

## Mobile Sleep Diagnostic Devices for Testing Around the World

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**Abstract** – About 4% of the population is affected by sleep apnea. It can cause high blood pressure and other cardiovascular disease, weight gain, memory problems, impotency, and headaches. Risk factors include being male, overweight, and over the age of forty, but sleep apnea can affect anyone at any age. However, because of the high cost and complexity of the diagnosis equipment, the vast majority of sleep apnea patients remain undiagnosed and therefore untreated, despite the fact that this serious disorder can have significant consequences such as job impairment and motor vehicle crashes. In the US, drowsy driving accounts for more than 100,000 police-reported crashes, and an estimated 1,550 deaths, 71,000 injuries and \$12.5 billion in loses every year. Part of this drowsiness is caused by sleep apnea and other sleep disorders.

Two new low cost sleep disorders diagnostic devices have been developed this past year for use in the sleep lab, home, hospital, nursing home, and other non-conventional sleep labs. Last year, Cleveland Medical Devices (CleveMed) presented the Crystal Monitor<sup>®</sup> Model 20-S, which provides two channels of EEG, two channels of EOG, ECG, chin EMG, leg EMG, pulse oximetry, airflow (pressure), snore (derived from airflow), thoracic effort, abdominal effort, body position, and an auxiliary DC input that can be used for a thermistor for a second oral or nasal airflow, a CO2 sensor, or other input. This Model 20-S device uses a 900 MHz radio, which is recommended for the Western Hemisphere, due to its long range and reliability.

Now, two new devices are also available. The Crystal Monitor<sup>®</sup> Model 20-B has all the same features as the 20-S, but uses a 2.4 GHz. Bluetooth radio, allowing it to be used anywhere in the world in this unlicensed band. It also has an SD memory card, allowing the device to be used at home, without a nearby computer.

The SleepScout is used to diagnose sleep disordered breathing (SDB) or it can be used as a screener for full sleep studies. It has nine channels: ECG, Leg EMG, Pulse Oximetry, Airflow, Snore, Thoracic Effort, Abdominal Effort, Body Position, and an Auxiliary DC input. Data is captured on an SD memory card, and can be downloaded and read on the Crystal Capture Software.

These small, wearable sleep diagnostic devices provide for easy installation without making facility modifications. This allows any bed in a home, hospital, hotel, nursing home, or anywhere, to become a sleep lab quickly. This allows current sleep labs to easily expand, and reduces the cost for new sleep testing businesses to open in underserved markets. Thus, more people can be diagnosed sooner, with less travel and expense. Another immediate application for the device is to diagnose Sleep Disordered Breathing (SDB) in the hospital room before surgeries. If left undiagnosed, SDB can cause surgical complications.

Keywords – Sleep apnea, sleep disorders, electrophysiology, diagnostic, wireless, Crystal Monitor, SleepScout.

## INTRODUCTION

According to the National Highway Traffic Safety Administration, drowsy driving accounts for more than 100,000 police-reported crashes, and an estimated 1,550 deaths, 71,000 injuries and \$12.5 billion in losses every year. Part of this drowsiness is caused by sleep apnea and other sleep disorders such as restless legs syndrome and undiagnosed narcolepsy. The US National Institutes of Health has been desirous of finding new ways to be able to conveniently diagnose sleep disorders, preferably at less cost. Several of the programs they funded were performed by Cleveland Medical Devices Inc. (CleveMed) of Cleveland Ohio to develop a new untethered sleep monitor. These programs led to the development of the Crystal Monitor<sup>®</sup> Model 20-S (hereinafter Crystal 20-S) (**Figures 1 and 2**), the Crystal Monitor Model 20-B (hereinafter Crystal 20-B), and the Sleep Scout<sup>™</sup>.<sup>1</sup> They will be discussed in detail below.

## DEVELOPMENT

Based on previous wireless medical monitoring research that CleveMed started in 1991, CleveMed received its first FDA authorization to market a wireless physiological monitor, the CRYSTAL-EEG MODEL 10, in 1997. The CRYSTAL-EEG Model 15 came out in 2000; and the Crystal Monitor Model 16 for medical physiological monitoring was released by CleveMed in 2002. In 2004, CleveMed developed the Model 16-S, the world's first small hand held wireless sleep device weighing less than ½ pound (~200 grams). The 16-S device had 11 channels (2 EEG, EOG, ECG, chin EMG, pulse oximetry, airflow, snore, thoracic and abdominal effort, and body position). However, several sleep labs, requested additional channels and improvements. Thus, later in 2004, CleveMed released the Crystal 20-S with 14 channels, adding a leg EMG, a second EOG, and an auxiliary DC input so that physicians can add another sensor at their discretion.

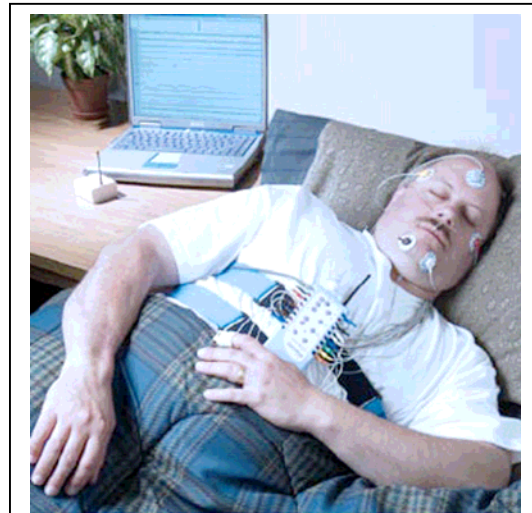


Figure 2 The Crystal Monitor Model 20-S is worn by the patient, and transmits to a nearby receiver, where the data is stored on a PC.



Figure 1 The Crystal Monitor Model 20-S is small enough to be held in the hand and wireless, allowing the sleep patient to get up in the middle of a sleep study without requesting assistance.

CleveMed's criteria for the 16-S was to develop a device that met all the requirements for a sleep study as required to obtain maximum reimbursement under United States CPT Code 95810. This would allow the sleep labs to be reimbursed at the maximum rate, with minimum cost, using the most advanced sleep technology. The 16-S is no longer manufactured as the Crystal 20-S has since superseded it.

**Crystal 20-S:** The Crystal 20-S is being used in labs in the US and Asia. Figure 2 shows a typical application. Labs such as Dayton Children's Hospital find the device particularly useful on pediatric patients. It is frequently difficult to keep pediatric and geriatric patients from moving around after the

sensors have been attached, but before going to bed. A wireless device solves this problem by allowing the patient the freedom to move about, as they desire.

Another application that is particularly appealing for a wireless sleep device is for pre-surgical sleep monitoring for sleep disordered breathing (SDB). Surgery patients, who are already medically compromised, may also have SDB. This can cause complications with the administration of anesthesia during the surgery. Performing a sleep test prior to surgery gives forewarning to the anesthesiologist that complications may arise due to the SDB. The attraction of a wireless sleep monitor is that it can be used in any room in the hospital, without requiring special rooms that have been prewired for sleep testing. This allows the patient's normal room to be used for the sleep test, eliminating the need for moving the patient, thus reducing overhead cost while making the surgery safer for the patient, and reducing liability for the hospital.

The Crystal 20-S uses a 902-928 MHz. transmission frequency. These frequencies are in the Instrumentation, Scientific, and Medical (ISM) Band. It can be used in those countries following the US Federal Communications Commission (FCC) frequency allocations. This includes the western hemisphere and much of Australasia, as well as Taiwan and a number of other countries. It provides high quality, medium range transmission (about 25-30 meters through a couple of normal walls). However, due to its limited use in non-FCC countries, CleveMed introduced a new 2.4 GHz. sleep diagnostic monitor device in 2006, the Crystal 20-B.

**Crystal 20-B:** The Crystal 20-B has all the same sensors as the Crystal 20-S, but the Crystal 20-B case shows two external changes (**Figure 3**). First, there is no external antenna. The antenna is built into the case on the Crystal 20-B. Second, an SD memory card has been added to allow data to be stored on the patient unit. A door covering the memory card can be seen on the right side of the patient unit.

The Crystal 20-B uses a different radio than the Crystal 20-S. It uses a Bluetooth<sup>2</sup> radio that operates in the 2,400-2,485 MHz. range. This is another ISM band, but is usable around the world. It has the advantage of being usable in any country, but at the cost of some range due its higher frequency.

**SleepScout™:** A simple yet powerful clinical solution, the SleepScout provides a convenient, accurate approach to diagnose sleep disordered breathing (SDB) and to screen for other sleep disorders such as sleep apnea. The handheld size makes the SleepScout comfortable to wear, eliminating the need for long lead wires that inhibit movement. Data is stored on a SD memory card for easy data download to a computer. **Figure 4** shows the SD memory card partially extracted from the door that covers the memory card when it is in-place. The SleepScout is built on the same technology as a full PSG system. This 9-channel device monitors the following signals: ECG, leg EMG, pulse oximetry, airflow, snore, thoracic and abdominal effort, body position and an auxiliary DC input. It does not have a radio; thus it does



Figure 3 The Crystal 20-B patient unit is the same size as the 20-S, but does not have an external antenna. The 20-B also has a removable SD memory card. The door covering the memory card is shown on the right side of the device.



**Figure 4** The SleepScout with SD memory card.

not provide real-time data. Its memory card stores the data from sleep studies, allowing the device to be sent home with the patient without the need of a PC. Because data is stored on a removable SD memory card, long-term ambulatory studies can be performed over several days/weeks without requiring the patient to return to the sleep lab until the end of the study. A 1 GB memory card stores 60 hours of data. If this is insufficient, a 4 GB memory card may be used providing 10 continuous days of data collection.

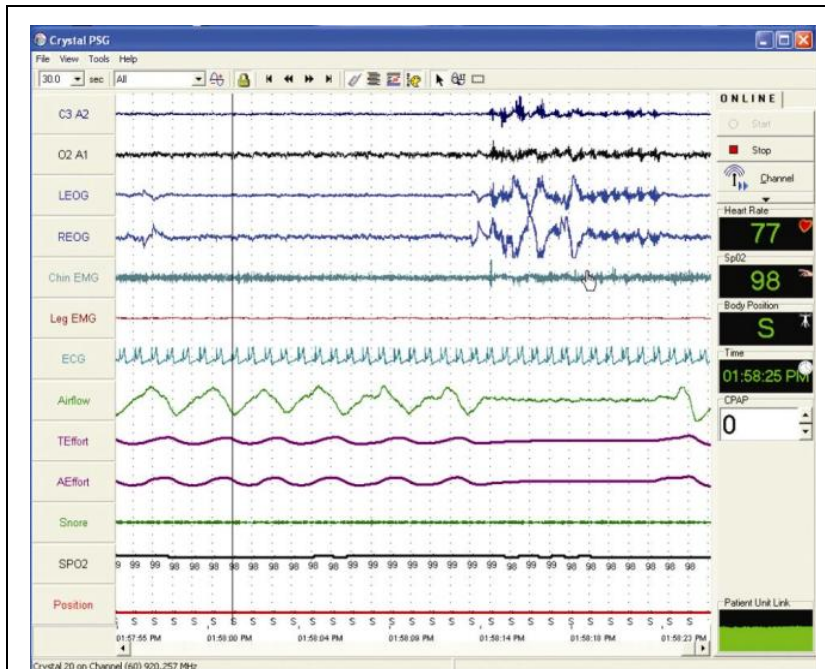
The sleep scout weighs only 210 grams and the 2AA batteries power the device for over 12 hours. The simplicity of the SleepScout system makes it practical for unattended sleep studies, yet because the technology was based on a full PSG system, the advanced signal acquisition and sophisticated software package make it a comprehensive solution for expanding the reach of traditional sleep labs.

**Software:** The Crystal PSG software is used with the Crystal 20-S, Crystal 20-B, and the SleepScout, allowing sleep labs to use one software package for both attended and unattended studies. The

Crystal PSG software offers a complete and powerful software package for managing patient data, data acquisition, scoring and reporting. This user-friendly software offers quick and easy system setup, as well as simple and convenient patient and study management.

### Scoring/Review:

- Data can be viewed with fully configurable waveform displays (**Figure 5**).
- Manual scoring is quick and efficient (**Figure 6**).
- Computer assisted scoring includes cardiac arrhythmia detection and respiratory events.
- A hypnogram and events list are available to give an overview of the study and to jump to points of interest within the raw data.
- The Display Manager controls the number of channels that are displayed and the filter and sensitivity settings for each trace.

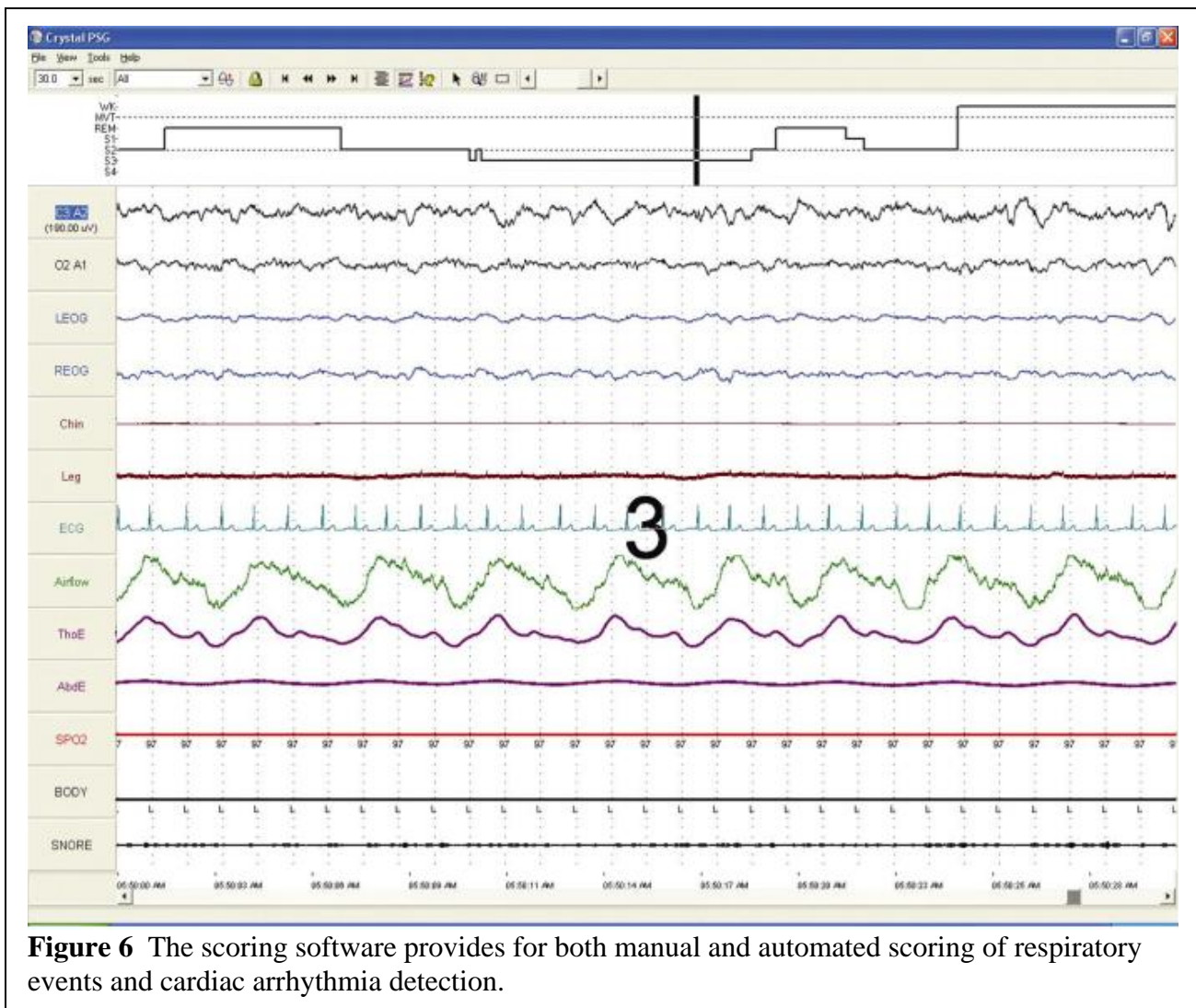


**Figure 5** The Crystal PSG Data Acquisition Software makes it easy to view data from anywhere.

## Reporting:

- The Report engine quickly and effortlessly creates professional reports.
- Reports are seamlessly integrated with the entire patient and study database.
- A variety of report templates are available for each user's specific needs.
- CleveMed can also assist you in creating custom report templates for your lab.
- After generating a report, additional information or test results can be added as needed.
- Reports can be shared and viewed by anyone who has access to standard word processing programs such as Microsoft Word.

Thus, the Crystal PSG software makes the sleep review, scoring, and reporting simple. Because the report engine is fully Windows<sup>3</sup> compatible, the reports can be easily prepared in Spanish or any other language. The reporting format can use one of the dozens of templates already created in the software, or they may be customized to the desires of the sleep lab. **Figure 7** shows one of the formats that can be automatically generated by the Crystal PSG software. This saves time and reduces errors in the sleep lab.



**Figure 6** The scoring software provides for both manual and automated scoring of respiratory events and cardiac arrhythmia detection.



Frederick Craig, M.D. F.A.C.S.  
Director of Operations

June 8, 2005

Diagnostic PSG:  
Doe, John M.  
June 8, 2005

**Sleep Study Interpretation**  
Ref: John Doe

Dear Dr. Brown:

Thank you for referring your patient, Doe, John, for sleep disorder evaluation. Mr/Ms Doe, born 07/16/45, has a history of snoring and daytime sleepiness. The patient's Epworth Score was 11/24. Therefore a complete polysomnography study was performed on June 6, 2005 to rule out sleep disordered breathing. During the study, EEG, EOG and EMG monitored the sleep stages. Respiratory variables included: (1) Airflow monitoring by thermistors at the nose and mouth (2) Respiratory movements by chest wall and abdominal impedance (3) Snoring detection by microphone (4) CPAP pressure (5) Arterial oxygenation was monitored by a finger pulse sensor (6) Heart was monitored by chest wall leads and (7) EMG sensors recorded jaw movements.

**SLEEP PARAMETERS:**

Total recording time was 480 minutes. Total sleep time was 123 minutes with a sleep onset of 30 minutes. Sleep efficiency was 26%. There were 2 REM episodes noted totaling 20 minutes (16% of total sleep time; N=20%). Delta sleep stage III was 3% and stage IV was 0% of total sleep time; N= 15%. EEG arousals were noted at a frequency of 65/hr and were observed mostly related to respiratory events.

**CARDIO-RESPIRATORY PARAMETERS:**

Snoring was heavy. Baseline respiratory recording without CPAP for 123 minutes revealed a total of 70 obstructive, 5 mixed, 1 central apneas and 24 hypopneas. During this period, the respiratory disturbance index (RDI) was 8/hr. The mean duration of the apnea/hypopnea index was 13 seconds. Baseline awake arterial oxygen saturation was 97%. During apnea/hypopnea events, the patient's arterial oxygenation intermittently dropped into the 78% range in REM and 85% range in NREM. The lowest arterial oxygenation was noted to be 70%. 45 minutes of sleep were spent at arterial saturation <90%.

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**Summary of Sleep Parameters**

**Patient Information**

Patient: Doe, John

Type of Study: Diagnostic Study

Test Date: June 6, 2005

Total Study Time (TIB) 377.50 min: Light off => Light on  
Total Sleep Time (TST) 320.00 min: REM + NREM + MVT (during SPT)  
Total NREM time (TNR) 224 min: I + S2 + S3 + S4 (during TIB)  
Total REM time (TRS) 92.00 min: REM (during TIB)

**Sleep Stages/latencies**

STAGES	DURATION (min)	TIB (%)	TST (%)	NORMAL (%)	Latencies	From	From
Wk(TIB)	56.50	8.98	---	---	Sleep onset	0.00	---
REM	92.00	14.62	8.62	25.00	REM	82.00	40.00
S1	29.50	4.69	2.77	5.81	S1	17.50	45.00
S2	188.00	29.88	17.62	50.82	S2	20.50	---
S3	6.50	1.03	0.61	1.83	S3	48.50	38.00
S4	0.00	0.00	0.00	0.00	S4	---	---
MVT	4.00	0.64	0.38	---	---	---	---

Sleep efficiency 84.77% 300 h TST/TIB

**Arousal Data**

Total # arousal 103  
Total arousal > 15 sec 0  
Total arousal with resp event 16  
Total number of Wk or MVT episodes 5  
Arousal index 9.650 (#/sleep)

**Respiratory Summary (Total sleep time)**

	Apneas	Events	Index	Mean	Long
Hypopneas	94		13.82	21.87	75.09
Central	0		0.00	---	---
Mixed	0		0.00	---	---
Obstructive	3		0.44	12.63	36.14
Total Events	97		14.26	21.39	75.09
Apneas Total	3		0.44	12.63	36.14

**Respiratory Disturbance Index (Total sleep time)**

	REM #/h (REM)	NREM #/h (NREM)	TST #/h (sleep)
RDI	22.83	11.77	14.26

**Figure 7** The automated, Windows compatible, reporting engine automates the report process, saving time and reducing errors.

**CONCLUSION**

Three polysomnography diagnostic systems are available to provide wireless and remote diagnostic sleep studies or screenings in sleep labs, hospitals, homes, or any location around the world. The handheld, battery operated hardware and the software were primarily developed under grants from the US National Institutes of Health.<sup>4</sup> Automated scoring and reporting makes the post-study paperwork easy for sleep professionals.

<sup>1</sup> Crystal Monitor is a registered trademark and Sleep Scout is a trademark of Cleveland Medical Devices Inc., Cleveland, Ohio.

<sup>2</sup> Bluetooth is a registered trademark of Bluetooth SIG; see <http://www.bluetooth.com/bluetooth/>.

<sup>3</sup> Windows is a registered trademark of Microsoft Corporation.

<sup>4</sup> Our thanks to the US NIH, National Institute of Neurological Disorders and Stroke and the National Heart, Lung and Blood Institute who provided funding for this work under the Small Business Innovation Research Program.