A Multi-Disciplinary Framework for Continuous Biomedical Monitoring Using Low-Power Passive RFID-based Wireless Wearable Sensors

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Abstract—We have applied passive Radio Frequency Identification (RFID), typically used for inventory management, to implement a novel knit fabric strain gauge assembly using conductive thread. As the fabric antenna is stretched, the strength of the received signal varies, yielding potential for wearable, wireless, powerless smart-garment devices based on small and inexpensive passive RFID technology. Knit fabric sensors and other RFID biosensors can enable comfortable, continuous monitoring of biofeedback, but requires an integrated framework consisting of antenna modeling and fabrication, signal processing and machine learning on the noisy wireless signal, secure HIPAA-compliant data storage, visualization and human factors, and integration with existing medical devices and electronic health records (EHR) systems. We present a multidisciplinary, end-to-end framework to study, model, develop, and deploy RFID-based biosensors.

I. INTRODUCTION

It is known that interruptions in continuous medical monitoring can be a contributing mortality factor in the hospital setting for some health conditions [1]. Continuous monitoring has the potential to benefit several medical domains. For example, the Centers for Disease Control (CDC) estimates that preterm birth (prior to 37 weeks gestation) affects 1 in every 8 infants born in the United States, and accounts for 35% of all infant deaths as of 2009 [2]. Preterm birth is the leading cause of newborn deaths with over 1 million casualties annually, 75% of which could have been saved with interventions available today [3]. Monitoring high-risk infants for respiratory events would be helpful in detecting apnea, which if not reversed in a timely manner, can lead to cardiovascular arrest. In addition, Venous thromboemboloism (VTE) is the leading cause of maternal death in the United States [4]. Deep Venous Thrombosis (DVT) and pulmonary embolisms (PE) are two types of VTEs. The clot, or thrombus, forms in the deep veins of the leg or pelvis, and then travels to the lungs as a PE. According to the Centers for Disease Control and Prevention, DVT/PE impacts between 300,000 to 900,000 people per year in the United States [5]. There is thus a strong need for effective and unobtrusive sensor technologies that can monitor quantities such as contractions and maternal ECG in pregnant women and respiration in newborn children.

However, monitoring of patient vital or other biomedical signals often requires cumbersome, tethered or adhesive equipment, and practitioner observation. In neonatology, this problem is compounded by the smaller body area available for sensor deployment and need for infant comfort. Practitioners observe and record this data in an Electronic Health Record (EHR), often manually, and little history about the biomedical sensor data are captured with it. We implement unobtrusive wearable monitoring devices via non-conventional fabrication and communication technologies using passive Radio Frequency Identification (RFID) tags. One of our fabrication approaches includes knitting to make smart garment devices that can be worn on the body in a non-invasive way. This mechanical strain gauge device works by knitting an RFID chip into a pocket surrounded by conductive thread [6], [7], embedded into an elastic garment "Bellyband." Alternatively, if electric biosignals are to be measured, the semiconductor circuitry can be soldered on compact, flexible printed circuit boards (PCB) for integration with a garment. Both knitted and PCB devices are monitored by continuously interrogating the RFID chip. For the knitted device, properties of the Received Signal Strength Indicator (RSSI) of the returned signal are continuously monitored. As the subject moves (e.g., uterine contraction, infant respiration), the garment and knit antenna assembly are stretched, resulting in tag efficiency and propagation channel modifications that impact measured RSSI. For biosignal monitoring, the RFID assembly is used as an onoff keying device wherein the absence of an RFID backscatter indicates the detection of a biosignal. The correlation of RSSI to activity detection is summarized in Figure 1.

Several challenges exist with the approach of using RFID to monitor mechanical or electrical signals. First, interactions between conductive and elastic threads in a moving garment are not well understood for various materials. Second, differences

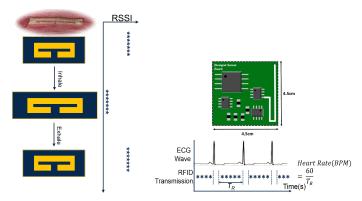


Fig. 1: Mechanical strain gauge sensor (left) utilizing the mechanical motion of the fabric antenna and corresponding changes in RSSI, and biosignal sensor (right) breaking RFID signal transmission at each ECG wave peak

in the subject's size, wearing position, and initial stretch of the garment necessitate unique baselines for each use. Because signal strength is the primary measure correlated to subject motion, a third challenge is that other types of motion, such as rolling over in a bed or walking down a hallway, are captured in-band and must be filtered out. Additionally, noise inherent in the wireless low-power electric signal requires signal processing and machine learning approaches to extract the pure signal indicating the subject's true state. Finally, expertise in design, engineering and computer science needs to be integrated with medical domain knowledge and human factor expertise. This additional perspective considers how people adopt and utilize technologies, and these synergistic interactions are summarized in Figure 2. In this paper, we present the Bellyband smart garment device as a product of synergy between medicine, fashion design, social human factors, electrical circuit design, software engineering, signal processing, and machine learning; we describe the multidisciplinary challenges and unique approaches taken to enable continuous biomedical monitoring using low-powered or powerless smart garments. The result is an end-to-end framework for continuous biomedical monitoring to solve an end-to-end health management problems currently addressed primarily through practitioner observation.

II. RELATED WORK

Recently, the technological integration of wireless smart devices into clothing has received considerable attention. Some example systems that currently use medical sensor patches are described in [8]–[11]. All of these systems rely on traditional printed circuit technology to produce sensing devices that are relatively bulky, which might not be comfortable for a patient to wear for prolonged amount of time. Such disadvantages might also get in the way of commercialization and wide adaptation. Several groups have developed techniques for routing power and signaling in woven textiles [12]–[14], which mainly focus on military applications. There is considerable interest in military applications, where long-term, unobtrusive

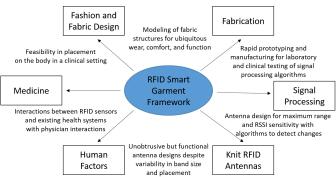


Fig. 2: Some example points of synergy between the several disciplinary areas of expertise involved with the Bellyband smart-garment framework

vital signal monitoring is of great interest [12]. Such systems would integrate fabric sensors and interconnects to measure temperature and humidity [13] with wearable antennas [14].

The feasibility of building electrical devices using conductive fabrics has been analyzed through electrical characterization of textile transmission lines [15], [16]. In addition, several groups have mounted wearable transmission lines and antennas onto separate, flexible, host materials by adhering conductive fabrics onto woven materials [17]. However, limitations of this adhesive approach have been shown in terms of electrical losses caused by the glue chemicals [18]. These limitations are addressed by our knitting based approach since the conductive threads are seamlessly incorporated into the host material in a single fabrication process, which makes our design robust, machine-washable, and reusable. It provides an optimal monitoring setup for medical applications.

III. MEDICAL APPLICATION DOMAINS

Each biomedical application (depicted in Figure 3) places unique requirements on the type, duration, and time sensitivity of motion being monitored. For example, infant respiratory monitoring utilizes a Bellyband worn about the abdomen or chest wall, and determines respiratory activity and rate by observing the change in RSSI values over time. By contrast, uterine contraction monitoring utilizes a Bellyband worn about the abdomen, and observes a uterine contraction when RSSI values suddenly change over time. Monitoring can also be accomplished using bio-signals like electrocardiograms (ECG) for heart rate and electrohysterograms (EHG) for uterine contractions. RFID communications are stopped momentarily when an ECG spike is detected or when successive spikes for an EHG signal occur; these stoppages can be correlated to the heart rate and frequency/durations of uterine contractions.

IV. SYSTEM DESIGN AND RESULTS

Our current setup for passive RFID based uterine contraction and infant respiration monitoring uses an inductively coupled passive RFID chip knitted into a small pocket at the feedpoint of a co-planar microstrip antenna made out of conductive and non-conductive threads [6], [19]–[21]. The passive RFID is powered by the energy from the RFID interrogator.

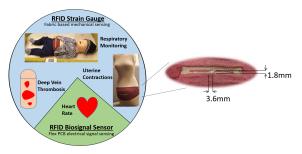


Fig. 3: RFID-based sensors deployed using knit-fabric strain gauge smart garments and with flexible board biosignal sensors.



Fig. 4: The end-to-end workflow of the wearable sensor framework

As the antenna stretches due to the biological process being monitored underneath the tag, the resonant frequency of the antenna changes and the inductively coupled RFID begins to decouple from the antenna structure. Both of these radio frequency changes manifest themselves in a loss of RFID reads or decrease in RSSI returned to the RFID interrogator.

The Bellyband framework, depicted in Figure 4, is an end-to-end solution connecting the patient to live biometrics and alerts, as well as to the medical practitioner via alerts and visualizations similar to those expected from traditional medical systems. It is expected that the alerts and biometrics generated by the system will be compatible with existing EHR systems via software adapters that conform to common EHR standards such as the Fast Healthcare Interoperability Resources (FHIR) while augmenting the data that can be stored there with a history of the patient's biofeedback measurements.

The RFID knit strain gauge and RFID biosignal sensor are manufactured either as fabric sensors or on small, flexible circuit boards, and worn by or deployed near the patient. This presents human factors challenges, such as the means by which the patient and practitioner interact with the system, which we address in this section. We also detail antenna design considerations in this section. The RFID interrogator and RFID data collector interact to collect data from the sensors, abstracting the data collection from the sensor design and the interrogator being used. The data collector module interacts with the encrypted data storage module to store this data in a variety of data stores. This approach facilitates testing of system components when a client/server architecture and database server are not readily available, and eases portability to other systems such as REDCap due to its abstraction from hardware-level components. The statistical processor and visualizer modules query the encrypted data store to provide animated graphical depictions of biofeedback trends, and to aggregate, filter, and perform signal processing and machine learning on the data to make decisions about the subject's current state that can be uploaded to an EHR system or utilized to alert the patient or practitioner.

A. Human Factors

Studies of technology innovation and implementation note the importance of identifying human factors early in the design process [22]–[26]. Working with stakeholders early provides insight into the cultural contexts, that is, the meanings that may be provoked by new technologies, as well as how new technologies may affect workflows; failure to take into account cultural contexts and work practices can result in adoption failures [27]–[31]. Despite this understanding of innovation processes, often the end users of a technology (e.g., professional staff, patients or family caregivers) are included late in the design process. Moreover, health-related electronic systems or products are often developed and implemented without a sufficiently deep understanding of users' needs and priorities, the complexities of healthcare, or the nuances of providerpatient interactions and practice workflows. At best such technologies increase some types of efficiencies, while at worst they hinder workflows, decrease user satisfaction, and create misleading data. Thanks to the participation of physicians on the collaborative team since the project's inception, we have been able to utilize stakeholder feedback throughout the multifaceted design process.

Our innovative, integrative approach unites expert knowledge of social contexts, values, workflows, and users with technical and design expertise early in the research and development process to improve both the design and adoption of novel smart textiles. Intervening during the design phase, or what is known as the midstream modulation point of innovation [32]. the team makes two contributions to human factor analysis. First, focus groups are being conducted with end users before the product is complete so that their input can be integrated into the Bellyband. Second, we expand who counts as users. In the case of the Bellyband to be used during pregnancy, for example, we went beyond focusing on traditional medical staff (e.g., physicians, nurses) to also include doulas and midwives, better reflecting the range of professionals that may be assisting birth. Instead of simply gathering feedback from pregnant women, we will also conduct focus groups with pregnant women's partners-partners can be crucial to the pregnancy process, and technologies should support their inclusion instead of potentially creating a barrier for their participation. Two focus groups are being conducted with each stakeholder group to identify potential concerns about the Bellyband design and science, possible workflow effects, and stakeholder priorities in relation to Bellyband use and design. Preliminary results show that stakeholders have clear preferences for band width, type of fabric, and device design. This data will inform the final form of the Bellyband.

B. RFID Strain Gauge Design

Shima Seiki knitting technology at Drexel University enables custom design and production of smart textile devices. Fabrics are designed using modeling software and then rapidly produced on knitting machines. These garments include specialty yarn inlays, multi-gauge shapes, and seamless WHOLE-GARMENTs. Conductive [6] and non-conductive yarns are knitted in a single process resulting in smart textiles that are unobtrusively integrated into the host garment Bellyband. The Bellyband sensor is composed of a textile folded dipole antenna, equipped with an RFID tag microchip. The way to vary RSSI when stretching the Bellyband is to design an antenna which transmission coefficient and radiation efficiency significantly increase or decrease simultaneously while the dimension of the antenna is changing. Murata MAGICSTRAP®, a 2-port IC tag employing inductive-coupling technology is selected as an RFID tag. As opposed to conventional microchips, the energy is inductively transferred through an internal matching circuit. The advantage of this inductivecoupling technology is in maintaining the full flexibility of the fabric even around the microchip area. Under large mechanical deformations, the RSSI variation is enhanced by the decoupling between the microchip and the antenna.

Unlike conventional metal based antennas, the textile complex sheet impedance should be determined through a series of parametric simulations and comparison with a measured prototype. The optimal sheet resistance and reactance values are $Z_s=0.8+j1.8~\Omega/sq$. Based on the estimated sheet impedance, the dimension of the antenna is tuned for matching with the complex microchip impedance $Z_c=25-j200$.

Figure 5 shows the 3D antenna HFSS model for numerical simulations, where the antenna layout is placed on top of the supporting polyethylene substrate. The outer dimension of the developed antenna is $W_{total} = 9$ mm and $L_{total} =$ 100 mm, while the internal slot dimension is $W_{slot} = 2mm$ and $L_{slot} = 25mm$. Using the differential analysis proposed in [33], in Figure 6 we show the simulation of the antenna's input impedance Z_a . At the center frequency of 890 MHz, the complex impedance is equal to $Z_a = 34 + j196$. The measurements show that at the frequency of 890 MHz, the impedance is equal to $Z_a = 42 + j192$, which yields a good conjugate matching with the RFID tag impedance Z_c . The -8 dB return loss bandwidth is about 80 MHz, covering with good impedance matching the frequency band from 850 to 930 MHz. Applying this Bellyband antenna on the Laerdal SimBaby programmable mannequin, we observe 10-15dB RSSI variation during respiration within the dynamic reading range of up to 6 feet, due to inductive-coupling and decoupling.

Safe exposure to radio frequency (RF) energy is one of the main concerns for wireless devices. The maximum peak Specific Absorption Rate (SAR) SAR_{10g} levels in adults and children is 0.8 W/kg [34]. If we keep the human body 50 cm away from the Reader antenna, the maximum peak SAR_{10g} values (0.25W/kg) are lower than these guidelines.

C. RFID Biosignal Sensor

The RFID biosignal sensor includes circuits for RF power harvesting, bio-signal amplification, spike detection, RFID tag and antennas, all integrated on a compact 4.5 cm^2 circuit

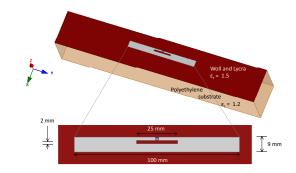


Fig. 5: Knit antenna design and substrate structure

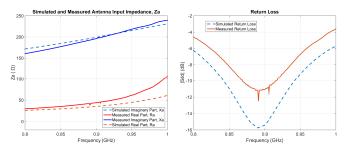


Fig. 6: Simulated and measured antenna input impedance (left), and return loss (right)

board. The power requirement of the sensor is low enough for it to entirely operate only on the harvested RF power; thereby eliminating the need for batteries. Figure 1 (right) depicts the principle of operation for such a device for the heart rate application. The RFID tag transmits its unique ID continuously in the absence of an ECG spike. However, every time a spike is detected, the tag is turned off momentarily causing an RFID outage. By finding, the time between such RFID outages, one can easily calculate the heart rate [35].

D. Data Collection from Proprietary Devices

The software module for data collection is dependent upon the type of chip being sensed and the type of interrogator being used. Moreover, it is necessary to compare this data to that collected by legacy medical equipment in a clinical trial setting in order to measure performance of and determine viability of the system. We developed a software framework for collecting data in real-time from heterogeneous medical devices and RFID sensors simultaneously, providing a consistent data representation for each. RFID data are collected from one or more interrogators and stored in an encrypted database. The RFID interrogator data must be obtained from specifications or reverse-engineered to determine its format and protocol. Different interrogators may communicate with different levels of compliance to the standard protocol (known as the Low Level Reader Protocol, or LLRP), or they may use their own proprietary formats. Critical to these efforts is real-time software-based signal processing algorithms capable of filtering the live data to detect events such as a uterine contraction, heartbeat, or infant movement. Network traffic from each RFID interrogator was observed to determine the degree of implementation of the Low Level Reader Protocol (LLRP) used by many RFID interrogators, and to develop reader software that utilizes the interrogator to collect data according to the protocol. We developed a modular software framework to communicate with several RFID interrogators, including the Impinj Speedway and portable Intermec IP30 RFID readers, over LLRP and Bluetooth protocols, and communicate using a RESTful web service over encrypted HTTPS to a modular database component enabling secure data storage such as REDCap. Signal processing algorithms collect data from this module via RESTful service calls.

E. Signal Processing and e-Health Records

Signal processing and machine learning on real-time RSSI data is implemented by comparing results to supervised training observations used to establish a baseline for each medical application. The baseline condition for respiratory monitoring is a change in RSSI, while the baseline condition for uterine monitoring is a relative lack of change to RSSI. Traditional signal processing approaches establish these baselines by observing the subject under controlled conditions: for instance, while the subject is known to be breathing or while the subject is known not to be experiencing a uterine contraction. This approach is feasible for some monitoring applications; for instance, DVT monitoring can establish a baseline while the subject is known to be moving and while the subject is known to be stationary, so that the RSSI data at any point in time can be compared to these two baselines to determine the subject's state of motion. However, it is impractical to induce a uterine contraction for the purposes of baseline data collection, and infeasible to collect baseline data on a subject that is known not to be breathing if the subject is an infant and due to the risk of hypoxia if this condition is held for prolonged periods. To analyze just-in-time subject state, such as "breathing" vs. "non-breathing," or "uterine contraction" vs. "at-rest," the RSSI data values are filtered using a Kalman Filter, aggregated into statistical features such as the mean and standard deviation of the past 4 seconds of RSSI values [36]. Some features were found to be more separable than others; that is, that the mean of a window of RSSI values is more significantly lower when in a non-actuated state as opposed to an actuated state, as compared with the median of those windows. The most separable features are collected, and for a period of time, the system is monitored so that the signal processing module can collect data that is known to be in a particular state (actuating or non-actuating). This way, new, unsupervised data points can be compared against these training observations to determine whether the subject is still in the same state as during the training phase. Specifically, a Support Vector Machine determines the optimal separating line between the subject states for a given set of features, and classifies new data windows into the appropriate class. The Support Vector Machine has classified these data points with 71% accuracy initially, and has been improved with filtering and training cross-validation to 94%. Actuation rate is calculated by filtering the data, computing the Fast Fourier Transform to obtain the highest magnitude actuation

frequencies in the Bellyband, and reconstructing an average of those frequencies weighted by their magnitudes [37].

Machine learning algorithms can also be used to improve data accuracy from the biosignal RFID sensor. As we are interested in determining whether a data point signifies the detection of a spike in the bio-signal or not, here again we need a two class classifier. Logistic regression based algorithms are used to improve the accuracy of RFID data points being classified as heart beats and non-beats. The algorithm is described in [38] and is able to achieve over 99% accuracy in heart beat classification. Additionally, a despiking algorithm is applied to further improve heart rate calculation accuracy. Testing of fabric designs, filtering and statistical approaches, and effects of noise from interference is conducted in the Drexel University Anechoic Chamber Testing (DUACT) facility using a SimBaby or a mechanically actuated pregnant mannequin, each wearing a Bellyband device; classification performance is compared against traditional medical monitoring devices.

Many traditional medical systems output visual medical data in the form of paper strips. These strips are usually printed only when certain alerts occur and this data is never stored for access at a later time. The Bellyband framework securely stores all medical readings, allowing for data access in real time and any point in the collection history. Multiple medical practitioners will be able to access real time alert data since alert records will not be restricted to a single strip of paper. Stored medical data can also be analyzed at a later time to determine trends and patterns of medical alerts. All data at rest or in transit follows HIPAA rules in terms of security, privacy, and confidentiality. Our setup not only provides convenience and more accurate depiction of a patient's history while connected to the Bellyband sensor but it also offers a foundation for any future expansions to allow "plug and play" capability and standards-compliant interoperability for other medical sensors, such as blood pressure and ECG sensors.

V. CONCLUSION AND FUTURE WORK

We have presented an end-to-end framework for wireless, wearable, biomedical sensors for continuous health monitoring from patient to practitioner. This framework utilizes interconnections between novel and multidiscilinary facets, spanning fabrication and fashion, conductive antennas on knit fabrics, signal processing of properties of RFID tag interrogations, human-machine interaction, and integration with EHR systems. In this paper we present the current state of our efforts in these areas as well as performance results.

The RFID interrogators used to obtain signals from the Bellyband have been standard, commercially available RFID equipment that were not designed specifically for medical applications. A Software Defined Radio (SDR) implementation of RFID will provide more control over the interrogation of the Bellyband. This control of the interrogation will be used to investigate RFID signal characteristics from the Bellyband and determine methods to obtain cleaner signals while maintaining the passive nature of this system. Interrogation of the Bellyband will also be investigated using mobile RFID readers for

Bellyband deployment in an environment that does not have a fixed infrastructure of RFID readers.

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