Open Wearables Mobile Platform to Support Personalized Medicine*

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***Abstract*— A clinically useful system for individual continuous health data monitoring needs an architecture that takes into account all relevant medical and technical conditions. The requirements for a health app to support such a system are collected, and a vendor-independent architecture is designed that allows the collection of vital data from arbitrary wearables using a smartphone. A prototypical implementation for the main scenario shows the feasibility of the approach.**

I. Introduction

Personalized medicine is a new medical paradigm that customizes medical decisions, practices, or interventions to the individual patient, based on their predicted response. The development of such a personalized model can be supported by the continuous collection of health data, not only inside the hospital premises but also in their daily lives.

Different kinds of wearables can be used in a comfortable and almost transparent way close to the body, like watches, chest-bands, or bed strips. They can gather several health-relevant parameters, like activity and movement, temperature, heart rate, electrocardiogram, breathing rate, sleep profile, etc. While indications of the medical potential of unspecific health monitoring exist, they are not yet fully evaluated [1]. Nevertheless, the increasing spread of the use of those wearables among patients leads to a self-assessment tendency and to a new type of corresponding medical consultations. There are integrated solutions for specific vital parameters available for medical cases such as cardiac monitoring [2] or activity data during chemoradiotherapy [3]. Big data analysis and machine learning can be used to understand the patterns of vital data parameters and diseases. A large-scale evaluation in the real clinical environment is required to prove medical evidence and enable a systematic approach. This needs an appropriate and freely adoptable platform for data handling, combining flexible and case-specific sensor composition with medical data interpretation in a clinical caregiving environment. These additional data can be used to complement the current making of diagnosis, therapy planning, monitoring of the patient's condition as well as clinical evaluation and research.

The realization of such a solution is the goal of the bwHealthApp project, firstly addressed in [4], in which a telemedicine system for personalized medicine is developed. As already mentioned in [4], the aim of this project is the establishment of an open and integrative IT platform consisting of a central server and a wearable mobile platform for body area networks (BAN). The system enables individual configuration for BAN for eligible medical use cases using arbitrary commercially available wearables. This paper presents the requirements analysis and architecture of the decentralized gateway of the system as well as first experiences with a prototype.

II. Methods

Using established software engineering approaches [5], use cases and scenarios of applications of the wearable mobile platform were developed and then generalized to a system architecture. The proof-of-concept has been tested with a first prototype. Medical partners of this project are the Center for Personalized Medicine (CPM) and the Clinic of Internal Medicine of the university hospital of Tübingen (UKT), Germany. The principal showcase underlying this work is the monitoring of patients undergoing chemotherapy treatment in medical oncological daycare units of the Clinic of Internal Medicine at UKT.

Use case scenarios were selected and analyzed through interviews and workshops with the stakeholders from CPM. Important non-functional criteria for changeability, extendibility, configurability and flexibility are considered. From these scenarios, functional and quality requirements were defined, as well as boundary conditions specified. As a result of the requirements analysis phase, the global system architecture and interfaces among the different components were defined. The feasibility of the approach has been proofed with a functional prototype via system tests.

III. Results

A. Use cases scenarios

Previous to the usage of the system, the attending physician needs to register the patient in the server, authenticate him or her, install the app on the smartphone and configure the vital parameter to be monitored, including the sample rate, data aggregation and synchronization schedule. They may also provide data entry forms to request PROs in structured and reproducible questionnaires. The configuration for the patient is stored in the server and transferred to the smartphone.

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The selected vital parameters are based on a catalog covering health care parameter standards such as the generic attribute profile (GATT) characteristics of Bluetooth Low Energy (BLE), a widespread protocol for fitness and medical wearables. The BAN gateway should be modular to extend to future BLE profiles or other wireless protocols like Zigbee, etc. If there is no medical need for uniform devices, the patients can select the wearable to use, assuming they provide the configured data.

The app saves the raw data received from the wearables. These can also be interpreted, visualized, and synchronized with the server. For questionnaires or reminders of single measurements, the patient will be notified by the app. Further needed functionalities refer to handling broken connections, error feedback, and data synchronization with the central server.

B. *Influential factors and boundary conditions*

Several influential factors and boundary conditions for the development and operation of the system have been identified. They include performance, battery lifetime, memory, network connectivity, operating systems and databases both on the smartphone and the server, as well as middleware and communication servers between the systems, existing libraries, frameworks and decision support systems, among others.

C. *System architecture*

The bwHealthApp consists of wearable devices, the smartphone application (health app), a gateway for the connection between client and server as well as the controller with access to subsystems and databases such as user management, clinical evaluation and administration. In this paper, the client-side of the system will be described.

Client-side

Wearables are external systems including one or more sensors to record relevant information from the patients or their environment. They group together forming a BAN under the control of the app that acts as an integration system with modules for user authentication and interaction, sensor management and data connectivity to the server.

The first architectural layer connecting the wearables and the app is the connection controller, which scans external devices and reads, writes or streams data. It runs as a background service. The recorded data is passed through a data manager to a data processor and interpreter, where it is converted or aggregated by a specific data descriptor. Conditioned data is persisted in the app storage according to the configured synchronization scheme. The app storage is also synchronized with the central server database. The data manager initiates the data transfer to the gateway of the clinical server, ensuring authentication and data security. Data, system state and configuration of the app can be visualized in specific graphical user interfaces (GUI), where also manual and event data can be captured and persisted.

D. *Functionality of the wearables and smartphone application*

The main usage of the health app is the individual recording of bio vital and environment data of the patient via sensors. The app implements the corresponding client-side protocol for BLE: it controls the wearable connection, handles these data flows and therefore needs permissions for Bluetooth, localization and temporary data storage. The raw sensor data is interpreted according to the UUID of the GATT characteristic. Therefore, interpretation logic for each supported UUID is provided as a configurable data descriptor. Manual health and event tracking data entries are supported to acquire patient-reported outcomes (PRO). The synchronized data is visualized on the GUI. Event issues, messages and alarms are displayed on the smartphone. The continuous collection of health data is independent of the number and type of used wearable devices and forms. The initial registration via international mobile subscriber identity (IMSI) makes the data associable. For the centralized management within the clinical infrastructure, all data is transferred to the gateway via specific FHIR service contracts.

E. *Prototype of the bwHealthApp*

The first prototype was developed for the android operating system (OS). The goals of the implementation were to examine if the architecture is flexible with respect to variations in the selected devices' sensors and parameters and if the recording of wearable data based on flexible sensor combinations and configurations is feasible.

Patient registration, sensor configuration

Patient registration and configuration are performed by the physician on the server. The app is installed on the patient's smartphone, and the configuration is automatically loaded.

Device initialization and measurement

The patient scans for available BLE devices and connects to the ones that he or she wants to use. For each connected device, the app checks if the configured characteristics are available. If multiple devices offer the same characteristic, all of them are measured. If one required characteristic is missing, it is notified. Notifications for the patient for user inputs are configured.

Data collection

Raw, hex values corresponding to each characteristic are interpreted on the smartphone. Data from different characteristic UUID have different formats; therefore the data processor and interpreter implement data conversion and aggregation logic separately for each of them. A sample of a simple characteristic can transmit multiple sensor values in varying combinations. In general, the interpreter maps each wearable data (in this case GATT characteristic) to its specific configured value types (data type descriptions).

An example of a compound characteristic is illustrated in Table 1. The heart rate measurement (UUID 0x2A37) of the cosinuss° One[1] sensor always contains the heart rate following by no, one or more RR interval(s). The raw and interpreted values as well as characteristic UUID, data type description ID, device ID, personal ID and timestamp, are buffered in the

[1] https://www.cosinuss.com/products/one/

app storage. The Sync Adapter is called to synchronize the app storage with the database. The vital parameters are presented in a tabular view in the GUI.

TABLE I. RECORDED VALUES FROM THE COSINUSS HEART RATE SENSOR

Sam-ple	Hex value	Value type	Interpre-ted value	Time-stamp
1	00 43	Heart rate	67bpm	2018-11-13 15:07:08.29
2	00 42	Heart rate	66bpm	2018-11-13 15:07:09.29
3	10 42 1F 04 F6 03	Heart rate RR interval RR interval	66bpm 1055ms 1014ms	2018-11-13 15:07:10.29
4	10 42 B 03	Heart rate RR interval	66bpm 891ms	2018-11-13 15:07:11.29
5	10 42 D 03	Heart rate RR interval	66bpm 829ms	2018-11-13 15:07:12.28
6	10 40 85 03	Heart rate RR interval	64bpm 901ms	2018-11-13 15:07:13.28
7	10 40 AE 03	Heart rate RR interval	64bpm 942ms	2018-11-13 15:07:14.29
8	10 41 52 03	Heart rate RR interval	65bpm 850ms	2018-11-13 15:07:15.28
9	10 43 00 03 66 03	Heart rate RR interval RR interval	67bpm 768ms 870ms	2018-11-13 15:07:16.29
10	10 45 D7 03	Heart rate RR interval	69bpm 983ms	2018-11-13 15:07:17.29

Scheduled pop-ups demand the user to enter specific information. For event recording, a GUI module contains buttons to confirm actions (e.g., going to sleep). The user can delete all temporary health data from the smartphone's app storage.

System tests

The functionality of the prototype of the smartphone app was tested on an Acer Iconia One 10 tablet with a combination of one to three simultaneously connected sensors with different acquisition schedules. Each patient device registry and configuration took place on the server-side and was transferred to the smartphone app. Sensors were the cosinuss wearable and self-implemented values for ambient light monitoring and a generic linearly incremented reference value based on the Nordic Semiconductor nRF52832 system on a chip. All seven sensor combinations and sampling schedules ranging from 1s to 120s yielded stable values over 30min. Reconnection was problem-free.

Extensibility

The BLE Toolbox is a web service developed and hosted at Reutlingen University, which allows the simplified creation of BLE profiles, the generation of source code for the profiles and their provision via a REST API for the dynamic configuration of an Android app (GATT client). In a previous work, a new BLE ECG profile was defined at Reutlingen University that is able to stream a one-channel ECG at rates between 550-950 Hz [6] (see Fig. 1) It is possible to provide the profile information of the BLE ECG profile for configuration purposes to GATT clients (e.g. Android App) via the BLE Toolbox. In the next version of the prototype, the interoperability between the BLE Toolbox and the bwHealthApp will be tested on the example of ECG devices.

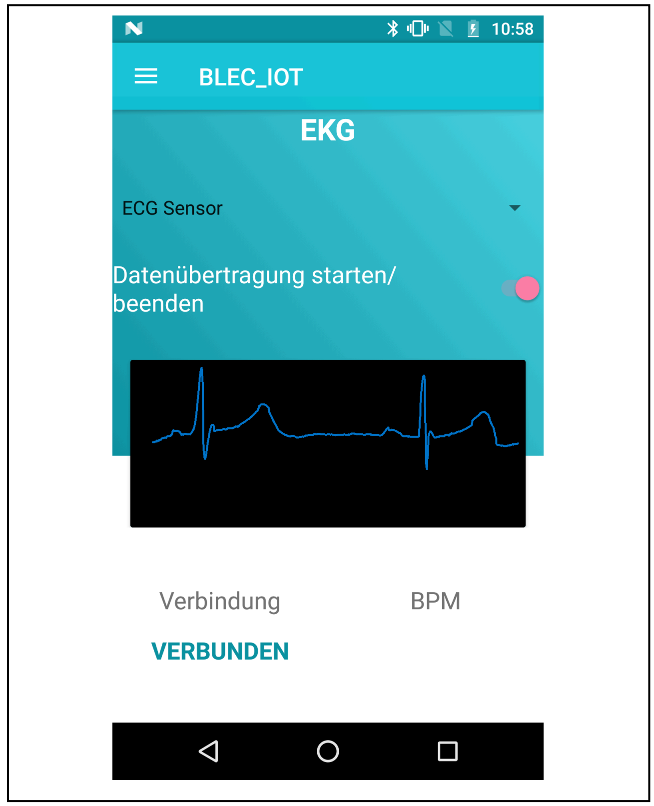

Figure 1. *Example of BLE ECG streaming*

IV. CONCLUSIONS

Clinically approved solutions for specific vital parameters are currently just available for specific medical use cases and diagnosis. The presented approach combines the case-dependent composition of existing wearables with medical data interpretation. The proposed solution is vendor-free and open. The feasibility of the architecture has been demonstrated with a prototype that collects wearable data independently of the used sensors and supported value types. The prototype was functionally evaluated and achieved the designated configurability and flexibility needed for the use cases.

The prototype is currently ready for the evaluation in the clinical environment, where the device handling, user acceptance, connection reliability and data quality will be assessed.

This work shows the comprehensive requirements analysis and architecture design for the bwHealthApp, concentrating on the client-side of the development. A prototype demonstrates the main functionalities. The collected data could support the diagnosis as well as therapy design for personalized medicine. The approach so far concentrated on technical issues of the platform, but it is planned to extend it with new medical, structural, organizational and administrative guidelines, and also to integrate data security and protection mechanisms.

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