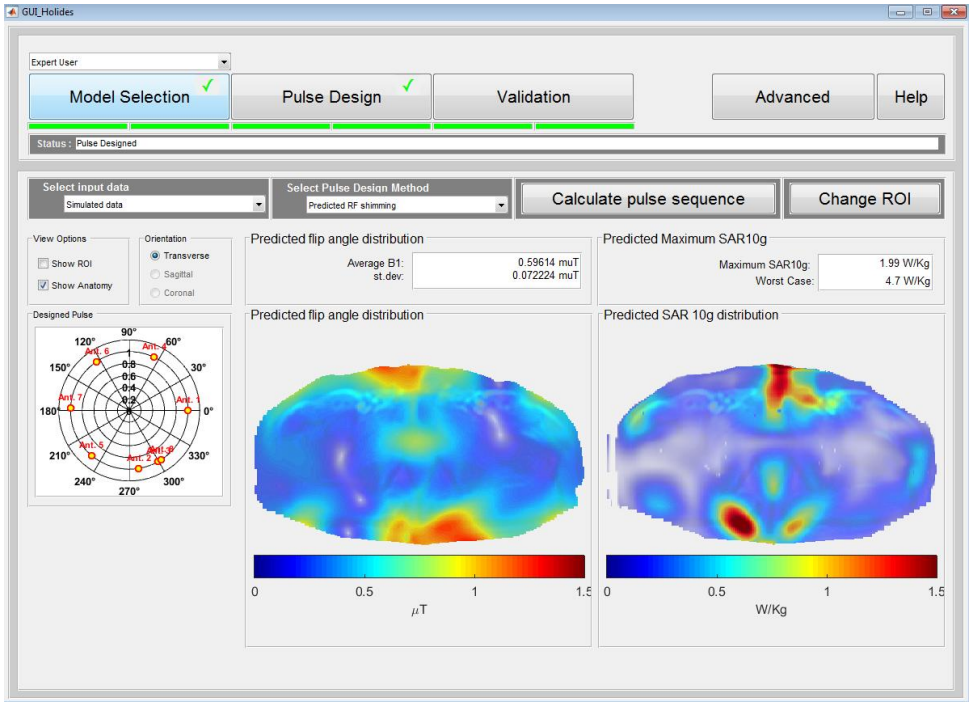


Figure 39 Expert mode – Pulse design

In Expert mode, the 'Pulse Design' stage of the work flow allows the user to look at the expected signal intensity distribution (left) and the expected heating pattern (right).

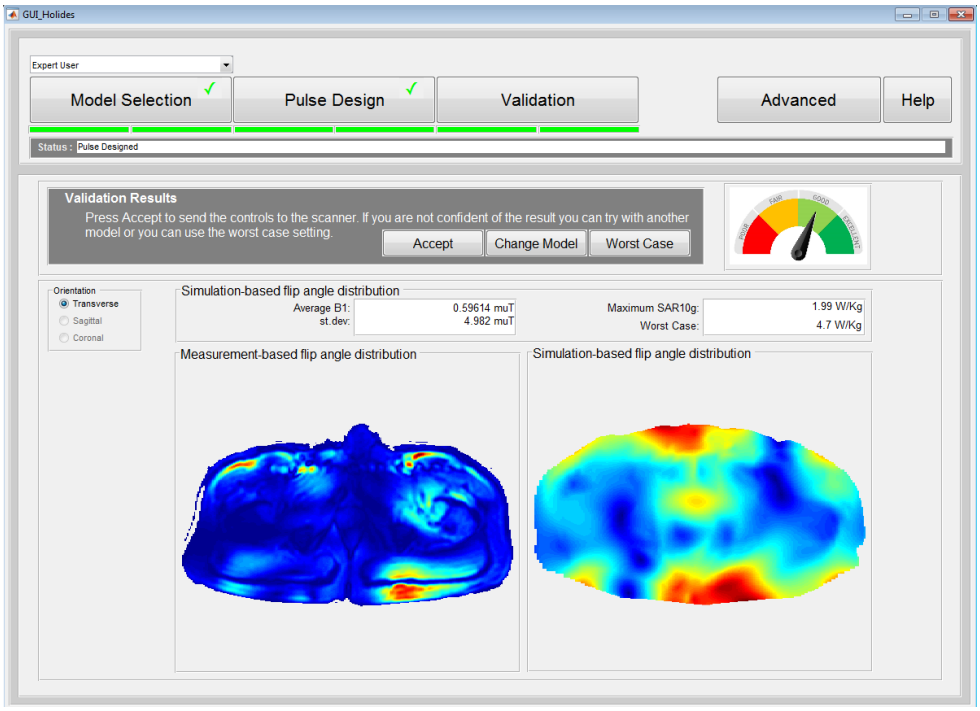


Figure 40 Expert mode - Validation stage

Expected signal distribution based on single channel measurements (left) and expected signal distribution based on model calculations (right) are depicted.

Improvement compared to baseline

The current GUI of the software tool is a result of an optimization process by means of focus group sessions in cooperation with SNV. The first draft of a GUI for this software was designed by one of the scientists (figure 6.7). The participants in the focus group session have been presented with the first version, resulting in a wide range of feedback. This has led to a fully new approach with the two and three stage workflow as described above. The final design has been presented again to a focus group session. The major positive feedback was that the user friendliness and intuitiveness has been improved considerably. Minor remarks have been implemented to further improve the functionality and user-friendliness.

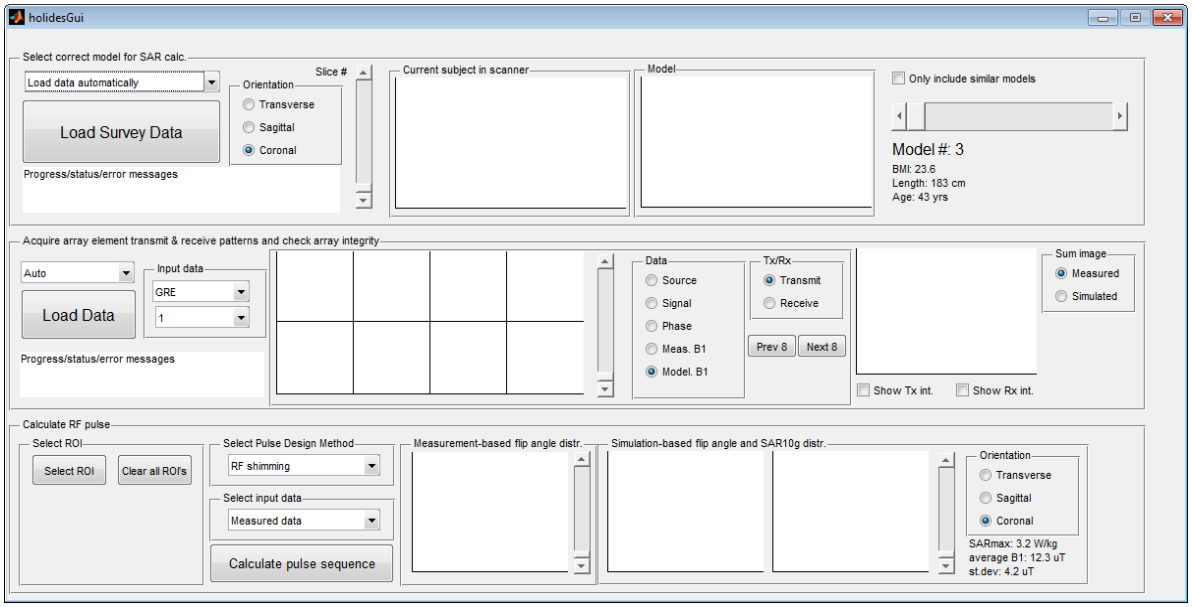


Figure 41 First draft version of a GUI design for the AdCos

Qualification and certification

The designed GUI is meant for use in a research setting. Qualification and certification is thus less a fundamental factor than for clinical products. Nonetheless, we aim at introducing a clinical interface in the coming years, thus the developed results from this Holides project will eventually have to go through the required certification steps.

6.3 HF-RTP assessment and recommendations

The Empirical Analysis tools provided by SNV were the MTT which has had the most impact on the building of the new graphic user interface (GUI). In cooperation with SNV, two Focus Group sessions have been organized to evaluate the layouts for the interfaces. The analysis tools provided by SNV led to a better designed GUI.

All the expert participants noticed the improvement of the GUI in terms of ease of use.

About the suitability of the new GUI for novice users, all the participants appreciated the introduction of the "standard user mode", but in their opinion the software is not yet fully self-explanatory for novice users. This

could be improved in future versions. However, also for the novice users, the usability and user-friendliness has improved considerable. Considering that this tool will not be used by operators without appropriate training beforehand, the usability of the tool is currently regarded sufficient. Relating to the intermediate assessment as reported in D6.7, we can conclude that the target of intuitive and easy usability has been achieved.

7 3D Acquisition

7.1 AdCoS description

An X-ray angiography system is typically used to visualize anatomy, catheters and other instruments during minimally invasive procedures like coronary stenting in the heart or aneurysm repairs in the brain. The X-ray images used to be only 2D, but advances in technology now also allow to make a 3D scan to better visualize the anatomy and use this 3D volume as planning and 'navigation' tool for the intervention.

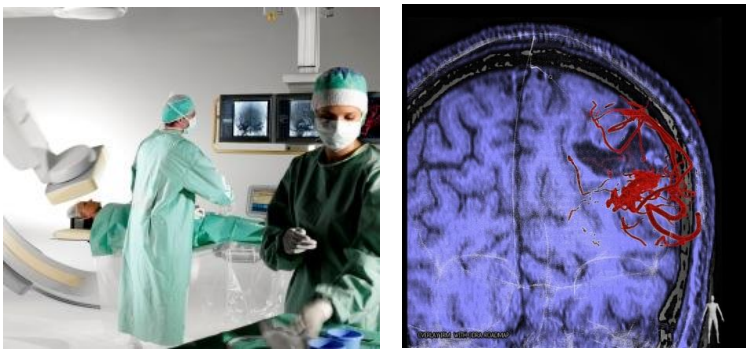


Figure 42 X-ray system acquires 3D volume to visualize the vessels (see red). In this example, it is than overlaid on a MRI scan that the patient had earlier (see purple).

A 3D scan allows better visualization of the anatomy, but is difficult to perform due to the amount and complexity of the steps that need to done. The tools require repetitive training and a lot of expertise, which is not always available in the hospital. Furthermore, staff rotation and variability in their task division (roles) is high, so users are not likely to become expert users before the end of their rotation. Because of this, highly skilled personnel are required to perform the 3D scan and in some cases, when the staff does not feel comfortable in making a 3D scan, they will rely on the 2D images only to do the procedure.

It is the objective of this AdCoS to help the staff become more confident in acquiring and using 3D data. This is done by analysing the workflow steps and developing an improved Human Machine Interface (HMI) that helps the user in the preparation and execution of the 3D Acquisition.

7.2 Final HMI

As explained in the introduction, performing a 3D rotational acquisition can be quite complex and requires a lot of expertise from the user. Many consecutive steps need to be made, during both the preparation as well as the actual acquisition. Omitting one step may lead to a failed test scan and requires that several preparation steps be repeated.

The new HMI features three new concepts that will improve the usability of the system and simplify the execution of the 3D rotational scan.

1. The HMI uses graphical user guidance and procedure cards for step-by-step assistance. It forces the user to follow a pre-defined flow of actions and thus prevents any errors in the 3D scan preparations.

2. The alignment of the system C-arm around the clinically relevant part of the anatomy, the Region Of Interest (ROI) is a complex task and requires much experience in both interpreting clinical images and in the handling of the X-ray system geometry. In the new HMI the user can indicate the ROI and the system automatically adapts its alignment based on this.

3. In the case of a system alignment that would lead to a collision between the C-arm and the patient or table, the system will automatically detect this and notify the user before the actual rotation is started.

The abovementioned HMI improvements are captured in Figure 43.

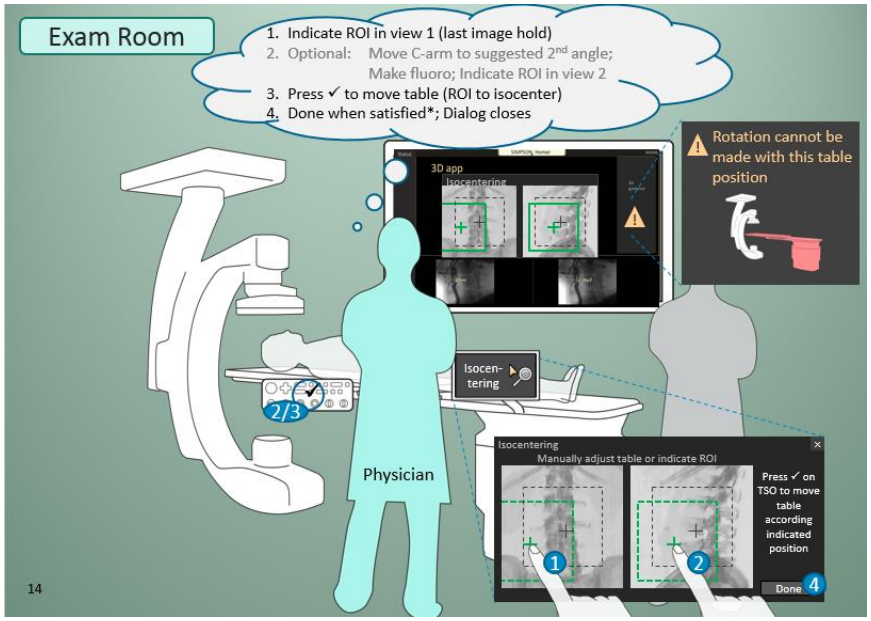


Figure 43 Guided user interaction between physician and the X-ray imaging system

Improvement compared to baseline
The new HMI has simplified the way of working in the exam room by guiding the physician through the successive steps in the procedure. By explicitly checking each step, the number of user errors will decrease and by automatically adapting the C-arm to the selected ROI, the number of failed test runs will decrease.

Although further evaluation will be necessary to derive statistically relevant conclusions, it is clear that the count of user errors will certainly decrease thanks to guidance provided by the AdCoS. From the task analysis and workflow simulations with the HEE tool, it became clear that the number of user actions, compared to the existing product, will generally decrease. In some cases, the number of user actions will remain the same or even increase, thanks to the additional checks provided by the new HMI. This than leads to less user errors, which will in turn lead to improved user satisfaction.
User satisfaction has been measured through SUS questionnaires and interviews. The questionnaires also addressed the satisfaction of the existing HMI, allowing a comparison of the new HMI against the existing

HMI. The SUS score has increased from 60 to 84, which is significantly above the industry standard of 68.

Qualification and certification
The release process of the AdCoS requires that evidence is provided about system functionality, e.g. usability, reliability and safety. Requirements traceability is part of this process, ensuring that all Critical to Quality (CtQ) requirements are implemented in the final design. In HoliDes, the use of the HEE tool was clearly beneficial because it forced the designers to explicitly think about every individual step in the workflow and describe it in the task analysis step. As a result, the quality of the certification process has improved: ambiguity in requirements is eliminated by modelling the workflow and verifying this model with application experts.

7.3 HF-RTP assessment and recommendations

The tailored HF-RTP for the 3D Acquisition AdCoS consists of several tools: A Task Editor to identify interaction tasks between the operator and system. The Human Efficiency Evaluator (HEE) to model the interaction capabilities of the environment, to demonstrate procedures for common tasks and to execute CASCaS, a cognitive architecture for prediction of human behaviour, allowing analysis of Human Factor Metrics. Deliverable D6.8 describes in detail how the tools in this tailored HF-RTP cooperate and which information is exchanged.

The tools in the HF-RTP, have provided valuable insights for the development process of the new HMI for 3D Acquisition. Furthermore, the HEE tool offers an interesting possibility to easily simulate and replay various scenarios. This may be an interesting, unanticipated, spin-off for training purposes of new usability designers or engineers to quickly understand the consecutive actions in a workflow. The HEE tool not only shows the order in which these actions take place, but it also graphically shows which part of the system HMI is addressed.

A recommendation for further improvement would be that the HEE tool is able to simulate how experienced and inexperienced users interact differently with the system. An inexperienced user would sometimes make

a mistake causing part of the tasks to be repeated. This could for instance be simulated in the HEE by allowing a loop in the chain of tasks.
The new HMI is mainly meant to help inexperienced users to feel more comfortable in performing, so it would be interesting to see how this is reflected in improved human factor performance metrics.

8 Internal analysis and reporting

8.1 AdCoS description

This use case provides a tool which analyses and generates clinical reports based on data coming from heterogeneous and fragmented healthcare information systems.

The access to the system must be available anytime and anywhere, apart from the hospital environment, so it will provide a web Graphical User Interface (GUI). This interface provides easier usage of the information and presents clinical information to the physician in an integrated way.

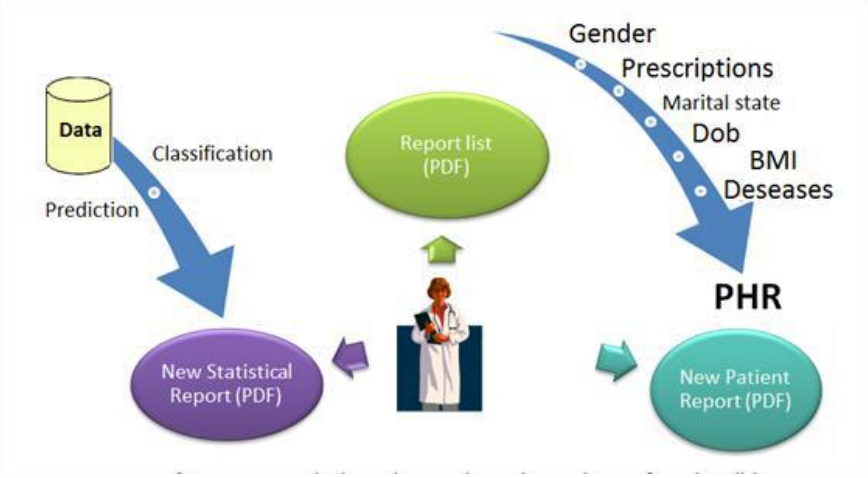


Figure 44: Internal analysis and reporting AdCoS.

With "Internal analysis and reporting" AdCoS the professionals can generate two different clinical reports (PDF format):

- **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.

- **Patient report:** This AdCoS permits to generate simple reports for the patients to provide a general overview of his/her health status. This custom report pretends to avoid additional CDs or paper reports given to the patient nowadays. This report includes clinical patient

data. MRI, Lab tests, prescriptions, etc. Any clinical information the professional considered desirable.

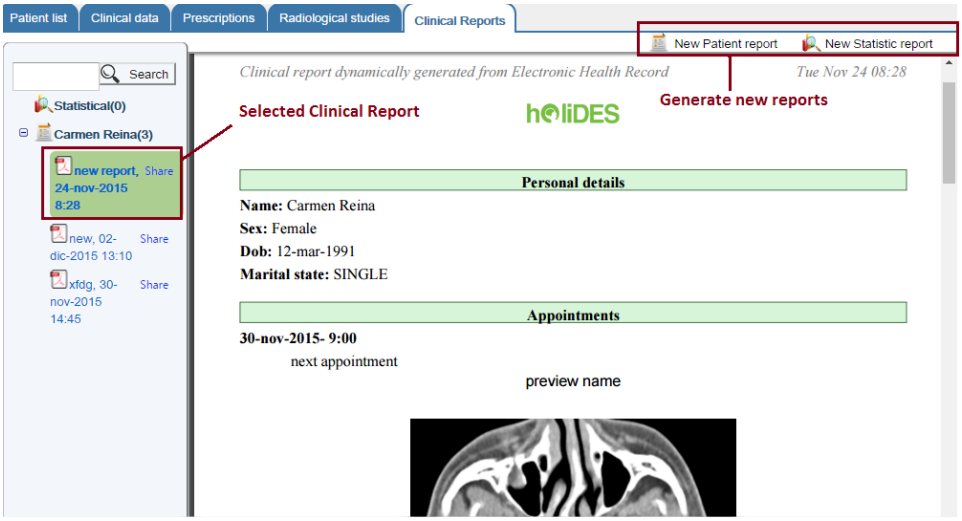


Figure 45: Internal analysis and reporting AdCoS main Interface

8.2 Final HMI

Internal analysis and reporting AdCoS main strength is its capability of data analysis. That is why we worked in the integration of APA and LEA tools, both, related to data mining and machine learning; analysis tools to provide better diagnostic and treatment. However, APA and LEA have been disregarded due to the lack of java integration capabilities. Even it provides interesting results, we need automatic feedback and dynamic integration to adapt the GUI to the user and APA and LEA are thought as a stand-alone application.

"Internal analysis and reporting" and "Querying open EHR data" AdCoS follow the same practical guidelines related to HMI and are described in chapter 3. However, it is listed below some particular considerations related to this AdCos:

• **Standard GUI Controls**: The intention has been that, from user point of view, there were no major differences in design between the two Adcos, this is why, the searcher, the tree data, such as how to present the information on the screen is very similar to both AdCoS. The backend is very different, but that is transparent for users, Figure 16: Display Patient Studies Graphical User Interface and Figure 17: Display Clinical Reports Graphical User Interface.

• **Simple interfaces:** This AdCoS is accessible and mainly managed by professionals with clinical and technological abilities, they have approved this interface; it is simple and easy to use. This has allowed us to focus in the patient clinical report, since this type of report is addressed to the patient (without clinical knowledge), paying special attention to how display information and texts. Even if patients seem satisfied with the information currently displayed, no updates are discarded in this sense.

• **Common design:** Following figure displays the common design related to Report generation (colors, light, contrast, controls, etc.).

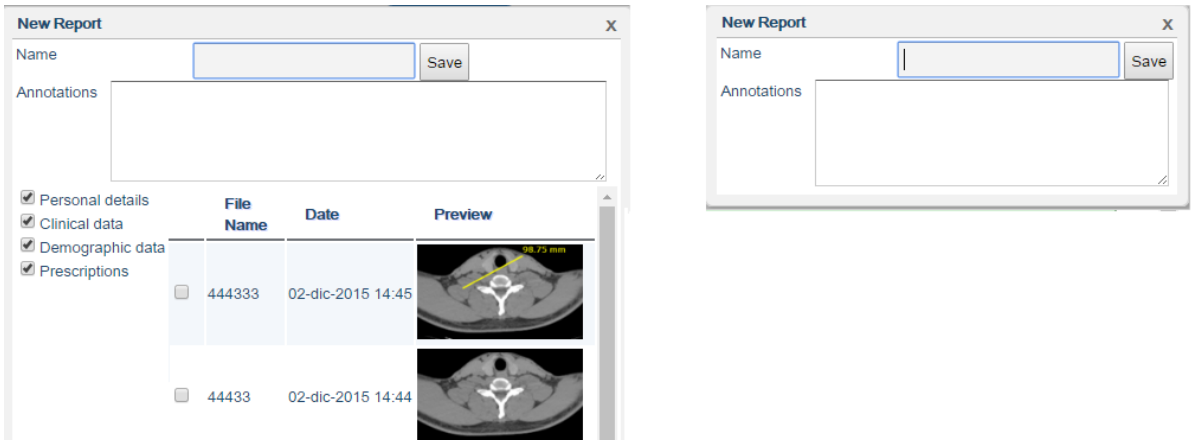


Figure 46: New Clinical Report (left) and New Statistical Report (right) Interface comparison

• **Keep the user informed (at any time):** These figures show some examples:

Figure 47: Tooltip label to keep the user informed

• **Defaults values:** In this AdCoS this item is not relevant due to there is only one required field (report name) and one optional field (Annotations). The rest of information to include are check boxes to check if the professional wants to include the related information, which is very simple and visual as you can see in following figure:

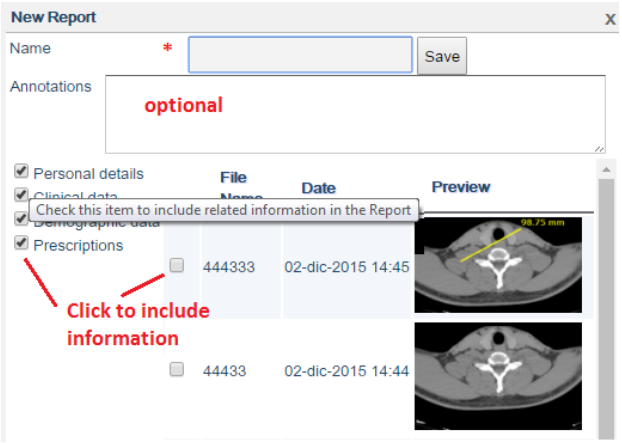


Figure 48: New Patient Clinical Report Interface

• **Personalization options:** In this item, customized details are transferred from "Querying open EHR data" AdCoS, see Personalization options.

• **Response time limits**: Response times must be as fast as possible; the AdCoS displays a "Busy" cursor if a command takes more than 8 seconds, an explicit progress if longer.

• **Display error messages:** If something is wrong, like report name, the AdCoS displays an error message explaining clearly, why and how the user can fix the problem, see following figure:

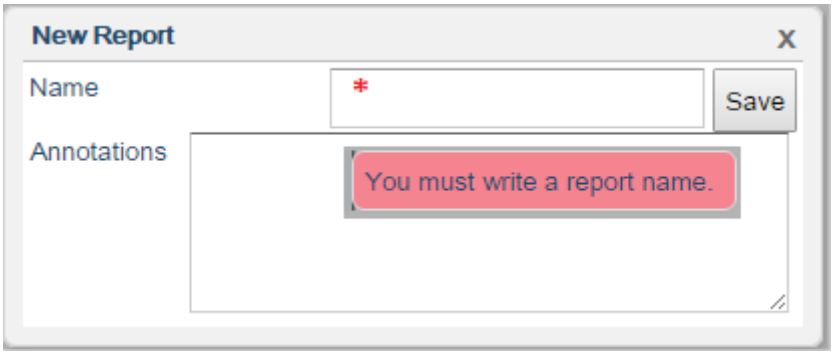


Figure 49: Empty file name information

• **Required fields:** In this AdCoS this item is not relevant due to there is only one required field (report name) and one optional field (Annotations). The rest of information to include are check boxes to check if the professional wants to include the related information, which is very simple and visual as you can see in previous figure.

Improvement compared to baseline
The new HMI has simplified the way professionals generate clinical reports. We have reduced the minimal number of steps needed to one; type report name, and click on save button. In addition, if further information is need the professional just need a click to include it (prescriptions, clinical images, etc.) which is very intuitive.

Because "Querying open EHR data" and "Internal analysis and reporting" Adcos are both similar from the point of view of the user; design, controls, access, etc. satisfaction survey was conducted jointly and the results were applied to both AdCoS. See improvement details in chapter 3 Querying open EHR data.

Qualification and certification
In this AdCoS, working in close collaboration with health care professionals was clearly beneficial because it forced the designers to understand the specific characteristics of the sector and develop a simple and specific workflow.

8.3 HF-RTP assessment and recommendations

AEON allows gathering heterogeneous information coming from different sensors and it is extremely easy to use with the incorporated GUI. In the case of APA and LEA, even they are suitable for the AdCos, it is to integrate them with our GWT GUI because they are stand-alone applications.

9 Conclusions

This deliverable gives an overview of the final Health AdCoS implementations. For each individual AdCoS, specific conclusions and recommendations are given.

AdCoS's in the health domain are products in a regulated industry, which requires a reproducible and documented way of working throughout the whole product realization process. HoliDes tools and methods (like means-end modelling, HF-TA and U-DAT) have contributed to improved requirements management and traceability, and task analysis. Structured documentation of process and results is facilitated by HF-Filer, by providing a means to archive relevant documents and results.

The use of the HEE tool was clearly beneficial because it forced the designers to explicitly think about every individual step in the workflow and describe it in the task analysis step. As a result, ambiguity in requirements is eliminated by modelling the workflow and verifying this model with application experts.

In general, it can be concluded that the usage of HoliDes methods and tools has led to various significant improvements in HMI designs and implementations. First evaluations show that the HoliDes results lead to better ease of use, less user actions, less user errors, and as a result in improved customer satisfaction.

10 List of figures