

ADMAIORA

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1 Executive summary

The ADMAIORA system consists of a number of software products run on a plurality of platforms. The main software components in the project are:

- Cloud Server
- Patient SmartPhone App
- Patient PC Agent
- Clinician Web Interface
- Knee Brace firmware

In addition, these software products communicate with API's (Application Programming Interface) for ready made products:

- Activity Wristband
- US imaging system/LIPUS system
- Balance device (COP)

In this deliverable a description of the software demonstrator is reported, highlighting each component and its function.

2 IoT Architecture definition

2.1 Overview

A software architecture has been designed to handle the needed communication, presentation and interaction between the different IoT devices and users in the ADMAIORA system. The heart of the IoT system is the cloud server where data are stored and routed between the dedicated users and devices for all instances of patients/clinicians present in the system.

The architecture is designed to handle many simultaneous patients and also many clinicians that each will have access to an appointed subset of all patient data storages. The architecture is scalable and data flows are designed to protect the patient's fundamental rights.

The general overview of the IoT network for the ADMAIORA project is shown in Figure 1 and Figure 2.

On the patient side the connected devices are:

- Ultrasound imaging system
- LIPUS system
- Center of Pressure balance pad
- Activity wristband
- Sensors in knee bracelet
- Patient Smartphone App

Data from all these devices are sent to and stored on the Server. The clinician accesses data through the Clinician Web Interface.

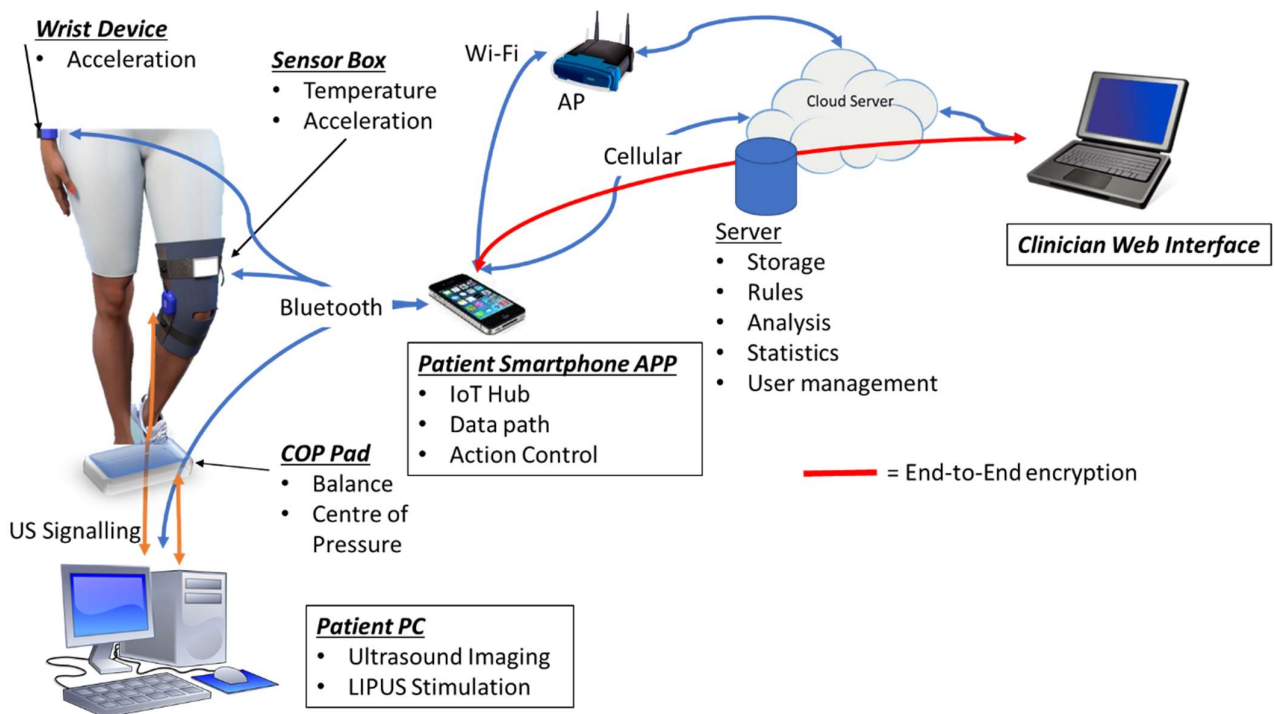


Figure 1: System Overview

The users in the IoT system are basically the patient and the clinician. The patient will have an app running on a smartphone where the needed main control and monitoring will take place. This app is designed to be easy to use and give information details at a reasonable level. For some connected devices, like the ultrasound systems for imaging and stimulation

and also the balance pad, the patient will use a dedicated PC to interface and control these devices.

The clinician will use a PC or other suitable devices with a web interface to the cloud server to access a more detailed view of all stored data for multiple assigned patients. This interface is more detailed, including more information and at a higher level of technical detail.

As shown in Figure 2, the Patient PC (paPC) is running an agent software to communicate with and allows Server access for the US-imaging, LIPUS and balance (COP) devices. This software is named paAgent. The Smartphone App (paAPP) handles a similar functionality for the knee brace and activity wristband, in addition to its own data and control channels.

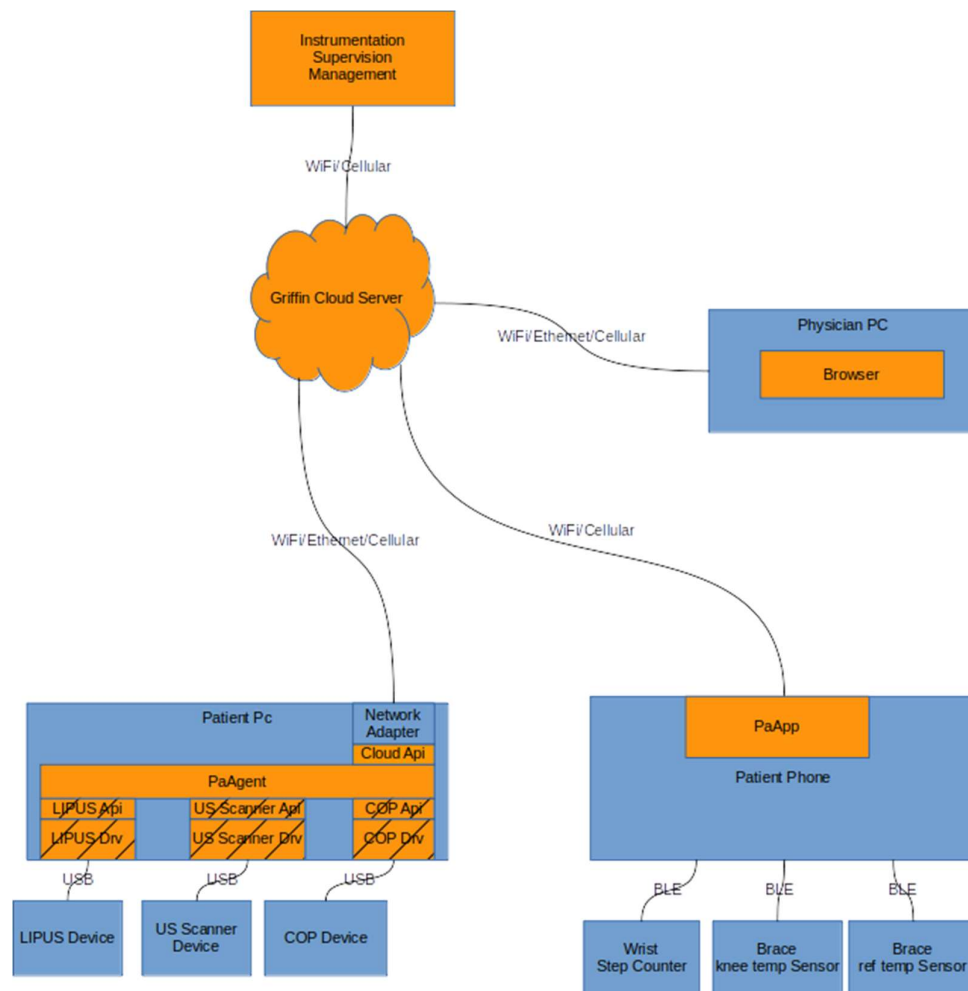


Figure 2: Software components (orange). Third party with diagonal lines.

All interactions, except from the low-level ones with physical devices, are established between client interfaces and the cloud server, as shown in Figure 3.

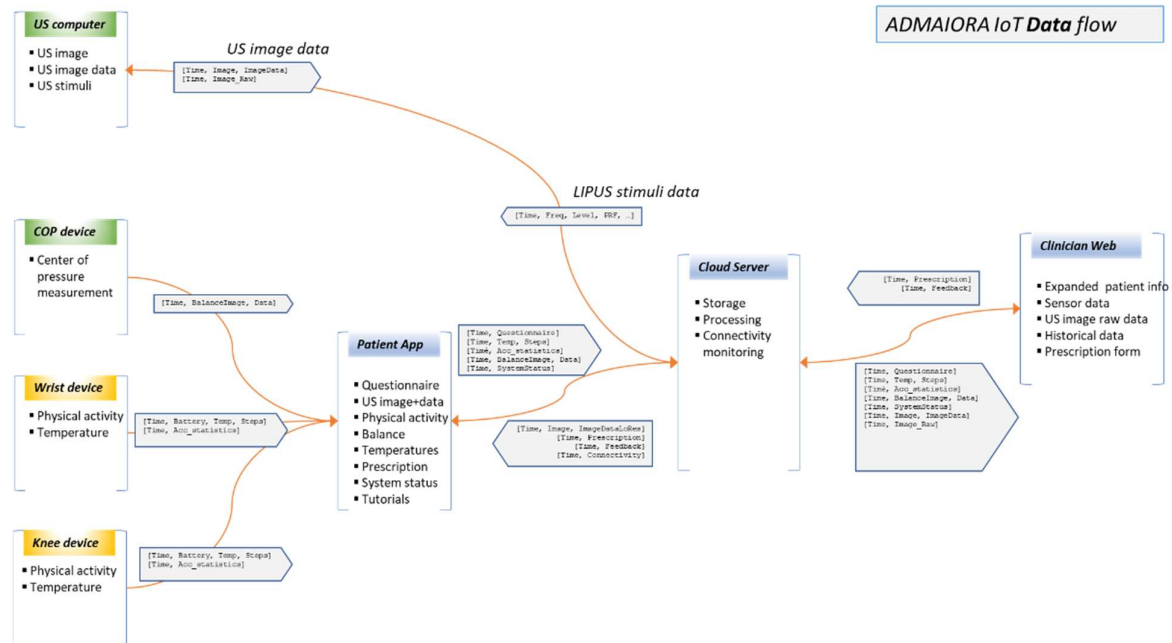


Figure 3: ADMAIORA System Data Flow

3 Patient Smartphone Software (patient app)

The patient app is a software that can run on a smartphone or tablet and is the patient interface to the ADMAIORA IoT system.

The functionalities in the app for the patient are:

- patient questionnaire;
- display of ultrasound images and image-derived quantitative data;
- data regarding physical activity;
- data regarding balance quantification (COP device);
- data derived from temperature sensors;
- prescription information and controls from the clinician;
- overall status and connectivity for the IoT system including local devices and cloud connection;
- tutorials on how to use the system including the ultrasound imaging protocol and stimulation device;
- functionality for a guided user-to-use pairing of the sensors and other local devices with the app and registration on the cloud server.

3.1 Functional overview

Many functions are implemented in the app, which are divided into a number of “screens” as follows:

- main screen with summary information;
- patient questionnaire;
- display of ultrasound images and image-derived quantitative data;
- data regarding physical activity;
- data regarding balance quantification;
- data derived from temperature sensors;
- prescription information and controls from the clinician;
- overall status and connectivity for the IoT system including local devices and cloud connection;
- tutorials on how to use the system including the ultrasound imaging protocol and stimulation device;
- functionality for a guided user-to-use pairing of the sensors and other local devices with the app and registration on the cloud server;
- indicators of the healing process (e.g. progress bar, info from the daily questionnaire, WOMAC index, US images with indications on the presence of liquid and on cartilage thickness, etc.).

3.2 App tree/relationship

There are many different screens in the patient app and these have been categorized as shown in the tree diagram of Figure 4.

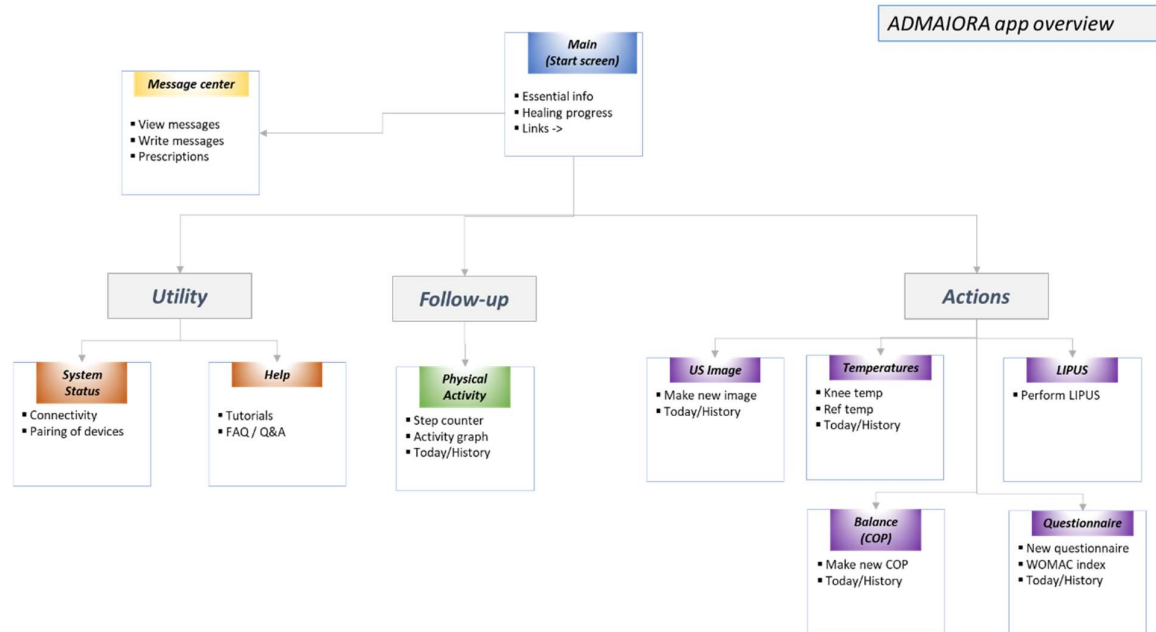


Figure 4: Functional Blocks in Patient App

3.3 Login, main screen and message-center

3.3.1 Login screen

When the patient opens the app, a login screen is shown (Figure 5) where the patient is asked to login to the ADMAIORA cloud server. Each patient has a separate account on the server where all information is stored for that patient. Login is alternatively performed with fingerprint recognition on supported devices. After login, connection is made to the server and necessary data are loaded, as shown in **Error! Reference source not found..**



Figure 5: Login screen

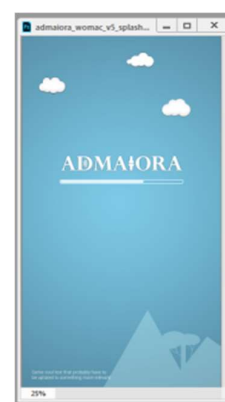


Figure 6: Loading screen

3.3.2 Main screen

The main/start screen is shown in Figure 7 and includes:

- Link to message center – with indication of number of unread messages
- Patient healing progress, indicating the pre-surgery starting value (flag) and the current value (pin).
- Today's summary
- Anterior cartilage status
- Posterior cartilage status
- Inflammation status
- Pain status, evaluated through the WOMAC index
- Physical Activity status
- Knee extension status
- Balance performance
- Drop list to other screens.

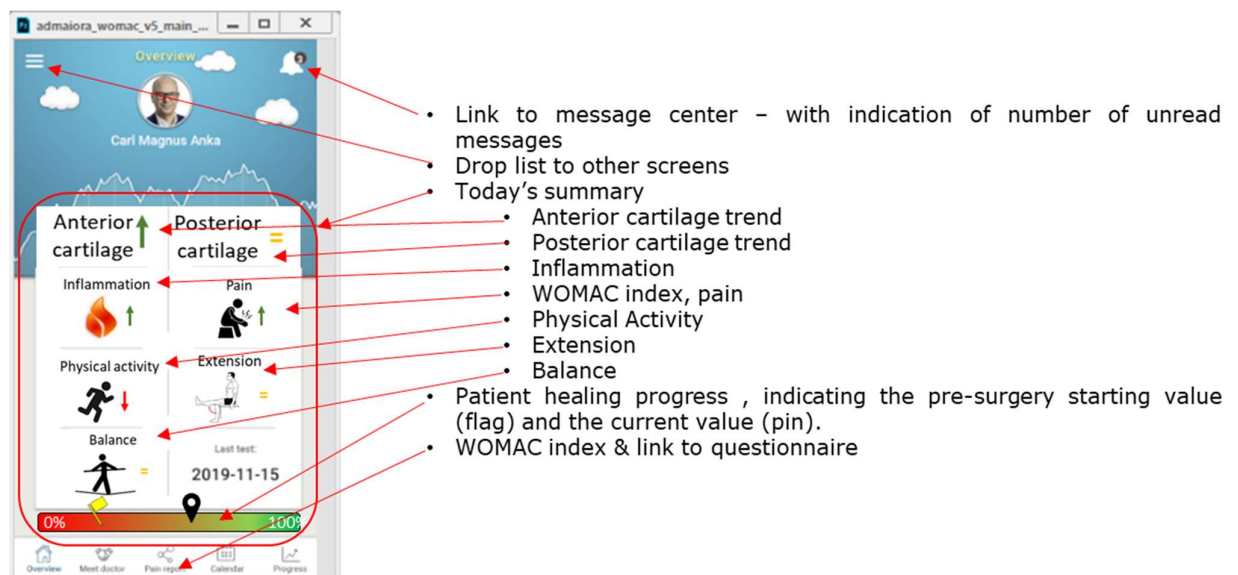


Figure 7: Main Screen

3.3.3 Message center

The message center screen is shown in Figure 8 and includes the following parts:

- New message indication
- View message from clinician
- Write message to clinician

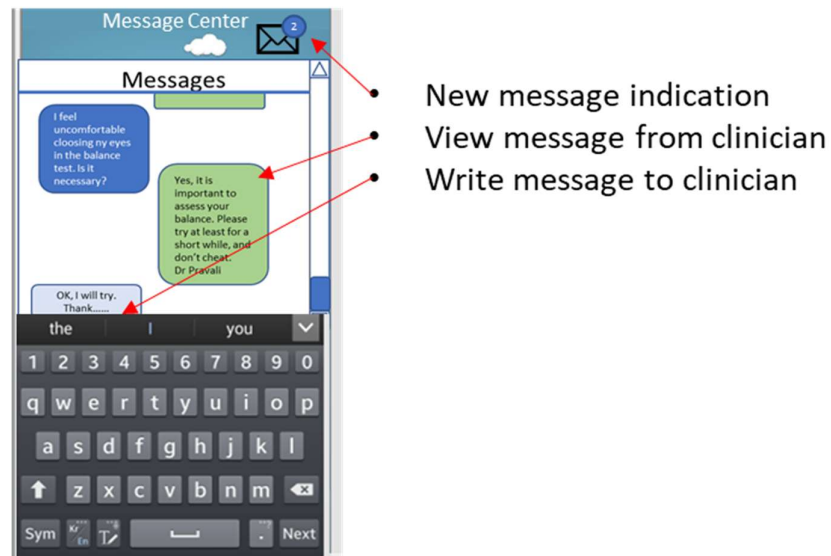


Figure 8: Message centre in app

3.3.4 Schedule (Calendar)

Over a day there are several tasks for the patient to be completed, according to the treatment plan. In the app there will be a calendar where the patient can see the schedule set by the clinician and which task the patient has to perform for the current day, as shown in Figure 9.

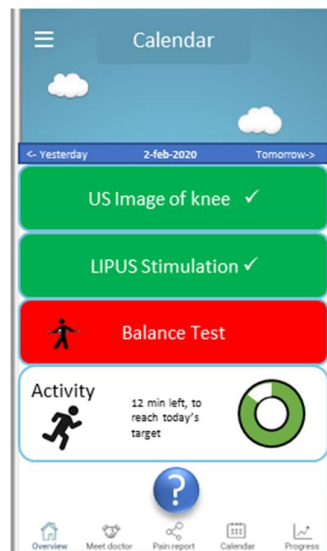


Figure 9: Calendar Screen

The app posts notifications on the phone to remind the patient of the tasks remaining to be completed, regardless if the app is activated or not, as shown in Figure 10.



Figure 10: Schedule Notification Examples

The Schedule is synchronized with the server, allowing the clinician to set up and modify the schedule and also to see the task completion.

3.4 Action sub screens

3.4.1 Balance menu (COP)

The Balance measurement (COP) screen (Figure 11) includes the following parts:

- Instructions on how to make a new measurement (Video, Animation)
- Instructions on how to view previous measurements (Video, Animation)
- Series of actions for performing a new measurement (Figure 12) that can be:
 - With both feet, open eyes
 - With left foot, open eyes
 - With right foot, open eyes
 - With both feet, closed eyes
 - With left foot, closed eyes
 - With right foot, closed eyes
- View history – previous measurements

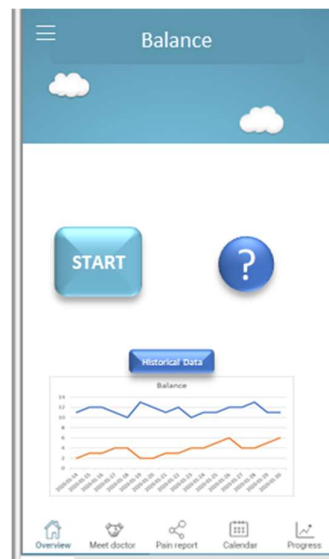


Figure 11: Balance, Main screen

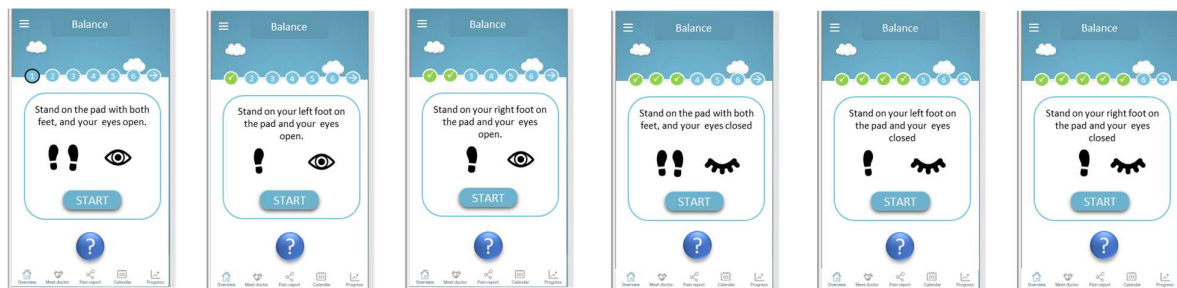


Figure 12: Balance Measurement screens

3.4.1.1 Balance Data

When measuring balance with a Center-of-Pressure device, two parameters are of interest. One is a measurement of the total displacement of the center of pressure, the other is the velocity of the displacement.

Once the patient has performed the measurement, the acquired data are reported to the server as shown in Table 1.

Table 1: Balance data format

Measurement	Timestamp	Mean sq. disp	Average velocity
Booth feet, open eyes	yyyy-mm-dd hh:mm:ss	15	4.3
Left foot, open eyes	yyyy-mm-dd hh:mm:ss	26	4.2
Right foot, open eyes	yyyy-mm-dd hh:mm:ss	28	4.2
Both feet, closed eyes	yyyy-mm-dd hh:mm:ss	18	3.6
Left foot, closed eyes	yyyy-mm-dd hh:mm:ss	48	2.8
Right foot, closed eyes	yyyy-mm-dd hh:mm:ss	44	3.1

3.4.2 Ultrasound image menu

3.4.2.1 Overview

This screen (Figure 13) includes the following parts:

- Today
 - Start new image series (Figure 14):
 - Position 1 - show a reference image
 - View of Image
 - Position 2 - show a reference image
 - ...
 - Repeat for all 7 positions.
- History
- View of Images
- Instructions on how to make a new measurement (Video, Animation)

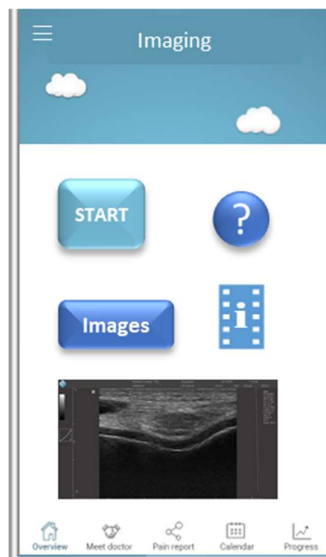


Figure 13: US Imaging Screen

3.4.2.2 Making new set of images

In order to make a new set of images, the app communicates with the US image system via commands to the server which redistributes the commands to the API/agent in the US image computer. The resulting image and related data are transferred directly from the US computer/API/agent to the ADMAIORA server. The app retrieves the images and data from the server.

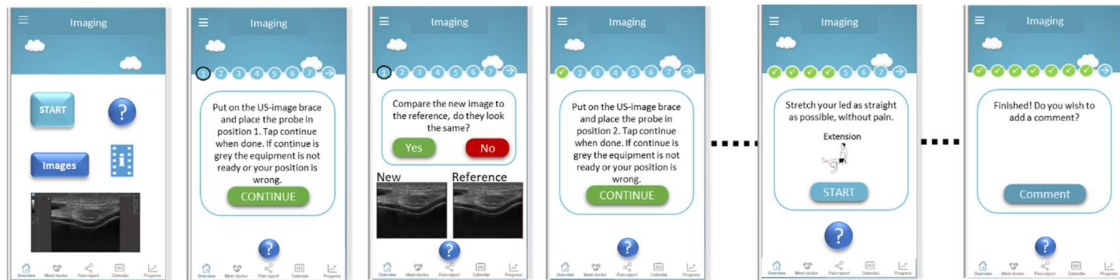


Figure 14: US-Imaging Capture Screens

3.4.3 LIPUS menu

3.4.3.1 Overview

This screen (Figure 15) includes the following parts:

- Instructions on how to use the LIPUS system
- Link to an animated sequence
- View of prescription/treatment and a button to start new treatment

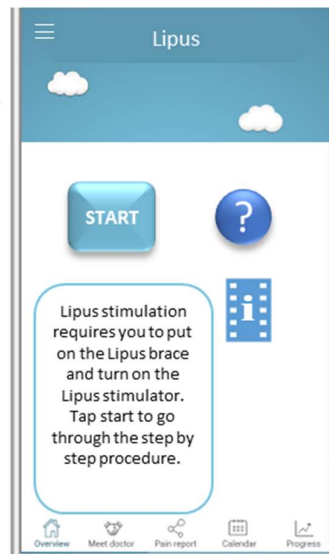


Figure 15: LIPUS main screen

3.4.3.2 New treatment

In order to perform a new LIPUS treatment, the patient needs to position the knee into the "treatment device" where the ultrasound stimulation devices are mounted. The patient will be guided by instructions in the app on how to do this (Figure 16). Once positioned, the patient will use the app to start the treatment process. The app then sends a command to

the LIPUS computer/API/agent through the ADMAIORA server since there is no direct contact between the LIPUS computer and the app.

The parameters for the treatment received from the clinician are transferred to the LIPUS computer. The start/activation is initiated from the app.

The parameters defining the prescription for the treatment are contained in a list as follows:

- Number of passes/entries
- Entry #1 Frequency | Level | Duration
- Entry #2 Frequency | Level | Duration
- ...
- Entry #n Frequency | Level | Duration

The treatment list has support for a sequence of consecutive stimulations. However, the patient will be able to see only information of the number of treatment steps and the duration and will be able to see the progress of the treatment by this indication.

The connectivity to the LIPUS system will be indicated by green color if the communication link is well established, or red color if there are issues with the connection.

The patient will press the start button for starting the treatment. Then a start command with the treatment data will be sent to the LIPUS computer. Feedback on the progress on the treatment steps will be given from the LIPUS computer and shown to the patient.

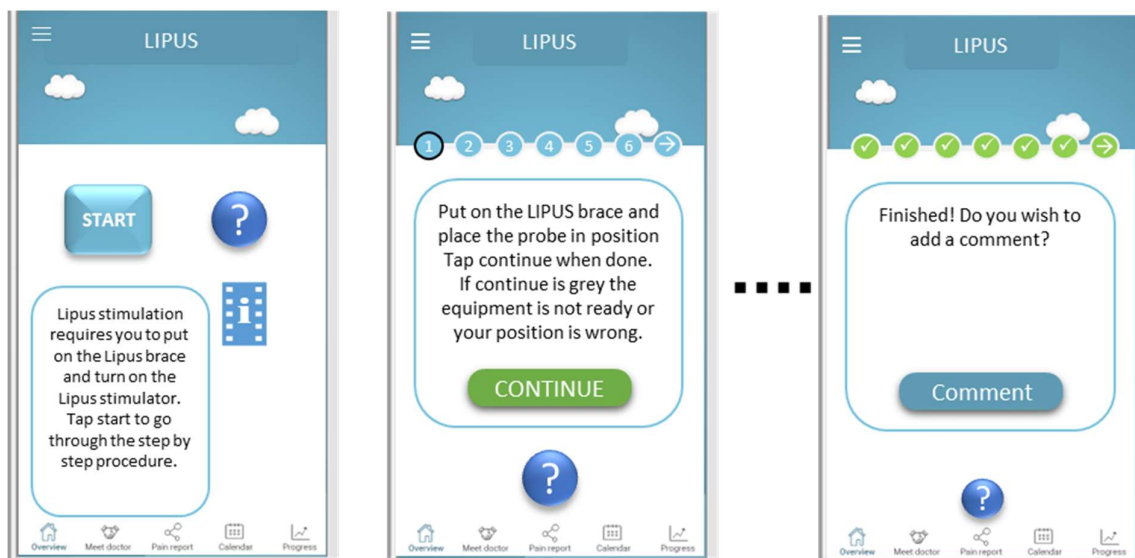


Figure 16: LIPUS stimulation sequence screens

3.4.4 Patient questionnaire / "Pain report"

There is a questionnaire that consists of 26 questions to get information from the patient about his/her level of pain, stiffness and physical function. For each question, there are five selection tick boxes that the patient will select to give answer to each question. The choices for each question are:

- None
- Mild
- Moderate
- Severe
- Extreme

The questions are divided into 3 sections (Section A – Pain, Section B – Stiffness, Section C – Physical function). Each section has a header text and guidance text to help the patient answer the questions.

Each question will be scored on a scale 0-4, corresponding to None (0), Mild (1), Moderate (2), Severe (3) and Extreme (4). The scores for each subscale are summed up, with a possible score range of 0-20 for Pain, 0-8 for Stiffness, and 0-68 for Physical Function. The WOMAC index is the total summary of all subscales and has a score range of 0-96.

When the questionnaire is complete, the patient has the possibility to leave a comment to the clinician.

The UX design/GUI consists of several screens. The patient will be presented the next question automatically once he/she has been answered the actual one, in order to minimize the clicking or swiping on the screen.

When entering the questionnaire, the first section for pain will be shown together with a pop-up window with the initial instructions to the patient, as shown in Figure 17.

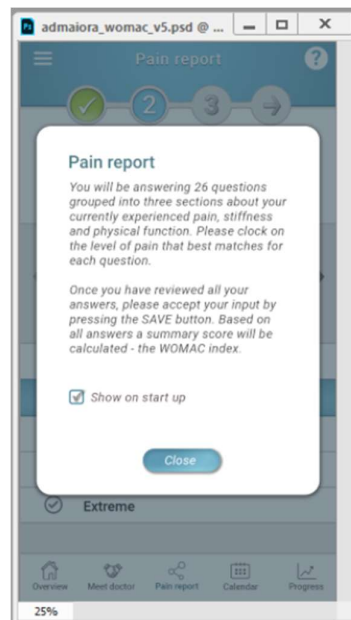


Figure 17: Pain report section 1, start screen

Then, the questions come one by one and when the patient clicks an item in the list, the screen scrolls to the left landing on the next question. The patient will also be able to use the left and right symbols to navigate, but when a selection is made, the shift to the next is automatic. Figure 19 below shows the fourth question in the pain section.

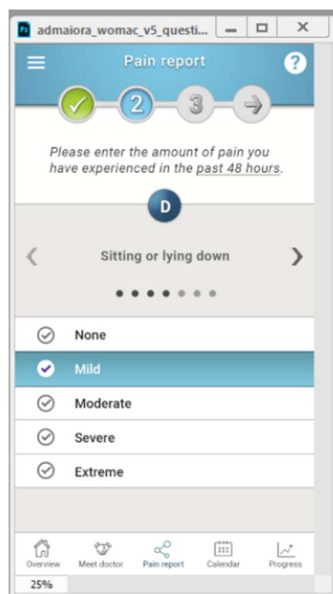


Figure 18: The fourth question in the pain section

When the patient has entered all questions in section one, another pop-up window is shown with the instructions for the next section (Figure 19).

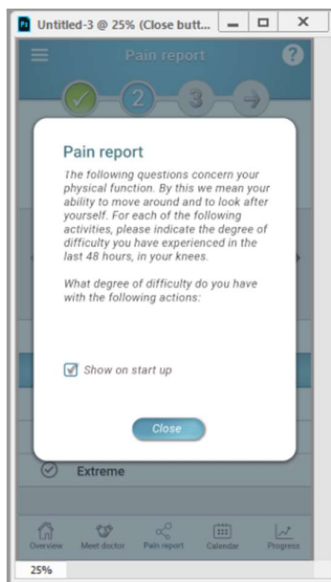


Figure 19: Pain report section 2

Then the questions for section 2 (stiffness) follow the same procedure as for section one (Figure 20) and then the same is applied for section 3 (physical function).

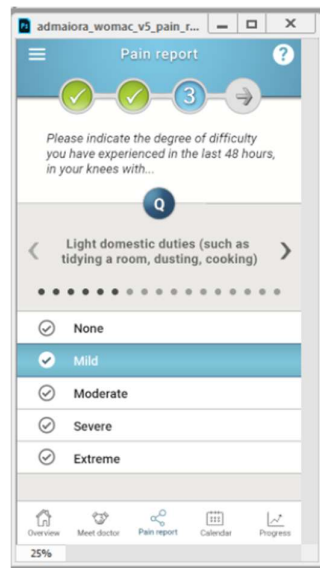


Figure 20: Pain report section 2, question screen

When the patient has finished all three sections, a pop-up window is shown (Figure 21) to inform the patient that the questionnaire is complete and that the patient will have a possibility to leave a comment. The patient will then click the CLOSE button to continue.

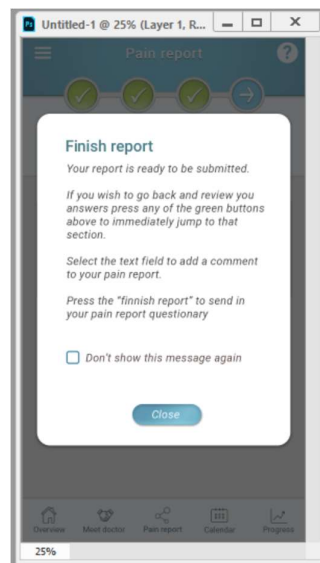


Figure 21: Pain report completion screen

If the patient wants to add a comment the comment field is pressed, and a keyboard is shown for entering the comment. (Figure 22 and Figure 23).

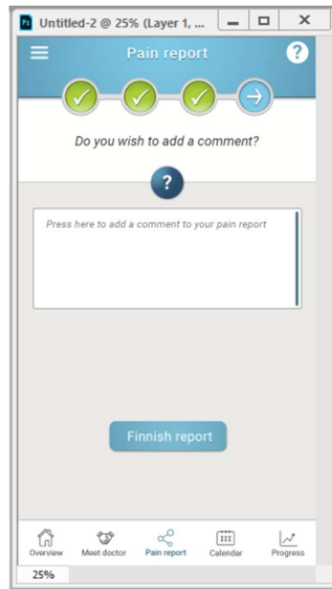


Figure 22: Pain report comment request



Figure 23: Pain report comment screen

When the patient clicks on the “Finish report” button, the answers for all questions are saved in the cloud server together with the comments. Then a pop-up with a text “Report sent” will be shown with a CLOSE button. When the patient clicks the close button, the patient is directed back to the main screen.

3.4.5 Temperature

3.4.5.1 Overview

Temperature is sampled without any action by the patient, as a part of the communication with the activity wristband and knee brace.

This screen (Figure 24) includes the following parts:

- Today:
 - Knee temperature
 - Reference temperature
 - Graph with temperature distribution over the day (24 hours)
- Historical data
 - Knee temperature
 - Reference temperature
 - Graph with historical data

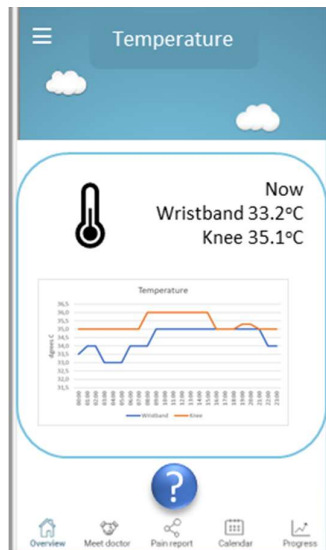


Figure 24: Temperature Screen

3.4.6 Extension Angle

The extension angled is measured with the US Imaging brace. As one of the steps when acquiring the seven images the patient is asked to extend the leg as much as possible (Figure 25). The brace reports the angle of extension to the app that forward it to the server with a timestamp.

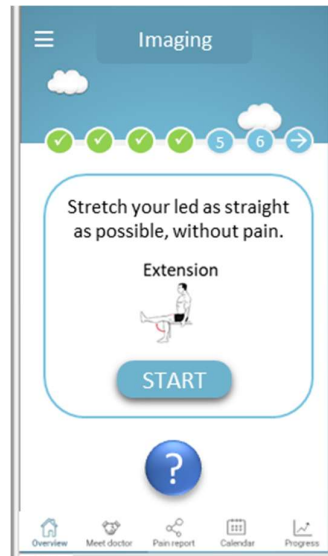


Figure 25: Extension Screen

3.5 Follow-up sub screens

3.5.1 Physical activity

3.5.1.1 Overview

This screen (Figure 26) includes the following parts:

- Today:
 - Number of steps
 - Physical movement
 - Graph with activity distribution over the day (24 hours)
- Historical data
 - Number of steps
 - Physical movement
 - Graph with activity historical data.

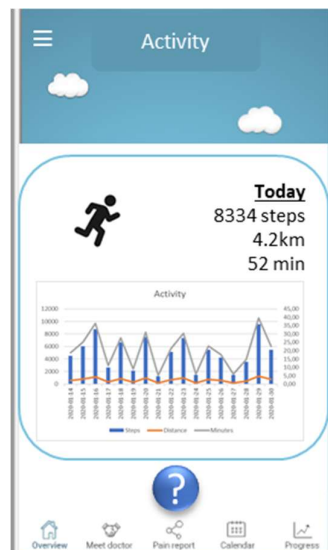


Figure 26: Activity Main Screen

3.5.1.2 Step calculation

The step counter resides in the wrist device and the app gets periodic data with number of steps taken.

3.5.1.3 Calculation of physical movement

The physical movement calculation is based on the level of activity from the accelerometer in the IoT bracelet device. The raw data is filtered in the IoT bracelet. The level of physical movement is a sum of the absolute values from the three movement directions x , y , z ($M = |x| + |y| + |z|$) sampled with period p and averaged over n seconds (p and n configurable). Initially the sampling period is set to 1 second and the averaging period to 15 seconds. This means that a frame with the movement information will be sent to the app every 15 seconds.

3.5.1.4 Pulse

Pulse data is retrieved from the wristband and shown as minimum, average and maximum over the day.

3.6 Utility sub screens

3.6.1 System status

3.6.1.1 Overview

The system status screen (Figure 27) includes summary information for the following parts:

- Status for connection to Wi-Fi
- Status for connection to server
- Status for connection to wrist device
- Status for connection to knee bracelet (IoT box mounted on bracelet)
- Status for connection to LIPUS computer
- Status for connection to COP device / Balance
- Status for connection to US image system
- View of which devices are currently paired with the patient ADMAIORA account
- Pairing of new local devices to the patient ADMAIORA account
- Remove paired devices



Figure 27: System Status Screen

In the list above, the connection to the LIPUS, US image and balance (COP) systems may only be active when using these subsystems. This means that a connection to these is only critical when performing the corresponding action/prescription from the clinician. When clicking on a specific status item a sub screen is shown with more detailed explanation on the status.

3.6.1.2 Connection status Wi-Fi

The information regarding connection status for the Wi-Fi is based on the connectivity status for the used smartphone to the present Wi-Fi network.

3.6.1.3 Connection status Server

The information regarding connection status to the server will be based on the frames that are continuously sent between the app and server.

3.6.1.4 Connection status LIPUS computer

Since the connection to the LIPUS subsystem is not continuous, the information regarding connection status for the LIPUS subsystem will be based on the establishment of communication link and the communication during the treatment sessions.

3.6.1.5 Connection status US image system

Since the connection to the US image subsystem is not continuous, the information regarding connection status for the US image subsystem will be based on the establishment of communication link and the communication during the imaging sessions.

3.6.1.6 Connection status COP device

Since the connection to the COP subsystem is not continuous, the information regarding connection status for the COP subsystem will be based on the establishment of communication link and the communication during the measurement sessions.

3.6.1.7 Connection status Wrist device & Knee bracelet

The information regarding connection status for the wrist device and knee brace will be based on the Bluetooth Low Energy (BLE) frames that are continuously sent from these devices to the app. The connection status includes:

- Connectivity status with indication for signal strength (green, yellow, red)
- Battery status of device

3.6.1.8 Pairing of sensors and local devices

The pairing sub screen includes text with information on pairing sensors and local devices with the app, and detailed instruction on how to do it during the pairing process. An information text will be shown: "Pairing is a term used to connect the app with the patient equipment such as wrist device and knee brace in order to be able to start use them with the ADMAIORA system. This is done once when new equipment is allocated or when equipment is replaced".

The pairing of a new device to the ADMAIORA system use Near Field Communication (NFC) or QR-code labels on the devices to be paired, in order to make it easy for the patient to perform this action and to achieve a good security to pair the correct device that is actually allocated to the individual patient.

3.6.2 Help Screen

3.6.2.1 Overview

The help screen (Figure 28) is divided into two main parts:

- tutorials;
- FAQ/Q&A.

There are tutorials/guides with appropriate text and pictures for the following:

- General description of the ADMAIORA system
- How to position the brace
- How to position the ultrasound probe for imaging
- How to position the wrist device
- How to operate the LIPUS system (ultrasound stimulation system)
- How to pair the equipment
- How to fill in the questionnaire.

The tutorials are in most cases short (i.e. 1 minute) instruction videos or animations, on how to perform a task.

The FAQ/Q&A section has a list of normal/common questions and their answers. This is a *pdf-file* that is downloaded from the server in order to be dynamic and easy to be upgraded with added new information.

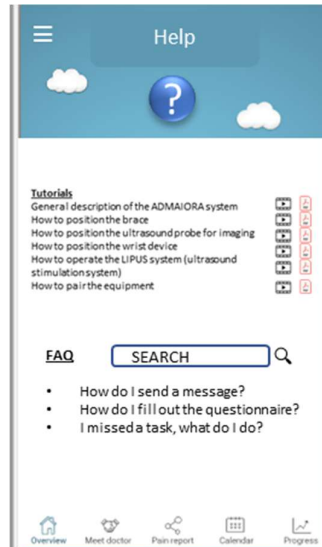


Figure 28: Help Main Screen

4 Clinician WEB Service Software

The initial outset was that the clinician would also have a smartphone app to monitor the data and handle patient communication with. However, developing this product as a WEB service has more benefits, like the necessity to manage many data at the same time. It has been implemented as follows:

- Larger screen, thus to show multiple images at the same time, so helping the visual inspection of US images
- Keyboard and mouse for easier entry of data

Access over all platforms, PC, Mac, Smartphone

After login, the list of all patients currently in treatment is shown, as reported in Figure 29.

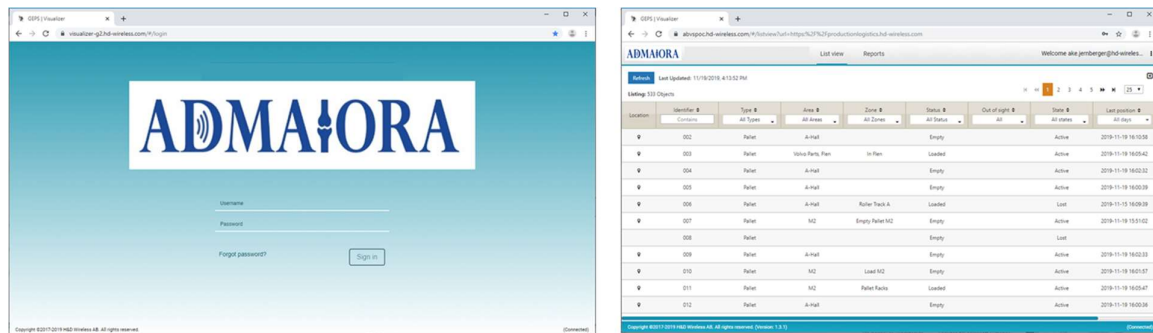


Figure 29: Clinician Login and List View

The list view allows direct filtering and sorting.

From the list the individual patient view can be opened. In this view (Figure 30) there are diagrams tracking the important data for recovery and the latest messages interchanged with the patient.

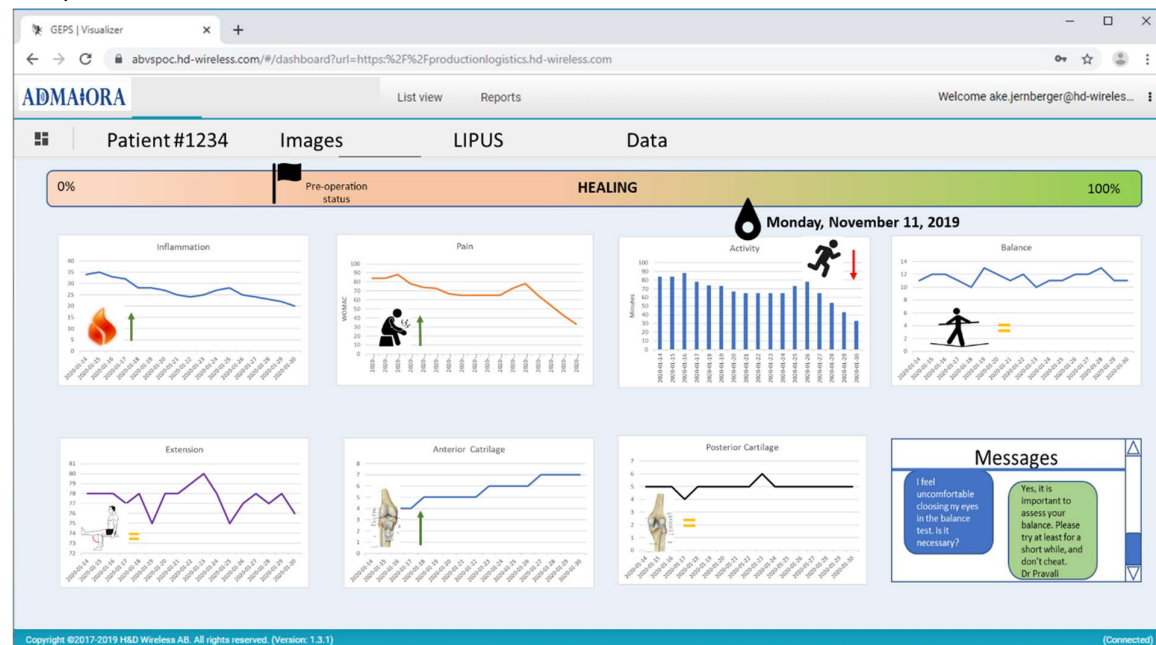


Figure 30: Patient Overview

4.1 Image View

In the image view (Figure 31) the clinician can view US image acquired by the patient and classify the cartilage regrowth, giving the image a score on how close it is to the targeted recovery

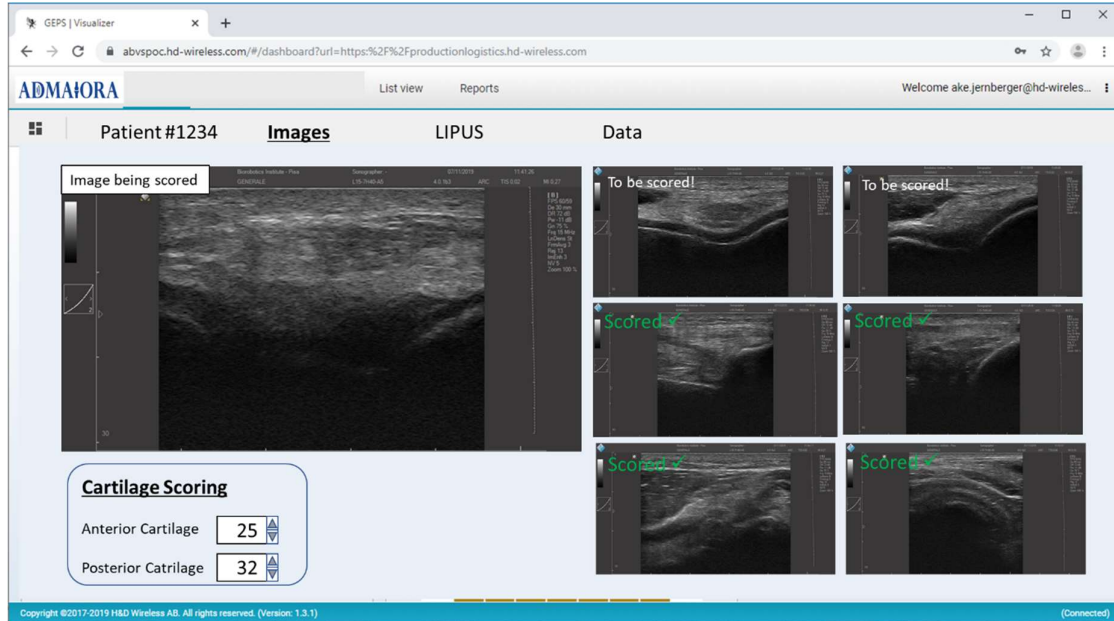


Figure 31: Image view

The images can be enlarged for detail inspection and compared side by side with the image taken earlier. A slider allows to split between the two images, which can be moved to show one or the other, as shown in Figure 32.

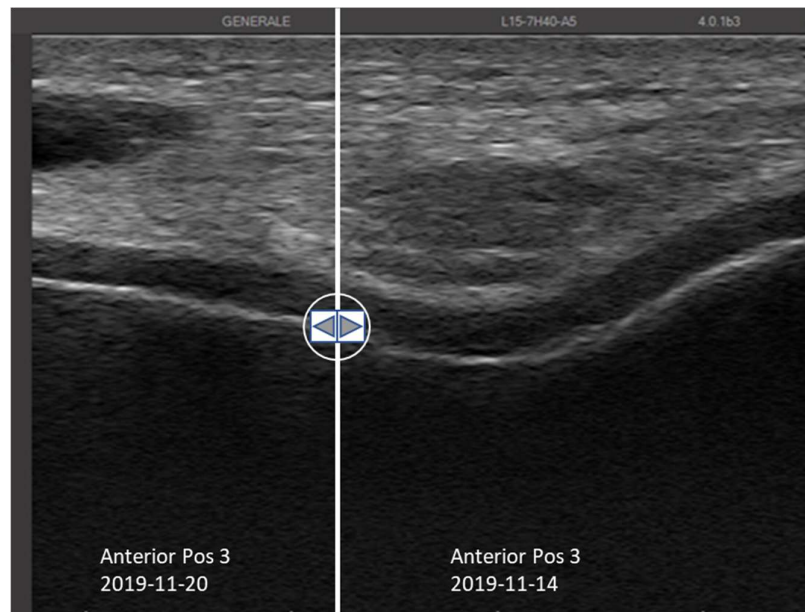


Figure 32: US image comparison.

4.1.1 Scoring

As a part of monitoring the healing process, the clinician has a task to analyze the US images and score the regrowth process. This data is included in the total score for the healing process. The clinician score is entered for each image and the server keeps track of images that needs to get scoring and which has been scored.

4.2 Balance data (COP)

Data from the balance tests can be viewed in a graph and table format (Figure 33).

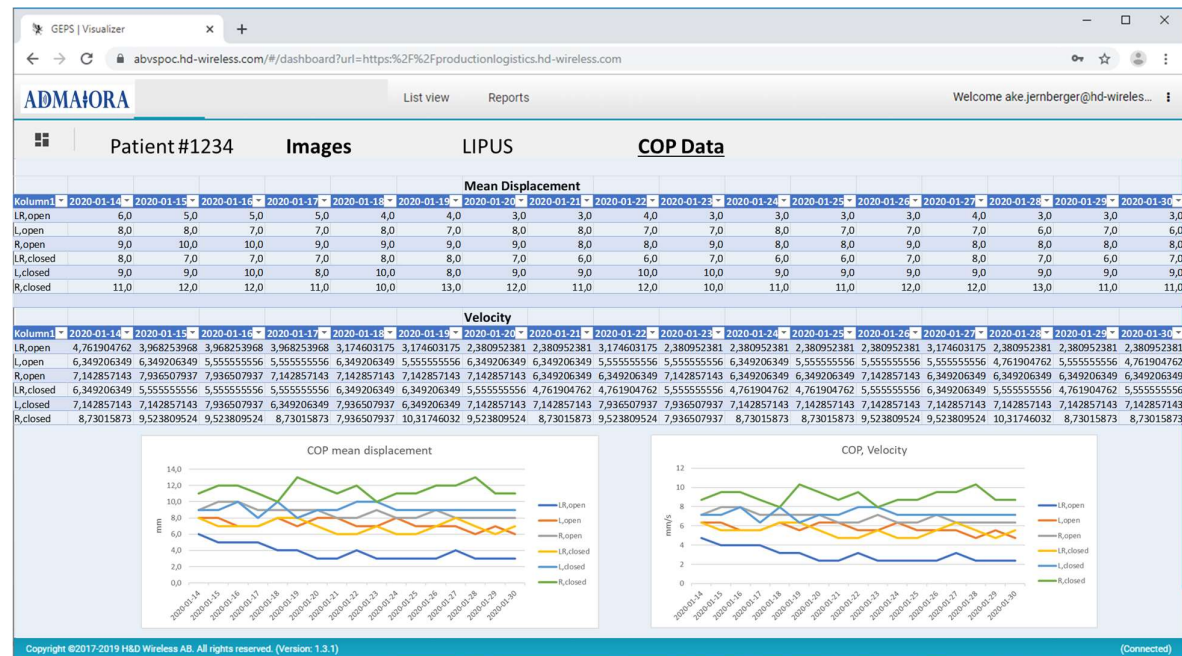


Figure 33: COP Data, Clinician's view

4.3 Message Centre

In the message center, SMS-like messages can be exchanged with the patient app. Also, the clinician can be able to send a message to the physiotherapists or trainers that follow the patient, suggesting them specific therapies or exercise. All history of conversation threads are kept (Figure 34).

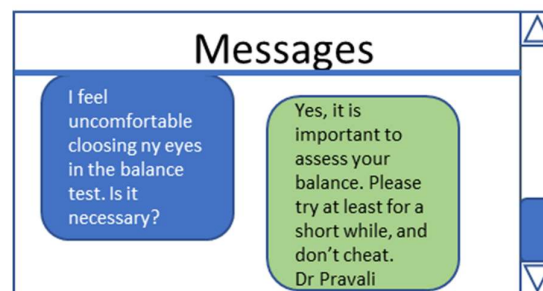


Figure 34: Message Centre

4.4 Scheduler

In the scheduler, the clinician will set all the task for the patient to be performed. The scheduler is in a calendar format, showing the task to be performed and task that has been

completed. A task which due date has passed is indicated in red to notify the clinician, as shown in Figure 35.

2020		January				
MONDAY	TEUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
30	31	01	02	03 LIPUS	04	05 COP
06 US Image	07	08 US Image	09	10 LIPUS	11	12 COP
13 US Image	14	15 US Image	16 Today	17 LIPUS	18	19 COP
20 US Image	21	22 US Image	23	24 LIPUS	25	26 COP
27 US Image	28	29 US Image	30	31 LIPUS	01	02 COP

Figure 35: Schedule view. In red is indicated the US imaging task that has not been performed in the previous day.

Tasks are defined by the clinician by clicking the date when they shall be performed as single tasks or the start of a series. The days the task has to be repeated and end date are also inserted.

Schedule Task

Type

LIPUS

Start

2020-01-17

Repeat Y/N

Every n:th Day

M

Tu

W

Th

F

Sa

Su

End

2020-03-31

Figure 36: Scheduler Task entry

4.5 Data Export

In the data export tab, selected data can be exported for import to an external system. The data is exported in comma separated values for generic data and as .jpg for images.

5 Server Software

The Cloud Server is the hub for all data transfers between the clinician and the patient. The benefits of implementing the server as a cloud service are several and the main are:

- Accessibility
- Scalability
- Security
- Cost

The cloud server is implemented with OS-level virtualization, also known as container, where each user space instance can see and access only the computer resources that has been made available to the program in the virtualization. This is an effective way to create scalability as the virtualization can be given just the right amount of resources, CPU memory and storage, as required, whilst the rest of the actual hardware resources can be used for other tasks.

The container virtualization is implemented without dependencies of vendor specific services, making it portable between different cloud computing suppliers, such as Microsoft Azure, Oracle, Amazon Web Services or on an on-premises server.

The cloud server is the central point of storage and communication. All client interactions with the server are carried over *https* using tokens for role associated credentials.

The backend part of the cloud server is the central point for scheduled logic, backup, security and content access.

5.1 Notifications

Interactions in the direction PaApp/PaAgent (see Figure 2) -> Cloud Server are mainly carried by Notifications possibly with attributes. Examples of Notifications are treatment progress metrics feedback, patient interaction feedback, presence of a new Image File, malfunctioning equipment, etc.

Notifications are, depending on the nature of the event, transported to cloud server either via real-time indications (beacons) or via none-real-time bulk time series streams.

All events are logged.

5.2 Messaging

There is a bidirectional channel free text messaging between the clinician and the patient. Message snippets are treated as files and are continuously synchronized between the PaApp and the cloud server.

5.3 Medical Alerts

Certain events can be configured to cause Alerts to be issued to the clinician (e.g. a new message from the patient or an Alarm). Alerts are presented to the clinician through the web browser interface.

5.4 Activity Orchestration

All activities related to a treatment period are orchestrated by the cloud server.

Treatment period activities are broken down into a set of Rules (see section 5.5).

Activities that have to take place outside of the cloud server execution domain (e.g. PaApp or PaPc) are compiled into a set of Activity Recipes (json formatted files) for distribution to the effected endpoints.

All activities related to a Treatment Period are logged within the cloud server.

A simplified example of Activity Orchestration can be used to control the sequence of a treatment session, and is described below:

- 1) The Treatment Scheduler dispatches a time scheduled "LIPUS Treatment Prepare" Rule Trigger.
- 2) The "LIPUS Treatment Initiate" Rule compiles a json Activity Recipe containing information to alert the Patient about the upcoming session and transmits this to the PaApp.
- 3) When the Patient is prepared to perform the LIPUS session, he/she will confirm to proceed via the PaApp.
- 4) The PaApp will dispatch a "LIPUS Treatment Init Confirm" Notification to the cloud server. This will cause a "LIPUS Treatment Start" Rule Trigger to be dispatched. The PaApp, based on the content of the Activity Receipt, continues to guide the Patient through the treatment session.
- 5) The "LIPUS Treatment Start" Rule compiles a json Activity Recipe containing order and instructions to initiate, start and control the LIPUS device and transmits this to the PaAgent.
- 6) The PaAgent receives the Activity Receipt and configures/starts the LIPUS equipment and returns a "LIPUS Treatment Started" Notification to cloud server.
- 7) The "LIPUS Treatment Started" Notification causes a "LIPUS Treatment Started" Rule Trigger. This Rule will notify the PaApp that treatment session has successfully started. The PaApp will notify the Patient and continue guidance throughout the treatment session.
- 8) Eventually when the treatment session duration has elapsed, the PaAgent shuts down the LIPUS equipment and returns a "LIPUS Treatment Done" Notification to cloud server.
- 9) The "LIPUS Treatment Done" Notification causes a "LIPUS Treatment Done" Rule Trigger. This Rule will compile an Activity Receipt for the PaApp that treatment session has successfully ended and possibly containing post session instructions to the patient.

5.5 Rules

Rules are python scripts executing within the Python runtime engine of the cloud server.

Execution of a Rule is always triggered by an event (Rule Trigger). Rule triggers may be timely scheduled events or asynchronous events (e.g. Alarms or Notifications).

5.6 Treatment Scheduler

All information related to a treatment period are stored in a Treatment Recipe implemented as a json formatted file.

The Treatment Scheduler is the entity that at top level orchestrates all treatment activities.

The Treatment Scheduler is implemented as a Rule.

5.7 Treatment Recipe

The Treatment Recipe fully describes all aspects of a Treatment Period.

Treatment session definitions as well as specification of observation/feedback metrics are collected here.

Some examples of Treatment Recipe are:

- LIPUS treatment schedule and configuration.
- COP schedule and configuration.
- Image Scan report interval

- Questionnaire and feedback interval
- Patient instructions
- Treatment duration
- Feedback metrics and related attributes (e.g. imaging, temperature measurement, physical activity measurements etc.).

It is important to note that the Treatment Recipe may be changed several times during a Treatment Period. However, each change of the Treatment Recipe will be fully logged for traceability.

5.8 Treatment Context

All data, information and equipment related to a specific Treatment Period are collected in the Treatment Context. There is a data storage associated to every Treatment Period Context.

Data stored are time series tracking records and related data (e.g. US Image files) and Treatment Recipe.

5.9 Treatment Tracking

All events, feedback and activities related to a Treatment Period are tracked. The purpose is not only to be able to generate accumulated graphs to indicate the progress of treatment effects, but also to be able to reconstruct the state of the treatment and related attributes to any point in past time during the Treatment Period.

A trace entity history is tracked in a time series record as depicted in Figure 37.

ID	-Timestamp -Attribute -Value	-Timestamp -Attribute -Value	-Timestamp -Attribute -Value	...	-Timestamp -Attribute -Value
----	------------------------------------	------------------------------------	------------------------------------	-----	------------------------------------

Figure 37: Example of treatment tracking.

Examples of tracked entities are:

- Treatment session and related attributes
- Treatment Recipe
- Ultrasonic Images
- COP Measurement results
- Knee temperature measurements
- Step Counter values
- WOMAC questionnaire results

Depending of the type of entity, the related "Value" could be either a numeric value (e.g. Step Counter Value) or a file reference (e.g. US Image file).

5.10 Alarms

Alarm generators are technically implemented as Rules.

Alarms may be issued based on a variety of reasons and some examples are failure to receive activity action confirmations from Patient, Patient premises equipment failure, exceeding of metrics thresholds, etc.

5.11 Management

Dedicated interface for instrumentation, supervision and management of the cloud server.

5.12 Clinician Interface

The physiotherapist interacts with the system either via pc/laptop or mac over a standard web interface.

The following main functional interfaces are provided:

- Treatment Context Registration
- Treatment effect progress supervision
- Patient interaction/messaging
- Treatment Context content modification

Depending on the registered access privilege of the actual clinician, only a subset of above functionalities may be available (see section 5.18).

5.13 Patient Phone App (PaApp)

The patient interacts with the system via a smartphone (Android or iPhone) app. The App incorporates the griffin cloud protocol stack for interaction with cloud server.

Interaction with cloud server is done over SSL/TLS socket. Wakeup events from cloud server are performed using standard push notifications.

The PaApp performs operations on behalf of the cloud server based on Activity Recipes.

5.14 Patient Agent (PaAgent)

It is assumed that third party devices, such as COP and therapeutic/scanning Ultrasound devices are provided only with pc-based drivers. As the target is that there will be no direct interaction between the patient and the pc, the patient pc is equipped with a piece of software, the PaAgent, which handles all interaction with the connected treatment equipment and the cloud server.

The PaAgent pc will run under Linux OS and possibly with a Windows Virtual Machine guest (depending on requirements set by external device drivers).

The PaAgent incorporates the griffin cloud protocol stack for interaction with cloud server. Interaction with cloud server is done over SSL/TLS sockets. The PaAgent will keep a constant tcp (transmission control protocol) connection with the cloud server.

The main software components of the PaAgent are:

- Device Controllers (LIPUS, US Scan, COP)
- Device Drivers
- Control Agent

The PaAgent performs operations on behalf of the cloud server based on Activity Recipes.

5.15 Device Controllers

The Device Controllers are part of the PaAgent and handle all interaction with the respectively connected device. Control operations include:

- Configuration
- Activation
- Deactivation

Supervision

The control is orchestrated by the cloud server. For every LIPUS session the cloud server provides the LIPUS controller with a session context which contains instrument configuration and duration information.

Supervision is continuously performed over the dedicated API. Any anomalies are logged (at the cloud server) and are subject to alarms at patient and/or clinician.

5.16 Third party drivers

The provided software package not only contain drivers, but also APIs that allow the PaAgent full control over the third-party devices.

5.17 Software upgrade

The PaAgent software, as well as third party device drivers, can be upgraded remotely from the cloud server.

5.18 Security

EU states "The General Data Protection Regulation (GDPR) recognizes data concerning health as a special category of data and provides a definition for health data for data protection purposes. Though the innovative principles introduced by the GDPR (privacy by design or the prohibition of discriminatory profiling) remain relevant and applicable to health data as well, specific safeguards for personal health data and for a definitive interpretation of the rules that allows an effective and comprehensive protection of such data have now been addressed by the GDPR. Processes that foster innovation and better-quality healthcare, such as clinical trials or mobile health, need robust data protection safeguards in order to maintain the trust and confidence of individuals in the rules designed to protect their data."

The protection of personal data in the ADMAIORA system is based on design combined with restricted access and encryption of sensitive data according to the EU Reg. 2016/679 General Data Protection Regulation (hereinafter also "GDPR").

A Data Protection Impact Assessment under article 35 GDPR will be performed in order to identify proper technical and organizational measures able to mitigate risks to compromise data confidentiality, availability, and integrity according to the best standards developed during the project lifecycle. In particular, the following features will be assessed and implemented.

5.18.1 Anonymization

The main feature is that all individuals are anonymized, no personal information, such as name, addresses or social security numbers are stored on the server or elsewhere in the system. The link between patient identity and the system ID is kept offline by the clinician.

5.18.2 Access

The patient app is protected by fingerprint identification to access the application. For older smartphones without fingerprint recognition username and password are used for access

The app communicates with the server with Transport Layer Security (TLS). The connection is secure thanks to that unique symmetrical keys that are created for each session. The keys are based on a shared secret negotiated at the start of the session. This will take place before any user data is transmitted over the link. The communication is also reliable as a breach in message integrity can be detected.

5.18.3 Server Content Protection

Content privacy for such entities such as receipts and images are stored at the cloud server protected by encryption suits with combined patient/Clinician end-to-end keys not known by the server.

Access privileges to Treatment Context via web interface is controlled through access groups. Every Treatment Context has its own access control record.

Two levels of access privileges are defined:

- 1) Full access privilege, meaning rights to edit and generate input to, as well as full read rights from, a Treatment Context.

- 2) Read Only access privilege, meaning only rights to read Treatment Context related data.

An Access Group may contain one or more “medics” (e.g clinicians, physiotherapists...). An Access Group may also contain one or more other Access Groups.

Every “medic” must be registered and assigned an account and user id before any access can be granted. Only the predefined user “admin” may register new “medics”.

Any “medic” may create a Treatment Context. Default Access privileges of this new context is the creator with Full access privileges.

The PaApp is restricted to access only a subset of the related Treatment Context such as feedback metrics (data, images), certain progress metrics, treatment schedule and details.

Highly sensitive data such as scan images stored at the cloud server may be protected by encryption using an end-to-end key not stored in the cloud server.

5.18.4 Content access

Content access at the server is protected privacy for entities. For example, prescriptions and images are stored at the cloud server protected by encryption suits with combined patient/Clinician end-to-end keys not known by the server.

5.19 Registration and Pairing

When preparing for the remote treatment at the patient premises, a Treatment Context is created, and all equipment related to the Treatment Context is registered and paired.

Registration and Pairing includes:

- Patient registration (see section 5.18.1)
- Creation and setup of a Treatment Context in cloud server
- Registration and setup of patient pc
- Installation and setup of patient PhoneApp
- Registration of sensor devices (temp sensors and step counters)
- Generation and installation of cloud server access keys (in PaApp and PcAgent)
- Generation and installation of end-to-end encryption key for sensitive patient data (see section 5.20)

5.20 Offline Patient cross-reference register

A cross-reference map between patient-id and physical patient identification information is kept offline in a separate register.

Some sensitive patient data are encrypted with an end-to-end key shared by the medic and Patient but not known by the cloud server. This key is also stored in this register.

The same security applies for the clinician web service, which runs HTTPS, i.e. HTTP over TLS.

5.21 Transparency and Data Subjects' rights

The app ensures the exercise of data subjects' s rights (both patients and clinicians) by a friendly interface which will include the information statements and a system of permission and tools in order to meet the ethical-legal requirements stated by the GDPR and national implementation (i.e. whereas the legal basis is patient's consent, a tool to collect and store it, etc.)

In particular, the app's privacy policy will include the information that is required under the articles 13 ff. GDPR and be sufficiently accessible to data subjects, according to the standards identified by ENISA, *Privacy and data protection in mobile applications. A study on the app development ecosystem and the technical implementation of GDPR*, issued in 2017 and Good

Practice for Security of Internet of Things, issued in November 2018, unless further relevant standards will be implemented. Based on this, we will implement:

- a link to the privacy policy of the app in the relevant app stores where users can review permissions and privacy statements;
- a tool for information through permissions that the app seeks to obtain from the user as regards the processing of personal data;
- a tool for information provided directly through the app in the context of user inputs and special notifications and explanations of the apps functionality in interaction with the user.

6 Conclusions

In this deliverable, pictures of the preliminary software structure for the patient app and clinician web interface have been reported, with descriptions of the functionalities of each component and software server.

With the proposed structure, it will be possible to implement systems that are secure, scalable and most importantly useful for both patient and clinicians.

The structure allows for the addition of more peripheral units as well as changes to the existing ones, without dramatic alterations. Thus, it can be good basis for further efforts to be pursued in the project course.