5. User Manual - AF (Atrial Fibrillation)

The AF mobile interface is an Android application which offers the possibility of monitoring symptoms, events, diet and exercise changes, weight, INR and blood pressure of the atrial fibrillation patient. This application allows the patients to perform a self-management process of their disease anytime and anywhere, while having the security of being remotely supervised by clinicians which can control their therapy status through recommendations.

The patient accesses the app via a smartphone provided by his caregiver. This solution enables the patient to get recommendations and feedback from the MG system. The Smartphone is equipped with several monitoring devices, such as a pedometer and accelerometer to measure physical activity intensity level. In addition to the Smartphone, the patient will upload his symptoms to the Smartphone app via Bluetooth connection and will enter the other values manually.

5.1 Patient Guidance System

5.1.1 Patient Materials

- **Smartphone**

The Smartphone Graphical User Interfaces (GUI) is the entry point of Mobiguide application for the patients and provides them with a unique guidance tool to manage their disease.

The GUI allows patients the visualization and insertion of clinical data such as blood pressure measurements, symptoms, diet specifications, exercise sessions; weight, INR, events and ; reception of personalized recommendations based on clinical guidelines; and physical activity monitoring using smartphone's internal accelerometer.

- **Physical Activity Detector (PAD)**

The Physical Activity Detector (PAD) is an android based mobile service which uses the internal accelerometer of a smartphone to detect, every 10 seconds, the type of activity that the user is performing: resting, waking or running.

The Smartphone will monitor physical activity according to the defined

guidelines and the patient's health state (in some cases the physical exercise could have medical or obstetrical contraindications, so the goal will be to monitor the physical activity to guarantee that the patient is resting).

- **Bio-harness (Zephyr sensor device)**

The bio-harness sensor monitors the patient Heart Rate. This sensor communicates with the Smartphone via Bluetooth. When available, this sensor will be used during the recording of any physical activity session in the AF domain.

- **Blood Pressure Monitor (Omron 708-BT)**

Blood pressure is measured by clinicians during encounters. If the patient presents anomalous blood pressure, additional measurements need to be taken by the patient at home.

Communication with this Bluetooth-enabled sensor is accessible via the Blood Pressure tab of the Logbook function.

5.1.2 Virtual Tour

Before you are enrolled in the MobiGuide system, the MG_Mobile GUI allows you to access a demonstration version of the application (MG Virtual Tour) so that you can figure out how to use different functions and for you to practice entering testing data.

In order to access the Virtual Tour, you can select the button "Virtual Tour", in the upper left side of the MG Mobile GUI. The functions of the Virtual Tour match those of the MG Mobile application and all the final functionality of the application has been mimicked. Some monitoring data have been entered automatically in the Virtual Tour for demonstration purposes.

5.1.3 First Use

The first time you access the system, your caregiver will enroll you to the application and will activate your profile by entering a user **ID** and a **BAN** (Body Area Network) code. The BAN code is unique for each patient and it is just for the first use, in subsequent uses, the system will request you to enter only your USER ID and a PIN code.

The steps to follow are:

5. Press the application button and the Login screen appears, then enter User Id and the BAN Activation Code.
   After completion, press the Activate button.

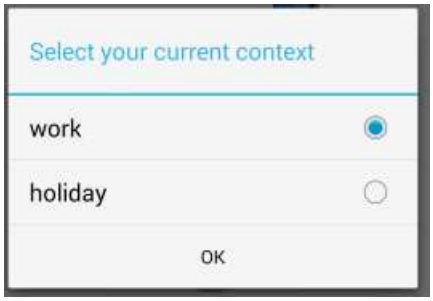
6. Then, a screen asking for a PIN number appears. Your caregiver will ask you to think of a PIN number. This number must contain four digits – only numbers, no alphabetic signs allowed - and will be required each time you use the application. Please take your time and **choose a PIN that you can always remember easily.** <u>It is advised that you write your PIN down and store it in a safe place at home</u>. **If you forget your PIN, all data collected in your personal record will be lost.**

7. Once you finish the previous step, the following screen appears to let you know that the activation process has been successful and the application is loading

8. Then the system will ask you to choose from two different context situations and indicate your current context. The names of these two context situations will be determined together with your caregiver, and are explained below:

   — **Work:** Is the daily routine personal context for data measurement, meal times and physical activity.
   — **Holiday:** Is a semi-routine personal context. The schedule is different from a work day.

   The schedule for Work and holiday would be defined with the caregiver, and it can be changed when needed.



5.1.4 Regular Access to the system

You can always access the application by selecting the icon MG_Mobile in your Application Menu.

Then you have to enter your user id and your PIN code.

The system will show a welcome back message while loading the application's data personalized to your clinical domain

5.1.5 Main Functions

It is recommended that you keep the MobiGuide application running for the whole day because this is the best way to make sure that you will receive reminders and recommendations in time. If the application is not running when a recommendation is generated, you will receive recommendations generated in the background when you log in to the system. You do not need to stop the application at any time.

It is expected that the Smartphone's battery lasts for at least 17 hours of talk time, which implies that using the MobiGuide functionalities for the expected average time should be longer than 24 hours. Even though the MobiGuide application provides mechanisms to inform about low battery states, it is recommended that you charge the Smartphone's battery every day. The expected battery recharge time for the Smartphone is 2 hours.

For the next and subsequent times, after entering your previously saved PIN number, the following screen will appear. This is the main screen of the application which will have five different functionalities that will be fully explained along this section.

Once you have entered the MG system, you will be directed to the Home screen of the application.
This screen allows you to access 5 different functions: 1) Logbook; 2) Therapy; 3) Exercise; 4) Recommendations; and 5) Settings.

Logbook

The logbook function allows you to visualize and enter monitoring data related to your disease. This functionality provides different menu options such as: a) Symptoms; b) Diet; c) Blood Pressure (BP); d) Exercise; e) Weight; f) INR; g) Events; and h) Surveys.

There are several ways to access to the different options, which will be fully explained bellow:

1. By Sliding your finger at the top of the screen to the left or to the right over the tabs with the names of the different options and selecting the desired tab (see next figure - orange arrow). Afterwards, you can slide your finger to the left or to

the right in other parts of the screen to navigate through the functionalities from the selected option. (See next figure - green arrow)

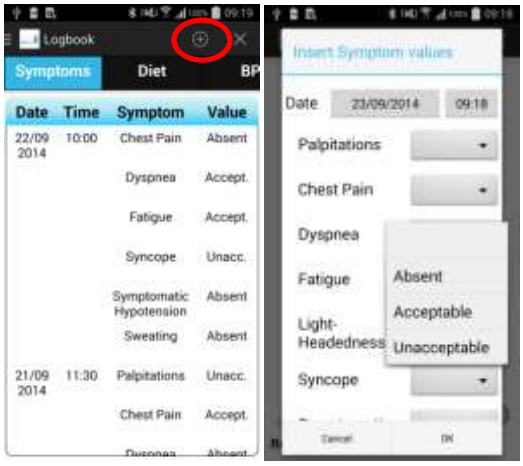
2. By selecting the MobiGuide logotype on the top left side of the screen,

3. By sliding your finger to the right, from the left-hand border of the screen, and the logbook menu appears so that you can select the desired option.

Logbook - options

a) Symptoms

This option allows you to visualize the history of AF symptoms, previously established by your caregiver, sorted by date and time. For each symptom it is possible to specify its degree (absent, acceptable or unacceptable). By pressing the **'+'** button at the top right-hand side of the screen.



Absent:	no pain or symptom at all.
Acceptable:	the level of symptom or pain that is still bearable for you
Unacceptable:	high level of pain or any other symptom that prevents you to have a normal life.

Press the **OK** button to store the data in the system.

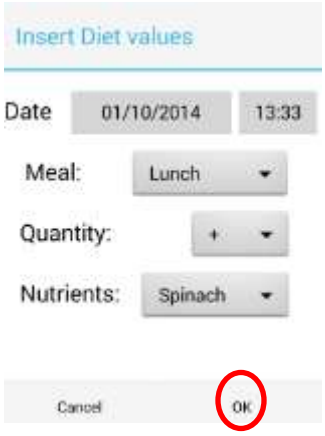
For a quick access to your symptoms dialog, just press the **"Emergency Action Button"** represented by a "Red Cross" at the top right side of the screen. See figure below:

This option provides an emergency access to report potential events where you may require immediate assistance from the MobiGuide system. You can introduce any serious symptoms you are experimenting.

b) Diet

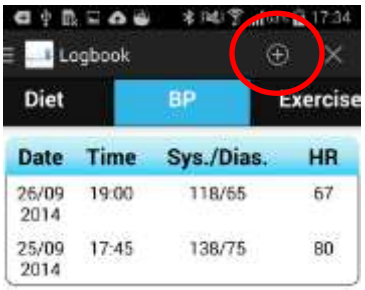
This option allows you to register your diet intakes related to any nutrients that interact with your disease. The list of nutrients has been previously chosen by your Caregiver. You can access the option to enter new intakes, at the '+' icon at the top right side of the screen.

For each intake that you enter, you should select in the 'Nutrients' menu if you estimate that the meal consumed, was higher (+), much higher (++), lower (-) or much lower (--), than it was recommended by your caregiver. Once you have finished, press the OK button to save the data registered.



c) Blood Pressure

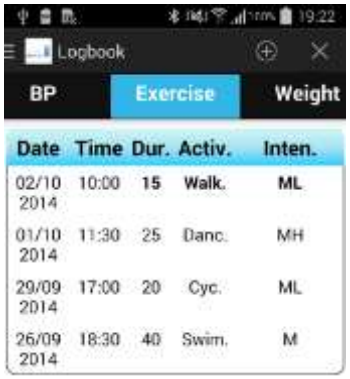
The option blood pressure (BP) presents a list of BP measurements registered previously. You can enter new BP measurements selecting the **'+'** button at the top right side of the screen.



If you would like to enter a new blood pressure measurement manually, you should enter the date and time, the systolic and diastolic values and (optionally) the heart rate. Press the **'OK'** button to store the data

d) Exercise

The option for exercise visualization shows data related to your exercise sessions, including date, time, duration of each activity, type of activity and activity intensity.

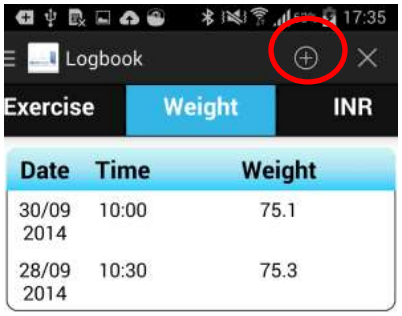


Due to the limited screen of the Smartphone, some abbreviations are used. If you would like to improve the visualization of exercise sessions you could rotate the Smartphone and use it in horizontal position:

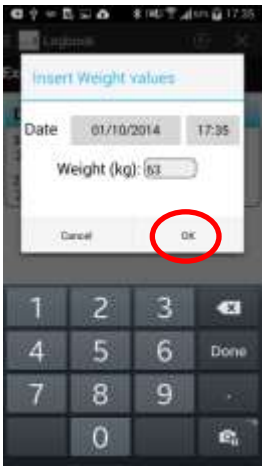
Even though the MG Mobile application includes an Exercise menu to monitor your physical activity sessions automatically, you can always enter exercise sessions manually using the **'+'** icon at the top right side of the screen. Automatic exercise sessions are marked in bold. If you would like to manually enter an exercise session, you should complete information related to date and time when practicing the activity, duration, type of activity, and the estimated intensity level in qualitative terms. Press OK button to store the information.

e) Weight

The logbook function for visualization of Weight allows you to visualize your weight values, including date and time of measurement and value in kilograms.

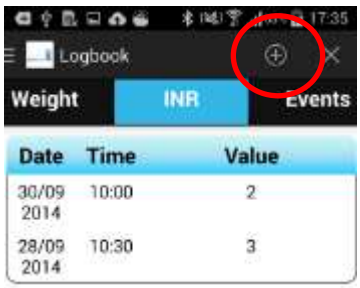


You can enter new weight values with the **'+'** button located at the top right side of the screen. Please, remember to select the **'OK'** button to store the values.



f) INR

The option INR (International Normalized Ratio) allows you to visualize your INR values and register new measurements.

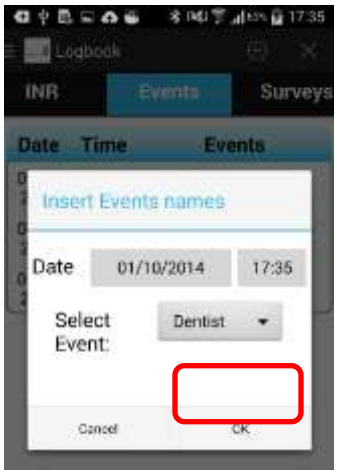


You can enter new INR values using the '+' button at the top right side of the screen. For new measurements that you enter, you should specify the date and time of measurement as well as the INR value. Then press the **'OK'** button to store the data registered.

g) Events

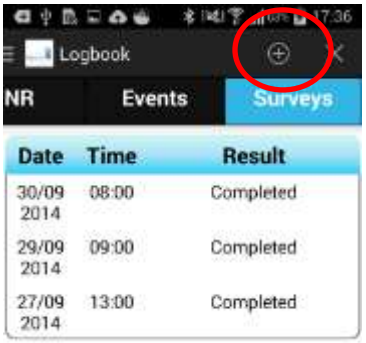
This option allows you to register meaningful events that might affect your health state in the future. The list of events of interest has been defined by your caregiver

You can enter new events by using the **'+'** button at the top right side of the screen. For new events, you have to enter date and time of the event and type of event (surgey, dentist, etc..) from a dropdown list. Then press the **'OK'** button to store the data registered

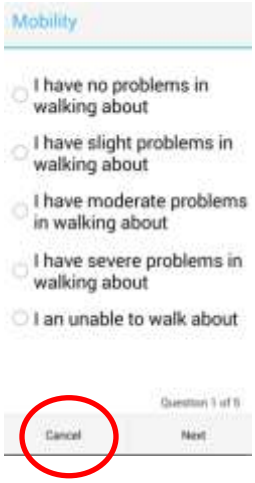


h) Surveys

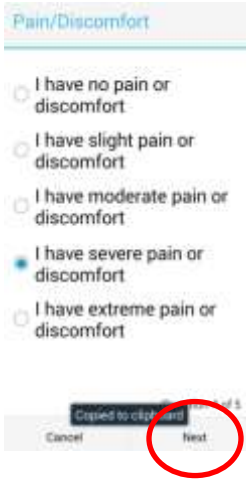
The MG application will periodically generate reminders to ask you to fulfil a survey about your quality of life. This option present a list of surveys already completed ordered by date and time. Each survey has 5 questions with 5 possible answers for each question.



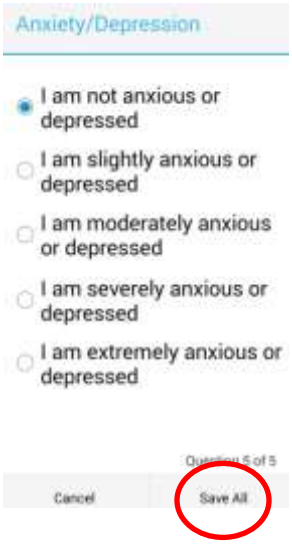
To start a new survey, you should press the '+' button at the top right side of the screen. You can cancel the survey at any time, by pushing the **'Cancel'** button.



Then you can start to fulfil the survey. Please note that it is required just one answer for each question. Once you finished press **"Next"** to continue with the survey.



After answering the last question, you will be able to save all the survey by pressing the **"Save All"** button.

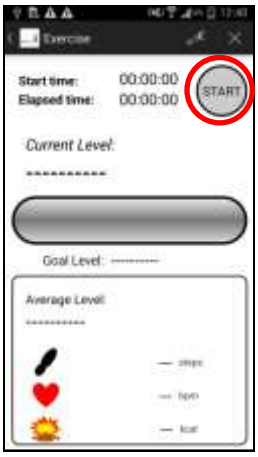


Exercise

This function is related to the physical activity performed by the patient. The treatment plan usually includes recommendations about the level and frequency of physical exercise, and the following of these recommendations is monitored by the system. This function has to be activated when the patient is going to practice some kind of physical activity. If you want to see the summary of all your exercise sessions, you must go to **Logbook – Exercise.**

The MG Mobile application allows you to automatically monitor your exercise sessions using the MobiGuide Physical Activity Detector (**MG_PAD)** application installed in your mobile. The PAD uses the internal accelerometer of the smartphone to calculate the type of activity you are doing: resting, walking or running; the intensity level at which you are exercising; the number of steps you have walked/run; and estimates the energy you have consumed by means of the calories burned. The algorithm implemented in the PAD has been calibrated to estimate the physical activity intensity and energy expenditure with the smartphone place on your pocket. The results obtained with the device placed in a different position, like your hand, may not be accurate. However, you may want to check how well are you performing during the exercise session. The design of the Exercise function allows you to check the status of the ongoing exercise session easily at a glance and place again the device on your pocket to continue with the activity.

To start monitoring you should press the **'START**' button on the top right corner of the screen:



Leave your smartphone in your pocket! It is mandatory that the smartphone is in close contact with your body; you must remember to wear pants with at least one pocket for the smartphone, or having a smartphone clip holder.

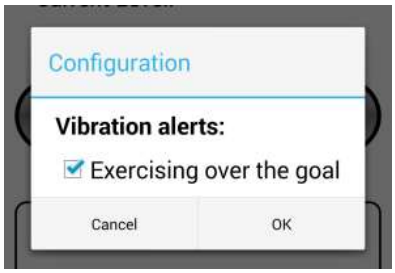
The top part of the screen shows the start and elapsed time of the exercise session and a snapshot of the actual state of the exercise session. This information is calculated every 10 seconds and the information in the screen is accordingly refreshed:

- The type of activity you were doing by means of a rag doll: resting, walking or running.
- The intensity level of the activity by means of a progress bar and a colour code, as well as written next to the type of activity: light green for Low or Moderate Low levels, bright green for Moderate level, and red for Moderate High and High levels.
- The goal level at which you should be exercising, prescribed by your caregiver, and shown written under the progress bar and depicted also in a yellow colour in the intensity bar so you can check if you are exercising under or over the prescribed goal in an easy way.

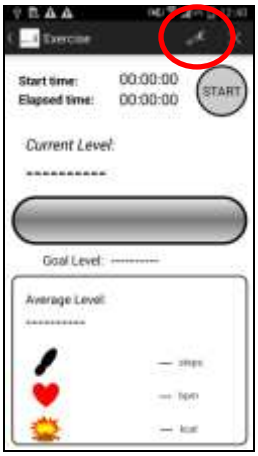
The bottom part of the screen shows a summary of the ongoing session:

- The average level at which you have been exercising during the exercise session
- An ‘emoticon’ that reflects how well are you doing so far, according to the goal level prescribed by your caregiver: you are exercising under the goal level (happy face), you are exercising at the goal level (jubilant face) or you are exercising over the goal level (sad face).
- A summary of the number of steps you have walked/run during the session – shoe icon
- A space prepared for your heart rate in beats per minute measured with a bioharness belt – heart icon.
- A summary of the estimated kilocalories burned –bonfire icon.

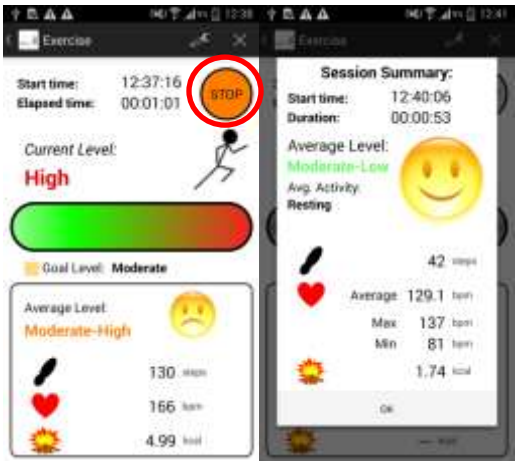
Every time the PAD detects an exercise intensity level over the goal level the application throws a vibration alert as a reminder whose length depends on how much you have overpassed the desired exercise level.



If you don't want to receive this type of alerts you can disable them by disabling this option in the popup configuration dialog which is show after pressing the '**wrench'** icon of the top title bar of the application (red circle in the figure below). You can change this setting along with other configurations of the MG application through the "Settings" functionality in the main menu.



Whenever you want to finish the exercise session you can press the 'STOP' button colored in orange in the top right corner of the function and a dialog with an extended Summary of the exercise session will be displayed. This dialog shows the duration of the exercise session; the average type of activity and intensity level; how well have you performed compared to the goal level by means of an 'emoticon' , the total number of steps and kilocalories burned and finally the average, maximum and minimum heart rate expressed in beats per minute.



After reading the summary you can press the **'OK'** button to return to the exercise menu. The data of the exercise session will be stored in the mobile and sent to the hospital. Your can check them back through the Exercise tab of the Logbook function: the duration, type of activity and intensity level will be marked in bold.

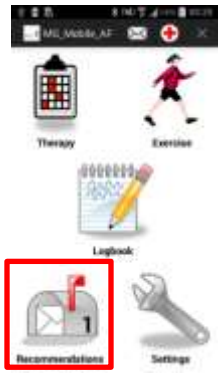
You can also add physical activity sessions manually by selecting a pre-defined list of activities.

Recommendations

The MOBIGUIDE system will generate recommendations according to your health status evaluated by computerized clinical guidelines. These recommendations will be stored under the mailbox icon; any time you have a

new recommendation from your caregiver your mailbox will contain an envelope. Your Smartphone can also be configured to vibrate with each new recommendation.

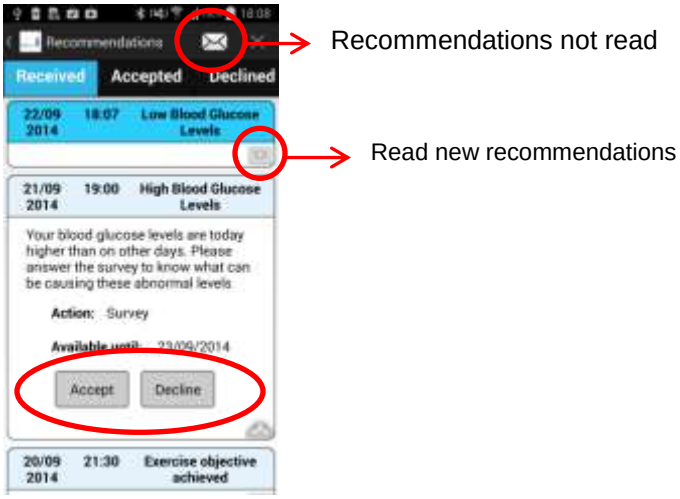
The number of recommendations not read is shown at the 'Recommendations' icon at the Main screen of the MG application.



You can always know that you have recommendations not read because an envelope will appear in all the menus. The envelope will be present up to you read all the recommendations.

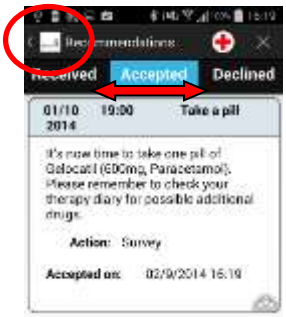
In order to read a new recommendation, you should open it by click on the arrow located in the right corner of a new recommendation. The list of the recommendations will open. The messages in light blue are already read recommendations, and the intense blue ones are unread recommendations. Please, note that the content of recommendations is different according to your health conditions and adapted to the illness that you have (GDM or AF).

Once a recommendation has been opened, you should accept or decline it. In case you don't accept or decline it, the recommendation will have a limited time of availability, also shown associated to each recommendation. Recommendations that are not accepted before the date of availability will be considered declined.

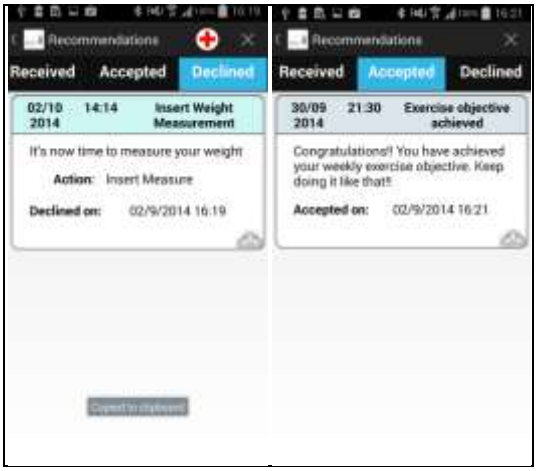


The **Decline** button will keep the recommendation open, until later action. The **Accept** Button will pop-up a certain measurement input screen.

Similarly to the logbook, you can see **recommendations received, recommendations accepted and recommendations declined**, sliding your finger to the left or to the right over the screen or pressing the tab with the name of the desired option. You can return to the Home screen of the application selecting the MG logotype which is located at the top left side of the screen. The option for recommendations accepted shows those recommendations that you have accepted and the date when you accepted them.

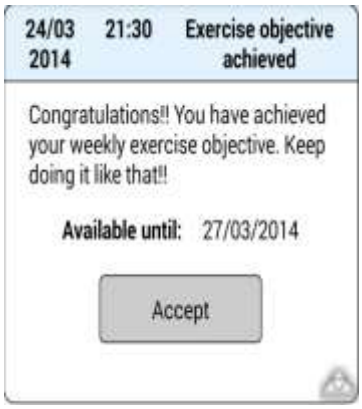


Those recommendations that have not been attended yet will appear in the option ‘Received’; those that you have declined, are shown in the option ‘Declined’; those that you accepted will appear under ‘Accepted’.

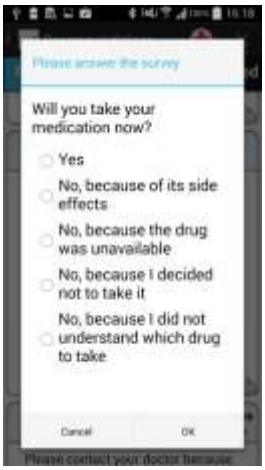


Note that you might receive different types of recommendations (reminders, congratulations, recommendations about therapy, etc.) and that recommendations might have or might not have actions associated to them. There are three basic types of recommendations:

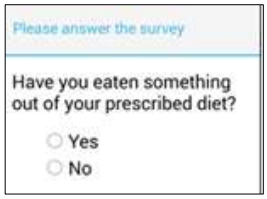
— **Notification** (only information - no action needed)



— **Survey** (the patient must answer the questions asked in the recommendation)



— **Measurement** (this recommendation will ask the patient to do a new measurement in case of any anomalies or doubts)



Therapy

Within this function, you can view and manage the therapy prescribed by your caregiver in order to ensure full compliance with the treatment. It will

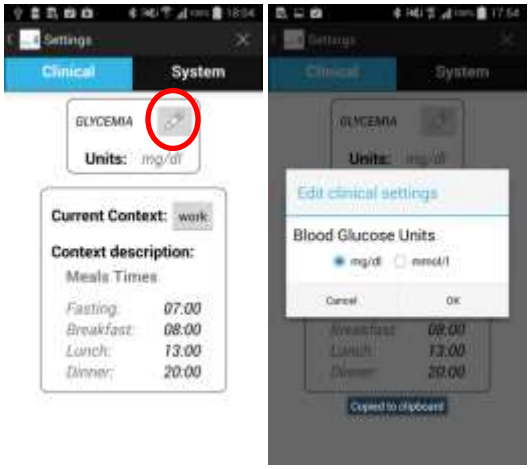
show a brief summary of your clinical history, including allergies and your current medication.

This screen contains the therapy's details such as the drug's name, the time, the dose and the frequency of administration.

Settings

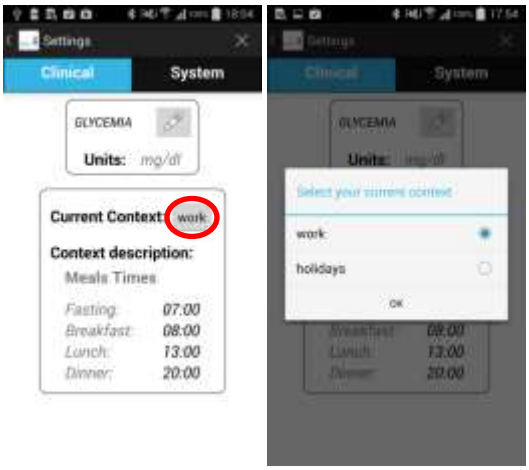
The settings option let you change the parameters for three different types of settings: clinical, context and system. **Do not forget to press OK to save the values.**

Clinical Settings: You can edit the parameters with the pencil icon at the top bar.



Context settings: You can edit the user context (work/holidays) with the button "Current Context". Choose this option to report to the system that your current context has changed, so the system can adapt its recommendations accordingly. The names of

the context situations are determined by you together with the caregivers at the time that you enrol into the MobiGuide system (e.g., “work”, “holidays”).



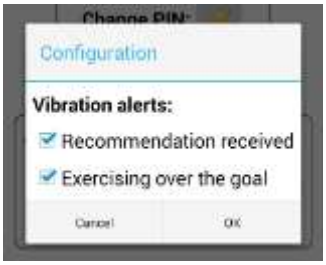
- **Work:** Is the daily routine personal context for data measurement, meal times and physical activity.
- **Holiday:** Is a semi-routine personal context. The schedule is different from a regular day.

System Settings: You can choose between these three options:

- **Change PIN number:** You can choose to change your initial PIN number at any time. If you need to change the PIN, you should press the “Change PIN button”. Your current PIN number needs to be entered in order to be able to select a new PIN. Then, you can select a new PIN number and you should enter the same choice twice. Remember that your PIN number should contain four digits – only numbers, no alphabetic signs allowed. You will be able to save the new PIN number by pressing ‘OK’. Please, make sure that you can remember your new PIN number. For security reasons, we cannot retrieve your PIN number if you forget it, so all data collected in your personal record will be lost if you forget your new PIN number.

— **Deactivate BAN:** The system's deactivation can be done using the "deactivate BAN" button. Please, do not select this functionality unless you have decided to stop using the system and your physician supervises this procedure. The system deactivation requires entering your PIN number in order to confirm the process. The idea of this feature is to allow a patient deactivation from the MobiGuide system in case a patient decides to drop from the pilot.

— **Vibration alerts:** You can choose to receive vibration alerts whenever a new recommendation is received or when you are exercising over the goal established by your caregiver. You can modify your preferences about receiving vibration alerts at any time by selecting the button labelled with a pencil. Then, a new screen will be shown so that you can select (or unselect) your preference to receive vibration alerts for recommendations, when exercising over the goal or in both cases.



5.1.6 Exit the System

You can exit the MG Mobile application by selecting the '**X**' situated at the top right side of the screen from any function.

A new screen will be shown so that you can confirm that you want to log out or cancel logging out.

5.2 Caregiver Guidance System

The caregiver interface is a web-based solution responsible for the management of MobiGuide patients and their data by caregivers (physicians, nurses, psychologists, etc…)

This interface includes the following aspects:

- Enroll new patients into the system;
- Retrieve and store patient data (e.g., demographics, clinical history, family history, therapy, diagnosis, etc.);
- View and execute recommendations;
- Manage messages (both from the system and from the patient).

NOTE: During enrollment phase, the caregiver will probably have to explain the operating instructions to the patients. Please remember that the patients require a PIN number to operate. Please ask your patients to think of a PIN number carefully. This number must contain four digits – only numbers, no alphabetic sigs allowed - and will be required each time the patient uses the application. Insist on the point that **the patient**

should choose a PIN that she can always remember easily. It is advised that the patient writes her PIN down and store it in a safe place at home. **If the patient forgets her PIN, all data collected in her personal record will be lost.**

5.2.1 Getting Started

Login Process

This section describes how to access the MobiGuide Caregiver Interface. The system provides a login functionality, which restricted the access to the resources of MobiGuide caregiver interface only to authenticated caregivers.

The login process requires two authentication steps to enter the application.

a) 1st step – User name and password

The user enters her username and password (see picture below) and if the login is successful, the second authentication procedure is performed, otherwise, her credentials are requested again

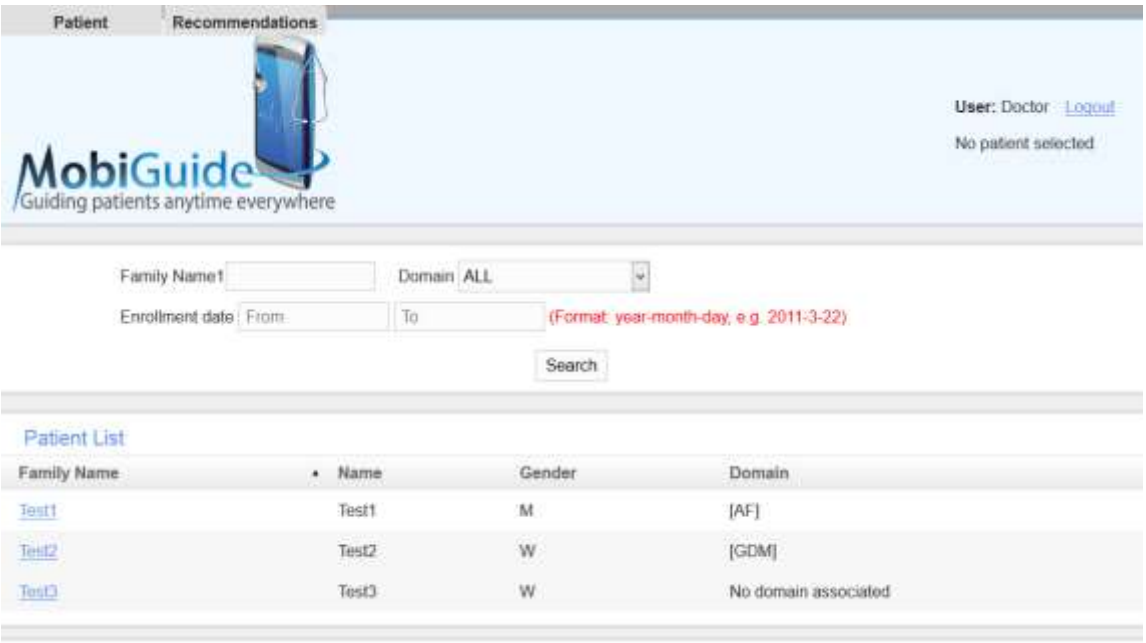
b) 2nd step – One Time password

A new screen appears asking for One Time Password (OTP); this password is unique and valid for just one session and ensures that only authenticated users are authorized to access the system.
The procedure is the following:

1. The user requests an OTP password by pressing the ***Request OTP*** button.
2. This will trigger a process that sends an e-mail to the caregiver with the requested password.
3. Then, the system will prompt the user to enter the received password and press ***Submit OTP*** button, after which the home page will appear.

Home Page

After authentication, the user is directed to the following page, where a list of all the patients currently enrolled in the MobiGuide system is shown:



The caregiver interface Homepage displays:

- the logged-in user;
- New Patient enrollment
- Selection and management of existing MobiGuide Patient
- Recommendation Management

The page is divided into three panels:

- **Top panel:** this panel is visualized in all the pages of the application. It includes some information: the user that is currently logged into the system with the possibility to log out, the name of the selected patient (if any) with the possibility of deselecting him/her, and the Menu bar. The menu bar shows different items depending on whether one patient is selected or not. (In the case no patient is selected the bar shows only two tabs: Patients and Recommendations). Moving the mouse over the menu items, sub-menus are shown.
- **Mid panel:** in this panel the user can search for a specific patient enrolled in the MobiGuide system. To perform the search the user can specify one or more of the following: Family Name, Domain (ALL, AF, GDM, No domain associated) and Enrollment Date. To retrieve the patients list the Search button must be clicked.
- **Bottom panel:** this panel shows the list of the enrolled patients. It shows basic information such as Surname, Name, Gender and the Domain associated.

Patients' selection can be performed by clicking on the patient's name. When a patient is selected, the user is directed to the demographics page.

The general menus and sub-menus that are shown when no patient is selected are:

- Patient
  - Select Patient: opens the list of patients
  - Enroll new Patient: opens the enrollment page to start the enrollment process

- Recommendation
  - Show List: opens the Recommendations list page

5.2.2 Main Functions

Patient Menu

Enroll new patient

In this section the enrollment procedure is performed, in order to add a new patient into the MG system. This procedure includes two components:

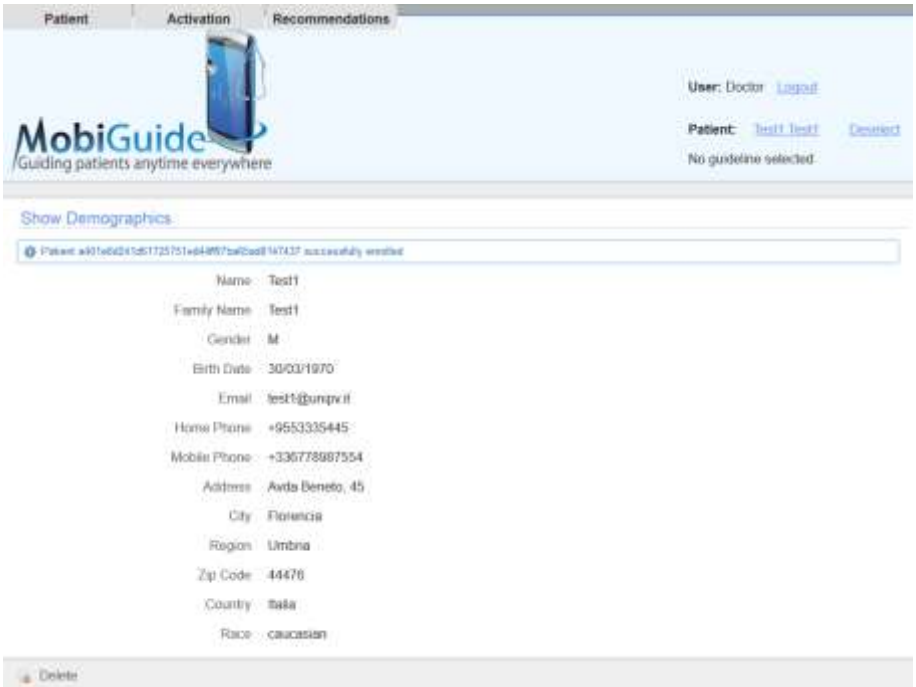
- Activate Guidelines
- Get BAN activation code.

1. Press the ***Enroll new Patient*** button in the ***Patient Menu*** at the top of the screen (see picture below).

2. The next screen allows you to enter the EMR and the BAN identifiers of the selected patient, press the ***Enroll button*** and the patient information will appear.

- EMR ID: patient's identification number in the Hospital Information System (HIS). This code is required to retrieve the patient's information available in the hospital Electronic Medical Record (EMR)
- BAN ID: the Body Area Network (BAN) identification number. This code can be found on the smartphone box.

Clicking on the **Enroll** button, the patient is enrolled into the system. If the enrollment is successful, a message is displayed and the user is directed to the demographics page of the patient.



An error is generated if:

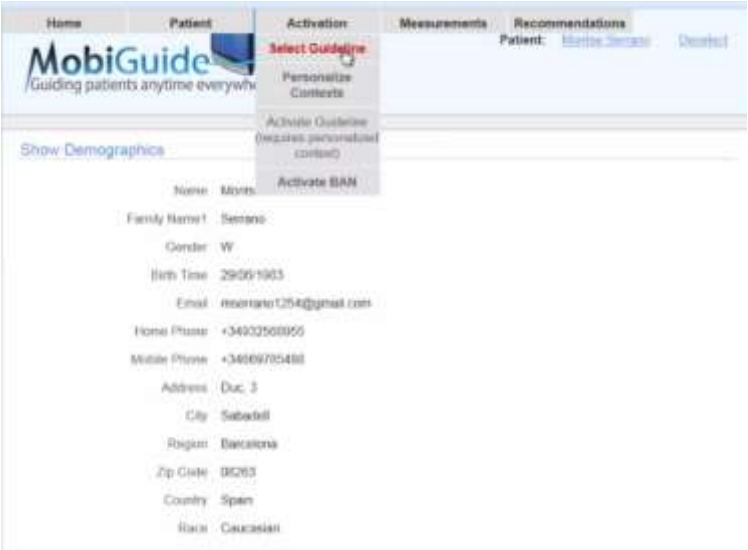
- the EMR ID is not found in the HIS
- the patient results already enrolled

- the BAN ID is not correct

After enrollment, a new menu tab is presented to the user: the Activation tab.

Activation Menu

Once the patient has been successfully enrolled, the ***Activation*** menu at the top of the screen enables the caregiver to: select and activate a guideline, personalize context and finally activate a BAN code for the selected patient.



Select Guideline

This component enables the caregiver to select a guideline for the patient, which is a mandatory step in the enrollment process. Once you press the Select Guideline option, a new screen appears asking for Available Guidelines. The caregiver must choose between two medical domains AF (Atrial Fibrillation) or GDM (Gestational Diabetes Mellitus), then press ***save*** button.

Personalize Context

Once you choose the patient domain, it is time to create a personalized context for the patient. This information will be sent to the Patient Smartphone Application.

The next screen allows editing the preferences for the Personal context for a GDM patient.

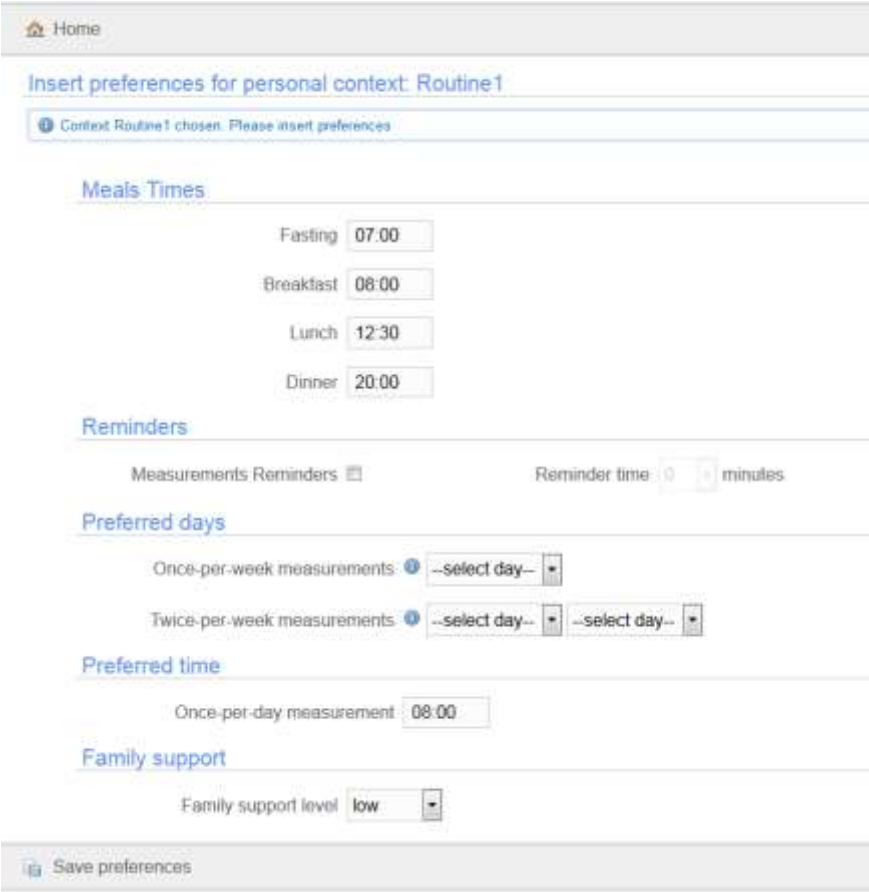
- CIG Customized Context:
  - Meals schedule-routine: **Regular/Work** Measurement, that means, the patient has a daily routine for her measurements.
  - Meals Schedule semi-routine: **Holiday** Measurement, that means the patient may have fewer measurements than her daily routine

- Personal Context Name: Regular/Work and Holiday

— Press ***Save*** button to save the information entered.

Once you finished, press the ***Save*** button to save the information and the page where preferences can be introduced will open.

The next screen allows you to define for each meal the preferred time, whether an associated measurement is required, and whether a reminder is desired and the eventual reminder time.



6) Meals times: the patient can specify his habits. In particular:
   a) Usual time he wakes up (Fasting)
   b) Usual time he has Breakfast
   c) Usual time he has Lunch
   d) Usual time he has Dinner
7) Reminders: in this section the patient can specify if he desires to receive reminders for taking measurements and therapy. In case reminders are selected, it is also possible to specify when to receive them (in terms of minutes before/after the time to take measurement or therapy).
8) Preferred days: measurements can be prescribed by the physician according to a specific schedule, which not necessarily requires taking each measurement every day. In this section, the patient can select his preferred days for each of the

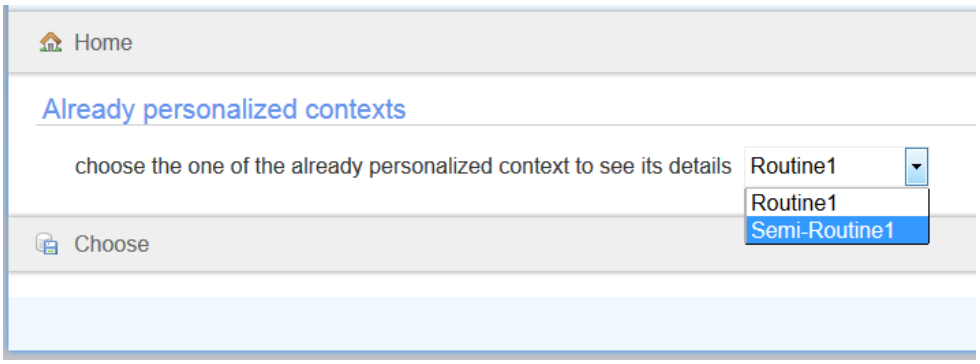
schedules. Clicking on , it is possible to visualize a list of the measurements that should be taken according to that specific schedule (e.g. parameters that could be measured once per week).

9) Preferred time: is the time in which the patient prefers to take a measure. It will be used by the system in those cases when a specific time is not defined by the physician.
10) Family support: you can insert the family support level of a patient.

Clicking on "Save preferences" saves the changes and directs the user to a page where the physician can specify the patient's personal events that will induce the specific context. For example, a semi-routine context can be triggered when the patient is on holiday or during weekends. The routine context will be triggered during the working week of the patient.

Visualize personalized context

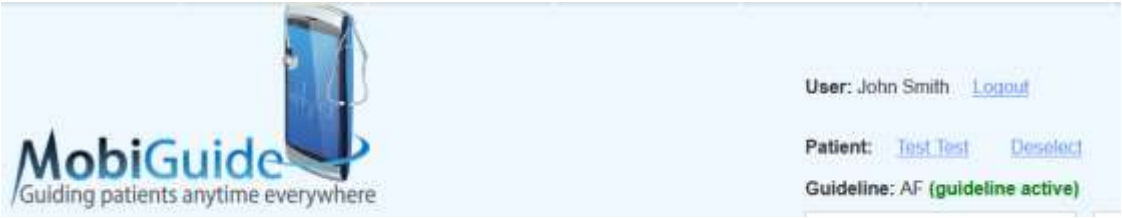
This option opens the page for selecting the already personalized contexts.



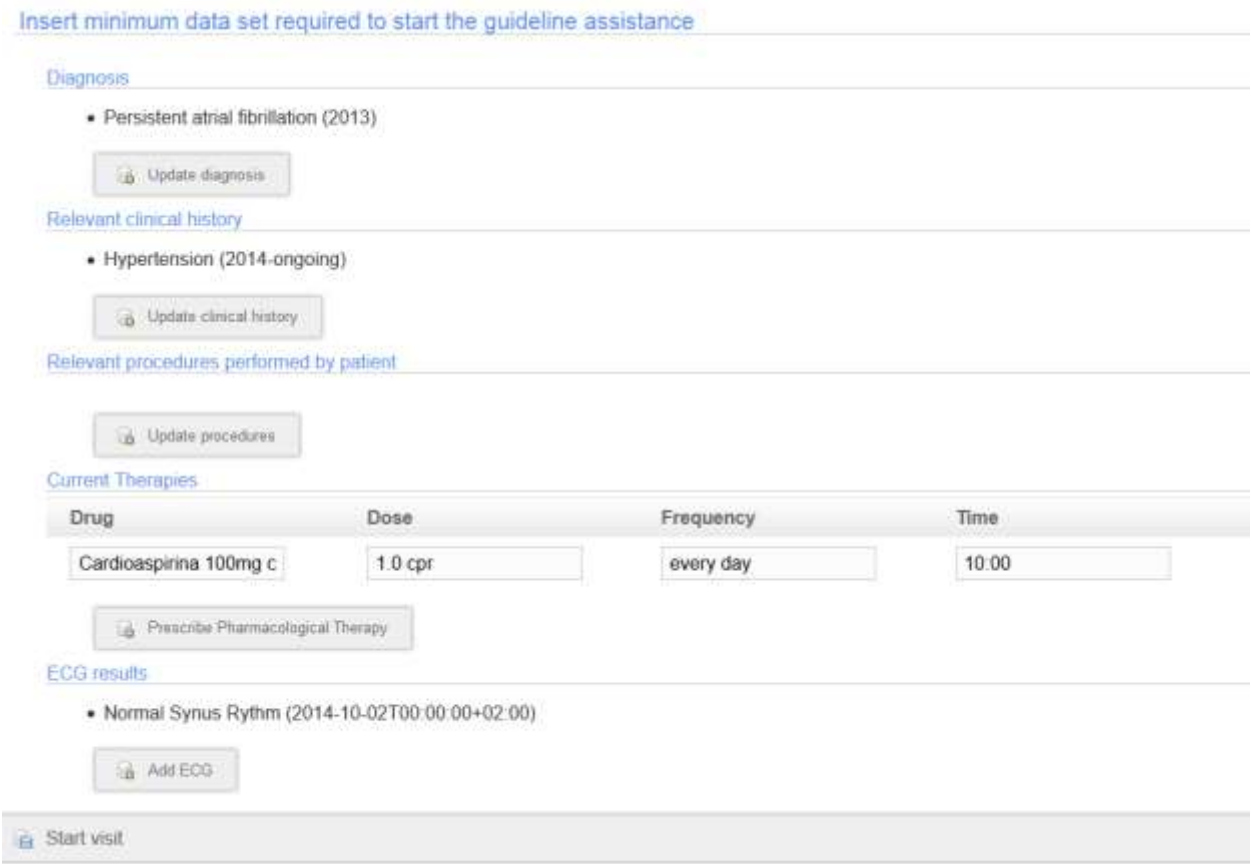
Activate a Guideline (in AF)

Press the ***Activate Guideline*** option in the Activation menu, at the top of the screen. This option activates a guideline for a specific patient after finishing the Personalize Context step.

A precondition for guideline activation is that at least one personalized context is saved. If guideline activation is successful, the top panel displays a "guideline active" message in green and the user is then directed to the domain-specific page where he can set all the data necessary for guideline execution.



When selecting the Activate Guideline sub-menu, the user is directed to a page where he is asked to revise/edit the minimum dataset needed for guideline execution (see figure below). The page is structured as a report, where the already available information (e.g. coming from the hospital EMR) for the patient are shown and the user is asked to update them if needed and to insert the data that are still not available. The sections of this page are about AF diagnosis, relevant patient's clinical history, relevant procedures the patient underwent, current therapies and ECG results. To insert/update data, the user is directed to the specific pages, which will be described in the following. After finishing to update data in the specific page, the user is redirected to the minimum dataset page, where the new inserted values are shown. Note that it is very important to have always updated data in this page, as these are essential for the correct functioning of the guideline.



Clicking on "Start Visit", the page in figure below is shown. In this page, the user has to specify a set of data that are specific for the current visit. In particular:

- **Goal of the visit**: states the main objective of the current visit. Possible values are: rate control, rhythm control with cardioversion, rhythm control with antiarrhytmic drugs, stroke prevention, other. It is possible to specify more than one goal, by clicking on ⊕. It is possible to remove one goal using the button ⊖.
- **Therapy Location**: is the place where the treatment will be performed. Options are Home and Hospital
- **Eligible for Pill in the pocket**: to specify if the patient is eligible for the pill in the pocket

The AF domain is equipped with both a guideline for physician and one for the patient. The guideline for the physician can be started at each visit, while the guideline for the patient is always active, but must be acknowledge whenever new data or prescriptions are entered. The two buttons on the right side of the top panel are used to control these options. In particular:

- **Start Visit (with GL assistance):** When clicking on this button the user is prompted to confirm his choice. Clicking on "yes", the user is directed to the page for entering the minimum dataset; it allows starting a new visit activating the guideline for physician. When the guideline for physician is activated, during the visit he will receive specific evidence-based recommendations related to the examined case. It is important to frequently check the recommendations page for updated advices. When a new recommendation is available, the recommendations menu will turn to red. This page includes the **End Visit (with GL assistance) button.** When clicking on this button the physician ends the visit with guideline assistance. IMPORTANT: The Stop Visit button is responsible for the activation of the patient's guideline with new projections. It MUST always be pressed at the end of a visit.

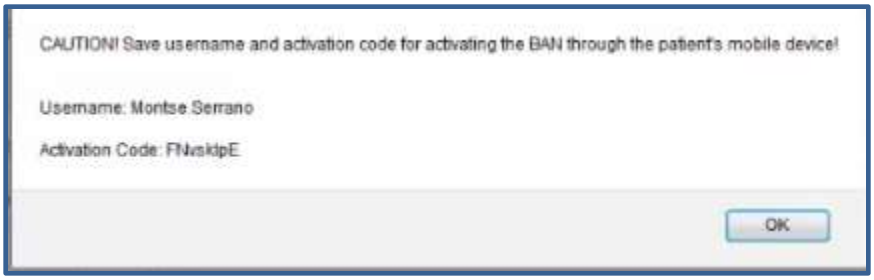
- **Update Patient Data:** This button allows starting a visit without assistance for the physician or just updating patient's data. When clicking on this button the user is prompted to confirm his choices. Clicking on "yes", new data are projected to the patient's guideline. Each time some of the patient's data necessary for patient's guideline execution are changed, the new data are projected to the mobile, which will then run updated plans for the patient.

Activate BAN

This is the last step of the Activation process. It allows activating the mobile app on the patient's smartphone. Once selected, the system will generate a Username and an Activation Code. A document containing this information is automatically printed and given to the patient for later use in the smartphone GUI.

Press the ***Activate BAN*** Button in the Activation menu at the top of the screen.

After activation process, a message in a pop-up window with the username and the activation BAN code appears. This information must be printed and used in the patient's smartphone application.



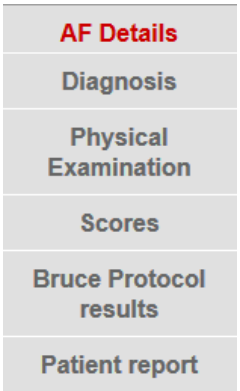
IMPORTANT: Username and Activation Code are mandatory to activate the smartphone app. When clicking OK the window is closed and these codes are lost. It is not possible to directly print the codes, so it is highly recommended to write them down before closing the window.

In case this information is lost, it is possible to request a new username and a new Activation Code through the "**Get new username and activation code for BAN activation**" sub-menu, which will appear under the "**Activation**" menu after a first BAN activation attempt, is performed.

When the AF guideline is selected and activated, the top menu will appear as in figure below

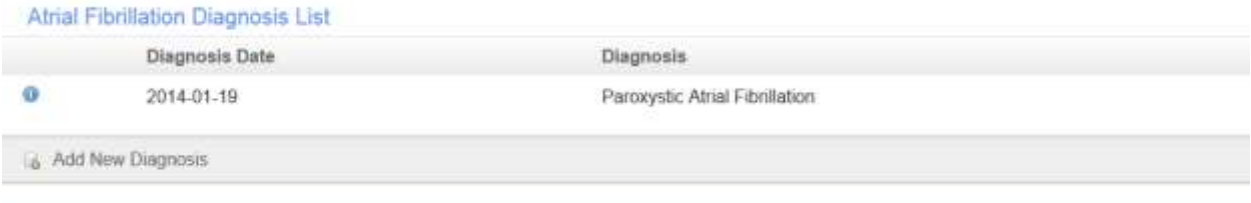
AF Details menu

The AF Details menu is divided into 5 sections, as shown in figure below



Diagnosis

In this page, the user can see all the diagnoses for the selected patient.



The details of a specific diagnosis are displayed by clicking on ⓘ, as shown in the figure below:

Show Diagnosis

Diagnosis Date	2014-01-19
Diagnosis	Paroxystic Atrial Fibrillation
Episodes Number	5
First Episode Date	2014-01-12
Last Episode Date	2014-01-18
Note	

Clicking on the "Add new Diagnosis" button, the application allows inserting a new diagnosis, as shown in figure below. Note that the fields marked with * are mandatory.

Insert Diagnosis

Diagnosis * Lone AF ☐ Post operative AF ☐

Diagnosis Date* 30 September 2014

First Episode Date 30 September 2014 Unknown ☐

Last Episode Date 30 September 2014 Unknown ☐

Note

Save

Physical Examination

In the section "Physical Examination" you can see the data that come from the hospital database. These data cannot be modified.

Physical Examination

Diastolic blood pressure	90 mmHg
Systolic blood pressure	140 mmHg
Weight	90 Kg
Height	1.80 m
Temperature	36.5 °C
Pulse	Racing
Respiratory rate	20 breath/min
Heart rate	130 bpm

Scores

In this option the user can calculate the CHA2DS2-VASc and the HAS-BLED score for the selected patient. (see the figures below).

Calculate CHA2DS2-VASc score

The CHA2DS2-VASc score is a clinical prediction rule for estimating the risk of stroke in patients with non-rheumatic atrial fibrillation (AF). It is a refinement of CHA2DS2 score and extends the latter by including additional common stroke risk factors. The minimum possible score is 0, while the maximum is 9.

Age	<65	65-74 +1	≥75 +2
Gender	F +1	M	
Congestive Heart Failure History	No +1		
Hypertension History	No +1		
Stroke/TIA /Thromboembolism History	No +2		
Vascular Disease History	No +1		
Diabetes Mellitus	No +1		
Score	0		

Whereas the stroke-risk for the CHADS2 = 0 group was 1.9% per year in the original validation,2 subsequent validations found lower 1-year stroke-risks, between 0.5 and 1.7%.4, 9 and 10 There is a large range of stroke-risk among patients with CHADS2 = 0, among whom appropriate therapy may range from oral anticoagulants (OACs) to acetylsalicylic acid (ASA) to no antithrombotic agent. Whereas about 20% of AF patients have a low-risk CHADS2 score (CHADS2 = 0),9 and 10 the prevalence of CHA2DS2-VASc = 0 AF patients is about 8.5%9 and 10 with a mean stroke-risk ≤ 0.5% per year. The principal value of CHA2DS2-VASc applies in these patients, most of whom do not require antithrombotic therapy. Patients with a CHADS2 ≥ 1 have a stroke-risk well over 2% per year and require OACs. Although most patients with a CHA2DS2-VASc score of 1 have sufficient risk to justify the use of OACs, a single CHA2DS2-VASc point based on vascular disease or female sex implies a stroke risk < 1.5% per year and ASA should be considered. Patients with a CHA2DS2-VASc ≥ 2 clearly have sufficient stroke risk to justify use of an OAC.[1]

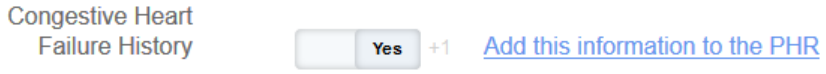
Calculate HAS-BLED Score

(HAS-BLED) score schema for predicting bleeding risk. HAS-BLED is based on the presence of hypertension, abnormal liver or renal function, history of stroke or bleeding, labile INRs, elderly age (> 65 years), and concomitant use of drugs that promote bleeding, or excess alcohol. The HAS-BLED score allows clinicians to assign individualized patient risks of major bleeding from about 1% (score 0-1) to 12.5% (score 5).[1]

Hypertension History	No +1	
Renal Disease	No +1	
Liver Disease	No +1	
Stroke History	No +2	
Prior Major Bleeding or Predisposition to Bleeding	No +1	
Labile INR	No +1	
Age	<65	≥65 +1
Medication Usage Predisposing to Bleeding	No +1	
Labile INR	No +1	
Age	<65	≥65 +1
Medication Usage Predisposing to Bleeding	No +1	
Alcohol Usage History	No +1	
Score	0	

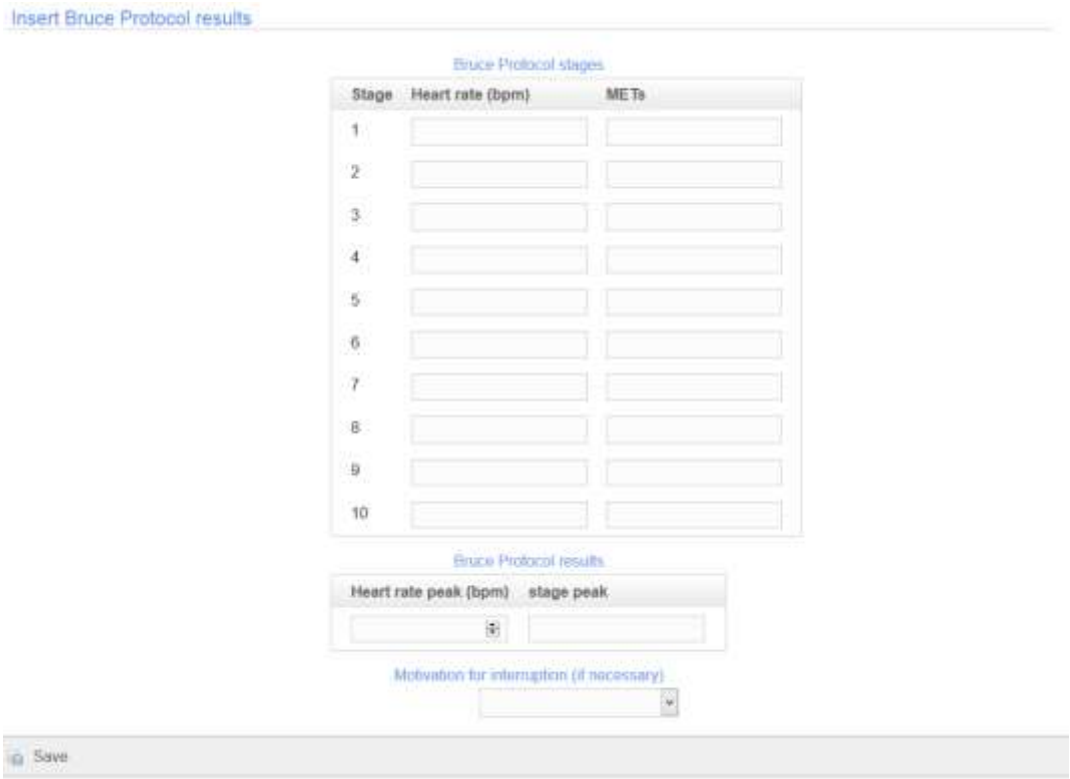
Save HAS-BLED Score

The system automatically checks the patient's clinical history, so some fields may be already pre-compile; in this case, they are read-only. If the physician wants to indicate the presence of a particular condition in the list, he has to click on the button “No” and it becomes “Yes”. The score is automatically updated and the physician has the possibility to add this new information in the PHR through a dedicated link (see the figure below).



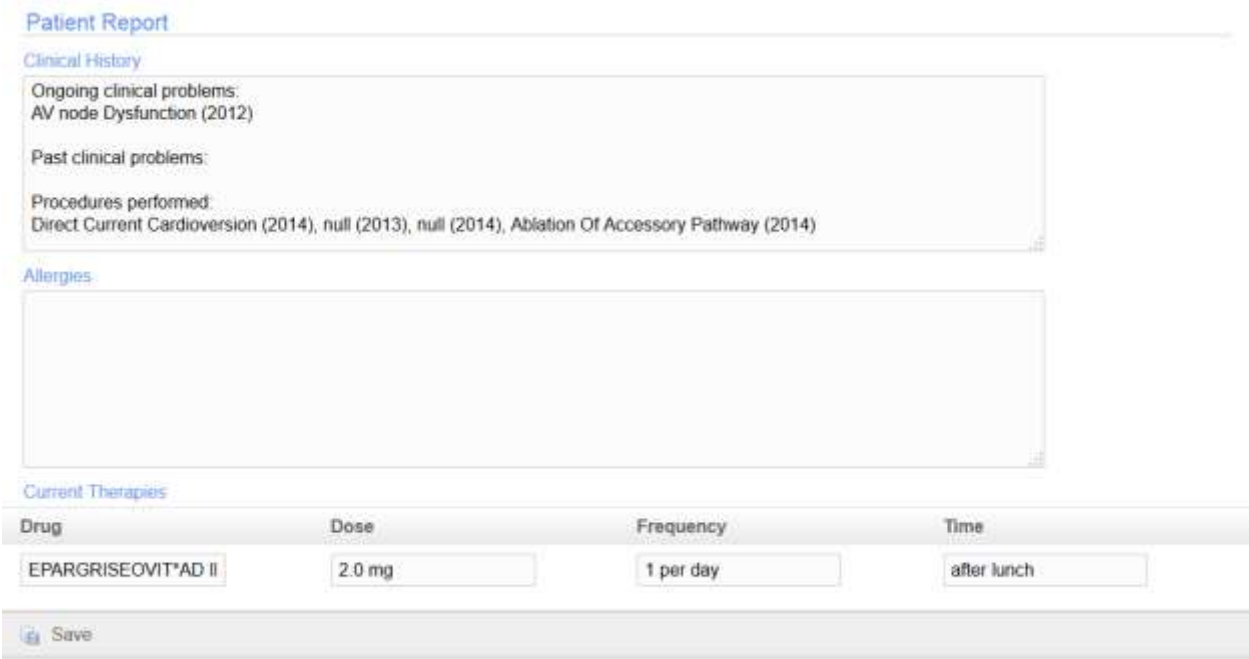
Bruce Protocol Results

Using this submenu, the physician can add the results of the Bruce Protocol (see the figure below).
The page allows to insert the Heart rate and METs values for each stage. Automatically, the maximum value for heart rate and the number of the stage with the maximum value are detected and shown it in the "Bruce Protocol Result" section.



Patient report.

Using this sub-menu, the physician can view the patient report which contains the information about the clinical history (ongoing clinical problems, past clinical problems and procedure performed), the allergies and the current therapies (see the figure below). The Clinical History and Allergies sections are editable while the Current Therapies section is read only. The report, once saved, can be visualized by the patient on his mobile and used if needed.



Clinical History menu

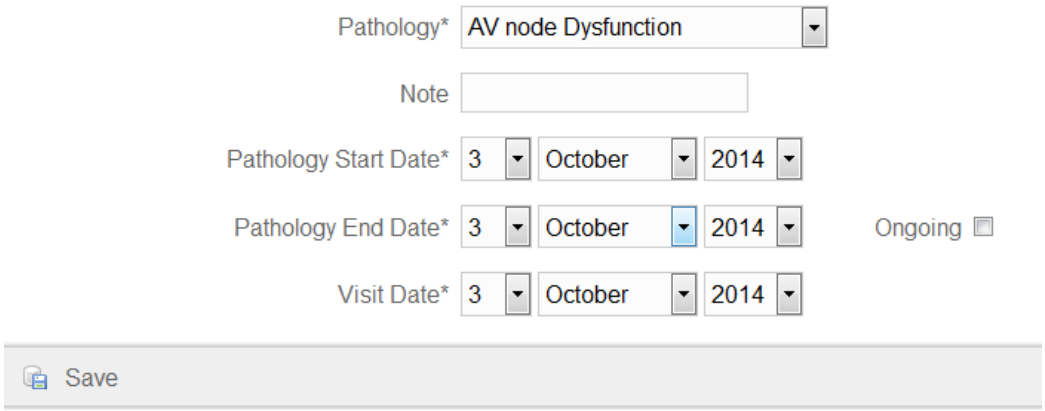
The Clinical History menu is divided into 5 sections, as shown in the figure below:

Pathologies

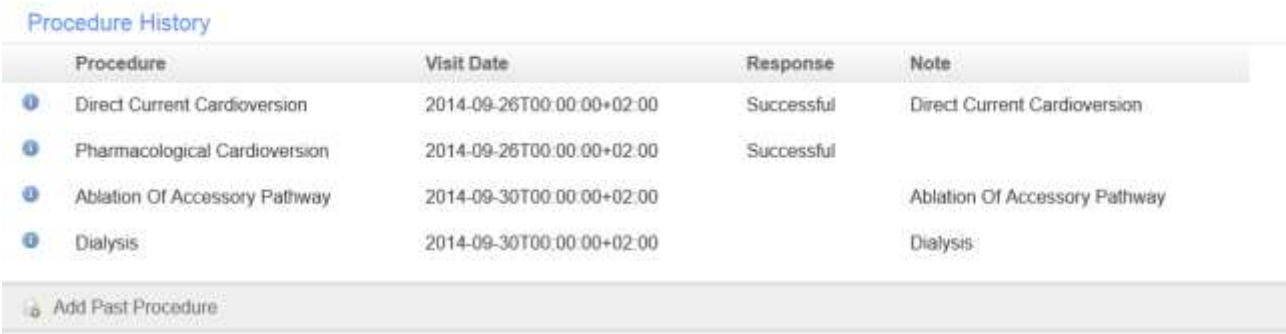
In this option the physician can see all the pathologies of the selected patient (see the figure below).

The details of each pathology is available by clicking on ⓘ.

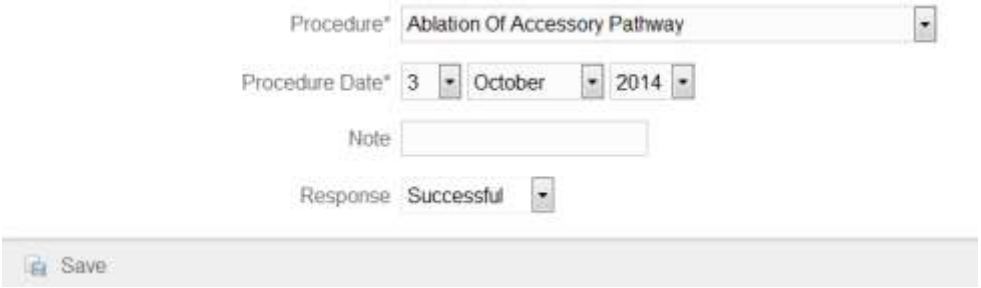
Clicking on the “Add Pathology” button allows inserting new pathology, as shown in the figure below.



The pathology drop-down menu lists all the pathologies that are included in the AF Clinical Procedures. In this section, the physician can see all the procedures performed on the selected patient (see the figure below).



The detail of each procedure is available by clicking in ⓘ.
By clicking on the “Add Past Procedure” button the user is allowed to insert a new procedure, as shown in the figure below.



The Procedure drop-down menu lists the procedures that appear in the AF clinical guideline.

Procedures

Within this option, the caregiver can see all the procedures performed on the selected patient

Procedure History

	Procedure	Visit Date	Response	Note
	Direct Current Cardioversion	2014-09-26T00:00:00+02:00	Successful	Direct Current Cardioversion
	Pharmacological Cardioversion	2014-09-26T00:00:00+02:00	Successful	
	Ablation Of Accessory Pathway	2014-09-30T00:00:00+02:00		Ablation Of Accessory Pathway
	Dialysis	2014-09-30T00:00:00+02:00		Dialysis

Add Past Procedure

The detail of each procedure is available by clicking in .

The “Add Past Procedure” button allows the caregiver to insert new procedure, as shown in figure below

Procedure* Ablation Of Accessory Pathway

Procedure Date* 3 October 2014

Note

Response Successful

Save

The *Procedure* drop-down menu, lists the procedure that is cited in the AF clinical guideline.

Atrial Fibrillation Episodes

In this option, the physician can see all the AF episodes stored for a selected patient (see the figure below).

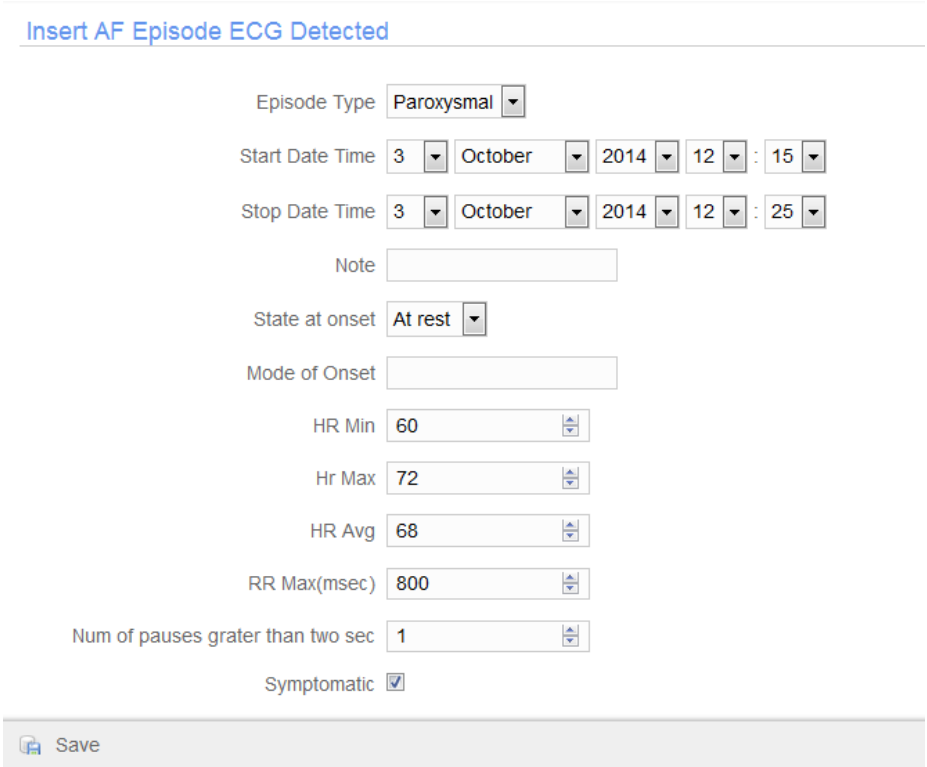
Atrial Fibrillation Episodes List

	Start Date Time	Stop Date Time	Episode Type	Symptomatic
	2014-09-30T17:04:00+02:00	2014-09-30T17:00:00+02:00	Paroxysmal	

Add New Episode

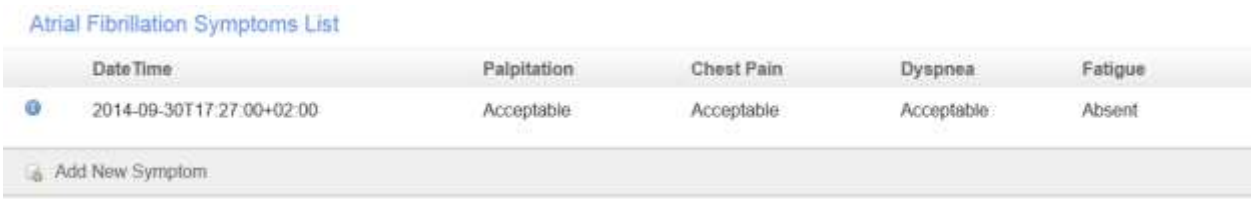
The detail of each episode is available by clicking in .

The “Add New Episode” button allows the user to insert a new episode, as shown in the figure below.

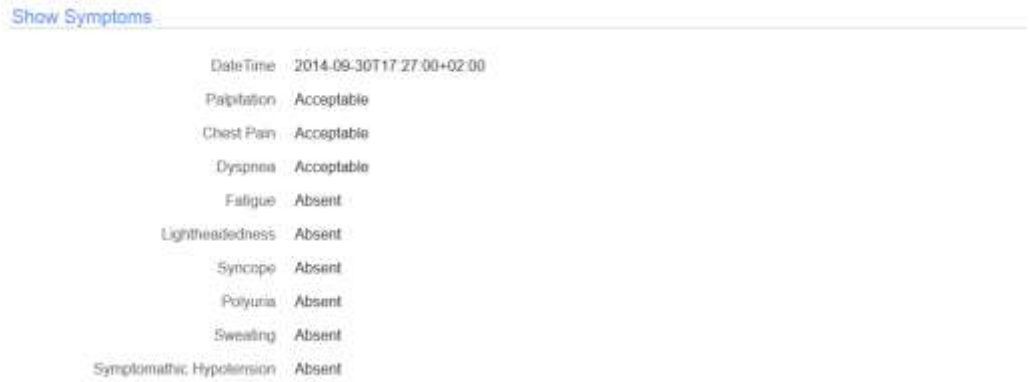


Symptoms Related to Atrial Fibrillation Episode

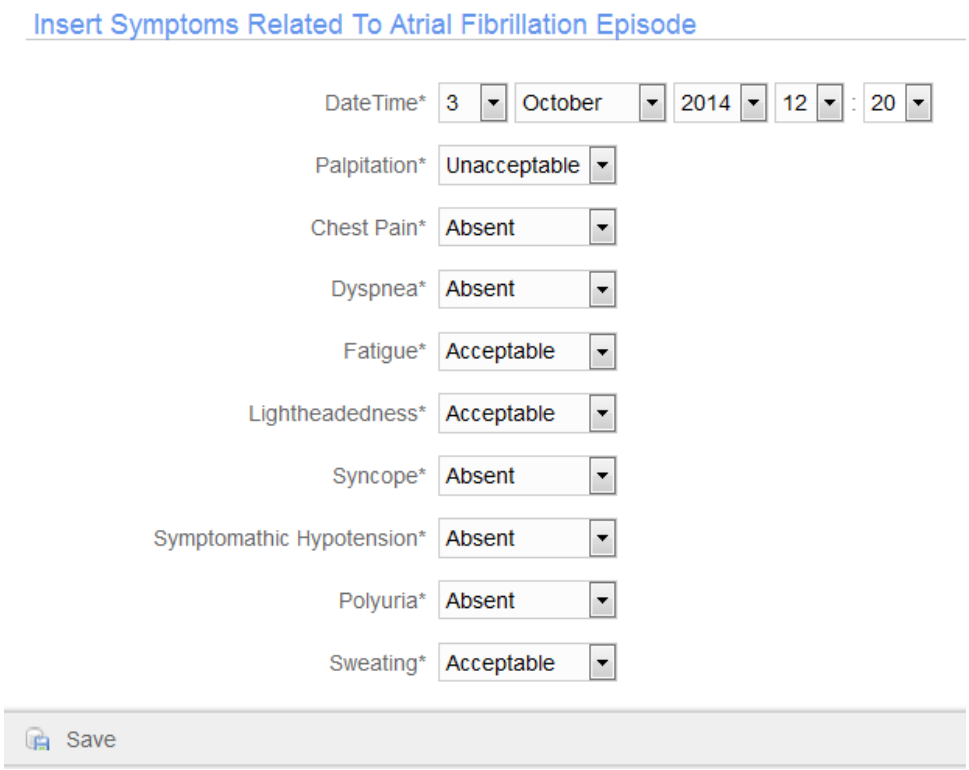
This sub-menu shows the list of all the symptoms of the selected patient during an AF episode.



The detail of each symptom is available by clicking in ⓘ, as shown in the figure below.



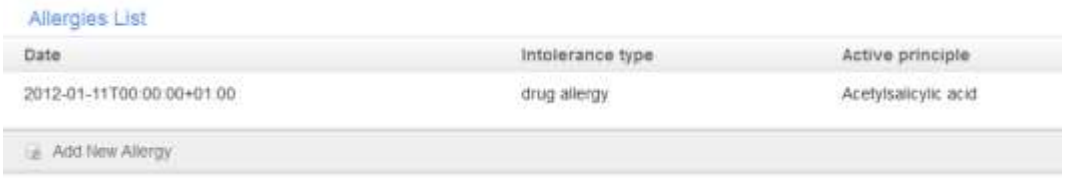
The “Add New Symptom” button allows to insert new symptoms, as shown in figure below.



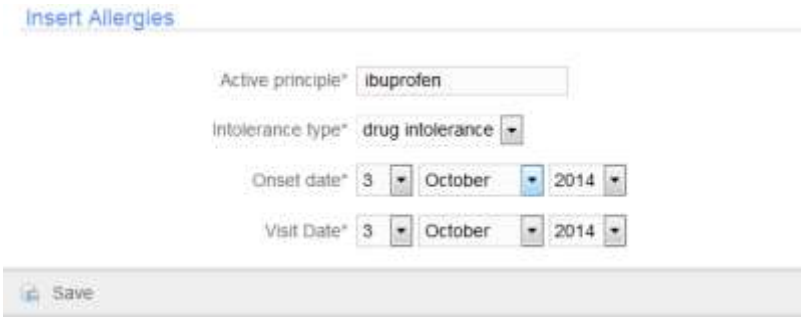
All the fields are mandatory, and for each symptom the drop-down field has the same possible values: Absent, Acceptable, Unacceptable.

Allergies

In this section the physician can see the list of all the patient's allergies (see the figure below).



To insert a new patient's allergy, click on the “Add New Allergy” button allows, as shown in the figure below.



Prescription

The Prescription menu is divided into 7 sections, as shown in the figure below.

Therapies List.

This section allows the physician to see the list of all the therapies prescribed for the selected patient (see figure below).

Show Pharmacological Therapy

Start Date	End Date	Drug	Therapy Purpose	
2014-09-30T00:00:00+02:00	2014-09-30T00:00:00+02:00	BLEFAROLIN*POM OFT 10G	Rate Control	Add Response
2014-10-19T00:00:00+02:00	2014-12-30T00:00:00+01:00	EPARGRISEOVIT*AD IM EV6FI+6FII	Rate Control	Add Response
2014-10-01T00:00:00+02:00	2014-10-30T00:00:00+01:00	MIONEVRASI*IM 5F+5F 3ML	Rate Control	Add Response
2014-09-30T00:00:00+02:00	2014-09-30T00:00:00+02:00	ABIOSTIL*UNG RIN 10G	Rate Control	Add Response
2015-01-30T00:00:00+01:00	2015-02-27T00:00:00+01:00	ACTIGRIP GOLA*COLLUT 200ML200M	Rate Control	Add Response
2014-09-30T00:00:00+02:00	2014-09-30T00:00:00+02:00	MEMOVIT B12*OS SCIR 6FL	Rate Control	Add Response
2014-09-30T00:00:00+02:00	2014-09-30T00:00:00+02:00	COUMADIN*30CPR 5MG	Rate Control	Add Response
2014-09-01T00:00:00+02:00	2014-10-30T00:00:00+01:00	COUMADIN*30CPR 5MG	Rate Control	Add Response
2014-09-30T00:00:00+02:00	2014-12-30T00:00:00+01:00	BIODERMATIN*30CPR 5MG	Rate Control	Add Response
2014-09-30T00:00:00+02:00	2014-09-30T00:00:00+02:00	ALBUMINA UM IMMUNO*50ML 25%+S	Rate Control	Add Response
2014-09-30T00:00:00+02:00	2014-11-30T00:00:00+01:00	BLEFAROLIN*POM OFT 10G	Rate Control	Add Response

The detail of each therapy is available by clicking on ⓘ (see the figure below). The screen is divided in two sections:

- **Pharmacological Therapy** section contains the therapy details such as the drug name, the start date, the end date, the therapy purpose and the days to skip (in case of no days to skip needed the label *every day* is displayed);
- **Administration details** section displays the dose and the administration time.

Pharmacological Therapy

Drug	Start Date	End Date	Therapy Purpose	Days To Skip
COUMADIN*30CPR 5MG	2014-09-30T00:00:00+02:00	2014-09-30T00:00:00+02:00	Rate Control	every day

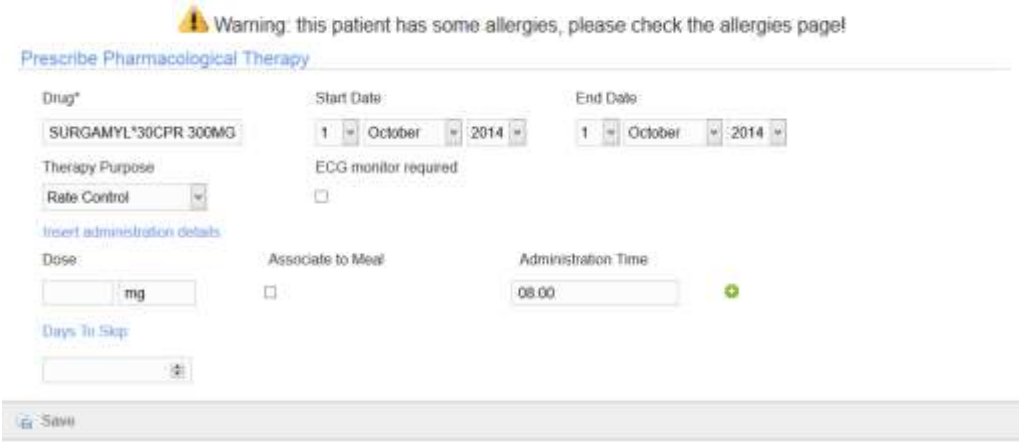
Administration details

Dose	Administration Time
55.0	08:00

You can insert the patient's response to the therapy, by clicking on the button "Add Response" (no figure available).

Prescribe Pharmacological Therapy.

In this section the physician can prescribe a new pharmacological therapy for the selected patient (see the figure below).

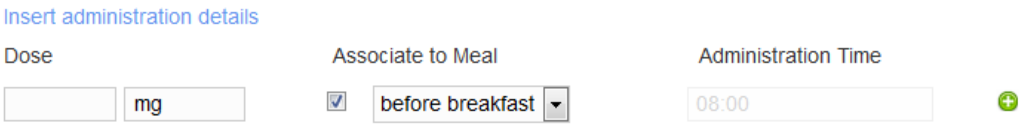


If the patient has some allergies, the system will display a warning message that recommends checking the allergies page.

In the administration details section, the physician can specify:

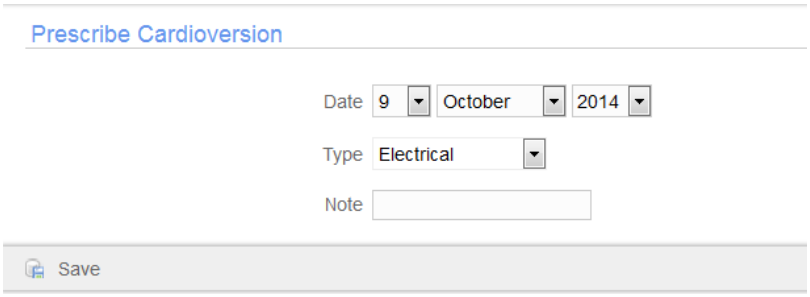
- the dose
- whether the administration is associated to meals (a new drop-down menu will be displayed when you make a selection on the checkbox, as shown in the figure below)
- the time at which the patient should take the therapy
- the days to skip (for every day therapy the physician has to specify 0).

You can add another administration details in case different doses for the same therapy are required; click on the button)



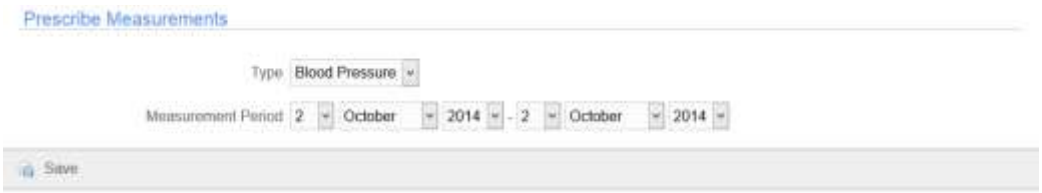
Cardioversion.

In this option the physician can prescribe both an electrical or a pharmacological Cardioversion (see the figure below).



Measurements.

This option allows you to prescribe a measurement, as shown in the figure below. The available types of measurements are Blood pressure, ECG, Weight and INR.



After clicking on the “Save” button, the new measurement prescription will be sent to the patient smartphone.

Blood Test.

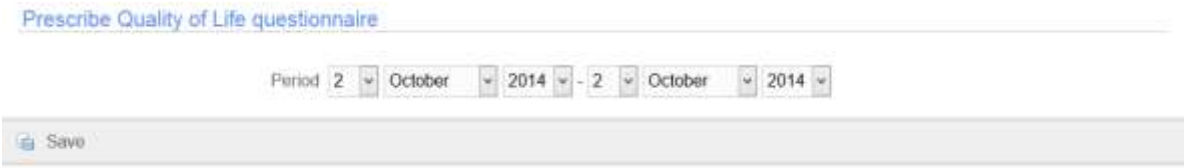
This option allows the doctor to prescribe a new blood examination for the selected patient by choosing the tests to be performed (see the figure below).

Physical Activity.

In this section the physician can prescribe the physical activity for the selected patient, as shown in the figure below. On the basis of the Bruce protocol results (shown in the upper part of the page), the physician can prescribe duration and intensity for each phase of the training activity (warm-up, training, cool down).

Quality of Life questionnaire.

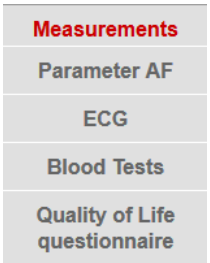
In this section the physician can prescribe the quality of life questionnaire for the selected patient, as show in the figure below.



After saving, the prescription will be sent to the patient.

Measurements

The Measurements menu is divided into 4 sections, as shown in the figure below.



Parameter AF

This submenu allows visualizing the list of all the parameters that the patient has measured (see the figure below).

Show Measurements

Date	Parameter	Value	BAN
2014-09-29T08:00:00+00:00	Blood Pressure	140/100 mmHg	

The data in this section are read-only since they have been inserted by the patient through his smartphone.

ECG.

This submenu allows visualizing all the patient's ECG, as shown in the figure below.

Show Measurements

	Date	ECG report
	2014-10-02T00:00:00+02:00	Normal Synus Rythm

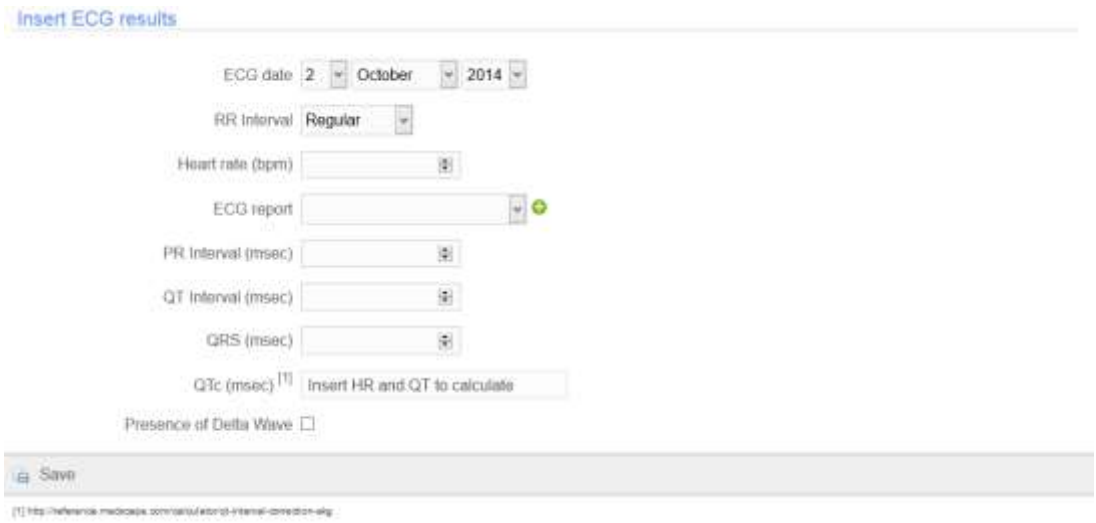
Add ECG

The details of each ECG are displayed by clicking on (see the figure below).

Show Episode

ECG date	2014-10-02T00:00:00+02:00
PR Interval	regular msec
Heart Rate	90.0 bpm
ECG report	Normal Synus Rythm
PR Interval	130.0 msec
QT Interval	300.0 msec
QRS	130.0 msec
QTc	367.4234614174767 msec

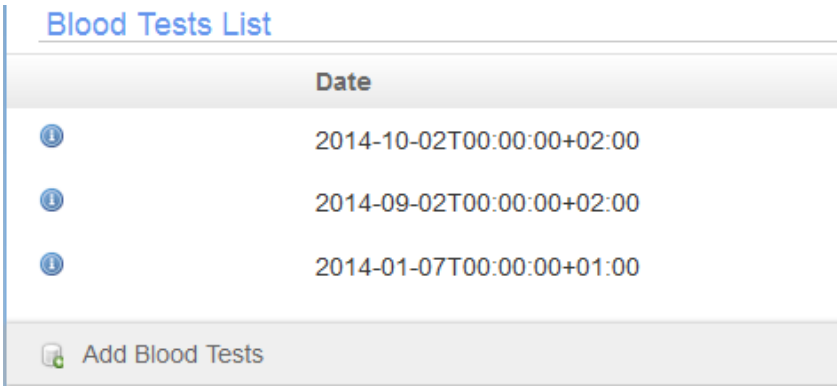
Clicking on the “Add ECG” button allows the physician to insert new ECG results, as shown in the figure below.



The ECG report drop-down menu lists the possible reports that are cited in the AF clinical guideline. Multiple values are allowed by clicking on ⊕ .

Blood Tests

This submenu allows visualizing all the blood tests available for the selected patient (see the figure below).



Clicking on the “Add Blood Test” button allows inserting new blood test results, as shown in the figure below.

Insert Blood Test

Date* 2 October 2014

Parameter	Value	Unit
GOT	1	mg
GPT	1	mg
TSH	1	mg
FT3	1	mg
FT4	1	mg
Azotemia	1	mg
Creatinine	1	mg
BNP	1	mg
Glucose	1	mg
Cholesterol	1	mg
HB	1	mg
HCT	1	mg
RBC	1	mg
Sodium	1	mg
Potassium	1	mg
ANP	1	mg
INR	1	mg
aPTT	1	mg
Protrombin Time (PT)	1	mg
AntiXaFactor	1	mg
Bilirubin	1	mg
ALP	1	mg
LDH	1	mg
GGT	1	mg
Total Protein	1	mg
Digoxin	1	mg
Magnesium	1	mg
Other	1	mg

Save

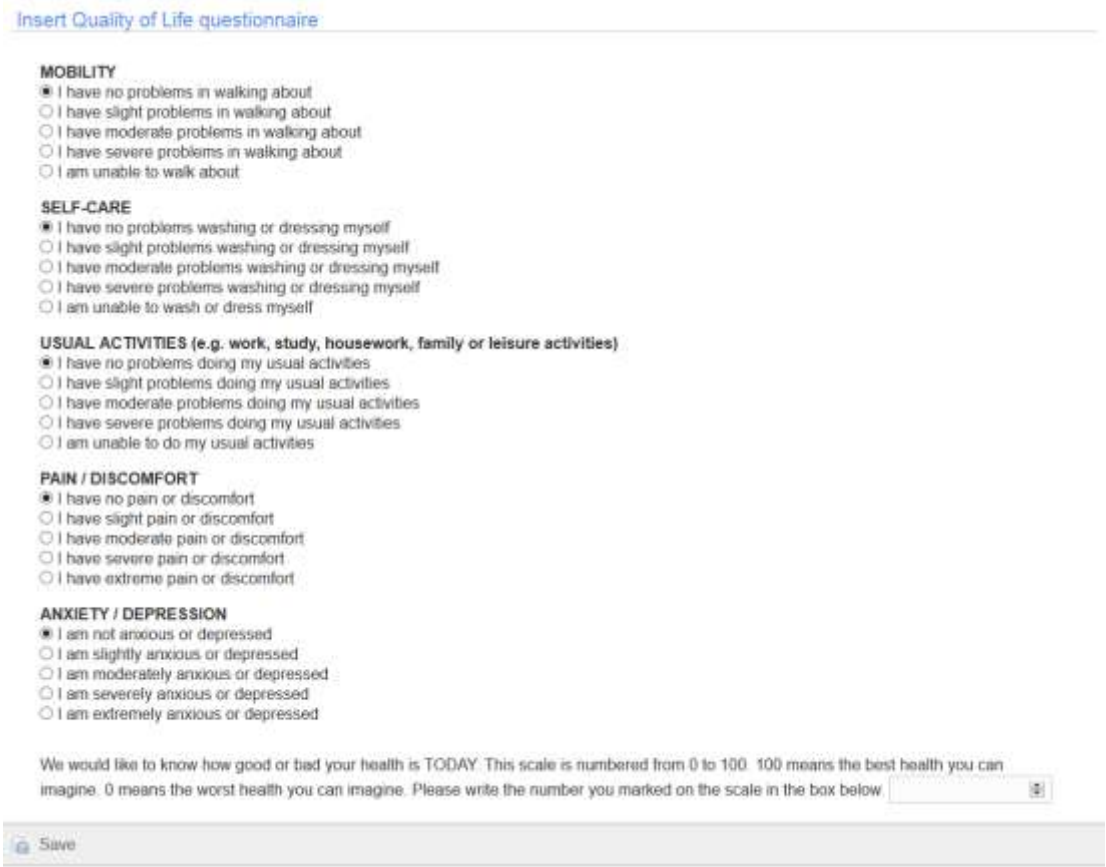
The details of each blood test examination are displayed by clicking on (see the figure below).

Show Blood Test

Parameter	Value	Unit
GOT	1.0	mg
GPT	1.0	mg
TSH	1.0	mg
FT3	1.0	mg
FT4	1.0	mg
Azotemia	1.0	mg
Creatinine	1.0	mg
BNP	1.0	mg
Glucose	1.0	mg
Cholesterol	1.0	mg
HB	1.0	mg
HCT	1.0	mg
RBC	1.0	mg
Sodium	1.0	mg

Quality of Life questionnaire.

This section allows the physician to insert a new questionnaire for the selected patient as shown in the figure below.



Recommendation Menu

The Recommendation Menu displays all the advices, notifications and recommendations coming from the patient and the Decision Support System.

The "**Show List**" sub-menu directs to the page listing all the recommendations either directed to the patients or the physician. A filtering functionality allows restricting the view only to recommendations directed to physicians. Recommendations are ordered to show on top those related to the selected patient, followed by the ones related to the other patients, ordered by descending date.

For each recommendation the following information is displayed:

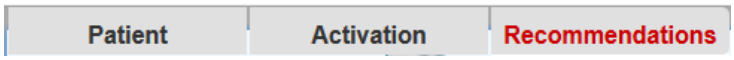
- **Patient:** name of the patient the recommendation refers to
- **Directed to:** the subject to whom the recommendation is directed (can be Patient or Physician)
- **Date:** the date the recommendation has been sent

- **Action:** the action associated to the recommendation
- **GL Recommendation text:** the text of the recommendation as reported in the guideline
- **Status:** is the status of the recommendation. If the user to whom the recommendation is directed accepts the action to be done, the status is set to Accepted. If the user rejects the action, the status is Rejected. If no action is required or no answer is given, the status is "-".

Patient	Directed to	Date	Action	GL Recommendation text	Status
Test Test	Patient	2014-09-23T11:17:36+03:00	Valores de cetona siguen alterados, por lo que en breve contactaremos contigo para darte una visita	please schedule a meeting with your caregiver	-
Test Test	Physician	2014-09-23T11:17:34+03:00	A meeting should be scheduled with the patient to balance patient's diet	next appointment	Rejected
Demo Demo	Physician	2014-09-23T11:14:38+03:00	carbohydrates	Valores de cetona alterados. Para corregir esta situacion debes aumentar una racion de hidratos de carbono en la recena (10gramos)	Accepted

The details of each recommendation can be displayed by clicking on the button ⓘ.
For each recommendation which requires a physician's action, a detailed page is provided, with the complete text and level of evidence, including two buttons for accepting or discarding the recommendation (see the figure below).

If new recommendations related to any patient are detected, the Recommendations tab in the interface menu is highlighted in red to the physician to pay attention that new unread recommendations are available.



Main flow: Support shared decision making procedure

The AF application main flow is as follows:

- The caregiver accesses the recommendation details page
- The caregiver explains to the patient the shared decision goal - with the support of the educational material available through the interface
- The Utility Coefficient Elicitation (UCE) interface is launched
- The Decision Tree (DT) tool is launched
- The caregiver takes the decision (e.g. prescribes a therapy)

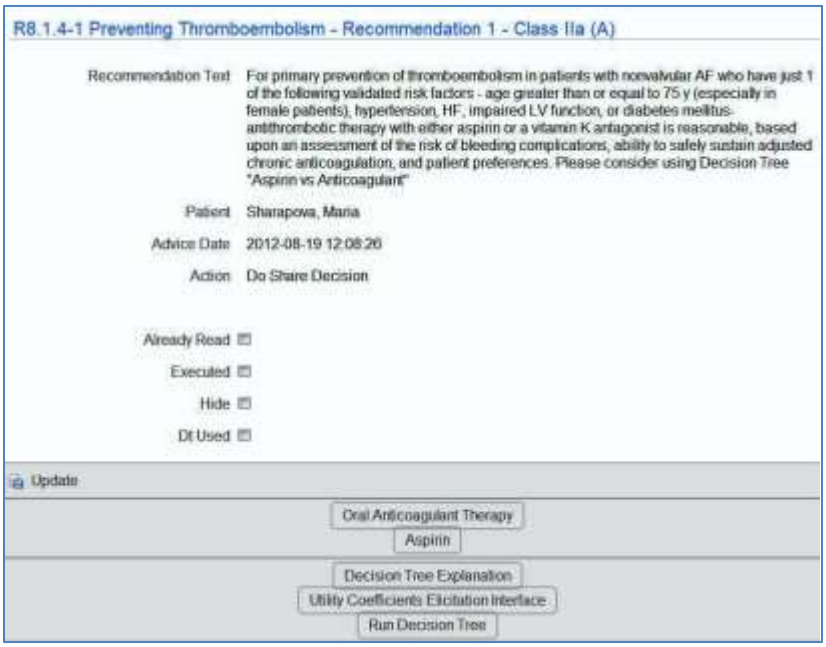
The recommendations detail page

The caregiver can view the recommendation/advice list.

Advice List

Id	Patient	User	Advice Date	Action	GL Recommendation	DT Available	Already Read
67	Sharapova, Maria	Dr. Smith, John	2012-08-19 12:08:26	Do Share Decision	R8.1.4-1 Preventing Thromboembolism - Recommendation 1 - Class IIa (A)	Yes	No

By clicking on the ID link, the caregiver can open the recommendation properties (mark as already read, executed, hide or delete) and have access to the menu related to any shared decision.



The Utility Coefficient Elicitation (UCE) Interface

The Utility Coefficients Elicitation interface (UCE) is a web tool for supporting the process of assessing the value of Utilities for a specific patient across a number of health state. These coefficients can then be used as parameters in decision models (e.g. Decision Tree component of Mobiguide) to perform shared and personalized decision making in clinical practice.

By pushing the button “Utility Coefficient Elicitation Interface” the caregiver accesses the UCE interface. In this page, for each health state and for each method, we can see the date of the last evaluation (if present) and the corresponding UC (utility coefficient) value. The caregiver can choose to perform a new elicitation or to keep the existing values by clicking on the corresponding buttons.

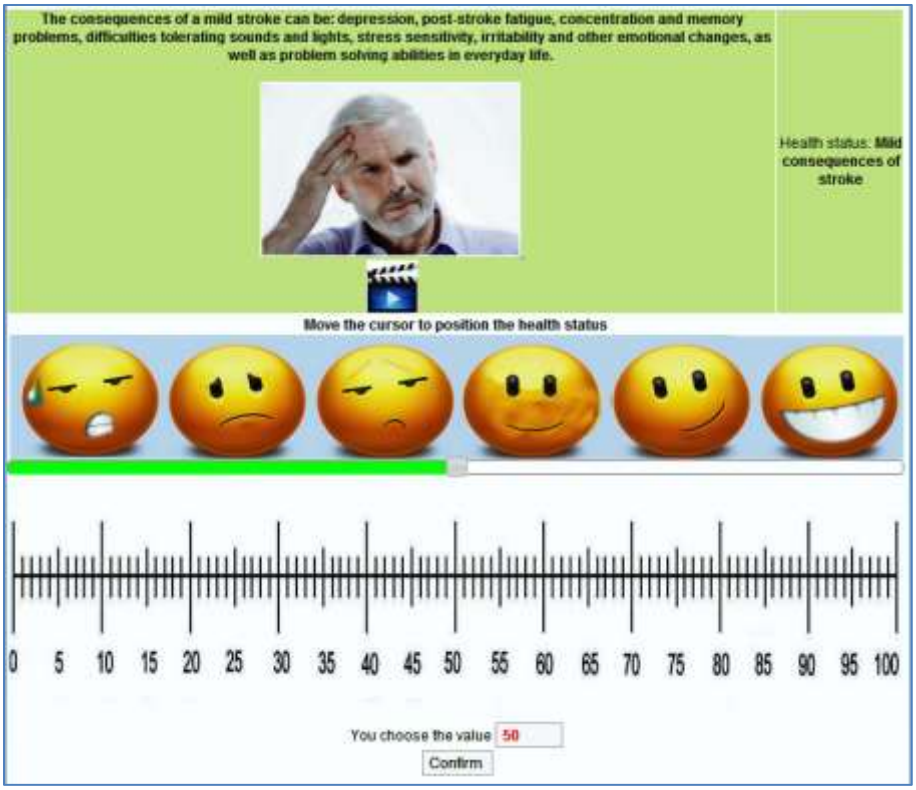
Rating Scale page

In the Rating Scale (RS) method, the patient is asked to rate all the available health states on a specific scale ranging from 0, associated to the worst health state imaginable (usually death), to 100, corresponding to perfect health. RS is usually quickly understood by patients and it is often used to order health states from the less to the most desirable, as multiple states can be placed along the scale in one go. Values collected using RS and properly rescaled to range between 0 and 1, represent a patient-specific ranking of the states.

When the caregiver chooses to elicit utility coefficients using the rating scale method, is directed to the page shown below.

At the top of the page, a description of the health state (in this case “mild consequences of stroke”) is provided. A picture linked to a PDF document and a video are also included. All these pieces of information are useful for the caregiver to better explain to the patient each health state. Besides using the information provided by this page, the caregiver usually spends some time to explain the scenario and the question to the patient, carefully verifying the capability of the subject to understand the requests.

The rating scale method has been implemented using both a graphical scale with smiles and a numerical scale.



Time trade-off (TTO) page

When the caregiver chooses to elicit utility coefficients using the time trade-off method, she is directed to the page below. The top part of the page is the same as the one of the rating scale. The life expectancy of the patient is calculated according to national statistic. In the case of AF, since the MobiGuide clinical partner is located in Italy (FSM), this value has been calculated using Italian National Institute of Statistics.

In TTO, the patient is asked to choose between living his entire remaining life (t1) in the specific health state being evaluated or to live shorter (t2<t1) but in a perfect health state. If the patient is experiencing really poor quality of life he will be willing to trade some of his remaining expected life (i.e. to live shorter) for a better quality of life. The amount of time a patient is proposed to give up to heal completely is varied until the patient is indifferent between the two choices.

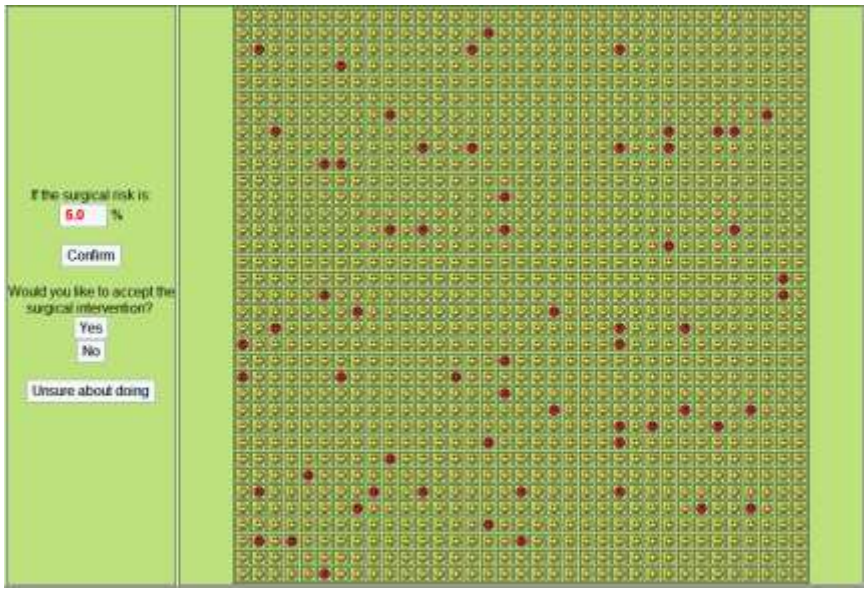
Also in the case of TTO, sometime is in general required for the caregiver to carefully explain the question scenario to the patient, to be sure to receive a reliable answer.

Standard gamble page

When the caregiver chooses to elicit utility coefficients using the standard gamble method, she is directed to the page shown below. The top part of the standard gamble page is similar to the ones for time trade-off and rating scale (to have a clear picture it has been cut this part from the screenshot).

The patient is asked to choose, within a hypothetical scenario, between living the rest of the life in the health state that is being evaluated or accepting a gamble whose outcomes are complete healing or sudden, painless death with probability p. The more a patient is experiencing a poor quality of life, the higher risk he would accept to have a chance of healing

Once the caregiver inputs a value for the surgical risk, the corresponding percentage of smiles turns red randomly. The number of red icons reflects the portion of patients that would die according to the risk of death actually being presented to the patient.



The Decision Tree (DT) tool

The DT is the component responsible for managing shared decisions between the caregiver and the patient. It can be opened from the caregiver interface by pushing the button “Decision tree” when a recommendation suggests the possibility of taking a decision considering also patient preferences. Its utilization is not mandatory because the physician could decide that a certain patient is not eligible for such a procedure, that requires the patient to answer a number of non-trivial questions.

DT allows the caregiver to explain the options to the patient, viewing the probabilities and adjust them if needed, running the tree and all the other analyses (e.g. sensitivity analysis, cost-benefit analysis, Montecarlo simulations, etc.), storing the updates to the default tree quantification and the tree result. When used, DT tool stores the DT results that are then used for the final decision by the caregiver through the caregiver interface. Utility coefficients are retrieved from the Utility Coefficient Elicitation Interface.

The functionalities of the DT tool are:

a) The DT parameters page (to view and edit DT variables);
b) The DT results page.

a) The DT parameters page

The figure below shows the visualization of the tree parameters (patient’s data, costs, probabilities, etc).

When a DT is started, default values are shown, but they can be edited, if required, by the physician. This can be done using the editable text boxes on the right.

Patient's age	48
Annual discount rate	0.035
Relative risk for major bleedings on aspirin with respect to warfarin	0.642
Relative risk for stroke on aspirin with respect to warfarin	1.83
Relative risk for major bleedings with respect to warfarin after treatment switch	0.5066
Relative risk for stroke with respect to warfarin after treatment switch	1.83
Need for caregiver visit (0=no 1=yes)	1
3-months cost for domiciliary caregiver	0
Cost for cardiology visit	45
Cost for caregiver' time for one visit	0
Cost for ECG visit	3
Cost for INR control visit	7.5
Cost for meals for one visit (one person)	10
Cost for patient' productivity loss for one visit	0
Cost for travel for one visit (one person)	8
Probability of death after MI	0.12
Proportion of mild ICH after treatment switch	0.163
Proportion of moderate/severe ICH after treatment switch	0.428
Proportion of temporary ICH after treatment switch	0.161
Sex (1= male, 0=female)	0
3-months probability of minor bleedings after treatment switch	0.018465
Relative risk for major bleedings on no therapy with respect to warfarin	0.42
Relative risk for stroke on no therapy with respect to warfarin	2.37
N 3-months INR visits	3.475
N 3-months control visit AF	1
Proportion of major bleedings that are ICH after treatment switch	0.179
Relative risk for new events after ICH or IS	2.6
Proportion of mild stroke after treatment switch	0.41
Proportion of moderate/severe stroke after treatment switch	0.3
Proportion of temporary stroke after treatment switch	0.11
Utility coeff. for mild stroke	0.86
Utility coeff. for moderate/severe stroke	0.27

b) The DT results page

The figure below shows the DT tabular results for the three payoffs with respect to three decision options. In this case, the DT compares three different therapeutic options for preventing thromboembolism, namely warfarin, aspirin (ASA) and no therapy. The table shows the results of the decision tree, i.e. the expected values of the payoffs for every decision option.

Tabular output for all payoffs

Expected Values

Payoff	Warfarin	ASA	No therapy
Life Years	22 years 3 months	22 years 1 months	21 years 1 months
QALYs	18 years 4 months	18 years 1 months	17 years 2 months
Patient Costs	10154 €	3179 €	3041 €

Submit

6. FAQ

General Information

How can I get the mobile application?
Your caregiver will provide you with a smartphone with the application already installed

Who will explain to me how to use the system?
Every patient enrolled in the MobiGuide project pilot will receive training before starting to use the system. In case of any question or problem, the patient will be able to contact her nurse or the technical team of the project for help while enrolled to the MobiGuide pilot system

Whom do I contact for support?
The contact point is the person assigned in your hospital as “Clinical Assistant”. This person will contact your medical caregiver in order to let you know what steps should be taken.

What do I have to do if the application doesn’t work properly?
Try to re-start your smartphone and open the application again, in case of failure; please contact your clinical assistant.

When should I contact my caregiver?
At the beginning of the study the caregiver will set some scheduled follow up visits according to the protocol and the medical needs. In the case something unexpected happens you should keep the standard routine with your physician and use the usual means to contact him (e.g., call the clinic). In case the system detects anything wrong it will advise you to contact your physician. In the case of an emergency you do not have to wait for a feedback from your caregiver but instead go to the closest emergency department.

Will I have to install updates?
During enrollment the MG administrative team will provide you with a Smartphone on which the MobiGuide application has been installed and will activate auto update option of the application. You will be able to set your personal context to your current state and to change your preferences whenever you wish.

How Can I provide feedback about the system?
You will be able to enter the MG project site and provide feedback directly to the developers. You can also ask your nurse or caregiver to send your feedback as well. In the case you are unable to reach an internet connection you may call your caregiver/nurse.

Safety Security and Privacy

How can I make sure that my information is protected in terms of privacy and security?
The system follows the "privacy by design" principles by which the system design enforces privacy and security using mechanisms for:

- authentication: verifying that "you are who you say you are";
- authorization verifying that "you are permitted to do what you are trying to do";
- awareness: functionality to enable the users to be informed of the usage made with their data.

The system's security and privacy design considers relevant European/national data protection regulations to make sure that only needed health information will be provided, only to authorized parties and for authorized purposes which are to the benefit of patients.

I forgot my PIN number to access the application
You have to contact your clinical assistant. He will provide you with a new one that must be changed once you access the application.

How do I know that the system recommendations are based on clinical evidence?
The MobiGuide project is working with clinical experts and with the most up-to-date clinical guidelines to ensure that the system recommendations are evidence based. The system is evaluated by EU committee to make sure that all the recommendations are evidence based. The guidelines that the MobiGuide project is using are:

- For the AF domain –Guidelines for the management of atrial fibrillation. The Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC).
  http://eurheartj.oxfordjournals.org/content/31/19/2369.full

- GDM domain – NICE clinical guideline Diabetes in pregnancy: management of diabetes and its complications from pre-conception to the postnatal period http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2563261/

System Usage

What do I have to do to start the application for the first time?
The first time, your caregiver will guide you to enroll the system, following the steps in Section 4 and 5

What will happen if the system detects that something is wrong?
In case the system detects that something is wrong it will alert the patient and the medical staff. For each clinical domain the system will react based on the clinical guideline and upon the specific actions defined by the physician.

How can I see what the system collects?

The collected data is sent to your caregiver. You can see some of your own data in the MG system. In case you want to see more data, you can request it from your caregiver. The caregiver has the final responsibility to check your charts and to provide you with medical reports.

How Can I transfer my data to the caregiver?

The caregiver has an interface to view the data collected, so you do not need to transfer data yourself.

Who will explain to me how to use the system?

Every patient enrolled in the MobiGuide project pilot will receive training before starting to use the system. In case of any question or problem, the patient will be able to contact his nurse or the technical team of the project for help while enrolled to the MobiGuide pilot system.

When using the MG system, Can I use my own smartphone and monitoring devices?

The MG system uses an architecture that allows us to plug-in different devices. During the pilot, we will provide all of the devices, including a Smartphone. In case you are currently using alternative devices (e.g., your own glucometer) please consult with your physician about using your own device.

Do I need to enter a lot of information in order to use the system?

No, the system reduces the amount of data that is required to be entered by the patient, since in most of the cases the system receives the data directly from the device and from hospital medical records. In some cases, where the quality of data is in question, the patient will be asked to confirm the data in the system.

How will I be involved in the decision process together with my caregiver?

Some of the medical decisions have to follow the medical guidelines while others require a shared decision between the patient and the caregiver. In this latter case, during the enrollment and during the following months when the system will be in use, you will be involved in the decision making process by defining your preferences and your personal information. Your caregiver will work together with you to understand which treatments and their expected consequent health states, are most suitable to your personal preferences and bring the best utility to you.

If I will encounter a new situation that I didn't discuss with my caregiver, what do I have to do?

In this case you should continue to follow the given treatment recommendations and set a new appointment with your physician to try and define more suitable recommendations to the new situation.

When should I contact my doctor?

At the beginning of the study the doctor will set some scheduled follow up visits according to the protocol and the medical needs. In the case something unexpected happens you should keep the standard routine with your physician and use the usual

means to contact him (e.g., call the clinic). In case the system detects anything wrong it will advise you to contact your physician. In the case of an emergency you do not have to wait for a feedback from your doctor but instead go to the closest emergency department.

How will the system take into account my preferences?

During the enrollment, the physician adds your preferences to the system and defines treatment recommendation based on your clinical and personal context and on your preferences.

How will I get updated on how well I'm complying with recommendations and regarding my health status?

The system will send you indications as to whether you are complying or not with your treatment recommendations. In order to see your health status you will be able to see some of the data through the smartphone; to see your full PHR you must ask your physician to send you your records.

How will my caregiver receive information about my compliance?

Your physician can access your data file to see how well you comply and what your health state is. In case your degree of compliance can increase your risks, your caregiver will be informed by the system.

How can I make sure that the system data is up-to-date?

The system's sensors that are connected to your smartphone collect up-to-date data all the time. The backend system is updated continuously whenever there is Internet connectivity. In case there is no connection, the data is saved until connection is restored. You don't have to do anything about it. The system reacts on collected data, when you are too long not connected; the system notifies both you and the caregiver.

Will I have to install updates?

During enrollment the MG administrative team will provide you with a Smartphone on which the MobiGuide application has been installed and will activate auto update option of the application. You will be able to set your personal context to your current state and to change your preferences whenever you wish.

How will I know whether I'm using the system correctly?

The system will indicate to you in case you are providing any wrong data or in case it detects that you are not using it correctly. In any case, the MobiGuide staff will be available to provide additional support according to the service-level agreement indicated in the patient's consent form.

How can I provide feedback about the system? Do I send it to my caregiver or directly to the developers?

You will be able to enter the MG project site and provide feedback directly to the developers. You can also ask your nurse or doctor to send your feedback as well. In the case you are unable to reach an internet connection you may call your doctor/nurse.