

Long-term Remote Monitoring of Vital Signs using a Wireless Patch Sensor

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Abstract—Remote monitoring and wearable technologies could help to effectively manage health, monitor safety and reduce the staggering health care costs. The present study is designed to investigate the efficacy of disposable wireless HealthPatchTM sensors for continuous and long-term monitoring in senior subjects over consecutive 50-days in their home setting. Patch sensor is worn on the chest that allows remote and real-time monitoring of vital sign measurements and falls. Patch data and nightly questionnaire responses were obtained in 76 participants (age 59-85 years) over 3603 days using 1333 patches, collectively. The performance of heart rate, respiration rate and skin temperature was assessed on day-1 and day-4 that estimated the mean absolute errors to be <3 beats/min, <3 breaths/min and <1.2 °C, respectively compared to their respective reference devices. The vital signs showed no significant differences between start and end of a 3-day wear cycle. False positive rate of fall detection was 0.0027 falls/day. The participants reported the patch wear very/fairly comfortable for 88.2% of days of wear. The wireless patch sensors have demonstrated high performance over its 3-day wear cycle, great compliance, and positive user feedback on wearability and usability. Thus, the patch sensors are very efficient and suitable for remote long-term monitoring at uncontrolled home setting.

Index Terms—Remote monitoring, Medical device, Electrocardiogram, Respiration, Fall detection.

I. INTRODUCTION

The senior population in United States is projected to grow double by 2050 as compared to 2010 according to the US Census Bureau [1]. The majority of older adults confront limited functionality, memory loss, and particularly one or more chronic conditions such as cardiovascular disease, chronic obstructive pulmonary disease, and diabetes. These challenges not only affect the health and quality of their life, but also drive staggering healthcare costs. The inpatient capacity needs to be expanded to meet the demand of rapidly increasing annual number of hospitalizations and readmissions especially due to aging and chronic disorders in older population [1]. Besides aging and chronic disorders, unintentional falls are also common in the older population that cause moderate-to-severe injuries among one in three older adults resulting in hospital admissions and direct medical costs [2]. Only one third of the fall events are often reported to the health care providers [3].

The innovations in remote monitoring technologies and wearable wireless sensors could provide solutions to effectively manage health, monitor safety and reduce the health care costs. The HealthPatchTM is such a novel wireless

biosensor developed by Vital Connect Inc. It is a disposable adhesive patch sensor worn on the chest that allows continuous, remote and real-time monitoring of electrocardiogram (ECG), heart rate (HR), heart rate variability, respiration rate, skin temperature, posture, steps and falls. The patch sensor can be used to continuously monitor 24 hours at various settings including hospital, physicians clinic, office and home, and thus allows intensive management of individual's health and safety.

One of our previous studies [4] reported the clinical validation of patch sensor measurements obtained in adults performing various tests including breathing exercises, activities of daily living, various stretches, stationary cycling, walking/running, and simulated falls. This study demonstrated high accuracy of patch sensor biometrics compared to conventional, larger and cumbersome reference medical devices. The performance of patch sensor was assessed in outpatient setting when the applied sensors were afresh and during the first 2 hours of wear. The performance of the patch sensor over a typical 3-day wear cycle needs further evaluation.

The present study is designed to investigate the efficacy of the patch sensors for continuous and long-term monitoring in older subjects over 50 consecutive days in their home setting. Specifically, the objectives of the current study are: 1) to determine the performance of patch sensor vital signs over a 3-day wear cycle, and 2) to assess the compliance, wearability and usability of the patch sensors over a 50-day trial in home settings.

II. MATERIALS AND METHODS

A. VitalConnect Platform

The VitalConnect Platform consists of the HealthPatchTM sensor and software libraries for relay and server. The patch sensor (Fig. 1) is a disposable adhesive patch sensor that incorporates two surface electrodes with hydrogel and a thermistor on the bottom of the patch, a battery and an electronic module with the embedded processor, micro-electromechanical system tri-axial accelerometer, and Bluetooth Low Energy (BLE) transceiver. The patch sensor facilitates continuous monitoring of single-lead bipolar ECG and human body acceleration signals (with a range of $\pm 4g$ where $g = 9.81 \text{ m/s}^2$ and a resolution of 0.0078g) at a sampling rate of 125 and 62.5 Hz, respectively. The device automatically performs calibration of the accelerometer to obtain vertical, antero-posterior, and left-right lateral directions during an initial period of standing upright or walking.

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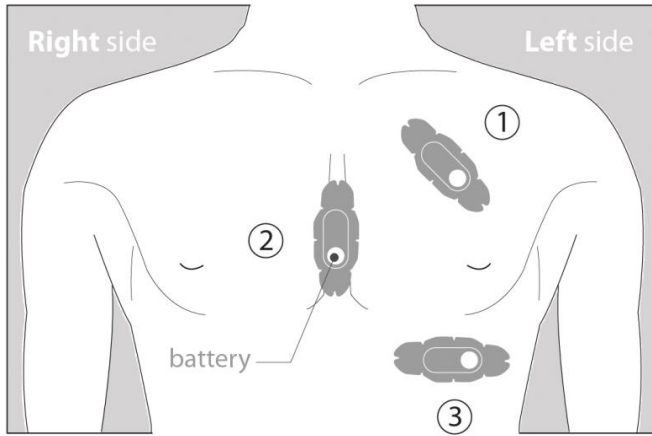


Fig. 1: The disposable HealthPatchTM sensor is illustrated with its recommended locations and orientations.

The firmware algorithms on the electronic module process the raw signals and transmit a stream of physiological measures as encrypted data including heart rate, heart rate variability, respiration rate, skin temperature, posture, step, and fall detection via an encrypted BLE wireless protocol to a relay such as a smartphone, where the live streams of data can be viewed and stored. The relay software library manages bi-directional communication between the patch sensor and the server software library, and is installed on a relay device. 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 VitalConnect Platform.

B. Algorithms

This article is primarily focussed on the performance of patch sensor over a 3-day wear cycle and the ease of sensor use for continuous wear. In particular, the performance of heart rate, breathing rate and skin temperature and fall detection, wearability and usability of VitalConnect Platform in a long-term home setting are evaluated. Hence, the algorithms on the vital sign measurements are briefly summarized here.

The RR intervals are computed as the time duration between successive QRS-complex peaks detected using a wavelet based algorithm [5]. The instantaneous heart rate values are computed using the reciprocal of RR intervals and smoothed by a 10-beat lowpass filter. Respiration rate is estimated as a weighted average of respiratory rates obtained using the independent respiratory waveforms of respiratory sinus arrhythmia, QRS wave amplitude and acceleration, and their respective quality estimates [6]. Checking several criteria including changes in the magnitude of the tri-axial accelerometer and thoracic angles performs fall detection. More information on these algorithms and of other patch sensor biometrics and their accuracies have been reported in detail elsewhere [4].

C. Study Group

The study recruited 76 volunteers with age of 59–85 years, body mass index of 13.5–59.5 and female/male of 49/27. The subjects had a wide range of medical histories including arthritis, asthma, cardiovascular diseases, chronic obstructive pulmonary disease, diabetes, hypertension, hypothyroidism, and sleep apnea. The exclusion criteria included severe skin reaction to adhesives and current pregnancy. A cohort of older subjects was selected for this study in order to mimic the worst-case scenario in assessing wearability, usability and compliance of patch sensors, since older adults may have more sensitive skin, difficulty in reading instruction manual and following instructions sequentially for use including sensor preparation, sensor attachment, and initiate data collection.

D. Study Design

The study is designed to evaluate the efficacy of patch sensor on three separate occasions: day-1, day-4 and day-50, over the course of a 50-day trial. During this study period, the participants were instructed to follow their daily routines, indoor and outdoor activities, exercise, shopping and traveling.

Day-1 protocol: Day-1 protocol evaluates the performance of the patch sensor measurements at the beginning of the wear cycle. Before the experimental protocol began on day-1, the written informed consent was obtained from each participant, and participant’s demographics were recorded. The skin sites for patch sensors were ensured with no hair, and wiped with alcohol preparation pads. The patch sensors were attached at three recommended locations (Fig. 1) to evaluate the performance at each location independently. Each patch sensor was paired to a smartphone where the data streams were viewed in real-time and recorded. The reference sensors, Actiheart (CamNtech Inc) and DataTherm temperature probe (GeraTherm), were attached to the participants chest per the manufacturer recommendations. The participant also wore a oronasal cannula which was connected to the Capnostream20 monitor (Oridion).

After sensor hook-up and initiation of synchronized data collection, the subjects performed series of breathing exercises and activities of daily living (ADL) over 50 minutes. The breathing exercises included 4 minutes of spontaneous breathing, followed by metronome breathing at 12, 15, 18, 21, and 24 breaths per minute (brpm) for 3 minutes each with a one-minute break between each block. ADLs included sitting-to-standing, reclining and rocking, standing-to-lying on a bed, bending, and walking for predetermined durations and paces. After the conclusion of day-1 protocol, data of the patch sensors and reference devices were downloaded into an encrypted laptop computer, and all reference devices were removed. Two of the three patches were removed and on-a-rotation basis one patch continued to be attached on the torso that enabled the continuous data collection through the 3-day wear cycle at home settings.

Day-4 protocol: Day-4 protocol evaluates the performance of the patch sensor measurements at the end of the 3-

day wear cycle. After ~ 72 hours of wear, the participants returned to the testing facility on day-4, and repeated the day-1 protocol with the exception that only one patch was attached to the subject at a predetermined remaining location. After completion of the day-4 protocol, the participants were instructed to continue with the 50-day trial for which the supplies were provided that included a module, relay (iPod touch), power cord, 20 patch sensors, alcohol pads, adhesive remover pads, the instructions for use, and information on answering the nightly questionnaire on relay, and patch locations to be rotated with new patch. They were instructed to report all potential adverse events to the clinical coordinator by phone. Further, they were informed to contact their medical provider or go to the nearest emergency room in case of any severe adverse events.

Day-50 protocol: Followed by the completion of the day-4 protocol, the participants continued the 50-day trial with one patch sensor attached to one of the three locations, and replaced the patch every three days. Upon replacement of the patch, the participants were instructed to rotate through all three-patch locations, but were allowed to avoid if any of the locations was uncomfortable. The participants were fully responsible to carry out all the instructions for use at their home. The participants kept the relay powered up next to their bed. The data stored on the patch sensor memory were automatically transferred to the relay each night via BLE.

The participants answered a set of questionnaires each night until the completion of the study via a relay application. The questions were related to the usability, wear and comfort. Some questions were logical and some were numerical with 5 discrete scales (e.g. 0 to 4). The nightly questionnaire responses were considered as the primary form of user feedback. Any interactions with the clinical coordinators during the 50-day trial were registered to track issues related to technical support and adverse events. Participants returned to the testing facility following day-50, returned all materials and compensated upon the completion of the study. The patch sensor data and nightly questionnaire responses were obtained over 50-day study period for data analysis.

E. Data Analysis

The performance of heart rate, respiration rate and skin temperature were assessed for each patch location on day-1 and day-4 separately, compared to their reference devices of Actiheart, Capnostream and Datatherm monitors, respectively. The mean absolute error (MAE) is a linear performance metric that is quantified as the average over the equally weighted samples of absolute deviations between the true and measured values. The statistical significance of performance over the 3-day wear cycle was assessed by comparing the MAE estimates of each measurement between day-1 and day-4 using Wilcoxon signed rank test.

The data collected over 50-day period in each subject was analyzed to obtain all the generated fall alerts in each subject. All the recorded falls were considered false positives, since none of the participants reported a true fall event. The false positive rate of falls is computed as the ratio

TABLE I: Comparison of mean absolute error of vital signs collected on day-1 and day4 representing the start and end of 3-day wear cycle, respectively.

Vital Signs	Day of recording	Location 1	Location 2	Location 3
Heart Rate (bpm)	Day-1	2.0 ± 0.1	2.2 ± 0.1	2.7 ± 0.2
	Day-4	2.4 ± 0.2	2.1 ± 0.2	2.5 ± 0.2
Breathing Rate (brpm)	Day-1	1.6 ± 0.1	1.6 ± 0.2	1.5 ± 0.1
	Day-4	1.7 ± 0.3	2.5 ± 0.6	1.8 ± 0.3
Skin Temp ($^{\circ}\text{C}$)	Day-1	0.9 ± 0.1	1.1 ± 0.1	1.2 ± 0.1
	Day-4	0.9 ± 0.2	1.1 ± 0.3	1.2 ± 0.2

Values are given as mean \pm standard error.

of sum of false positive fall alerts in all the subjects to the total number of days of data collection. The recorded nightly questionnaire responses were analyzed to assess the wearability and usability of patch sensors for home use.

III. RESULTS

Performance: The performance of patch sensor's vital sign measurements over a 3-day wear cycle is compared in Table I. The data obtained for day-1 and day-4 included 76 and 71 subjects, respectively. One participant decided to discontinue the study due to personal reasons and patch sensor battery depleted in 4 subjects, prior to day-4 testing. Depleted batteries were anticipated after at least 72 hours of wear that may represent the worse case assessment of battery life over the 3-day wear cycle. The average MAE of heart rate, breathing rate and skin temperature were <3 beats/min, <3 breaths/min and <1.2 $^{\circ}\text{C}$ compared to their respective reference devices including all the three locations, day-1 and day-4. No significant differences ($P>0.05$) were noticed in the vital sign measurements between day-1 and day-4 assessments. Therefore, the performance of patch sensor is found to be accurate through the 3-day wear cycle.

The VitalConnect Platform was used in 76 participants over a 50-day period in their home settings. The participants collectively used 1333 patches over 3603 days of wear at their home settings. The analysis of the patch data recorded over 3603 days determined the false positive rate of moderate-to-severe falls to be 0.0027 falls/day.

Compliance and wearability: Seventy (70) participants successfully used VitalConnect Platform to wirelessly acquire their physiological measurements 24 hours a day for 49 days on average. The percentage of time period during which the patch was applied on the body and collecting physiological data was objectively estimated to be 88% of the 50-day period (~ 44 days) based on the measured body impedance. Six (6) participants voluntarily dropped out at various stages of the protocol due to the reasons including requirement of shaving the chest hair, personal life style choices, frequent travels, skin irritation and compensation.

The wearability of the patch sensor was also assessed based on user feedback in nightly questionnaire responses. The participants filled out questionnaires each night for 3401 days, collectively. The participants described the patch

very/fairly comfortable for 88.2%, had experienced itchiness/irritation none/little for 86.5%, and had observed peeling of the sensor none/little for 88.0%, with reference to the reported overall questionnaire responses.

Usability: Usability assesses the user's ability to follow the instructions for use including sensor preparation, sensor attachment, and data collection, repetition of the steps to change the patch each wear cycle, and comfort of patch sensor use in a home setting. All participants were able to successfully perform the instructions for use on their own at their home setting with an average use of 19 patches per participant over the 50-day trial period. Instructions of use with graphics, figures, and markings were found to be effective for ease of use. The participants also felt removing the patch as very/fairly easy for 80.4%, experienced none/little pain while removing the patch for 90.7%, performing preparation and application of sensor as very/fairly easy for 77.3%, compared to the overall nightly questionnaire responses.

IV. DISCUSSION

The current study assessed the performance of HealthPatchTM sensor over its 3-day wear cycle, quantified the user compliance, user's feedback on wearability and usability over 3603 days among 76 senior participants. The results demonstrated high performance of vital sign measurements, high compliance for sensor use, and encouraging positive feedback on wearability and usability of unobtrusive patch sensors for continuous home use.

The existing solutions for long-term remote monitoring primarily include smart clothing otherwise known as electronic textile technologies that involve attachment of wearable body electronics on the clothing. The wearable smart fabric technology has major issues of limited accuracy, comfort, reliability, 24 hour monitoring capability, mass production, cost, and lack of standards [7]. On the other hand, the patch sensors overcome many of these limitations and demonstrated effective for 24 hour monitoring.

The sensitivity and specificity of fall detection systems/algorithms are usually assessed at controlled laboratory environments using simulated falls performed by young subjects and number of ADLs. Very few studies incorporated data from older subjects and tested the performance in real-life for extended period, resulting in relatively worse performance than laboratory settings, particularly with significant number of false alarms [8]. The present study is unique and demonstrated a great false positive rate of fall detection during long-term monitoring of older subjects at their uncontrolled home settings. The sensitivity of fall detection has been reported in our previous validation study [4]. The algorithm can be further customized for an individual according to the user's demographic input.

In the current settings, the reference thermistor was secured with medical tape close to location 2. Hence the reference and patch thermistors measured the skin temperature at different locations on chest. The reference probe could not be placed under the patch sensor, since it might cause peeling of the sensor and the probe to be unsecure. The blood perfusion

on chest changes site to site and causes large variation in local skin temperature that primarily caused the difference in skin temperature accuracy. However from the laboratory testing, the accuracy of patch thermistor was found to be $< 0.3^{\circ}\text{C}$ for a range of temperatures that fulfills the requirement of American Society for Testing and Materials.

The patch sensor can send notifications to self, family, assisted living facilities regarding abnormal changes in vital signs, long-term trending of vital signs, unusual activity/no activity, and falls. The health-related information on individuals would be valuable for effective patient/elderly care management in health care as well as home settings. The wireless patch biosensor solution could reduce the direct and indirect medical costs and make the routine consultations very effective providing the principle care physician by providing objective physiological trends collected over the days before the office visit.

The current results particularly on the wearability and usability are very significant because the study assessed the worse case scenario of suitability of VitalConnect Platform for home use on a challenging cohort of elderly participants who are less likely to be comfortable with latest technology and more likely to have sensitive skin. This study indicates that VitalConnect Platform with the HealthPatchTM sensor is highly efficient and convenient for long-term monitoring at home setting.

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