An Accurate Contact-Free Heart and Respiration Rate Monitor - Overview of Clinical Performance

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SUMMARY

A total of 49 volunteers, 35 children and 14 adults were enrolled in this study to evaluate the performance and accuracy of the ES-16 system vs. the standard device used in sleep laboratories to measure heart rate and respiration rates.

ES-16 system is a contact-less continuous measurement system for heart and breathing 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. Because the EarlySense ES-16 sensor is located under the patient's mattress and no direct contact with the patient is required for data acquisition, the system enables monitoring of both children and adults at various medical facilities as well as the home environment.

The continuous monitoring of respiration and heart rate patterns as enabled by the EarlySense device is valuable for monitoring patients in different clinical conditions including post surgical patients receiving sedative substances that might affect their respiratory and heart rate patterns or other patients who suffer from different respiratory diseases. In this study a prototype device was placed under the mattress of a standard bed in sleep laboratory, while children and adult volunteers were connected to standard sleep laboratory devices that measure respiratory and heart rate in a standard method (polysomnography and ECG). The objective of this clinical trial is to determine the agreement between the EarlySense and Gold Standard measuring systems.

Our data show that the EarlySense system successfully measured respiration and heart rates for all participants aged between 2 to 43 years. An accuracy of 92% was achieved when Earlysense system results were compared to a simultaneous reference measurement with absolute relative error (aRE) of 4% for respiration and aRE of 4% for heart rate.

INTRODUCTION

There is a large amount of variability in both quality of care and the safety of patients in health care today. This variability is evident in hospital mortality rates [1]. A review of the literature reveals that there are three main systemic issues contribute to the problem: Failures in planning, failure to communicate and failure to recognize deteriorating patient condition. Thousands of people die in their hospital beds each year in the United States because caregivers didn't check their vital signs frequently enough. The Institute for Health Care Improvement (IHI) report that review of patient charts that suffered cardiac or respiratory arrest most often reveals that alterations in subjective complaints and vital signs preceded the event from hours to days in advance. Widespread use of an easy to use monitor that requires no compliance, with unstable

patients and patients who are prone to respiratory failures and/ or are likely to suffer cardiac arrest, might often prevent unnecessary death.

ES-16 System is designed to provide continuous measurement of basic vital signs (heart rate and respiration) without use of any electrodes, leads, cuffs or cannulae. Testing of system in sleep lab demonstrated accurate, safe, reliable and convenient measurements of heart and respiration rates as compared to conventional measurement methods. The system includes a proprietary piezo-electric sensor which produces an electrical signal in response to physiological stimulation. Using proprietary signal processing algorithms the system measures respiratory and heart rates without contacting the patient. Thus, the ES-16 system simplifies the monitoring of patients while saving time and effort for the caregivers.

OBJECTIVE

The study objective was to evaluate the accuracy of the ES-16 system in measuring the basic vital signs when comparing to conventional methods.

METHODS

The study was performed in total no. of 49 children and adults at Tel- Aviv Sourasky Medical Center (TASMC) Sleep lab by the Principal Investigator Dr. Joseph Ben-Ari. All studies were performed according to approved IRB protocols.

Subjects admitted to the TASMC sleep lab were monitored using standard sleep lab procedures, which included measurement using the Embla Sleep Lab System (ECG and polysomnography). The ES-16 Sensing Unit was placed under the subject's bed mattress, connected to the Control Unit, and automatically began and ended operation at predefined hours generally correlated with the entire sleep lab measurement period. The ES-16 System and laboratory PC were time-synchronized and the results were compared to evaluate ES-16 accuracy. For Respiration Rate this was done vs. the Embla Manual Gold Standard which included manual scoring of the respiration rates by two blinded, qualified technician; for Heart Rate this was done vs. the Embla Automatic measurement

RESULTS

35 children (28 Males/ 7 Females), ages 2- 16 years (7.2±3.4) and 14 adults (6 Males/ 8 Females), ages 24- 43 years (30.6±5.6) fulfilled all protocol requirements.

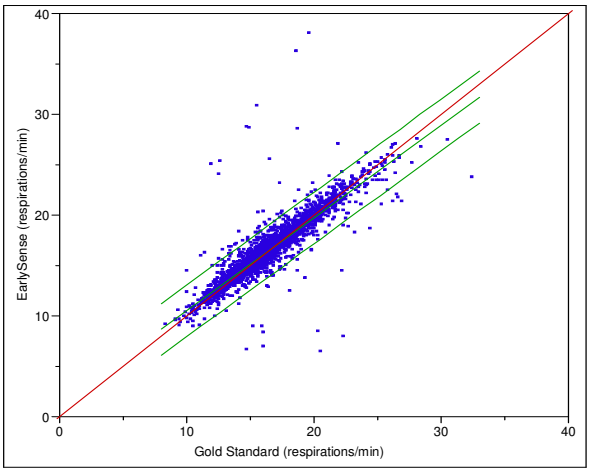
Table 1 summarizes the demographics of the subjects.

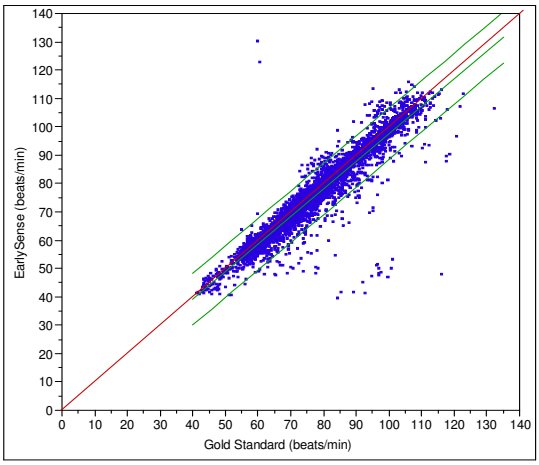
Table 1: Demographics Information

	Gender		Age (Years)		Weight (Kg)	
	Male	**Female**	**Range**	**Mean ± SD**	**Range**	**Mean ± SD**
Children	28	7	2 - 16	7.2 ± 3.4	10 - 69	27.6 ± 14.6
Adults	6	8	24 - 43	30.6 ± 5.6	47 - 103	68.5 ± 15.5

Respiration Rate Accuracy of ES-16 was 0.92 ±0.05. Mean absolute Relative Errors (aRE) was calculated to be 0.04 ±0.014, meaning that the overall average accuracy across subjects was within 4% with a correlation of r=0.898. Heart Rate accuracy of the ES-16 was 0.91 ±0.08. Mean

aRE was 0.040 ±0.017, meaning that the overall average accuracy across subjects was within 4% with a correlation of r=0.94. Respiration rates and heart rates as measured by the ES-16 vs. the gold reference methods are presented in the following Figure**.**





Accuracy Non-Dependence on Weight

The effect of weight on the system's accuracy was evaluated by comparing the accuracy level and the aRE in the lighter vs. the heavier adult population, where the median weight was set as the cut off point. i.e., those with weights below median were included in the "Light" group and those above the median were included in the "Heavy" group. Table 2 summarized these findings.

Table 2: Effect of Weight on System's accuracy

	Mean Accuracy		Mean aRE	
	RR	**HR**	**RR**	**HR**
Light	0.92 ± 0.06	0.95± 0.05	0.04 ± 0.01	0.04 ± 0.01
Heavy	0.90 ± 0.09	0.88 ± 0.12	0.04 ± 0.02	0.07± 0.09

It was shown that both the accuracy levels and aREs were similar in the two weight groups and differences were not statistically significantly (For RR p=0.733 and p=0.917, for accuracy and aRE respectively and for HR: p = 0.161 and p = 0.355 respectively).

SAFETY

No issues that had any impact in patients' safety or ant adverse events were observed.

CONCLUSIONS

The new ES-16 system is an accurate system for measuring Respiration Rate and heart Rates. The overall accuracy of the system is equivalent to existing devices currently being used in sleep labs that require connecting the patients to leads.

REFERENCES

Jarman B, Nolan T, Resar R. *Move Your Dot™: Measuring, Evaluating, and Reducing Hospital Mortality Rates (Part 1)*. IHI Innovation Series white paper. Boston, Massachusetts: Institute for Healthcare Improvement; 2003.