Using Piezoelectric Sensor for Continuous-Contact-Free Monitoring of Heart and Respiration Rates in Real-Life Hospital Settings

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Abstract

In this paper we review over 1-million hours of experience with vital signs monitoring using piezoelectric sensor in real clinical settings. The sensor developed by EarlySense ltd is placed under the mattress and has no direct contact with the patient. The force exerted on the sensor is a summation of 3 sources, originating from gross body movement, chest wall movement due to respiration, and recoil of the body due to heart pulse (cardioballistic effect).

The piezoelectric transducer generates a signal that can be separated into motion, respiration and ballistocardiogram (BCG) waveforms, from which movement, respiration rate (RR) and heart rate (HR) can be obtained respectively.

Clinical trials to validate the extracted HR and RR values were performed with 16 adults and 37 children in real-life sleep lab settings and 42 ICU patients. The resulted absolute relative errors (aRE) over a wide range of values, including tachycardia, bradycardia, tachypnea, and bradypnea, was 8% or lower. Controlled studies were used to validate movement against actigraph, and bed exit against visual inspection.

In this work we also report some added values of this monitoring method to various irregular, yet hospital abundant, clinical cases; These include insights to end-of-life process, monitoring capabilities for patients with Left-Ventricular Assist Device, monitoring ventricular fibrillation during electrophysiological study, detecting apnea, and unique breathing patterns.

1. Introduction

Recent studies have shown that continuous monitoring of HR and RR can predict over 64% of major clinical deteriorations in general medical or surgical units [1, 2]. Studies have shown that changes in the respiratory status might indicate a pending in-hospital adverse event such as cardiac arrest, sepsis and drug-induced respiratory depression [5]. However, patients in the general floors are not monitored continuously due to various obstacles, amongst are: low nurse-to-patient ratio, alert fatigue due to high false alarm rate and requirements to keep the patients independent and mobile.

Ballistocardiogram (BCG) is the recording of micro-body movements associated with the ejection of blood bolus in each heart pulse (cardioballistic effect).

During the 50's and 60's, heart functionality analysis based of BCG was an active topic for research among cardiologists, however, research activity faded in the years to come due to practicality issues and the advancements in ECG analysis.

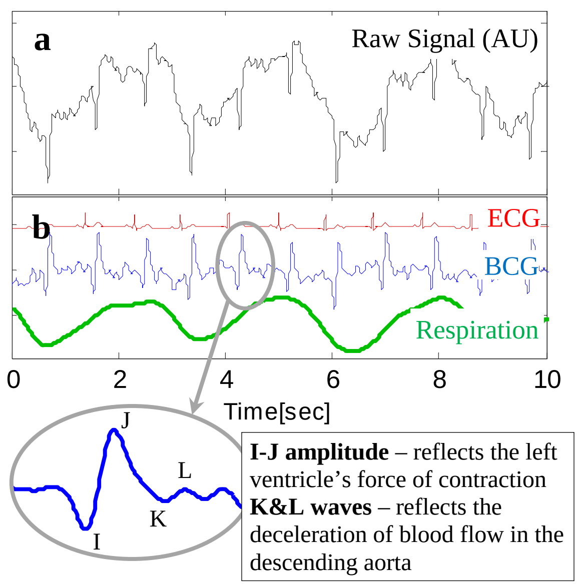

Figure 1. a) Raw signal detected by under-the-mattress piezoelectric sensor. b) BCG and respiration signals filtered from raw signal, along with reference ECG.

With the emergence of piezo-based mechanical sensors, and the availability of digital and real-time signal processing, use of BCG has gradually increased once again. Examples range from research of the heart functionally [3] to fitness monitoring applications [4].

The BCG reflects the mechanical aspect of the heart function. The amplitude of the BCG pulse correlates with stroke volume and ventricle contractility [6]. The BCG is commonly fragmented into subsections, linking each subsection to specific stages in the hemodynamic cardiac cycle. The zoom in circle in figure 1b illustrates the subsections of a single pulse cycle, as acquired by the piezoelectric sensor.

Based on the BCG, we developed a contact-free (under-the-mattress) piezoelectric (mechanical) sensor that allows continuous monitoring of vital signs. The sensor records a superposition of body motion, chest wall movement, and cardioballistic recoil of the body. Since the later 2 are related to respiration effort and stroke volume, we use proprietary algorithms to extract RR and HR from each respectively.

2. Validation

EarlySense system is composed of a piezoelectric sensor connected to a bed side control and processing unit. Proprietary algorithms continuously analyze the superimposed signal, and extract the instantaneous HR, RR, and body movement rate. In the following subsections we describe the validation of system.

2.1. Heart rate and respiration rate

Two clinical studies were held for the purpose of heart pulse and respiration signal validation. The sleep lab study took place in the Dana Children's Hospital at Tel-Aviv Sourasky Medical Centre (TASMC) in Tel Aviv, Israel. The study group comprised of 16 adults and 37 children referred to the sleep lab for any indication and who were willing to sign an informed consent.

The ICU study was conducted in the General ICU at TASMC. Patients hospitalized within the ICU who met the study's inclusion and exclusion criteria were enrolled. Inclusion criteria were: hospitalization in a critical care unit and consent from the patients or their next of kin (for intubated and ventilated patients) to participate in the study.

In the sleep lab the gold standard reference for respiration rate (RR) was an Embla N7000 with Somnologica Studio Software System (Embla Systems, Iceland), using abdominal and thorax respiratory inductance plethysmography belts, and for heart rate (HR) the Embla Sleep Lab System with automatic scoring. Only subjects with at least 20 minutes of full measurement on both monitors were included in the study.

In the ICU, all subjects' heart rates were simultaneously measured by standard ECG monitoring (Datex/Ohmeda, GE Medical, Madison, WI, USA) as part of the routine monitoring for ICU patients. Measurement of respiration for ventilated patients was done by an end-tidal CO2 (CO2) module.

For patients not ventilated, respiratory rate was sampled manually by trained research assistants in several time periods. These measurements, for both HR and RR, served as gold standards reference.

One minute averages of HR and RR were calculated for EarlySense system and reference devices. A minute was considered valid if both EarlySense and reference devices were able to extract a value. The absolute relative error (aRE) for each valid minute was calculated as follows:

$$aRE[\%] = 100 \cdot \frac{|\text{Reference Value} - \text{Tested Value}|}{\text{Reference Value}}$$

Overall aRE was the average of all valid minutes. Results are summarized in table 1. No significant correlation was found between aRE values and either age, gender, BMI, bed type, average HR, or average RR [elaborated results can be found in ref 7].

Table 1. Comparison vs. reference Gold standard in sleep lab and ICU patients.

		# of patients	points compared	aRE Avg±Std
Sleep lab - adults	HR(ECG)	16	5792	3%±3%
	RR(RIP)	16	1341	4%±1%
Sleep lab - children	HR(ECG)	37	11309	5%±3%
	RR(RIP)	37	3646	4%±2%
ICU	HR(ECG)	42	45470	3%±3%
	RR(CO2)	13	7625	7%±6%
	RR(man.)	35	734	8%±8%

2.2. Movement and bed occupancy

Movement is the most prominent part in the recorded signal. Entering and exiting the bed make use of the full dynamic range of the signal. Hence it was important to validate the ability to accurately detect movement and bed occupancy.

The ES system measures motion and integrates duration of movement into 5 levels of activity (None, Low, Medium, High, Extremely high), with 3 seconds resolution. Validation of movement was against an actigraph placed on the torso to balance the impact of left and right movements. In order to validate this measurement, a controlled experiment was performed with male and female subjects, aged between 6-68 years old, and weights range of 19-99kg. Subjects were asked to move different body parts according to a protocol, and then move freely.

Overall 3640 segments were compared to visual reference and actigraph readings. 100% match was found between manual and automatic score.

Bed occupancy was also validated in a controlled experiment where subjects were asked to lie in bed, sit upright, and exit the bed. Since the results of this controlled part showed 100% success in identifying bed exit, we were able to use it as reference for real life hospital data, and validate a predictive algorithm for bed exit. We used 186 nights and a total of 310 referenced bed-exits in real hospital patients during night-time, to compare a 3-level indicator, based on movement and signal-to-noise ratio, as predictor of bed exit. The positive predictive values (1st column) of this indicator as well as its sensitivity (2nd column), and indication time before bed-exit (3rd column) are shown in table 2. In real hospital setting, a typical response time of a nurse to a bed-exit alert is 40 seconds, hence the importance of this predictive indication.

Table 2. Bed occupancy predictive indicator performance.

	PPV	sensitivity	Time (s)
Level 3	45%	71%	50
Level 2	24%	84%	83
Level 1	17%	87%	94

3. Irregular cases

By now we have collected over 1 million hours of recordings in various clinical facilities. Among these recordings are some interesting less-common use cases which were not validated vs. a reference device. However, retrospective clinical evidence was available to support our interpretation of the signal.

3.1. Left ventricular assist device

The second generation (and more common) LVAD implants replace the function of a failing heart by generating a continuous (vs. pulsatile) blood flow from the left ventricle to the aorta. Hence patients with LVAD II have no palpated pulse, although their right ventricle function and ECG are not affected. In a long term care facility echocardiography was used to spot check normal rhythm in LVAD patients. After installing our system they were surprised to have readings from these patients. Looking at the raw signal we saw 2 interesting findings: (1) the cardioballistic effect of the right ventricle alone is strong enough to be captured by our sensor, (2) the BCG signal was lacking the recoil part (JK segment in figure 1) produced by the blood bolus being forced to change direction in the aortic arch.

3.2. Ventricle Fibrillation (VF)

Another interesting example is BCG during ventricular arrhythmia. In an Electrophysiological Study (EPS) at Sourasky Medical Center, Tel Aviv, we recorded simultaneously BCG and conventional reference devices, during pacing of the ventricles and eventually evoking Ventricle Fibrillation (VF).

While following this procedure we could see the mechanical beat following the electrical beat, disappearing when the pace exceeds a certain threshold, and then back again a few seconds after defibrillation shock and after normal electrical beat could be observed (see figure 2).

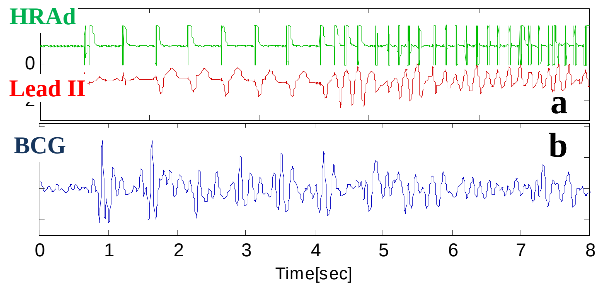

Figure 2. a) 8 seconds of lead II ECG and high right atrium (HRAd) during VF. b) BCG during the same time.

3.3. Paradoxical breathing and apnoea

Paradoxical breathing or asynchrony between chest wall and abdomen movement during respiration, can be a symptom of obstructive sleep apnea (if occurs during sleep) or late stage Chronic Obstructive Pulmonary Disease (COPD). During paradoxical breathing ventilation is poor and there is a use of accessory muscles. The forced breathing exerts a unique double-peaked-respiration pattern. Each respiration cycle consists of two sub-sections – initialization of a “normal” rib-cage movement and an additional, lower-amplitude movement, generated by the contraction of accessory muscles - aiding in the breathing process. Figure 3a depicts a case of this unique pattern.

Short periods of paradoxical period are common, especially among adult patients, often during sleep. However, in our experience, periods longer than 2 hours of paradoxical breathing are indicative of acutely ill patient.

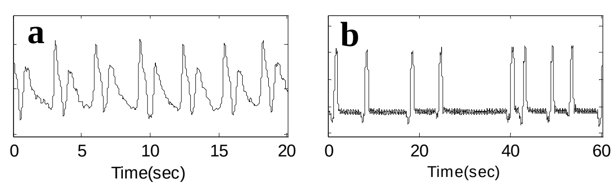

Figure 3. (a) Example of accessory muscles use for breathing, (b) increasing apnea example between labored breathing (gasps) before patient expiration.

Apnea is typically a more common state of breathing cessation. In most cases central apnea are 10-60seconds long. figure 3b depicts a case of increasing apnea duration between labored breathing cycles. Although the occurrence of a single sleep-apnea event has no severe implications, frequent apneas have cardiovascular implications, and adversely affect prognosis. In extreme cases, such as a deteriorating patient, apnea duration may increase gradually leading to a complete cessation of breathing.

3.4. End-of-life

The vast majority of patients who died were under Do-Not-Resuscitate protocol; only a few were unexpected to die. Continuous monitoring allows patient deterioration eo be monitored, and action taken. Each individual death is different, depending on the clinical state of the patient, however the EarlySense system allows monitoring 5 different aspects of vital signs (see figure 4): (1) HR, (2) RR, (3) pulse amplitude, (4) respiration amplitude, and (5) movement level. In each case a different combination of vital signs, showed a deteriorating trend. In the case depicted in figure 5, there was a decreasing trend in respiration amplitude and pulse amplitude; HR also gradually decreased, and movement reduced to practically nothing in the minutes before death. In this example respiration rate did not change till the end.

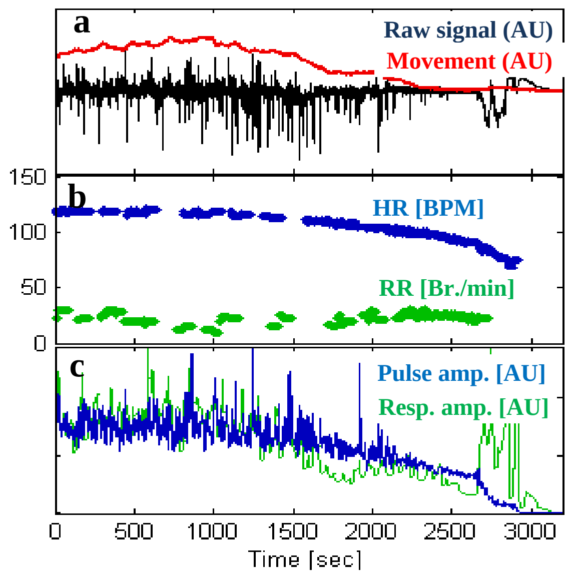

Figure 4. Declining HR and decreasing heart pulse and respiration amplitudes minutes before death.

4. Discussion

This paper reviewed our experience with contact-free piezoelectric based monitoring system. The piezoelectric sensor records a superposition of body motion, chest wall movement, and cardioballistic recoil of the body. The later 2 are related to respiration effort and stroke volume, and allow extraction of RR and HR.

This monitoring system is robust, and was validated against gold standards in ICU unit, and sleep lab setting. Validations showed aRE of 8% or lower for all vitals measurements. aRE for HR (3-5%) was similar in both setting, and better than respiration aRE (4-8%). This could be explained by the difficulty to find a reference for RR. Although RIP technology is considered gold standard for monitoring respiration, the algorithms to extract RR are not yet robust enough.

Obviously, measuring heart function based on its mechanical properties has advantages and disadvantages compared to electrical function and ECG. We showed where the mechanical pulse can unveil equivalent information to ECG, as in VF; and where there is an added value of monitoring mechanical function, as in LVAD or end-of-life patients. In many other applications, the use of this technology is yet to be proved.

Regarding respiration – there is a clear value in not only monitoring the RR, but also looking at breathing patterns. This contact free system allows easy continuous monitoring of large populations, and opens a vast field of pattern analysis that is yet to be explored.

Lastly, the ease of continuous monitoring also allows viewing and analyzing trends. As shown in the end-of-life example, following a trend is often more informative than specific absolute HR or RR values.

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