Title: A Continuous Nocturnal Monitoring Device for Predicting Asthma Exacerbation in Children

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Introduction: Asthma is the most prevalent chronic disease in childhood. The respiratory circadian rhythm reveals that the system is at its lowest point of effectiveness during the night. Current home monitoring solutions (PEF and diaries) require active patient compliance. The EarlySense device (ES) continuously monitors nocturnal breathing patterns, breathing rate, heart rate and sleep quality. **Objective:** To test the effectiveness of ES in predicting asthma exacerbations. **Methods**: This is an open labeled, prospective, self controlled study. Patients with a previous history of at least three physician confirmed episodes of asthma were enrolled. ES was placed under the mattress and contact-less, continuous, prolonged nightly measurements were taken. Follow up included: Diary, Daily FEV1 and weekly spirometry. Classification of days: event or non-event was determined by a clinician. Based on the measured parameters, multivariate logistic regression model and receiver operating characteristic analysis were used to produce an ES score. The score of each day was taken as the maximum score of the preceding 3 nights. **Results**: 15 asthmatic children, 8 males, mean age 9.8+/-2.7 years with 18 asthma exacerbations were monitored. Analysis indicated that breathing rate and a measure of heart rate variability produced the most useful event model. 17 events were detected 1 to 2 nights before they were reported (94% sensitivity) with 1 false positive out of 87 confirmed non-event nights (1.2%). **Summary**: The ES device can be used for continuous asthma monitoring. It does not require patient compliance. The ES device predicted most asthma exacerbations at least 1 night before they were reported, allowing early intervention and likely improved outcomes.

Funded By: EarlySense Ltd

Accepted to ATS (American Thoracic Society), May 18th-23rd, 2007, San Francisco, California.