Using Multiple Devices for Patient Monitoring in Clinical Studies: The TOLIFE Experience

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***Abstract*—In the contemporary age of human-centered computing, smartphones, smartwatches, and IoT devices are currently being used in the medical sector for continuous monitoring of patients. Existing clinical applications generally rely on a single type of device, while the adoption of a multi-modal data collection where multiple heterogeneous devices are employed is still not adequately explored. In this paper, we present the approach of the European project TOLIFE, in which a multi-modal data collection approach is proposed to monitor the health status of Chronic Obstructive Pulmonary Disease (COPD) patients. In this paper we present our experience in integrating commercial and ad-hoc devices into a single system for unobtrusive data collection, presenting the overall approach and highlighting the challenges we faced. Specific focus is offered to our experience in integrating commercial devices into the system to assess whether they are suitable for continuous monitoring in terms of fine-grained data collection and usability.**

***Index Terms*—TOLIFE, patient monitoring, multi-modal data collection**

I. INTRODUCTION

The contemporary era is pervaded by human-centered computing, where pervasive devices are already a significant part of our daily life. Smartphones give us instant access to information, smartwatches or wearable activity trackers monitor our daily activities and well-being, Internet of Things (IoT) devices provide the ability to monitor our personal environments or remotely control some of their functionalities.

The widespread use of such devices has also implications in the medical sector. Commercial wearable devices are already capable of monitoring different biomedical signals such as electrocardiogram (ECG) or blood pressure, while commercial activity trackers are already common to monitor the level of our daily activities or detect sleep patterns. Their use for continuous monitoring of patients [1] or to track health-related physical fitness metrics such as walking distance or steps taken on a large scale [2] is already being used. The adoption of specialized IoT devices for patient monitoring [3] or for rehabilitation [4] at home is currently maturing rapidly.

Despite the potential availability of diverse types of devices, health care monitoring and clinical applications in general mainly relied on a singular type of device, e.g., [5], [6] and [7]. The opportunity to adopt a multi-modal data collection approach in which data from multiple commercial (e.g., smartphones and smartwatches) and ad-hoc devices for patient monitoring still remains unexplored. A holistic approach where multiple data sources are exploited to collect patients' data, however, holds the promise of offering a more comprehensive insight into the health status: a collection of heterogeneous and substantial datasets could be used to develop an innovative approach using techniques from the real of big data, thus facilitating more accurate and personalized healthcare intervention.

In this context, the European project TOLIFE[1] is one of the first research efforts that aims at exploiting a multi-modal data collection approach to monitor the health status of Chronic Obstructive Pulmonary Disease (COPD) patients. To this aim, a mix of commercial devices, i.e., a smartphone and a smartwatch, and ad-hoc IoT devices will be employed to collect heterogeneous data on different health aspects of the patients in an unobtrusive manner. The collected data will be offloaded to a cloud platform and analyzed to develop Artificial Intelligence (AI) based solutions. Such solutions will aim at enabling the optimised and personalized treatment, assessing the health outcomes and the quality of life of the patients and predicting the exacerbation of the disease. The approach and the technologies developed will be validated in two different clinical studies involving in total more than 150 patients.

In this paper, we present the TOLIFE experience in developing a system that employs multiple heterogeneous devices for patient monitoring in clinical studies. Our goal is to present our first hand experience in developing a system that includes a mix of commercial and custom devices, highlighting all the issues that faced during their development and integration. Specific focus is offered to our experience in using and integrating commercial devices into the system to assess whether they are suitable for continuous monitoring and fine-grained data collection via a set of real experiments, to offer a set of guidelines for practitioners and future implementations.

The remainder of the paper is organized as follow: In Section II we present the requirements for the TOLIFE system, in Section III we provide an overview of the implementation, in Section IV we provide some insights on the challenges we faced for the implementation, in Section V we present some experimental results of our experiments, finally we draw some conclusions in Section VI.

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[1] TOLIFE project homepage: https://www.tolife-project.eu/

II. System Requirements

The TOLIFE system aims at collecting data from COPD patients including different and heterogeneous metrics to assess the progress of the disease. To this aim, the following measurements were identified as of interest to monitor each patient as they are correlated with the progress of the disease:

- *Physical activity*, in order to collect information on the level of physical activity and track how often the patient moves;
- *Sleep tracking*, in order to assess the sleep quality;
- *Hearth rate*, in order to assess the fatigue of the patient;
- *Ventilation*, in order to measure the volume of air inspired and expired by the lungs;
- *Environmental data*, in order to assess the air quality of the environment where the patient lives;
- *Ambient sound data*, in order to detect the coughing frequency of patients.

Metrics are collected via a set of devices, each device must collect data in an *unobtrusive* manner. Continuous monitoring is paramount in order to obtain a complete view of the health status of a patient, consequently, the devices must not have a significant impact on the patient's lives, so they can be used as extensively as possible. For the same reason, wearability should be preferred over data accuracy.

The set of devices is a mix of commercial and ad-hoc devices, in order to balance the trade-off between costs and data collection accuracy. The adoption of commercial devices is prioritized, however, in case a commercial device is not available to cover a certain measurement or the commercial device available is intrusive, an ad-hoc device is developed for the project.

The selection of devices to be included in the set aims to cover all the required measurements. Moreover, the set should also allow to collect certain key metrics from *multiple sources*, i.e., physical activity measurements. This requirement is important to verify, at least in the first stage, the accuracy of the collected data for the definition of the data analysis algorithms.

The selection of commercial devices is carried out by evaluating several factors, including measurement accuracy, compatibility with clinical needs and market availability, while the creation of ad-hoc IoT devices is based on mature prototypes that were already realized in the framework of past research activities and thoughtfully tested.

III. TOLIFE System overview

In this section, we present the overall architecture of the TOLIFE system for patients' monitoring and data collection from COPD patients. First, we provide an overview of the set of devices that are used (Section III-A), then we will provide an overview of the overall architecture of the system (Section III-B) and the data management (Section III-C).

A. Monitoring Devices

An overview of the devices included in a TOLIFE kit is presented in Figure. 1.

Fig. 1. TOLIFE monitoring devices, from the left to right: SmartPhone (Samsung Galaxy A14), SmartWatch (Samsung Galaxy Wear 5), SmartShoes, Smart Mattress cover, Environmental unit and Spiromiter (Smart One OXI)

The main two devices are commercial devices, i.e., a smartphone and a smartwatch. They are two popular commercial devices that are unobtrusive and are already familiar to the users. Moreover, generally they are equipped with a rich set of sensors, which are capable of covering multiple of the measurements required.

In order to select the specific type of smartphone and smartwatch, we conducted a thorough review of the scientific literature to identify devices that have been shown to provide reliable and accurate data. In addition, we consulted medical experts and engineers to obtain qualified feedback on device selection. In addition, the compatibility of devices was assessed by considering the devices' ability to collect the specific parameters required for patient monitoring, for example, we checked whether the devices were able to measure heart rate, physical activity and sleep adequately. Eventually, market availability was also an important criterion as we had to ensure that the devices were easily accessible to the patients involved in the study and the medical staff.

This selection process leads to a Samsung Galaxy A14 smartphone[2] and a Samsung Galaxy Wear 5 smartwatch[3]. These devices are capable to track physical activities, sleep quality and hearth rate. The Samsung Galaxy Wear 5 was selected as the smartwatch with the most rich set of sensors, including FDA-approved ECG, running Wear OS. The latter was a crucial requirement in order to support the deployment of a custom application developed to implement our collection process. Consequently, a Samsung smartphone was selected, as it is mandatory to enable some of the features on the smartwatch. In this case, we selected the Samsung Galaxy A14, as it is the Android smartphone that provides the best tradeoff between cost and data storage capabilities, with the minimum set of sensors required for our goals, i.e., microphone, accelerometer and gyroscope.

In order to collect data on ventilation a commercial portable spirometer was added to the set [4]. The device was selected as it offered a Software Development Kit (SDK) to collect data from an Android application using a Bluetooth connection.

In order to complete the data collection two ad-hoc devices are developed and included: an environmental unit and a smart mattress cover. The environmental unit is an embedded system that includes two different sensors: an air quality sensor to collect environmental data and a microphone to collect

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[2] Samsung Galaxy A14 homepage: https://www.samsung.com/uk/smartphones/galaxy-a/galaxy-a14-5g-silver-64gb-sm-a146pzsdeub/

[3] Samsung Galaxy Wear 5 homepage: https://www.samsung.com/it/watches/galaxy-watch/galaxy-watch5-40mm-graphite-bluetooth-sm-r900nzaaitv/

[4] Minispir device homepage: https://www.mirsmartone.com/it/shop/catalogue/smart-one-oxi_8/

ambient sound data. The smart mattress cover comprises a matrix of piezoresistive sensors made from textile materials connected to an embedded system. This matrix is constructed using the resistive matrix method detailed in [8]. The matrix, placed on top of the mattress beneath the sheets, collects data on the pressure exerted by individuals lying on it, enabling the collection of detailed information about sleeping posture and breathing activity. The cover has a small thickness and can be installed on the bed by the patients without adding discomfort.

To complete the set of devices, a pair of smart shoes is also included. The smart shoes [9] are regular shoes modified in order to include integrated sensors to record fine-grained data on patient movements. The collected data can be offloaded to a smartphone via a Bluetooth connection. The data collected can provide fine-grained data on walking, thus augmenting the data collected by the smartwatch.

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B. Architecture

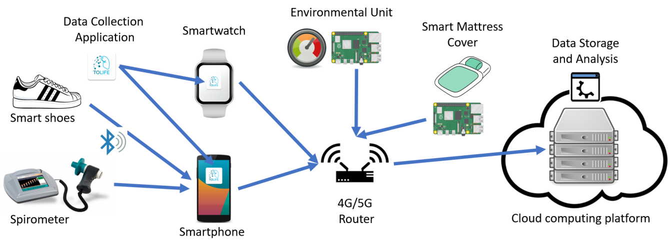

Fig. 2. TOLIFE overall system architecture.

The overall architecture of the TOLIFE system is illustrated in Figure 2. The key components of the architecture are the following:

- Set of commercial devices for data collection. As already mentioned the set includes a mix of commercial devices, i.e., smartwatches, smartphones and spirometers, and a set of ad hoc devices, i.e., smart mattress cover, environmental unit and smart shoes.
- A 4G/5G mobile router that creates a local Wi-Fi network to connect the patient's devices to the Internet. A dedicated router is provided together with the devices to ensure a dedicated interference-free connectivity.
- Two mobile applications deployed respectively on the smartphone and on the smartwatch. Such mobile applications are customised applications developed to collect data from the sensors of the smartphone and the smartwatch with a certain frequency. The smartphone application also implements a graphical user interface to allow patients to view their data in real-time.
- A cloud computing platform for data storage and analysis. All the devices offload the data to the platform that is responsible for receiving and storing the data. The platform is implemented in order to enforce data security and privacy, ensuring that patient data is treated securely and in compliance with applicable laws.
- A data storage and analysis service. A cloud computing platform hosts a data storage and analysis service, which is responsible for receiving the data from the device and storing it into a database. In addition, the service is also responsible for hosting the logic that analyzes the received data.

It is worth highlighting that among all the devices of the kit, we have two devices that are not directly connected to the 4G/5G router as they are equipped only with a Bluetooth connection, i.e., the smart shoes and the spirometer. Data from these two devices is collected by the smartphone, on which an additional application that is responsible to manage the Bluetooth connection with the devices, collecting and uploading the data to the cloud platform is deployed.

The usage of the devices by the patients is expected to be continuous for smartphone and the smartwatch, except for recharging periods. The environmental unit is expected to operate continuously, while the smart mattress cover device operates continuously, however, it collects data only when a person lying on the bed is detected. Smart shoes are expected to be worn by the patients for short periods of time during outside walking, while the spirometer will be used once a week, upon notification from the smartphone application.

C. Data Management

Each device collects data with a frequency that depends on the specific metric. Each device is programmed to initially store the data locally, and offload the data to the platform periodically or when certain conditions are met.

Battery operated devices, e.g., the smartwatch and the smartphone, are programmed to offload the data only when they are in charge, as the offloading operation has a significant impact on the battery lifetime of the device, naturally in addition to the data collection frequency. This behaviour allows also to ensure data collection continuity, which can take place when the patient is far from the 4G/5G router, e.g., he/she outside of the house.

Devices connected to a power source, e.g., the environmental unit and the smart mattress cover, instead, are programmed to offload the collected data periodically, as they do not have power restrictions. In this case, the devices are installed in the same environment as the 4G/5G router, so there is no need to account for the loss of connectivity.

A different data collection configuration is required for the spirometer and the smart shoes as they are programmed to generate data only when they are operated. The spirometer application prompts the patient for measurements at regular intervals (e.g., once a day), while the smart shoes, upon detecting movement, send a notification to the smartphone application, triggering data collection. In both cases, the data is collected by the smartphone via Bluetooth which is responsible for locally store the data and offload it together with the data generated by its sensors.

Collected data is offloaded to the cloud platform via an HTTPS connection, as the cloud service exposes a set of REST APIs to receive the data from the sensors. This data is then made available for analysis to medical personnel and researchers involved in the project, initially for the development of the AI algorithms, and subsequently for their test in real-time. A dedicated dashboard allows us to control the current status of all the devices, and to detect issues and malfunctions.

Data security is a key consideration in the deployment of the system. Advanced security measures have been implemented to ensure the protection of sensitive patient data. These measures include encryption of data in transit and storage, strict authentication for data access and access policies. In addition, the system complies with privacy regulations, ensuring that data collection and management is carried out by applicable laws.

IV. CHALLENGES AND ISSUE

In the course of the implementation of the system, we encountered several relevant issues. In this section we provide an overview of the main issues we faced, focusing in particular on the challenges in integrating and using commercial devices for continuous patient monitoring. In this paper we omit to report the challenges faced for the design and deployment of custom ad-hoc, as such issues are very specific and they are already analyzed in some previous works, e.g., [9] [10]. Instead, we focus on the challenges related to the programming and management of commercial devices, as our experience could be of interest to future research activities that consider adopting commercial devices for continuous patient monitoring in clinical trials.

In the remainder of the section we first discuss the issues we faced in creating the data collection applications running on the smartphone and the smartwatch (Section IV-A), then we conclude in Section IV-B by discussing one of the most significant issue we tackle, battery management, which affects significantly the capability of the devices to monitor the activities of the patients continuously. The latter is also assessed via a set of real experiments in the following section.

Another issue was also a concern during the selection of the devices, i.e., data accuracy. The latter is a major concern as the collected data will be exploited to derive AI tools to monitor the evolution of COPD patients. Although the accuracy of ad-hoc devices can be easily controller at design, different is the case for commercial ones, which result in an accuracy that is not controllable and can vary greatly between different devices from different manufacturers. To validate the precision of the data obtained from the chosen commercial devices, especially the smartwatch, additional tests are conducted to assess the conformity of the signals with data collected from professional equipment considered the gold standard. This aspect, however, is not analyzed in this paper due to space constraints.

A. Data Collection

The applications running on the smartphone and the smartwatch are required to continuously collect data from the sensors of the device, store the data locally and then, whenever appropriate, offload the data to the cloud platform. To this aim, the application must start automatically and must stay active all the time, regardless of the users' activity. In addition to this, the smartphone application must show a user interface, that can be invoked by the patient to check the flow of data in real-time. The user interface is also displayed automatically whenever an action from the patient is required, e.g., a spirometry test is scheduled.

In details, the applications are programmed as follows:

- They automatically initiate upon the startup of the smartwatch or smartphone, ensuring a seamless experience for the user. This functionality is achieved by leveraging Android's "RECEIVE_BOOT_COMPLETED" feature. Based on the conducted tests on the two devices, the smartphone launches the applications within 30 seconds of startup, while the smartwatch requires 2 minutes and 30 seconds to initialize background services.
- Each application automatically initiates upon startup and generates notifications for various services it activates. These notifications correspond to functionalities such as battery management, sensor utilization, noise collation, WiFi management, data push management, and logging. In addition, the phone incorporates a service for the automatic management of shoe connections and data exchange through Bluetooth. These services operate in the background persistently, and even if the user closes the applications, they are automatically restarted. Only the explicit termination of background activities by forcing their closure prevents their continuous operation.

B. Battery Management

Battery management is a significant issue when using commercial devices, particularly when it comes to long-term monitoring. Battery life varies between devices and it strictly depends on how intensive the data recording is performed.

The need to recharge devices frequently can lead to gaps in the data, therefore a battery management plan is needed to keep the device operational for the desired operating period. To this aim, on one side the energy consumption of the device should be minimized, on the other, a proper configuration of the collection/offload parameters is required to ensure sufficient battery lifetime.

Both smartphone and smartwatch applications are programmed with the following phases, which are defined taking energy efficiency in mind:

- *Data collection*. Data is collected for every sensor of interest with a given frequency. The collection frequency of each sensor is tuned considering the tradeoff between energy consumption and data value. In order to assess the energy consumption of each sensor, a preliminary set of tests was run to identify the most energy demanding sensors.
- *Data storage*. Initially, data is stored locally using files. The option to use a lightweight database, e.g., SQLlite, was also explored for both devices, however, the usage of files was shown to be more energy efficient by experimental results.

- *Data offloading*. Data is offloaded to the platform only when the device is charging. Data offloading is energy demanding as it requires continuous wireless transmission, for this reason, we decided to enable data offloading only during charging periods and not offload the data in real-time. This, in particular, is beneficial for the smartwatch that has a lower battery capacity than the smartphone.

Considering the significant volume of real-time samples the application needs to collect and store to the database, a specific Java class is developed to retrieve and save the data from the sensor with a certain policy. Specifically, the collected data is initially stored in a buffer in RAM and saved to a file only when its size gets over a predefined threshold. This is introduced to mitigate the energy drain caused by frequent write operations, consequently, the write operations are performed only when a certain set of data is available.

In order to minimize energy consumption, real-time data transmission is avoided for data uploading, which is performed only when the device is charging. In case the device stops charging data transmission is temporarily suspended

The process of sending files is managed by a background thread that performs the data upload asynchronously. The offloading of each file is sequential, thus ensuring proper transmission before moving to the next one. In the event of failure during upload, a retry policy is implemented.

V. EXPERIMENTS AND ANALYSIS

In this section, we report a detailed experimental analysis in order to assess how the battery lifetime is influenced by the data storage technology used (Section V-A) and by the data collection frequency (Section V-B). Our goal is to provide some guidelines for the implementation and configuration of data collection systems based on smartphones and smartwatches that can be helpful for future research activities.

A. Data storage techniques

The goal of this first set of experiments is to determine the best option for local data storage technology, i.e., store data on files or use a database. In the latter case a lightweight database is considered, e.g., SQLlite. The tests are run on a smartwatch, as it is the device with the lower battery capacity. Experiments were conducted under uniform conditions, exploring various settings for saving data. Specifically, in the case of file storage, different buffer sizes were evaluated, namely 1000, 2000, and 5000 samples; each configuration results in different file sizes as once the buffer is full all the samples are saved in a single file. For the database option, three different configurations were examined:

- *SQL 1000*: Samples were stored in a buffer of 1000 elements before being bulk-inserted into the database.
- *SQL*: Each new sample is stored directly into the database without using a buffer.
- *SQL trans*: The same policy of the *SQL* configuration is adopted, however, in this case, the SQL code is included into a transaction.

Figure 3 shows the discharging curve, i.e., the value of the remaining battery over time. The different curves report different buffer size (for the file option) and different database configurations. The test is run for one hour. The results show that different buffer sizes do not result in different discharging curves as the discharge among different files configurations are almost comparable. Conversely, for SQL storage options, all the configurations exhibit an inferior performance compared to the file storage configuration. Notably, among the SQL configurations, SQL trans emerges as the most efficient.

Considering that the file option is shown to be the most energy-efficient one, subsequent tests are performed with the file data storage and a buffer size of 2000 samples.

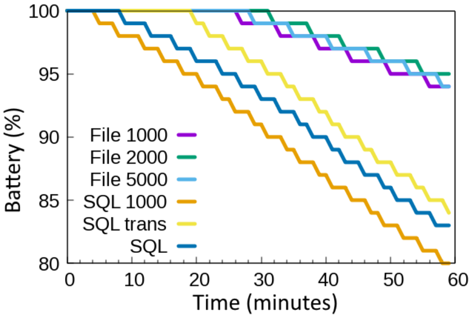

Fig. 3. Device discharging curves with different data storage configurations

B. Frequency collection

In order to find the proper balance between data collection frequency and energy consumption, different configurations are tested. The maximum data collection frequency is set depending on how the Android module responsible for sensor management is configured, i.e., the SensorManager[5]. Specifically, the system allows for four different data collection modes, each one resulting in different maximum data collection delays and consequently a maximum data collection frequency:

- SENSOR_DELAY_NORMAL (N) rate suitable to detect screen orientation changes - max delay 200ms, max frequency 5Hz;
- SENSOR_DELAY_UI (UI) rate suitable for the user interface - max delay 60ms, max frequency 16.6Hz;
- SENSOR_DELAY_GAME (G) rate suitable for games - max delay 20ms, max frequency 50Hz;
- SENSOR_DELAY_FASTEST (F) get sensor data as fast as possible - delay as low as possible, max frequency depends on the sensor;

In our test, we run experiments with the configurations reported in Table I.

Experiments were conducted over 12 hours and they were repeated 5 times to get statistically sound results. The goal was to evaluate energy consumption and determine the period during which the devices remained operational before discharging.

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[5] https://developer.android.com/reference/android/hardware/SensorManager\#SENSOR_DELAY_FASTEST

TABLE I
SAMPLING FREQUENCY OF SENSORS ON THE SMARTPHONE AND SMARTWATCH IN DIFFERENT CONFIGURATION

Sensor	Phone	Watch	S1	S2	S3	S4
Accelerometer	X	X	N	UI	G	F
Gyroscope		X	N	UI	G	F
Step Counter	X	X	N	UI	G	F
Light		X	N	UI	G	F
Heart Rate		X	N	UI	G	F
PPG		X	N	UI	G	F
Orientation	X		N	UI	G	F

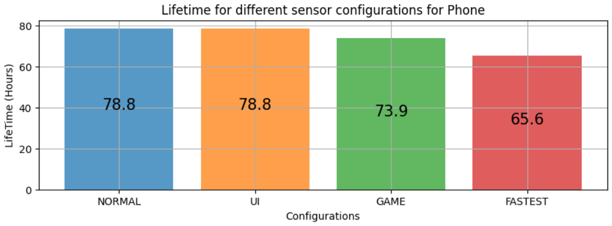

Fig. 4. Graph of smartphone device lifetime in different configurations.

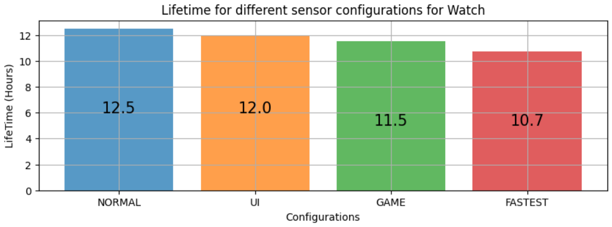

Fig. 5. Graph of smartwatch device lifetime in different configurations.

In the following, we report the average battery lifetime of each device over the experiments and the different configurations considered.

Figures 4 and 5 depict the lifetime of the smartphone and smartwatch, respectively, with the corresponding setups as previously detailed. As expected, the configurations with higher sample rates exhibit increased power consumption, thereby impacting the overall battery life.

The battery lifetime of the smartphone (see Figure 4) in the N and UI configurations exhibits are comparable, showing how the lower latency of UI configuration results in a negligible extra power consumption, yielding a lifetime of 78.8 hours. As the frequency increases, the G configuration leads to a reduced lifetime of 73.0 hours, while the F configuration further decreases the lifetime to 65.6 hours. Those results show that it is feasible to monitor for nearly three days even with the higher frequency without recharge, thus demonstrating the feasibility of using the device for a whole day for continuous monitoring.

A similar behaviour is reported in Figure 5 for the smartwatch. In this case, the N and UI configurations yield nearly equal lifetimes, i.e., 12.5 and 12 hours, respectively. If the frequency is increased, the G configuration results in a reduction to 11.5 hours, and the F configuration further reduces the lifetime to 10.7 hours. Such results show that for the smartwatch a full day of continuous monitoring (not considering nighttime) is feasible, however, it is paramount to balance the frequency vs energy consumption tradeoff. For instance, an optimal configuration for daily monitoring could be the G configuration.

VI. CONCLUSIONS

In this paper, we introduced the approach adopted by the European project TOLIFE to patient monitoring using commercial devices. Specifically, we analyzed how multiple devices are used to collect heterogeneous data on patients with chronic diseases, showing how a mix of custom and commercial devices can be exploited for continuous monitoring. Our implementation and a set of experimental results showed that the usage of smartphones and smartwatches is a viable solution for continuous monitoring, as they can ensure a full day of data collection. The implementation and the data collection settings, however, must be tuned accordingly, in order to balance the tradeoff between collection frequency and battery optimization and avoid frequent re-charges, which could impact significantly the usability.

ACKNOWLEDGMENT

The work is supported by European Union's Horizon Europe Research and Innovation Programme under grant agreement No. 101057103 – project TOLIFE.

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