An Integrated Sensing Platform for Remote Fetus Continuous Monitoring

João Andrade[1], Artur Arsenio[2] and Andreia Duarte[1]
[1]Instituto Superior Técnico, Universidade de Lisboa, Porto Salvo, Lisboa, Portugal
[2]IST-ID, Universidade da Beira Interior, Covilhã, Portugal

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Abstract: Technological developments on health sensing devices, associated with the growing computational capabilities of mobile devices, enable the creation of solutions that address mobility concerns of patients, especially those located on remote locations or facing mobility constraints. This paper proposes an integrated sensing platform, which works transparently with new sensing, portable equipment sensors, but maintaining as well compatibility with currently deployed commercial tools. This platform targets fetus health monitoring in pregnant women, presenting a new non-invasive portable alternative system that allows long-term pregnancy surveillance. Additionally, it can be applied to other users' communities, such as remote elderly monitoring at home. We address technology adoption problems related to non-invasive, portable sensing technologies, data security and equipment heterogeneity.

1 INTRODUCTION

Ubiquitous health sensing technology is becoming a reality, and it will be part of our lives in the near future. This trend follows recent technology advances in sensing, computation, storage, and communications (Campbell et al., 2008; Lane et al., 2010) allowing the integration of large scale sensing with high dataset processing capabilities for intelligent data analysis (Zhang, Guo, Li, & Yu, 2010). People become the holder of sensing devices, and both producers and consumers of information (Miluzzo et al., 2008). As a consequence, the recent interest by the industry in open programming platforms and software distribution channels is accelerating the development of people-centric sensing applications and systems (Lane et al., 2010; Miluzzo et al., 2008).

People-centric sensing therefore enables a different approach to sensing, learning, visualizing and data sharing. This approach is not only self-centered, but especially focused on the surrounding world. Such systems are especially well suited for Healthcare applications, to facilitate both monitoring and sharing of automatically gathered health data (Campbell et al., 2008; Abdelzaher et al., 2007). As most people possess sensing-enabled phones, the main obstacle for the widespread adoption of smart medical devices is not the lack of an infrastructure. Rather, the technical barriers are related to performing non-invasive signal acquisition (dealing eventually with a large set of heterogeneous equipment), and addressing data privacy and lack of connectivity issues, whereas supplying users and communities with useful feedback (Lane et al., 2010).

This paper addresses these problems, and presents a solution developed under the scope of a HMSP collaborative project "Improving Perinatal Decision-Making: Development of Complexity-based Dynamical Measures and Novel Acquisition Systems. The work focus on developing Remote Fetus Monitoring from biosensors, involving medical groups at Harvard and Portugal, two sensing device companies (Omniview Sisporto in Portugal, and DynaDX in Taywan), and two groups focusing on applying technologies in biophysics and wireless communications. This solution can also be applied for monitoring different user communities, such as elderly people or physiotherapeutic patients in recovery (carrying other bio-signal sensors with them), as addressed by the AHA-Augmented Human Assistance project.

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1.1 Remote Fetus Monitoring

Throughout pregnancy, the placenta is responsible for supplying the fetus with oxygen and nutrients, as well as removing carbon dioxide and other waste gases from the fetal environment. Therefore, malfunction of the placenta may result in low oxygen delivery repercussions, in a condition known as fetal hypoxia. This condition is associated with as much as 10% of perinatal deaths and 15% of long-term damage cases, such as cerebral palsy (Graham et al, 2008).

Electronic fetal monitoring (EFM) may provide detection of fetal hypoxia on a early stage, thus enabling medical interventions before irreversible changes take place, which is why the relevance of continuous EFM in reducing neonatal mortality and morbidity has been acknowledged for some years (Devoe, 2011; Jenkins, 1986; Banta & Thacker, 2001). In fact, nowadays EFM is used as standard care during pregnancy (Banta & Thacker, 2001) and labour (Alfirevic et al., 2006) in most developed countries. Such monitoring has special relevance in high risk pregnancies, which include maternal hypertensive disorders and intrauterine growth restriction (American College of Obstetricians and Gynecologists, 2009).

Current EFM methods have various contraindications, which include active genital Herpes infection, Hepatitis, HIV and lacked monitoring before 34 weeks of gestation. Cardiotocography (CTG, see Figure 1), the most common EFM method, is associated with highly complex fetal heart rate (FHR) patterns, making standardisation difficult (Alfirevic et al., 2006). Moreover, this method is not suitable for long term monitoring for a number of reasons, namely: it is active, restrictive and requires large power (Alfirevic et al., 2006; Piéri et al., 2001).

On the other hand, the use of transabdominally recorded electrocardiogram (fECG) carries a number of advantages: it is passive, uses low-cost electronic components and standard ECG electrodes. fECG, is also suitable for long-term ambulatory recording, not relying on the presence of highly trained professionals (Crowe, Harrison, & Hayes-Gill, 1995; Graatsma et al., 2009; Karvounis et al., 2010). Other benefits include the possibility of extracting beat-to-beat FHR data, along with averaged fECG waveforms, which are easier to opine on (Piéri et al., 2001).

Making fECG a reality will enrich the knowledge on FHR tracings and improve current protocols and signal interpretation (Devoe, 2011; Taylor et al., 2003; Thomas et al., 2008). Furthermore, computer analysis of fECG is 100% reproducible and can include parameters difficult to evaluate visually, something especially important if we consider reports associating over 50% of intrapartum deaths with CTG use and interpretation (CESDI 7th Annual Report - CTG Education Survey, 2000).

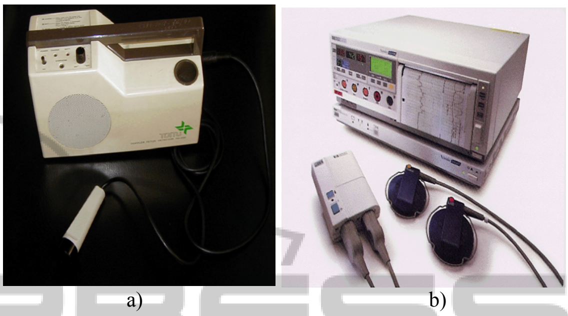

a) b)

Figure 1: Traditional methods for Fetal heart rate measurements: auscultation, Doppler ultrasound (a), and cardiotocography (b).

1.2 Sensing Devices Heterogeneity

The aforementioned heterogeneity found on remote fetus monitoring poses several challenges, concerning:

- The monitoring device technology
- The communication technology, from traditional cabling systems connecting devices to printers on hospitals, up to wireless technology that can transmit signals to the other side of the planet
- The technology for processing the biosignals
- Integration of equipment from different vendors into an integrated platform.

Besides sensing diversity, there is also currently significant heterogeneity on available wireless technologies for sensors, from celular comunications on mobile phones, to WiFi or Bluetooth on mobile devices, or WiMax.

Under the scope of the HMSP project, our proposed solution was integrated with current commercial software: Omniview-SisPorto, which is employed for monitoring in-loco the patients. This tool uses a proprietary algorithm for detecting fetus abnormalities. A new methodoly developed at Harvard, denoted multi-scale entropy, was also evaluated. Yet another goal was the upgrade of a portable ECG device, from DynaDx, to support wireless, continuous communications (previously, the device stored 24h of data, to be posteriorly downloaded at a clinical facility). This portable device also uses its own propeietary technology for the descrimination of the fetus ECG signal from the mixed pregnant/fetus biosignal.

1.3 Data Security

Respecting users' privacy is a critical concern for mobile sensing system (Lane et al., 2010; Zhang et al., 2010). People are sensitive about how their data is captured and used, especially if it contains their location (Lane et al., 2010), speech (Lu et al., 2009), sensitive images (Lane et al., 2010), or personal records such as private health information. Interestingly, social network application's users may take privacy as a less relevant concern (Miluzzo et al., 2008).

Collected data may inadvertently reveal information about people. For instance, a connection between mobile sensors and observed parties may be implicit in their users' relationships (Abdelzaher et al., 2007). Revealing personal data can risk privacy and sharing community gathered data can reveal information on community behaviours (Zhang et al., 2010).

Countermeasures such as pausing the collection of sensor data, are not suitable as they may cause a noticeable gap in the sensing data stream (Lane et al., 2010). Revealing too much context can potentially compromise anonymity and location privacy. Conversely, the inability to associate data with its source can lead to the loss of context, reducing the system's ability to generate useful information (Abdelzaher et al., 2007). Some relevant security concerns for fECG are as follows:

- Privacy: Protection involves different variables, including identity (who wants data access), granularity (level of data revealed), and time (retention time of data) (Zhang et al., 2010).
- Authentication: Deals with validating the user to the system. The sheer amount of users in mobile sensing systems might pose impediments to cryptographic authentication. Nonetheless, there is the possibility of relying in the redundancy of sensor data to validate a source anonymously (Abdelzaher et al., 2007).
- User control: Control over data sharing allows users to define their participation in the system, empowering the decision making process (Zhang et al., 2010). One approach is keeping sensitive relations from being exposed, either by local filtering or by providing users with an interface to review data before it is released (Abdelzaher et al., 2007). In (Lu et al., 2009), the user has complete control in how information is presented in the different system interfaces.
- Anonymization: Before data release and processing, different algorithms may be applied with the objective of not revealing the user identity (Zhang et al., 2010). In personal sensing, a solution is processing data locally (Lane et al., 2010; Lu et al., 2009). In the context of community sensing, there is the risk of leaking personal and community information. A solution is for privacy to be based on group membership. Sensitive information is only shared within the groups in which users have existing trust relationships (Campbell et al., 2008; Miluzzo et al., 2008).
- Trust: Ensuring both data sources are valid and that information is accurate should be a system concern. In addition, correct system usage should be promoted to prevent abuses. Data correctness must be verified without violating privacy (Abdelzaher et al., 2007). In opportunistic sensing schemes user trust may become a barrier to wide-scale adoption (Campbell et al., 2008). These issues may be addressed by providing sensing device users with a notion of anonymity through k-anonymous tasking (Campbell et al., 2008).

Mobile health (mHealth) security has recently gathered significant attention. New attack and defense models surged (e.g. unauthorized origin crossing). Zapata et al. (2014) analyzed with respect to security issues a total of 24 free mobile personal health records applications for Android and iOS. MedApp (Lomotey & Deters, 2014) explores privacy and security options for the accessibility of the medical data records in mHealth, enhancing privacy through the implementation of authentication policies.

This paper presents a new non-invasive portable alternative system that allows long-term pregnancy surveillance. The designed system architecture will be thoroughly described, as well as the developed platforms. Connectivity between health sensors and a healthcare provider over heterogeneous wireless networks, making use of any available access network technology, was addressed. In order to ensure always-on connectivity, our system also allows the usage of mobile devices (such as a mobile phone or a tablet) as a bridge between the portable device and the healthcare provider.

2 FETUS HEALTH SENSING

A low-cost, ambulatory device will allow fetal monitoring to be performed at home or in outpatient clinics during pregnancy (Crowe, Harrison, & Hayes-Gill, 1995; Graatsma et al., 2009; Karvounis et al., 2010). In order to provide this kind of solution, efficient wireless transmission techniques were investigated to enhance the clinical utility of the signal processing technology. The portable monitoring device brings the additional requirement of internet connectivity, i.e., transmitting FHR information, and warnings in case of pathological dynamics detection, from the sensor device to a healthcare expert at a clinic.

Due to the fetus proximity to the monitoring device, communications power should be kept to a minimum for safety reasons (Gandhi et al., 2012). Information from the recording device will thus be first relayed through the mobile device employing low-power wireless technologies for body area networks like Bluetooth, or through USB cable. The mobile device therefore acts as an edge gateway, connecting to the healthcare provider through any of the available wireless technologies at a specific location, such as mobile cellular technologies (supporting various generation mobile technologies), as well as through WiFi (IEEE 802.11 technology).

In cases where the pregnant woman has internet connectivity available, our system also supports direct connection to the internet without bridging through the mobile device. These capabilities are currently unmatched by any other fECG sensing device currently available on the market.

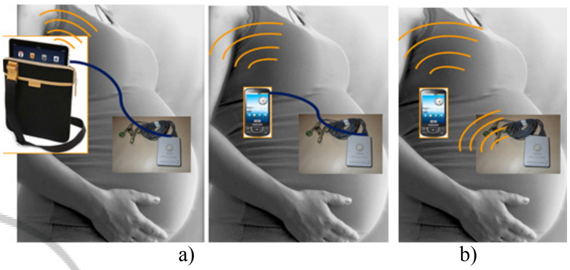
Another challenge to be tackled is energy consumption, since communications can consume a significant percentage of a portable device power. Energy is a scarce resource on these portable devices and this constraint can directly affect a pregnant woman's mobility.

2.1 Use-cases

Current EFM methods still constrain the patient and thus are not suitable for long-term monitoring. Our solution allows continuous monitoring of the fetus throughout pregnancy and antepartum. In fact, using a low-cost fECG sensing device (appropriately connected to a mobile phone or a tablet, or directly to the internet), all the data registered will be reliably transferred to a remote server.

We consider several usage scenarios. Figure 2 presents two of them:

1) USB Tablet/ Mobile Phone: the sensing device is connected to a tablet or mobile phone using a USB cable (Figure 2a);
2) Bluetooth Mobile Phone: the sensing device transmits the data to a mobile phone or a tablet using Bluetooth technology (Figure 2b).



a) b)

Figure 2: Use-cases including the sensing device and the mobile device components.

The major advantage of this solution is mobility. Featuring an always-on connection, the fetal beat-to-beat data will be available to the health care provider in quasi-real time, since we have to consider the raw data must be processed using CPU expensive data processing algorithms. Furthermore, the mobile device is provided with an interface that monitors GPS location of the patient and allows exchange of alerts between the patient and health care provider. Both can visualize the data collected by the sensing device using commercial software Omniview-SisPorto, or using a new software created under this project that provides the user an Omniview-like User Interface on the mobile device.

3 WIRELESS BIOSENSORS

Applications that offer good reliability and user experience without significantly altering the lifetime of the sensing devices should be offered (Miluzzo et al., 2008). Some sensors use a varying amount of power depending on external factors. Lack of sensor control limits the management of energy consumption (Lane et al., 2010).

A real time sensing system should usually supply sensor data at high rates. However, such an approach yields high-energy costs. Mobile data upload can consume a large amount of energy, especially when the sensing device is far from base stations (Miluzzo et al., 2008).

The DynaDx device was used to acquire the fetus ECG. Initially the data was stored in the device's internal memory. After the acquisition period ended, it was then possible to extract this information at a medical provider. This approach is common in other

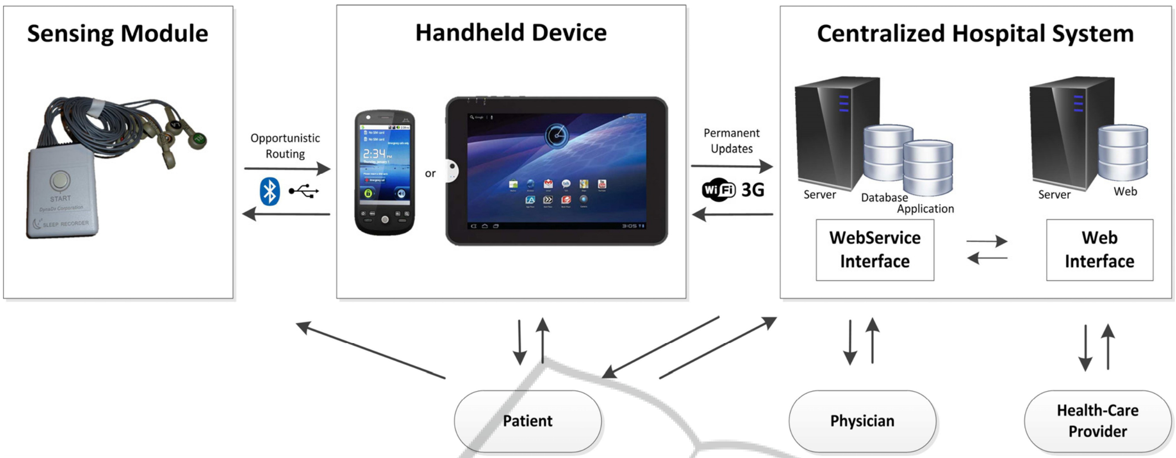


Figure 4: System Components.

marketplace solutions.

To overcome this limitation, the device in this project was integrated in a first version with a wireless communication capable Bluetooth Arduino pro-mini module, allowing the wireless transmission of stored signals to a mobile phone or a server on a delivery room. The Arduino program was responsible for reading data from the sensor and sending it, as well as for receiving reading commands and trigger the start of sensor readings.

A second version of the device was created afterwards enabling the realtime communication of these signals (see Figure 3). The integration consisted in connecting the DynaDx device to a MAX232 circuit board, which converted the RS232 signal to a Transistor-Transistor Logic (TTL) signal. This board was connected to an Arduino processing unit, which communicates through a Bluetooth shield, enabling the device to receive and transmit. The system is compact, portable, and solely requires an additional AAA battery, summing to a total of two AAA batteries per device. All the electronics fits within the original sensor case.

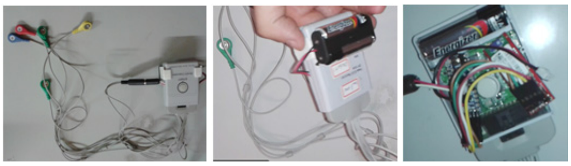


Figure 3: The upgraded DynaDX ECG sensing device for continuous, wireless transmission.

Hence, a system for wirelessly acquiring fECG signals was developed, as shown in Figure 4. In this system a sensing device carried by a pregnant woman acquires fetus biosignal data in real-time and transmits it to a custom hardware module. This module is capable of offloading data through a Bluetooth communication interface. Possible receivers are any such devices that can communicate in the aforementioned communication protocol. In the developed system these devices can either be a mobile device running an Android application or a machine running the Omniview-SisPorto software client. The mobile device is also capable of communicating the acquired data wirelessly in an opportunistic fashion to a back-end middleware (also developed under this project), in order to save energy and to retransmit data after lacking connectivity.

4 ARCHITECTURE

The architecture for remote fetus health monitoring comprises two main set of devices (see Figure 5): sensing modules and handheld devices, which can be mobile phones or tablets. The mobile device collects sensor data, being responsible for permanent updates to a centralized hospital system. The webserver receives and stores the raw data, processes it and makes it available for both the patient and health care provider sites, offering user interfaces to properly display the data. Furthermore, users (patients and health professionals) can also use the web interface at any given time to visualize the data, with no location restrictions.

This monitoring solution aims to target a large number of pregnant women, which is feasible given the conditions it offers, namely: low cost sensing device, handheld device and cellular technologies common in developed countries, low restrictions in mobility of the pregnant women associated with the sensing device. Furthermore, a network comprising pregnant women, physicians and other health care providers can be established on the solution social web application. All the gathered information is securely integrated and made available between strictly defined subjects.

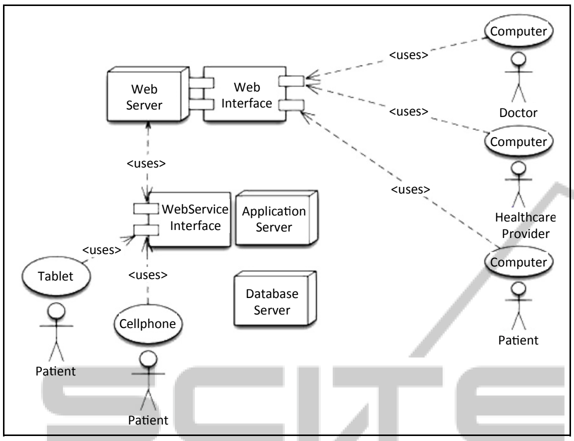


Figure 5: System Architecture.

Considering the two aforementioned use-cases, as well as the customized monitoring system developed, different methods of communication can be considered (Figure 6). Either the sensor is directly connected to the back-end (BE) platform, or it communicates with the monitoring device (MD), which then communicates with the BE. Communications are established by USB (the arrows in Figure 6) or wirelessly, by WiFi or Bluetooth technologies.

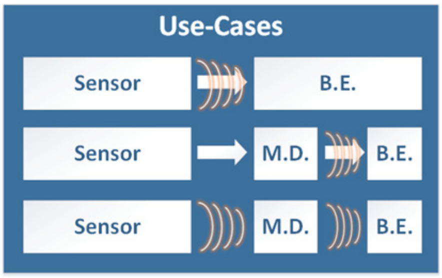


Figure 6: Communication scenarios' use-cases.

4.1 Mobile Application Architecture

A mobile application (MA) was designed complying with the system requirements (see Figure 7). The first step in using the system is registration. From the end-user point of view, only the unique pair username-password (login data) is relevant. However transparent to the user, there are two additional authentication levels, related to the handheld device in use and the communication protocol with the backend (BE) platform.

Each handheld device (either a tablet or a mobile phone) has an unique identity, which is recognized by systems and allows improved security: only registered devices are able to exchange information with the BE platform. Upon enrolling in trial with this platform, the user is provided with a pair username-password and associated with the handheld device identity in the BE. The personal data included also refers name, age, gestation time and associated doctor, together with relevant characteristics to the health care provider.

The second level of authentication is transparent to the user and is renewed each time the application is started. The first interaction between the end-user and the MA is authentication using the login data. This pair is tested using a webservice and, in case of success, returns a cookie to be used throughout the session, i.e., until the program is closed and login verification is required again. This cookie is associated with each webservice based request used in the application, to ensure the identification of the request source by the BE.

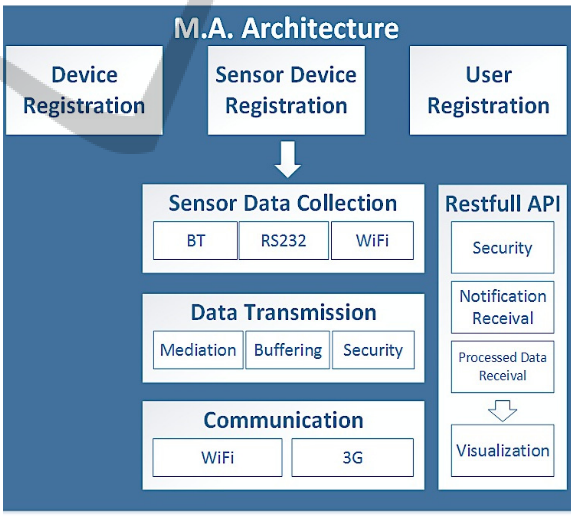


Figure 7: Main application architecture.

The next step is the selection of the monitoring device. With this goal in mind, the mobile application was built in a modular manner, so that sensing devices can be exchanged. In fact, the temporary databases associate a parameter "type" with the data, which makes it easier to increment the available options. The possibilities are nearly endless. For instance, if the new version of the current sensing device includes uterine contractions measurement, the upgrade for this new feature will be trivial. On the other hand, the connection type between the sensing and the mobile devices can be extended as well, with limitations that can only include available hardware. For options besides RS232 and Bluetooth, exposure security cautions must be of course kept in mind (Gandhi et al., 2012).

Upon authentication, the device connection starts several actions besides opening the main menu. To simplify the user experience, all the collecting and uploading of data is transparent to the user, which means the user only has to start the connection to the device by clicking an option and the entire data gathering and upload processes are done in background services. The GPS monitoring is independent of the sensing device, since it is only based on the handheld device, and is transparent to the user as well. All the data exchanged between the mobile application and the webserver is encrypted using a security certificate created for this system, to ensure the privacy of all the participants.

The data collected from the sensing device and internal mobile phone GPS is temporarily saved in local databases. This method ensures that no information is lost. The MA is built to choose a WiFi connection if present, but use 3G if the first is not available. If there is no internet connection in any given moment, the data is buffered on the mobile application until a connection is available and uploads are re-established.

Besides security, the Restful API has two additional modules: notification and processed data reception, which in turn allow for data visualization. Notification reception refers to the exchange of private messages between the associated members of the network, for instance patient and physician. Whenever a new message is received, the mobile application generates a user alert, which remains visible until the message is read. This feature is relevant namely for recommendations from the physician or health care provider, as well as doubts from the patient.

Also concerning the Restful API is the visualization of data plots. This is relevant for evaluating the patient's condition at any given time. If the user is a physician or health care provider, one can choose the desired patient and data. There are relevant options included before visualizing the data plot, namely type of data and time span wanted. By default, current time is selected, which results in quasi-real time monitoring. Acknowledging the mobile application uploads raw data, which is then processed by the webserver and sent back to the MA, then a delay of some seconds is expected and is tolerable by physicians. Current CTG methods carry a delay of some seconds as well.

In order to perform the assigned tasks, a MA was developed for Android mobile devices, including both tablets and mobile phones. Keeping in mind always-on monitoring and user friendliness, some user options were agreed upfront to be present in the main menu. The end-user might be a patient or a healthcare provider, and the menu will present accordingly. The first snapshot in Figure 8 shows the main options for a patient verifying device and internet connectivity, visualizing plotted data, using the web interface to access a restricted social network, exchanging alerts and updated user information. The other snapshot shows the options menu for configuring the visualization of the plotted data.

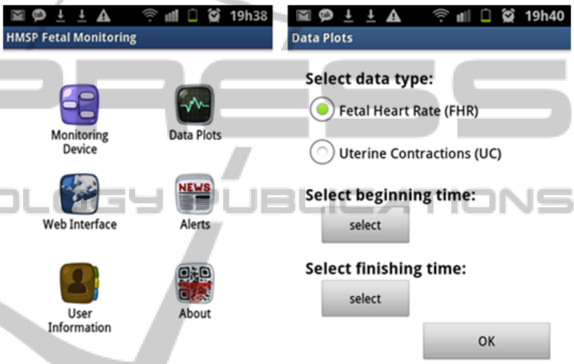


Figure 8: Snapshots of Android Mobile Application Graphical User Interface (GUI).

4.2 Backend Architecture

The backend architecture (as shown in Figure 9) is constituted by the following modules: "Sensor Data Collection", the "Transmission", "Display" and RESTful API.

The "Sensor Data Collection" module is responsible for acquiring system input. It supports different input sources, such as the DynaDx device. The communication of this input is performed with information security concerns: the confidentially of the transmitted data, supported by users authentication; the integrity of the backend data, made possible by the underlying authorisation system that assigns a profile to a given user upon registration. It is also assured the mutual authentication of the backend and its users.

The "Transmission" module accounts for the communication of processed data (graphs and notifications) to the system's client (the MA). Notifications result from the complexity analysis of the pre-processed acquired signal that is performed by Omniview-SisPorto using MultiScale Entropy

(MSE) technology developed by Harvard team. Graphs are built for the visualization of the time series that results from the acquisition of the pre-processed sensed signal. Both these data types can be requested by a mobile device through the RESTful API.

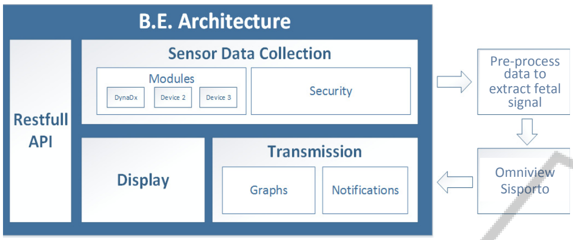


Figure 9: Backend architecture.

The ”Display” module is capable the different types of data that compose the system (namely the sensed signal graphs and associated notifications). The web application framework ”Lift” is used to display this information. More specifically, Lift’s Flot plugin is responsbile for displaying the graphs.

The ”RESTful API” module establishes a uniform communication interface for the system. Communication is achieved through the use of a RESTful webservice-based interface. A webservice based approach tackles issues of system universality, as it allows different types of devices to access the system, providing flexibility in terms of programming languages (Kansal, Goraczko & Zhao, 2007). This module defines a standard system API that is composed by a set of services that are made available.

The exposed services are as follows:

1) Authentication (Login; Logout);
2) Notification (Subscribe; Unsubscribe; Submit notification);
3) Plotting (Access data plot);
4) Signal Processing (Request signal pre-processing, Request data loading from the filesystem; Request data offloading to the filesystem);
5) Domain (Access all data entries for a given data domain entity; Access a specific data entry for a domain entity; Access filtered data properties for a given domain entity; Access filtered data properties for a domain entity).

Each of the API’s features is bound to a specific set of one or more HTTP methods. The system is flexible regarding data inputs, i.e. both JSON (Javascript Object Notation) and XML are supported. Furthermore, all CRUD (Create, Read, Update, Delete) functions support data that can be specified in either scalar or vector formats. For instance, it is possible for the client to update either one device or a set of them in the same request. It is also highly extensible, i.e. when a required data type is defined the system’s standard domain RESTful API is immediately made available.

Through this interface mobile clients can offload different kinds of data, such as historical traces of raw sensory data, the output of signal processing at the back-end, or notifications (see Fig. 10). Data is communicated asynchronously and must have an acquisition timestamp assigned by the client. In this approach, a publishing client on the sensing devices phone collects samples and uploads them using the web service interface, after applying data filters and according to network availability.

A client (a patient, a doctor, a healthcare provider, a sensor, or a mobile device) must be authenticated in the system for information to be sent to the backend, so prior registration is required.

5 CONCLUSIONS

An integrated sensing platform was presented. This solution aims at improving the current pregnancy surveillance paradigm, while taking advantage of the recent technologies developments in both mobile devices and communication infrastructures. Mobile device and Web technologies were integrated into this paradigm, constituting a flexible modular platform that could be customised to the application domain’s requirements.

The development of this solution had to address several challenges, since both DynaDX sensor and SisPorto OmniView had already its own communication technologies implemented, and upgrading to a wireless protocol had an impact on these tools workflows.

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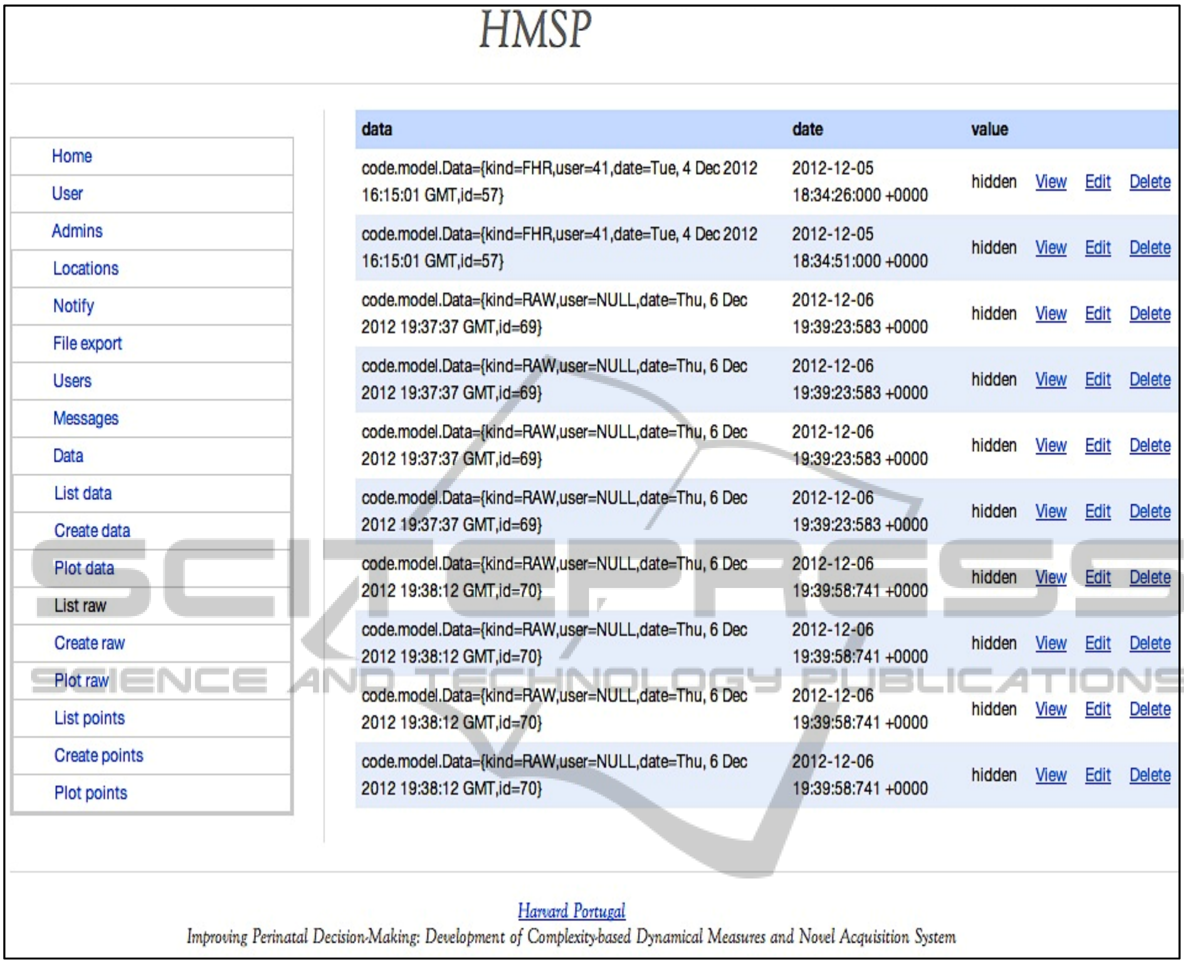

data	date	value
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code.model.Data={kind=FHR,user=41,date=Tue, 4 Dec 2012 16:15:01 GMT,id=57}	2012-12-05 18:34:51:000 +0000	hidden View Edit Delete
code.model.Data={kind=RAW,user=NULL,date=Thu, 6 Dec 2012 19:37:37 GMT,id=69}	2012-12-06 19:39:23:583 +0000	hidden View Edit Delete
code.model.Data={kind=RAW,user=NULL,date=Thu, 6 Dec 2012 19:37:37 GMT,id=69}	2012-12-06 19:39:23:583 +0000	hidden View Edit Delete
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Figure 10: Snapshot of web interface for the backend platform and applications.

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