An Integrated Wearable Wireless Vital Signs Biosensor for Continuous Inpatient Monitoring

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Abstract—A compact, light-weight and low-power wireless vital signs monitoring system based on Wireless Body Area Network (WBAN) protocol has been developed. The system, VySys, includes two compact wearable biosensor devices for continuous vital signs capturing and transmission, a gateway to relay the message collected from the biosensors to cloud, and finally a client apps to access and display the stored data in the cloud. Both biosensor devices can last for 24 hours and weigh less than 22 g and 44 g, respectively. They consist of proprietary in-house bio-sensing integrated circuit (IC) and commercial off-the-shelf Bluetooth Low Energy (BLE) module. VySys has been deployed in clinical trials with 14 subjects. From the studies, the accuracy and advantage of VySys are evaluated and the five vital signs captured (heart rate (HR), respiration rate (RR), temperature (TMP), oxygen saturation (SpO₂) and systolic blood pressure (SBP)) are benchmarked against a commercial medical-grade device. The results show strong statistical correlation (r > 0.68). In terms of clinical significance, all its mean difference are within limits of accepted clinical discrepancies. In terms of efficacy by comparing against the best known reported results, (1) VySys is more precise by 28.2%, 36.2%, 70.0%, 37.6% and 34.4% for HR, RR, TMP, SpO₂ and SBP, respectively and (2) has a narrower 95% limit of agreement (LoA) by 24.5%, 23.9%, 50.6%, 37.4% and 34.4% for HR, RR, TMP, SpO₂ and SBP, respectively.

Index Terms—Wearable, low-power, wireless, sensor, aging population

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DEVELOPED countries with ageing population are facing increasing healthcare cost. Statistically, elderly are four times more likely to get admitted and tend to stay two times longer than the younger population [1]–[3]. Continuous monitoring of vital signs is crucial to assess the condition of a patient and to avoid adverse events. This has been the norm for patients under the intensive care unit (ICU). Even for normal ward, it is common to monitor patient’s five vital signs during every interval of 4 to 6 hours [4]. This is usually labor intensive, and accounts for about 30% of a nurse’s workload.

The advancement in wireless and sensor technology has brought an opportunity to mitigate the above-mentioned issue. In terms of sensing using fabric materials, [5], [6] have brought about techniques to measure vital signs using textile materials embedded onto clothing which can potentially improve patient compliance. However, they are limited in capturing a few vital signs such as heart rate (HR) and respiration rate (RR). In addition, these technologies are not very mature and are yet to appear in the commercial space. For commercial wearable light-weight wireless patches, the reported results are usually with fewer than two vital signs, such as HR and RR which are...
still insufficient to serve as a complete monitoring tool for inpatient [7]–[10].

There were also research attempts where certain vital signs such as HR, oxygen saturation (SpO2), blood pressure (BP) and temperature (TMP) are derived from a single continuous sensor such as an accelerometer and PPG [11], [12] but only remained in the research settings. In recent papers, there were works to increase the number of vital signs that can be captured but it still lacks the complete five vital signs and it is bulky without wireless capabilities [13], [14]. In [15], significant effort has been made to miniaturize an ‘all-in-one’ vital signs measurement device to reduce its size and weight. However, RR monitoring is absent and it is not suitable for wearable and continuous wireless monitoring.

There were also research done to increase the comfort of patients while being monitored at home by means of a wearable wireless monitoring with specialized anomaly detection but they lack in providing all the five vital signs [16], [17]. In [18], a complete five vital signs monitoring system was proposed but it lacks in terms of weight, dimension, continuous operating duration and accuracy. In addition, the article gave a high-level overview of the wireless performance but made no performance analysis or comments on data loss during multiple concurrent sensors transmission. Although they have been many reported compact and low power wireless sensor device targeting for such application, we have yet seen a fully integrated, wearable continuous, light-weight, end-to-end five vital signs system reported to date. There is also a lack of studies on the feasibility and effectiveness of such wireless system.

In this work, we developed Vital Signs Systems (VsSys) to investigate the feasibility and effectiveness of such system while addressing some limitations of the existing systems. VsSys is the most comprehensive and light-weight end-to-end wireless vital signs monitoring platform reported to date. It provides up to five real-time vital signs monitoring, i.e. electrocardiogram (ECG) with HR, RR, TMP, SpO2 and derived systolic blood pressure (SBP). It leverages on cloud infrastructure to enable centralization of data storage and easy data access on demand. More importantly, client apps with graphical user interface (GUI) are tailored based on the input of healthcare personnel.

To target for wearability and long hour of continuous monitoring, the wireless wearable biosensors are miniaturized and optimized for low-power consumption. This is made feasible with our own proprietary low-power bio-medical integrated circuit (IC) [19]–[25], which can provide continuous 3-lead ECG and RR monitoring at nano-watt level. In addition, customized data packet and protocol are employed to maximize the energy efficiency of the adopted Bluetooth Low Energy (BLE) module.

In this paper, we will report the results obtained using the developed system through clinical trials on 14 subjects. These results are benchmarked against a commercial instrument, and shine light on its feasibility and effectiveness.

The contributions of this work are summarized as follows:

1. Design and implementation of a light-weight, low-power, wireless end-to-end continuous five vital signs monitoring system supporting up to 24 hours.
2. Reported on the efficacy or accuracy of the wireless end-to-end continuous monitoring system for 14 healthy subjects.
3. Reported on the robustness of the wireless end-to-end system under 24-hour continuous and simultaneous transmission for 4 subjects.
4. Comparison methodology at 12-second interval enabling larger measurement pairs to be captured in contrast to manual methods of data collection.
5. BLE configuration of the connection interval and slave latency while buffering and packing of raw signals on application data frame before transmission enabling reliable continuous transmission and power reduction on the biosensors.
In Section II, we introduce the system architecture for the overall end-to-end integrated system of VsSys. This is followed by Section III where we discuss the clinical trial setup and its results. In Section IV, we compare the results of VySys against other devices, the effects of motion artifacts and the trends of wearable sensors. Finally, we conclude in Section V.

II. SYSTEM ARCHITECTURE

VsSys consists of three key components, i.e. wireless vital signs biosensors for data capture, gateway and cloud infrastructure for data storage and analytics processing, and client apps for displaying clinically vital information as shown in Fig. 1.

A. Biosensors

There are two wearable biosensors for vital signs monitoring as shown in Fig. 2: 1) NUS_TRE which captures ECG, RR and TMP signals through on-body electrodes; 2) NUS_PPG which captures photoplethysmography (PPG) signal through finger clips.

The NUS_TRE has 6 snap-in electrodes. Four of them are used for 3-lead ECG, positioned at the left-arm (LA), right-arm (RA), left-leg (LL), and right-leg (RL) electrodes. The other two are used for RR, positioned across the chest at LL and RA, respectively. Proprietary low-power integrated 2-channel ECG and 2-channel bio-impedance (IMP) analog front end (AFE) chip [19]-[25] is used to amplify and digitize these captured signals. The acquired data is then sent to a microcontroller unit (MCU), CC2540, via serial peripheral interface (SPI).

For body TMP sensing, the NUS_TRE employs an external thermistor which is placed under the armpit of test subject. The resulting voltage information is then captured by an analog-to-digital converter (ADC) embedded within the MCU.

The MCU also control a BLE transceiver to link up the biosensor with the gateway for data transmission. Design efforts through component selection and printed circuit board (PCB) design optimization have led to device miniaturization down to 32×2.9×0.9 mm as shown in Fig. 3. The detailed design specifications are listed in Table I.

The NUS_PPG employs transmissive light-based technology to measure the rate of blood volume changes and oxygen saturation (SpO₂). A finger is placed between two emitting LED diodes (red and infrared) and a receiving photodiode. The MCU then controls the LEDs emission, and samples the received illumination intensity of the photodiode [26]. Similarly, a BLE transceiver is used to send the data to the gateway as shown in Fig. 4. The detailed specifications are listed in Table II.

Wireless module consumes the most energy of the whole system. Hence, the data packet and wireless communication protocol of the BLE module employed have been redesigned to achieve low power consumption with high data rate transmission. Much design and implementation effort are put into tuning the BLE’s generic access profile (GAP) to attain a suitable trade-off between the power consumption and robustness during each rapid processing and transmission cycles. In addition, at the BLE’s generic attributes (GATT) layer, we made the data packaging customizable to support additional throughput, making it easier to incorporate more sensor data in the future. The connection interval and slave latency in the GATT are configured to 7.5 ms and 0 ms, respectively. The connection interval is set to the lowest supported value and no connection events can be skipped enabling a more reliable transmission at the cost of increased power consumption. To reduce the power consumption, the MCU buffered the acquired raw sensor data and packed 20 bytes (maximum allowable application data frame for BLE) before the physical wireless transmission. This has led to about 43.7% power reduction. The resulting biosensors can operate continuously for about 24 hours with a single battery charge.
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B. Gateway and Cloud with Analytics

The gateway is employed as a conduit between the biosensors to the Cloud [27]. To conserve the biosensor power consumption, it is unrealistic to expect long distance with continuous transmission from the biosensor device. The low-power wide-area network (LPWAN) such as LoRA and Sigfox, supports low-power and long-range transmission but it is unable to support the bandwidth required for streaming continuous raw signals due to its inherent low data rate [28], [29]. After much investigation, the low-power BLE interface was chosen as the wireless interface between the biosensor and the gateway as shown in Fig. 1. The gateway and the Cloud should be able to receive, store, process and retrieve the biosensor data. Given the processing power of Cloud, it makes sense to incorporate signal processing algorithms to extract key biometrics for the biosensor data, such as HR, RR, TMP, and SpO2. Signal processing algorithms can also be employed to mitigate the commonly observed motion artifacts.

The HR is calculated based on the time interval between two successive R-R peaks in the ECG waveform. Techniques similar to [20] have been employed, such as smoothing filter, integration, thresholding, and averaging. The RR is calculated based on the time interval between two successive crests in the IMP waveform. Eight successive intervals are observed to average the RR. The SpO2 is calculated based on the modulation ratio between the received red and infrared signals of the PPG waveform. We used the Contec MS100 Simulator along with a high dependency (HD) medical grade predicate (gold-standard) device to calibrate our SpO2 through a modulation plot [26], [30]. The relationship between the measured ratio to the corresponding SpO2 level is stored in the Cloud as a look-up table (LUT) to ease the data extraction by the client apps. Similarly, calibrated thermistor reading to the corresponding TMP is stored as LUT to extract the correct TMP reading for client apps [31].

C. Client Apps

The client apps are tailor-made based on the survey results collected from hospital healthcare personnel. This is critical as it shows very similar user interface as existing hospital medical instrument, and also incorporates features that are considered useful by the main user. For example, it provides both ward view and bed view as shown in Fig. 5. The overall ward view summarized the key vital signs and biometrics for all patients while the individual bed view displays more detailed and enlarged vital signs for a specific patient. Furthermore, it also allows query for past collected data from the Cloud which is helpful for diagnosis.
III. CLINICAL RESULTS

Our biosensors have undergone preliminary (pre-scan) IEC medical safety test (IEC60601-1), electromagnetic disturbance and radiation immunity test (IEC60601-1-2 and IEC61000-4-2). The IEC60601-1-2 recommends CISPR 11 standard for electronic emission test on industrial scientific and medical (ISM) devices, and our biosensors have passed the emission test [32]. The rationale of the emission test is to ensure that the biosensors do not generate unwanted emission above a certain threshold as this could potentially disrupt the operation of the existing medical devices in the hospital. Two trials, i.e. controlled clinical trial and the extended clinical trial, using our developed system were carried out after obtaining ethics approval from institutional review board (IRB) and domain specific review board (DSRB) approval under the reference number IRB–B-16-264 and 2017/00605, respectively. After the clinical trials, we evaluated the data collection overhead and robustness of wireless packet transmission. We also benchmarked the efficacy of VsSys.

A. Controlled Clinical Trial

The objectives of the controlled clinical trial are to evaluate the safety of the biosensor device, efficacy and the robustness of the wireless vital sign monitoring system. Besides subjecting our biosensor to IEC test as mentioned earlier, the biosensor is also closely monitored for its warmness and wearability throughout the trial. In terms of efficacy, the measured results from our system are compared against the predicate device used in the hospital. In terms of robustness, the gateway and cloud are closely monitored to observe any drop-in data packet. In this trial, a total of 10 participants were recruited and monitored continuously for 8 hours. With 2 participants involved each day, the whole trial duration lasted for 5 days. The details of the cohort are tabulated in Table III.

To evaluate the robustness of the wireless communication link, participants were allowed to leave for toilet and lunch breaks. Upon returning, it was found that our biosensors can automatically be probed to re-establish the BLE connection without any human intervention. The reliable communication range of the biosensors with the gateway is also established to be around 3 meters. Beyond which, the packet loss becomes intolerable. In addition, to mitigate the wireless interference issue due to the crowded spectrum at 2.4-GHz industry, ISM radio band, we have configured the Wi-Fi router to operate at 5-GHz ISM band.

B. Extended Clinical Trial

After the controlled clinical trial on healthy subjects, we proceed with the extended clinical trial under hospital ward environment as shown in Fig. 6. Similar objectives such as efficacy and robustness are evaluated in this trial. However, the trial duration has been extended to 24 hours to further stress on the system’s performance (biosensor, gateway, cloud and client apps) of the end-to-end system. The cohort size was 4 and the statistics are summarized in Table IV. Unlike the controlled clinical trial, the participants were also allowed to move within the hospital ward environment.

<table>
<thead>
<tr>
<th>ID</th>
<th>HR (%)</th>
<th>IMP (%)</th>
<th>TMP (%)</th>
<th>PPG (%)</th>
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<td>0.0102</td>
<td>0.0073</td>
<td>0</td>
<td>0.0106</td>
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</tbody>
</table>

Fig. 7. Packet Loss Rate – a) NUS_TRE (Top): ECG packet loss for 24 hours for the 4 subjects. b) NUS_PPG (Bottom): PPG packet loss for 24 hours for the 4 subjects. The data loss is mainly contributed by collision, obstruction or signal attenuation due to distance between the biosensor and the gateway.
clinical trial, a medical practitioner is present onsite to access the subject’s eligibility to wear our biosensor for long hour. In addition, 4 subjects are on trial concurrently instead of 2 to evaluate the capacity of our system. From the trial, all the biosensors are found to operate beyond 24 hours, and no serious adverse events have been observed during the trial.

C. Data Collection Overhead

For manual vital signs monitoring, it takes a nurse roughly 10 minutes for each patient, and is repeated every 4 hours. This accounts for around 30% of her time. In comparison, the VySys requires only a one-time installation of about 10 minutes per patient, which results in significant time saving for such monitoring activities.

D. Robustness of the Wireless End-to-end

Wireless based monitoring always raise concerns on the robustness of the wireless link, which could incur critical data loss. In our studies, we investigated the data loss by tracking the data packet sequence number incorporated within each transmission packet. The results of the data loss based on each subject during the 24-hour extended clinical trial are tabulated in Table V. The ‘30 Mins’ refers to a 30 minute data capture that is used for benchmarking for the first four subjects in the next sub-section. The results of the data loss for entire trial is depicted in the ‘24 Hours’ row. The 24-hour data loss is shown in Fig. 7. The mean data loss is 0.0657%, 0.0496% and 0.0112% for ECG, IMP and PPG, respectively. For ECG, this accounts to about a single sample loss for every 6 complete ECG cycles with HR of 60 bpm (beats per minute) which is considered to be negligible for HR estimation. For IMP, this accounts for around 30% of her time. In comparison, the VySys requires only a one-time installation of about 10 minutes per patient, which results in significant time saving for such monitoring activities.

For the first approach, 2 complete ECG cycles of Lead II from both VsSys and the predicate, and is more than most clinical evaluation [13], [14], [18], [15]. In this evaluation, we employed different techniques such as overlaying vital signs from both VsSys and the predicate device. We chose a 30-minute period for the comparison, which statistically provides sufficient number of measurement pairs of VySys by benchmarking our results against predicate device. The observed difference is insignificant, and the subtle morphological differences could be due to the small difference in electrode placement. The prominent PQRST waveform can be clearly observed for both cases. The small differences between them did not impact the HR estimation.

E. Benchmark and Efficacy

As mentioned earlier, it is important to evaluate the efficacy of VySys by benchmarking our results against predicate device. We chose a 30-minute period for the comparison, which statistically provides sufficient number of measurement pairs from both VsSys and the predicate, and is more than most clinical evaluation [13], [14], [18], [15]. In this evaluation, we employ different techniques such as overlaying vital signs from different devices, and statistical methods.

For the first approach, 2 complete ECG cycles of Lead II from both VsSys and the predicate device are overlaid together as shown in Fig. 8. The observed difference is insignificant, and the subtle morphological differences could be due to the small difference in electrode placement. The prominent PQRST waveform can be clearly observed for both cases. The small differences between them did not impact the HR estimation.

As the predicate device also produces 12 seconds interval of HR, RR, TMP and SpO2 against predicate over a period of 30 minutes where each time instance T is a multiple of 12 seconds. ‘bpm’ and ‘brpm’ denotes beats per minute and breaths per minute, respectively.

Fig. 8. Overlaying our ECG waveform against the predicate device for the 4 subjects.

Fig. 9. Overlaying HR, RR, TMP and SpO2 against predicate over a period of 30 minutes where each time instance T is a multiple of 12 seconds. ‘bpm’ and ‘brpm’ denotes beats per minute and breaths per minute, respectively.
with similar trending patterns. This includes HR (top-left of Fig. 9) ranging from about 60 to 95 bpm indicating the heart rate variability (HRV), RR (top-right of Fig. 9) ranging from 12 to 23 brpm, TMP (bottom-left of Fig. 9) ranging from about 36.7 °C to 36.9 °C, SpO₂ (bottom-right) ranging from 98% to 100%.

The HRV is due to the regulation of the autonomic nervous system [34].

For the statistical method, we used scatter plot to visualise the relationship between the measurement pairs (the predicate is represented on the x-axis and VsSys on the y-axis) and to estimate the correlation coefficient, r, which determines the closeness of the measurement pairs between both devices. Referring to the Taylor’s systems [35], r values < 0.35 are categorized as weak correlation, 0.36 to 0.67 as moderate correlation and 0.68 to 0.89 as strong correlation and values > 0.9 as very high correlation.

However, a strong correlation alone does not mean good agreement on the measurements between both devices. Hence, we also applied the Bland-Altman analysis [36], [37] to obtain two levels of gauge, which are the mean difference and the 95% limits of agreement (LoA) for each vital sign. Mean difference is defined as the average measurement difference between the measurement pairs. The mean difference shows how bias VsSys is against the predicate, where a positive/negative value indicates that VsSys produced readings that are higher/lower than the predicate. The LoA tells us that 95% of the data are within the specified range of the mean difference, indicating the certainty of the deviation. The LoA is composed of the upper bound (+1.96SD) and the lower bound (-1.96SD) of the mean difference. The upper/bound is obtained by adding the mean difference with the multiplication of positive/negative 1.96 by its standard deviation, respectively. We compare the results
obtained from the Bland-Altman against the acceptable discrepancies metric used in various clinical trials as tabulated in Table VI [18]. Vital signs within the acceptable discrepancies are deemed to be clinical significant. The scatter and the Bland-Altman plot of 14 subjects for HR, RR, TMP, SpO\textsubscript{2} and SBP from both the controlled and extended clinical trial are shown in Figs. 10 to 14, respectively. The resolutions in the scatter and Bland-Altman plot appears discrete when the measurement pairs are plotted directly, given that the predicate device produces vital signs resolution in whole number (except for TMP in one decimal point). As such, both the measurement pairs were randomized via a uniform de-rounding distribution function to its desired decimal point (HR, RR, TMP and SpO\textsubscript{2} to one decimal place and TMP to two decimal places). For example, the RR value of 15 brpm can be randomized and take a value from 14.5 to 15.4 brpm and TMP value of 36.5 °C can be randomized and take a value from 36.45 °C to 36.54 °C. In Figs. 10 to 14, ‘n’ is defined as the sum of an equal number of measurement pairs from each subject for 30 minutes at 12 seconds interval, ‘r’ is defined as the correlation coefficient. In Fig. 10, the HR has 2100 measurement pairs with a very high correlation score of 0.98, one standard deviation of ±1.58 and mean difference of -0.37 with LoA of -3.48 to 2.73 bpm. The RR has 2100 measurement pairs with a strong correlation score of 0.80, one standard deviation of ±2.19 and mean difference of -0.67 with LoA of -4.97 to 3.63 brpm as shown in Fig. 11. The TMP has 2100 measurement pairs with cluttered measurement pairs since there are minimal variation of TMP within the 30 minute period as shown in Fig. 12. In Fig. 13, the SpO\textsubscript{2} has 2100 measurement pairs within the range from 92% to 100%.

Fig. 15. The impact of ambulatory movement during continuous monitoring on various actions ((a) rest, (b) walk, (c) run and (d) rest). The top diagram shows the vital signs trend for a duration of 100 time units (20 minutes) and the bottom diagram shows a snapshot of the continuous raw signal for 3072 samples (12 seconds). The action ‘(a) rest’ occurs from about 0 to 25 time units, ‘(b) walk’ occurs from about 25 to 50 time units, ‘(c) run’ occurs from about 50 to 75 time units and ‘(d) rest’ from about 75 to 100 time units. The instantaneous vital signs from the vital signs trend at 13, 38, 63 and 88 time units are intersected by the blue, red, green and yellow lines, respectively. Each of these line points to its corresponding continuous vital signs as indicated by the blue, red, green and yellow boxes, respectively. Within each box, the ECG, IMP and PPG is represented by blue, red and green, respectively.
In Fig. 14, for SBP, we have limited blood pressure points from the predicate device as it takes about 3 minutes for generating a single value and the subject may not feel comfortable using the cuff-based predicate device throughout the trial. In literature, it is reported that the systolic blood pressure (SBP) is correlated with the pulse transit time (PTT) approach [38], [39]. Based on the collected ECG and PPG data, we model the SBP by extracting the PTT based on the time difference between the R-peak of the ECG and the PPG. Given the limited points available for analysis, we perform 5-fold cross-validation over 280 samples so that we can reuse the data that has been used for the test. The SBP has a strong correlation score of 0.78, one standard deviation of ±7.87 and mean difference of 0.61 with a LoA of -14.81 to 16.03 mm Hg.

The overall numerical metrics of the plots for each vital signs are summarized in Table VII. ‘n’ is defined as the total number of measurement pairs, ‘r’ is the correlation coefficient, ‘±1SD’ is the one standard deviation variation from the mean, ‘md’ is the mean difference, ‘ULOA’ and ‘LLOA’ is the upper and lower bound of LoA, respectively. In terms of efficacy with regards to the correlation r, all five vital signs possess strong correlation against the predicate results. In terms of clinical significance with regards to Table VI, the mean difference and one standard deviation of all vital signs are well within limits except for RR and SBP’s one standard deviation which is deviated by 0.19 bpm and 2.87 mm Hg, respectively. The LoA of HR, TMP and SpO₂ are also well within limits in terms of clinical significance. However, the upper and lower LoA of RR and SBP are deviated by a margin of [-2.97, 1.63] and [-9.81, 11.03], respectively.

IV. DISCUSSION

A. Performance Evaluation

We investigated the feasibility and effectiveness of continuous monitoring using VsSys for a cohort of healthy subjects in clinical trial settings. Table VIII is an extension of Table VII, and it shows the performance of VsSys against other works that were introduced in the earlier literature survey. From Table VIII, VsSys has demonstrated improved efficacy compared to other reported result, especially in one standard deviation (precision) and a narrower LoA. In terms of performance efficacy against the best reported results in literature, VsSys is more precise by 28.2%, 36.2%, 70.0%, 37.6% and 34.4% for HR, RR, TMP, SpO₂ and SBP, respectively and a narrower LoA by 24.5%, 23.9%, 50.6%, 37.4% and 34.4% for HR, RR, TMP, SpO₂ and SBP, respectively. The improved efficacy is contributed by several factors such as low-noise signal acquisition of sensor, analytics and also our methodology that captures the measurement pairs at similar time interval in contrast to cases of several minutes of lapse in certain trials due to manual recording [15]. Furthermore, inter and intra-observer variability were eliminated since we captured the continuous raw signals to derive the measurements of the vital signs. In addition, measurements done at a shorter interval of 12 seconds can provide better care and surveillance as vital signs can change drastically for patients under critical conditions [40]–[42]. The comparison of sensor specifications as listed in Table VIII are shown in Table IX. The parameter for comparison are ‘weight’ which refers to the total weight in grams, ‘DIM’ which refers to the dimension in terms of length (L), width (W) and height (H) in mm, ‘Hours’ which refers to the duration (number of hours) of continuous operation, ‘Wearable’ indicates if the sensor can be worn during monitoring, ‘CONT Raw’ indicates if the sensor could transmit continuous raw signals such as ECG, ‘IoT Capable’ indicates if the sensor could be connected wirelessly to the internet, ‘5 Vital Signs’ indicates if the system could provide five complete vital signs during monitoring and ‘HR, RR, TMP, SpO₂ and SBP’ indicates which type of vital signs are supported by the system. From the comparison, VsSys is a relatively light-weight wearable wireless five vital signs system while being able to achieve 24 hours of continuous operation with Internet of Things (IoT) capabilities. The closest matching continuous wearable wireless five vital signs that we could find is [18] where VsSys excels in terms of weight, dimension, duration of continuous operation and accuracy.

B. Limitations

A limitation of this study is the relatively low number of subjects. However, given that this was a preliminary feasibility study, further clinical evaluation with a significant number of subjects can be carried out to re-affirm the results. It is estimated that at least 385 subjects are required using the Cochran’s sample size formula with z-score of 1.96, population proportion of 0.5 and margin of error at 0.05 [43].
C. Performance during Ambulatory

In the clinical trials, subjects were monitored at rest and we were unable to make inference concerning the performance with patients during ambulatory motion. We made a quick study on the impact of ambulatory artifacts on the vital signs which are derived from the continuous raw signals (ECG, IMP, and PPG). These continuous raw signals are time-aligned using the timestamp and sampled at below 256 Hz has been up-sampled to 256 Hz. We introduced three actions, which are ‘rest’, ‘walk’ and ‘run’ to observe the accuracy and changes of the vital signs as shown in Fig. 15. The ‘rest’ involves the subject to be sitting on a chair and remaining still. This is used as a baseline where the continuous raw signals is free from motion artifacts. The ‘walk’ involves the subject to be walking and ‘run’ involves the subject to be running. Each action will be performed for about 5 minutes starting with ‘(a) rest’ followed by ‘(b) walk’, then ‘(c) run’ and then back to ‘(d) rest’. The purpose of these sequence of actions is to induce an increasing activity and then back to stationary.

Several observations can be deduced from these plots. The HR trend of VySys is similar to the predicate. This is mainly because the R-R peaks in the ECG waveform is still prominent and can be easily detected by our algorithm even in noisy and baseline wandering waveform. It is also observed that the HR trend increases when the subject increases the amount of activity and begins to decrease when the subject is at ‘(d) rest’. For TMP, the trend between the predicate and VySys is correlated. It can be seen that there is a gradual increase in TMP as the subject transit from ‘(a) rest’ to ‘(b) walk’, ‘(b) walk’ to ‘(c) run’ and a gradual decrease from ‘(c) run’ to ‘(d) walk’. It is also noted that the TMP is immune to motion artifact for all cases. For SpO$_2$, the PPG waveform appears to be oscillating more as the movement increases in contrast to ‘(a) rest’ and ‘(d) rest’. Even though the SpO$_2$ trend remains at 100% most of the time, the slight decrease and increase in SpO$_2$ at around the 40th time units to the 65th time units shows that there exists correlation trend even during increasing activity. The accuracy and correlation remains good during increasing activity because the modulation ratio derived from the PPG signals is independent of the oscillation in the waveform. However, there will be an impact on deriving pulse rate using the PPG peaks as the peaks of the PPG waveform (which represents the systolic
not detected, thus reducing false positives rates.

Additional spikes that resemble the R peaks of the ECG were during both ‘walk’ and ‘run’, as indicated by the asterisk on the IMP waveform. There are no significant changes in the TMP signal. However, the PPG waveform appears to experience abrupt baseline drift during ‘coughing’ and ‘sneezing’ and this is also reflected in its corresponding IMP signals. Looking at the continuous raw signal on each sub-figure of Fig. 16, classification of various user action using machine learning techniques can be further explored.

E. Trends

With regards to the trend on vital signs monitoring, we observed that the interest in electric and fiber-optic sensors embedded into textiles [5], [6] seems to be decreasing in recent years due to the need to have a wide range of apparel or belt shapes to adjust to the body. These sensors are now being replaced by patch monitors [45], [46] as they provide reliability in signal acquisition and ease in setup. In addition, non-contact sensors embedded into a bed or seat including direct skin-contact sensors [47] that do not require additional steps in the preparation for monitoring are also gaining traction and appealing given the minimal disruption on the user’s activity.

For future works, VsSys can also be extended to enable other healthcare application. This includes preventative healthcare through wide-scale deployment in a community or home care. The massive vital signs data collected through our innovative system would lead to a more affordable and better healthcare system. Future works can incorporate the use of the five vital signs into the modified early warning score to assist nurses and detecting patients with physiological deterioration [15], [18].

V. CONCLUSION

Our VsSys features a comprehensive in-house clinical grade ~66g continuous wireless low-power wearable biosensors (3-lead ECG, RR, TMP, Sp$_O_2$ and SBP) capable of 24-hour operation. The results from the system show strong correlation, within clinical accepted discrepancies for its mean difference and a narrower LoA for all vital signs when compared against reported results. This study proves the feasibility of employing wireless vital signs monitoring system to improve the productivity of hospital staff.

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REFERENCES


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