

Reliable Clinical Monitoring using Wireless Sensor Networks: Experiences in a Step-down Hospital Unit

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Abstract

This paper presents the design, deployment, and empirical study of a wireless clinical monitoring system that collects pulse and oxygen saturation readings from patients. The primary contribution of this paper is an in-depth clinical trial that assesses the feasibility of wireless sensor networks for patient monitoring in general hospital units. We present a detailed analysis of the system reliability from a long term hospital deployment over seven months involving 41 patients in a step-down cardiology unit. The network achieved high reliability (median 99.68%, range 95.21% – 100%). The overall reliability of the system was dominated by sensing reliability of the pulse oximeters (median 80.85%, range 0.46% – 97.69%). Sensing failures usually occurred in short bursts, although longer periods were also present due to sensor disconnections. We show that the sensing reliability could be significantly improved through oversampling and by implementing a disconnection alarm system that incurs minimal intervention cost. A retrospective data analysis indicated that the system provided sufficient temporal resolution to support the detection of clinical deterioration in three patients who suffered from significant clinical events including transfer to Intensive Care Units. These results indicate the feasibility and promise of using wireless sensor networks for continuous patient monitoring and clinical deterioration detection in general hospital units.

Categories and Subject Descriptors

C.2.4 [Computer-communication Networks]: Distributed Systems

General Terms

Design, Implementation, Measurement, Experimentation

Keywords

Wireless sensor networks, Patient monitoring, Reliability

1 Introduction

Clinical deterioration in patients in general hospital units is a major concern for hospitals. Of the hospitalized patients, 4% – 17% suffer from adverse events such as cardiac or respiratory arrests [1,6,24]. A retrospective study found that as many as 70% of such events could have been prevented [17]. A key factor in improving patient outcomes is to detect clinical deterioration early so that clinicians may intervene before a patient's condition worsens. The detection of clinical deterioration is possible because most patients exhibit changes in their vital signs hours prior to an adverse event (median 6.5 hours, range 0 – 462 hours) [2]. Automatic scoring systems aimed at identifying clinical deterioration in patients based on their vital signs are being developed [13, 14]. However, the efficacy of such systems is significantly affected by the scarcity of up-to-date vital signs. This may not be a problem in Intensive Care Units (ICUs) where vital signs are monitored by wired devices. However, the population that would most benefit from early detection of clinical deterioration is in general or step-down hospital units. In such units, vital signs are often measured manually at long time intervals. For example, in postoperative care, nurses measure the vital signs only 10 times during the first 24 hours following an operation [26]. This could lead to a prolonged delay until clinical deterioration is detected. Thus, it is necessary to develop a real-time monitoring system for collecting the vital signs of patients in general hospital units.

Collecting vital signs in general hospital units poses unique challenges that are poorly addressed by existing commercial telemetry systems. In contrast to cardiac or epilepsy care which require high data rate EKG, EEG, or acceleration measurements, the collection of vital signs¹ requires *low data rates*. For low data rate applications, wireless sensor networks based on the IEEE 802.15.4 standard may be a better choice than Wi-Fi networks based on the IEEE 802.11 standard for the following reasons. First, 802.15.4 radios are more energy efficient than 802.11 at low data rates. As a result, patient devices that use 802.15.4 radios would have a longer battery life. The nursing staff is routinely overloaded and the bothersome and error-prone process of changing batteries may interfere with their primary function – provid-

¹The primary vital signs used for patient care in hospitals include temperature, blood pressure, pulse, and respiratory rate, which typically change over minutes.

ing care. Second, results from the clinical trial indicate that sensing was the primary source of unreliability and that, at the low data rates required by vital sign monitoring, wireless sensor networks are already highly reliable (the median patient reliability was 99.68%). Therefore, the minor gains in network reliability that may be achieved by using a well-engineered Wi-Fi network would only improve system reliability marginally. Third, the cost of deploying a mesh network consisting of wireless sensors is lower than that of installing a Wi-Fi system since mesh networks do not require a fixed wired infrastructure. Therefore, the cost of adopting our system in a hospital without Wi-Fi infrastructure (e.g., field hospitals, rural areas, developing countries) is lower than that of existing commercial systems. While an increasing number of hospitals do have Wi-Fi infrastructure today, Wi-Fi access is not pervasive in the general hospital units even in major hospitals like the one in which we performed our study. Moreover, since hospitals perceive Wi-Fi access as a value added service, Wi-Fi coverage may be insufficient to ensure reliable patient monitoring as we observed in our own deployment (see Section 6). Finally, wireless sensor networks may be deployed on demand. This flexibility may be important for hospitals which do not have sufficient resources to monitor all patients hospitalized in general units. Accordingly, it may be desirable to deploy a wireless monitoring system *on-demand* when a patient at high risk of clinical deterioration is admitted to a general hospital unit.

The requirements of low data rate and flexible deployment motivate the development of a patient monitoring system using wireless sensor network (WSN) technology based on the IEEE 802.15.4 standard. While wireless sensor networks have gained attention as a promising technology for elderly care [25], disaster recovery [10], epilepsy care [21], and patient monitoring [7, 19], there has not been an in-depth clinical study of the feasibility of wireless clinical monitoring systems for in-patients in general hospital units. In this paper we present the first in-depth reliability study of a patient monitoring system based on sensor network technology operating in-situ. The patient monitoring system was deployed in a step-down cardiac unit at Barnes-Jewish Hospital, St. Louis for seven months. During this time, the system collected heart rate (HR) and blood oxygenation (SpO₂) from 41 consenting patients. This resulted in over 41 days of continuous data monitoring. The time a patient was monitored varied significantly from a few hours to three days.

Collected data indicates that the median network and sensing reliabilities per patient were 99.68% and 80.55%, respectively. Somewhat surprisingly, the primary source of unreliability was sensing, not networking. Therefore, even if wired communication would have been used the overall system reliability would have been similar to our wireless patient monitoring system. While sensing failures were common, the sensors usually recovered from most outages quickly. However, the distribution of sensing outages is long-tailed containing prolonged outages caused by sensor disconnections. Through trace analysis we show that oversampling and automatic disconnection alarms can substantially improve sensing reliability with minimum manual intervention.

The ultimate goal of such a system is to detect clinical deterioration based on real-time vital signs. We developed an algorithm for detecting clinical deterioration based on time series analysis techniques. By inspecting the medical records of patients admitted to the study, we divided the patients in two groups: patients diagnosed with a significant cardiac or pulmonary disease and patients without such a diagnosis. Retrospective time-series analysis on the pulse oximetry data collected by our system indicated the feasibility to detect significant clinical deterioration based on the data streams collected by our wireless clinical monitoring while incurring a low false alarm rate. These results suggest the benefits of integrating the collection and analysis of vital signs for detecting clinical deterioration.

The remainder of the paper is organized as follows. The next section reviews the related work. The patient monitoring system is described in Section 3. The methods and results of the clinical trial are presented in Section 4, while a retrospective study looking at the feasibility of detecting clinical deterioration based on vital signs is presented in Section 5. We discuss our experience with the design and the operation of the patient monitoring system in Section 6. Conclusions are presented in Section 7.

2 Related Work

Numerous systems for measuring a patient's physiological state have been developed. These systems employ various wireless technologies: cell phones [5, 20], Wi-Fi [7, 10, 18], and wireless sensor networks [10, 19, 25]. In the following, we focus on systems that use sensor network technology due to its energy efficiency and ease of deployment. Wireless sensor networks have been developed for elderly care [25], disaster recovery [7, 10, 15], and clinical monitoring [5, 7, 16, 20]. The monitoring of vital signs is a basic function which is supported by these systems. Our work is closely related to the work done as part of the Code Blue, AlarmNet, and MEDiSN projects. Code Blue focuses on disaster response applications and supports many-to-many communication through a publish/subscribe system [3]. The AlarmNet project supports the collection of data from mobile and static sensors through a query service [25]. MEDiSN and our own project independently developed similar network architectures: stationary relay nodes are deployed to ensure connectivity between a patient worn sensor and a base station. However, we adopt different solutions for handling patient mobility and radio power management.

In spite of the numerous patient monitoring systems that have been developed, they are seldom evaluated with real users and real-world deployment. The evaluation of most systems does not focus on reliability and is usually performed in laboratories rather than in healthcare environments. However, there are a few notable exceptions. The MEDiSN [16] and SMART [7] projects focus on monitoring patients waiting in emergency rooms. In [16], networking statistics were collected in the emergency room at Johns Hopkins Hospital. The study focused on understanding the low-level channel characteristics of a typical clinical environment which is particularly useful for developing novel wireless communication protocols. The study focuses on

a small scale deployment and, more importantly, it ignored sensing reliability which we will show dominates the overall system reliability. A *holistic*, system-level reliability study is a key contribution of our clinical study. In [7], pulse and oxygenation measurements were collected from 145 patients for an average of 47 minutes (range 5 minutes – 3 hours). No data regarding the reliability of the system is reported. Results from disaster response drills are reported in [7, 10]; however, these results do not measure network performance or system reliability.

Before deploying the clinical monitoring system in the hospital, we performed extensive tests of its networking performance. We evaluated the impact of mobility on networking performance through a small scale study which involved data collection from healthy volunteers in an office environment. These results were reported in [4]. During these experiments, no actual vital signs were collected. In contrast, the focus of this paper is the holistic evaluation of system reliability through a clinical study performed in a step-down hospital unit. A distinguishing aspect of this study is its scale: the system was deployed for seven months and collected pulse and oxygenation measurements from 41 patients. This resulted in more than 41 days worth of pulse and oxygenation data. Moreover, the system we deployed had 18 relays and required multi-hop communication for data delivery. To the best of our knowledge, this is the first study that analyzes the reliability of such a system from a holistic perspective including both sensing and networking reliability. Additionally, a preliminary study indicates that the traces of pulse and oxygenation collected during the trial may be used to detect clinical deterioration.

3 Clinical Monitoring System

This section presents the system architecture, hardware components, and software we developed for the patient monitoring system. The presentation focuses on the key design decisions we made to meet the challenges of vital sign monitoring in general hospital units.

3.1 System Architecture

Our clinical monitoring system consists of a base station, a set of relays, and patient nodes attached to patients. The base station runs a data collection application that saves the collected patient data in a local database. In addition, the base station supports remote login for debugging and data backup through the hospital’s Wi-Fi network. Patient nodes (shown in Figure 1(a)) measure and transmit the heart rate and blood oxygenation of patients. The *relay nodes* (as shown in Figure 1(b)) form a mesh network that provides connectivity between the patient nodes and the base station. The delivery of patient data may involve multiple hops. As patients may be ambulatory, we deploy sufficient relay nodes to ensure that a patient node is always one hop away from at least a relay node.

The system architecture has three notable features. First, unlike commercial medical telemetry systems, our system does not require the relay nodes to be connected to the hospital’s wired network. In the case when Wi-Fi access is not available, the cost of our system would be significantly lower than that of a similar 802.11-based system since we do not

require additional wiring.

Second, in contrast to other environments in which sensor networks operate (e.g., habitat monitoring), power outlets are widely available in hospitals. We take advantage of this by deploying the relay nodes using USB-to-power adaptors plugged into electrical outlets. This simple deployment approach, coupled with the self-organizing features of mesh networking protocols, enables on-demand deployment. Note that power management remains necessary on patient nodes since they operate on batteries.

Finally, the proposed architecture isolates the impact of patient mobility: mobility may affect only the delivery of packets from the patient node to the first relay, while the remaining hops are over static relay nodes. As discussed in Section 3.3.1, this allows us to reuse the widely used Collection Tree Protocol (CTP) [11] for forwarding data over the static relays and develop a new protocol that finds the best relays to be used by a node even in the case of frequent mobility. To improve network reliability, we prohibit patient nodes from relaying patient data. This has the additional advantage of simplifying the radio power management on sensor nodes.

3.2 Hardware

The relay and patient nodes use the TelosB mote as an embedded platform. Each TelosB mote has a 16-bit RISC processor with 48 KB code memory and 10 KB RAM. Wireless communication is provided using a Chipcon CC2420 radio chip compatible with IEEE 802.15.4. The radio operates in the unlicensed 2.4GHz band and provides a raw bandwidth of 250 kbps. TelosB also has a 1MB external flash which may be used for logging.

A patient node integrates a TelosB mote with an OxiLink pulse-oximeter from Smiths Medical OEM. Both the OxiLink and TelosB support serial communication, albeit at different voltage levels. We developed a custom circuit board which performs the necessary voltage conversions to enable serial communication between them. The circuit also enables the TelosB to turn on and off the OxiLink through a hardware switch controlled by one of the TelosB’s I/O pins. This mechanism enabled us to duty-cycle the sensor as discussed in Section 3.3.3. Similar hardware capabilities have been developed and used as part of ALARM-NET [25], MEDiSN [16], AID-IN [10], SMART [7], and WIISARD [15] projects.

3.3 Software Components

The patient monitoring system was developed using the TinyOS 2.0 operating system [12]. The system has three key software components: networking, sensing, and logging. Next, we describe each component.

3.3.1 Network Protocols

TinyOS supports data collection from nodes through the *Collection Tree Protocol* (CTP), a commonly used data collection protocol in sensor networks. CTP has been shown to achieve high reliability in stationary networks [11]. We developed a system prototype which used CTP to collect data from patient nodes. In this prototype, CTP is deployed both on the patient and on the relay nodes. This initial prototype suffered from low reliability in the presence of user mobility.

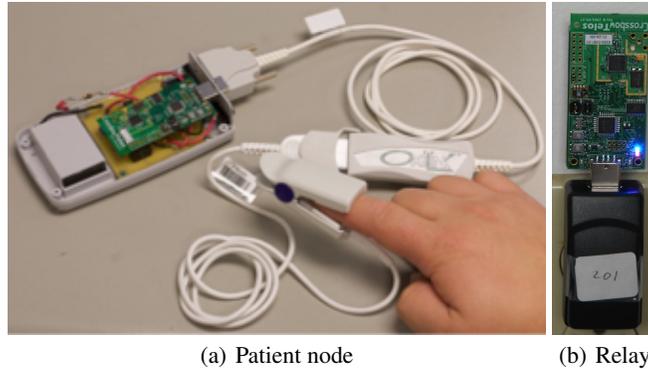


Figure 1. Hardware used in the wireless clinical monitoring system. The cover of the patient node was removed for illustration purposes. During the clinical trial adult disposable probes were used instead of the clip-style probe shown in the picture.

Through experiments with healthy volunteers in a sensor network testbed, we discovered that the following scenario results in significant data loss from a mobile user [4]. The patient node discovers the nodes within its communication range and adds them to its neighbor table. Out of these neighbors, the patient node selects the neighbor with the lowest-cost path to the root as its parent. When the patient’s movement breaks the link to the current parent, CTP will select the next lowest-cost neighbor as parent. However, as result of mobility, it is likely that many of the neighbors in the neighbor table are now out of the communication range. Accordingly, using the stale information present in the routing table would result in repeatedly selecting nodes outside the communication range of the patient node. Automatic re-Request Retry (ARQ) used by CTP exacerbates this problem by repeating a packet transmission multiple times (e.g., 31 times by default) before dropping the packet and changing the route.

A pragmatic approach to achieving high end-to-end reliability is to isolate the impact of mobility from multi-hop routing. In our network architecture we divide the problem of data delivery from patients nodes to the base station into two parts: single-hop communication from the patient node to the first relay and (potentially multi-hop) communication from that relay to the base station. We deploy CTP on the relay nodes to forward data to the base station since it achieves high reliability over static relay nodes. Next, we designed a new protocol called *Dynamic Relay Association Protocol* (DRAP) which is deployed on patient nodes to discover and select relays as the patient moves.

The design of DRAP must address three questions: how are neighbors discovered, how to select the best relay to associate with, and how to detect mobility. DRAP discovers new neighbors by listening for beacons periodically broadcast by the relay nodes. DRAP estimates the average Receive Signal Strength Indicator (RSSI) for each neighbor by using a low-pass filter over the RSSI values from both beacons and data packets. DRAP associates with the relay which has the highest RSSI estimate. As packets are sent to the current relay, DRAP keeps track of the number of packet failures. DRAP will invalidate the current neighbor when the number

of retransmissions exceeds a threshold. DRAP’s approach of combining feedback from the physical (RSSI) and link layer (number of retransmission) in assessing link quality is similar to that proposed in [9]. The novelty of DRAP is that it can also detect mobility by using a single counter which keeps track of the number of *consecutive* relay invalidations: the counter is incremented when a relay is invalidated and reset to zero when data is successfully delivered to a relay. When the counter exceeds a threshold, DRAP flushes the neighbor table and rediscovers neighbors using its discovery mechanism. The threshold for the number of consecutive relay invalidations involves a trade-off between the expected churn caused by dynamic channel conditions and the possibility that a large number of entries are invalidated due to mobility: if the constant is set too low, DRAP will spend most of the time rebuilding routing tables without relaying packets; conversely, if the constant is set too high, DRAP will waste energy and bandwidth in transmitting numerous packets to nodes outside its communication range. In our system, we set this threshold to three.

It is worth noting that a patient’s vital signs are stored in the flash memory of each patient node. This data may be downloaded reliably upon the discharge of a patient. However, for the medical application of our interest – detecting clinical deterioration – this information has little value. We opted not to implement any reliable transport protocol, because the added complexity of such mechanisms may not be justified by the small margin of potential improvements over the high reliability delivered by our current protocols during the clinical trial.

3.3.2 Radio Power Management

The radio may have a significant contribution to the energy budget of patient nodes. In low data rate applications, the radio wastes most of the energy when it is active without transmitting or receiving packets. To address this issue DRAP is augmented with the following power management policy. Typically, power management protocols involve mechanisms that enable a sender and a receiver to coordinate the exchange of packets. These mechanisms assume that power management is performed on both the sender and the receiver. However, in our system, the relay nodes do not

require power management since they are plugged into wall outlets. Accordingly, the patient node could turn on the radio when it has a packet to transmit and turn it off after the associated relay acknowledges the reception of the packet. This simple policy handles the bulk of the traffic sent from the patient node to its associated relay without explicit coordination between them. However, a problem arises during the discovery phase of DRAP: the patient node must be awake to receive beacons from the relay nodes. This problem is solved by keeping the radio awake when the neighbor table is empty (e.g., after it was flushed due to mobility or when a node boots up) for a fixed period of time after the discovery of the first relay node. This allows DRAP to populate its neighbor table with several relays.

Our power management scheme has two salient features. First, in contrast to existing power management schemes, DRAP requires neither time synchronization nor additional packet transmissions. Second, the policy is flexible in that the time the radio of a patient node remains active changes based on the observed link dynamics, variations in workload, and mobility.

3.3.3 Sensor Component

The sensor component supports serial communication between the TelosB mote and the OxiLink pulse-oximeter and performs power management. The sensor component measures pulse and oxygenation at user specified rates. Accordingly, every sensing period, the OxiLink sensor is turned on by signaling a hardware switch on the custom board to power up the sensor. The OxiLink sensor provides an indication of the validity of each measurement. The values reported by OxiLink are averages over eight seconds. As a result, during the first eight seconds after the sensor is powered up, it reports invalid measurements; subsequent measurements may be valid or invalid. Patient movement or improper sensor placement may lead to invalid measurements. The sensor component reads the measurements provided by the OxiLink sensor continuously until a valid reading is received for up to 15 seconds.

3.3.4 Logging Component

We have developed a logging component which is primarily used for debugging and profiling the patient monitoring system. The logging component dedicates a significant portion of the RAM to buffer the generated statistics. Periodically or when the buffer is about to be full, the content of the RAM is saved to the flash in a single batch. We found that batching the flash writing can significantly reduce the amount of time the flash is active, hence reducing energy consumption.

4 Clinical Study

To evaluate the feasibility of employing wireless sensor networks for patient monitoring in general hospital units, we performed a clinical trial that focuses on the following questions at Barnes-Jewish Hospital:

1. How reliable is the clinical monitoring system?
2. What is the distribution of failures of the sensing and networking components?



Figure 2. Deployment of the wireless clinical monitoring system in the step-down unit of Barnes-Jewish Hospital. The blue square denotes the base station. The red circles denote relay nodes.

3. How often would nurses need to intervene to achieve high reliability?
4. Does the system provide sufficient temporal resolution for detecting clinical deterioration?

4.1 Methodology

We deployed the patient monitoring system in a step-down hospital unit at Barnes-Jewish Hospital. Step-down units provide care for higher risk patients that do not require intensive care, but do require more intensive monitoring and nursing care than can be provided on general care units. Patients admitted to step-down units may be ambulatory. We chose to perform the clinical trial in a step-down unit rather than a general unit because patients in step-down units have a greater risk of clinical deterioration. The step-down unit provides cardiac care for up to 32 patients. The unit is already equipped with a commercial wireless EKG monitoring system. The data collected by the hospital's system was not made available to us. Moreover, due to the significantly different sensing technology, a direct comparison of the two systems would not have been possible.

Participants were recruited in two phases: the unit's head nurse identified patients who were suitable candidates; we then sought the consent of the identified patients to participate in the trial. On average, one in six patients accepted to participate in the trial. A main reason for denying participation was the inconvenience of wearing two monitoring devices: one provided by us and the one already used in the unit. We expect the acceptance rate to be higher in units without telemetry systems.

After obtaining consent, a patient node was placed in a

telemetry pouch around the patient’s neck with the pulse-oximeter probe attached to his/her finger. We used adult disposable probes during the trial. Patients were monitored continuously until their discharge or for up to three days. During this time, patients often left the unit for diagnostic testing. The nursing staff recorded the times when a patient was not monitored by our system using a time sheet posted in the patient’s room. A total of 20 such events were recorded for the 41 participants suggesting that these events were underreported. We excluded from the presented results only the time intervals recorded by the nursing staff. Upon discharge, the statistics stored in the flash of the patient node were downloaded and stored in a database. These data indicated whether the sensor reported a valid measurement, whether the data were successfully delivered to a relay node, and the duty cycle of the radio, flash, and sensor components. New 9V batteries, monitoring pouches, and disposable pulse-oximetry sensors were used for each patient. After each use, the patient node was disinfected with a bleach solution.

The data collected by our clinical monitoring system was not available to the nursing staff. The hospital was not obliged to act based on the measurements collected by our experimental system. Usually, each morning we logged into our system remotely and checked whether the collected vital signs were valid. If the data provided were invalid, the nursing staff was notified to check whether the sensor was disconnected. Such manual checking of data validity was performed infrequently (usually daily).

The unit has 16 patient rooms and covers an area of 1200 m². We deployed 18 relay nodes to provide coverage within the unit as shown in Figure 2. Most of the relays were placed in the patient rooms. The hospital has two independent power circuits: one dedicated for critical equipment and one for non-critical equipment. The relay nodes were plugged into the power outlets on the power circuit dedicated to non-critical equipment. During the trial, the custodial staff unplugged the relay nodes occasionally to power their cleaning equipment. In addition, two relays were destroyed by impact with cleaning equipment. Due to the redundancy of the deployed relays, neither of these events had adverse effects on network reliability. The base station was deployed in a room behind the nurse’s station. The base station was powered and had access to the hospital’s Wi-Fi network. The system operated on 802.15.4’s channel 26 such that it would not interfere with the existing Wi-Fi network or other telemetry systems. During the deployment, the maximum number of hops varied between 3 – 4.

Patients were enrolled in the study between June 4, 2009 and January 31, 2010. During this time, a total of 46 patients were enrolled. Demographic data is presented in Table 1. We excluded the results of five patients from the reliability study. The data from the first patient admitted to the trial was excluded because it had poor network reliability. We determined that an older version of CTP was the source of the problem and updating it to the latest version available solved this issue. The other patients were excluded because no data was collected from them. This was the result of a improperly handled exception in the data collection software

Variable	Number
Gender	18 male 28 female
Age	range 34 – 89
Race	24 Caucasian 22 African American
Adverse events	2 patients transferred to ICU 1 patient diagnosed with severe sleep apnea
Total	46 consented patients 41 patients included in data analysis
System up time	7 months
Total monitoring time	41 days, 4 hours, 48 minutes

Table 1. Demographic information of patients consented

running on the base station.

The pulse and oxygenation were measured at 30- and 60-second intervals. We selected two sampling rates to evaluate the impact of sensing rate on sensing reliability and energy consumption. Note that at these rates the temporal resolution provided by our system is orders of magnitude higher than that achieved by manually collecting vital signs. The system collected more than 41 days of pulse and oxygenation data. The duration a patient was monitored varied from a few hours to three days (average 25.36 hours, range of 2 – 68 hours). The system monitored up to three patients simultaneously during the clinical trial and usually monitored one patient at a time. During the trial the condition of two patients deteriorated and they were moved to the ICU. An additional patient was diagnosed with life-threatening sleep apnea.

4.2 Reliability

In this section, we provide a detailed analysis of the system reliability. To quantify the reliability of the clinical monitoring system we introduce the following metrics:

- *Network reliability* is the fraction of packets delivered to the base station.
- *Sensing reliability* is the fraction of packets delivered to the base station that had valid pulse and oxygenation readings. The pulse oximeter indicates the validity of each reading and uses an error code to represent invalid readings. Our system sends both the valid readings and the error codes to the base station for reliability analysis. In a production system the invalid readings may be dropped at the patient nodes to save energy.
- *Time-to-failure* is the time interval during which a component operates continuously without a failure. A network failure refers to the case when a packet is not delivered to the base station, while a sensing failure refers to pulse-oximeter obtaining an invalid measurement. The *time-to-failure* is a measure of how frequent failures occur.
- *Time-to-recovery* is the time interval from the occurrence of a failure until the component recovers. The *time-to-recovery* is a measure of how quickly a component recovers after a failure.

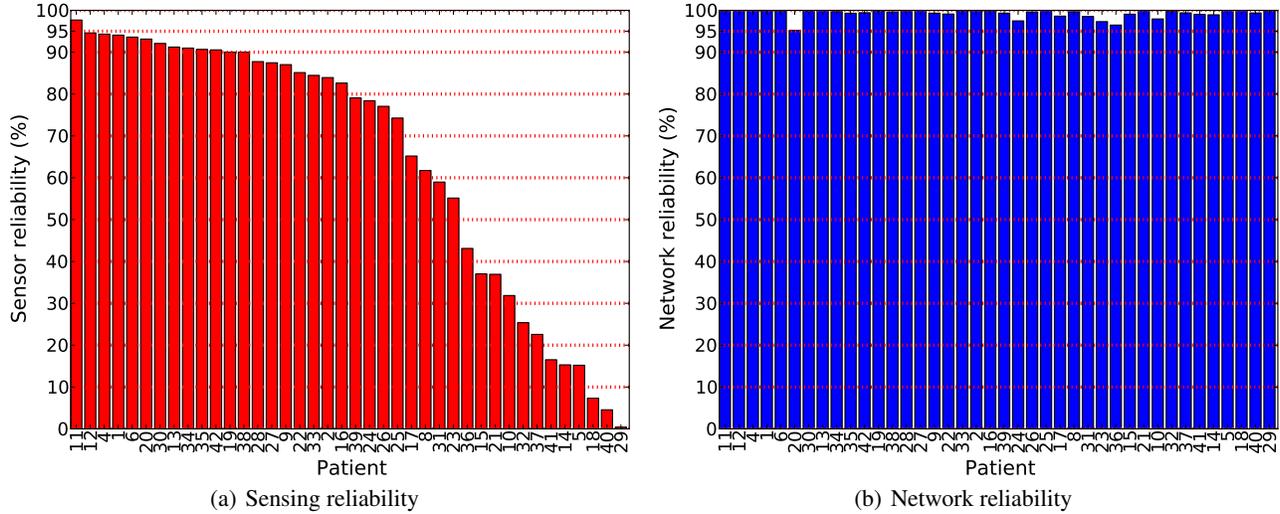
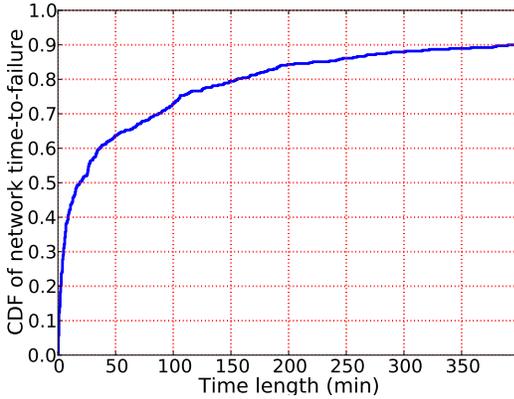
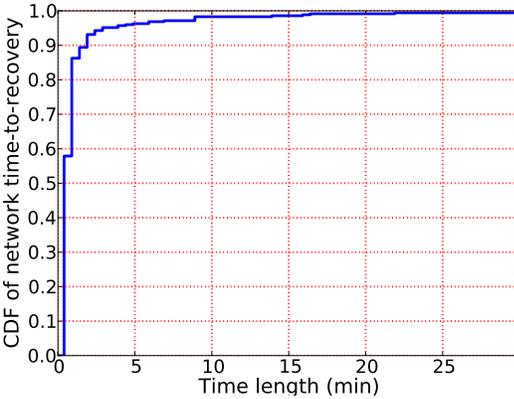


Figure 3. Network and sensing reliability per patient



(a) CDF of time-to-failure for network



(b) CDF of time-to-recovery for network

Figure 4. Distribution of time-to-failure and time-to-recovery of the network

4.2.1 System Reliability

Figure 3 plots the network and sensing reliability for the vital sign data from each patient. As shown in Figure 3(b),

the system achieved a median network reliability of 99.68% (range 95.2% – 100%). In contrast, the sensing reliability was significantly lower as shown in Figure 3(a). The median sensing reliability was 80.85% (range 0.46% – 97.69%).

Several key observations may be drawn from this data. First, the results indicate the system achieved high network reliability for *all* patients in spite of dynamic channel conditions and relay failures. This demonstrates the robustness of CTP and DRAP as well as that of our network architecture which integrates the two protocols. Second, the median sensing reliability is sufficient to provide health practitioners with pulse and oxygenation data at two orders of magnitude higher resolution than that achieved through manual collection. However, the wide range of the sensing reliability is disconcerting: 12 patients had reliability below 50%. An in-depth analysis of sensing reliability is deferred to Section 4.2.3. Third, the system reliability is dominated by sensing reliability rather than networking reliability. Therefore, even a wired patient monitoring system with perfect network reliability, would have had similar system reliability.

Result: *The system reliability is dominated by sensing reliability. Therefore, a wired system would have had similar system reliability as our wireless system.*

4.2.2 Network Reliability

To analyze the network reliability in greater detail, we study the distributions of time-to-failure and time-to-recovery. Figure 4(a) plots the CDF of the time-to-failure for all patients. The median time-to-failure is 19 minutes. Figure 4(b) plots the CDF of the time-to-recovery for all patients. The 90%- and 95%-percentiles of the time-to-recovery were shorter than 2 and 2.5 minutes, respectively. Thus, the network components recover from failures quickly.

Result: *The network component provides high reliability: the network experiences failures infrequently and recovers within 2.5 minutes most of the time.*

We profiled the behavior of DRAP for twelve of the patients. DRAP remained associated with the same relay for five of the patients. This is a consequence of the low noise

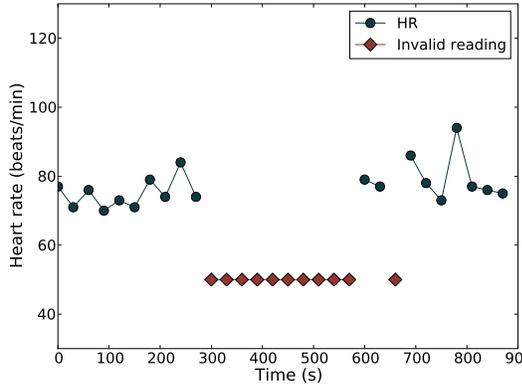


Figure 5. Impact of movement on sensing

level on 802.15.4’s channel 26 which does not overlap with other wireless devices. For the remaining seven patient nodes, DRAP changed the relay association at least once. Logs indicated that DRAP’s mechanism for detecting mobility was invoked four times. It is also worth mentioning that two patients changed rooms while being monitored. No manual system reconfiguration was necessary for handling this change.

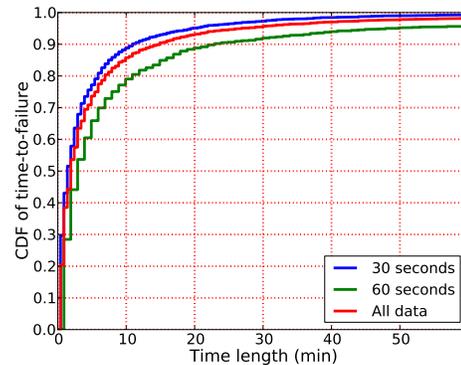
4.2.3 Sensing Reliability

The quality of pulse and oxygenation readings was significantly affected by patient movement, sensor disconnections, sensor placement, and nail polish²; this experience is consistent with results previously reported in literature [22]. Patient movement which includes movement of the arm on which the pulse oximeter was placed, finger tapping, or fidgeting may lead to invalid readings. The impact of body movement may be significant (see Figure 5): when a healthy volunteer moved his hand up and down (300 – 600 seconds), none of the obtained measurements were valid. In contrast, when the volunteer did not move his arm, a single measurement was invalid. This experiment also indicates that it is unlikely for the sensor errors to be the result of software bugs in the serial driver since valid readings were obtained when the volunteer did not move his arm. Sensor disconnection also had a significant impact: sensor outages longer than 30 minutes were observed in 17 patients.

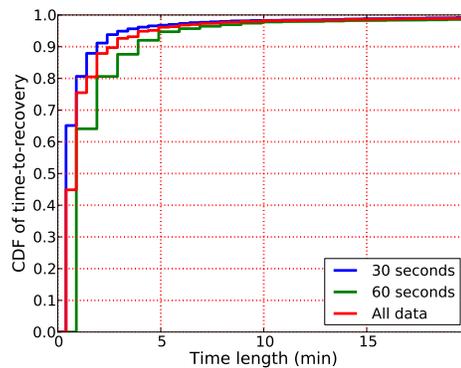
The distributions of time-to-failure and time-to-recovery for the sensor component are shown in Figure 6. We remind the reader that a sensing failure occurs when the pulse oximeter sensor reports an invalid reading. The median time-to-failure is 1.9 minutes, as shown in Figure 6(a) when the data from all patients is considered. As few as 8.4% of the time-to-failure intervals are longer than 19 minutes (the mean time-to-failure for the network component). The short duration of the median time-to-failure indicates that sensor failures are common.

Figure 6(b) plots the CDF of time-to-recovery. The results support two important observations. First, the time-to-recovery is short: 75.5% of the outages last for less than a

²Nursing staff indicated that nail polish was the cause of sensing errors in a patient. After removal, valid sensor readings were obtained.



(a) CDF of time-to-failure for sensor



(b) CDF of time-to-recovery for sensor

Figure 6. Distribution of time-to-failure and time-to-recovery of the sensor

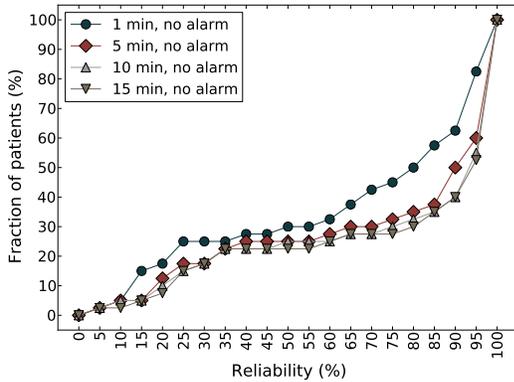
minute. This suggests that the sensing distribution is characterized by frequent failures which occur in short bursts. These types of failures are the result of patient movement or improper sensor placement. Second, the distribution of time-to-recovery is long-tailed: 1.3% of the sensing outages are significantly longer than 20 minutes. The longest time-to-recovery was 14.3 hours. These long outages are due to sensor disconnections. Nurses did not have access to the patient’s data and we checked for disconnections infrequently. In Section 4.3, we consider the effectiveness of an alarm system both in terms of its alarm rates and in the number of interventions required by the nursing staff.

Result: *The sensor failure distribution is characterized by frequent failures which usually occur in short bursts; occasional disconnections cause prolonged sensing failures.*

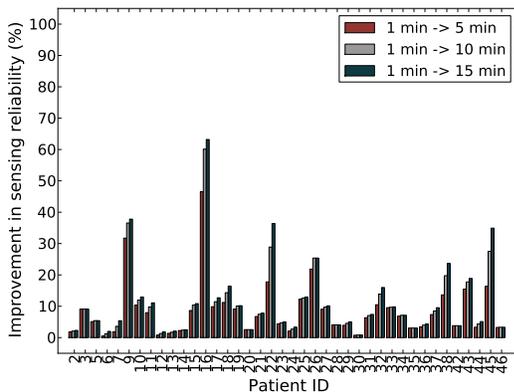
Since most sensing failures occur in short bursts, the sensing reliability may be improved through oversampling: the sensor could take measurements at a rate higher than the one specified by clinical needs. It is important to note that increasing the sampling rate would be beneficial only if the duration of a patient’s motion is shorter than 60 seconds. To test this hypothesis, we reduced the sampling interval from 60 to 30 seconds. Figures 6(a) and 6(b) also plot the time-to-failure and time-to-recovery when measurements were taken

every 30 and 60 seconds. Data indicates that reducing the sampling period from 60 seconds to 30 seconds, results in shorter time-to-failure as well as shorter time-to-recovery. The reduction in time-to-recovery is expected because the sensor is sampled at a higher rate. The 90-percentile of the time-to-recovery is reduced from 3.9 minutes to 1.9 minutes when the sampling rate is increased from once to twice a minute. The short time-to-recovery also explains the increase in the prevalence of short time-to-failure: since numerous outages are shorter than 30 seconds, then when sensor is sampled at a higher rate, some of the outages may not be observed. The median sensing reliability of the patients monitored at 30 and 60 seconds were 84% and 75%, respectively. This shows that oversampling leads to improved reliability.

Result: *The sensing reliability may be improved through oversampling.*



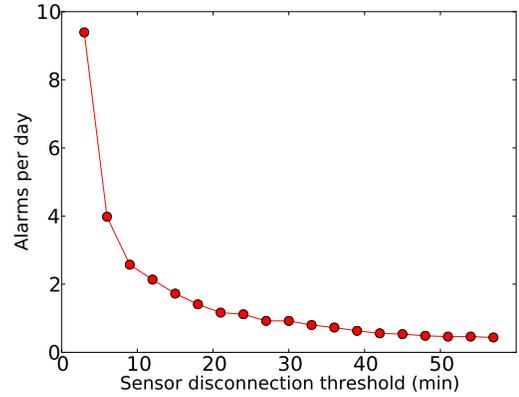
(a) Impact of oversampling on sensing reliability



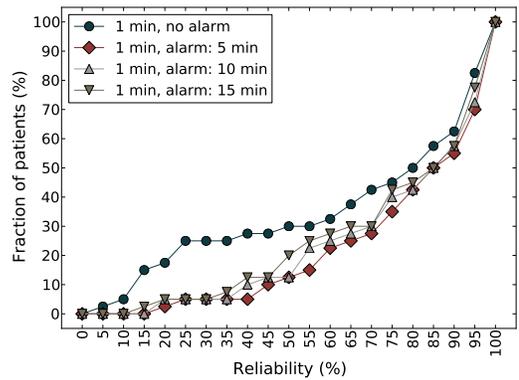
(b) Improvements in sensing reliability

Figure 7. Impact of oversampling on sensing reliability

To further quantify the impact of sampling rate on sensing reliability, we consider the reliability of the system when the requirement of receiving valid pulse and oxygenation measurements is relaxed to receiving at least one valid reading every 1, 5, 10, and 15 minutes. The updated sensing reliability results are computed based on the collected traces sampled at 30 and 60 seconds. Note that even under these relaxed sensing requirements, the resolution provided by our system



(a) Number of interventions



(b) Impact of alarms on sensing reliability

Figure 8. Expected performance of a sensor disconnection alarm system

remains significantly higher than it is possible through manual collection. As expected, the sensing reliability per patient increases as the sensing requirement is relaxed, as shown in Figure 7(a). For example, the fraction of patients whose sensing reliability was below 80% was reduced from 50% to 35% when the sensing requirement was relaxed to 5 minutes. In fact, as can be seen in Figure 7(b), the increase in sensing reliability can be as much as 62.4%. The patients which benefited the most from these improvements had medium and low reliability sensing reliability. Most of the performance improvements were observed when the sensing requirement was relaxed to 5 minutes; further relaxation of the sensing requirement resulted in smaller improvements. This may be explained by the fact that the bursts of sensing errors are short. The highest additional increase in reliability when the sensing requirement was relaxed from 5 minutes to 10 minutes was 13.4% for patient 16; while the highest additional increase in reliability for lowering the sensing requirement from 10 minutes to 15 minutes was 8% for patients 22 and 45. While the sensing reliability of most patients improved, it is worth mentioning that oversampling had limited impact on the sensing reliability of some patients. In the case of these patients, the low reliability was caused by the sensors becoming disconnected rather than intermittent failures. Hence, reducing the sampling requirement had no impact.

4.3 Benefits of Disconnection Alarms

As previously discussed, when a sensor became disconnected, the nursing staff should be notified to adjust the sensor. We propose an alarm system to notify the nursing staff when the sensor is disconnected. A disconnection may be detected by keeping track of the time since the last valid sensor reading was obtained by the sensor. When this time exceeds a disconnection threshold, the alarm is triggered. The selection of the disconnection threshold must consider the trade-off between the nursing effort (i.e., the number of notifications for manual intervention) and the amount of time that no valid sensor readings are obtained. Figure 8(a) plots the number of alarms that our system would have triggered for different values of the disconnection threshold based on the data traces collected from the clinical trial. As expected, the system shows that as the disconnection threshold is increased, the number of alarms triggered per day is reduced. When the disconnection threshold is 3 minutes, the number of required interventions per patient per day is 9.3 times. This is comparable to the number of times pulse and oxygenation are manually measured in postoperative care. A disconnection threshold between 10 – 15 minutes results in about 1.5 interventions per patient per day. At this threshold value, our system significantly reduces the burden on the nursing staff compared to manual collection, while achieving a sampling rate two orders of magnitude higher than manual collection.

Figure 8(b) shows the impact of the alarm system on the sensing reliability. The sensing reliability values are computed as follows. Sensing outages longer than the disconnection threshold are identified. The system is penalized for the sensor failures during the time interval from the start of the outage until the disconnection alarm is triggered. The remaining time, from when the disconnection alarm is triggered until the end of the outage, is excluded from the re-computed sensing reliability. We assume that the nursing staff would respond timely to such alarms.

The CDF of patient sensing reliability looks similar for different disconnection thresholds. The most pronounced differences are for patients with reliability in the range 10% – 75%. As expected, the best sensing reliability is obtained when the disconnection threshold is set to its lowest value of 5 minutes, but increasing the threshold interval has only a small impact on sensing reliability. Outside the reliability range 10% – 75%, the impact of the disconnection threshold is negligible. This shows that a disconnection threshold in the range 10 – 15 minutes results in a desirable balance between sensing reliability and intervention cost.

Result: *Disconnections may be mitigated through an automatic alarm system with low alarm rates.*

In the following, we estimate the potential benefit of combining oversampling and the disconnection alarm system to achieve even better performance. First, we consider the base case when the sensing requirement is one sample per minute. As previously discussed, reducing the sampling requirement to a sample every 5 minutes results in significant reliability improvements for most patients (see Figure 9). Similarly, incorporating an alarm system with disconnection threshold of 15 minutes also results in reliability improvements. By com-

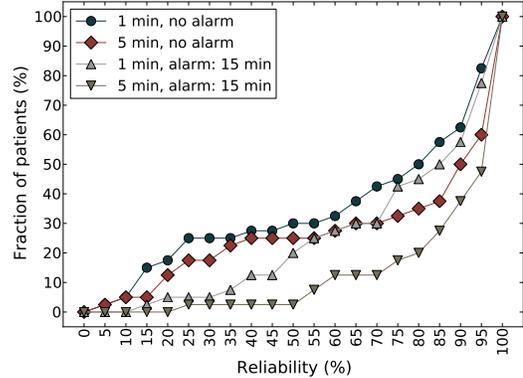


Figure 9. Combining oversampling and sensor disconnection alarm systems

paring these two curves (*5 min, no alarm* and *1 min, alarm: 15 min*), one can see that the two mechanisms act in different ways. The sensor disconnection alarm system has the most impact on patients with low reliability (i.e., those that had disconnections) while the oversampling mechanism handles intermittent sensing errors. Combining the two mechanisms results in significant improvements: only 5 patients (12% of patients) had lower than 70% sensing reliability when the measurements are required once every 5 minutes and a disconnection threshold of 15 minutes is used. From the patients whose sensing reliability was below 70%, we obtained less than 8.5 minutes of valid measurements. This makes their reliability unrepresentative for the case when an alarm system would be employed.

Result: *Oversampling and disconnection alarms are complementary and can be combined to achieve further improvement in sensing reliability.*

5 Detecting Clinical Deterioration

Thus far, our focus has been on assessing the feasibility of using wireless sensor network technology for real-time and reliable collection of heart rate and oxygenation measurements. The ultimate goal of real-time patient monitoring is that the collected vital signs may be analyzed to detect the onset of clinical deterioration and, as a result, improve patient outcomes. In this section, we start by presenting traces obtained from three patients which suffered significant clinical events during the trial. In addition, we develop an algorithm for detecting clinical deterioration using a time series analysis technique. We apply the developed algorithm to the collected traces retrospectively. While this is a preliminary exploration, our analysis indicates the feasibility and potential for detecting clinical deterioration based on sensor data streams collected by wireless clinical monitoring systems.

5.1 Major Clinical Events

During the trial, there were three major events. Patient 3 (see Figure 10(a)) suffered from bradycardia (low heart rate). Upon being admitted in the unit, the patient had a average heart rate of 55 beats per minute. By the time the patient was transferred to the ICU, the heart rate dropped to 35 beats per minute over a period of about two hours. A slight degradation in oxygenation is also present.

Patient 19 (see Figure 10(b)) suffered from pulmonary edema and required intubation and was transferred to the ICU. The collected pulse and oxygenation trace indicates two correlated increases in heart rate and decreases in oxygenation. Most clearly towards the end of the trace, we see both an increase in the heart rate as well as a decrease in oxygenation with SpO2 being below 90%.

Patient 24 (see Figure 10(c)) suffered from sleep apnea – a sleep disorder during which a person stops breathing – later confirmed to be severe sleep apnea by a formal sleep study. Significant drops in the SpO2 levels are one sign of sleep apnea. Based on our traces, the SpO2 levels dropped below 80% indicating severe oxygen desaturation.

These examples highlight that the patient monitoring system provides sufficient resolution for a clinician to identify life-threatening conditions such as bradycardia or oxygen desaturation resulting from sleep apnea or pulmonary edema. Physician review of the data traces confirmed that the data traces of these patients are consistent with their medical conditions indicated in the clinical records.

Result: Preliminary results show that the system has sufficient resolution for detecting clinical deterioration.

5.2 Automatic Detection of Clinical Deterioration

To assess the feasibility of detecting clinical deterioration based on the collected heart rate and oxygenation traces, we implemented an event detection algorithm based on the CUSUM algorithm [8]. The CUSUM algorithm is capable of detecting statistically significant changes in a series of measurements. The CUSUM algorithm takes as input a series of measurements along with a confidence level. The algorithm outputs the point in the series at which statistically significant changes are detected. If no such point is found, then the series of measurements are statistically similar at the specified level of confidence. The algorithm can be applied recursively to identify all intervals that contain statistically similar measurements. It is important to note that even though consecutive intervals may have statistically different vital signs, it does not necessarily imply that the patient’s condition has deteriorated. To determine whether an alarm should be issued, we consider each interval in which CUSUM identified data to be similar with a confidence level of 99%. We compute the following statistics for each interval and vital sign: the 5-th percentile, 95-th percentile, and the slope of the linear fit over the data points in each interval. Clinical deterioration is detected using thresholds on the computed values. For example, bradycardia may be detected when the 5-th percentile is below a set threshold. Similarly, tachycardia may be detected when the 95-th percentile exceeds a different set threshold. Finally, the slope of the trend line may be used to identify sharp declines/increases in pulse or oxygenation measurements which may be signs of clinical deterioration. The use of such thresholds for identifying abnormal changes in vital signs is common to automatic scoring systems [14, 23].

The proposed algorithm has several advantages over computing statistics over sliding windows. First, sliding window algorithms tend to be susceptible to the choice of window sizes. In contrast, CUSUM automatically identifies intervals

in which points are statistically similar. Second, the processing complexity is lower since statistics are computed over the identified intervals rather than at each data point as required by an algorithm based on sliding windows.

We have retroactively applied the automatic event detection algorithm to the collected traces. As previously discussed, some of the traces were short due to sensor disconnection. These traces are excluded from our results. By inspecting the medical records of patients admitted to the study, we divided the patients in two groups: a total of 29 patients diagnosed with a significant cardiac or pulmonary disease and 7 patients without such a diagnostic (see Table 2). By constraining the threshold values for heart rate and oxygenation to clinically relevant values we were able to compute the performance of the alarm systems for different configurations. Figure 11 plots the Receiver Operating Characteristic (ROC) for the alarm system. The straight line in the figure denotes the performance of an alarm system which would trigger an alarm at random. The closer the points are to the (0, 1) corner of the graph, the better the performance of the alarm system is.

Condition	Signs	Patients
Bradycardia	low HR	3, 14, 30, 34
Sleep apnea	low SpO2	2, 10, 18, 22, 23, 24, 35, 38
Desaturation	low SpO2	11, 12, 19, 26
Pulmonary edema	low SpO2	19
Tachycardia	high HR variable HR	6, 27, 31
Congestive heart failure	low SpO2	8, 9, 20, 21, 25, 30, 41
Atrial fibrillation		8, 11, 13, 28

Table 2. Medical conditions of the patients admitted in the trial.

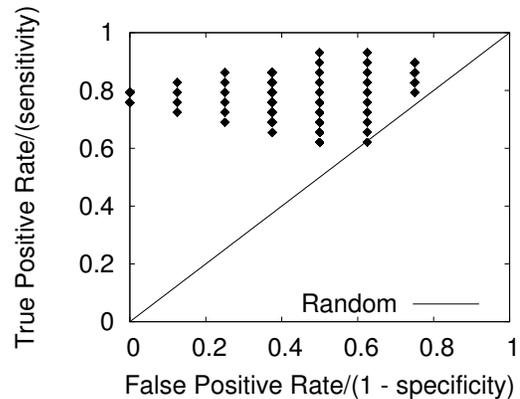


Figure 11. ROC curve of the event detection system under different threshold configurations

In hospitals, alert fatigue results from high false positive rates. Therefore, we are interested in the case when the false positive rate is zero i.e., when the algorithm would correctly not trigger an alarm for any of the patients which did not have any major conditions. The lowest false positive rate observed for the considered threshold combinations was 0%

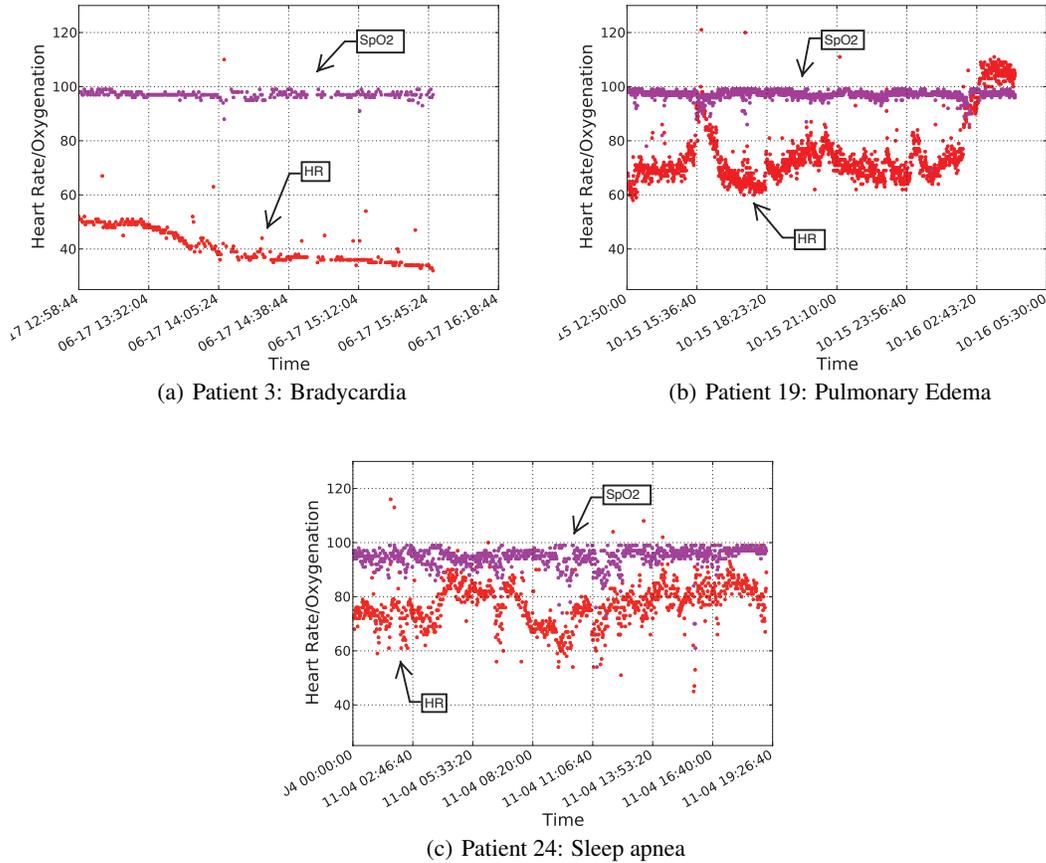


Figure 10. Pulse (red) and oxygenation (purple) measurements from patients which suffered clinical deterioration

i.e., no alarm was issued for patients which were not diagnosed with heart/pulmonary rate. At this false positive rate, the true positive rate was 79.3%.

The obtained results are encouraging. First, vital signs measurements collected at frequencies as low as 0.016Hz provide sufficient resolution for detecting a range of signs that may be indicative of potentially dangerous conditions such as bradycardia, tachycardia, and sleep apnea. We note the possibility of applying the devised system as a screening tool for sleep apnea. Patients whose oxygenation drops significantly during sleep without an alternative explanation would be required to undergo sleep studies. Second, other vital sign measurements (e.g., blood pressure, temperature) and clinical tests may provide additional valuable information to improve the detection of clinical deterioration. To this end, we plan on integrating our system with patient electronic records to explore the possibility of integrating other low data rate sensors in our system. Finally, the preliminary study shows that the proposed algorithm for issuing alarms performed well on the collected data sets. As part of our future work, we plan on integrating the data collection and data analysis components for detecting clinical deterioration in real-time. It is our intention to validate the performance of the constructed system through a larger study. This would allow us to directly quantify the impact of such a system on

patient care and outcomes.

6 Discussion

Relay Redundancy: The need to ensure network coverage within the step-down unit was one of the concerns raised during the planning of the clinical trial. We considered the possibility of minimizing the number of relay nodes necessary for ensuring coverage. However, this would have required performing in situ measurements to assess the coverage of the relays, which could have been a significant inconvenience to the care providers. Instead, we opted to deploy a redundant network of relays to ensure coverage. The architecture of the system which relies on mesh networking and the availability of power outlets in the hospital makes the deployment of the system effortless. It is worth noting that we were able to redeploy the entire system within 15 minutes. Relay redundancy was essential for tolerating the unplugging of the relays by the cleaning staff and the damaging of relays. Our data indicates that these failures did not adversely impact network performance. Moreover, it is unlikely that any packet losses may be attributed to coverage gaps. In retrospect, adopting the more practical solution of deploying additional relay for redundancy was the right choice due to the unexpectedly frequent relay failures.

Existing Wi-Fi support: Even though this paper focuses

on reliability concerns, we have not yet discussed the most unreliable part of the system: the 802.11 wireless link from the base station to the hospital's wireless infrastructure. The poor link quality often prevented us from logging into the base station to determine if valid readings were obtained from the monitored patients. Additionally, the transfer of large files was impossible due the same reason. In spite of these issues, we chose not to move the base station in order to maintain a consistent network setup.

It has been argued that a patient monitoring system should take advantage of existing 802.11 infrastructure. If the patient monitoring system would have been required to use this Wi-Fi link, the network reliability would have been significantly lower than that reported in this trial. It is worth noting that the hospital invested numerous man-hours to ensure "100% coverage". However, Wi-Fi users are accustomed to having to change their location to achieve better performance and, as a result, there is little incentive to deploy more routers to provide true "100% coverage". In contrast, in our system redundancy may be easily achieved and, with 802.15.4 technology, it comes at a low cost.

Power Management: During the clinical trial, patient nodes achieved a life time of up to 69 hours by duty cycling the radio, sensor, and flash. This meets the maximum time we can monitor a patient per our human subject study agreement. The radio and sensor duty cycle was measured on six nodes. The radio consumes 19 mA and had a duty cycle ranging from 0.12% to 2.09%. The sensor draws 24 mA and its duty cycle depends on the sampling rate. Existing pulse-oximeters take up to 8 seconds until average values for hear rate and oxygenation are reported. After 15 seconds, the sensor is turned off to conserve power. Accordingly, when the sampling rate is 30 seconds, we expect a duty cycle between 26.66% – 50.00%. On the observed devices we obtained duty cycles between 27.3% – 40.27%. Similarly, for a sampling rate of 60 seconds, we expect duty cycles between 13.33% – 25%. In the field, we observed duty cycles in the range 16.24% – 18.97%. These numbers indicate that sensing dominates the energy budget of the patient nodes. The obstacle in achieving lower duty cycles is the prolonged start-up time.

We believe that there are significant opportunities for further reducing the time the sensor is active. For example, a significant amount of energy is wasted when the patient node is left active while a patient goes for treatment outside the unit. A simple policy of reducing the sampling rate after multiple consecutive sensing failures could save significant energy. However, note that even without any of these more complex power management policies, we achieved a lifetime of 3 days. Interesting opportunities also exist for improving energy efficiency by using additional sensors. For example, accelerometers which have lower energy consumption than pulse oximeters, may be used to asses whether a patient is moving. The detection of patient movement would prevent us from turning on the pulse oximeter sensor when it cannot provide valid readings and waste energy as a result. The cessation of patient movement would constitute a trigger for the start of measurements.

7 Conclusions

This paper presents the design, deployment, and evaluation of a wireless pulse-oximetry monitoring system in a hospital unit. The study presented in this paper involves real patients monitored in a clinical setting. The patients were monitored in situ to realistically assess the feasibility of WSN technology for patient monitoring. The system we deployed had 18 relay nodes and required multi-hop communication for data delivery. As part of the study, we monitored 41 patients recruited over seven months for a total of 41 days of continuous monitoring. Our work makes several main contributions to wireless sensor network technology and clinical monitoring. (1) Our network achieved a 99.69% median reliability over 41 hours of monitoring. The high network reliability indicates the feasibility of applying wireless sensor network technology for clinical monitoring and the efficacy of separating end-to-end routing from first-hop relay association in a clinical environments. (2) System reliability is dominated by the sensing reliability of the commercial pulse oximeter. This shows that the performance of our system is comparable to that of a wired pulse-oximetry system with additional benefits of increased flexibility and lower cost. Sensing failures are frequent, but usually occur in short bursts with the exception of prolonged sensor disconnections. Oversampling and disconnection alarms that could substantially enhance sensing reliability. (3) Our study provides clinical examples that show the potential of wireless clinical monitoring system in enabling real-time detection of clinical deterioration in patients. Moreover, a retrospective study shows that an alarm system was able to issue alarms for patients with severe clinical conditions based on the collected vital signs traces. This analysis of the data traces collected by our system shows the promise of using real-time and low data rate monitoring of vital signs for detecting clinical deterioration in patients. Our work also points to several important future areas of research, such as the integration of real-time clinical monitoring systems with the electronic health record systems and the development of clinical event detection algorithms based on real-time sensor streams.

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