Fully Disposable Wireless Patch Sensor for Continuous Remote Patient Monitoring

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Abstract— **Continuous remote monitoring with convenient wireless sensors is attractive for early detection of patient deterioration, preventing adverse events and leading to better patient care. This article presents an innovative sensor design of VitalPatch, a fully disposable wireless biosensor, for remote continuous monitoring, and details the performance assessments from bench testing and laboratory validation in 57 subjects. The bench testing results reveal that VitalPatch's QRS detection had a positive predictive value of >99% from testing with ECG databases. The accuracies of HR, BR and skin temp (in mean absolute error, MAE) from bench testing were <5 bpm, <1 brpm, $< 1°C$ respectively. The laboratory testing in 57 subjects revealed the accuracy of HR and BR to be 2.2±1.5 bpm and 1.7±0.7 brpm respectively for stationary periods. The absolute percent error in detecting steps was 4.7±4.6%, and the accuracy in detecting posture was 96.4±3.1%. Meanwhile, the specificity and sensitivity of fall detection (n=20) was found to be 100% and 93.8%, respectively. In conclusion, VitalPatch biosensor demonstrated clinically acceptable accuracies for its vital signs and actigraphy metrics applicable for continuous unobtrusive patient monitoring.**

Index Terms— **Patient Monitoring, Wireless Biosensor, Vital Signs, Actigraphy, Algorithms, Performance.**

I. INTRODUCTION

Traditional hospital patient care involves checking of vital signs manually on acute care floors and continuous monitoring with sophisticated bedside equipment in critical care units. Early detection of patient deterioration may not be possible by spot checks [1]. Intermittent symptom-based monitoring is highly inaccurate compared to continuous monitoring [2]. On the other hand, continuous monitoring can help to identify the risks of impending clinical crisis with aberrations in vital signs, improve the clinical outcomes in hospitalized patients and reduce overall cost [1]. Implementation of continuous monitoring in a 33-bed medical surgical unit led to savings of over $9 million in 5 years [3].

Contemporary continuous monitoring usually involves wired sensors on the patients such as ECG leads, a nasal cannula and a SpO2 clip connected to a bedside monitor that does not provide remote access to instantaneous/trending data, rather it is available visually only at the bedside for clinical interventions. Furthermore, patient confinement to the hospital bed combined with stress of illness, immobility and the sense of incapacitation may have negative physiological consequences including substantial decrease in stroke volume and cardiac output leading to deconditioning of the cardiovascular system [4]. Therefore, continuous remote monitoring with convenient wireless sensors is attractive for early detection of patient deterioration, preventing adverse events and leading to better patient care.

Towards this goal, we first developed a wireless sensor called as HealthPatch® consisting of a disposable adhesive patch and a reusable electronic module [5] that allows continuous monitoring of vital signs, activity and fall detection very conveniently from patient's chest. We previously reported the efficacy of HealthPatch for long-term monitoring in 76 senior subjects over 50 days at home settings [6]. This unique unobtrusive HealthPatch sensor has received FDA clearances for remote continuous monitoring in hospital and home use.

Besides clinical acceptance of our semi-disposable sensor, reuse of the electronic module with proper disinfection, sterilization and sealing inside a new disposable patch may still pose risk for cross contamination [7]. Thus, a single-use biosensor can effectively eliminate risk for contamination and improve patient safety. To this end, we have recently developed a fully disposable novel biosensors called as VitalPatch® designed for comprehensive, comfortable and continuous remote monitoring in hospital and home settings.

In this article, we first present the innovative sensor design of our disposable biosensor, associated sensing modalities, vital sign and actigraphy measurements. Secondly, the article details the performance assessments from bench testing and clinical validation from 57 subjects in laboratory settings.

II. MATERIALS AND METHODS

A. Innovative sensor design and functionalities

VitalPatch is an inexpensive fully disposable adhesive patch device ($11gm$, $115 \times 36 \times 8mm$) worn on the left chest for continuous monitoring of a patient's physiological measurements, and core body activities (Fig. 1). This medical device allows sensing of high quality single-lead bipolar ECG waveforms using a flexible electronics layer consisting of flex circuit with coated surface electrodes, skin temperature using a precision thermistor connected to the flex circuit, and core body motion using a triaxial MEMS accelerometer on a printed circuit board assembly on one end of the sensor that houses a proprietary VitalCore^{TM} system-on-chip (SOC) processor, on board memory and Bluetooth Low Energy (BLE) transceiver for wireless communications and data transfer. The other end of the sensor flex circuit houses a zinc-air battery and actuator switch with a breathable membrane that allows diffusion of air for powering the inexpensive, high energy density zinc-air cell battery. The electronic flex circuit layer is coupled to multiple construction layers including a top foam layer with anti-static coating to reduce triboelectricity buildup due to

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Fig. 1: A fully disposable VitalPatch sensor worn on chest allows seamless 24 hour patient monitoring.

frictions on the clothing and a medical grade skin adhesive bottom layer with electrode gels and adhesive release liners. SOC processor allows firmware signal processing algorithms to carryout real-time computations with high performance at a very low power consumption and enables continuous operation of the sensor for a wear cycle of 4 or more days.

The Vista Solution^{TM} is a comprehensive platform solution that is comprised of the VitalPatch biosensor for collecting patient vital sign data, relay devices such as a tablet or a wall mounted hub for bidirectional communications, computer/tablet monitor for viewing the data in real-time. The relay software library manages bi-directional communication and data transfer between the sensor and the relay device using encrypted BLE communications protocol, and allows plotting/viewing of the raw and derived measurements on a tablet/computer, storing, and further processing on the server/cloud. The server software library is installed on a central server, manages the upload, processing and storage of sensor data, as well as real-time configuration and notifications from the Vista Solution Platform. This platform solution is very unique that allows real-time continuous monitoring, recording of patient data with secured encryptions, and allow performing automated predictive analytics or subjective assessment for patient deterioration, recovery and clinical conditions.

B. Vital signs and actigraphy measurements

The modified bipolar ECG signal measured at chest is processed by firmware algorithms to determine the QRS waveform peaks in each cardiac cycle and produces beat-to-beat R-to-R interval time series corresponding to instantaneous cardiac time intervals that are further processed to obtain the HR values currently at every 4s. The respiratory surrogate waveforms are generated independently from respiratory sinus arrhythmia, QRS amplitudes and chest wall movements captured by accelerometer. Breathing rates (BR) are further estimated as a weighted sum of respiratory frequencies and signal quality estimates derived from these 3 respiratory sensing modalities as described in [8]. Skin temperature (ST) measurement is determined by the electrical response of a thermistor while in contact with skin surface of chest.

Besides these vital sign measurements, various measures of activity such as signal magnitude area (SMA), thoracic angle, posture detection, pedometer step count, and fall detection were computed simultaneously. SMA is calculated as $l1$-norm of the triaxial MEMS accelerometer signals in 1s windows as a measure of the intensity of core body movements. Thoracic angle is measured as the vertical angle between calibrated Yaxis of the sensor to the gravity vector, and is used to classify static postures including standing, supine and leaning. Step count is incremented according to the consecutive peaks in the vertical acceleration and their uniformity. Dynamic postures such as walking and running are detected based on the magnitude of the vertical acceleration as well as the step detection outputs. True positive human falls are detected based on several criteria including the magnitudes of change in core body acceleration, vertical body angle, and associated time intervals during impact.

C. Bench testing validation

Performances of QRS detection and HR were assessed per the IEC-60601 standard. Accordingly, ECG database waveforms such as MIT-BIH, AHA were converted into desired format and rate, and ran through the hardware test setup including arbitrary waveform generator, debug board and sensor. The QRS locations and HR determined by the patch sensor algorithms were analyzed to assess the sensitivity (S_e) and positive predictive value (PPV) of QRS detection, and mean absolute error (MAE) of HR compared to the database references.

Single-lead ECG and triaxial body acceleration signals were synthetically generated for a constellation of two input parameters: heart rate (HR) as a fundamental frequency(f_c) of ECG and reference BR as a modulating frequency (f_r), added with noise and variability, and quantized. These synthetic signals mimicking the sensing modes of VitalPatch were input to the BR algorithms and the performance of output BRs are evaluated for a region-of-interest of the constellation limited by the Nyquist and physiological variability via a constraint ($f_c/f_r \geq 3$ & $f_c/f_r \leq 8$). More information on this simulation platform is detailed in [9].

Per the ASTM-E1112 standard requirements, the accuracy of skin temperature was tested in a water bath test up, where the reference water temperature was varied from $15°C$ to $50°C$. The VitalPatch's ST output was compared to the reference to determine the MAE.

D. Validation with laboratory protocol testing

Fifty seven healthy volunteers (n=57, 35±11 years, M/F: 33/24, BMI: 25.5±5.2 kg/m^2) participated in an independent IRB approved laboratory testing with informed consent. In each subject, a VitalPatch sensor was applied on the left chest after preparing the skin with a alcohol wipe. An oronasal cannula was inserted into the nostrils, secured and connected to a portable bedside Capnography monitor (Capnostream20, Oridion) for BR reference. An Actiheart device (CamNtech) was also attached on chest with 2 standard surface ECG electrodes for HR reference. Pedometers from Omron was attached on the waist belt and an Apple watch was attached to the wrist. Manual step counts and visual annotations associated with postures and human falls were the other references employed for the performance assessment.

TABLE I: Performance of VitalPatch measurements from laboratory testing (n=57).

Measurements	State/parameter	Mean±SD
Heart rate (MAE)	Stationary	2.2±1.5 bpm
	Overall	3.8±3.0 bpm
breathing rate (MAE)	Stationary	1.7±0.7 brpm
	Overall	3.1±1.2 brpm
Posture	Accuracy	96.4±3.1%
Step count	APE	4.7±4.6%
Fall detection (n=20)	Sensitivity	93.8%
	Specificity	100%

After the attachments with biosensor and reference devices and brief rest, subjects carried out a protocol (∼1.5 hour) in our clinical laboratory that included body posture changes, metronome breathing at 10−30 brpm, various mild activities of daily living (ADL) and strenuous exercises such as walking/running on treadmill at different speeds and climbing up and down on stairs. Besides, a subset of young study participants (n=20, ≤ 30years) also performed various types of controlled falls (33) onto large crash mats with protective gear, as detailed in [5]. The participants continued to wear biosensor for several days after the lab protocol to evaluate the wear duration. The biosensor data were collected wirelessly on a tablet. All data from the VitalPatch biosensor, reference devices, and spreadsheets were transferred and stored for data analysis.

The performances of VitalPatch derived HR and BR were assessed with MAE and standard deviation of AE (SDAE) and Bland-Altman agreement metrics of bias and 95% confidence intervals compared to their respective references. Accuracy of step counts was assessed with absolute percent error (APE) and false positive rates (FPR) compared to the reference manual counts. Posture accuracy was determined by the agreement between VitalPatch's posture outputs and visual annotations. S_e of the fall detection was evaluated by the ratio of true positive falls to the total number of falls.

III. RESULTS

A. Performances in bench testing

QRS testing in 44 BMIT-BIH database ECG waveforms determined the Se and PPV of QRS detection implemented in VitalPatch as 99.1% and 99.7% respectively, and the MAE of HR was <1 bpm. Similarly, Se and PPV of QRS detection in 152 AHA database ECG waveforms were 98.1% and 99.3% respectively, and the MAE of HR was <5 bpm. The synthetic waveform simulations assessed the BR accuracy (MAE) to be <1 brpm. VitalPatch's skin temperature had an MAE of <0.1°C for the range of $15° - 50°C$.

B. Performance of HR and BR in laboratory testing

The performance of patch sensor measurements from laboratory testing in 57 subjects is given in Table I. The overall accuracy (MAE) and precision (SDAE) of HR were 3.8±3.0 bpm and 5.2±4.4 bpm respectively compared to the Actiheart reference device. Bland−Altman analysis of HR determined the bias to be 0.4 bpm and 95% agreement limits

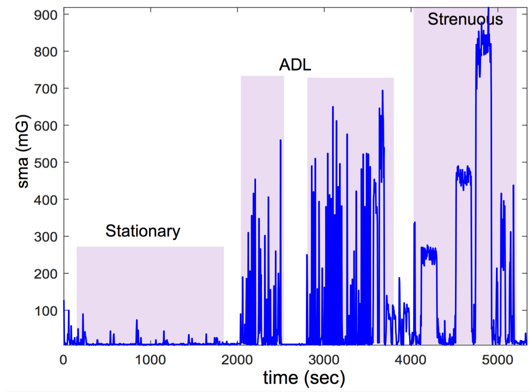

Fig. 2: Sample time series of signal magnitude area (SMA) metric identified with protocol test groups.

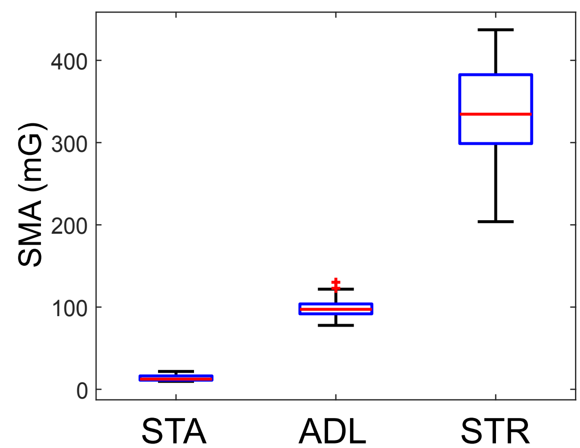

Fig. 3: Boxplot of average SMA measured during stationary (STA), ADL and strenuous (STR) tests (n=29).

as (−8.7, 9.5) bpm. Likewise, The overall BR performance in terms of MAE and SDAE were 3.1±1.2 brpm and 3.1±1.0 brpm respectively compared to the Capnography reference. BlandAltman analysis of BR revealed the bias at −1.8 brpm and 95% agreement limits as (−10.1, 6.5) brpm. Considering the stationary periods alone, the accuracy of HR and BR were 2.2±1.5 bpm and 1.7±0.7 brpm respectively.

C. Performance of actigraphy metrics in laboratory testing

Besides vital sign measurements, VitalPatch also provides assessments core body movements and activities. Fig. 2 show a sample time series of SMA values measured during the protocol that illustrates varying degree of body movements at stationary, ADL and strenuous tests. Fig. 3 further illustrates the boxplots of average SMA (in mG) during stationary, ADL and strenuous tests obtained in 29 subjects, who had this feature enabled for logs. The SMA distributions of 14.0±3.8 mG, 99.4±11.9 mG, and 332.4±66.8 mG shows further distinct separation between body movements/activities among stationary, ADL, and strenuous tests respectively.

While SMA captures the intensity of activities with reference to the gravity, determined thoracic angles measure

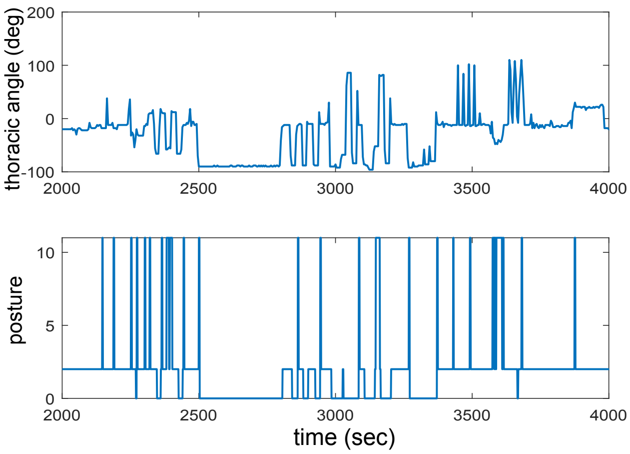

Fig. 4: Thoracic angle and estimated posture of VitalPatch during activities of daily living. The posture transitions from supine (0), standing (2), and leaning (11).

the relative body angle with reference to the gravity (Fig. 4 (top), leading to human readable posture classifications such as standing, supine, walking, running and leaning as shown in Fig. 4 (bottom). The overall accuracy of detecting postures was 96.4±3.1%. The accuracies of detecting standing, supine and walking postures individually were 95.1±5.9%, 96.2±3.0% and 97.3±7.8% respectively.

The specificity of fall detection (n=57) was estimated to be 100% by analyzing the ADL tests from all subjects while the overall sensitivity (n=20) for fall detection was 93.8%. The VitalPatch had highest accuracy with APE of 4.7±4.6% and lowest FPR of 7.5±11.2% for step counts. On the other hand, APE and FPR were 6.4±18.5% and 16.0±10.6% in Omron, and 29.1±22.8% and 63.6±24.6% in Apple watch respectively. Finally, the average wear duration of VitalPatch from 57 subjects was 110.5±23.9 hours.

IV. Discussion

Continuous monitoring of vital signs is necessary for the assessment of patient's health and early detection of patient deterioration. This article presented a fully disposable adhesive VitalPatch sensor for unobtrusive continuous remote monitoring of patient's vital signs, and demonstrated clinically acceptable performances for continuous patient monitoring. VitalPatch's core body activity monitoring capability can further provide insights into the patient's body movements/activities and allow correlating the elevations in vital signs with core body movements.

Compared to the consumer wearable devices attached at body peripherals, our medical device worn on chest offer great accuracies for step count, body postures and a very distinct feature of fall detection. Recently, continuous monitoring with our patch sensors was tested in the general ward to detect clinical deterioration at an earlier stage compared to the traditional early warning scores. This pilot study determined the continuous use of our wearable sensor to be positive and comfortable for most of the hospitalized patients [10]. In another exploratory study, our biosensors were applied on surgeons and residents for continuous monitoring of their stress levels during surgery and other activities, and reported highest stress particularly in residents while performing operation [11].

Our biosensor can be worn conveniently on the chest of the patient for several days to measure vitals while enabling movement and normal daily activities. Data transmitted to a remote, web-enabled device can be used by caregivers to monitor the patients physiological measurements. The VitalPatch biosensor is therefore appropriate for general hospital and home vital sign monitoring. Live and trending data can be accessed from a web enabled device through convenient and user friendly interfaces, enabling caregivers to intervene when necessary. Patient measurements including vital signs and body activities can be applied to deep/machine learning for predictive analytics that can lead to the new era of personalized medicine and proactive care.

In summary, the fully disposable patch sensor enables unobtrusive remote monitoring of physiological activity and demonstrates clinically acceptable performance consistent with medical and ergonomic requirements. Our platform solution can help to deliver better care for aging population, reduce hospital readmissions and associated healthcare costs.

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