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Preface

Information and communication technologies support telemedicine to lower health access barriers and to provide better health care. While the potential in Active Assisted Living (AAL) is increasing, it is difficult to evaluate its benefits for the user, and it requires coordinated actions to launch it. The European Commission's action plan 2012–2020 provides a roadmap to patient empowerment and healthcare, to link up devices and technologies, and to invest in research towards the personalized medicine of the future. As a quickly developing area in medicine, telemonitoring is a demanding field in research and development. Telemonitoring is an essential component of personalized medicine, where health providers can obtain precise information on outcare or chronic patients to improve diagnosis and therapy and also help healthy persons with prevention support. Telemonitoring combines mobile and wearable devices with the personal AAL home environment, a private or (partly) supervised home, most often called 'smart home'. The focus of this workshop is on new hardware and software solutions specifically designed to be applicable in AAL environments to empower patients. This workshop presents system-oriented solutions covering wearable and AAL-embedded devices, computer science infrastructure both at the users' and the medical premises, to handle the data and decision support systems to support diagnose and treatment.

Prof. Dr. Natividad Martínez Madrid
Berlin, July 2019

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Open Wearables Mobile Platform to Support Personalized Medicine*

Denise Junger, Natividad Martínez Madrid, *Member, IEEE*, Nisar P. Malek, Christian Thies

***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.

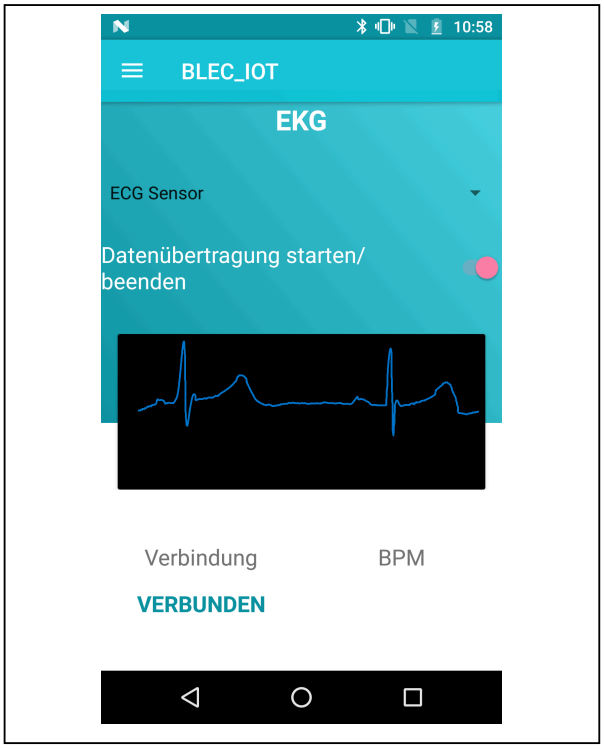

Figure 1. *Example of BLE ECG streaming*

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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Integrated System for Individual Decentralized Monitoring for the Personalized Medicine*

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***Abstract*— Integrating tools and applications into a clinically useful system for individual continuous health data surveillance requires an architecture considering all relevant medical and technical conditions. Therefore, the requirements of an integrated system including a health app to collect and monitor sensor data to support personalized medicine are analyzed. The structure and behavior of the system are defined regarding the specific health use cases and scenarios. A vendor-independent architecture, which enables the collection of vital data from arbitrary wearables using a smartphone, is presented. The data is centrally managed and processed by attending physicians. The modular architecture allows the system to extend to new scenarios, data formats, etc. A prototypical implementation of the system shows the feasibility of the approach.**

I. Introduction

Personalized medicine focuses on the person itself, its characteristics and needs. By enriching existing patient information through continuously collected health data, personalized medicine could be supported. Therefore, wearables can be used which are worn by the patients, for example, as a watch. Indications of the medical potential of unspecific health monitoring exist but are not yet thoroughly evaluated [1]. Furthermore, the increasing spread of patients using wearables for self-assessment is already affecting medical consultations.

For specific medical use cases such as cardiac monitoring [2] or activity data during chemoradiotherapy [3], integrated solutions for specific vital parameters are available. Understanding patterns of vital parameters and diseases is an emerging application for big data analysis and machine learning.

A flexible and user-friendly platform for the continuous monitoring of patients' health data, including medical data interpretation, should be developed together with a large-scale evaluation in the real clinical environment, in order to provide medical evidence and enable a systematic approach. This platform 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.

A new project initialized by the ministry of social affairs and integration from the state of Baden-Württemberg in Germany called *bwHealthApp*, firstly addressed in [4], has the goal of developing a telehealth system for personalized medicine, including both a central server and decentralized gateway applications for body area networks (BAN). The system should provide tools for data recording by arbitrary commercially available wearables as well as examination and validation. Moreover, interfaces to systems for automated data analysis, alarming or deep learning for predictors should be developed. This work presents the requirements, the design and the architecture for such an integrated system, focusing on the central server.

II. Methods

Established approaches [5] were used for the requirements analysis and architecture definition. A showcase application of individual decentralized monitoring from the medical routine was selected. Its use cases and their particular scenario requirements were analyzed. The requirements were generalized towards a system architecture covering the principal needs for applications of individual continuous data collection as needed for the 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 users of the main showcase are patients undergoing chemotherapy treatment in medical oncological daycare units of the Clinic of Internal Medicine at UKT. Here, continuous monitoring of vital parameters can support the detection of critical situations or overall changes in the patient's condition [3]. These may require an adaption of the therapy regimen or therapy in general. Since one of the main goals of medical daycare is keeping a patient in his accustomed environment, the collection of data has to be as flexible as possible, with as little interference with daily life as possible. Besides the patient's situation itself, the needed type, quality and quantity of vital data or patient-reported outcomes (PRO) relevant for monitoring as well as their correlation with pathophysiological processes are object of research [1, 2, 3]. The continuous use of available and user-friendly consumer wearables can provide medical data, with all limitations of unsupervised applications, from a so-far unavailable situation. Concerning the personal involvement of the patients, appropriate compliance considering the application of the tools can be assumed.

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In the first step, principal use case scenarios considering the routine operation of the system were obtained by interviews and workshops with the stakeholders from the CPM. Within the specific use cases, important functionalities for changeability, extendibility, configurability and flexibility were considered. System characteristics, as well as functional and quality requirements, were defined covering the core task and general goals needed for the new approach. Influential factors and boundary conditions were defined for a more specific system presentation. The requirements analysis leads to components as well as professional and technical interfaces to define a comprehensive concept of the entire system architecture. The concrete architecture was developed, and a functional prototype demonstrates the feasibility of the approach via system tests. It focuses on the recording of wearable data and configuration options to allow changeability, extendibility and configurability.

III. Results

A. Use cases scenarios

Patient registration

The first step for using the app in treatment is patient registration and configuration. The attending physician registers a patient to be monitored in the medical daycare unit. Therefore, the smartphone application is installed on the patient's phone. After the installation, the authentication of the patient takes place for the initial registration (e.g., QR code scans). The patient's personal information is linked with the smartphone to be used as the BAN gateway via the international mobile subscriber identity (IMSI). This makes the patient and sensor data as associable as possible. The IMSI is also used for identification during operation. For specifying the use case of the monitoring scenario, the attending physician configures the functionalities, which are needed by the patient.

Device initialization and measurement

For the first usage of the smartphone app, the devices and measurements need to be configured. If the medical question does not need uniform devices, the patient can use the wearables he prefers if they provide the necessary interface and parameters. The app checks which characteristics are covered by which connected device. Missing components are notified, and feedback is requested. Regarding the configuration created by the physician, background services are constructed for each health care parameter (e.g., characteristic). The services are configured for each specific sensor data separately to collect the characteristic data continuously.

Data collection

By starting the data transfer, the sensor data is recorded from the wearables in the defined interval within the background. For each characteristic, the received raw data is interpreted, saved and visualized. The saved data contains the characteristic UUID, the sample ID, the raw and interpreted value, a timestamp, the personal ID and the IMSI number. The patient is reminded of questionnaires like forms or single values through a pop-up or message in the defined interval. After entering the information, he can save the data to be transferred to the server for storage. Event data in the form of event recording or status reporting like confirming actions are saved the same way.

Connectivity and operation

During data collection, further functionalities are needed to handle broken connections, error feedback and reconnects. These have to be realized by the BAN. In contrast to current more supervised monitoring approaches (e.g., Holter monitor), this will need to be evaluated with respect to clinical viability. Data synchronization with the central server also has to be realized. A fundamental challenge will be general usability for people with limited capability to operate the smartphone app. In case of need, the smartphone app informs the user about relevant issues or messages from the attending physicians. If available and sufficiently evaluated, even alarms may be issued.

Flexibility and further use cases

The parameters to be recorded by the smartphone app, as well as their configuration, aggregation, evaluation and valid wearables, may be changed, updated or deleted during operation. This requires a flexible software infrastructure for the efficient deployment of the connected patient's smartphone app. Here, app stores provide well-established concepts for version management and stable deployment mechanisms. Further use cases concerning functionality, reliability, usability, efficiency, changeability and transferability, like data safety and security, error handling as well as system administration and operation are not considered here.

B. System characteristics and requirements

The core task of the bwHealthApp system is the centralized recording of individual health data from decentralized data sources i.e. BANs. The wearables should be combined individually with respect to medically required parameters and independent of specific vendors. To record the data, an individualized smartphone application should take control of the processing of the data from the wearables so that it can be stored and transferred for further processing to a centralized clinical server. This data will be used for diagnostic purposes and to enrich existing patient data available in other health information systems. All data should be provided for treating physicians. The paradigm for data monitoring on the smartphone is continuously and unlimited in contrast to classical limited approaches (e.g., Holter monitor). The whole system should be generic, modular, integrative and open. High flexibility and configurability, as well as changeability and extendibility, should be the main features of the system. Other aspects and related quality requirements are important as well but are not the focus of this work.

Influential factors for the system are the hardware and software infrastructure. Also, the performance of smartphone and server processors, as well as technical limitations of for instance battery lifetime, memory or network connectivity, must be considered. Different operating and database systems as well as middleware and communication servers between systems, their interfaces and protocols must also be taken into account. Other factors like handling offline and online modus for the app and essential external systems needed for the running system are relevant. For the programming, existing libraries, frameworks and systems (e.g., decision support), as well as existing interface specifications, data structures and

models are to be used. The communication is based on standardized protocols as far as available. Effects concerning human life by monitoring health data and resulting diagnosis have to be identified and secured. All of these factors will be evaluated during the bwHealthApp project.

C. System architecture

The targeted solution is organized as a client-server system. The client-side includes a variable set of commercially available wearable devices and the smartphone application. The server-side consists of a gateway for the connection to the clients as well as the controller with access to internal systems. Each internal system may contain further subsystems and databases. In this paper, the server-side of the system will be described.

Wearables able to record information from the patients are combined into a BAN for which the smartphone app acts as data integration and preprocessing element. The data manager of the app initiates the data transfer to the gateway of the clinical server, ensuring authentication and data security.

Server-side

The gateway provides the interface between client and server, and manages authentication and access to the clinical infrastructure. Synchronous and asynchronous communication by standardized protocols, for instance exchanging configurations, is supported. The Fast Healthcare Interoperability Resources (FHIR) standard using JavaScript Object Notation (JSON) is applied as principal interface technology regarding system evolution, sustainability and interoperability.

The controller on the server dispatches data to the encapsulated application logic of the internal and external subsystems. The internal and specific subsystems of the bwHealthApp cover the administration of management data such as user identities, registered devices and individual parameter configurations, as well as runtime data such as assigned sensors and measured values. These are complemented by systems for data visualization, diagnosis support, and messaging for notifications. An identity manager provides authentication information for the gateway.

The bwHealthApp is designed for interoperability with external applications for clinical information processing like hospital information system (HIS) or tumor boards. It also serves as a data source for research applications such as machine learning excellences for predictor development or evidence-based medicine and provides the needed data warehousing tools.

D. Functionality of the server-side

The BAN and the app act as a patient frontend including storage, preprocessing and synchronization functionality. For the centralized management within the clinical infrastructure, all data is transferred to the gateway via specific FHIR service contracts.

Gateway and controller

Incoming messages are processed and evaluated regarding the validity, conformity, etc. Data security is ensured by encoded communication protocols and established authentication mechanisms (X.509). The messages are forwarded to the receiving controller. For communication, access information is configured within the internal components. The controller dispatches the administrative and health data to the integrated, encapsulated and clinical application logic. Therefore, the controller communicates with internal (e.g., identity management) as well as external subsystems (e.g., HIS) by providing medical standard interfaces (e.g., HL7, DICOM). This allows a flexible replacement of subsystems and even extendibility with other components.

Subsystems and databases

Internal, administrative subsystems take control of data management for user identities, device and measurement configurations, etc. The purpose is the management of individual monitoring cases. The system provides the visualization of individually monitored health data and in the first step is used by physicians for manual evaluation during individual consultations. Since there are yet no medical guidelines on how to use individual monitoring for personalized medicine, this marks the current system boundary. The further enrichment of a patient's electronic medical record (EMR) within a medical information system with a medical finding takes place in the respective external system. Interfaces are provided to transfer data, e.g., medical outcomes, to external subsystems for learning of predictors and ensuing automated alerting. Each internal and external subsystem manages persistency via its own database.

E. Prototype of the bwHealthApp

The proof-of-concept of the system has been tested with an initial prototype developed for the Android operating system.

Registration, configuration initialization, and data collection

The prototype provides a simple person model. The physician registers the patient in his role-specific GUI by associating a user ID and credentials to an existing person with a patient role. GUI modules for the patient are assigned regarding its specific medical question (e.g., a form for PRO questionnaires). The user ID is used for identification, login, measurement assignment, etc.

For the flexible and individual combination of data sources, the physician selects needed types of data from a list of identifiers for supported GATT characteristics as well as single items for manual data entry. Afterward, the sampling rate for each value as well as the synchronization schedule is configured. The configuration is saved.

Finally, the app is installed on the patient’s smartphone, where it can detect compatible wearables, establish the connections, and record the data according to the configured necessary characteristics for the patient.

Connectivity, operation and flexibility

If the connection is interrupted, the app automatically reconnects to the configured devices. Relevant issues and error situations are presented in specific status widgets.

The server includes prototypical implementations of required internal and external subsystems to test the data exchange between app and server. The server is implemented as a three tier Representational State Transfer (REST) architecture. Current functionalities provided by the REST

server are, for instance, login, patient registration, receiving and storing measurement data. The application logic maps to the internal and external specific data models of the bwHealthApp. The data access layer provides a simple in-memory persistence solution, which covers the required data models.

Data model

The flexible handling of the measured data is the essential part of the data model. Therefore, the relation of device and characteristics is realized to represent the wearable configuration. Different value types for the characteristics (e.g., heart rate and RR interval for the heart rate measurement) are distinguished through data type description models that contain a unique identifier and are associated with the corresponding characteristic UUID. The combination of device, characteristic and data type descriptions is associated with the medical relevant values. This ensures the mapping of raw data to a semantic medical representation. The data model also represents manual, event, patient and user data, configurations, GUI modules, etc., necessary for the use cases.

System tests

The prototype has been successfully tested on an Acer Iconia One 10 tablet with a combination of one to three simultaneously connected sensors with different acquisition schedules. On the server-side, the patients were registered, and the needed characteristics and sampling requirements were configured. All seven sensor combinations and sampling schedules ranging from 1s to 120s yielded stable values over 30min. Connectivity and reconnections scenarios were also successfully tested.

IV. Discussion

Integrated and clinically approved solutions for specific vital parameters are just available for specific medical use cases and diagnosis. In contrast to these restricted monitoring applications, the depicted approach needs to combine changeable and case dependent sensor composition with medical data interpretation. The presented data integration solution was developed to enable the clinical validation of this open approach in the clinical environment. The designed system architecture depicts a vendor-free and open solution consisting of a centralized server and decentralized BAN gateway applications. The decoupling and separation between sensor data and value types allow handling varying sensor value combinations and sequential data representations (e.g., different sensor values within a GATT characteristic via BLE). The prototype was functionally evaluated and achieved the designated configurability and flexibility needed for the use cases.

For evaluation in the clinical environment, the prototype is currently finalized. Within the first evaluation phase, the reliability of connections, user acceptance, device handling, battery lifetime, and resulting data quality need to be assessed.

V. Conclusions

In conclusion, the work depicts the requirements analysis and architecture for the bwHealthApp, focusing on the server-side. The prototype's functionalities allow configuring required sensor data, synchronization schedules as well as connected devices for the patient's need. Via the app, data is continuously collected. The health data could support the making of diagnosis or therapy planning for personalized medicine. Flexibility and configurability, as well as changeability and extendibility, are central aspects of the system. This approach will need new medical, structural, organizational and administrative guidelines, which also have to be developed. To realize the comprehensive system, data security and protection mechanisms must be integrated.

Acknowledgment

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Personalized health service in assistive environments and telemonitoring of sleep patterns*

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***Abstract*— assistive environments are entering our homes faster than ever. However, there are still various barriers to be broken. One of the crucial points is a personalization of offered services and integration of assistive technologies in common objects and therefore in a regular daily routine. Recognition of sleep patterns for the preliminary sleep study is one of the health services that could be performed in an undisturbing way. This article proposes the hardware system for the measurement of bio-vital signals necessary for initial sleep study in a non-obtrusive way. The first results confirm the potential of measurement of breathing and movement signals with the proposed system.**

I. Introduction

Health and care services based on AAL technologies are being the topic for the investigation for a long time, yet they have barely made it into patients' homes. Some of the barriers are technological and are due to the lack of integration of device data (including heart rate, heart signals, blood oxygen saturation, breathing, muscle movement, temperature, falls, sleep patterns). As a rule, they only offer isolated solutions. Integrated use of the data, which is hardly taking place at the moment, would result in great potential.

Sustainable health services should be comprehensive and accompany the user throughout the full cycle:

- consulting,
- planning,
- implementation,
- operation,
- support.

Such services are always provided by individuals and performed using AAL technologies. Sustainability is strongly influenced by user acceptance, but also by economic implementation and cost models.

Recognition of sleep patterns is one of the areas of home health services with the detection of sleep stages as its essential part. Performing this task in a non-obtrusive way is the main topic presented in this article work.

II. State of the Art

The analysis of sleep patterns is a subject of many scientific articles [1, 2, 3]. In this summary, only a few relevant publications are mentioned.

The article [4] presents an approach for the identification of awake and sleep stages using the ECG signal and a neural network-based algorithm. For the evaluation of the proposed algorithm, 16 PSG data sets from the MIT-BIH database were used. The heart rate variability (HRV) was calculated from the output signal for further processing with a neural network algorithm of Extreme Learning Machine using a single hidden layer [5]. The results after the training achieved an accuracy of about 90%.

As in [6] presented, the algorithm based on multinomial logistical regression has achieved 72% of accuracy recognizing Wake, NREM, and REM stages. Ten derived from breathing, heart rate, and movement signal parameters were used as the input for the software system. These signals can be obtained in a non-invasive way, for example, using the sensors under the bed mattress [7,8].

There is also a high amount of investigations dedicated to sleep study using the signals, which actually cannot be obtained in a non-obtrusive way (e.g., EEG [9]), but these publications are out of scope of this work, as in this article the main accent is done on sleep study using the contactless sensors.

III. Methodology

The presented State of the Art articles confirm the potential of sleep stage classification using the breathing, heart rate, and movement signals. Obtaining these signals in a non-obtrusive way is one of the main aims of the presented in this manuscript method.

As signals should be obtained during the sleep without any direct contact with a human's body, the bed itself could be used for placing the sensors. Force sensing resistors (FSR) sensors were chosen in this work to obtain signals from the human body.

In contract to many other approaches, the sensors are placed under the mattress and connected to sensor nodes,

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which give an individual address to each sensor and convert a signal from analog to digital. The placement of sensors under the mattress ensures the unnoticeability of the system for the users. All sensor nodes are connected to a computational unit, which executes the preprocessing and storing of the obtained from sensors data. It can be reached via a Wi-Fi connection to download and process the stored data. In this work, both Intel Edison and Raspberry Pi were used as a central computational unit but other or similar embedded systems can be used as well. As a backend, a web server was running on it for easy access to the stored data.

The hardware structure of the bed installation is presented in Fig. 1. The setup is not different from a commonly used bed. The only attributation are the sensors that are placed on top of the bed's frame support, and therefore, below the mattress. Following components are forming the system:

1. bed structure
2. bed frame
3. computational unit
4. FSR sensor
5. sensor node
6. cable connection
7. mattress

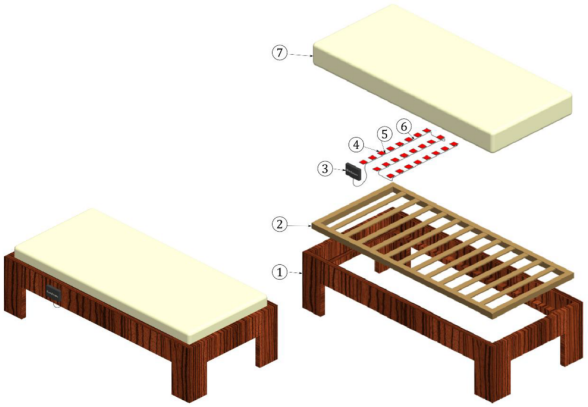

Figure 1. Bed's system structure

IV. Results

For the evaluation of system work, some experiments have been executed. Sixteen sensors have been placed under the bed mattress and connected to the computational unit. The study was performed with three test persons with the age of 26 ± 4 years old and weight 65 ± 7 kg. The frequency of sending sensors' signals to the computational unit is 1Hz. The results of system work are represented in Fig. 2. For the clearness of the visualization, the signals of only three sensors are displayed.

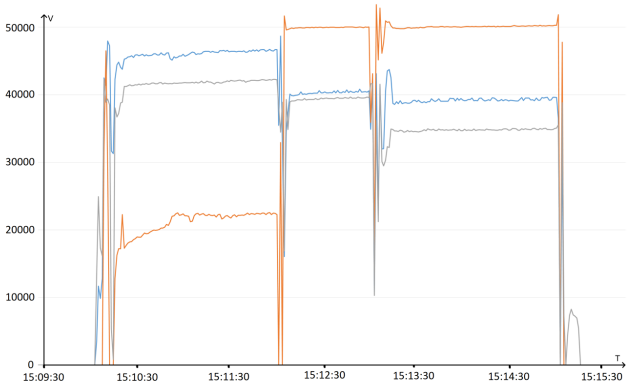

Figure 2. Visualization of signals from 3 sensors

Three visualized sensors are placed under the mattress under the chest in the middle (orange line), on the left (blue line) and right (grey line) sides of the bed frame. X-axis represents the time of measurement and Y-axis shows the output voltage of the sensors. All movements of the person can be clearly recognized in the presented chart as changes in the output voltage over time. Furthermore, zooming in the obtained throughout the measurement signal, breathing can be distinctly recognized as a periodical signal. A similar level of accuracy was reached for all three test persons.

V. Conclusion

The proposed in this manuscript approach confirms the potential of non-invasive measurement of necessary bio-vital signals for telemonitoring of sleep patterns. The results have indicated, that movement and respiration monitoring in a conventional bed can be performed without any contact to the human's body and therefore without influencing the usual sleep flow. Further work will be concentrated on the improvement of signal frequency and herewith on recognition of the heartbeat signal. Furthermore, the connection of developed hardware system with the software algorithm [6] for the classification of sleep stages as a part of the personalized health system in the assistive environment is one of the principal aims for the future research.

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On the Reliability of Consumer Devices for the Assessment of Sleep

Manuel Schabus, Mohamed Ameen

I. Introduction

We spend around one third of our day sleeping, yet we still know little about the nature, the core function or most importantly the necessity of sleep for our well-being and life expectancy. This lack of knowledge has motivated scientists and researchers from various backgrounds to investigate and better understand the biological foundations of sleep. As a consequence, the past years have added significantly to the basic knowledge about sleep. Recent research has provided us with unprecedented knowledge about the structure of sleep, its influence on cognitive and motor abilities as well as ways to directly manipulate sleep experimentally.

What is still lacking however is the reliable measurement of sleep outside the laboratory, that is, ambulatory sleep assessment directly in the habitual sleeping environment; i.e. the participants home. Thus, in the past few years we have witnessed a surge on commercial sleep aids, sleep devices or mobile phone applications that aim to assess and ultimately improve sleep. In order that such devices or applications can provide credible and reliable information about the quality and structure of sleep, they must be tested in a robust scientific way and against the "gold-standard". That is, their performance must be described and assessed in terms of their agreement with the current gold-standard which is polysomnography (PSG) (i.e., EEG, EOG and EMG data). Only this can ensure the meaningfulness and validity of the new methods advertised by the industry.

Unfortunately, this vital step is skipped by literally all the consumer devices available on the market.

For this reason, we decided to start with the assessment of some of the common consumer devices available on the market which are claiming to monitor sleep and provide reliable information about sleep quality of the end-user night-by-night.

II. Methods

We recorded polysomnography data (PSG) from 18 healthy participants (13 Females, mean age: 29 ±13) using a 256-electrode GSN HydroCel Geodesic Sensor Net (Electrical 478 Geodesics Inc., Eugene, Oregon, USA) and a Net Amps 400 amplifier. Simultaneous electrocardiography, electromyography and electrooculography were recorded using bipolar electrodes. Sleep staging was performed using the sleep classification system developed by the SIESTA group (Somnolyzer 24×7; The SIESTA Group Schlafanalyse GmbH., Vienna, Austria) following the standard criteria described by the American Association for Sleep Medicine (AASM). The SIESTA output was considered our gold standard and compared to the consumer devices/application. Specifically we assessed sleep data from two devices and one application against the gold-standard: (1) a commercial activity tracker: the Mifit band v2 (Xiaomi, BJ, ROC); (2) a scientific actigraph (Actiwatch): Motionwatch 8 (CamNTech, CB, UK), and (3) a readily used mobile phone application for sleep assessment: Sleep Cycle v3.0.1.2511-release (Northcube, GOT, SE). For the later we used the option to estimate sleep via sounds not movement.

Four main sleep parameters were evaluated: (I) sleep onset latency (SOL), (II) sleep efficiency (SE), (III) total sleep time (TST), and (IV) wake after sleep onset (WASO). SOL, by definition, measures the difference between the time when the participant went to bed and the time when the participant actually fell asleep. SE was calculated as Sleep Efficiency = Total Sleep Time / Total Time in Bed. Measurements from all the devices were synchronized to the start of the PSG recording and correlations were computed non-parametrically using spearman correlations and means and standard deviations are reported. For Mifit measurements: we calculated SOL, SE, TST, while we report WASO values provided by the device, for Sleep Cycle measurements: we calculated SOL, SE, TST and WASO and for the actiwatch we report SOL, SE, TST and WASO values provided by the device. Values provided by the devices are reported in red while calculated values are reported in blue.

III. Results

A. Sleep Onset Latency (SOL)

No significant correlation was detected between SOL estimates from our gold standard sleep scoring and any of the three devices (*Mifit: r=0.24, p=0.42* (n=13); *Sleep Cycle: r= -0.41, p=0.23* (n=10); *Actiwatch: r= -0.09*, *p=0.77* (n=12). In addition mean values vary widely (M_{siesta}*: 30 ± 20.49,* M_{mifit}*: 15.53 ± 36.88,* $M_{Sleep\ cycle}$*: 36.4 ±21.64;* M_{Acti}*: 19.33 ± 21.95*).

B. Sleep Efficiency (SE)

A positive correlation was found between SE values derived from the Mifit band and that of our PSG gold standard (*r=0.57, p=0.04).* No correlation was revealed with the Actiwatch or the Sleep Cycle application (*r= 0.34, p=0.28 and r= -0.20, p=0.58, respectively*). In addition mean values vary again widely (M_{siesta}*: 82.40 ± 13.82,* M_{mifit}*: 97.97±3.74,* $M_{Sleep\ cycle}$*: 92.56±4.41;* M_{Acti}*: 88.13 ±5.56).*

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C. Total Sleep Time (TST)

No correlation was found between the total sleep time measured by the three devices/applications and our gold standard (*all p's >0.1*). In addition the mean values for estimated TST time again vary immensely (M_{siesta}: *378.5±95.2,* M_{mifit}*: 463.8 ± 56.7,* $M_{Sleep\ cycle}$*: 461.9 ±53.4;* M_{Acti}*: 417.20 ± 35.80).*

D. Wake After Sleep Onset (WASO)

Significant positive correlations between PSG estimates of WASO time in minutes and that of the Mifit band (*r=0.57, p=0.03*) as well as that of the actiwatch (*r=0.75, p=0.004*) were revealed. For the Sleep Cycle we only had 4 data sets available. WASO time estimates vary again widely between the evaluated devices and the PSG gold-standard (M_{siesta}*: 44.44 ± 38.66,* M_{mifit}*: 11.23 ± 23.60;* $M_{Sleep\ cycle}$*: 26.25 ± 7.50,* M_{Acti}*: 34.17 ± 20.70).*

IV. Discussion

Our preliminary results suggest that current consumer devices for sleep-monitoring are only able to deliver sleep data in a very inaccurate and general manner. Correlations between our PSG gold-standard derived data and these consumer devices were only found for sleep efficiency (MiFit) and wake after sleep onset time (MiFit and scientific actigraphy). However, also there the absolute values provided by consumer devices are far from the true gold-standard values. For example, for sleep efficiency (SE) these values vary between 82% (in PSG), to 93% (Sleep Cycle App) or even 98% in the MiFit device. The large amount of disagreement is crucial as a SE below 85% would be indicative of a real, clinically significant sleep problem, whereas a SE of 95% and above would on the other hand indicate sleep of very good quality. The low variance which is evident between nights for the consumer devices indicates that these devices and apps cannot to date capture the natural variation between individual nights which is present in real-world data.

For wake after sleep onset (WASO) we likewise found a wide range of sleep estimates with an average of 44 min WASO in our gold-standard (PSG) to 26 min in the Sleep Cycle App or even only an average of 11 min WASO in the MiFit device. This finding is however not surprising as devices mainly relying on activity measures are known to capture especially (transient) wake states poorly. In principal the MiFit device would in addition come with a photoplethysmogram (PPG) sensor and would have heart rate data available for its estimations, however, this does not seem to benefit the overall WASO estimation of this device to date. The important sleep measures "total sleep time" (TST) and "sleep onset latency" (SOL) of the consumer devices were especially poor in our analyses and revealed no relations to the PSG gold-standard; derived mean values for TST indicate that TST is strongly overestimated in the tested consumer devices and apps to date.

In our view the next necessary step to take would be to improve the accuracy of these devices and apps. Key measures of sleep (such as reported here) need to be compared to the PSG gold-standard, and ideally in big sleep laboratory studies with healthy young, as well as older poor sleeper controls in order to verify an acceptable accuracy also of consumer devices on the market.

Ultimately these devices should also allow reliable sleep scoring minute by minute sleep. To date the sleep staging output of these devices (although not statistically evaluated yet) seems rather arbitrary with highly implausible percentages of wake, light and deep sleep as well as a circadian variation of these states over the night which are literally impossible in human sleepers.

What these devices probably will not be able to capture in the near future is fine-grained sleep scoring and scoring accuracy as known from the PSG standard. For example, the differentiation in wake, transitional non-Rem sleep (N1), light non-Rem sleep (N2), deep non-Rem sleep (N3) and REM ("dreaming") sleep – although being standard in any sleep laboratory or polysomnography – is not yet implemented in any of the tested consumer devices. Likely this will also not be possible without a full polysomnography (PSG), that is without brain (electroencephalography), muscle (electromyogram) as well as eye (electrooculogram) activity from the sleeper.

Analysis-wise pending is the evaluation of the specificity and sensitivity of the sleep staging provided by these consumer which needs to be derived from epoch-wise agreement with the PSG gold-standard. That is, the agreement of the sleep staging information provided by the Mifit device and Sleep Cycle App with our PSG staging in 30sec or 1min epochs over the whole night. Scientifically it is still under investigation which degree of accuracy can actually maximally be derived if such consumer devices rely on movements and/or cardiac activity (Mifit), or simply sounds (or mattress vibrations) at bedside (Sleep Cycle).

In summary, we believe that current "sleep monitoring" consumer devices on the market must undergo a more robust validation process before being made available and distributed in the general public. This is especially noteworthy as there have been first reports in the literature that inaccurate feedback of such consumer devices can worry subjects and may even lead to compromised well-being of the user.

Technologies in the bedroom that improve the quality of sleep*

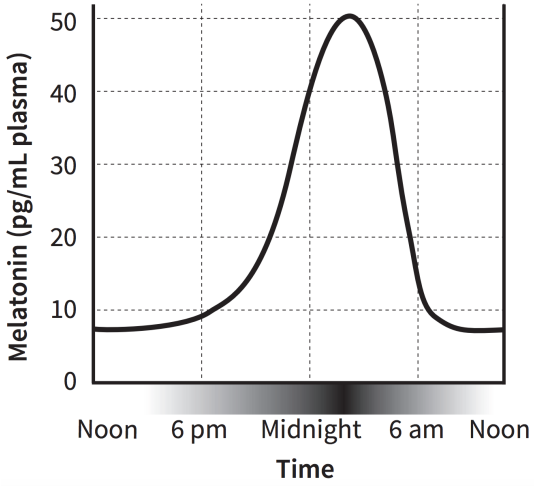
Karin Trommelschlaeger and Guido Kempter

Abstract—**During two researches the influence of technologies on sleep were analyzed. The first one is about the effect of light on the circadian rhythm and as consequence on sleep quality of persons in a vegetative state. The second one, which is still running, surveys the influence of several technical tools on the sleep of elderly people living in a nursing home.**

I. Introduction

Sleep is essential for our health Healthy sleep decreases the probability of diseases like cancer, diabetes type 2 or heart attacks [1, ch.8]. Sleep follows the individual circadian rhythm, which is normally fixed like a program in the brain. Many parameters are controlled by the circadian rhythm, like e.g. body temperature or the production of the hormone melatonin. Melatonin is also called the "sleep hormone" and is mainly produced during nighttime (Fig. 1). Environmental factors like the time spent in daylight, which has usually a higher brightness than artificial light, are essential for the high production of melatonin at night. Although the circadian rhythm is fixed for any individual, it can be supported by light, which has the changing brightness and light colors as it is in nature. Other factors may disorganize the circadian rhythm. During lifetime, the level of melatonin production decreases and for critically ill persons the melatonin production is disturbed. Both lead to a disturbed sleep with less deep sleep phases and in succession to a disturbed circadian rhythm. [1, ch.5; 2; 3]

Figure 1: The cycle of melatonin Source: [1, p. 24]



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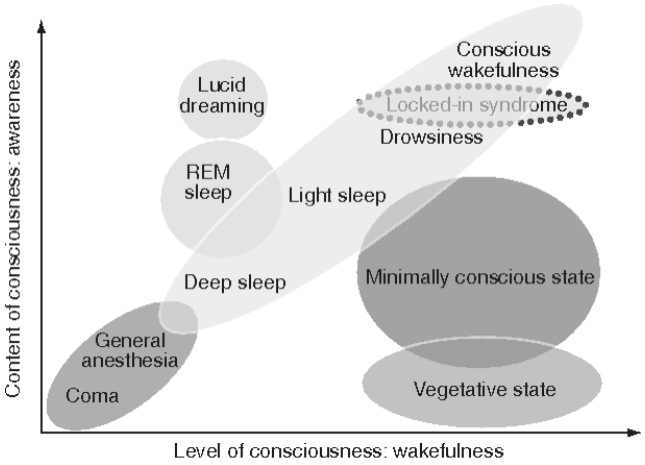
II. Influence of Light on Patients with Impaired Consciousness

There are several states between the dimensions wakefulness and consciousness (Fig. 2). Persons in a vegetative state are awake with open eyes but do not have consciousness. Their movements are sometimes directed toward auditive or visual stimuli and sometimes they are uncontrolled. It seems that persons in a vegetative state sleep with closed eyes. Berkinschtein et al. [5] showed that it is possible to identify a weak circadian rhythm by actigraphy.

Figure 2: Simplified illustration of the two major components of consciousness and the way they correlate within the different physiological, pharmacological and pathological modulations of consciousness. Source: [4]

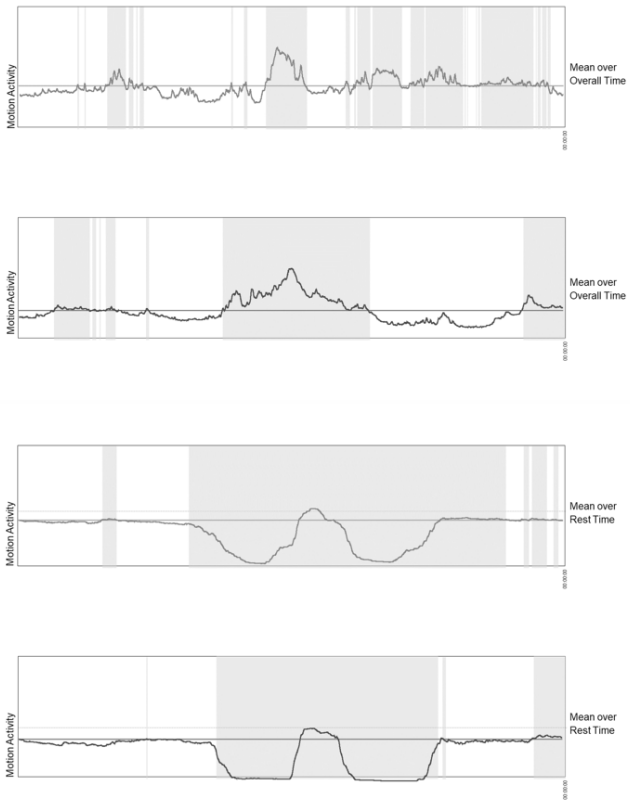


During two single-case studies the activities of two patients were measured to record the circadian rhythm and the phases of sleep. Instead of the measurement at the wrist, as described in [5], a three-parted, pressure-sensitive mat was used, which allows do differ the movements of legs, body and head. Therefore, it was also possible to detect interventions like mobilization.

One of the patients was in a vegetative state; the other had phases of conscious wakefulness but left the bed only for two hours in the morning and in the afternoon to stay in a wheelchair. As the patients are mainly exposed to artificial light, which is insufficient to support the circadian Rhythm, and it is known, that the effect of light is a significant factor to maintain the circadian rhythm [6], a light system has been used to intervene. This light system allows the simulation of natural light and considers the seasons.

There was nearly no rhythm for the patient in a vegetative state at the beginning of the intervention by light (Fig. 3, upper line chart). With the influence of dynamic light the daily routine is more structured and the dormancy was less dissected (Fig. 3, second line chart, white areas).
You can see the mobilization times for the second patient in Fig. 3, third line chart, which structured the daily routine. Even lying in bed, the dormancy was restricted to eight hours. The dormancy increased with the light control (Fig. 3, lower line chart, white areas).
As conclusion, it could be shown that the circadian rhythm of persons with impaired consciousness can be strengthen by intervention with light.

Figure 3: Activity protocol of the patients



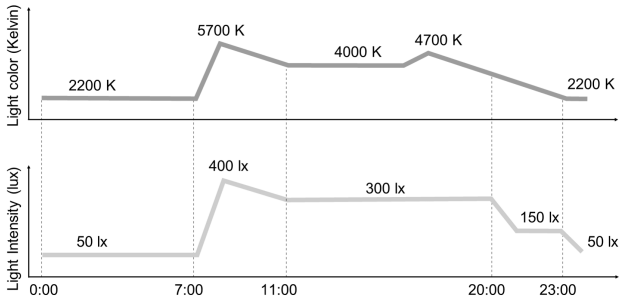
III. TECHNICAL SUPPORT FOR ELDERLY PERSONS IN A NURSING HOME ENVIRONMENT

Although elderly people need as much sleep as younger one, sleep quality decreases in middle and old age. Especially the phases of deep sleep are shorter [1, ch.5]. Together with a nursing home as partner, the quality of sleep of the residents and the possibilities to improve the sleep by technologies were researched. To get an imagination of the sleep circumstances and the subjective rating of the individual sleep, the residents were interviewed in a focus group discussion. Most of them do not think they have less sleep quality, which coincide with the findings in [1, ch.5]. Nevertheless, most of the participants have a fragmented sleep, most because of urge to urinate. Some of them have difficulties to fall asleep because of circle of thoughts, which may be based one unconscious anxieties. Other problems are unpleasant odors from the environment and noise pollution. Most of the residents take sleeping pills. Most persons are restricted in their mobility, which lead to few stay outside at daylight. A weak light at night was perceived as calming and as important for orientation, when getting up at night.

Based on the findings of the focus group discussion, technical solutions were defined.

A central aspect is the effect of light, as it is a main trigger for the melatonin production. Daylight impulses are important for the melatonin production; however, a bright, cold white light at night stops it. A light system similar to this one described in chapter II can create a light scene, which simulates the natural light. It has a weak, warm colored light in the morning and in the evening, as well as a bright, cold white light at noon. Color and brightness change during daytime, like shown in figure 4. Therefore, the light supports a smooth waking up and creates a relaxing scene in the evening. The light should be nonglare. Additionally the light system should provide a weak, warm white light for orientation at night.

Figure 4 Light color and intensity over the day



To interrupt the circles of thoughts, sound therapy in form of calming noises or white noise can be used. With sound, you can create a relaxing atmosphere either with smooth music, like some classic music, or sounds from nature like e.g. the sound of ocean waves. Such kind of music or sound is able to distract from thoughts and helps to fall asleep. [7] Overlaying the sounds with ultrasound, which is not audible, intensifies the effect, which is discussed in [9; 10; 11]. Applying White Noise has the effect of calming and distracting from thoughts as well [8].

Additionally, White Noise also helps against noise pollution by masking of environmental noise, which happens by adding an unstructured noise. The environmental noise and the white noise together generates an unstructured sound, which can be filtered by brain. Another possibility to reduce the disturbance by noise pollution is to apply Active Noise Cancelling (ANC). An ANC machine records the noise of the environment and analyses it. A so-called anti-noise, which is a destructive inference, is used to suppress the noise [12].

For improvement of the air quality the application of fragrance dispensers or air purifiers are possible. Fragrance dispensers just apply another scent to the sleeping room. To

choose the appropriate scent individual preferences should be respected as well as a relaxing effect of the scent. Although the effects of scents are discussed controversially, some researches found that fragrances could be used for relaxing and activating [13]. Air purifiers, however, filter out particles in the air, which deteriorate the quality of air. For this use, there are different devices with different technologies, e.g. HEPA (high efficiency particulate air) filters or photocatalytic oxidation.

Based on this perceptions four patient's rooms has been equipped with technical features as they are: circadian light system in form of a free-standing luminaire (two rooms), sound therapy either integrated in a pillow providing classic music (one room) or a sound system providing relaxing or activating sounds (two rooms), weak warm white light as night light (one room) and fragrance dispenser, which are able to spray relaxing or activating fragrances (two rooms). The free-standing luminaire, the sound system with activating and relaxing noises and the fragrance dispenser can also be used during daytime, if necessary, to activate or calm the persons like described in [11]. The activating or relaxing atmospheres are then triggered by the nursing staff. For recording the activities and sleep phases, an actigraph is used, which the persons wear at the wrist. The actigraph measures activity, wrist temperature and light exposure and the according software allows many interpretations of the recorded data as main and secondary sleep phases, rest phases, sleep interruptions and activities. Additionally the testpersons fill out the PSQI Questionnaire (Pittsburgh sleep quality index).

The study is still running and first result are expected in this year.

IV. Conclusion

Light, which simulates daylight in brightness and light color, is an appropriate instrument to structure the daily routine and to improve sleep quality. This effect occurs also for persons in a vegetative state, which could be shown. This insight has an impact on life quality for the patients and relieves the nursing staff in hospitals.

The most elderly persons do not perceive the decrease of sleep quality. It is important to empathize with the persons for realizing the sleep disturbing factors. Main aspects are sleep interruptions because of urge to urinate and circle of thoughts. A circadian light system is essential in this setting, but also other technologies could be defined to increase sleep quality, like technologies, which can interrupt circle of thoughts, improve air quality and reduce noise pollution. Healthy sleep extends lifetime, improves life quality and relieves the caretakers in nursing homes.

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mHealth for therapeutic adherence

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Abstract— **Smartphone, NFCs and web technologies are used in this work to help patients in carrying out their own therapies. The implemented system ensures the identification of the drugs through NFC and it allows remote assistance from healthcare staff and family members.**

I. Introduction

Therapeutic adherence is the measure by which a patient follows the doctor's directions and recommendations. According to the report "Adherence to long-term therapies: evidence for action" [1] issued in 2003 by the World Health Organization (WHO), only 50% of patients suffering from chronic diseases correctly follow the prescribed therapies in developed countries, a percentage that drops in the other countries.

Even the Italian Medicines Agency (AIFA), reveals worrying data: in 2013 only 55.1% of patients suffering from hypertension took continuous antihypertensive treatment [2]; almost 50% of patients treated with antidepressants stopped treatment in the first three months of therapy and over 70% in the first 6 months; in 2012 the percentage of patients adherent to antidiabetic treatments was 62.1%, while for asthma and chronic obstructive pulmonary was only 14.3% (data obtained from observational studies and from the administrative databases of the ASL). In addition to being a danger to patients, non-observance of care is a significant economic burden on the health system coffers. Many studies have been carried out in recent years to analyze the problem and propose solutions.

Often, the incorrect medication intake is not intentional. As highlighted in [3], the drugs themselves can mislead the patient: the same drug can occur in many similar packages but with different dosages and modes of administration, or completely different drugs can have almost identical name or packaging. All this shows that the problem relating to therapeutic adherence includes not only the missed drug intake, but, even more dangerously, the error in therapy, from the dosage and method of administration to the incorrect identification of the drug to take.

The main cause, remains distraction; especially in long-term therapies, repeating the same gestures several times a day reduces due attention, often leaving the patient with the doubt of having taken or not the drug and consequently with two possible choices, both potentially dangerous: skipping the dose or doubling it. The frequency of error increases significantly in visually impaired people, or elderly people: AIFA has established a special study group, the "Geriatrics Working Group" (GWG), whose investigation [4] reveals that 50% of over 65s take between 5 and 9 drugs a day and 11% more than 10 drugs, resulting in a drastic decline in adherence to treatment.

This work aims to remedy these problems operating in the context of the Ambient Assisted Living (AAL), with the attention paid especially towards the elderly and people with disabilities. To this aim, the technologies we used are Smartphone and Near Field Communication (NFC). High connectivity capacity, increasing performances and extremely wide diffusion make smartphones the basis of mHealth (mobile health), that is the use of mobile devices in medicine and in public health.

Many are the applications available for smartphones addressed to the therapeutic adherence, but few of them have features that go beyond the functions of electronic diary. They offer a good monitoring of drugs intakes schedule, sometimes offering also storing the measurements of vital parameters, such as heart rate, arterial pressure and glycemia; some offer also the possibility to easily share such information, for example to send it to the doctor. Advanced features, such as support for web services, access to drug databases, saving data to the cloud, integrated ordering services linked to pharmacies, can also be found. Finally, the use of automatic verification systems of the identity of drugs, is almost totally absent, entrusted at most to the presence of images with which the user can make a visual comparison. A brief list of commercial apps is the following:

- Whatpills [5], one of the few based on the NFC technology.
- MediSafe [6], which has the ability to synchronize data in real time with other devices, such as family members, in order to allow them to assist the user and be notified in case of intake omission, and it is also characterized by a great care in the realization of the interface in order to simplify understanding and use.
- myHealthbox [7] instead is a service accessible via the web and through mobile applications, which does not offer intake scheduling, but creates a huge international database of information on drugs and

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more generally on health products, allowing not only to have all drug data at hand, but also by providing real-time safety warnings, for example in the case of finding new side effects or withdrawing lots from the market unsafe.

- Med Helper [8], Pill Reminder [9], are free apps which are almost exclusively limited to the scheduling and notification of appointments, with good results from the point of view of clarity and simplicity of use;
- Pill Manager [10] allows to manage the ordering of medicines to registered pharmacies;
- Dosecast [11] offers a flexible scheduling of intakes, allows to access to a drug database.

Researches in the AAL area have proposed solutions to the problem of poor therapeutic adherence, or more generally, they have highlighted the potential of mobile health and NFC. Dohr et al. in [12] analyze how the combination of NFC technology together with active remote monitoring can bring benefits in the implementation of an effective system of AAL. In [13] Engel et al. explored how mobile devices and NFC can be used in the implementation of medical assistance systems, suggesting the decentralization of functions and information with the aim both of involving the patient more in his own care, also improving the self-sufficiency. Strong emphasis is placed on the need to create applications with a clear, immediate and simple to use interface and flow. The work in [14] by Morak et al. is based on a so-called smart blister, a typical blister for medicines to which an electronic circuitry has been added, capable of detecting, storing and then transmitting via NFC the instant in which a pill is extracted. The system presented in [15] by M. Vergara et al., also based on NFC technology, is addressed to enable patients getting prescriptions from home: tables with explanatory images are provided, approaching the phone to the NFC tag equipped image, activates the related function.

In [16], Tsuruoka et al. present a patient-pharmacist communication system enabling pharmacists to remotely monitor the prescription drug compliance of home-bound patients. The studies presented in [17]–[19] focus on the construction of systems based on centralized databases, with detailed information on medicinal products as well as on the clinical situation of patients, and on the implementation of applications for consulting them in order to avoid complications due to adverse drug reactions, due to allergies and intolerances or negative interactions between multiple therapies carried out simultaneously.

The projects carried out in [20]–[22], addressed to visually impaired people, are aimed to develop "talking" packs of drugs, using identification through NFC, to convey the appropriate information, such as name of the drug, expiry date, dosage and timing of administration, through audio messages generated by the device's voice synthesizer.

The aim of the present work, novel with respect to the state of the art, is to create a user assistance system that can respond to the previously evidenced problems, in particular: it reminds for drug intakes (or more generally for therapeutic adherence); it verifies the correctness of the drug intake; it is a centralized system of the patient's therapeutic condition and provides a complete clinical review of ongoing care. It allows external monitoring of the state of adherence to the therapies, so as to be able to intervene in case of need. Furthermore, the system must be as user-friendly, convenient and easy to use as possible, taking into due consideration the fact that it is aimed above all at elderly people. The idea of inserting an NFC in the drug box has been presented by the authors in [23]. The present work shows the development of the complete system with new features and with the development of the central database and the interaction between user and assistants.

Section 2 presents the assistance system with details on user client, assistant client and administration interface. Section 3 draws the conclusions.

II. System Archiecture

From the analysis of the state of the art, we defined the key guidelines that the system we propose must follow:

- Decentralization of assistance functions: providing the user with the means and systems to be able to carry out autonomously and self-sufficiently his life at home environment.
- mHealth: the maintenance of a contact with the assistance staff through mobile communication devices guarantees the patient autonomy and awareness of being followed, giving him greater security. Through the use of dedicated web services, the assistance staff can carry out active monitoring and also a direct intervention in the management of the patient's therapeutic regime.
- Centralization of information: the implementation of a web service allows the creation of a centralized information of the patient's clinical situation, available anytime and anywhere. This can avoid harmful situations due to its fragmentation, as episodes of adverse drug reactions due to intolerances or allergies or negative interactions between multiple therapies carried out simultaneously.
- Simplicity of use: the simplicity of use must be a fundamental point of its development, especially considering that it is mainly addressed to elderly people. This translates into the care of both the graphic interface, both of the flow of use of the application. However, this simplification must not be achieved by hiding the information from the user, but organizing it in such a way as to present it only when necessary.
- Relevance of NFC technology: the immediacy in the use of NFC technology is one of the main factors that can help to realize the simplicity of use desired in the previous point. As already pointed out, the ability to automate device operations based on the content read allows you to create new ways to interact with the application. The NFC technology, thus, should be a constituent part of the interaction interface.

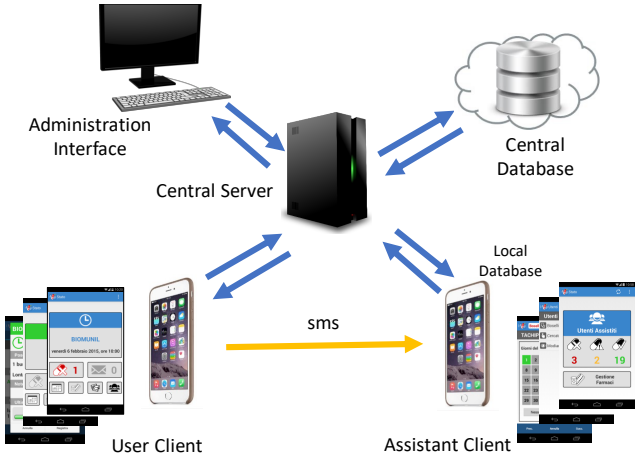

Figure 1. Architecture of the assistance system.

Keeping in mind these general guidelines, we created a system that can provide new functionality without changing the current doctor-pharmacist-patient relationships. No ad hoc device and no interference with the usual methods of supplying medicines must be introduced; the only change required is to insert NFC labels on the packages. Considering that the application is dedicated to people with a high number of prescriptions and long-term care, its use must be reduced to a few simple operations; a great contribution in this sense is given by the use of the NFC.

To reduce the complexity of the patient involvement, the only operation required to the patient is to record the successful intake of a drug. The phase of inserting data about prescriptions, that in the other apps often constitutes the last stumbling block in the simplification process, must therefore be entrusted to who assists the patient. Furthermore, the monitoring activity by the assistants will have to be as least invasive as possible.

The structure of the assistance system implemented is represented in Figure 1. The system consists of:

- an Android app, called "user client", intended for the person who needs assistance; it provides the reminder functions of drug intakes, the safe identification of drugs by reading the NFC tags affixed on the packages and finally the recording and communication to a central server of the events of successful or missed intake;
- a second Android application, called "assistant client", intended for assistance staff (doctors, family members, ...), through which it is possible to remotely manage the patient's medical prescriptions, interacting with the related user clients, and at the same time supervising the continuation of the therapy;
- a central server, the primary depository of information, with the aim of making it available and thus guaranteeing the assistance functions performed by the Android applications;
- an administration interface created on a web platform, through which the user accounts of the system can be managed.

Each assistant can follow multiple users through its application and to each user can be associated multiple assistants: a register keeps track of the actions performed by each of them in order to be able to go back to the author. In addition, assistants can take on different roles that are distinguished by the degree of operation: a role dedicated to medical personnel, and a role designed for the patient's family, which allows to follow the correct continuation of therapy without being able to modify it.

The system has been tested and verified by the developers. Furthermore, it has been applied in few real situations with some middle age users accustomed in the use of smartphone and some elderly people not used in app and smartphone.

III. Conclusions

The entire system has been developed for the implementation of following services: drug identification, recruitment reminders, information centralization and remote monitoring. The system does not require any disruption to the habits of the subjects involved and is immediately usable, although exclusively through NFC technology.

The target that the monitoring activity is the least invasive possible and transparent to the user has been realized through the automatic sharing of data and not being present any form of direct interaction between the assistant and user. Perhaps in this way the application is too aseptic and without a human contact, but it must be underlined that the system must be simply complement and support to the doctor-patient relationship.

The graphical interface and the flow of use have been developed following principles of clarity and simplicity, made up of elderly people, often not accustomed to the world of information and technology.

However, a first testing phase and the different hours of use during the development phase have already confirmed at least the potential of the features on which the system is based, highlighting the importance and effectiveness.

The creation of a central repository of information has made it possible to share among the various subjects, allowing to avoid that fragmentation of knowledge of the therapeutic situation of the patient, potentially harmful, and at the same time to monitor the effective compliance of the therapies.

The increasingly widespread use of mobile devices compatible with NFC technology and the simplicity and immediacy of its use were the reasons that led to focus on NFC as a fundamental mechanism in the use of the application.

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A Decision Support System for Diabetic Patients: Closing the loop for MDI users*

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Abstract— **Type 1 diabetes is a chronic and a life-threatening disease, an adjusted treatment and a proper management of the disease are crucial to prevent or delay the complications of diabetes. Although, during last decade the development of the artificial pancreas has presented great advances in diabetes care, the multiple daily injections therapy still represents the most widely used treatment option for type 1 diabetes. This work presents the proposal and first development stages of a application focused on guiding patients using the continuous glucose monitors and smart pens together with insulin and carbohydrates recommendations. Our proposal aims to develop a platform to integrate a series of innovative machine learning models and tools rigorously tested together the use of the latest IoT devices to manage type 1 diabetes. The resulting systems actually closes the loop, like the artificial pancreas, but in an intermittent way.**

I. Introduction

The Internet of Things (IoT) advocates an ecosystem of interconnected objects with the ability to perform a dynamic and periodic collection of data for the purpose of analyzing and obtaining valuable information for decision making. There is a large number of areas which will be benefited from further developments of the IoT but the health sector is one of the areas with more room to take advantage of these technologies, especially in terms of the control of chronic diseases. In this sense, apart from the applications to the healthcare professional area, the empowerment of the patients themselves is considered as a key feature to design next generations of decision support tools.

An important group of these chronic diseases is well-known as diabetes mellitus, which is the result of a dysfunction of the glucoregulatory system [1]. The primary consequence of this dysregulation is a chronic hyperglycemia that is associated with long-term complications. This short note will focus in the treatment of the type-1 diabetes (T1D) which requires exogenous insulin to regulate blood glucose (BG) and is related to long-term neurological, microvascular, and macrovascular complications [2]. Over time, hyperglycemia leads to several complications such as neuropathy, nephropathy, retinopathy, and cardiovascular disease [3]. Reductions in micro- and macrovascular complications have been demonstrated in intensively treated adults with T1D [2], [4]. Hypoglycemia is a serious complication of T1D and constitutes a major concern in patient safety, being one of the most significant fears of T1D patients [5], which may lead to seizures, coma, and even death.

Over the last decade, the entire paradigm of diabetes management has been transformed due to the integration of new IoT technologies such as continuous glucose monitoring (CGM) devices and the development of the artificial pancreas (AP) along with the exploitation of data acquired by applying these novel tools. Thus, advanced data analysis techniques are also attracting an increased attention in the field because the amount of data available from patients suffering diabetes has grown exponentially. Next sections of the paper present the background, aims and design of a real-time IoT-based continuous decision support system with a novel focus on the treatment of T1D and using a novel combination of machine learning methods.

II. Background, motivation and aims

Various technologies and tools have been developed for the management of T1D. CGM systems provide glucose levels in real-time, allowing patients to perform specific actions when necessary. In addition, the combination of continuous subcutaneous insulin infusion with CGM sensor has resulted into the sensor-augmented pump systems (SAP) which have paved the way to the first automation features in commercial insulin pumps, such as low glucose suspend (LGS) and predictive low glucose management (PLGM). LGS allows basal insulin infusion to be interrupted for up to two hours if the glucose level goes below a preset threshold and the patient does not respond to the hypoglycemia alerts [6], [7], whereas PLGM suspends insulin infusion if hypoglycemia is predicted to occur within 30 minutes and resumes insulin delivery when glucose levels begin to rise [8]. In a next step towards automation, integration of closed-loop glucose control algorithms into SAP gave birth to hybrid closed-loop control systems, the so-called AP, which automatically adjusts basal insulin infusion every 5 minutes based on glucose levels [9].

Although the results achieved using the aforementioned techniques represent a great advance in diabetes care, there is still much room for improvement, especially regarding patient safety and the prevention of hypoglycemia. In addition, some of these technologies may not be suitable for all people affected by T1D, and reimbursement barriers are also an impediment to their dissemination. Therefore, MDI, which is the combination of a slow-acting analogue for basal coverage, taken once or twice a day to keep BG levels consistent and a fast-acting analogue at meal times, to control

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BG levels after eating [10], still represents the most widely used treatment option for individuals with T1D [11].

The objective of this proposal is to extend AP research to MDI therapy using a smart insulin pen and a continuous glucose monitor (CGM), that "closes the loop" automatically guiding patient's manual actions when needed for an improved glycemic control. Next sections of the paper present the architecture of the proposed real-time IoT-based continuous decision support system based on a novel combination of machine learning methods.

III. System Architecture and current progress of the proposal

The IoT-based architecture comprise a complete system starting from sensor nodes to a back-end server. The platform ecosystem incorporates a glucometer to collect punctual BG measurements, a CGM monitor to periodically gather BG values, a smart insulin pen to automatically register the insulin administration and a physical activity monitor for the collection of steps, heart rate and activity events. The system allows patients easily monitor their glycemic outcomes via a smart-phone application. Sensor nodes of the system are able to obtain several types of data (i.e. BG values, administered insulin, physical activity and other types of physiological data) and transmit the data wirelessly to a smart-phone unit which centralize the data acquisition.

The data gathered by the IoT ecosystem compose the source to extract the features which feed the two main subsystems: the AP tools and a the machine learning engine. The system will utilize machine learning methodologies to enhance patient safety by anticipating adverse glycemic events using: 1) mid-term (1-4 hours) continuous BG levels prediction, 2) hypoglycemia risk assessment during postprandial periods, 3) overnight hypoglycemia forecasting, and 4) clusters of different profiles according to patient condition. The AP tools consist of a series of algorithms to: a) recommend insulin boluses [12], [13], b) detect missed bolus [14], c) recommend carbohydrates intakes when high [15], and d) provide predictive alarms. These tools will be tuned according to the predictions and classifications given by the machine learning module.

Continuous predictions are driven by an implementation based on grammatical evolution (GE). The mid-term continuous predictions of BG levels are challenging because the high variability, delays of meal and insulin absorption, and lagging BG measurements. This module appropriately address such delays to provide accurate forecasts. The standalone implementation of this module is detailed and largely tested in Contreras *et al.* [16], [17]. Postprandial risk is assessed using a support vector classifier (SVC) methodology. The prediction of hypoglycemic events when a patient announces a meal allows the assessment of the impact of the insulin bolus on the postprandial response, and makes it possible to optimise the bolus to achieve safer dosages. This is detailed and validated in Oviedo *et al.* [18]. The predictions of hypoglycemic events during the night are managed by an artificial neural network (ANN) methodology. Nocturnal hypoglycemia occurrence is a critical hazard in T1D management. The module aims to allow patients to reduce the basal insulin delivery rates and/or consuming a snack in case of hypoglycemia prediction. The ANN is described in detail and tested in Bertachi *et al.* [19]. Compositional Data (CoDa) analysis and clustering techniques are applied to identify different scenarios of glycemic control. The identification of the most common situations affecting BG control allows a further customisation of therapies to the specific scenarios faced by T1D patients. Methodologies applied in this proposal are described and validated in previous studies of Biagi *et al.* [20], [21] and Contreras *et al.* [22].

The integrated data driven approach use IoT devices to increase patient safety by forecasting unwanted events using both classification and regression approaches. These techniques will be used in conjunction with a bolus calculator to calculate meal boluses and correction boluses, carbohydrate suggestions to prevent impending hypoglycemia, mechanisms to reduce postprandial hyperglycemia during missed meal boluses, preventative action to prevent nocturnal hypoglycemia, and methodologies to improved exercise management and reduce exercise-induced hypoglycemia. Basal adjustments and adaptation in insulin dosing will also be implemented.

IV. Conclusions

The IoT industry is having a drastic transformative effect on the healthcare industry. As barriers to these technologies are being slowly lowered (price, power consumption, internet access), the IoT is becoming an integral part of health monitoring and management healthcare industry. At the same time, machine learning methodologies are increasing its importance because the related increasing availability of digitized health data. Decision support tools are one of the most benefited areas which is currently being revitalized and reinforced by IoT devices and machine learning methodologies. This increment of available digital data is also occurring in the context of the diabetic populations, that along with the emerging devices and advanced methodologies, such as the AP and machine learning techniques, suggests that we are moving toward a new paradigm for management of diabetes. This new outlook proposes to achieve a personalized management and empowerment of diabetes care while customising professional practices, medical decisions, and treatments to individual patients.

The methodology proposed here has presented a novel IoT-based system aimed for the management of T1D. The system proposes the combination of CGMs and smart pens and a patient guiding process through insulin and carbohydrates recommendations. The system design integrates classic decision support tools and advanced machine learning techniques for an improved glycemic control and quality of life. The results obtained by each individual module have been previously validated and the combination of the different module are promising, especially in terms of increasing patient safety in front of glycemic events and help patients to take more accurate decisions on the management of their disease.

ACKNOWLEDGMENTS

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Correlation Between Respiratory Action and Diaphragm Surface EMG Signal

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Abstract— **This paper investigates the possibility to effectively monitor and control the respiratory action using a very simple and non invasive technique based on a single lightweight reduced-size wireless surface electromyography (sEMG) sensor placed below the sternum. The captured sEMG signal, due to the critical sensor position, is characterized by a low energy level and it is affected by motion artifacts and cardiac noise. In this work we present a preliminary study performed on adults for assessing the correlation of the spirometry signal and the sEMG signal after the removal of the superimposed heart signal. This study and the related findings could be useful in respiratory monitoring of preterm infants.**

I. Introduction

Electrical signals captured from muscles' activity are very helpful in recognizing human movements or sports exercises, as well as in monitoring a person's body posture, physical performance, and fitness level, as it has recently been investigated [1]–[9]. This is due to the fact that sEMG signals can be easily acquired using noninvasive sensor devices. Indeed, these signals are related to the electrical potentials generated by muscle contractions, thus they can be collected by simply contacting small and inexpensive electrodes to the skin surface [10]–[12].

Among the body activities, the respiratory activity is the result of the interaction between the respiratory muscles, lung and rib cage compliance, and the airflow in the airways.

The diaphragm is the main muscle involved in inspiration. However several additional muscles participate to this activity such as the external and parasternal intercostal, scalene, upper trapezius, large dorsal, sternocleidomastoid, and the pectoralis major muscles. As a result, the contractions of these muscles can be monitored placing in correspondence of them surface electromyography (sEMG) sensors across the surface of skin [13]–[17].

Unfortunately, these signals are affected by cardiac noise and movement artifacts. In this context several works were devoted to the study of the activity of inspiratory muscles in adults and elderly people and to implement procedures to record surface electromyography (sEMG) signals acquired from them [18]–[22]. However, in preterm infants using noninvasive sEMG signals is an excellent technique alternative to expensive complex endoesophageal probes for the identification and monitoring of apnea, by detecting the contractility of the diaphragm and triggering a mechanical ventilator.

Usually, sEMG signal based techniques for breathing detection use several surface electrodes, in a variable number comprised between 3 and 12, which are placed anteriorly and posteriorly on the skin above the diaphragm to detect its contractility. These electrodes are small in size (i.e. 20 mm), easy to find and do not require specific positioning skills. The correlation between surface respiratory electromyography and esophageal diaphragm electromyography has been investigated [23]. However, the sEMG techniques are inherently more easy to implement than the endoesophageal probe that requires a considerable experience of the operator for its correct localization. Moreover, besides being more expensive than the surface electrodes, the probe is at risk for displacement (especially in non-collaborative subjects such as the infants).

Nonetheless, sEMG is prone to the interference of various factors (artifacts) such as cardiac activity, skeletal muscle contraction during movement; also, the relatively small skin surface available in newborn patients limits the size and number of applied sEMG electrodes. Therefore, the use of the sEMG breathing detectors is not yet widespread in neonatal clinical practice.

Some studies have shown the usefulness of sEMG for monitoring heart rate and respiration, for weaning from noninvasive ventilation. Furthermore, other works have shown a good correlation between respiratory function indices and diaphragm electromyography [24], [25].

The creation of a specific wireless sEMG system specifically designed for neonatal use and equipped with one or more miniaturized electrodes could be a great advantage either for the identification and monitoring of apnea, and for future use as a measuring system for triggering mechanical ventilators instead of expensive complex endoesophageal probes.

In this work we present a preliminary study performed on adults for assessing the correlation of the sEMG signal, obtained from a single lightweight wireless sensor placed in a sternal position and hence affected by cardiac and movement artifacts, to the breathing activity detected by simultaneous recording of the signal from a spirometer worn by the subject over their nose and mouth.

This study and the related findings could be useful in the optimal design of a respiratory monitoring systems for preterm infants.

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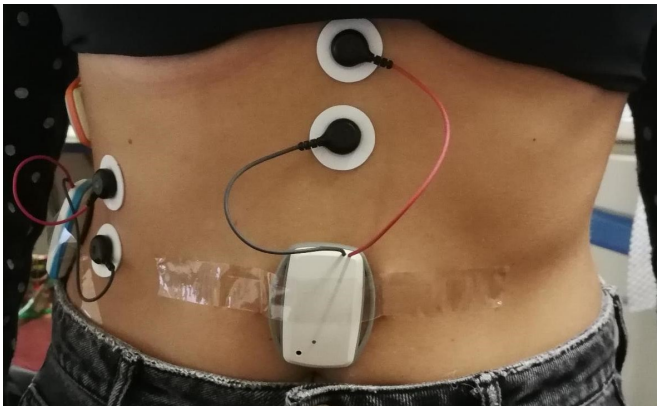

Fig. 1. Electrode placement.

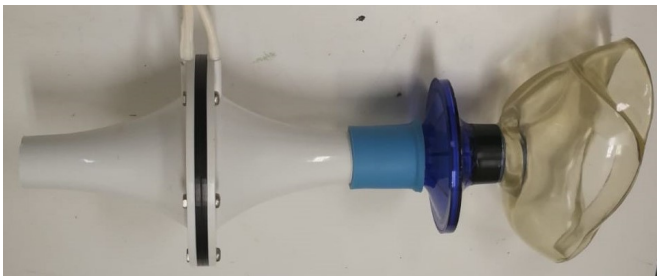

Fig. 2. Spirometer.

II. Methods

The sEMG signals were acquired using the setup shown in Fig. 1. Of the three electrodes placed to investigate the best position to sense the diaphragm muscle, the one on the side was selected as giving the strongest signal level. A picture of the used spirometer can be seen in Fig.2.

Eight adult volunteers participated in the study. Full details on the recording conditions and apparatus can be found in [26], together with the full dataset used for this investigation.

In order to investigate the possible correlation between the acquired sEMG signals and the respiratory activity, a suitably simple and descriptive feature must be extracted from the signal. We chose to analyze the mean absolute value (MAV) of the sEMG signal, as it is a feature well known to be related to muscle activation level [6], [11]. Still, computing MAV in this particular case is not straightforward because of the strong contamination of the sEMG signal by the heart pulses. This contamination must first be removed.

To this end, the average pulse subtraction technique [27] was employed. To apply it, the positions of the cardiac QRS complexes must be found in the signal, a window around every R peak is then extracted from the signal. The average of all the extracted windows is finally computed. This approach is based on the assumption that the shape of the contaminant QRS wave does not change in the short period of time of analysis. Thus, the averaging process does not distort much their shape, having the waveforms been aligned. The main sEMG signal, on the other hand, has a zero mean value, and so its average vanishes.

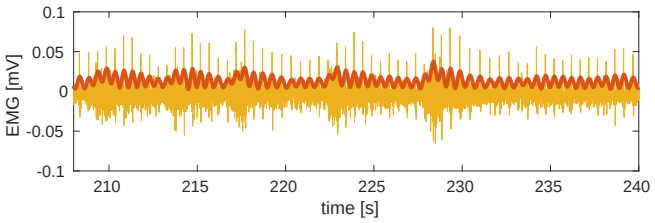

Fig. 3. Raw EMG signal recorded from the lowest intercostal space, with superimposed amplitude envelope in thick red line.

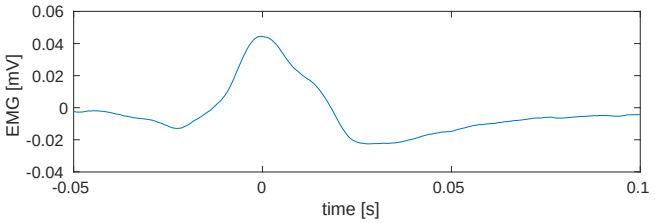

Fig. 4. Average ECG contamination in a window around the QRS complex.

Many techniques exist to locate the QRS complex in an ECG signal. In our case, a simple peak detector suffices. It works as follows.

First, the sEMG signal is resampled so that it has a uniform 2 kHz sample rate. Let us call $s_{\mathrm{M}}(t)$ the result of the resampling. Then, its absolute value is computed and low-pass filtered with a 2.5 Hz cut-off frequency, to obtain its amplitude envelope given by

$$e_{\mathrm{M}}(t) = |s_{\mathrm{M}}(t)| * h_{\mathrm{LPF:2.5}}(t) \tag{1}$$

where $h_{\mathrm{LPF:2.5}}(t)$ is the filter impulse response and "$*$" denotes the convolution operator. For reference, the signal $\pi/2 \cdot e_{\mathrm{M}}(t)$ is shown in Fig. 3 as a thick red line superimposed to the original sEMG signal (scaling by $\pi/2$ was done for visual purposes only, to approximately compensate the crest factor so that the curve appears near the envelope of the original signal).

As can be seen, the cardiac contamination continues to affect the signal envelope. To remove it, a simple peak detector was implemented. The sEMG signal $s_{\mathrm{M}}(t)$ is low-pass filtered at 75 Hz to remove some noise while retaining the fundamental shape of the QRS complex, obtaining the signal $s_{\mathrm{H}}(t)$

$$s_{\mathrm{H}}(t) = s_{\mathrm{M}}(t) * h_{\mathrm{LPF:75}}(t) \tag{2}$$

then the positions t_i of the peaks that are above a prescribed threshold k of the envelope are sought

$$t_i \;:\; s_{\mathrm{H}}(t_i) > k\, e_{\mathrm{M}}(t_i) \quad i = 1, \ldots, N \tag{3}$$

where the optimal value of k was experimentally found to be $k = 1.6\,\pi/2$, and N is the number of peaks found. To remove spurious peaks due to noise, the t_i's that do not fall within a 100 ms interval from local maxima of $e_{\mathrm{M}}(t)$ are discarded.

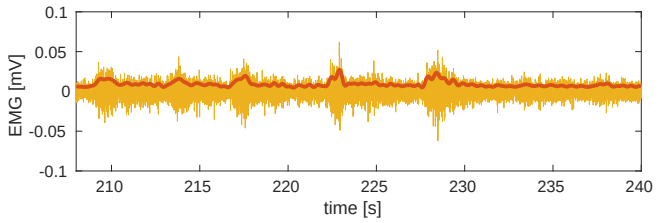

Fig. 5. EMG signal cleaned of the ECG contamination, with superimposed amplitude envelope.

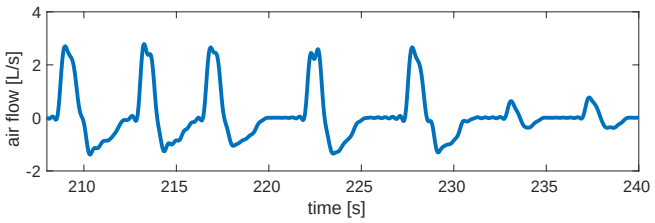

Fig. 6. Filtered air flow with compensated offset.

Once the positions of the QRS complexes are known, the waveforms are averaged as

$$s_{\mathrm{QRS}}(t) = \frac{1}{N}\sum_{i=1}^{N} s_{\mathrm{M}}(t+t_i) \quad t \in [-50, 100]\ \mathrm{ms} \tag{4}$$

and the result is shown in Fig. 4.

Since $s_{\mathrm{QRS}}(t)$ is an average signal, before subtracting it from the original sEMG signal it is necessary to scale and offset it so that it best matches the specific contamination to be removed. The baseline of the sEMG signal is indeed not perfectly stable due to cable movements and other factors, and the exact amplitude of each pulse can be slightly different as well.

So, for each i in $1, \ldots, N$, the coefficients a_i^0, a_i^1, $a_i^{\sim}$ are computed as the least-square solution of

$$a_i^0 + a_i^1\, t + a_i^{\sim}\, s_{\mathrm{QRS}}(t) \simeq s_{\mathrm{M}}(t+t_i) \tag{5}$$

and then the cleaned sEMG signal $s_{\mathrm{C}}(t)$ can be computed as

$$s_{\mathrm{C}}(t) = s_{\mathrm{M}}(t) - \sum_{i=1}^{N} s_i(t) \tag{6}$$

where

$$s_i(t) = \begin{cases} a_i^0 + a_i^1\, t + a_i^{\sim}\, s_{\mathrm{QRS}}(t) & t \in [-50, 100]\ \mathrm{ms} \\ 0 & \text{elsewhere}\ . \end{cases} \tag{7}$$

As a final step, the possible baseline wander is removed by high-pass filtering the previous result, yielding the signal

$$s_{\mathrm{F}}(t) = s_{\mathrm{C}}(t) * h_{\mathrm{HPF:5.0}} \tag{8}$$

where $h_{\mathrm{HPF:5.0}}$ is a 5.0 Hz high-pass filter impulse response, and then computing its amplitude envelope, re-applying again the procedure (1)

$$e_{\mathrm{F}}(t) = |s_{\mathrm{F}}(t)| * h_{\mathrm{LPF:2.5}}(t)\ . \tag{9}$$

The result is shown in Fig. 5, which reports $\pi/2 \cdot e_{\mathrm{F}}(t)$ as a thick red line together with the cleaned signal $s_{\mathrm{F}}(t)$. As can be seen, the cardiac contamination was nearly completely removed.

As a reference, Fig. 6 reports the air flow, filtered with the same 2.5 Hz low-pass filter to reduce some noise, for the same time interval.

A correlation between the extracted signal $e_{\mathrm{F}}(t)$ and the air flow is apparent, as will be investigated next.

TABLE I

CANONICAL CORRELATION BETWEEN EXTRACTED FEATURE AND AIR FLOW, AFTER AUTOMATED SIGNAL ALIGNMENT.

subject	correlation	lag [s]
1	0.7760	0.488
2	0.3290	1.984
3	0.1061	1.056
4	0.4900	0.528
5	0.4706	−0.120
6	0.3757	−1.704
7	0.3564	1.712
8	0.5808	0.504

III. RESULTS

To investigate the correlation between the extracted feature and the actual air flow, a dataset consisting in recordings from 8 adult volunteers was used. Each recording consists in two manually synchronised traces, one from the sEMG sensor and one from the spirometer. Since the spirometer signal manifested a significant offset, its mean value was removed before any further processing. Let us call $s_{\mathrm{A}}(t)$ this signal, with the convention that inhaled air corresponds to $s_{\mathrm{A}}(t) > 0$, and exhaling to $s_{\mathrm{A}}(t) < 0$. Since the diaphragmatic muscles are in principle only involved while inhaling, only the positive part of the signal $s_{\mathrm{A}}(t)$ should be correlated to the sEMG envelope. Hence, the negative portion was removed, by posing $e_{\mathrm{A}}(t) = \max(0, s_{\mathrm{A}}(t))$.

The canonical correlation between $e_{\mathrm{F}}(t)$ and $e_{\mathrm{A}}(t-\tau)$ was then computed for different time lags τ, to compensate for small misalignments between the two traces, and the maximum value recorded.

The results are shown in Table I, and a few significant examples are reported in Fig. 7, which reports the $e_{\mathrm{A}}(t-\tau)$ signal and the $k_0 + k_1\, e_{\mathrm{F}}(t)$ signal, with k_0 and k_1 estimated for best least-square fitting of the two curves.

As can be seen, the sEMG envelope provides a good estimation of the positive portion of the airflow. Sometimes, especially for subject 4, diaphragmatic muscle activation was also detected during the exhaling phase.

IV. CONCLUSIONS

In this work we presented a simple feature extraction technique that can be applied to a sEMG signal recorded from the diaphragmatic muscle to obtain a first rough estimate of the breathing activity. After cardiac and cable motion artifacts are removed, the sEMG signal envelope shows a significant correlation to the ground true airflow

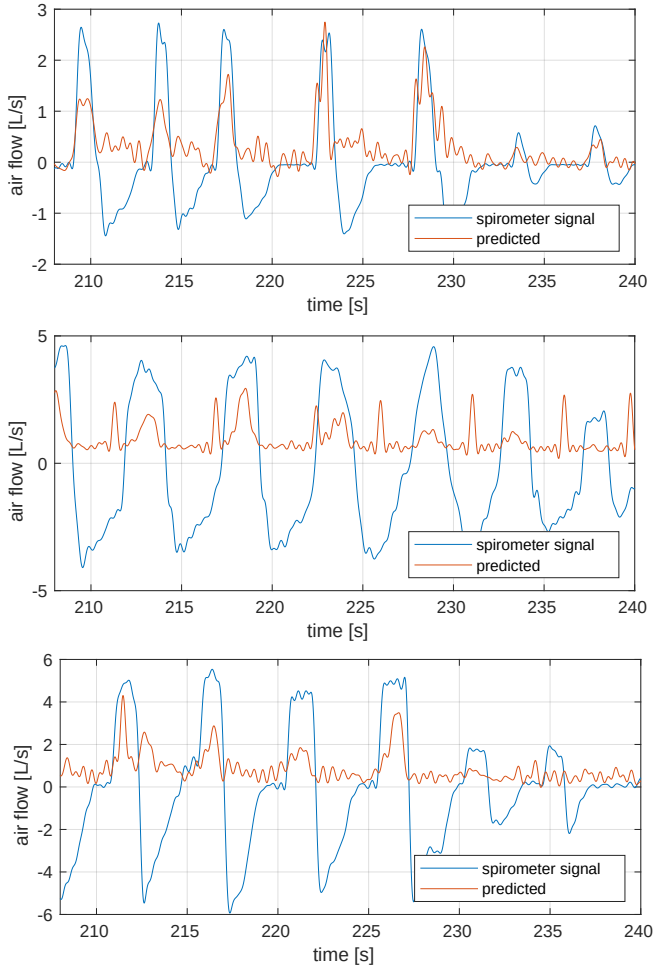

Fig. 7. Predicted inhaled air flow vs. spirometer signal for subjects (from top to bottom) 1, 4, and 8.

obtained by simultaneous recording with a spirometer. Least-square fitting of the sEMG-derived feature to the positive (inhaling) portion of the air flow shows that it could be possible to estimate this signal from electrical measures of diaphragmatic activity.

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Combining smart sensor systems with gamification to increase the efficiency of therapies

Dr. Christoph Rathfelder[1], Nathalie Hipp[2], Hahn-Schickard

***Abstract*— The potentials and opportunities created by digitized healthcare can be further customized through smart data processing and analysis using accurate patient information. This development and the associated new treatment concepts basing on digital smart sensors can lead to an increase in motivation by applying gamification approaches. This effect can also be used in the field of medical treatment, e.g. with the help of a digital spirometer combined with an app. In one of our exemplary applications, we show how to control an airplane within an app by breathing respectively inhaling and exhaling. Using this biofeedback within a game allows us to increase the motivation and fun for children that need to perform necessary exercises [1].**

I. Introduction And Motivation

Gamification, digitization, mobile health care, personalized medicine and bio-feedback are upcoming trends in medicine or in medical technologies. Their aim is to improve the quality and effectiveness of therapies in terms of reaction on individual, personalized needs of patients, prevention of side effects, increase of efficiency and reduction of costs. Mobile devices and applications form a useful basis for those trends [1].

Over the last few years, mobile devices such as smartphones and tablets became a standard in everyday life. Children grow up with the use of such devices and for older children it is a "must-have" equipment. For this reason, it is a promising approach to use mobile devices not only for entertainment. Additionally, body-worn sensors with integrated mini-computers, the so-called wearables, have a growing number of usage. The hype surrounding mobile data collectors, such as smart watches, will continue over the next years.

Smart sensor systems enable innovative solutions for improving our health. Typical applications are both numerous and heterogeneous: They range from mobile diagnostic devices for rapid on-site analysis of infectious diseases over intelligent oral medication dosing systems to assistance systems during medical rehabilitation, or improvement of medical instruments [2].

The combination of mobile devices, gamification, and smart sensor systems builds up new possibilities and perhaps more motivation for therapies.

II. Application Examples

In order to implement a gamification approach with a smart sensor system, it needs to be clarified which disease or handicap should be treated and if it makes sense to create an application for it. Often the success of a training therapy highly depends on the execution quality and quantity of training exercises though a continuous daily exercise is beneficial.

A. Example SpiroSpiel[3]

Cystic fibrosis is a metabolic disease that causes the formation of mucus through a genetic defect in organs such as the lungs disturbing the activity of this organ. The lungs with the airways are most and worst affected [3]. Various breathing techniques and respiratory training equipment help patients to reduce the discomfort of their disease. Figure 1 shows the volume distribution within the lung with different respiration cycles. Patients should train all three marked areas [3].

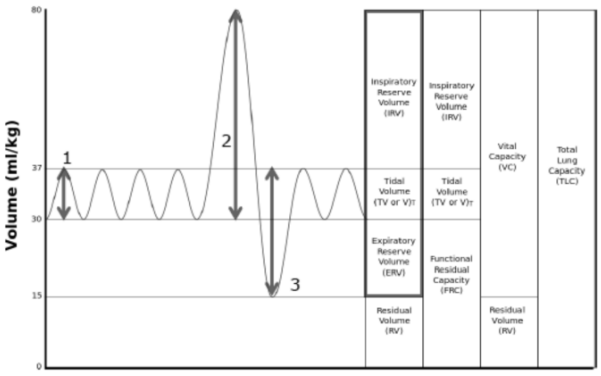

Figure 1. Volume capacity of the lung [4]

In one of our exemplary applications, we use a respiratory flow sensor developed by Hahn-Schickard for therapeutic use [5]. This digital spirometer is equipped with a Bluetooth interface. In the following, we describe our app *SpiroSpiel* showing the gamification of the therapeutic use for children suffering from cystic fibrosis. The data collected by the sensors are not only made available to the patient, but can also be used to be inspected and analysed by the attending physician or therapist in order to determine whether the therapy needs to be adapted [4].

Figure 2 shows the use case diagram for the *SpiroSpiel* application [4]. Different persons have access to the game: patient (child), parents, doctor and therapist. These four users access the *SpiroSpiel* in different ways. The left-hand side represents the home area, e.g. the area of self-directed

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[3] *SpiroSpiel* is an Hahn-Schickard named game.

exercises at home between two sessions with the therapist. The specialist staff with doctor and therapist that can make adjustments to the system respectively training parameters in addition to the control view. The system itself is divided into six (main) use cases: games, user data, training control, configure breathing curve, training data sets, and long-term control. These use cases describe the purpose for which the *SpiroSpiel* system has been developed [4].

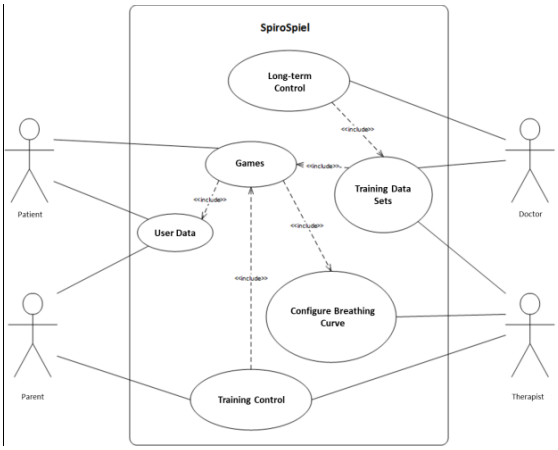

Figure 2. Use case diagram of the *SpiroSpiel* [4]

Looking at the home user side containing the patient and its parents, the use case diagram shows that only the use-cases *games*, *user data* and *training control* are relevant for independently performing the exercises at home. The training control gives a chronological list of performed exercises [4]. Parents can check whether the child has performed the exercises regularly and with which intensity. The user data contains information about the patient itself.

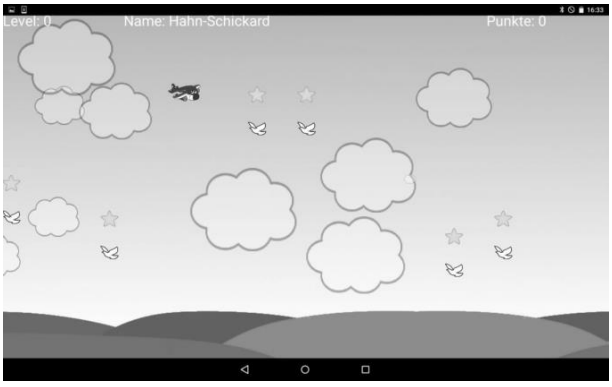

Figure 3. Screen of *SpiroSpiel* [4]

B. *Example DermaPad*[4]

The *DermaPad* is a multi-function sensor-actuator system for recording and processing bio signals [6]. It can also deliver a TENS[5] pulse to the skin surface. The wireless connection to one or more *DermaPads* creates a so-called Wireless Body Area Network (WBAN). In such networks, mobile terminals (e.g., smartphones or tablets) can conveniently interact with near-body sensor systems [6].

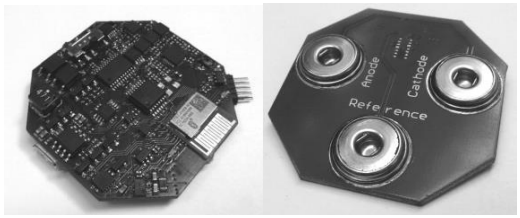

Figure 4. *DermaPads* [6]

Figur 4 shows the *DermaPad* with all its sensors and actors:

- Derivation of bio potentials, e.g. ECG, EEG, EMG
- Skin conductance measurement
- Pulse oximetry (heart rate, oxygen saturation)
- Accelerometer
- Touch sensor
- TENS

In our exemplary application, we demonstrate the navigation of visually impaired person using TENS pulses. We place several *DermaPads* at appropriate places on the visually impaired person's body that all connect to a mobile device [6]. The software activates the TENS function of the different pads, causing the blind person to experience a stimulus. The location of the stimulus allows an interpretation for the navigation direction or movement (stopping, forward etc,). For example, a TENS pulse perceived on the right half of the body corresponds to a corresponding right turn of the navigated person. Since our application focuses on the feedback channel and not an autonomous navigation, the navigation of the visually impaired person and operation of the software is done by an additional user. As an extension, of course, a supplement with navigation software or additional sensors for obstacle detection is possible.

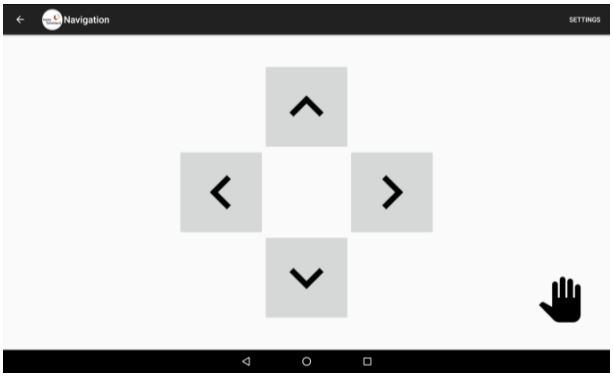

Figure 5. Surface Navigation App **[6]**

For navigation, a simple scheme similar to the arrow keys on a keyboard is used. When an arrow key is pressed, the app activates the TENS function of the associated derma pad or a combination of derma pads. The visually impaired person receives the desired TENS feedback and can react accordingly. If a pulse is perceived only subliminally, the TENS parameters can be adjusted via the option menu "Settings". Since the navigation requires multiple derma pads

[4] *DermaPad* is a Hahn-Schickard given name and consists on the one hand of the Latin word "Derma" for skin and on the other hand the English word "pad".

[5] TENS - transcutaneous electrical nerve stimulation

combined in different feedback groups, the navigation buttons are activated only if two or four derma pads are connected. In the following, the key assignment of the TENS activation patterns are explained as an example in the shoulder area.

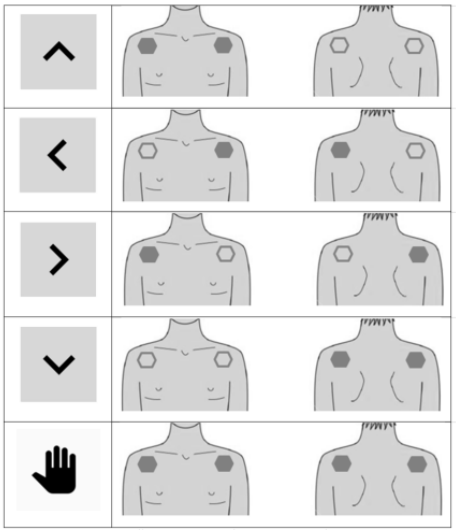

Figure 6. Navigation part [6]

In the case of the implementation with four derma pads, two derma pads are located on the front of the body and two pads on the back of the body.

III. Results And Discussion

Our exemplary applications show the benefits that can be reached by combining medical sensors with smart phones. Especially the capabilities of smart phones in term of connectability, user interfaces, and data processing power in combination with their high spread allow multiple applications. The *SpiroSpiel* application highlights that a pure sensor system measuring the breathing airflow can be extended to a complete digital therapy system. This system on the one hand opens completely new application domains and on the other hands creates additional value due to the intelligence that is hidden within the gaming app.

Discussions with parents of children with cystic fibrosis show that, children and adolescents often see the necessary exercises as very boring due to less variation and low motivation. Exercises in combination with inhalers are often associated with static and calm posture. It is also a special challenge for parents and therapists to motivate the children, as they are kept away from playing with friends or toys during this time. Furthermore, it is hard to adapt the exercises reflecting the current health status since it has not been quantitatively measured. Additionally the automatically digital monitoring of health data and therapy results offers new individual studies and evaluation of therapies and provides the basis for personalized and individually optimized therapies.

The *DermaPad* example shows that medical sensor actor systems can be applied in applications that have not been foreseen when developing the system itself by adding new functionality in terms of an additional app. With our app for visually impaired person, we demonstrated only one possible application. Many different applications can be envisioned that require a feedback channel that is not as noticeable as visual or audible feedback.

IV. Conclusion And Outlook

In our paper, we showed two exemplary applications in which we extended medical sensor systems with an additional app running on a smart phone. Using the breathing data to control a game, allows us to increase the motivation for children to perform necessary exercises based on a gamification approach. The second example demonstrates the use of body-worn sensor-actor system as feedback channel allowing the interaction between app and human being based on a TENS stimulus instead of the often used visual or audio feedback.

In our future work, we plan to follow-up and extend our approach on using gamification techniques combined with medical or body near sensor systems on smart phones to increase the motivation and efficiency of therapeutic exercises. Furthermore, the collected data can be used to optimize therapies in general or to optimize them according to the individual needs or therapy results of a patient.

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The Use of Digital Technology in Palliative Care

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***Abstract*— Due to the rising need for palliative care in Russia, it is crucial to provide timely and high-quality solutions for patients, relatives, and caregivers. A methodology for remote monitoring of patients in need of palliative care and the requirements will be developed for a hardware-software complex for remote monitoring of patients' health at home.**

I. Introduction

The number of citizens in need of palliative care is increasing in all regions of the Russian Federation. Also, when a situation arises when a patient begins to need such help, he and his relatives cannot always find the right solution for how to quickly and efficiently organize proper care for such a patient.

To provide timely and high-quality palliative care, it is necessary to provide the patient, his relatives, caregivers with the opportunity to find the right decision on how and where such medical care can be obtained, how to accurately organize the patient's referral to a specialized institution, and how to organize a home telemedicine hospital to ensure proper care. [1]

The purpose of the use of digital methods in medicine is the management of patient flows and the organization of medical care using digital technologies for patients in need of palliative care. [2,3]

II. Objectives

The following results will be achieved:

- Ensuring accessibility and transparency for patients in the process of receiving palliative care;
- Ensuring the availability of essential drugs needed to treat a variety of symptoms, including pain and psychological disorders;
- Integration of palliative care in all levels of the national health system with the creation of the necessary financing and management mechanisms;
- Strengthening and developing human resource capacity for palliative care, including education and psychological support for health workers to prevent burnout;
- Assist in research activities to assess the needs of palliative care and develop effective standards and models for the provision of services in conditions of limited resources.

III. Methodology

The objectives of introducing digital technology into palliative care are as follows:

- Development of a concept for the creation of a Vertically Integrated Information System for Palliative Medical Care for the registration of patients requiring palliative medical care;
- Development of requirements for the Federal Register of Patients in Need of Palliative Care, regulatory documents on its operation, testing;
- Development of requirements for the medical information system for patients in need of palliative care, regulatory documents, testing;
- Development of a methodology for remote monitoring of patients in need of palliative care, requirements for organizing a telemedicine in-patient care at home (including creating a register of mobile devices that allow for effective monitoring of health status), regulatory documentation;
- Development of a methodology for applying virtual and augmented reality methods to alleviate the condition of patients in need of palliative care, developing prototype solutions, regulatory documentation, testing;
- Development of requirements for distance education of medical workers involved in the provision of palliative care, the creation of educational courses, testing educational modules;
- Analysis of information risks and development of proposals for their minimization (protection of personal data, identification, and authentication of a medical worker and patient, etc.).

In developing a methodology for remote monitoring of patients in need of palliative care, requirements will be

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developed for a hardware-software complex for remote monitoring of patients' health at home. The complex will include a set of mobile (compact) medical devices and a device management software package. The experiment method will determine the required set of mobile medical devices, allowing to determine the state of health of the patient accurately, and support the doctor to determine his condition.

An exciting direction in the development of remote monitoring for a patient will be or the realization of video surveillance. It recognizes a patient's position in the bed and movements. Figure 1 shows a fragment of the monitoring system for a bed patient.

Figure 1. Intellectual monitoring system for the bed patient

The system records the position of the patient, the time spent on each side, stalling the bed. When the time is exceeded, it signals the doctor (carer). The system will be expanded by taking into account medical prescriptions and monitoring the required manipulations of the nurse.

IV. Results

As a result of the work described in the Russian Federation, requirements will be developed for the vertically integrated information system of palliative medical care. The implementation will seriously optimize the process of referral to palliative medical care, implement it at home in the form of a telemedicine hospital, apply artificial intelligence, virtual reality and substantially improve the quality of palliative care.

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