Contact less Heart and Respiratory Rate Continuous Monitoring:

Validation of an Innovative Tool

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ABSTRACT

**Background:** The need to improve recognition and response to changes in hospitalized patient’s condition requires that patients be monitored continuously for vital signs. Advanced technologies might allow appropriate monitoring for low to medium-risk patients. The EverOn™ system is a contact-less continuous measurement system for heart and respiration rates (HR and RR). We set out to assess the accuracy of this system on patients in a sleep lab and in an intensive care unit (ICU) setting.

**Methods:** In both the ICU and the sleep-lab setting EverOn's sensor was placed under the mattress with the data recorded. Reference measurements were conducted by ECG for HR, while for RR end-tidal CO₂/manual counting was performed in the ICU and plethysmography for sleep-lab patients. One minute measurements of both the reference and the EverOn™ were averaged and compared on a minute to minute basis.

**Results:** Of the 41 children and 16 adult patients evaluated in the sleep lab RR accuracy was 93.1% and 90.6% (for adults and children respectively) while HR accuracy was 94.4% and 91.5% (respectively). For the 42 ICU patients evaluated RR accuracy was 82.0% and 75% (compared to end-tidal CO₂ and manual measurements respectively) while accuracy of HR was 94.0%. The Everon™ was found to be superior to the impedance technique used to measure RR.

**Conclusions:** The monitoring system described here was found to be sufficiently accurate in accordance with standard regulatory and industry criteria. The EverOn presents a unique tool capable of measuring continuous HR and RR in a contact-less, easily applicable manner.
**Introduction:**

In recent years growing attention is placed on minimizing preventable complications during hospitalization. It is estimated that unnecessary deaths in hospitals has claimed the lives of almost 200,000 Medicare patients between 2000 and 2002. Among these, delayed or suboptimal intervention for inpatients with unexpected clinical deterioration is an important clinical problem associated with increased morbidity and mortality.

The chronic shortage of nurses in general hospital wards has adversely affected the quality of healthcare patients receives, enabling gaps of 4-8 hours between rounds to check patient vital signs. By the year 2020, this shortage is expected to exceed 800,000 nurses in the USA. Today, 80% of the general floors patients are left unattended between nursing rounds, void of regular monitoring to detect signs of clinical instability. The most critical period of inpatient care is during the night-shift, when hospital staff is often further undermanned. Thus, patients' health risk often increases during sleep as change in their condition often goes unsupervised.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) highlighted this need in its 2008 National Patient Safety Goals for hospitals - Goal 16: "Improve recognition and response to changes in a patient’s condition." The rationale, as expressed by the Joint Commission, was that critical events such as cardiopulmonary and respiratory arrests or changes in patient’s vital signs are estimated to occur in 4% to 17% of inpatient admissions and that a significant number of these events are preceded by warning signs for an average of 6 to 8 hours.

Advanced technologies may help nurses to provide high-quality care and improve patient safety. The EverOn ™ system (EarlySense LTD, Ramat-Gan, Israel) is a
contact-less continuous measurement system for heart and respiration rates. The system is based on a piezo-electric sensor that is placed under the patient’s bed mattress and automatically starts measuring with no need for patient / nurse activation, involvement or contact with the device. The data is accumulated and analyzed continuously while the patient is in bed and displayed as vital signs reading on a bed side monitor and in a central nurse station.

Our objectives were to study the accuracy of the EverOn system for heart and respiratory rate measurements in patients during ambulatory evaluation in a sleep lab setting and in patients hospitalized in an intensive care unit (ICU).

**Methods:**

**Study population**

The sleep lab arm of the study took place at the Dana Children's Hospital at Tel Aviv Sourasky Medical Center (TASMC) in Tel Aviv, Israel. Subjects included in the study were adults (age above 18 years) and children (aged 4-18) referred to the Sleep Lab for any indication and who were willing to sign an informed consent (for children - legal guardian able and prepared to sign informed consent form).

The ICU arm of the study took place at the General ICU at TASMC. Patients hospitalized within the ICU which met study's inclusion and exclusion criteria were enrolled in the study. Inclusion criteria included hospitalization in critical care unit and obtaining patients,' or their next of kin (for intubated and ventilated patients) consent of participating in the study. Subjects were withdrawn from analysis due to unavailable results of reference device - external noise.
interference from ventilator machine, short period of monitoring (i.e. due to patients discharge, transfer to another unit or death in the unit), or system malfunction. The study was approved beforehand by an independent institutional review board (IRB) for both arms of the study.

At the time of enrollment, patient age, sex, height, weight, admission details, medical diagnosis and study ID number were recorded on the case report form (CRF). The CRFs were also used to document any input received from the clinicians (nurses and physicians), during the usage of the system.

**Measurements**

In both the sleep lab and ICU studies, the Piezoelectric sensor was placed under the mattress and connected to the EverOn™ control unit. The EverOn™ system automatically started measuring with no need for patient, nurse or technician activation, while the patient was in bed.

In the sleep lab gold standards measurements for respiration rate (RR) was the Embla N7000 with Somnologica Studio Software System (Embla Systems Inc. Iceland), using abdominal and chest belts, featuring Respiratory Inductive Plethysmography (RIP) technology, and for heart rate (HR) - Embla Sleep Lab System, automatic scoring. Subject's RR and HR were measured simultaneously by both the gold standard device and the Everon for the entire night (21:00-06:00). The EverOn™ System and laboratory PC were time-synchronized. The data acquired by the EverOn™ System were analyzed using EverOn™ System’s signal processing
algorithm. Only subjects who had 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) as part of the routine monitoring for ICU patients. Measurement of respiration for ventilated patients was done by End-tidal CO2 (ET CO$_2$) module. For patients not ventilated, respiratory rate was measured manually by trained research assistants for a representative time period. RR was also measured for both ventilated and non-ventilated patients using a standard impedance technique used routinely in the ICU (Datex-Ohmeda GE Medical).

Heart and respiratory rates for these subjects as measured by the Datex system were logged into the Collect S5 system (GE Medical) – a data collection program that collects data, waveforms and alarms directly from the Datex Ohmeda monitor and the ET CO$_2$ module through a PC serial interface cable- on a minute to minute basis.

**Data and statistical analysis:**

The reference measurements and the EverOn were time synchronized. One minute measurements of both the reference and the EverOn system were averaged and compared on a minute to minute basis. The measurements were compared to calculate the accuracy and the detection rate of the EverOn as well as to compute the absolute relative error for the contact-less system. The EverOn measurements were considered as accurate if its measurements were either within ± 10% of reference measurements or within ± 5 BPM for HR or ± 2 Br/min for RR whichever is higher, both criteria are considered as accepted industry criteria level to show equivalence between different measurement methods, while having no clinical impact on clinician's decision$^6$. The
Absolute Relative Error Rate (aRE) was computed as: $aRE = \frac{(Reference - EverOn)}{Reference}$. The primary endpoint was one-minute segment-level RR or HR scored dichotomously as accurate or inaccurate, relative to the gold standard reference according to computed aRE (segment level was considered accurate if $aRE \leq 0.10$). To assess the interaction between accuracy of the EverOn and Body Mass Index (BMI), a potential bias, we used correlation tests. For the linear regression and for the BMI-accuracy correlation, we used the Pearson correlation coefficient.

**Results:**

**Sleep lab measurements:**

In the sleep lab 41 children and 16 adult patients were evaluated. Table 1 summarizes the demographics of the evaluated subjects. Of the 1341 RR readings (minutes) performed on adults, accuracy was 93.1% with an aRE of 0.04 ± 0.01. Comparison of RR accuracy to 0.80 was significant (P < 0.01). Of the 5792 HR readings (minutes) performed in adults accuracy was 94.4% with an aRE of 0.03 ± 0.03. Comparison of HR Accuracy to 0.80 was significant (P < 0.01). No significant correlation was found between BMI and both HR and RR accuracy in the adult sleep lab patients.

Of the 41 children analyzed, 4 had missing data and did not match the minimum criteria to be included in the study. Of the 37 remaining patients, for the 2730 RR readings the accuracy was 90.6% with a mean aRE of 0.04 ± 0.02 (comparison of RR accuracy to 0.80 was significant (P < 0.01)). While the accuracy comparing the 10348 HR readings to the gold standard was 91.5% with an aRE of 0.05 ± 0.03 (comparison
of RR accuracy to 0.80 was significant (P < 0.01)). Table 2 summarizes the statistics for the sleep lab measurements including the correlation (r) of the Everon measurements to the gold standard.

We found no significant correlation between BMI and RR accuracy in the pediatric subjects, but found a significant negative correlation (r = -0.38; P = 0.01) between BMI and HR accuracy. However, this was due to a single outlier (BMI=33, Accuracy=0.43) that when excluded yielded r=0.15 (P=0.19). Thus, it would appear that BMI, in the range measured, does not affect accuracy of HR. There were no significant relationships between EverOn™ accuracy and the gender and age covariates.

**ICU patients:**

Forty two ICU subjects, ages 16-86 years (54.8±17.4), completed the protocol. Simultaneous measurements by the EverOn and reference device varied between 6-24 continuous hours in ICU patients. Table 1 summarizes the demographics of the evaluated subjects.

For the HR monitoring, out of the 45470 readings compared, the accuracy of the EverOn monitoring was 94% and the mean aRE was calculated to be 0.03 with a correlation of r=0.91 (table 3). Comparing RR, on the subgroup of patients that were intubated and were connected to an ET CO\textsubscript{2} module (13 patients), out of the 7625RR readings accuracy was 82% while mean aRE was calculated to be 0.07 with a correlation of r=0.82 (table 3). On the subgroup of patients that were not intubated and that comparison was done on manual RR readings (35 patients, 6 patients were included in both groups after being weaned from mechanical ventilation) the RR accuracy of the 734 readings compared was 75% with a mean aRE of 0.08 and a
correlation of $r=0.93$. Comparing the impedance RR measurements to the gold standard showed lower accuracy rates (52% for ET CO$_2$ and 55% for manual method) and a higher aRE (0.22 and 0.16 comparatively) (table 3). Again, no significant correlation was found between BMI and both HR accuracy and RR accuracy. In both the ICU arm and in the sleep lab, no adverse events related to the EverOn were recorded.
Discussion:

As indicated, patient safety advocates in recent years are demanding earlier recognition and response to changes in a hospitalized patient’s condition to allow better clinical outcomes. This mainly poses a challenge in non-ICU settings, namely on hospital wards where most patients are not put on continuous monitoring of vital signs. These non-ICU beds, which pose a large majority of all hospital beds, occupy patients who at admission seem less acute. Some of these patients are nevertheless severely ill and may deteriorate during hospitalization due to either worsening of their primary acute disease or due to an in-hospital complication. Working to improve patients safety requires continuous monitoring that would be appropriate for this non high-risk population.

In response to this issue, advocacy groups such as the Institute for Healthcare Improvement (IHI) are promoting the use of Rapid Response Teams (RRT) for early intervention during medical crises. The success of a RRT solution lies in early recognition of patient deterioration. For efficient RRT deployment, healthcare workers must have a monitoring system that is advanced enough to supply real-time alerts of health deterioration, yet simple enough to use with large numbers of patients without adding to the burden of the hospital staff.

The EverOn monitor described here has the potential to answer for this important need. In attempting to set its accuracy rate we compared HR and RR of the EverOn to well established gold standard monitoring in both a "sterile" sleep lab setting and in a general ICU setting. We have found both RR and HR to be within the pre-defined parameters for accuracy of 10% in both the sleep lab patients and the ICU
patients. We also found that BMI, and obesity specifically, a concern first brought up as a possible interfering factor, did not affect accuracy.

When comparing the EverOn accuracy in measuring RR, versus the commonly used impedance technique, we found the EverOn to be much more accurate. Transthoracic impedance pneumography is used increasingly and involves the direct measurement of thoracic impedance changes associated with respiration, to provide a display of respiratory rate\(^8\). The principle involved is based on the change in impedance that occurs across transthoracic electrodes during breathing. On inspiration, air fills the lungs resulting in an increase in voltage; on expiration, voltage drops and resulting impedance changes are computed. However, any patient motion, whether respiration or any other movement (cardiogenic artifacts and signal degradation with change in position), will cause a change in the impedance signal\(^9\).

Several studies have shown that a delay in diagnosis and triage of decompensating patients is associated with marked increase in mortality. Young et al have documented a 3.5 relative risk increase for absolute hospital mortality when transfer of decompensating ward patients' to the ICU was delayed\(^{10}\). These patients were also less likely to have had a bedside physician evaluation within the first 3-hours of deterioration compared with rapid-transfer patients. The authors also found that slow-transfer patients suffered greater declines in physiological function during the period prior to transfer. Kaboli and Rosenthal termed ICU transfer delay as a "preventable adverse event" that "must be addressed"\(^{11}\). Furthermore, researchers have found that sixty percent of in-hospital cardiac arrests, deaths and emergency unplanned intensive care admissions are preceded by antecedents (mostly hemodynamical) that, if identified, might lead to earlier response by health teams\(^{12}\).
Recently, much focus has been put around the world and in the USA specifically, on RRT. These are teams of health professionals which are called for a pre-specified set of physiologic abnormalities, symptoms, or signs, triggered by on-site personnel. Generally, published experience suggests that the use of RRT's improve patient's outcomes. This was specifically shown in reducing cardiac arrest rates, mortality from cardiac arrests and over-all in-hospital mortality at an Australian hospital implementing an intensive care-based medical emergency team \(^\text{13}\) and in a similar experience in a UK hospital showing comparable improvement in cardiac arrest outcomes \(^\text{14}\). Another report showed reduction in post-surgical mortality following implementation of a RRT \(^\text{15}\) while two other studies reported that an RRT program resulted in a reduction of unanticipated ICU transfers with no increase in in-hospital arrest rate or total death rate \(^\text{16,17}\). Furthermore, in a randomized controlled trial performed in a UK hospital in which 16 wards were randomized to receive clinical care outreach services, researchers showed that the outreach did indeed reduce mortality in general hospital wards\(^\text{18}\). On the other hand, a large scale cluster-randomized controlled trial, involving 23 hospitals in Australia\(^\text{19}\) and a recent single US hospital study\(^\text{20}\) did not show outcome benefit from RRT utilization. Nevertheless, this has not decreased the support and enthusiasm from such programs. Indeed, this enthusiasm was recently translated to wide endorsement by both the IHI and JCAHO in the US and by Britain's National Health Service recommending implementation of similar Outreach Team concept \(^\text{21}\).

The evidence that early response by health teams to clinical decompensation improves outcome of in-hospital patients, and the growing embrace of the RRT program by health care improvement organizations and bodies of accreditation, has brought forth the need for a new technology. To achieve monitoring of vital signs for
all non-ICU hospital beds, such monitors need to be reliable, easy to use by the staff, convenient to the patients (many of them self-sufficient and want to move around the ward), and at the same time be economically cost-effective to be used in large numbers across hospitals. The system described here might provide these needs. Furthermore, the EverOn's ability to measure with sufficient accuracy continuous respiration rate is a valuable advantage that provides hospital staff with important clinical information which is not available for patients in non-ICU settings today. Such continuous vital signs monitoring devices could play a center role in the future hospital when connected to central monitoring stations, personal digital assistant carried by health professionals and intervention teams, computerized patients records and physician order entry programs and connected to treatment protocols equipment such as intra-venous pumps (for administering patient controlled analgesia for example). Indeed, such novel ideas have been brought up and issues like connectivity between devices have been recently debated\textsuperscript{22}. While the contactless device might provide convenience to patients, its major draw-back is that it will measure and alarm only when patients are in bed, thus will not cover fully the patients while in hospital.

We have described here a preliminary study aimed at validating a new monitoring system. The results prove that this technology is sufficiently accurate to be used to monitor non-ICU patients at average risk for clinical deterioration. However, further research is needed to specifically establish its place in monitoring patients at different settings - both in-hospital (medicine, post surgery, obstetrics, pediatrics) and ambulatory. First of all, there is a need to prove feasibility of use in non-ICU departments exploring technical issues, staff and patients opinions and exploring the various settings that would most benefit from the technology. Second, an interventional large scale study attempting to evaluate changes in outcomes
(mortality, unintentional ICU transfers, stay in ICU and probably readmission rates) following implementation of this monitoring system in non-ICU settings should be performed to assess its clinical value. Further issues like affect of cardiac arrhythmia (atrial fibrillation for example) on accuracy of readings and exploration of further application of the system (such as alarming for bed falls) should also be explored.

In conclusion, the monitoring system described here was found to be sufficiently accurate in accordance with standard regulatory and industry criteria. The EverOn presents a unique tool that measures both HR and RR in a contact-less, easily applicable manner. Specifically in measuring RR, we found the EverOn to be more accurate than impedance-based technologies widely used today. Although further research is needed, we believe that this tool could prove valuable in allowing earlier recognition and response to changes in a hospitalized patient’s condition.
Table 1: Demographic characteristics of sleep lab subjects and ICU patients included in the study.

<table>
<thead>
<tr>
<th></th>
<th>Number of patients</th>
<th>Sex</th>
<th>Age (years, Mean ± SD)</th>
<th>BMI (Kg/m², Mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep lab – adults</td>
<td>16</td>
<td>8:8</td>
<td>30.6 ± 5.3</td>
<td>24.2 ± 4.7</td>
</tr>
<tr>
<td>Sleep lab – children</td>
<td>41</td>
<td>32:9</td>
<td>7.6 ± 3.6</td>
<td>18.4 ± 5.7</td>
</tr>
<tr>
<td>ICU</td>
<td>42</td>
<td>25:17</td>
<td>54.8 ± 17.4</td>
<td>26.9 ± 6.6</td>
</tr>
</tbody>
</table>

BMI – Body Mass Index
**Table 2:** Comparison of EverOn readings vs. gold standard device in the sleep lab patients

<table>
<thead>
<tr>
<th></th>
<th>Detection points</th>
<th>Accurate points, number (%)</th>
<th>aRE ± Std</th>
<th>Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RR</strong></td>
<td>Adults (16)</td>
<td>1341</td>
<td>1249 (93.1%)</td>
<td>0.04 ± 0.01</td>
</tr>
<tr>
<td></td>
<td>Children (37)</td>
<td>3646</td>
<td>3346 (91.8%)</td>
<td>0.04 ± 0.02</td>
</tr>
<tr>
<td><strong>HR</strong></td>
<td>Adults (16)</td>
<td>5792</td>
<td>5475 (94.4%)</td>
<td>0.03 ± 0.03</td>
</tr>
<tr>
<td></td>
<td>Children (37)</td>
<td>11309</td>
<td>10348 (91.5%)</td>
<td>0.05 ± 0.03</td>
</tr>
</tbody>
</table>

RR = respiratory rate; HR = heart rate

aRE = Absolute relative error; Std = Standard deviation
**Table 3**: Comparison of EverOn and the impedance readings vs. gold standard device in the ICU patients.

<table>
<thead>
<tr>
<th></th>
<th>Number of patients</th>
<th>Detection points compared</th>
<th>Accurate points, number (%)</th>
<th>aRE ± Std</th>
<th>Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Everon vs. gold standard</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HR</td>
<td>42</td>
<td>45470</td>
<td>42752 (94%)</td>
<td>0.03 ± 0.03</td>
<td>0.91</td>
</tr>
<tr>
<td>RR (ET CO\textsubscript{2})</td>
<td>13*</td>
<td>7625</td>
<td>6288 (82%)</td>
<td>0.07 ± 0.06</td>
<td>0.82</td>
</tr>
<tr>
<td>RR (manual)</td>
<td>35*</td>
<td>734</td>
<td>547 (75%)</td>
<td>0.08 ± 0.08</td>
<td>0.93</td>
</tr>
<tr>
<td><strong>Impedance vs. gold standard</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RR (ET CO\textsubscript{2})</td>
<td>13*</td>
<td>6388</td>
<td>3310 (52%)</td>
<td>0.22 ± 0.11</td>
<td>0.37</td>
</tr>
<tr>
<td>RR (manual)</td>
<td>35*</td>
<td>635</td>
<td>352 (55%)</td>
<td>0.16 ± 0.14</td>
<td>0.81</td>
</tr>
</tbody>
</table>

* Six patients are included in both groups.

RR = respiratory rate; HR = heart rate

aRE = Absolute relative error; Std = Standard deviation
References

1. FindArticles.com. "Study: Hospital errors result in 195,000 deaths per year". 


7. 100,000 lives campaign. 


22. CY J. Medical devices lag in iPod age. 