

# Innovative wireless sleep disorders diagnosis system

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## Introduction

Over 10 million patients in the U.S. with obstructive sleep apnea (OSA) remain undiagnosed and untreated (1). The need to expedite sleep diagnosis is further highlighted by significant comorbidity between OSA and other diseases, which often complicates standard patient care. The Crystal Monitor<sup>®</sup> 20-S developed by CleveMed is a wireless PSG system, facilitating setup in any hospital or clinic room that permits sleep monitoring on patients who may be incapable of transport to a sleep lab.

The Crystal Monitor 20-S wireless PSG patient unit.



## Methods

A side-by-side comparison of the Crystal Monitor 20-S and a commercial system was conducted at Cleveland Clinic Sleep Disorders Center in 6 subjects undergoing routine polysomnography. Most of the channels were connected to both systems via a "Y" connection between head boxes. A separate pulse oximetry sensor was worn for each system.

The wireless system includes a patient unit, computer unit and sleep analysis software. The system uses the 900 MHz ISM band for wireless transmission to provide real-time data display, scoring and flexible report generation capability. The patient unit weighs approximately 210g and measures 5.25" x 2.5" x 1". The system acquires fourteen channels: C3-A2, O2-A1, LOC-A2, ROC-A1, ECG, chin EMG, leg EMG, pulse oximetry, airflow, snore, chest and abdominal respiratory efforts, body position and an auxiliary DC channel. A pressure transducer inside the patient unit detects the airflow signal. Algorithms derive snore from the airflow cannula.

## For further information

More information on this and related projects can be obtained at [www.clevemed.com](http://www.clevemed.com).

## Conclusions

The two systems gave comparable results in sleep architecture evaluation and respiratory disturbance detection. Overall, this study shows the potential viability of this new wireless system as an accurate and convenient way to monitor sleep in traditional and non-traditional patient populations such as hospital inpatients and pre-surgical patients.

Work has continued with the development of a 2.4 GHz radio for international use where 900 MHz may not be permitted. An SD memory card has also been added to allow for unattended studies and a back up to the radio connection if interference is encountered.

## Literature cited

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## Results

The overnight PSG recordings were collected by three different technologists. The leads and sensors stayed in place for the duration of the night for all the studies allowing excellent quality recordings. Five of the six subjects wore the Crystal Monitor 20-S on their torso with the patient unit clipped to their waist band or the thoracic effort belt so that their body position could be collected with the internal body position sensor. The recordings were scored, including sleep staging and cardio-respiratory events, by one technologist for both recordings.

Both systems yielded the same diagnosis. Sleep staging was within intrascorer variability indicating similar sleep architecture results. Both devices yielded identical OSA diagnoses in all subjects (2 normal (AHI < 5), 1 moderate (5 < AHI < 30), 3 severe (AHI > 30)). Though the diagnosis was the same, the AHI value for subject five was significantly higher with the commercial system. The limb movements were scored similarly for all but one of the subjects.

100% of the epochs were scored on both systems. Four of the Crystal Monitor 20-S studies had very short dropouts in radio transmission but did not impact scoring. The Crystal Monitor 20-S is powered by two AA batteries. These studies were conducted using Duracell Ultra Alkaline batteries, which lasted through the night.

