FP7-287811

MobiGuide

Guiding Patients Anytime Everywhere

Collaborative projects - Large-scale integrating project (IP)

Start date: 1-Nov-2011   Duration: 48 months

Deliverable 11.2: Living lab demonstration assessment document

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Dissemination Level		
PU	Public	**X**
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

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1. Versions history

Version	Date	Author	Comments
0.4	16/10/2015	Rosana Valle (ATOS)	Sections 4, 5, 6, 7 and 8
0.5	28/10/2015	Enea Parimbelli (UNIPV) Mor Peleg (HU)	Technical comments
1.0	30/01/2015	Belen Gallego (ATOS)	Final refinement.

2. Executive Summary

D11.2, Living lab demonstration assessment document, is the second of two deliverables in WP11, Demonstration.

This deliverable summarizes the technical constraints and recommendations, the guidelines and materials that were needed for the configuration of the MobiGuide Living Lab, a real environment in which the pilots took place.

The pilot had two stages:

(1) Pre-pilot stage; during which a selected group of healthy volunteers and caregivers tested the functionalities of MobiGuide and actively contributed with their opinions and suggestions to the refining of the system.
(2) Pilot stage, that has been conducted with a group of atrial fibrillation patients referring to the Fondazione Salvatore Maugeri Clinica del Lavoro e della Riabilitazione in Italyand another group of patients with gestational diabetes mellitus referring to Corporaciò Sanitaria Parc Taulí de Sabadell in Spain.

More details about the pilot can be found at D9.1: Functional and usability evaluation report.

After the pilot some questionnaires were administered in order to evaluate the users' satisfaction.

3. Introduction

D11.2 describes the technical constraints and materials that were needed for the configuration of the MobiGuide Living Lab for the pilots.

- Section 4 introduces the MobiGuide platform and presents briefly its basic architecture.
- Section 5 contains devices that should be used for the pilots and the configuration details (hardware requirements and software configuration).
- Section 6 presents a brief description of the demonstrations that took place in Spain and Italy.
- Section 7 mentions that the work done in pilots has been extensively described in WP9 deliverables.

Conclusions, acronyms and references complete the report.

4. MobiGuide Platform

MobiGuide has developed an intelligent decision-support system for patients with chronic illnesses, which involves patients and their care providers in managing their illness. The demos have been focused in two domains for GDM (Gestational Diabetes Mellitus) and AF (Atrial Fibrillation).

The MobiGuide Platform is divided in two levels:

1. Front-end; the components reside on client web-interfaces and on patients' mobile devices,
2. Back-end level, the DSS components reside on a server system that is responsible for management and control of the DSS process.

The MobiGuide Platform has been tested in two real environments in Spain and Italy and further explained in the next sections.
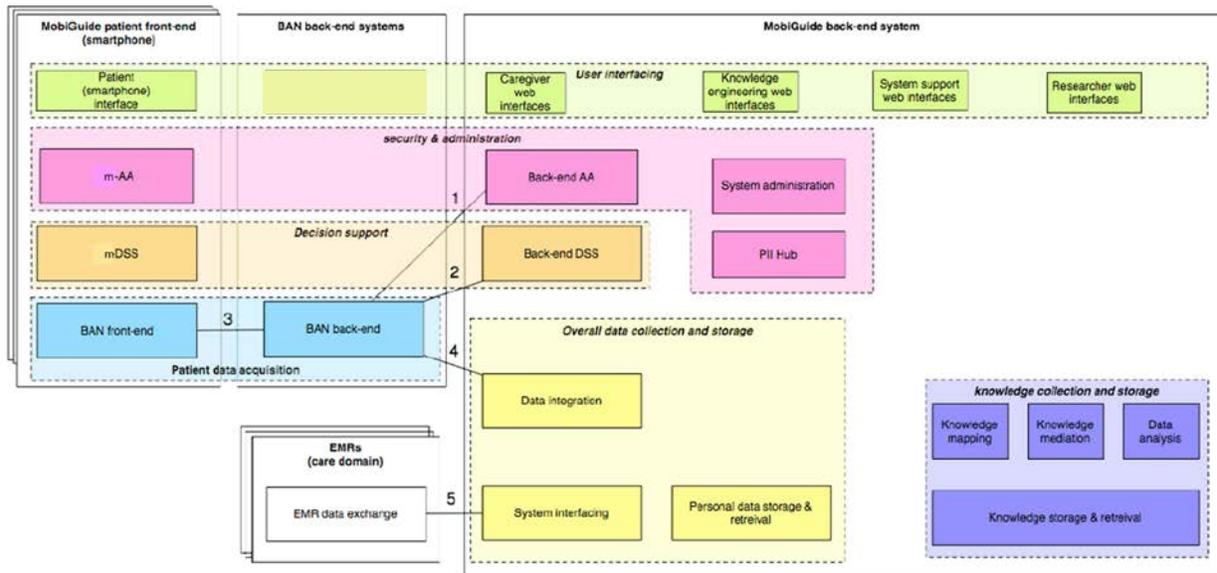
Figure 1 – MobiGuide system logical architecture. Front-end components are shown on the left.

5. Preparation of the Demos

This section contains a brief explanation related to the configuration details for the components that should be installed in the patient's mobile devices and the components that should deployed on the hospital.

Further information has been provided in deliverables *D5.3 Working Prototype* and *D12.2 Training Materials*.

5.1 Hardware Requirements

5.1.1 Patient interface

5.1.1.1 Smartphone

Smartphone device with 3G/4G data network capability, specially designed to monitor the patients and to automatically provide advices based on the continuous integration between biophysical signals, patients baseline presentation, therapies and current AF/GDM Guidelines.

The reference device for the base implementation was Samsung Galaxy S4. However the MG application can run in any Android-compatible smartphone with an android version of 4.0.6 or above.

The smartphone includes an accelerometer to detect the level of physical activity

5.1.1.2 Glucometer

The MobiGuide application will support the ability to import blood glucose data automatically via Bluetooth using a Continua-certified glucometer by Roche, Accu-Chek Aviva Connect for GDM patients. Communication with this sensor is accessible via the Blood Glucose tab of the Logbook scenario, and is specific to the GDM domain.

Note: The Smartphone does not detect the glucometer with an Android version of 4.3

5.1.1.3   Bio-harness 3 (Zephyr sensor device)

The Zephyr ECG belt allows monitoring the patient hearth rhythm/heart rate (dual mode) and communicates with the smartphone via Bluetooth. This device is already CE approved for use. The sensor includes a single-lead ECG monitor, an accelerometer to detect the level of physical activity and a respiration monitor for AF patients.

5.1.1.4   Blood Pressure Monitor (Omron 708-BT)

This sensor is a blood pressure monitor that could transfer data using Bluetooth technology and it is certified by the Continua Alliance and implements the 11073 communication protocol.

Communication with this Bluetooth-enabled sensor is accessible via the Blood Pressure tab of the Logbook scenario. Automatic insertion of blood pressure data is currently supported in the GDM domain.

5.1.1.5   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 the type of activity that the user is performing: resting, waking or running. This sensor is available for both clinical domains.

5.1.2 VMs requirements of the MG components

The following table summarizes the whole virtualized MobiGuide environment and its requirements:

Component	OS	Hostname	Socket	CPU	RAM (GB)	HD (GB)	MG components interaction
ADMIN	Linux Ubuntu 13.10 Desktop	MG-FSM-ADMIN	1	1	2	16	
Mobile Telemonitoring system	Linux Debian 7.2.0-amd64-	MGMHBV	1	1	1	16	BAN FE, Data Integrator, IDP, Caregiver interface.

	netinst						
Data Integrator	Linux Ubuntu 12.04.3_amd64bit LTS	MGATOSDI	1	1	1	50	The DataIntegrator receives requests from: DSS (Picard), Mediator, Caregiver Interface, BAN and KDOM
Professional (Caregiver) Interface	Linux Ubuntu 12.04.3_amd64bit LTS	MGUNIPV	1	1	1	16	DI, IdP, BE-DSS, Knowledge store, Data visualization GUI (VISITORS from BGU), + BAN-BE for getting active BAN list
KDOM	Linux Ubuntu 12.04.3_amd64bit LTS	MGHU	1	1	1	16	The KDOM WS receives requests (RPC) from the Mediator and KDOM GUI desktop application, sends requests (RPC) to the Data Integrator (DI). The KDOM GUI desktop application sends requests (RPC) to the KDOM WS. The KDOM GUI accessed via VPN connection.
Kernel	Linux Ubuntu 12.04.3_amd64bit LTS	MGZORG	1	1	1	16	It receives requests from the Data Integrator
Guideline Application Engine	Windows Server 2012 (x64) (English)	WIN-H8TTCI7L84E	1	2	6	100	It receives information from the Data Integrator and KDOM
Identity Provider	Linux Ubuntu server provided by ATOS	MGATOSIDP	1	1	1	18	It sends info to the CG interface and to the Data Integrator It receives requests of the Mobile Telemonitoring System

5.2 Software Configuration

5.2.1 Mobile components

The MobiGuide Mobile application is composed by several components which need to be installed separately in the patient's Smartphone, in the following order:

1. Mobile DSS (mDSS).
2. BAN messaging system (Mobihealth Banservice).
3. Quality of Data Broker (QoD Broker).
4. Physical Activity Detector (MG_PAD)
5. In case of a gestational diabetes patient, you will need to install the Glucose Service (MG_GLUC).

6. MG Mobile Graphical User Interface (MG_MobileGUI).

5.2.1.1 mDSS

This component is deployed in the patient's smartphone to provide decision support based on locally available patient data. The mDSS is compatible with Android version 2.2 (Froyo) and higher, but it is recommended to run the mDSS on Android version 4.2 (Jelly Bean) at the minimum.

No configuration is necessary for the mDSS to run, but the user may wish to upload a custom simulation dataset to test the MobiGuide system. In this case, the user-defined dataset should be structured as shown in Appendix A and should be saved in the "/mh/mobiguide/" folder as a CSV file with ASCII format, semi-colon separators and the filename "SimulationData.csv". If such a file is not found, the data simulator in the mDSS will simply run its default simulation dataset which is included in the provided APK.

5.2.1.2 BAN (Mobihealth Ban service).

The MobiHealth BAN service is an infrastructural component that provides a number of services to other components running on the Smartphone:

1. Secure login and storage. The BAN service verifies login credentials with the (remote) IDP, and uses the credentials to encrypt/decrypt any data stored locally.
2. Messaging infrastructure. Components on the BAN can send messages to each other (e.g. the mDSS notifying the GUI with guidance for the patient), or securely exchange information with remote components (e.g. the mDSS and backend DSS cooperating).
3. Data source/sink service. Components on the BAN can publish data sources (e.g. glucose sensor) to which other BAN components can subscribe to receive a real-time data stream. The BAN service also transports certain data to the remote backend (e.g. raw ECG data).
4. BioHarness and smartphone (e.g. battery) sensor data. The BAN service implements these data sources such that other components can receive it.
5. Irregular heartbeat analysis data. The BAN service contains an algorithm that annotates sensor data based on whether BioHarness data shows an irregular heartbeat.

Besides installing the software APK, some additional configuration is necessary. In short:

- A configuration file that contains a known, unique identifier and security token for the system (e.g. MG001) such that the remote BAN backend service can already reject communication with unknown devices even before the follow up authentication (patient activation token) is performed.
- A configuration file that contains information about coupled sensors (e.g. the Bluetooth address of the BioHarness sensor)
- Some (empty) application folders (e.g. for logging)

5.2.1.3 Quality of Data Broker (QoD Broker)

QoD Broker is a mobile component for MG system. It operates in the mobile platform and it provides Quality of Data (QoD) information to the components subscribed to the channel (QoD Tester), such as DSS (mDSS and BE-DSS via the PHR), stores QoD into the PHR via the DI and provides technical recommendations to the patient via the patients GUI in the corresponding language: Italian, Spanish, Catalan, English (default).

5.2.1.4 Physical Activity Detector (MG_PAD)

The Physical Activity Detector (PAD) is a mobile service which uses the internal accelerometer of your smartphone to detect, every 10 seconds, the type of activity that you are performing (The supported activities are: resting, walking or running).

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. Apart from this consideration, no other configuration is needed to use it.

5.2.1.5 MG_GLUC

The MobiGuide Glucose meter Service (MG_GLUC) is a service that allows you to automatically upload data from your Roche Accu-Check Aviva Connect glucose meter to your MobiGuide application via Bluetooth.
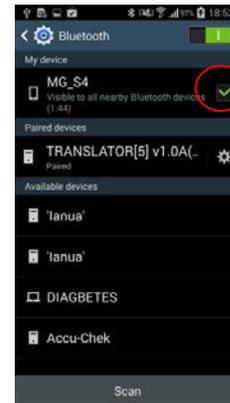
Before using the Glucose meter service to download the patient's blood glucose measurements, it is required to pair the device with the smartphone by using its Bluetooth configuration. This process needs to be done only once- by selecting the 'Settings' menu. Select the link 'Connections' and activate the Bluetooth connection. The name of the smartphone will be shown at the top of the screen. (The smartphone must be visible to other devices.)

Access to the Settings menu	Activating the Bluetooth connection	Making visible the device

Switch on the glucose meter and use the buttons with an arrow and the 'OK' button to select. You will need to select 'Settings'-'Wireless'-'Pairing'-'Pair Device' as shown in the pictures below. After pressing the 'OK' button, the glucose meter will show a pairing code (this code will be different each time that you try to pair the device).
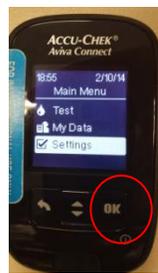

Select Settings	Select Wireless -Pairing	Select Pair device	Check pairing code

After seeing the pairing code shown at the glucose meter, select the name of the glucose meter that it is shown under 'Available devices' in the smartphone. Enter the pairing code in the 'Bluetooth pairing request' and press 'OK'. In order to confirm that the pairing has been done correctly, please check that the name of the glucose meter is under 'Paired devices' in the smartphone. Also, the glucose meter will show a confirmation screen.
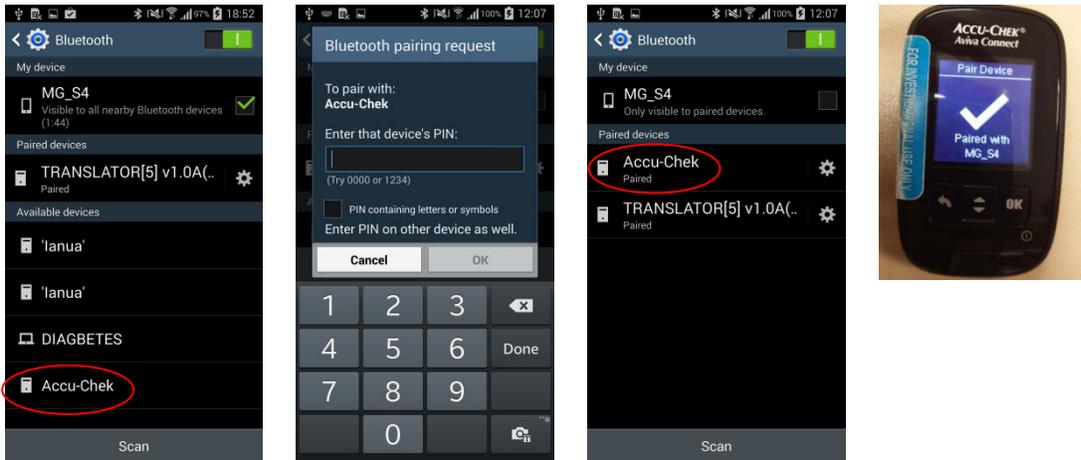
| Start the pairing process | Enter the pairing code | Check that the glucose meter has been paired | Confirm that the device has been paired |

The Bluetooth connection of the smartphone should be active if you want to communicate the glucose meter with the MG Mobile GUI. Finally, before starting downloading data, please check that the 'Sync Time' is set to ON in Wireless category in the Settings menu of the glucometer.

The MG_MobileGUI's User Manual for more details about the communication process.

5.2.2 Caregiver Interface

The Caregiver interface is developed with Grails. Grails is an open source web application framework inspired by Ruby on Rails, but running with Groovy. Groovy is an object oriented programming language based on Java Virtual Machine (JVM).

To install the caregiver interface component, the following programs must have been installed on the machine:

- jdk 1.7.0. (http://www.oracle.com/technetwork/java/javase/config-417990.html)
- Apache Tomcat 6 (http://tomcat.apache.org/index.html)

The application has been developed and tested using the Oracle version of the Java JDK.
In addition, it is important to install the Policy Agent to connect to the Identity Provider, which provides the A&A&A services. The steps to import the IdP certificate into the system and to install the policy agent into Tomcat are described in details in deliverable D8.4 (Section 5.6).

Finally, https protocol should be enabled for the TomCat server using the MobiGuide certificate. This can be done following the steps listed in section 5.7 of deliverable D8.4.

All the data needed from the caregiver interface are stored in the PHR and retrieved dynamically through web services. Thus no database management system installation and configuration is needed.

6. Pre-pilot / Pilot Demonstrations

This section presents a brief description of the pre-pilot and pilot demonstrations that were developed in two clinical centers in Spain and Italy. Further information is found in *D9.1 Functional and usability evaluation report* and *D12.3 Training Materials.*

6.1 Pre-Pilot Demonstration

The pre-pilot demonstration for both domains (AF and GDM) was performed by healthy volunteers involved in the project. The main goal of these pre-pilot studies is to test the system before giving it to patients in order to refine and improve the caregiver interface and the Smartphone GUI.

These demos were deployed in two clinical centers at FSM (Fondazione Salvatore Maugeri Clinica Del Lavoro E Della Riabilitazione) and CSPT (Corporacio Sanitaria Parc Tauli De Sabadell).

6.1.1 Pre-pilot Scheduled and Recruitment

AF: Pre-pilot started at March 1st 2015 and involved nine volunteers: six subjects from UNIPV and three from FSM.

GDM: The pre-pilot started at February 15th 2015 and involves 7 volunteers: two engineers from UPM, and one IT staff subject, two endocrinologists and two nurses from CSPT.

6.1.2 What we have tested?

AF
The AF pre-pilot included the testing of the AF Guidelines for the patient and the caregiver, as well as well as the EMR import data process, the Caregiver interface, the Smartphone GUI, the mobile decision support system (mDSS) and the BAN components.

GDM
The pre-pilot included the simulation of EMR import data processes, BAN activation processes, entry of GDM relevant monitoring parameters in a daily basis and checking of guideline recommendations and reminders both at patient and caregiver GUIs. Monitoring data entered by users during this period included simulated glucose values, diet, ketonuria, insulin, real blood pressure measurements, and real physical activity sessions.

6.2 Pilot Demonstration

The pilot demos were run on eligible patients in both domains GDM and AF, with the main objective of evaluating the system from the user perspective in a real environment. The pilot studies are deployed at the same clinical centers as the pre-pilot (FSM, CSPT).

6.2.1 Pilot Scheduled and Recruitment

AF
For the Pilot at FSM, 10 patients have been recruited with the diagnosis of paroxysmal, persistent or permanent AF. The enrolment started in April, and the patients have used the system for 7 months, depending on the enrolment date.

GDM
The Pilot at CSPT, involved 19 pregnant women with Gestational diabetes (GDM) diagnosed according to National Diabetes Data Group criteria 1 dropout. The enrolment started in May and patients have used the system for 6-7 months, from the inclusion visit to the baby's delivery day.

Pilot	Nº patients	Start	End	Months	Min time/patient	Max time/patient	Average
AF Pilot	10	09/04/2015	still ongoing	7	3 months	7 months	3 months
GDM Pilot	19	05/05/2015	still ongoing	6	19 days	91 days	49,4 days

6.2.2 What we have tested?

AF
The pilot has included home monitoring which consists on daily recording of ECG sessions, and on reporting measurements of blood pressure, weight, and INR in order to gather data useful for testing the MobiGuide environment effectiveness in supporting the management of patients with atrial fibrillation. We also tested AF detection algorithm performance (reported in D9.3) and correctness of the recommendations given to patients (for both medications and measurements) and physicians (GL recommendations on cardioversion).

GDM
The pilot has included assessment of the glucose control, ketonuria evaluation, weight evolution, blood pressure and physical activity in GDM patients. Recommendations generated by the system were also tested for correctness.

6.2.3 Components used

AF

- The patients used the following components:

    - Smartphone device with 3G/4G data network capability and specifically designed software to collect clinical data and allow bi-directional messaging system.

    - An ECG/physical activity recording device. The MG-AF trial will implement the BioHarness 3 (Zephyr Technologies). The sensor includes an ECG recording electrode, an accelerometer to detect the level of physical activity and a respiration monitor (not currently used in the system).

GDM

- The patients used the following components:

    - Smartphone device with 3G/4G data network capability and specifically designed software that will collect the clinical data and bi-directional messaging system (patient _doctor and doctor _ patient). The smartphone includes an accelerometer to detect the level of physical activity. The MobiGuide application allows to manually introduce the results of blood glucose measurements, fasting daily ketonuria determination (-/+/++), weight, insulin doses administered, and diet intakes in qualitative amount (-, =, +, ++).

    - A glucometer device with Bluetooth connectivity.

    - A blood pressure monitor with Bluetooth connectivity.

For both domains

The entire infrastructure of the back-end components (shown in Figure 1) was used in the two pilot deployment sites to enable testing of the full-fledged MobiGuide system functionalities. In particular:

- Data integrator and PHR: used for patient data storage and retrieval. The DI also manages data imports from the proprietary EMR of the two hospitals.
- DSS: provides the guideline execution capabilities that enable patient guidance. The DSS is also responsible for delegating part of the guideline execution to the mDSS.
- Knowledge store and Gesher knowledge acquisition tool: provide capabilities for the formalization and storage of the CIG.
- KDOM: manages the mappings between concepts defined in the knowledge base and the actual data items stored in the PHR.

- PII hub: provides centralized, secure storage of the different patient identifiers across the entire system.
- Identity provider: manages authentication and authorization policies in a centralized fashion across the whole system. Both front-end and back-end components rely on the identity provider to secure all the inter-component interactions.
- BAN back-end service: handles the communications between mobile components and any of the server-side components.

7. Pilot evaluation

WP9 deliverables describe extensively the pilots. The questionnaires descriptions for the evaluation are included in D9.1.

8. Conclusions

This deliverable presented all the technical configuration and materials that have been needed for the preparation of the Living Lab.

The multidisciplinary team in MobiGuide decided which materials were needed to create the most appropriate environment. The group of patient was carefully selected by the practitioners, and during the pre-pilot phase, a first group of testers, both practitioners and patients worked in close contact with the technics and engineers and contributed with their suggestions not only to correct the bugs but to enhance the user interface configuration.

The procedure for configuring the software and hardware of the Living Lab was designed and described in detail to be shared with all the technical staff in the two location of the pilot.

9. Definitions, acronyms and abbreviations

ADC: Associació de Diabètics de Catalunya
AF: Atrial fibrillation
BGU: Ben Gurion University
BMIR: Biomedical Informatics Research
BP monitor: Beat Pulse monitor
CIG: Computer Interpretable Guidelines
CSPT: Corporaciò Sanitaria Parc Taulí (Sabadell)
DI: Data Integrator component
DSSs: Decision Support System
EHRs: Electronic Health Record
FSM: Fondazione Salvatore Maugeri Clinica Del Lavoro E Della Riabilitazione
GDM: Gestational Diabetes Mellitus
GUI: Graphic user interface
HU: Haifa University
IEEE EMBS: Institute of Electrical and Electronics Engineers / Engineering in Medicine and Biology Society
KDOM: Knowledge Domain Ontology Mapper component
KR4HC Knowledge Representation for Health care
M: Month
MG: MobiGuide
MHBV: MobiHealth BV
PAD: Physical Activity Detector
PGS: patient Guidance System
UNIPV: Universita Degli Studi di Pavia
UPM: Universidad Politécnica de Madrid
UT: University of Twente

10. References

Deliverable 5.3: Working prototype (including the DSS, LB-DSS components and interfaces)

Deliverable 8.4: Authentication and Authorisation in MobiGuide

Deliverable 9.1: Functional and usability evaluation report

11. List of annexes

N/A