

Evaluation of EarlySense Device for Automatic Detection of Nocturnal Cough in Asthmatic Children - Preliminary Results

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INTRODUCTION:

- **Cough is the most common symptom for which individuals seek medical advice.**
- **Chronic cough, as the sole presenting complaint, is known to account for 10–38% of all referrals made to respiratory physicians.**
- **Cough is known to be correlated with worsening asthma.**
- **No cough monitor is currently accepted as a gold standard.**
- **The EarlySense device (ESD) continuously monitors nocturnal breathing patterns, breathing rate, heart rate.**
- **An advanced version of ESD automatically detects cough through simultaneous analysis of body motion and acoustic signals in a contact-less manner.**

Objective

To evaluate the accuracy of ESD in cough detection, as a preliminary step in providing an improved early warning for asthma exacerbations.

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Method:

An open labelled, prospective, non randomized, one-center, self controlled observational study.

Subjects:

- 11 asthmatic children (5 males), mean age 10.5±2.8 Y, and 10 healthy children – control group (4 males), mean age 10.9±1.8 Y.
- All studies were at home during natural sleep.
- The study was approved by the Tel-Aviv Medical Center Ethics Committee. Informed consent was obtained.

Monitoring and Study Design

- The Piezoelectric sensor was placed under the subject's mattress and connected to bedside unit that also performed a digital audio recording (Figure 1).
- The system was automatically activated every night at a predefined time without patient intervention.
- The physiological parameters (breathing rate, heart rate and cough) were logged for each patient for the duration of the sleep time.
- The data obtained by the ESD were stored and analyzed only at the end of the study.
- The data were not available to the clinicians, and thus no clinical decisions were based on information obtained from the ES device.

Quantification of Cough – Reference Method

- The overnight recordings were divided to 10 second blocks.
- Cough was quantified in terms of the amount of time spent coughing, i.e. the number of blocks containing at least one explosive cough.

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- The explosive phase is always present in a cough sound and is the characteristic sound of cough.
- Objective reference cough counts were determined via Auscultation by headphone to audio records by trained technicians.
- These reference cough counts were subsequently compared to the ESD output.



Figure 1: Sensor and control unit

Statistical Analysis

Sensitivity, Specificity, Positive and Negative Predictive Values of the ESD output as compared to the manual counting were calculated. Anova was used to compare the number of coughs between healthy and asthmatic children.

Results:

- Asthmatic patients were monitored for a duration of 119 nights (714 hours) and healthy children for a duration of 245 nights (1470 hours).

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- There was a significant difference in number of cough per night between all asthmatic and healthy children 6.0 ± 13.2 (range 0-103) vs. 0.2 ± 0.7 (range 0-5) respectively ($p < 0.01$).
- There was also a significant differences in number of coughs between non-exacerbation nights of asthmatic and healthy subjects 4.1 ± 6.4 (range (0-18)) vs. 0.2 ± 0.7 respectively ($p = 0.03$).
- Manual auscultation (reference method) detected 753 coughs during all nights as compared to 570 coughs that were detected by ESD (75.7% detection rate)
- The acoustical patterns of coughs were found to be similar in both population
- Table 1 presents the capability of ESD to detect coughs both in healthy and asthmatic children

Table 1: Summary of Cough Detection in Healthy and Asthmatic Children				
Population	Manual Cough Count (Reference)	ESD Detection	Detection rate	Absolute Relative Error (aRE) – coughs/night
Asthma	713	537	0.75	5.4
Healthy	40	33	0.83	1.2
All	753	570	0.76	2.6

Average number of coughs/night for Asthmatic children was found to be 6, the sensitivity (SE), specificity (SP), negative and positive predictive values (NPV, PPV) of ESD for several cut-off values are presented in Table 2.

Table 2: SE, SP, NPV and PPV				
	Cut-Off Value (coughs/ night)			
	>3	>5	>7	>10
SE	0.76	0.76	0.76	0.76

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SP	0.99	0.99	0.99	0.99
PPV	0.63	0.68	0.75	0.76
NPV	0.99	0.99	0.99	0.99

- **Sample recordings of a single cough event, sleep talking and external noises as detected by ESD are shown in Figures 2, 3 and 4.**

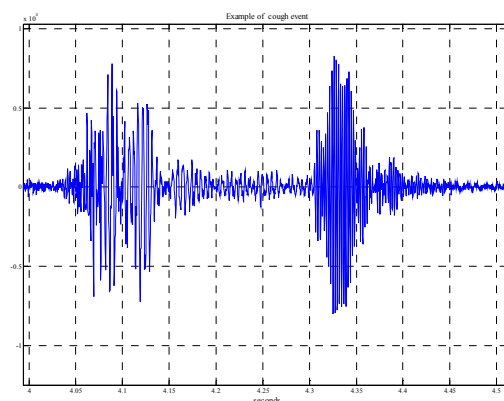


Figure 2: Recording of Single Cough Event

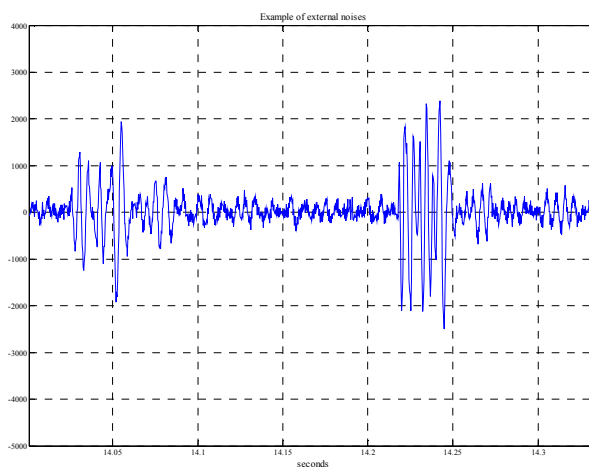


Figure 3: Background noise

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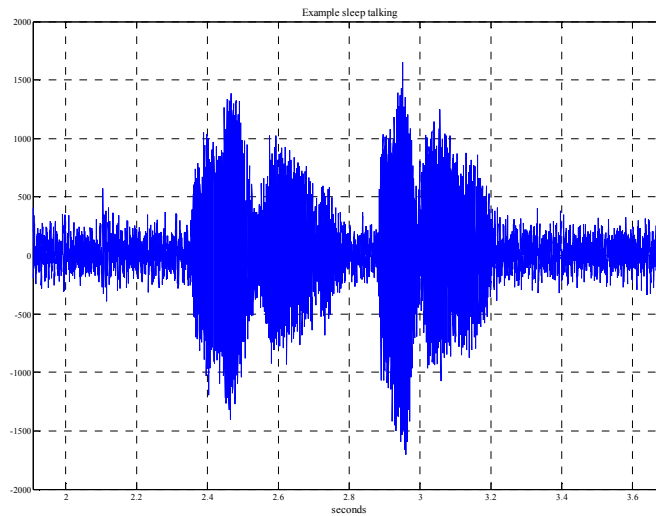


Figure 4: Sleep Talking

Summary:

- **These preliminary results suggest the capability of ESD to detect cough in various population.**
- **Increasing the threshold, from 3 to 10 coughs/night, improves the PPV of the ESD system (Table 2). The change in number of coughs per night during exacerbation of Asthma, COPD and CF are usually more than 10 coughs per night.**
- **ESD has the advantage of operating in contact less manner and is automatically activated; therefore no patient's compliance is required.**
- **We expect that integrating cough detection with our previously reported respiratory parameters will improve the ability of ESD to provide early warning of asthma exacerbations.**