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FULL ARTICLE

Wireless vitals—Proof of concept for wireless patient monitoring in an emergency department setting

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Vital sign assessment is a common task in emergency medicine, but resources for continuous monitoring are restricted, data is often recorded manually, and entangled wires cause frustration. Therefore, we designed a small, wireless photoplethysmographic device capable of continuously assessing pulse, respiratory frequency and oxygen saturation on the sternum and tested the performance and feasibility in an emergency department setting.

Fifty (56.3 ± 20.2 years), consenting emergency patients (29 male) were recruited. Heart rate, respiratory rate and oxygen saturation were recorded simultaneously using the device and standard monitoring equipment. Data was compared using Bland-Altman plotting (heart rate, respiratory rate) and mean difference (oxygen saturation).

The bias for heart- and respiratory rate was 0.4 (limits of agreements −11.3, 12.2 and −6.1, 7.0). Mean difference for oxygen saturation was −0.21 ± 2.35%.

This may be the first wireless device to use photoplethysmography on the sternum for vital sign assessment. We noted good agreement with standard monitors, but lack of standardization in data processing between monitoring systems may limit the generalizability of these findings. Although further improvements are needed, the feasibility of this approach provides proof of concept for a new paradigm of large scale, wireless patient monitoring.

KEYWORDS

Emergency medicine, physiologic monitoring, Hospital emergency service, emergency medicine, humans, photoplethysmography

1 | INTRODUCTION

1.1 | Background

Vital sign assessment forms the basis of most triage systems used in Emergency medicine [1]. It is a deceptively simple task associated with many potential sources of error [2, 3]. Abnormal vital signs at triage are recognized as predictors of poor outcome, such as in-hospital mortality, intensive care unit (ICU) admission or risk of readmission upon emergency department discharge [4–6]. Often, however, capacity for continuous monitoring is limited and a patchwork of different, often wired devices is used to measure vital signs and substantial resources are consumed to manually enter data into patient records.

1.2 | Importance

Incomplete recording of vital signs has been identified in over 70% of hospital patients prior to deterioration and development of adverse events [7]. Automation allowing for more frequent

vital sign assessment and documentation also holds promise for early detection of deterioration in emergency department (ED) patients [7, 8], as well as in patients admitted to wards [9–12]. Furthermore, monitoring equipment with the capacity to stay with patients through transitions in the healthcare chain could reduce loss of information or gaps in monitoring at handovers, which is a known patient safety problem [13].

Several innovative solutions have recently been proposed to address these issues, for instance acoustic and radar-based respiratory detectors [13–15] and cutaneous piezoelectric blood pressure patches [16]. Still, however, standard emergency department monitoring generally relies on the use of one or several wired devices for intermittent or continuous monitoring.

1.3 | Goals of this investigation

The goal of this proof-of-concept study was to (a) design a novel, wireless dual wavelength photoplethysmographic device to measure vital signs based on sternal blood flow and (b) assess the feasibility and accuracy of continuous, simultaneous monitoring of heart rate, respiratory rate and blood oxygen saturation using this device.

2 | METHODS

2.1 | Study design and setting

This was a prospective clinical proof-of-concept study comparing a novel dual wavelength photoplethysmographic device (RespiHeart, RH) with a standard monitoring device (Philips IntelliVue MP30) in a standard of care setting at a single emergency department (Linköping University Hospital, Sweden) in late 2016 and early 2017.

Based on the findings in the clinical study, a subsequent investigation to validate respiratory measurements was carried out on healthy volunteers in a physiological research lab at Linköping University Hospital in the summer of 2017.

2.2 | Selection of participants

The study was approved by the Regional Ethical Review Board in Linköping (permit number 2016-15-31).

A convenience sample of 50 ED patients (without life-threatening medical conditions) determined to need monitoring of vital signs was recruited to the clinical study. A standard informed consent procedure was followed.

Inclusion criteria were:

- In need of continuous vital sign monitoring.
- Moderate to high medical priority at admission according to the Swedish standard triage tool rapid emergency triage and treatment system (RETTS) [17].

Exclusion criteria were:

- Unwillingness to participate or inability to provide informed consent.
- Immediately life-threatening condition or rapid clinical deterioration at initial assessment.
- Known allergy to adhesive materials (any type).
- Injuries to or anatomical abnormalities of the thorax.

The subsequent validation of respiratory rate measurements included 10 consenting, healthy volunteers (colleagues).

2.3 | Design of the device

Pulse oximetry measurements in peripheral sites, such as the fingertip, are associated with several potential sources of error [18, 19]. Common causes of misleading SpO_2 values are low perfusion induced by vasoconstriction, for example, hypothermia of varying degree which is abundant both in the prehospital setting and in emergency department patients [20]. In a recent study, our group has investigated the effects of lowered ambient temperature on the cutaneous microcirculation in various anatomical locations using real time reflectance spectroscopy perfusion imaging [21, 22]. Our results show that the forehead and the sternum are highly resistant to thermal challenge, whereas the fingertip quickly and highly variably reacts to cold temperature with diminished cutaneous circulation. It has been shown that forehead SpO_2 monitoring provides better monitoring quality in emergency care compared to peripheral monitoring [23]. Despite earlier attempts, however, the forehead is not an ideal site for simultaneous measurement of heart and respiratory rate based on photoplethysmography, since respiratory signals are difficult to track at the forehead. Also, it is relatively cumbersome to attach a device to the forehead. Therefore, to us, the sternum provided the best location for multiple, simultaneous measures of vital signs using photoplethysmography. An additional, potential benefit of using the sternum is its proximity to the central circulation with its main blood supply originating from the internal thoracic artery [24].

The RH device was designed and developed at the Department of Biomedical Engineering, Linköping University in collaboration with emergency department staff and based on the analysis of suitable anatomical sites. It measures 48 × 40 mm, which is small enough to fit on the sternum of most adult patients and utilizes photoplethysmography in reflectance mode for measuring sternal blood flow (Figure 1A). It consists of four photodetectors, two near-infrared light emitting diodes (810 nm) and two red light emitting diodes (660 nm) placed in a specific pattern and embedded in black colored polyurethane (Figure 1B). The center-to-center distance between the light emitting diodes (ELEDS) and the photodetectors is 20 to 22 mm, which facilitates monitoring of blood flow in deeper lying vessels in the sternum. This distance was chosen based on several previous studies on distance optimization for diffuse photoplethysmography in both soft tissue and rigid bone tissue [25–27].

The LEDs at 810 nm served as isosbestic reference ensuring that the blood flow signal would not be affected by

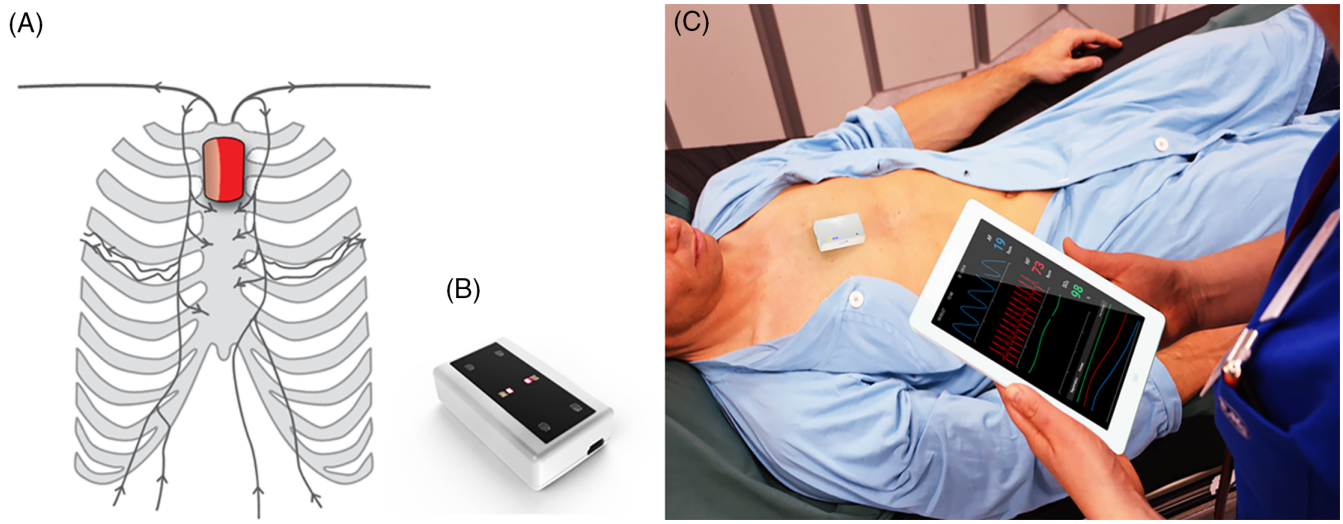

FIGURE 1 Schematic overview of the sternum vascular supply and its relation to the location of the RespiHeart module (A). Picture of the RespiHeart prototype module (48 × 40 mm) used in the study (B). The black surface contains the light emitting diodes and the photodetectors. Conceptual overview of the RespiHeart sensor applied to the sternum (C) (of a consenting colleague) and the tablet software visualization presented to the user

variations in oxygen saturation, and the LEDs at 660 nm were used due to maximal sensitivity to variations in hemoglobin oxygenation. Arterial oxygen saturation was determined according to the equation: $S_{RH}O_2 = fRH\ DC\ (810\ nm)/DC(660\ nm)$, where fRH is a functionality constant. DC stands for total light recorded by the photodetectors transformed to voltage. Respiratory rate and heart rate was determined according to the filtering procedure described in the data analysis section.

The device was attached to the skin of the sternum (Figure 1C) by double adhesive medical grade tape (Stockvis Tape AB, Norrköping, Sweden).

The device can be cleaned in accordance to clinical standards using detergents and surface alcohol disinfectant.

2.4 | Measurements

Digitized readings from the RH module were transferred wirelessly via Bluetooth communication to a signal acquisition program on a reading plate (Samsung Galaxy Table S2, SM-T710) with a sampling rate of 100 Hz.

In the clinical study, data on respiratory rate, heart rate and blood oxygen saturation from Philips IntelliVue MP30 were recorded as video files using a GoPro camera (GoPro Hero 4 Silver Edition). Continuous timestamps were used on all recordings and the time setting of the camera was exactly calibrated to the timestamps of the RH device. Recorded values at predetermined time points (see below) were exported for further analysis.

In the subsequent study in healthy volunteers, RH and the Philips IntelliVue MP30 were compared to manual counting of respiratory rate. For that purpose, the GoPro camera was positioned to simultaneously film the screen of the MP30 and the chest and abdomen of the volunteer (without exposing the face of the subject). Subjects were asked to breathe normally for 2 minutes and then momentarily double the respiratory rate and keep that rate for 2 minutes before returning to the original respiratory rate for another 2 minutes. This set of breathing exercises was repeated once, the second time aiming at an even higher respiratory rate compared to the first chosen by the subject. Finally, the subjects were asked to decrease the respiratory rate below the normal breathing rate for 2 minutes, followed by 1 to 2 minutes resting/normal breathing rate.

2.5 | Outcomes

The primary outcome measures were agreement between RH respiratory rate and heart rate values compared to synchronous values presented by Philips IntelliVue MP30 as determined by Bland-Altman plotting, and mean difference in blood oxygen saturation between the devices.

Secondary outcomes were: (a) agreement between RH data and data generated by Philips Intellivue MP30 after transforming RH raw data according to the Philips device mode of presentation. (b) Agreement between RH, Philips Intellivue MP30 and manual counting of respiratory rate in the sub study in volunteers.

2.6 | Analysis

The photoplethysmographic readings (raw data) from the RH device were temporarily stored on the tablet and subsequently analyzed in Matlab (R1014a; Mathworks, Massachusetts) in order to determine respiratory rate, heart rate and blood oxygen saturation. The signals related to respiration and heart rate from the near-infrared channel (810 nm) were first separated by applying electronic filtering (bandpass; second order high pass at 0.5 Hz and third order low pass at 1 Hz). In the next step, a specially designed program in Matlab was used to track signal peaks related to respiratory rate and heart rate. By determining the period time

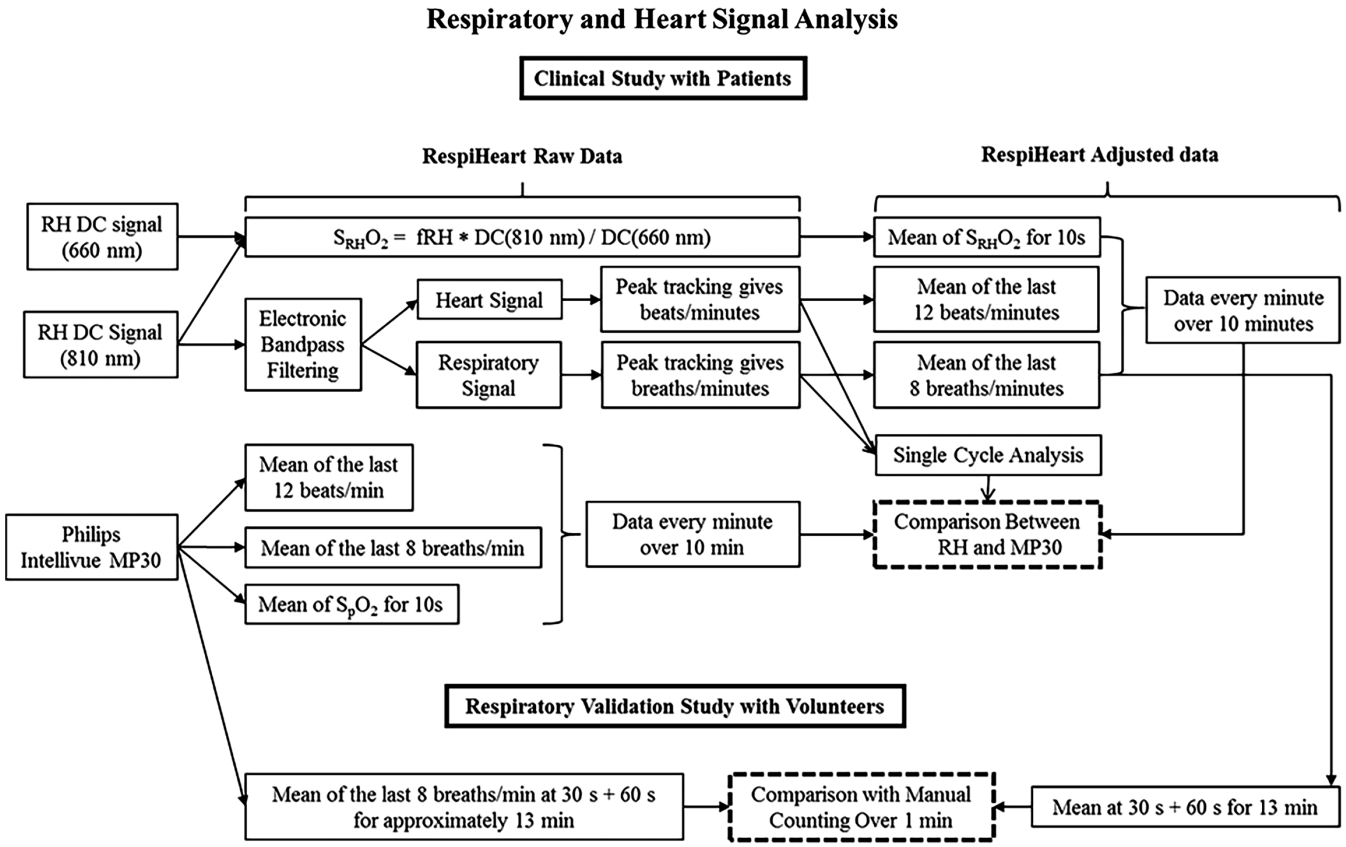

FIGURE 2 Schematic over the signal processing for the RespiHeart module and the MP30, adjustment of RespiHeart data and the different comparisons made between the two techniques (in patients and volunteers)

(T) and taking 60/T, the processed data was at each peak presented as respiratory rate in breaths per minutes and heart rate in beats per minute, respectively. This was defined as single cycle analysis (Figure 2). Determination and calculation of $S_{RH}O_2$ utilized the DC values at the 810 and 660 nm wavelengths according to the equation shown in the design section. Calculations were done in Matlab.

As the values for data processing using the MP30 were pre-set (factory standard) to form a mean of the last eight breaths per minute for respiratory rate, a mean of the last twelve beats per minute for heart rate, and a mean value of the foregoing 10 seconds for blood oxygen saturation the same procedure was used for analyzing data from the RH system. This was defined as adjusted data (Figure 2). Finally, data was taken every minute during 10 minutes of recording before comparison between the methods.

For the subsequent study in healthy volunteers concerning the respiratory signal, similar analysis was performed according to Figure 2, except that the mean of the respiratory rate for the last eight breaths at 30 seconds and the last eight breaths at 1 minute was used to compare both RH and MP30 with manual counting of respiratory rate for exactly 1 minute. This was done to achieve approximately similar comparison conditions during the analysis as the Philips MP30 is presenting the mean of the last eight recorded breaths.

Manual counting of respiratory rate was performed for exactly 1 minute and based on the filming of the subject's chest movements during approximately 13 minutes (in average). A breath was defined as a full cycle of inspiration and expiration.

3 | RESULTS

3.1 | Characteristics of study subjects

Fifty-five patients were screened for participation. Four declined participation and one was excluded due to excessive chest hair that interfered with the RH signal. Fifty patients (29 men) completed participation. Age of the participants was 56.3 ± 20.2 years (men: 57.4 ± 21.3; women: 54.8 ± 18.9 years). Table 1 shows demographic data of the participants.

Volunteers: Ten healthy volunteers (3 men) with a mean age of 24.4 ± 2.8 years (men: 24.3 ± 3.8; women: 24.4 ± 2.6 years) participated in the respiratory validation study.

3.2 | Main results

The RH device and adhesive tape were well tolerated by all patients and volunteers, and no adverse events related to the device or the recording process occurred.

In the clinical study, complete data sets were obtained in 45 patients for respiratory rate (446 data pairs), 44 patients for heart rate (436 data pairs) and 47 patients for blood oxygen

TABLE 1 Demographics of study participants

	Age		
	Mean	**Min**	**Max**
All (n = 50)	56.3 ± 20.2	19	93
Men (n = 29)	57.4 ± 21.3	19	93
Women (n = 21)	54.8 ± 18.9	20	82

saturation (429 data pairs). The main reasons for lost data were connection disturbances in the RH Bluetooth connection or excessive chest hair resulting in poor adhesion or scattering of incident light. We subsequently discovered that shaving of the chest at the site of measurement completely resolved the issue of poor adhesion, but since this was not preplanned in the study design, no removal of chest hair was done in this study.

Because of the different ways of presenting respiratory rate (RR) and heart rate (HR) data of the RH and MP30, initial comparison between the two methods showed poor agreement. Bias for the RR data was −0.45 breaths per minute with limits of agreement between −13 and 12. For HR data bias was −1.3 and the limits of agreement −33 to 31 (Figure 3). Data from the RH was therefore re-analyzed and presented in a similar way as by the MP30, for a more equal evaluation on agreement (Figure 4).

After adaptation, Bland-Altman plot analysis of RR data showed a mean difference of 0.4 breaths per minute and limits of agreement of −6 and 7. For adapted HR data, the mean difference was 0.4 beats per minute between and the limits of agreements −11 and 12.

Oxygen saturation measurements showed a mean difference between the two methods of −0.21 ± 2.35% (Figure 3). Worthy of note is that most patients showed normal, stable levels of oxygen saturation around 98%.

Data analysis from the validation study on healthy volunteers showed correlation coefficients for raw RH respiratory rate data and chest movements, and MP30 RR data and counted chest movements of 0.99 ($P < 0001$) and 0.78 ($P < .0001$) respectively. Bland-Altman plot analysis showed a mean difference in RR of 0.0 breaths per minute between RH raw data and manually counted chest movements, with limits of agreement of −2.3 and 1.9 (Figure 5A). The mean difference

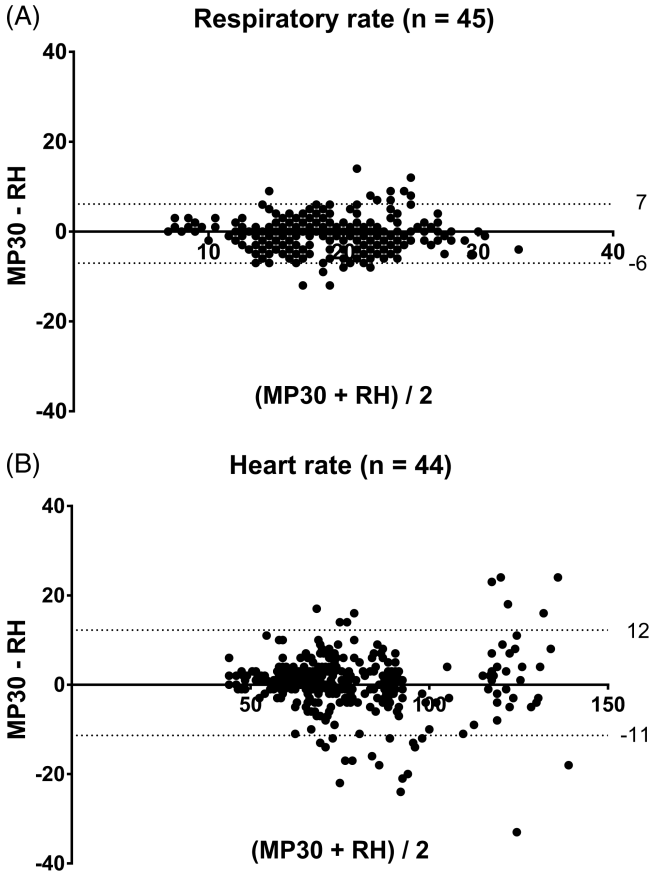

FIGURE 4 Bland-Altman plot for comparison of agreement between the MP30 and adjusted respiratory rate data from the RespiHeart module (A). Bland-Altman plot for comparison of agreement between the MP30 and adjusted heart rate data from the RespiHeart module (B)

in RR between MP30 and manually counted chest movements was 1.4, with limits of agreement of −17 and 14 (Figure 5B).

RH and MP30 exhibited comparable RR patterns, but as exemplified in Figure 6 in supplementary files (one, representative healthy subject) differed in how rapidly they responded to a sudden change in RR. This represents a delay in response for MP30 when the subject increases the respiratory rate, whereas RH shows a gradient increase. MP30 seems to overestimate the RR whereas RH does not.

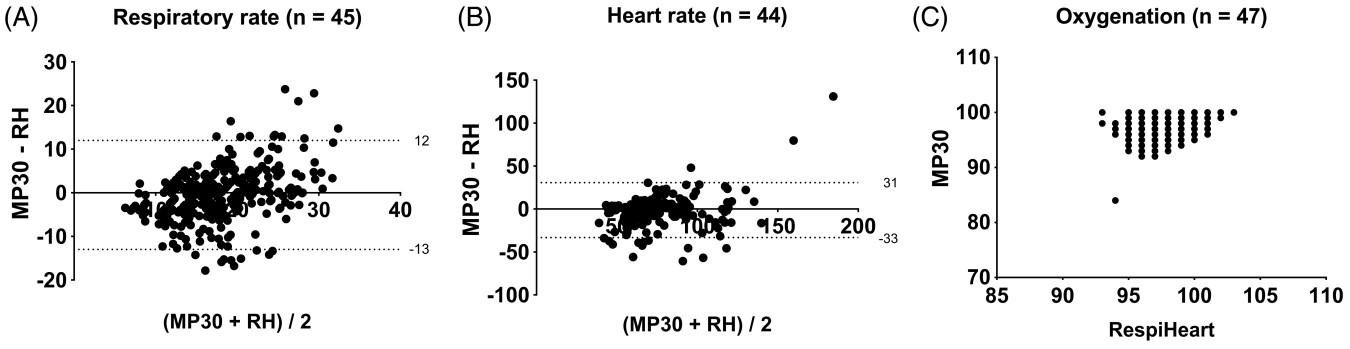

FIGURE 3 Bland-Altman plots of respiratory rate (A) and heart rate (B) measurements by the RespiHeart module (raw data) and the Philips IntelliVue MP30. Dotted lines represent limits of agreement. C shows oxygen saturation measurements. Mean difference between the RespiHeart module and the MP30 was −0.21 ± 2.35%

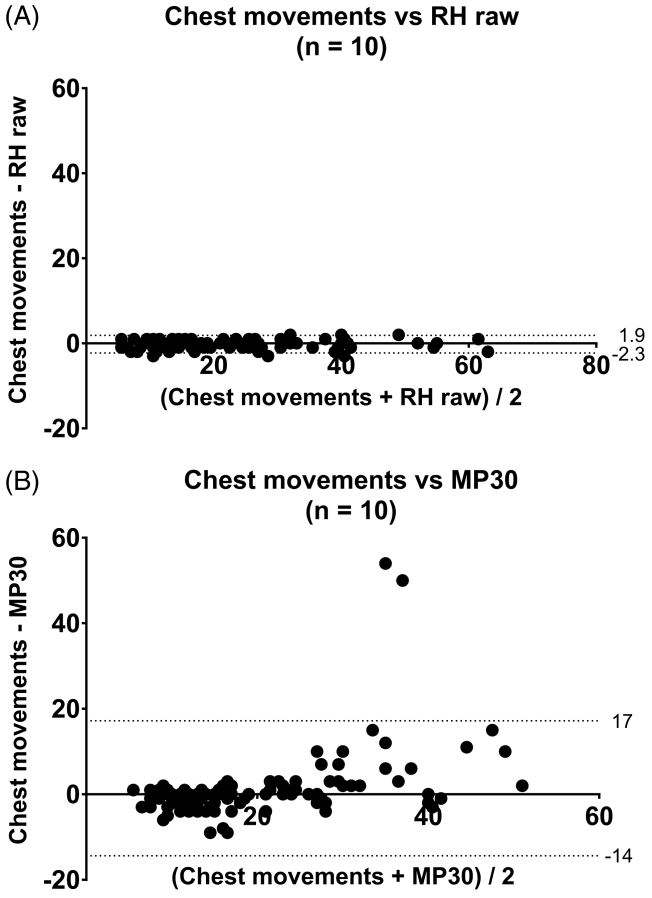

FIGURE 5 Bland-Altman plots showing the difference between manually counted number of breaths and measured number of breaths using the RespiHeart module (A) and the difference in manually counted breaths and number of breaths using the MP30 (B)

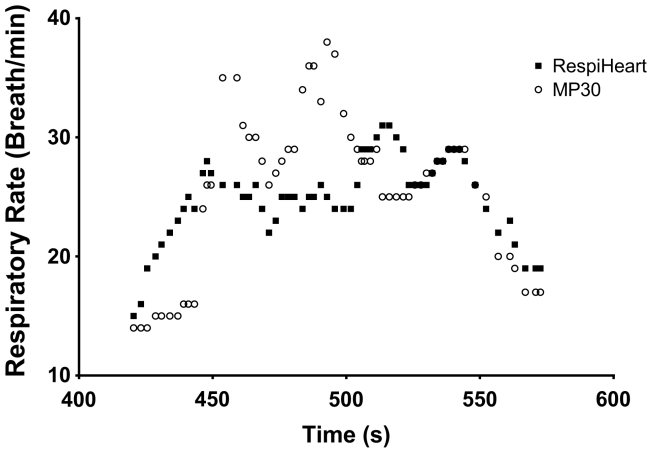

FIGURE 6 Example of time delay in reporting of alterations in respiratory rate between the RespiHeart device and Philips Intellivue MP30 in one representative patient. Each value represents the mean of the last eight breaths for both techniques

3.3 | Limitations

This study was designed to test the feasibility of a new concept for patient monitoring in an emergency department setting and to give an indication of the potential challenges associated with this novel technology. A main limitation of this study is the comparison with only one commercial monitoring system Since there is no uniform market standard for data processing and presentation of vital signs in monitoring equipment, use of another system would, most likely, have generated a different result, limiting the external validity of the specific agreement between the RH device and other monitoring equipment. Since the RH device generates raw data that may be easily transformed, just as we have shown in this study, this may however be managed by adapting the data processing algorithm.

Another important limitation is that we have not used criterion standard technique, such as end tidal CO_2 monitoring or arterial blood gas sampling, to validate the performance of the novel device in this study. In our view, however, this is justified by the intention of primarily investigating the feasibility compared to pre-existing monitoring equipment at a standard care level, which, at the time, was Philips Intellivue MP30.

Another limitation associated with the RH device is the lack of capability to measure blood pressure in its current version. We fully acknowledge that blood pressure monitoring will be required for a wireless monitoring device to have the potential to fully replace current, stationary equipment for continuous monitoring. There are positive indications that the photoplethysmographic signal may be analyzed by pulse wave analysis to estimate blood pressure, but experimental validation will be required prior to clinical testing [28, 29].

Further, wireless devices based on photoplethysmography are potentially sensitive to signal disturbances, which are not acceptable in a clinical setting and the choice of wireless transfer technology will be further evaluated.

Although we did not experience any signal disturbances due to motion of the subjects in this study, we are planning to add a motion sensor (accelerometer) to the device to identify other movements than those caused by respiration and allow for filtration of potential artifacts occurring in more challenging settings (ie, prehospital or transport use).

Prolific chest hair caused poor adhesion of the device in a few subjects, as described in the results section (Section 3). We have since discovered that shaving of the skin at the site of the device solves this problem, but since this was not preplanned in the design of this study, shaving was not performed. For any future studies, removal of excessive chest hair will be performed. In addition, we have also developed a disposable elastic textile band to provide additional fixation of the device to the sternum in settings with high risk for dislocation.

4 | DISCUSSION

Wireless monitoring solutions carries good potential to streamline the process of triage and patient monitoring in an

ED setting since it reduces the need for physical attachments such as wires and allows for uninterrupted monitoring at handovers. Also, data may be easily fed directly into most electronic health record systems and potentially integrated with tools for clinical decision support. Several wireless monitoring systems have been presented [30, 31], but they still make some use of tubes or wires to connect the unit to the patient. As an alternative, solutions using acoustic detectors, infrared cameras or radar have been suggested. [15, 32] Most of these noncontact technologies, however, rely on a relatively fixed position of the patient in relation to the device, making them less suitable for settings with many transitions, such as an emergency department. Also, camera-based technologies require free line of sight to the preferred area of detection, which is usually the face [32]. This may be difficult to obtain in many emergency department patients, both due to frequent transitions and common respiratory support devices covering large parts of the face, such as Bi-Level ventilation or continuous positive airway pressure.

The device presented in this study is completely free of external tubes or wires and does not require access to the face or any of the patient's extremities, reducing the footprint on the patient and the need for specific positioning in the room (Figures 1 and 2). To the best of our knowledge, this is the first wireless device to use a dual wavelength photoplethysmography on the sternum as an approach to vital sign assessment. The RH device was well tolerated by all patients and volunteers, and no adverse events related to the device or the recording process were noted during the study. We found good agreement between standard, impedance-based measurements of HR and photoplethysmography. Also, measurements of oxygen saturation were concordant, although we note that most patients had completely normal levels of oxygen saturation throughout the trial.

Interestingly, however, there was a significant offset in the RR measurements between the two devices that was most apparent in rapid RR changes. The reason for this finding was that the comparator device in this study, like many other standard monitoring systems [33], presents RR mean values for a block of respiratory cycles to represent RR, whereas our initial algorithm for analysis of RH data updated the RR based on single cycle analysis. Single cycle analysis provides a more agile means of measuring changes in RR and more closely resembles continuous counting of chest movements [33]. Further, our initial algorithm had no built-in delay in data reporting, whereas many monitoring devices have a fixed update frequency. For the Philips MP30, we estimate that this delay is approximately 2 seconds. This study was not designed to determine if this difference in representation of RR is clinically relevant, but it is interesting to note that standard monitoring techniques may be associated with a substantial reporting delay upon abrupt changes in respiratory frequency, as we could show using healthy volunteers quickly altering their RR. Since there is no general standard for the use of block mean values in RR monitoring, the differences in RR between single cycle analysis and methods used in current emergency room (ER) standard systems most likely differ. Since end tidal CO_2 monitoring is generally accepted as a standard method for noninvasive, accurate respiratory monitoring, we plan to further investigate the correlation between this method and RH using single cycle analysis.

Given the modular design of this type of device, more functions can be easily added. For instance, electrodes for one-lead electrocardiography (ECG) may be integrated at the interface between the patient and the device, and skin temperature can be monitored by integration of a temperature sensor. There are also positive indications that the photoplethysmographic signal may be analyzed by pulse wave analysis to estimate blood pressure, but experimental validation will be required prior to clinical testing [28, 29].

Extensive technical development and testing remains before this type of technology can replace current standard equipment, but the transition from wired, location-based monitoring to wireless, patient-based monitoring is currently underway.

CONFLICTS OF INTEREST

Authors J.G., J.H. and D.W. have no conflicts of interest to declare. Author L.G.L. is one of two owners of the company RespiHeart AB, which aims to commercialize RespiHeart as a product in the future. The company RespiHeart AB, in turn, is the owner of pending patents regarding RespiHeart in Europe, China, Japan, India and USA.

Author contributions

D.B.W. conceived the study and designed the trial. L.G.L. designed the device. D.B.W. and L.G.L. obtained research funding. D.B.W. supervised the conduct of the trial. J.G. undertook recruitment of participants and L.G.H. assisted in data acquisition. L.G.H. and J.G. performed the validation experiment in volunteers. L.G.H. and J.H. were responsible for data analysis, with assistance from all co-authors. D.B.W. drafted the manuscript and all authors contributed substantially to its revision. Author J.G. takes responsibility for the paper as a whole.

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