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RePulmo: A Remote Pulmonary Monitoring System

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Abstract

Remote physiological monitoring is increasing in popularity with the evolution of technologies in the healthcare industry. However, the current solutions for remote monitoring of blood-oxygen saturation, one of the most common continuously monitored vital signs, either have inconsistent accuracy or are not secure for transmitting over the network. In this paper, we propose RePulmo, an open-source platform for secure and accurate remote pulmonary data monitoring. RePulmo satisfies both robustness and security requirements by utilizing hospital-grade pulse oximeter devices with multiple layers of security enforcement. We describe two applications of RePulmo, namely (1) a remote pulmonary monitoring system for infants to support the Children's Hospital of Philadelphia (CHOP) clinical trial; (2) a proof-of-concept of a low SpO2 smart alarm system.

Keywords

Pulmonary Monitoring, Remote Monitoring, OpenICE-lite

Disciplines

Computer Engineering | Computer Sciences

Comments

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ABSTRACT

Remote physiological monitoring is increasing in popularity with the evolution of technologies in the healthcare industry. However, the current solutions for remote monitoring of blood-oxygen saturation, one of the most common continuously monitored vital signs, either have inconsistent accuracy or are not secure for transmitting over the network. In this paper, we propose RePulmo, an open-source platform for secure and accurate remote pulmonary data monitoring. RePulmo satisfies both robustness and security requirements by utilizing hospital-grade pulse oximeter devices with multiple layers of security enforcement. We describe two applications of RePulmo, namely (1) a remote pulmonary monitoring system for infants to support the Children's Hospital of Philadelphia (CHOP) clinical trial; (2) a proof-of-concept of a low SpO2 smart alarm system.

KEYWORDS

Pulmonary Monitoring, Remote Monitoring, OpenICE-lite

1 INTRODUCTION

As technologies evolve, the healthcare industry is rapidly delivering high-tech solutions and remains among the fastest to adopt the Internet of Things. The increase of advanced medical devices and wearable technologies has greatly improved the patient outcomes and reduced healthcare costs. It has been shown that continuous monitoring of vital signs can help to detect clinical deterioration at an earlier stage, which allows clinicians to take corrective actions and potentially save lives [15]. A great example of early detection is the story of a man saved from his heart attack by early warnings of abnormally high heart rate from his Apple watch in the middle of the night [2]. In fact, the International Data Corporation (IDC) estimates that the market for remote health monitoring will grow to over $12.4 billion in 2018 [1].

One of the most common continuously monitored vital signs is pulse oximetry. Pulse oximetry is a non-invasive method for monitoring patient's blood-oxygen saturation; it does so by providing peripheral oxygen saturation (SpO2) readings. Remote pulse oximetry monitoring can be done using wearable devices such as smart watches. Although offeringfl exibility, these devices have inconsistent accuracy and are prone to environment affects such as movements, lighting condition, and skin characteristics [6]. In addition, proprietary technologies and closed-source software limit the use case of these devices and also pose the risk of privacy and security.

On the other hand, hospitals employ medical device manufacturer system (e.g., Capsule, IntelliBridge) to remotely collect patient data from bedside monitoring system. Since medical devices are federally regulated and provide much better measurements [9], we can ensure the collected data have the highest quality. However, these systems are designed to work mainly within the hospital controlled environment and do not usually provide interoperability (i.e., information exchange between devices from different manufacturers). Furthermore, they also incur a significant cost in both installation fees and operation/maintenance expense.

To leverage the advantages of both approaches, we propose RePulmo, a remote pulmonary monitoring system that provides remote medical data acquisition via existing medical devices. Such a system should satisfy both robustness (i.e., accurate andflawless even in interrupted conditions) and security requirements. RePulmo is constituted from two parts: a remote collector device for each patient to continuously measure and send back SpO2 data, and back-end infrastructure to receive data from all collector devices and securely store data to a database. The proposed system utilizes the widely used Masimo Rad-8 Pulse Oximeter device [10] (e.g., for hospital bedside monitoring) to ensure that the collected data are aligned with hospital-grade accuracy and also provide the seamless experience for the patient. Furthermore, RePulmo is open-source and designed in a modularized fashion to encourage research collaboration.

We demonstrate the usefulness of RePulmo with a successful application to support the Bronchopulmonary Dysplasia Saturation TARgeting pilot trial at the Children's Hospital of Philadelphia (CHOP); this trial aims to collect oxygen saturation data from babies who experience Bronchopulmonary Dysplasia in an effort to determine whether long-term supplemental oxygen might reduce intermittent hypoxemia. In addition, we also show that RePulmo can be extended to support not just logging functionality by a proof of concept of a smart alarm system to reduce false SpO2 low alarms.

Remote physiological monitoring is an active area of research, and there has been a significant amount of work done on developing

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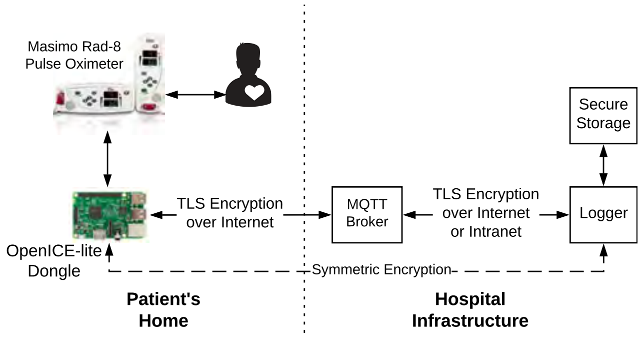

Figure 1: The RePulmo design.

hardware solutions for this purpose. Dedicated hardware modules have been suggested as a means to record vital signs remotely including the popular smartwatches, activity trackers, or similar form-factor. There are also proposals [13] for custom wearables to include multiple physiological measurements such as electrocardiography (ECG) sensor, SpO2 sensor or augmenting existing devices [13]. However, due to their compact designs, they tend to not work well in noisy and extreme conditions (e.g., with movements). In addition, these wearables are not classified as medical devices and thus are not regulated by the Food and Drug Administration (FDA). Hence, it is reasonable to question the accuracy and reliability of these devices in the market.

Perhaps the closest designs to RePulmo are Integrated Clinical Environment (ICE) compliant systems [12, 14], which are based on the ICE reference model to ensure safety in the development of medical devices. However, as ICE does not provide security guidance, these systems also lack security guarantees for remote monitoring over the Internet. ICE can also be extended with security modules such as authentication framework [4], although there is no fully secure solution for ICE yet. RePulmo, however, provides security properties via multiple layers of encryption.

To summarize, the contributions of this paper are two-fold: (1) the design and implementation of RePulmo, a modularized and open-source platform for remote pulmonary data acquisition to provide secure and accurate measurements; (2) demonstrations of real-world application of RePulmo to foster clinical trial.

The remainder of this paper is organized as follows. We present the design of RePulmo in Section 2. Section 3 then discusses different aspects of RePulmo implementation. Finally, we describe the two applications of RePulmo in Section 4 and provide concluding remarks in Section 5.

2 DESIGN OF REPULMO

This section describes the architecture and the various components of the RePulmo design (for easy reference, the architecture diagram is presented in Figure 1).

At a high level, RePulmo operates as follows. Each patient has a dedicated Masimo Rad-8 Pulse Oximeter device measuring arterial oxygen saturation and pulse rate. This device outputs in real-time the collected data through its serial port to an attached Raspberry Pi running OpenICE-lite, a general purpose middleware for medical device interoperability. OpenICE-lite under the hood features Message Queuing Telemetry Transport (MQTT) as the communication protocol, which sends the encrypted data to the hospital's logger client via a centralized MQTT broker. Note that all the communication channels between these components are secured using the Transport Layer Security (TLS) protocol. Finally, the data are stored in an encrypted database for further analysis.

Each component of the RePulmo architecture is described in more detail in the remainder of this section.

2.1 Masimo Rad-8 Pulse Oximeter

The Rad-8 is a non-invasive, arterial oxygen saturation and heart-rate monitor manufactured by Masimo. The device is widely used in hospitals for bedside monitoring due to its versatility and accuracy. The measurements are taken by placing a sensor on a patient (fingertip for adults and hand/foot for babies), which then sends back the signal data to the instrument.

There are two main reasons that we choose the Rad-8 for collecting SpO2 data. First, while the sensor uses the standard infrared and red lights passing through the capillary bed to estimate the oxygen saturation, the Rad-8 features additional techniques to ensure accurate measurements. For example, the traditional approach assumes that arterial blood is the only blood moving within the measurement site, which is prone to noise due to low values during patient movements. Instead, Masimo utilizes parallel engines and adaptive digitalfi ltering to reduce noise and reliably reports the true SpO2 value.

Second, the Rad-8 supports data acquisition via its serial port (standard DB9 connector) by directly writing all the device states in ASCII format every second. This feature greatly simplifies the design requirements for RePulmo in comparison with other sophisticated medical devices (e.g., requiring hand-shake protocol) or wearable devices with proprietary protocols. The output data include timestamps, device serial number, SpO2 measurements, heart rate measurements, and alarm codes as illustrated in Listing 1. In addition, Line 3 of Listing 1 shows an example of low SpO2 alarm with alarm code 0004.

Listing 1: Sample Masimo Rad-8 output trace.

```
1 02/07/18 09:39:47 SN=xxxxxxxxxx SPO2=095% BPM=076 PI=--.--% SPCO
      =--.-% SPMET=--.-% DESAT=-- PIDELTA=+-- ALARM=0000 EXC=000800
2 02/07/18 09:39:48 SN=xxxxxxxxxx SPO2=094% BPM=074 PI=--.--% SPCO
      =--.-% SPMET=--.-% DESAT=-- PIDELTA=+-- ALARM=0000 EXC=000800
3 02/07/18 09:39:49 SN=xxxxxxxxxx SPO2=089% BPM=080 PI=--.--% SPCO
      =--.-% SPMET=--.-% DESAT=-- PIDELTA=+-- ALARM=0004 EXC=000800
4 02/07/18 09:39:50 SN=xxxxxxxxxx SPO2=090% BPM=085 PI=--.--% SPCO
      =--.-% SPMET=--.-% DESAT=-- PIDELTA=+-- ALARM=0000 EXC=000800
```

2.2 OpenICE-lite and Raspberry Pi Dongle

In order to enable medical device interoperability, we developed OpenICE-lite, a general-purpose Internet of Medical Things (IoMT) middleware for safe and secure medical device interoperability [8]. RePulmo evolves as one of the successful applications of OpenICE-lite, which features its Masimo Rad-8 driver to receive all measurement data and the publish/subscribe communication model to assure availability and quality of service.

In particular, each Rad-8 is attached with a dongle implementing OpenICE-lite service via its serial port. The main functionalities of this service are to receive measurement data, encrypt them based on pre-configured settings, then send them to the back-end logging service. In RePulmo design, we choose the Raspberry Pi mode B to deploy the dongle service due to its small size, low cost, and feature richness. Each Raspberry Pi houses a 1.2 GHz 64-bit quad-core processor, 1 GB of RAM, and built-in 802.11n wireless adapter. The device is ideal for the proposed architecture since it has a small footprint without limiting the capability of the system. Furthermore, the integrated wireless adapter is also a great feature to improve the versatility of the end-user hardware.

It is worth mentioning that by employing OpenICE-lite, RePulmo is not limited to a particular medical device or middleware protocol. For instance, since OpenICE-lite also supports other pulse oximeters such as Nellcor N-595, it is possible to use it in place of the Rad-8 if needed. However, this architecture has the best components that we propose for general applications.

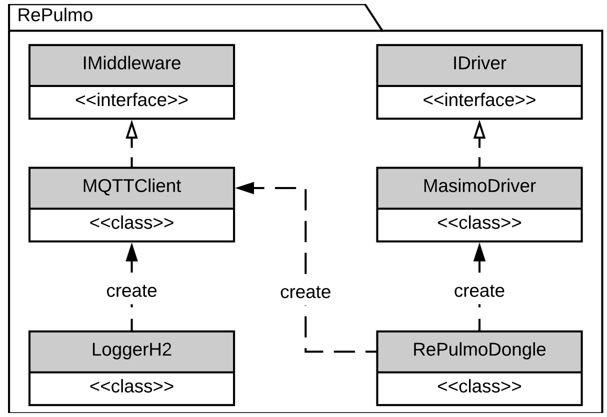

Figure 2: The RePulmo class diagram.

2.3 MQTT Broker

To ensure a reliable communication channel, RePulmo uses the MQTT publish-subscribe messaging protocol to facilitate communication between the end points of the system. MQTT is a lightweight protocol [3] designed for constrained devices and provides a scalable, cost-efficient way to connect devices while being able to deliver messages in near real-time. The MQTT middleware consists of an MQTT broker and MQTT clients that communicate via the broker. In RePulmo, the Raspberry Pi dongles and the back-end logger are MQTT clients that transmit information to and receive information from the broker respectively.

The MQTT broker is a centralized node that manages and transports all communication within the system. It is a single point of failure and potentially causes significant damage to the system if being attacked. Therefore, it is recommended to host the broker in a controlled and secure environment, preferably within hospital infrastructure and behind afi rewall. In addition, it is possible to deploy MQTT broker in a cluster fashion to address scalability and reliability concerns [5, 11].

Since RePulmo works with medical data, secure communication is one of the primary requirements of the architecture. All the communication channels between the MQTT broker and clients over the network are protected using the industrial standard TLS protocol. This security enforcement is feasible thanks to the powerful Raspberry Pi device, which permits robust symmetric and asymmetric encryption algorithms. With TLS protection in place, RePulmo is able to defend against different classes of attack such as eavesdropping, injection, and replay attacks.

However, due to end-points residing at the broker, the messages from dongles are still decrypted in the broker before being encrypted again to be sent to the receiving node via a different TLS channel. Therefore, RePulmo enforces another layer of symmetric key encryption, whose key is only known to the dongle and the back-end logger during the provisioning process (i.e., unknown to the broker). Thisfi nal layer ensures that only the designated logger is able to decrypt the medical data.

2.4 Back-end Logger and Secure Storage

The logger node is essentially an MQTT client subscribing to all the data topics correspond to its assigned Rad-8 dongles. Upon receiving the data message from the broker, the logger decrypts the collected medical data using the provisioned symmetric key (must be unique for each dongle). It then permanently saves the plaintext data in the secure storage. The current version of RePulmo stores data in an embedded H2 database, although the design is not restricted from storing data in any other types of database. H2 database engine makes sure that the collected data are easily transferred to other location with its small footprint: the database is just a singlefi le. Nevertheless, the whole database is automatically encrypted using Advanced Encryption Standard (AES) and fully supports SQL syntax.

Note that the logger node is not limited to just logging functionality. It can easily be augmented with additional features such as real-time monitoring (e.g., to trigger alarms with pre-defined rules).

3 IMPLEMENTATION

Based on the proposed design, we describe the implementation decisions made in this section. This sectionfi rst overviews the hierarchy of RePulmo implementation, then describes how RePulmo can be deployed to ensure security and reliability guarantees.

3.1 RePulmo Class Hierarchy

We implemented RePulmo in Java (JDK 8u161) with two applications: *RePulmoDongle* and *LoggerH2*. These applications represent the main modules that constitute the RePulmo architecture. Although having different functionalities, they share the core entity in the design for supporting heterogeneity, namely the middleware implementation. The class diagram of RePulmo is presented in Figure 2.

The core components of RePulmo are inherited from OpenICE-lite, namely the *IMiddleware* and the *IDriver* interfaces. The primary property of OpenICE-lite, modularity, is enforced via these interfaces, which provide the necessary Application Programming Interface (API) that all the drivers and middleware must implement.

As described in Section 2, the current version of RePulmo supports Masimo Rad-8 device (via *MasimoDriver* class implementing *IDriver* interface) and MQTT middleware (via *MQTTClient* class implementing *IMiddleware* interface). With this design hierarchy, RePulmo can be easily extended to support other medical devices and middleware by replacing the corresponding class with other core interface implementations.

The *LoggerH2* is essentially a wrapper with an *MQTTClient* instance to subscribe to the MQTT broker and write data to H2 database. On the other hand, *RePulmoDongle* also includes an *MQTTClient* instance in combination with a *MasimoDriver* instance to read data from the Rad-8 device and publish to the broker.

3.2 Deployment

In the typical scenarios, RePulmo is used to collect data from the patient remotely with the assumption that the patient can quickly start the dongle. In addition, we cannot expect them to perform any technical configuration or troubleshooting; hence, the system must require as few steps as possible, ideally plug-and-play. With that in mind, the current implementation is developed with the ability to withstand a connection being lost and different exceptions.

However, to minimize the number of steps needed to initialize, each RePulmo dongle needs to be provisioned before releasing to the end-user. This provisioning stage must complete two tasks: (1) register *RePulmoDongle* as system service with auto-start after boot, (2) encode the symmetric key for encryption and optionally private key and certificate chain for MQTT network connection. The system service registration is essential to guarantee that the application is restarted even after power failure. It is worth mentioning that no patient personal information is stored on the device to ensure anonymity. The collected data should only be deanonymized during data analysis where the device unique ID is joined with the patient record.

4 APPLICATIONS OF REPULMO

With the modular design, RePulmo can be readily applied to various contexts. In this section, we discuss two applications that directly employ RePulmo for pulmonary data acquisition: (1) the BPD STAR pilot trial; (2) a smart alarm system to reduce false low SpO2 alarms.

4.1 BPD STAR Pilot Trial

Bronchopulmonary Dysplasia (BPD) is a chronic lung disease of prematurity that is associated with poor long-term outcomes, yet no therapies have been proven to improve the outcomes of children with BPD. The frequency of intermittent hypoxemia (IH) in extremely preterm infants during the newborn period is associated with death or developmental disability at 18 months, and infants with BPD may be at risk for continued IH, even after hospital discharge. The risks and benefits of using supplemental oxygen to target different oxygen saturation levels have been evaluated extensively in preterm infants during the initial hospitalization, but have not been studied in infants with established lung disease as they approach term corrected age and are discharged home. To answer this question, the Bronchopulmonary Dysplasia Saturation TARgeting (BPD STAR) pilot trial conducted at CHOP aims to collect oxygen saturation (SpO2) data from infants who experience BPD in an effort to determine whether long-term supplemental oxygen might reduce intermittent hypoxemia.

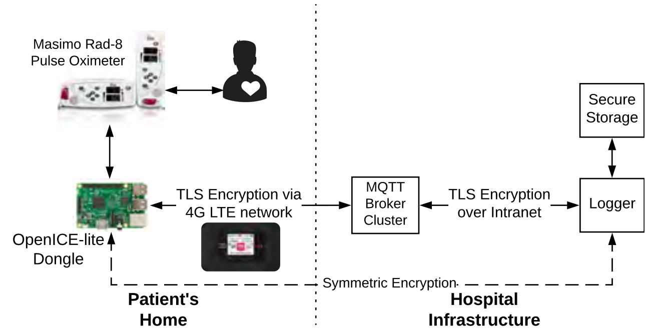

Figure 3: The RePulmo architecture in the BPD pilot trial.

To collect data remotely from babies at home, we deploy RePulmo system with a slightly modified architecture as illustrated in Figure 3. The two main differences are the MQTT broker cluster and the addition of the Verizon Jetpack 4G/LTE Mobile Hotspot. These changes are necessary to minimize the efforts needed from the parents to use RePulmo. Each patient will be given a set of one Masimo Rad-8 device, one mobile hotspot device, and one Raspberry Pi dongle with pre-configured settings to automatically connect to the Rad-8 device and the hotspot wireless network. As MQTT is optimized specifically for high-latency and unreliable networks, it works well with the 4G/LTE network while the MQTT broker cluster ensures high-availability on the back-end side. This pilot trial is currently under deployment at CHOP and we are expecting to support 42 patients over the course of six months continuous monitoring.

4.2 Low SpO2 Smart Alarm

Another application of RePulmo is the proof of concept of a smart alarm system to reduce false low SpO2 alarms. As pulse oximetry is the most common source of physiologic monitor alarms and oxygen saturation is a good indication of a person's oxygen levels, clinicians set threshold alarms for low SpO2 measurements. However, there are many factors influencing the effectiveness of the low SpO2 alarm threshold such as patient size, skin condition, sensor technology, patient movement, and the employed signal processing algorithm. As a result, many low SpO2 alarms do not require clinician intervention and contribute to the "alarm hazards," stated as the number one health technology hazard for 2015 by the ECRI Institute [7]. Therefore, the goal of the smart alarm system is to reduce false low blood oxygen saturation alarms using real-time measurements from RePulmo system.

Such smart alarm system can use machine learning algorithms to predict if an alarm is valid or not. The input features could be the RePulmo collected data within a sliding window. In this proof of concept, we developed a machine learning algorithm based on the ensemble method on Matlab, which can be exported as a Java package using Matlab Code library and naturally integrated into the RePulmo system. Furthermore, the smart alarm system can be installed on a logger node to monitor multiple Masimo Rad-8 devices, or it can also run directly on the Raspberry Pi dongle without the need of the middleware layer (thus there is no requirement for a network connection).

5 CONCLUSIONS

In this paper, we described RePulmo, an open-source platform for secure and accurate remote pulmonary data monitoring. Leveraging existing medical devices, RePulmo is able to collect reliable measurements and securely transfer data to back-end logger node via MQTT protocol. Although RePulmo can satisfy our current requirements, we still plan to extend its capability in the future. For instance, the current Masimo Rad-8 driver only supports up to 1 Hz data rate as limited by Masimo Rad-8 ASCII mode. However, the device itself is able to output waveform format under Philips VueLink setup. Reverse-engineering this communication protocol is challenging and will be one of our focus research direction.

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