DELIVERABLE

«Implementation Study»

Deliverable D4.3.1
WP4: Joint Monitoring System

The project is implemented in the framework of INTERREG V-A "Greece -Bulgaria 2014-2020" Cooperation Programme and is co-funded by the European Regional Development Fund (ERDF) and by national funds of the countries participating in the Programme

http://www.ehealthmonitoring.eu/

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1 The project EHEALTH Monitoring

The project "eHealth Monitoring" aims to develop and validate an efficient and advanced ICT based integrated health information system, that not only provide a mean for monitoring health parameters outside of the traditional hospital environment but also is able to create a permanent link between patients and healthcare personnel, providing in this way a direct improvement of the concept of equal access, equal quality and efficiency of health monitoring for the societal and economical development of enlarged Europe. The strategic goal is the improvement of public health and quality of life, adapting to changing needs and utilizing existing and new technological capabilities, while at the same time increasing the efficiency and cost-effectiveness of these services. The main target of the project is to study, design and implement a novel, user friendly, flexible, highly efficient, interactive mobile application for health monitoring anyplace, anytime, for anyone.

The project contributes to E2020 strategy regarding "smart growth", "sustainable growth" and "inclusive growth" objective by promoting "access for all" to health care taking actions foreseen by the programme "telemedicine and telecare infrastructure and other technology-oriented health care provision methods" and will try to improve access to primary and emergency health care (at isolated and deprived communities) in the cross border area by providing a personal mobile healthcare system on the base of the mobile video supporting device allowing ambulant patients:

(1) Remote monitoring of the patient's state;

(2) Patient's continuous self control;

(3) Live contact from any place -any time with professional medical staff through modern communication network.

The system with micro-electrodes integrated directly into cellular device/PDA is intended for healthy population interesting in health status self-control but can be adopted also for chronically ill population.

The project consists of 6 partners, 4 Greek partners and 2 Bulgarian partners. LB is the "Centre of caring and solidarity of Komotini municipality" cooperating with "Central Union of Municipalities in Greece" which will disseminate the project results to Greek municipalities, with "Democritus University of Thrace" in Komotini and the "Medical Association of Rodopi" together with Municipality of Kirkovo (District of Kardjali) and the "Association „EURORADAR"" (District of Smolyan).

The project lifetime is 24 months and it is expected to start implementation at 1/9/2017 and ending 31/8/2019. It consists of 5 Work Packages. None of them will be implemented outside the eligible programme are. However there is a partner involved in the project who is settled outside the programme area (KEDE in Athens) but its activities are for the benefit of the Programme area, are essential for the implementation of the project, since it represents all the Greek municipalities and is going to increase Communication & Dissemination, Policy Integration and training & awareness raising. Its budget does not exceed the 20% of the support from the ERDF.

The Work Packages (– WP) of the project are:

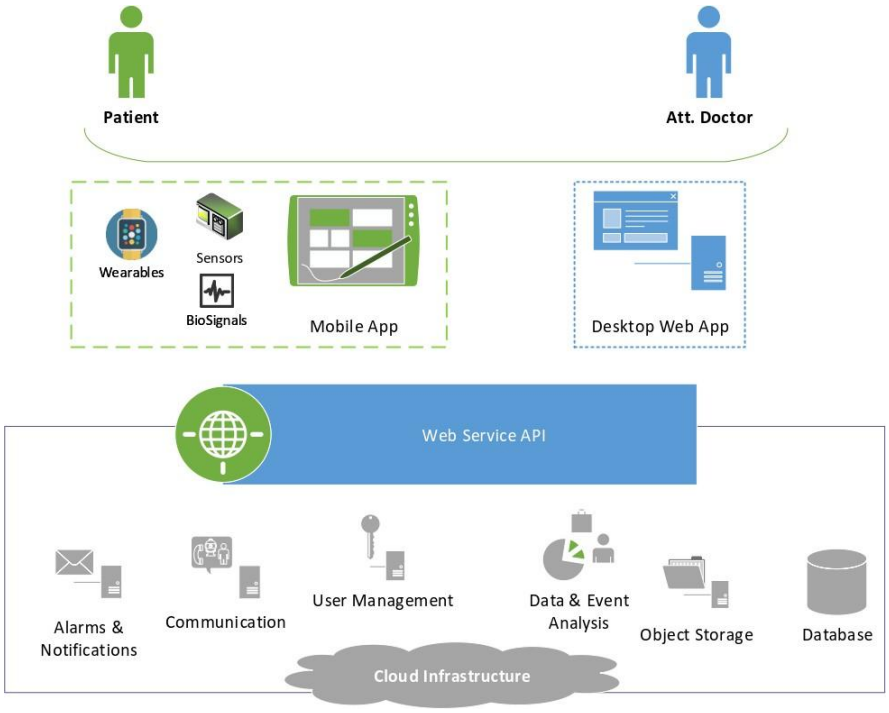
- WP 1: Project Management & Coordination
- WP 2: Communication & Dissemination
- WP 3: Policy Integration
- WP 4: Joint Monitoring System
- WP 5: Information, training & awareness raising

2 THE INTEGRATED HEALTH MONITORING SYSTEM

The Integrated Health Monitoring System, which will be designed within the frame of the **"EHEALTH Monitoring"** project**,** consists of four main sub-systems that realize the required functionalities, as well as a cloud back-end platform, which supports all other subsystems. These subsystems have been designed and developed utilizing a rich set of state-of-the-art technologies and tools, in order to secure optimal levels of robustness, security and extendibility and the finest user-experience.

The system follows a service-oriented architectural design, exploiting the advancements and flexibility of cloud offerings, and implements modern UIs for all types of users. Cloud Computing allows for ubiquitous access to shared resources and common infrastructure, offering services on-demand, serving the constantly changing needs of the health-centric digital services. To that end, we have developed an integrated system for patient monitoring at home, utilizing Cloud Computing concepts and tools for data managements and analysis. The proposed solution focuses on the system decision support functionality, which is utilized within the smartphone app for initial assessment, as well as in the Cloud.

A combination of Java and JavaScript technologies and frameworks are used for implementation and communication of the various application components and services.



Picture 1 The proposed system

The main functionality of the platform is recording and analysis of biosignals. Java technologies have been utilized for development and the functionality is offered via Web Services. Similarly, synchronization and central administration functionalities of the application subsystems are provided. The following features are supported:

- ✓ User account management
- ✓ Data analysis
- ✓ Data storage
- ✓ Reminders and notifications to patients and other end-users in cases of measurements out of normal range, detection of errors, measurement and medication schedule, etc.
- ✓ Videoconferencing functionality based on the WebRTC protocol, which is utilized both for the Web app and the mobile app.

As mentioned above, the proposed integrated health monitoring system consists of four main sub-systems that realize the required functionalities. These subsystems have been designed and developed utilizing a rich set of state-of-the-art technologies and tools, in order to secure optimal levels of robustness, security and extendibility and the finest user-experience. To that end, the proposed solution follows a service-oriented architectural design, exploiting the advancements and flexibility of cloud offerings, and implements modern UIs for all types of users.

A combination of Java and JavaScript technologies and frameworks are used for implementation and communication of the various application components and services. A cross-layer technology that has a key role on the realization of the communication and videoconferencing functionality is WebRTC[1], which is used both for the desktop and mobile applications.

Android App

For a simplified, flawless and ubiquitous access to the system, a mobile app for Android devices has been developed. Besides the core functionality for communicating with the backend, the mobile applications allow for the integration of Bluetooth devices, sensors and wearables. The native android application targets (API) Android 21 / Lollipop.

The application incorporates the required functionality for communicating with the cloud-based platform services and also acts as a platform gateway to the various Bluetooth devices (biosensors και wearables).

Web App

[1] http://www.webrtc.org/

The web app includes the core functionality for interacting with all user types. In contrast to the mobile application, which is lightweight and simplified so as to ease the interactivity with the elderly users and patients, the web application has rich user interface for configuring the user and application parameters, and also for visualizing the biosignals and health records. WebRTC based communication is also provided through the web application.

Cloud Platform

The back-end platform is set of several cloud-based services and components. The main technology used for the platform is JEE and most of its features are exposed to the aforementioned applications through web services. In addition, it is possible to implement communication with external healthcare providers for updating the patient's PHR in case data are available.

3 DESIGN AND DEVELOPMENT METHODOLOGY

The methodology used for design and development follows the Design-Build-Test cycle, known also as the Prototyping Model. According to this model, a prototype of the software, including only the basic features of the final version is developed first. Testing of the prototype provides feedback, which can be used to improve the system. This model is useful when it is not easy to derive requirements for the system, or the requirements may change significantly during the development process. The software development process within the prototyping methodology consists of four stages:

- ✓ Defining basic user requirements
- ✓ Development of the prototype of the system
- ✓ Testing of the prototype to redefine user requirements
- ✓ Revision and improvement of the prototype

The use of the specific methodology allows for improved design, based on the evaluation of the prototype by users and experts, resulting in the development of applications that satisfy user requirements to the fullest extent.

4 FUNCTIONAL REQUIREMENTS OF THE HEALTH MONITORING SYSTEM

4.1 User Roles

The user roles are described in the following table:

Role	**Description**
Patient	The main user of the system (recipient of the service)
Contact	A user that can communicate with Patients. Every Patient may have more than one Contacts.
Attending doctor	Doctors
System Administrator	Technical and administrative role. Has access to all reports/MiS.

4.2 General Requirements

The general application requirements are the following:

Application	**Role**	**Functionalities**
Web app	Patient	• Contact management • Videoconferencing with contacts • Account and personal info management • Reminders management • View PHR and add content • View recorded biosignals • Manage medications and relevant settings
	Attending doctor	• Account management • View patients • Videoconferencing with patients • Manage medications and relevant settings (for patient)

		• View patients' biosignals • View patients' PHRs and add content
	Contact	• Contact management • Videoconferencing with contacts
Mobile app (Android based)	Patient	• Videoconferencing with contacts • Reminders management • View PHR • Record, view and upload biosignal measurements
	Contact	• Contact management • Videoconferencing with contacts

4.3 Non-functional Requirements

Cloud infrastructure will be used for platform hosting and support of the various sub-systems. Exploiting **Cloud offerings** allows for:

- ✓ **Improved resources management**: Preparing services which may later not cover user requirements can be avoided. Cloud computing reduces costs and maximize utility, since resources are provided only when needed.
- ✓ **Flexibility**: All systems and software remain constantly available.
- ✓ **Accessibility**: Cloud computing allows ubiquitous access to applications and data, with encryption security, via the Internet. When connection to the Internet is not available, bandwidth requirements can be covered even with a 3G connection.
- ✓ **Cooperation**: Accessibility of applications and data over the cloud facilitates cooperation between different components, since applications can have simultaneous access to data.
- ✓ **Disaster recovery & Business continuity**: Recent research indicates that approximately 90% of businesses do not have adequate plans for managing total or partial loss of their computer infrastructure, in order to ensure uninterupted operation. Ccloud computing allows for automation of disaster recover processes through the use of backups, as well as maintaining servers that can operate as others' images.

4.4 Criteria for Infrastructure Design & Selection of Development Tools

The main criteria for the Design of the Infrastructure are the following:

- ✓ **Functionality:** The main focus of the design process is to satisfy all functional and technical requirements (communication between components, communication with end-user devices, etc.).
- ✓ **Costs**: Operations and initial deployment cost. Open-source software bears no intial deployment cost (software licences for server web apps, database, etc.), as well as maintenance costs. Distributions are provided for free even for commercial use, while the open-source community offers continuous support through new versions (often with the capability for automated installation).
- ✓ **Application Support**: Support of applications – development tools, in terms of updates, as well as on operational level, by official guides or the user-developer community was and important consideration in the choice of development tools.
- ✓ **Scalability**: Both the architectural design and the development tools should allow the addition of new modules, as well as new functionalities, without the need for redesign or radical changes in implementation.
- ✓ **Security:** The hosting and operational environment should be secure, incorporate strict user and access-rights management, and support on the application level state-of-the-art mechanisms for user authentication and secure data transfer. The following aspects have also been considered:
  - o securing integrity and availability of information
  - o protection of stored and processed personal data, by methodically selecting and applying technical measures and organizational processes.
  - o composition of the required documents for terms of use and privacy policy
- ✓ **Electronic Health Record Specifications**
  - o Cloud technologies support and web-based access.
  - o Incident based structure and visualization.
  - o Patient authentications using their SSN.
  - o Classified access/recording, depending on each role's access rights
  - o Stored data
    - Demographics.
    - Medical History: diseases, medications, allergies, etc.
    - Biosignals
    - Other exams if available (in case of examination at home or if provided by a user)

- ICD-10 diagnosis, if available, enriched with free text.

✓ **Relevant Legislation**

- Institutional and legal framework in force (directive 95/46/EK, protection of personal data Law 2472/97, protection of personal data in the telecommunications sector Law 2774/99).
- The General Data Protection Regulation (EU) 2016/679 (GDPR).

✓ **Usability Requirements**

- Convenience and user-friendliness. Common theme for all applications, unified and consistent functionality.
- Special care for elderly user needs.

5 Web App Requirements Analysis

5.1 Web App Requirements

The following table lists the requirements particular to the Web app:

Web-App	**Functionality**	**Role**	**Description**
A1	User account management	Patient, Contact, Attending doctor	All user account info, except the Username can be edited.
A2	Personal info management	Patient, Contact, Attending doctor	All users can edit all fields. Every Patient, Contact, Attending doctor add/remove a Profile pic.
A3	PHR management	Patient	The user can view their health information which have been recorded in their PHR, which are visualized appropriately, depending on the data type. The user can search for specific records. The user can add records to the PHR.
		Attending doctor	Attending doctors can access their patients' PHRs only upon the patients' consent.
A4	Biosignal management	Patient	The patient can view recorded biosignal measurements and perform new measurements

			of the following vital signs: • Blood Oxygen • Blood Glucose • Blood Pressure • Spirometry • Temperature • Weight • Steps Measurements may be: • Recorded via biosensors used by the patient • Manually input by the patient The aforementioned biosignals should be visualized graphically.
		Attending doctor	Attending doctors can access their patients' biosignal measurements only upon the patients' consent.
A5	Contact management	Patient, Contact	Every user can send and receive requests to add other users to their contact list.
A6	Reminders management	Patient	The user can create reminders for any event, based on the following: • Reminders are classified as 'Measurement', 'Medication' and 'Message' • Reminders can have occurrence Once, Daily, Monthly, Yearly and for each one a data and time is set • The user can delete or edit reminders
A7	Videoconferencing	Patient, Contact, Attending doctor	The user can call or receive calls from anyone on their contact list at any time. Communication begins upon confirmation of the receiver. The user receives image and

			sound.

5.2 Usability Requirements

- ✓ Convenience and user-friendliness. Common theme for all applications, unified and consistent functionality.
- ✓ Special care for elderly user needs.
- ✓ Mechanisms for detection of errors and erroneous data input

5.3 Implementation Specifications

The following technologies were utilized for the development of the application:

- ✓ **Java Programming Language** for the development of the Business Logiv of the Web app and communication with the database.
- ✓ **Apache Tomcat Servlet Container** for the deployment and operation of the application based on Java technologies.
- ✓ **Apache Web Server - Load balancer** for for seamless operation of the application even in cases of high load and number of simultaneously connected users.

From the end-user's point, the only requirement is the use of a web browser that supports the WebRTC protocol, which can be any of the following:

- Google Chrome >= 65
- Mozilla Firefox >= 60
- Opera >= 54

6 Mobile App (Android) Requirements Analysis

6.1 Mobile App Requirements

The following table lists the requirements particular to the mobile app:

B. Mobile (Patient)	Functionality	Description
B1	Reminders	The UMU (tablet) must be able to display reminder notifications at specific time intervals. Reminders can be set via: • The web app, by the Patient or the Attending doctor • The mobile app by the Patient. In this case, the user must be able to set the same parameters as in the Web app. Reminder notifications must be displayed on the screen (potentially with an image or animation/video) and accompanied by an audio alert, which should be repeated until the user presses a specific button. The alert stops after a preset maximum time interval.
B2A	Connection with biosensors	The device can connect to biosensors (e.g. blood pressure monitor, glucometer) in a wireless manner via Bluetooth. The connection status is displayed on the screen.
B2B	Record biosignals	Recorded measurements are stored on the cloud and displayed on the screen. The user is also able to view past measurements.
B3A	View contacts	All of the user's contacts are displayed on the device.
B3B	Videoconferencing	The user can call any other user from their contact list by pressing a (green) button. The call ends by pressing a red button. The device can receive incoming calls (video or voice only) even on standby mode.

6.2 Non-functional Requirements

The **Android** platform has been chosen for the end-user unit and the development of the videoconferencing functionality, biosignal recording and other various features of the application (e.g. content display, reminders, etc.).

Android is an open-source development platform for smart mobile devices (smartphones, tablets, etc.). It supports development of applications with a graphic user interface, automated updates, videoconferencing and data transfer via available networks (WiFi or/and 3G). It is widely accepted by mobile device manufacturers and is an optimal choice for the proposed solution, as:

- ✓ client applications will be compatible with a wide range of devices (smartphones, tablets and set-top-box), without need for further development of compatibility issues
- ✓ there is significant available support for the specific development environment, which is certain to be maintained in the following years
- ✓ there is a great number of existing compatible applications
- ✓ Android applications have relatively low hardware requirements
- ✓ There is no need to acquire costly licenses.

7 REQUIREMENTS ANALYSIS FOR BIOSENSORS AND MOBILE DEVICES

The biosensors that will be proposed for deployment in the frame of the "**EHEALTH Monitoring**" project must be unobtrusive mobile devices, which allow for monitoring of the user's health status, providing measurements of the following vital signs:

- ✓ Heart rate
- ✓ Oxygen saturation
- ✓ Blood pressure (systolic and diastolic)
- ✓ Physical activity (step count and sleep)

The smart mobile devices – User Mobile Units (UMU) – should be suitable for running the remote health monitoring application (mobile app).

In order to record measurements and store them on the platform, the utilized biosensors must be able to communicate with the UMU and the mobile app. Device communication and data transfer must be implemented in a wirelessly via Bluetooth. The biosensors must connect with the UMU and communicate with the application for data transfer in an automated manner, without need for user interference, so as to ensure maximum user-friendliness.

More specifically:

A/A	**Biosensors' Specifications**
1	Must be unobtrusive
2	Must have LCD display for measurement results
3	Must be appropriate for personal use at home
4	Must be low cost, according to the project's objectives
5	Must be mobile devices
6	Must be CE certified
7	Must provide accurate measurements of the required biosignals (heart rate, oxygen saturation, blood pressure). Certification from a competent body after clinical trials (e.g. FDA, ESH) is considered proof of device quality.
8	For rechargeable devices, a minimum of 24 hours battery life is required.
9	Must be accompanied by at least one (1) year warranty.
10	Must have LCD display where results appear after each measurement.
11	Must support wireless connectivity and data transfer via Bluetooth Low Energy (BLE).
12	Connection with the UMU and the application must be possible.
13	The biosensors should be able to connect to the UMU and communicate with the application for data transfer automatically, without need for user interference.

A/A	**User Mobile Units Specifications**
1	Must be able to connect to the Internet over WiFi
2	Must be able to connect with other devices via Bluetooth Low Energy (BLE)
3	Must have display size of at least 7''

A/A	User Mobile Units Specifications
5	Must have display resolution of at least 1024x600
6	Must run Android operating system (version 6.0 Marshmallow or later)
7	Must have at least 1GB RAM
8	Must have at least 8GB storage space
9	Must have satisfactory autonomy with at least 10 hours battery life
10	Must be accompanied by at least one (1) year warranty

8 IMPLEMENTATION PLAN

WP4 is the core of the project. The WP4 will be delivered by LB (Centre of caring and solidarity of Komotini Municipality), PB3 (Democritus University of Thrace - Department of Economics - Special Account for Research), PB4 (Medical Association of Rodopi), PB5 (Municipality of Kirkovo) and PB6 (Association "EURORADAR").

Democritus University of Thrace - Department of Economics - Special Account for Research will be responsible for the requirements, specifications and design of the system and it will deliver the following deliverables:

- Implementation study
- Application/Software Development

The **Centre of caring and solidarity of Komotini Municipality** will be responsible for the installation of Equipment. 100 bio-sensors accompanied with User Mobile Unit (UMU) and Expert Mobile Unit (EMU) will be provided by LB, in order to be used by citizens/patients in Greece. Furthermore, it will perform a pilot implementation report. The objective will be to evaluate the implementation of the system and to draw interesting conclusions regarding the achievement of the objectives and future plans of the project.

PB4 (Medical Association of Rodopi) will be in control of the integration, parameterization and testing of the Integrated Health Monitoring System. In more details, it will provide the essential support by offering the necessary technical information regarding the system design the system

integration and the activity monitoring, as well as the analysis of the data by the responsible doctors. Moreover, it will perform a pilot implementation report throughout the implementation of the project.

PB5 (Municipality of Kirkovo) will provide 40 bio-sensors accompanied with User Mobile Unit (UMU) and Expert Mobile Unit (EMU) in Bulgaria and will support the pilot implementation reports throughout the implementation of the project.

Finally, **PB6 (Association "EURORADAR")** will provide 60 bio-sensors accompanied with User Mobile Unit (UMU) and Expert Mobile Unit (EMU) in Bulgaria. PB6 will also be in control of the integration, parameterization and testing of the Integrated Health Monitoring System in Bulgaria. In addition, it will develop all the necessary progress reports on the evaluation of the information system.

Involved in the pilot testing of the Integrated Health Monitoring System and the development of the necessary progress reports, as well as the preparation of reports on the support, management and evaluation of the information system

The potential patients and doctors involved the types of diseases to be analyzed as well as the areas in Greece and Bulgaria, where the Integrated Health Monitoring System will be implemented will emerge throughout the implementation of the Project "eHealth Monitoring", always in full collaboration of all partners involved in Work Package 4 (WP4).