

# Mobile Sleep Diagnostic Devices for Testing Around the World

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# CleveMed, Cleveland Ohio USA

- World leader in wireless sleep diagnostics
- Creator of digital wireless EEG (1995)
- First FDA wireless EEG device (1997)
- Complete family of sleep diagnostics

## Sleep Diagnostics



SleepScout™  
Sleep Recorder



Sapphire PSG™  
Sleep Recorder

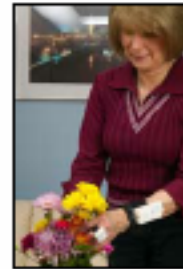


Crystal Monitor™ 20-5  
P&B anywhere



Crystal Monitor™ 20-8  
P&B anywhere

## Movement Disorders - Clinical



Kinesia™  
Motion Tracking System

## Movement Disorders - Research



KinetiSense™  
Motion & Activity System

## Teaching & Research



CleveLabs™  
Laboratory Course System



BioCapture™  
Motion Tracking System

CleveMed

Cleveland Medical Devices Inc.

# Cleveland Medical Devices Inc.

- Founded in December, 1990
- Use the Thomas Edison Model, Invention Factory
- Stock owned by employees
- Awards
  - **Inc. 500**, 2000, 812% five year growth
  - **Inc. Inner City 100**, 2000 (34), 2001 (15), 2002 (27)
  - **Weatherhead 100**, (NE Ohio), 1999, 2000/01/03/04/05/06
  - **Ohio Emerging Technology Award**
  - **Tibbetts Award**, Best SBIR Companies (2002/2006)
  - **NIH Success Story** (NIH Website)
- 2003 Quote from Governor of Ohio Bob Taft  
*“More brain power per square inch than anywhere in Ohio”*

# Cleveland, Ohio USA

## “The Medical City”

**Cleveland, Ohio USA**  
“The Medical City”



CITY OF CLEVELAND

Cleveland, Ohio is in the US Midwest. It is on Lake Erie, one of the Great Lakes. They are the largest group of fresh water lakes in the world, containing 20% of the world's fresh water supply.

Cleveland, Ohio



**University Hospitals of Cleveland**



- 140 year history
- 947 bed tertiary medical center
- Rainbow Babies and Childrens Hospital - 3rd best neonatal care facility; 4th in pediatrics in USA
- Inland Cancer Center in top 26 in USA
- 3,000 physicians & health care professionals

**Case Western Reserve University**



- Founded in 1826
- Ranked among top 40 universities in US
- 12th in research funding for private universities
- 3,500 students, 60 majors, student/faculty ratio 7:1
- 4th in Biomedical Engineering in USA

**CleveMed**



- Founded in 1990
- Conducted over \$40 million USD of medical research
- Developed first digital wireless EEG system (1990)
- Developed first FDA approved wireless EEG system
- One of the serial success stories for the US National Institutes of Health

**Cleveland Cavaliers Professional Basketball**



**LeBron James**

- Cavs founded 1970
- 2007 - Cavs play for National Basketball Championship
- LeBron James leads one of the best playoff performances of all time: “King James” scores 45 points

**The Cleveland Clinic**



- Founded in 1921
- Ranked # 3 hospital in the USA
- Ranked # 1 hospital in heart program for 12 years in a row
- Ranked # 5 in neurology and neurosurgery in USA

**Cleveland Indians Major League Baseball**



- Cleveland Spiders, Cy Young pitched in 1890
- 1910 - Cy Young wins 600th game
- 1920, 1948 - Indians win World Series
- 1954, 1955, 1957 Indians win American League
- 2007 - Indians in 1st place in AL Central

**Rock & Roll Hall of Fame**

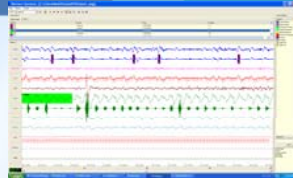
- 1983 - Hall of Fame Foundation founded
- 1995 - Cleveland selected as the home of the Rock and Roll Hall of Fame and Museum

7.7 km



# CleveMed's Medical Products

## Sleep Disorders – Crystal 20-S & 20-B



- Diagnoses sleep apnea, insomnia, narcolepsy,.....
- Easy and simple setup - Small, sophisticated circuitry, wireless capability
- Complete software review and analysis package

## Brain Monitoring – Crystal 20-E



- Wireless monitor to detect patient neurological status in ER.

## Movement Disorders - Kinesia

- Wireless monitor to quantify the symptoms of Movement Disorders at home / office



## Pressure Ulcer Mgmt - PressoreStep



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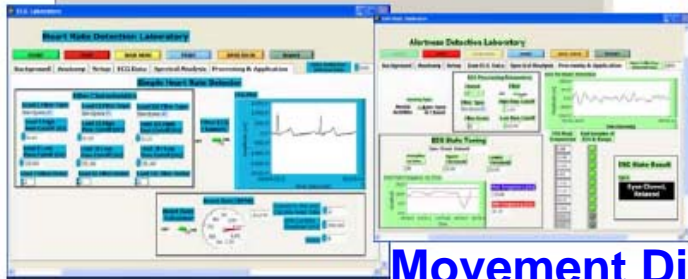
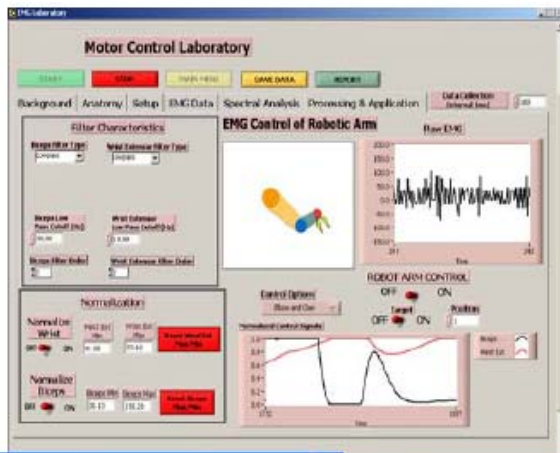
# CleveMed's Research and Teaching Products

## CleveLabs™

Laboratory Course System

## BioCapture™

RESEARCH SYSTEM



**Movement Disorders - KinetiSense**

NIH SBIR Conference, Las Vegas, NV, Feb 26, 2007



**CleveMed**  
Cleveland Medical Devices Inc.

# When you learn on CleveLabs, you enhance your Career



Delhi, India, July 2007

# CleveMed's Spin-offs

CleveMed



NeuroCAP™

An objective assessment of sleepiness based on the integrated analysis of EEG and task performance.



NeuroSENSE™ Monitor

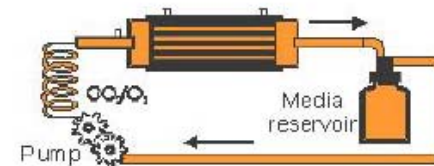
Peri-operative monitoring of the Central Nervous System (CNS) during Anesthesia



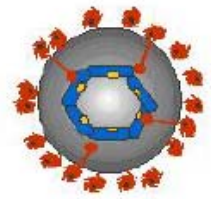
Flocel

[www.flocel.com](http://www.flocel.com)

Dynamic In Vitro  
Blood Brain Barrier Model



DIV- BBB System



Cross Section of  
A single lumen



CleveMed

Cleveland Medical Devices Inc.

# Background

- Need for sleep diagnostic systems that are
  - Simple to use but meet all requirements of a full sleep diagnostic device
  - Provide maximum reimbursement
  - Wireless for most flexibility for patient and technician
  - FDA cleared to market
  - Usable in the US, or around the world.
  - Useable in traditional sleep labs, hospitals, long-term care facilities, at home, or other locations.
  - Provide cardiac monitoring such as arrhythmia analysis

# CleveMed-More than a Decade of Wireless EEG

1994



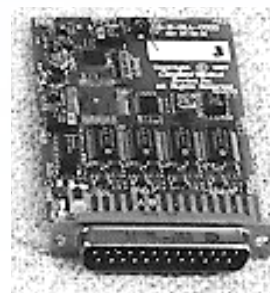
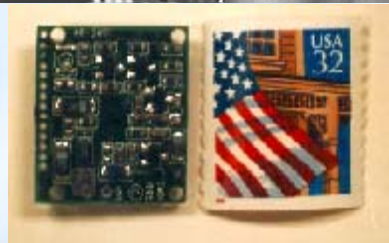
1996



1997



1999



Auditory Evoked Response Epilepsy

Sleep

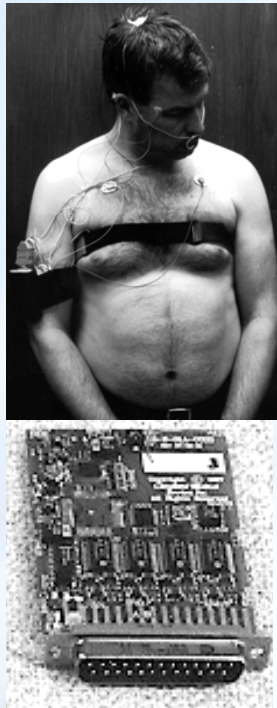
Non-Convulsive Seizures

**CleveMed**

Cleveland Medical Devices Inc.

# CleveMed-A Decade of Wireless Sleep Experience

1997



2002



2004



Research Sleep Device Crystal Monitor 16

Crystal Monitor 16-S

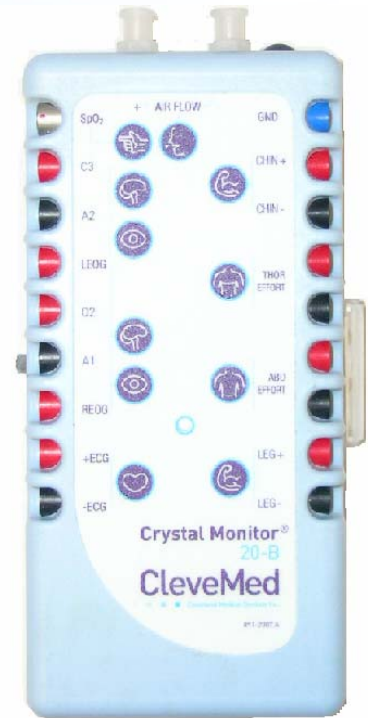
# 2006-Crystal Monitor<sup>®</sup> Model 20-S Wireless Sleep Diagnostic Monitor



Delhi, India, July 2007

# 2007- Crystal Monitor<sup>®</sup> Model 20-B

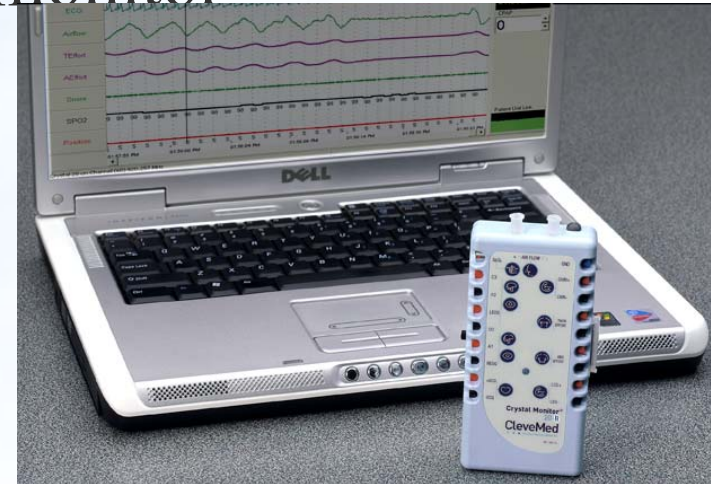
- The Crystal 20-B has all the same sensors as the Crystal 20-S.
- Video from a Wireless Infrared Camera is available.
- The Crystal 20-B case shows two external changes
  - No external antenna. The antenna is built into the case on the Crystal 20-B.
  - SD memory card has been added to allow data to 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 Bluetooth<sup>™</sup> radio, 2,400-2,485 MHz. ISM band. It has the advantage of being usable in any country around the world, but at the cost of some range due its higher frequency.



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

# Crystal Monitor Model 20-B Wireless Sleep Monitoring System

- Lightweight, wireless physiological monitor
- Viewing and recording
  - 2-EEG, Central and Occipital
  - ECG,
  - 2-EMG, Chin and Leg
  - 2-EOG, Left and Right Eye
  - Airflow, pressure
  - 2-Respiratory Effort, Thoracic and Abdominal
  - Body Position
  - Pulse Oximetry, pulse rate and SpO2
  - Snore (derived)
  - Auxiliary DC input
- 2- way, 2.4 GHz. radio usable around the world with robust radio link (ack-nak) and retransmission of packets



# Crystal Monitor Model 20-B Specifications

- Dimensions: 135 mm x 63 mm x 25 mm (5.3" x 2.5" x 1")
- Weight: 210 grams (7.3 oz.) with batteries
- Radio Range: ~15 meters (~25 meters for 20-S)
- Filter Input bandwidth 0.5 Hz - 250 Hz. 960 sps (-3dB attenuation); CMRR 100 dB
- Noise:  $< 1 \mu\text{V RMS}$  (0.5 Hz – 100 Hz)
- Input Impedance  $> 20 \text{ M}\Omega$  @ 10 Hz
- Input Interface Standard no-touch 1.5 mm connectors
- Power Supply 2 AA batteries, Battery Life  $> 12$  hours continuous use with Ultra battery
- Video frames from wireless camera linked to data



# 2007- SleepScout™

- 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.
- The SleepScout is built on the same technology as a full PSG system, so the advanced signal acquisition and sophisticated software package make it a comprehensive solution for expanding the reach of traditional sleep labs.
  - The simplicity of the SleepScout system makes it practical for unattended sleep studies.
  - A built-in radio allows data to be viewed in real-time for instantaneous review, anywhere.



# 2007- SleepScout Specifications

- 9-channel device monitors: ECG, leg EMG, pulse oximetry, airflow, snore, thoracic and abdominal effort, body position and an auxiliary DC input.
- A 2.4 GHz radio provides real-time data, at ~15 m. through a wall and can then be sent through a PC and the Internet around the world.
- 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 SleepScout weighs less than 210 grams
- 2AA batteries power the device for over 12 hours.



# 2007- Sapphire PSG™

- Sapphire provides a more powerful tool to diagnose sleep disorders.
- The portable size makes the Sapphire wearable, eliminating the need for long lead wires that inhibit movement.
- Data transmitted by a 900 MHz or 2400 MHz radio to a nearby computer, and can then be retransmitted around the world for real-time viewing and scoring.
- Data can also be stored on a SD memory card for easy data download to a computer.



# 2007- Sapphire PSG Specifications

- *22 Channels:*

- 6 Channels of EEG

- F3-A2

- C3-A2

- O1-A2

- F4-A1

- C4-A1

- O2-A1

- 2 Channels of EOG

- LOC-A2

- ROC-A1

- ECG

- Temperature

- 3 Channels of EMG

- 2 Channels of Chin EMG

- Pulse Oximetry

- Airflow (pressure based)

- Snore (derived)

- Thoracic Effort

- Abdominal Effort

- Body Position

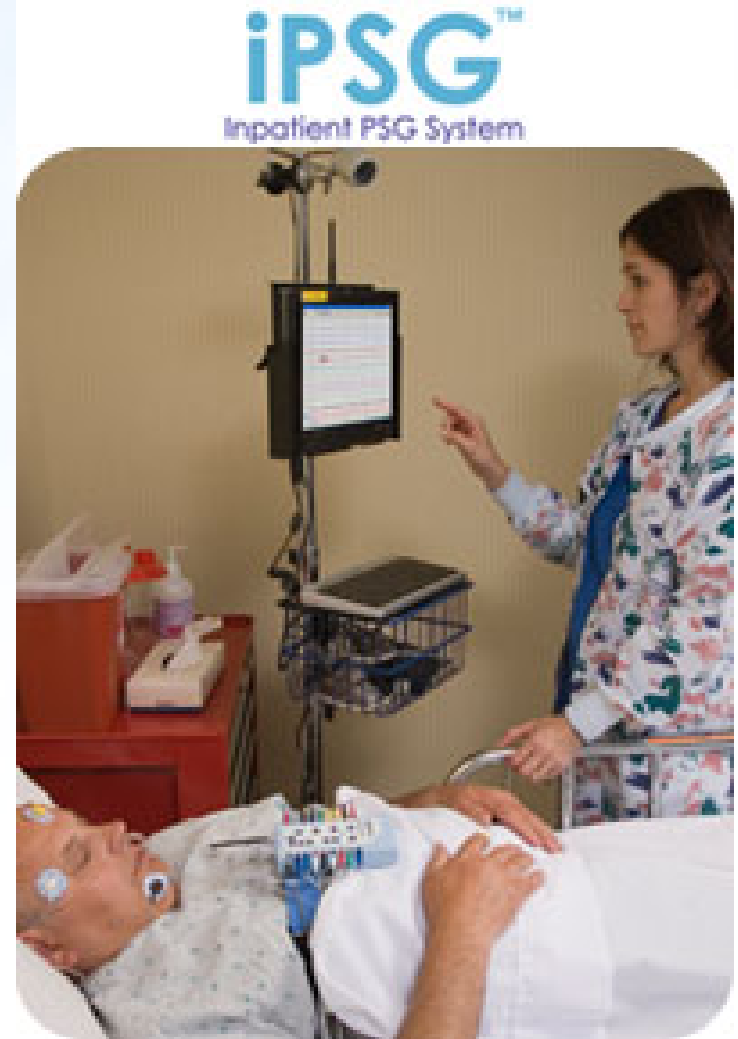
- Auxiliary DC

- The Sapphire weighs 538 grams
- 4 AA batteries power the device for over 12 hours.



# iPSG™

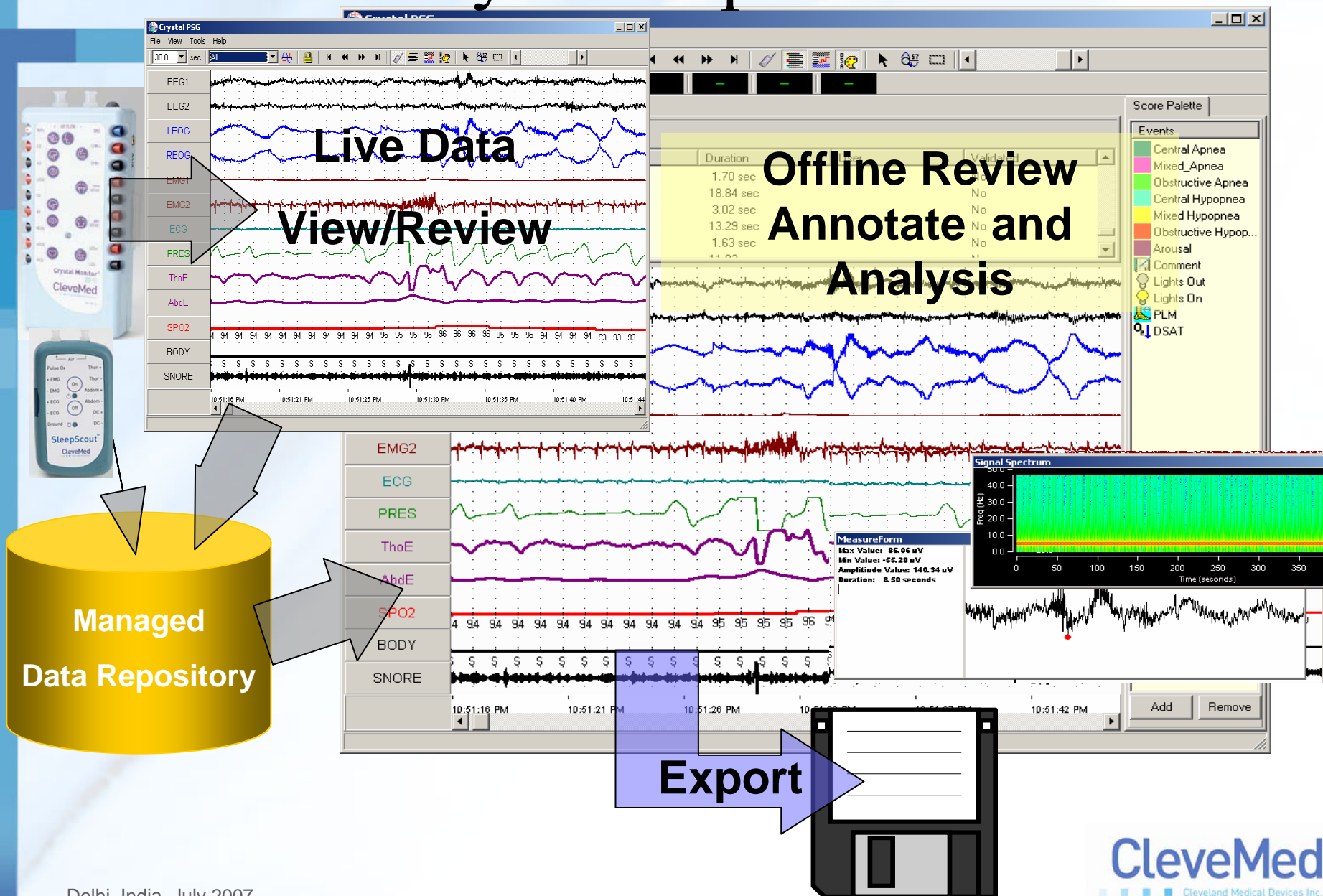
- In-Patient PSG
- Uses CleveMed wireless Monitors
- Mounts on an IV Pole
  - PC
  - Camera
  - Internet Connection or Digital Cell Phone Connection
  - Basket for supplies
- Provides real-time sleep data and video to anywhere in the world.



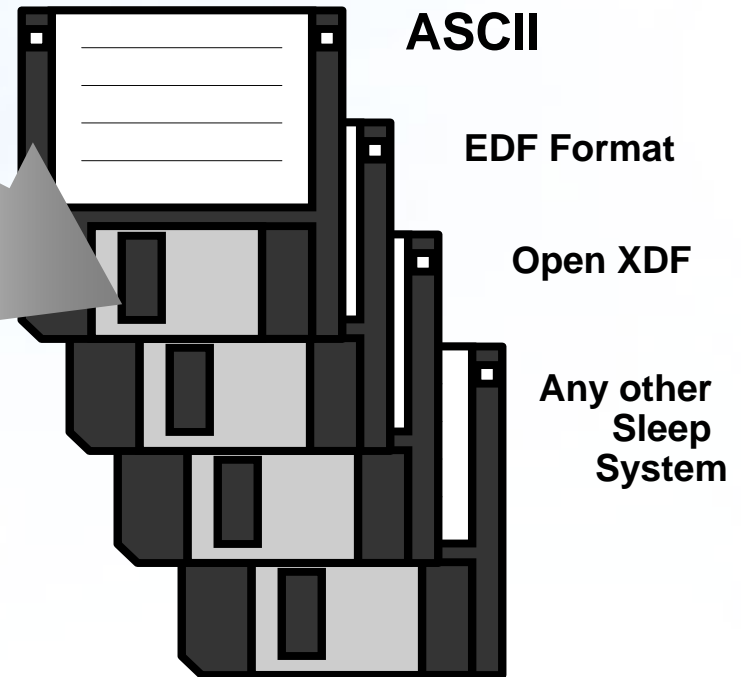
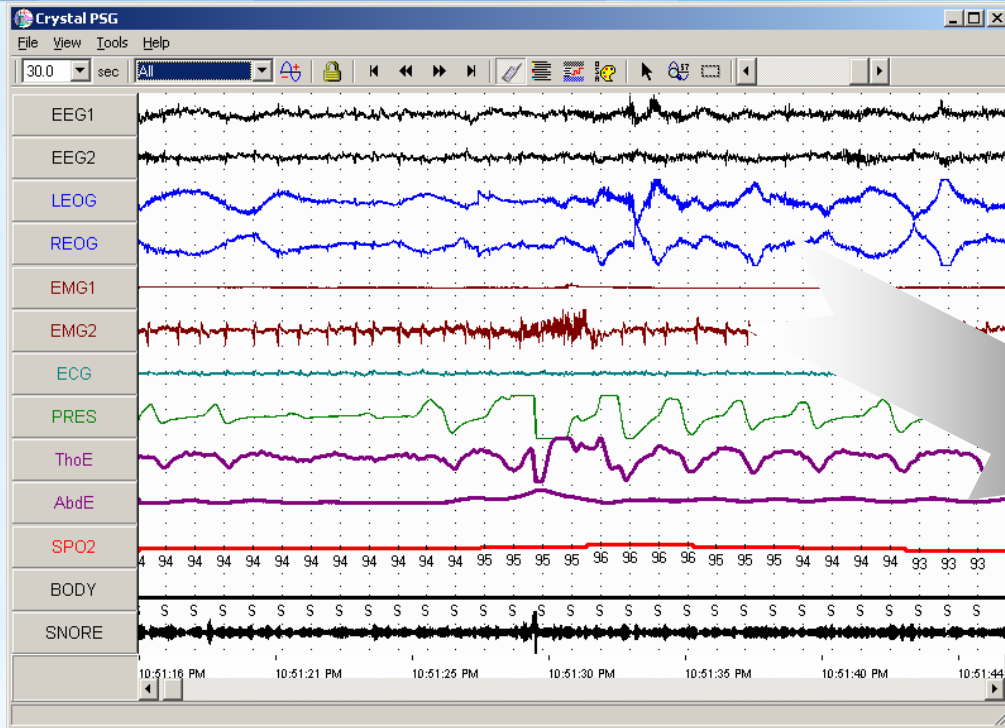
# PSG@Home

- PSG@Home
- A Briefcase Size PSG System
- Contains
  - PC
  - IR Camera
  - Cell Phone Digital Card

# Software - Crystal Capture Features



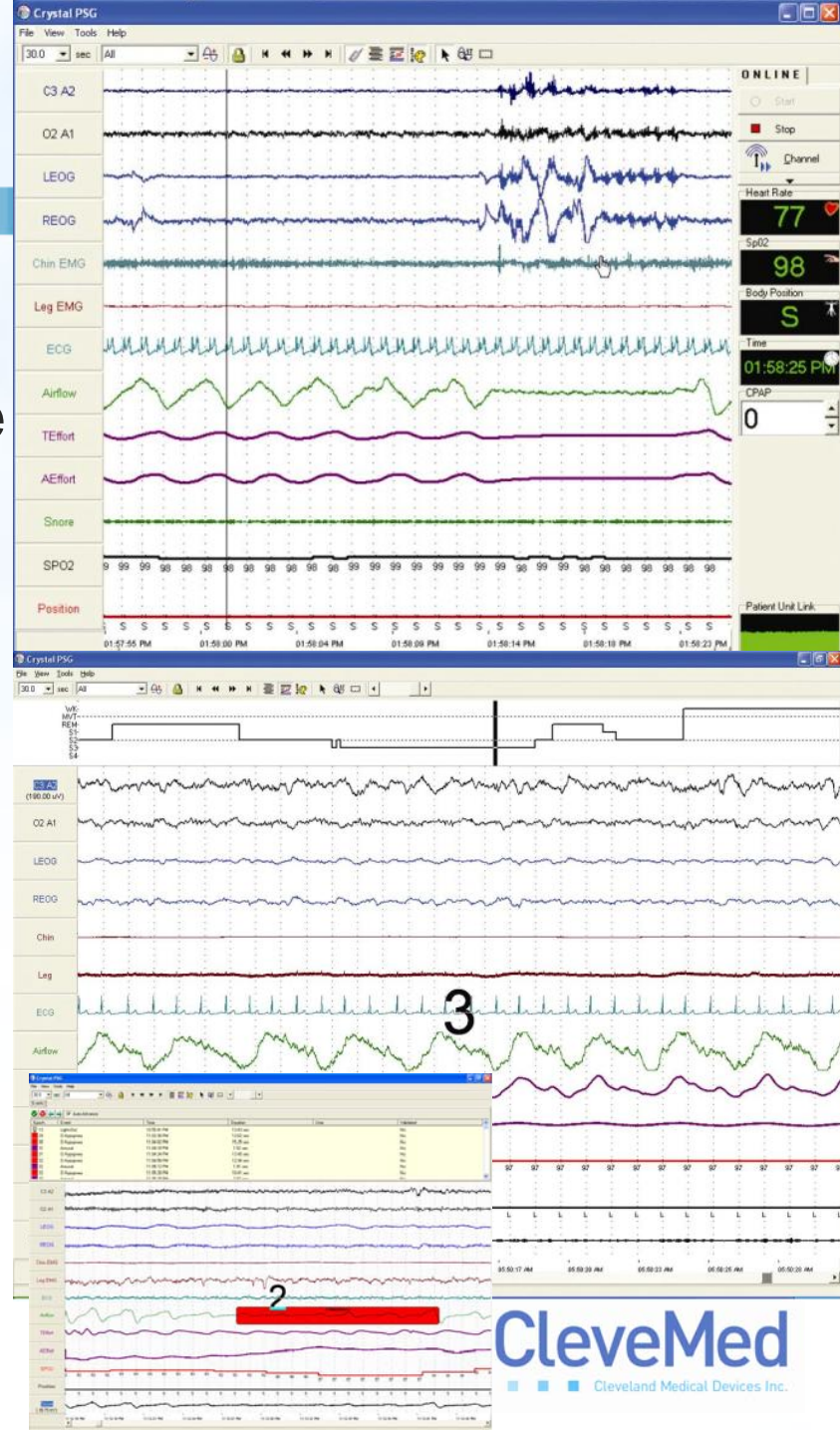
# Data Export



Export of data files to a variety of different other system formats will enhance the utility of the system for research collaboration

# Viewing/Scoring:

- Data can be viewed with fully configurable waveform displays
- The Display Manager controls the number of channels that are displayed and the filter and sensitivity settings for each trace.
- Manual scoring is quick and efficient
- 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.



# 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.



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 8, 2005 to rule out sleep disordered breathing. During the study, EEG, ECG 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%). Data sleep stage III was 3% and stage IV was 0% of total sleep time, N=15%. EEG arousals were noted at a frequency of 85/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 75% 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%.

4415 Euclid Ave., Cleveland OH 44103-5705  
FAX: (216) 791-6720



**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 + MVY (during SPT))  
Total NREM time (TNR) 224 min (1 + S2 + S3 + S4 (during TIB))  
Total REM time (TRM) 92.00 min (during TIB)

**Sleep Stages/Latencies**

STAGES	DURATION	TIB	TST	NORMAL	Latencies	From	From
(min)	(%)	(%)	(%)			Light off	2 sleep onset
WAKE	26.50	2.95			Sleep onset	0.00	
REM	92.00	14.62	8.62	20	REM	82.00	60.00
N1	29.50	4.69	2.77	5	N1	17.50	43.00
N2	188.00	29.88	17.62	50	N2	20.50	--
N3	6.50	1.03	0.61	10	N3	48.50	38.00
N4	0.00	0.00	0.00	10	N4	--	--
MVT	4.50	0.64	0.28				

Sleep efficiency 84.77% 100 x TST/TIB

**Arousal Data**

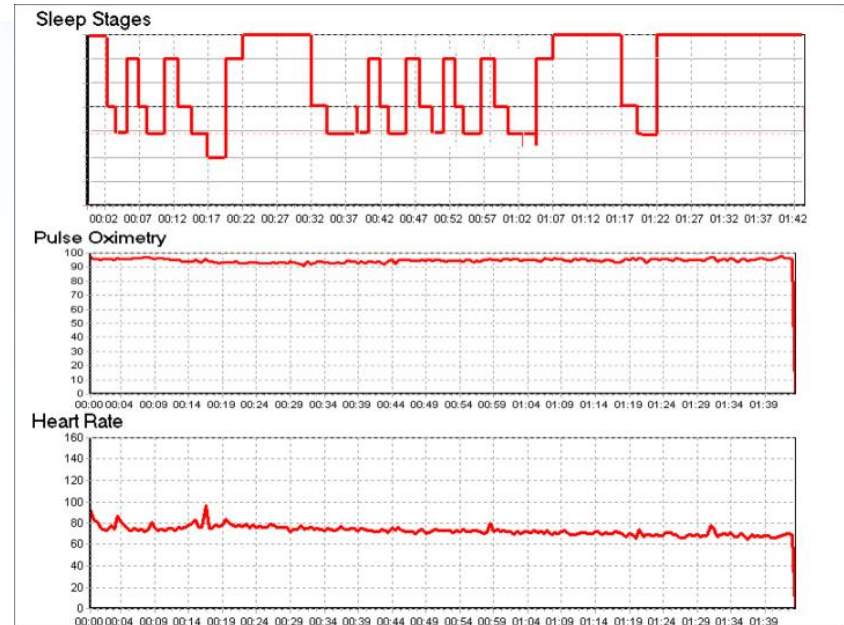
Total arousals 103  
Total arousals < 15 sec 0  
Total arousals with sleep event 16  
Total number of WTC or MVY episodes 5  
Arousal index 9.650 (avg)

**Respiratory Summary (Total sleep time)**

Apneas	Events	Index	Mean	Long
Hypopneas	94	13.82	21.87	93.00
Central	0	0.00	---	---
Mixed	0	0.00	---	---
Obstructive	94	9.44	12.63	36.14
Total Events	97	14.26	21.59	93.00
Apnea Total	0	0.44	12.63	36.14

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

REM	NREM	TST
#/h (REM)	#/h (NREM)	#/h (sleep)
22.83	11.73	14.26

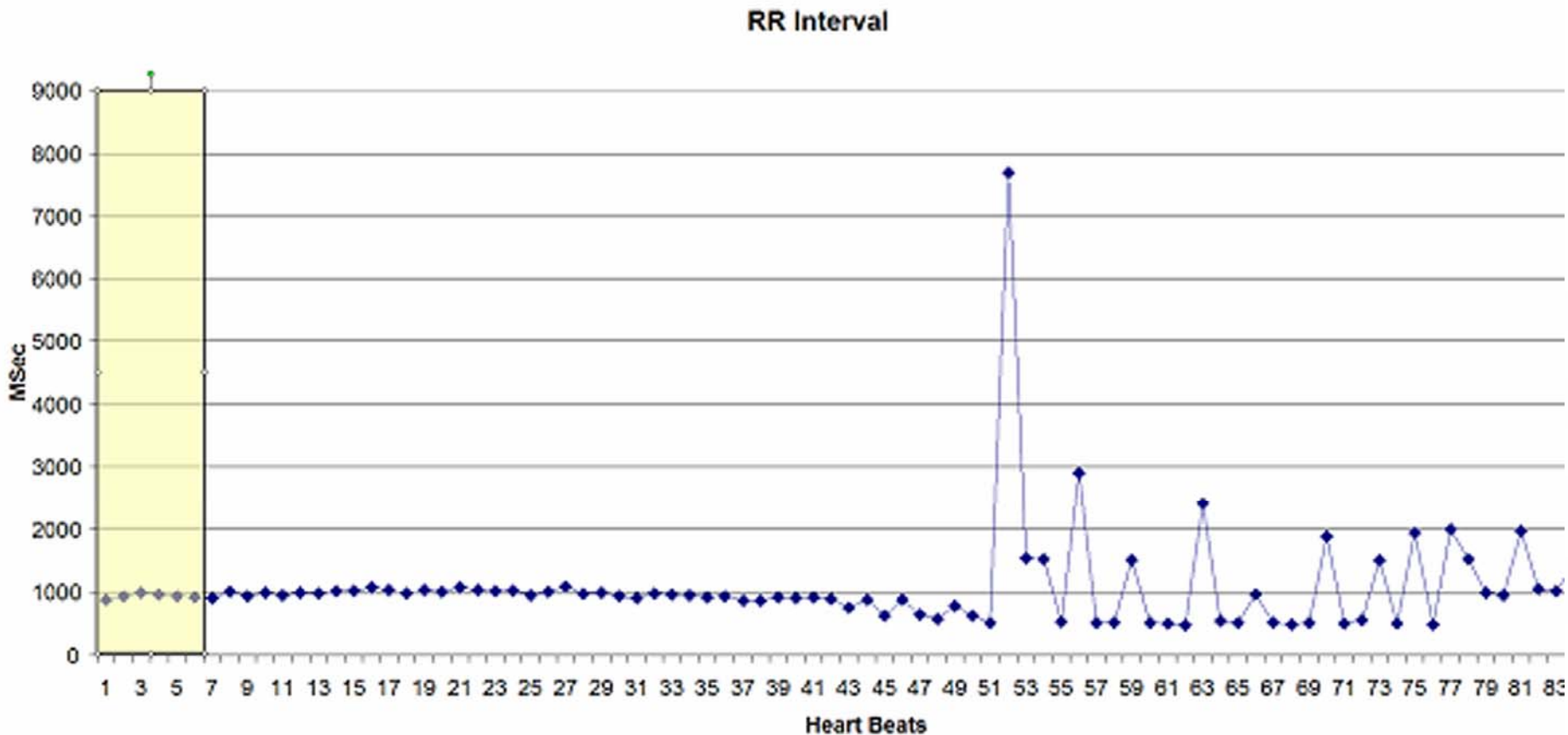


Cleveland Medical Devices Inc.

# Arrhythmia Analysis Software

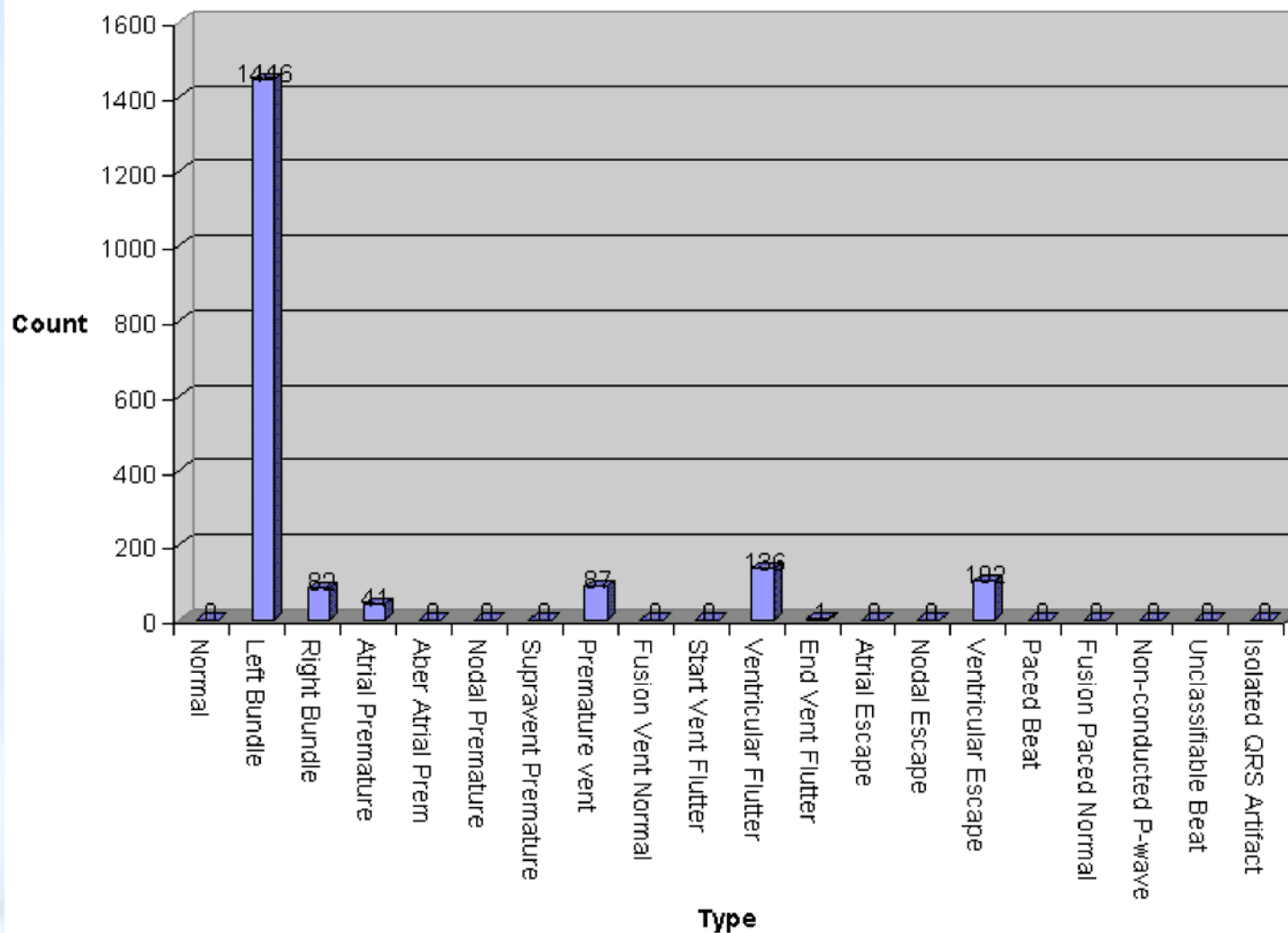
- Many studies have shown a strong link between cardiovascular disease and sleep disorders.
- A new, innovative, neural network based analysis software, capable of accurately detecting heart rate variability and many cardiac arrhythmias for the sleep specialist, was developed and tested against the MIT Arrhythmia Data Base, 108,000 heartbeats.
- The wave analysis section, that detects heartbeats, has a **98.7% accuracy**.
- The neural network based section has greater than a **96% success categorizing heartbeats as normal or to a specific arrhythmia**.

# Arrhythmia Heartbeat Detection, 98.7%



# Arrhythmia Classification Results, 96%

Arrhythmia Histogram



# Crystal Monitors Advantages Over Other Traditional Sleep Systems

- Lower Cost
- Available on two frequencies for use in any country
  - 900 MHz.
  - 2.4 GHz.
- Easy to use in non-traditional environments such as hospitals and nursing homes, extending the reach of the sleep lab.
- Simple to use, but provides full reimbursement (CPT Code 95810)
- FDA cleared to market
- SleepScout Screener also available for sleep apnea or to diagnose SDB

# Conclusion

- Four polysomnography diagnostic systems (20-S, 20-B, SleepScout and Sapphire PSG ) are available to provide wireless and remote diagnostic sleep studies or screenings in sleep labs, hospitals, homes, or any location around the world.
- Automated scoring and reporting makes the post-study paperwork easy for sleep professionals.
- The handheld, battery operated hardware and the software were primarily developed under grants from the US National Institutes of Health.

# ACKNOWLEDGMENT

Many thanks to:

The US National Institutes of Health

- National Institutes of Neurological Disorders and Stroke
- National Heart Lung and Blood Institute

Which provided funding contributing to the development of the hardware and software under a number of Small Business Innovation Research programs.

# For Questions Contact



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