Automated integration of wireless biosignal collection devices for patient-centred decision-making in point-of-care systems

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The proper acquisition of biosignals data from various biosensor devices and their remote accessibility are still issues that prevent the wide adoption of point-of-care systems in the routine of monitoring chronic patients. This Letter presents an advanced framework for enabling patient monitoring that utilises a cloud computing infrastructure for data management and analysis. The framework introduces also a local mechanism for uniform biosignals collection from wearables and biosignal sensors, and decision support modules, in order to enable prompt and essential decisions. A prototype smartphone application and the related cloud modules have been implemented for demonstrating the value of the proposed framework. Initial results regarding the performance of the system and the effectiveness in data management and decision-making have been quite encouraging.

1. Introduction: The immediate delivery of healthcare and monitoring services, or the so-called point-of-care service, is a key issue for improving the quality of life, especially for the ageing population [1]. Mobile healthcare technologies support a wide range of applications and services including telemedicine, assistive care, location-based medical services, emergency response, independent living and pervasive access to medical data. However, the implementation of mobile data management includes several challenges such as data capture, storage and management (e.g. different devices, various communication protocols, availability and maintenance), interoperability issues, fusion of heterogeneous resources, security and privacy (e.g. permission control, data anonymity), unified and ubiquitous access etc. The trend in modern personal monitoring systems is the utilisation of the cloud computing paradigm [2]. Cloud computing provides the possibility to exploit shared resources and common infrastructure in order to obtain services on-demand and to perform operations that meet the changing user needs. Following this paradigm, an integrated system for health and patient monitoring has been developed, utilising a cloud computing infrastructure for data management and analysis. The proposed solution focuses on the decision support functionality of the system, implemented both within the smartphone application for provisional analysis and also in the cloud.

The rest of this Letter is structured as follows: Section 2 presents related work and discusses background information about cloud computing and biosignals collection, whereas Section 3 presents the adopted approach for biosignals life cycle and data modelling. In Section 4, we present the proposed framework and the corresponding software components, whereas in Section 5 we evaluate the framework in practice and describe the decision-making functionality. Finally, Section 7 concludes this Letter.

2. Related work and background information: Pervasive healthcare information systems for monitoring and assisting chronic patients, elderly and disabled persons have already been acknowledged and well established [3]. The utilisation of captured biosignals is considered essential for understanding the health condition of an individual in such systems [4]. In this context, the reliable acquisition, aggregation and secure transmission of the

biosignals or any kind of medical data to remote computing infrastructures are the major challenges during the establishment of point-of-care systems. The widespread use of mobile devices with significant networking and computing capacity has enabled their utilisation as intermediate or gateway nodes alleviating the need to integrate sophisticated networking technologies in specialised health sensing devices. The three-tier model composed of (i) biosignals sensors, (ii) biosignals aggregators and gateways and (iii) cloud infrastructure allows the efficient use of hardware and communication resources at low costs.

Manufacturers of sensor devices concentrate on the efficient biosignals acquisition, while they use standardised short-range wireless technologies to transmit data. Gateways and aggregators may be implemented using mobile or embedded platforms with an off-the-shelf operating system (OS). A challenging issue though is the compatibility between health devices and gateway nodes. The extensive analysis of biosignals sensor types is beyond the scope of this Letter; however, some key aspects are discussed in order to highlight the diversity in communication methods including means and protocol specifications, data exchange formats, and provide application program interfaces (APIs) for managing the sensors' data.

Biosignal sensors mostly transmit their data using Bluetooth and Universal Serial Bus (USB) interfaces, while the use of mini-jack is also seen for some types of sensors. However, even in the case of Bluetooth, different protocol specifications are available. Sensors or computing devices and receivers implement only a subset of the available versions. The two main versions of Bluetooth communication can be identified as (a) the classic Bluetooth standardised by the Institute of Electrical and Electronics Engineers (IEEE) as 802.15.1 and (b) the Bluetooth low energy (BLE) (or Bluetooth Smart) [5]. BLE, built on Bluetooth version 4.0, is considered a breakthrough allowing for more effective data transmission, lower power consumption and simpler communication processes compared with the classic Bluetooth. The software model of BLE, introduces the concept of generic attribute profile (GATT), which is a generic API for communication with any BLE device. The model proposes also several specific profiles for certain device types and communication purposes such as positioning, healthcare, headset communication [6] etc.

The International Standards Organisation (ISO)/IEEE 11073 standard [7] provides the framework for the connectivity of health devices using wireline (USB) or short-range wireless communication technologies (wireless fidelity, Bluetooth, Zigbee) to gateway devices. Nevertheless, health device manufacturers have integrated short-range wireless connectivity comparatively recently and in practice many still use proprietary protocols to transmit data to the cloud. The Continua Health Alliance has proposed a framework to promote interoperability between ISO/IEEE 11073 and BLE devices. However, the utilisation of particular communication profiles and standards for healthcare purposed is currently limited. On the contrary, the manufacturers commonly use custom and proprietary protocols over GATT for communicating with BLE sensors, or low-level messages for communicating with classic Bluetooth sensors.

The abundance of available devices, where each manufacturer follows different communication specifications and implements non-standardised data formats, introduces immense complexity to the third-party tools and applications intending communication and use of these sensors. In addition, the diverse types of biosignals and the different measuring techniques raise additional challenges to the communication with the sensors and the acquisition and management of biosignals data. For instance, pulse oximeters provide streaming data, while blood pressure monitoring devices deliver single measurement results, and in that sense, the devices connecting to them should provide different probes for acquiring and managing the data.

It is also common that a sensor manufacturer provides particular APIs for communicating with their products, abstracting the access to the Bluetooth components in order to provide better control and communication performance over them. However, the integration of multiple protocols and APIs from manufacturers into the same software such as a smartphone app is not always straightforward due to compatibility issues and aggressive use of device resources.

A variety of system architectures have been presented and various facets of the systems have been evaluated. More specifically, a survey of wireless interconnection protocols is presented in [8] which can be used for common health devices such as blood pressure monitors and pulse oximeters. Santos *et al.* [9] propose an architecture based on IEEE 11073 which utilises ‘personal health managers-patient health information (PHI)’, which operate close to the user and ‘internet health managers’ located on cloud infrastructure and communicate with the PHIs, Bluetooth enabled health sensors (pulse oximeter and electrocardiogram (ECG) modules) are also used for the communication of data to an Android-based device, which then carries out transfers to the server with the message queuing telemetry transport (MQTT) connectivity protocol [10]. The capability of mobile Android devices as gateway devices concerning the resource usage and battery life impact is evaluated in [11]. The findings of this Letter highlight that mobile devices can carry out this role, but battery life can be significantly affected. Finally, home monitoring technologies are evaluated with clinical trials and key performance characteristics and regulation requirements of basic modules in a home health telemonitoring platform have been identified [12]. Authors highlighted the need for better precision of health devices and propose online support by trained specialists to filter and interpret the collected data.

Regarding decision support, there exist several pattern recognition and data classification techniques for biosignals analysis [13–17]. More specifically, there are a variety of classification methodologies ranging from statistical methods such as linear and logistic regression or Bayesian networks to more sophisticated artificial intelligence (AI) techniques such as neural networks and genetic algorithms, or the more recent support vector machines. Additional categories of hybrid AI systems are neuro-fuzzy systems, which comprise of an adaptive fuzzy controller and corresponding predictors. Further information regarding data

Fig. 1 BioAssist platform

classification techniques can be found in [18]. In addition to presenting information, it is strongly desirable to automatically execute commands, or reconfigure the system on behalf of the user according to decision changes. For instance, in case of health condition deterioration the intelligent module should response with alarm triggering and provision of the corresponding context information indicating why the alarm is triggered. Appropriate training and calibration of the AI modules are required in advance.

The baseline for the proposed patient-centred decision-making approach was the homecare and assisted living platform of BioAssist S.A. [<http://www.bioassist.gr>]. The platform (Fig. 1) facilitates the creation of a patient-oriented social and support network of healthcare professionals, relatives and friends, and also provides the framework and the required services for effective communication and management of a wide range of wearable devices and sensors, enabling constant monitoring of the patient's biosignals and activities.

3. Biosignal life cycle and data modelling: To properly design and implement a framework for measuring, managing, storing and analysing biosignals, it is necessary to study first the overall life cycle of a biosignal from the moment that is captured to its permanent storage to a database repository. This life cycle spans across several components of the framework both within the patient's environment and also on the cloud (Fig. 2). The various operations in the patient's side are realised in an application that is in charge of the (a) capturing the biosignals from the various

Fig. 2 Biosignal life cycle

sensors using specific drives that have been implemented for each sensor, (b) aggregating the measurements and transforming them to a common model and format, (c) performing a provisional analysis to evaluate the quality of each measurement and (d) the periodic synchronisation of the measurement data with the cloud platform.

In the proposed framework, we have selected to use only sensors with Bluetooth network interface. The rationale behind this choice is as follows: (a) Bluetooth is available in all modern computing devices, smartphones and tablets, (b) it is easy to use, (c) it does not require additional cables or equipment improving significantly the user experience, and (d) it provides the required performance and capacity for biosignal data management.

On the Cloud side, the platform components perform the heavy-weight operations focusing on (a) the acquisition of biosignals for the apps and/or other external sources, (b) their storage, (c) analysis consolidating multiple parameters, models and real-time and historical biosignal data, and finally (d) reporting and communicating the analysis and decision support results in cases of emergencies to appropriate services and personnel.

One of the main concerns during the design and implementation of the overall system was the use of as a single format and model for all biosignals in order to simplify all operations in the biosignal life cycle and across all platform components. Instead of using a custom approach, the schemata of Open mHealth [19] are exploited. The specific approach not only simplifies the development of the components, but also improves the operational processes and the performance of the platform, which as a result advances the quality of the analysis processes. In addition, the communication with external providers is also standardised, in that sense allowing for smooth integration with their systems based on a common message structure and vocabularies.

4. Biosignals acquisition and management framework: The proposed framework covers the complete life cycle of a biosignal, from its measurement using a sensor to its analysis and storage in a Cloud environment, focusing on the use of standards in order to achieve the highest possible compatibility with other systems and extensibility for the integration of future biosignals and analysis

tools. The framework (Fig. 3) consists of two main elements: (a) a smartphone application for the communication with the biosignal sensors and the initial evaluation of the data and (b) a cloud-based platform for storing and analysing the biosignal data, while communicating with external services when identifying abnormal situations or emergencies is also available.

The prototype smartphone application uses the Android environment and requires devices with KitKat (API 19) and above, which natively supports BLE. The application has been designed and developed so as to allow the communication with multiple biosignal devices, and to support additional devices with the minimum changes. Conceptually, this was realised by implementing three main *services* that performed the communication with the devices using (a) BLE, (b) classic Bluetooth for the paired sensors, and (c) manufacturers proprietary APIs for other sensors (i.e. smartwatches). In the cases of BLE and paired sensors, appropriate drivers have been created which executed the various communication operations with the sensors, whereas for the smartwatches, API libraries from the manufacturers have been used.

The *drivers* approach allowed for a generic design concerning the BLE and classic Bluetooth services, and each driver was implemented following the communication protocol of each manufacturer for exchanging messages and acquiring biosignal data from the sensor. Particularly, each driver was able to perform operations for: (a) communication initialisation, (b) pre-measurement setup, (c) processing of measurement data, and (d) post-measurement and termination.

The measurement process is controlled by the services of each communication type, which scans for available sensors, load the appropriate drivers and relay the measurement results to the *Biosignals Subsystem*. In addition, the sensor drivers' and the services that control them are designed to support the different measurement method of each sensor. The system can effectively communicate with sensors that provide either a single measurement result such as blood pressure monitors, and glucometers, or streaming real-time data from sensors such as the pulse oximeters, and aggregate properly the biosignal data. It should be noted that in the case of streaming biosignals, the measurement periodicity might also considerably vary from a few milliseconds (e.g. ECG data)

Fig. 3 Conceptual architecture

to seconds and minutes (e.g. body temperature sensors and blood pressure holders). This fact introduces additional complexity for the aggregation, management, and analysis of the data.

Core element of the smartphone application is the *Biosignals Subsystem*, which consists of the *Aggregator*, *Manager*, *Provisional Analyser*, and *Synchroniser* components. Following the biosignal life cycle, each measurement result and stream captured by the driver is relayed to the Biosignals Subsystem and particularly to the Aggregator component.

The role of *Aggregator* is to combine the different biosignal types and transform the raw data from sensors into a structured document that represents single or multiple measurements and follows certain formats and specifications. These documents are used for all the following operations in the biosignals' life cycle and across all platform systems and components. In addition, the measurement documents are fused with additional information for the particular user, the sensor, timestamps, other metadata that can be valuable for the analysis and evaluation.

The *Provisional Analysis* component is a rule-based single signal decision support tool with the objective to perform an initial evaluation of the quality of each measurement. This component is configured with generic rules for each device type in order to inform the system and the patient if the latest measurement(s) should be considered acceptable or if the measurement process should be repeated. Examples of such rules refer to indication of blood pressure measurement for loose cuff or the jitter in the streaming data of a pulse oximeter. Especially for the oximeter, due to its limitations as sensor [20], analysis of measured pulse and oxygen saturation (SpO₂) signals is performed using the cumulative sum methodology to filter the unreliable data. In addition, personalised rules can be set, which are comprised of thresholds for measurements results that potentially indicate uncertain biosignal values. These rules are defined by the medical personnel or the system itself, based on the analysis of the patient's biosignals history on the cloud. In such cases the system may suggest additional measurements before creating events that indicate abnormal situations or emergencies. Detailed rule examples are available in the evaluation section.

The *Manager* and the *Synchroniser* components have, respectively, the roles of coordinating the Biosignals Subsystem and controlling the communication with the cloud platform. Finally, user interface (UI) elements are provided in the application for interacting with the patients and controlling the measurement and communications processes.

The main analysis of the biosignal measurements takes place on the Cloud, where the required computational resources are available and the complete dataset of patients' health records can be accessed. The platform provides *Listener* components for the communication with the biosignal sources and providers. This Letter is focused on the acquisition of biosignals from sensors through the smartphone application; however, other listeners allow for obtaining records from external healthcare providers and public organisations as well as for the manual submission of measurement results. The overall coordination on cloud environment is performed by the *Biosignals Manager* that acquires the data from the listeners and stores them permanently in a database. As part of this process, the biosignals are constantly analysed by the *Analytics and Decision Support* component and any events detected are reported and proper actions are triggered. These actions may vary, from the classification of the patient to a high risk group, to the notification of emergency services if patient's life is at risk. The analysis considers both the real-time and also the historical data in order to identify patterns and trends, patients' activities of daily living (ADLs)/instrumental activities of daily living (IADLs), and ultimately be able to assess patient's health condition. The users are able to access their profile, the historical data of their measurements as well as the analysis results through a web application that was also available as part of the proposed cloud-based solution.

Technically, the internal and external integration points of the platform are implemented as representational state transfer (REST) APIs through which JavaScript Object Notation (JSON) messages are exchanged. To this direction, the data are also persisted in JSON format in document-based data storage systems, which is the case of the proposed platform is MongoDB [21]. For the biosignal data, JSON messages are structured as data points (Fig. 4) based on the respective schema proposed in Open mHealth specification [21].

In addition, APIs for consuming biosignal data from all popular biosignal and activity providers and platforms (e.g. HealthKit and Fitbit) are available simplifying the processes for communicating with them. Therefore, the biosignals and activity data can be effectively manipulated and transformed data into the Open mHealth format, while electronic health records (EHRs) in Health Level 7 (HL7) are also partially supported.

Finally, the specification provides well-defined extension points to the models, as well as templates for creating additional quantitative measurement schemata that are not natively supported yet. In the case of the proposed solution, this was particularly useful for the definition of new models for peripheral capillary oxygen saturation – SpO₂ and photoplethysmogram [22] that are measured by pulse oximeters and are considered as key sensors for the provided decision support operations. Similarly, the headers of the data points have been extended in order to include information to identify the sensor that was source of each measurement, using as identifier the sensors' medium access control (MAC) address. The latter allowed for extensive analysis of the various measurements by correlating information of patients and sensors. To this direction, the decision support system of the platform is able in addition to provide insight on the patients' health condition, to also estimate the sensing reliability and identify potentially malfunctioning sensors based on the rate of invalid measurements [23].

5. Evaluating the framework: The prototype of the proposed implementation has been deployed and instantiated for testing with 30 patients with cardiovascular and chronic obstructive pulmonary diseases equipped with sensors (pulse oximeters and blood pressure monitors) as well as with Pebble smartwatches

```
{
  "header": {
    "id": "123e4567-e89b-12d3-a456-426655440000",
    "creation_date_time": "2013-02-05T07:25:00Z",
    "schema_id": {
      "namespace": "omh",
      "name": "blood-pressure",
      "version": "1.0"
    },
    "user_id": "user1432",
    "sensor_id": "01:23:45:67:89:ab"
  },
  "body": {
    "systolic_blood_pressure": {
      "value": 130,
      "unit": "mmHg"
    },
    "diastolic_blood_pressure": {
      "value": 75,
      "unit": "mmHg"
    },
    "position_during_measurement": "sitting"
  }
}
```

Fig. 4 Open mHealth measurement example [27]

[24], which were used as activity trackers. The patients were using the smartphone application for acquiring biosignals measurements from the sensors, whereas the smartwatches were directly communicating the activity data to the listeners of the cloud platform.

The smartphone application of each patient has been pre-configured with the required drivers for the sensors used, as well as with specific rules for the provisional analysis component. The rules of the experimentation setup were as follows:

- (a) *Pulse oximeter valid measurement*: This rule determines that the measurement values for heart rate, and most importantly for SpO₂, are stable before their permanent storage, so as to avoid inaccurate measurements due to the misplacement of the sensor on the patient's finger. The system informs the users to continue the measurement process until a measurement is characterised as valid.
- (b) *Blood pressure valid measurement*: This rule examines the measurement data from the sensor regarding (i) body movement, (ii) cuff too loose and (iii) irregular pulse, and in case any of these flags are true, asks the user to repeat the measurement process.

- (c) *System thresholds*: The system thresholds were automatically set by the platform through analysis of the previous measurements on the cloud to indicate the expected normal measurement values.
- (d) *Medical experts' thresholds*: Patients' doctors are also able to define boundaries for the measurement results beyond which, the measurement should be repeated to ensure its accuracy.

The provisional analysis component takes into consideration only single signal, real-time data. On the contrary, the analytics and decision support component that is running on the cloud examines both real-time and historical data of multiple types. The analysis focuses on the following aspects:

- (a) Comparison of the recent measurement with the historical data of the patient for the particular day of the week and hour of the day.
- (b) Multi-signal analysis correlating the recent and streaming measurements with other biosignal measurements (e.g. high blood pressure with low SpO₂) as well as data from the patient activities monitored through the smartwatch. The specific functionality can be used for finding correlation or predicting independent variables using statistic (i.e. regression) or AI techniques (i.e. neural networks).

Fig. 5 Decision-making flowchart

- (c) Analysis of the signal using contextual information of the user such as location, weather conditions, taking into account that there is a correlation of weather conditions with vital signs [25, 26].
- (d) Fusion of the biosignal data with information about an ongoing medical treatment allowing the decision support system to quantify the effect of the medication to the patient's vital signs.
- (e) Identification of invalid measurements for the smartwatch such as no activity due to the fact that the smartwatch was not equipped or it runs out of battery.
- (f) Identification of malfunctioning sensors comparing each sensor's data with patient's data from other sensors.

The result of the decision support components, both in the smartphone application and on the cloud, produce a series of events indicating the (ab)normal state for the patient's health condition, the system and the sensors. On the basis of these events, the experimental prototype supports a *360° view of the patient* including: (a) repetition of the measurement process with the same or different sensor, (b) modification of the measurement timeplan of each patient for more/less often measurements, (c) notifications to the appropriate actors, based on the importance of the event, to deal with the patient emergency situation (e.g. to emergency services, to relatives or to the patient's doctors for updating the medical treatment).

The overall decision-making process is presented in Fig. 5. Initially, the sensor measurements are evaluated before their synchronisation with the core platform components on the cloud. In our experimental setup, the provisional analysis indicated several cases of invalid biosignal values for which the measurement should be repeated. A significant percentage (above 15%) of device measurements were considered invalid and the data were ignored. It should be noted that 80% of the invalid measurement data referred to the data acquired during the first 10 s after placing the oximeter on patient's finger. Similarly, 30% of blood pressure measurement results showed strong body movement during the process notifying the patients to repeat the process. The framework has been also tested with system thresholds that indicated potentially invalid measurements if the deviation of the measurement result was more than 20% from the average measurements of the patient during the last week.

On the cloud, the initial step before the analysis and decision support on the biosignal data from the recent measurement were the consolidation of data from previous measurements, external sources (e.g. weather), smartwatches, and the expected biosignal values based patient's ongoing medical treatment. The cases for detection of emergencies and medical treatment updates were only tested using artificially generated measurements as a proof of concept for this functionality. The findings, however, on the other cases were very interesting. Initially the system was able to effectively identify a malfunctioning oximeter that always indicated about 10% lower values, when it was also used by another patient. Furthermore, the system notified the patients who were recently measured with increased pulse rates (>100 bpm) using oximeters, to also measure their blood pressure.

Regarding the evaluation of the framework for decision-making on the cloud, an experiment concerning the identification of the user's activity is conducted. Five users participated in this experiment. Users have been asked to use the motion sensor (smartwatch) and a pulse oximeter in order to collect data performing all three kinds of motions. More specifically the dataset has been built on 20 min of jogging and fast walking, 30 min of walking and 60 min of doing low activity. The smartwatch and the oximeter transmitted the data and the user defined the corresponding motion type during his exercise in an accompanying application running on a tablet or smartphone. Subsequently, after the data collection the decision model was built on the cloud. A number of different classifiers have been evaluated using the motion (smartwatch accelerometer) and pulse oximeter (oxygen saturation and heart rate) data. The

Table 1 Activity classifiers evaluation results

Classifier	Accuracy, %
naive Bayes	93
support vector machines	89
decision tree (J48)	78
regression	81
neural networks	91

Table 2 Accuracy per class/activity type

Activity type			Total accuracy: 93%
High	Moderate	Low	Accuracy per class
194	10	—	95.10%
21	271	14	88.56%
2	28	582	95.10%

features utilised for the construction of the classification models are the acceleration changes in the *X*, *Y* and *Z* axes, measured by the smartwatch, and the oxygen saturation and heartbeat rate (captured every 10 s). In our experiment we have examined three classes, which were: namely, jogging and fast walking (high activity), walking (moderate activity) and sitting or lying (low activity). The original dataset has been divided into a training set that contains the 66% of data and a test set containing the rest 34%. The corresponding results are provided in Table 1. The ability to train the classifier on the cloud provides a great benefit for the expandability and customisation of the system. This means that in case new users are added, a customised model can be easily developed on demand maximising the classification accuracy.

In addition, Table 2 illustrates the confusion matrix and the accuracy per class/activity type of the best classifier (naive Bayes).

6. Conclusion: In this Letter, we present an advanced framework for biosignals aggregation and processing aiming at efficient patient monitoring at home environments. The main contributions of the framework are the standardisation of biosignals collection and the introduction of local and cloud decision support modules in order to enable prompt and online point-of-care decisions. The conducted experiments have proven the usefulness of the proposed framework. Nevertheless, the extension of the framework may be continued in order to include additional biosignals sensors and decision support modules, both in the smartphone application for preliminary analysis and also on the cloud.

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