

A New Wireless Sleep Disorders Diagnostic Device

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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 approved
 - Additional Optional Features (not yet FDA approved):
 - Arrhythmia Analysis
 - *NeuroCAP*TM
 - *NeuroAD*TM

More than a Decade of Wireless EEG

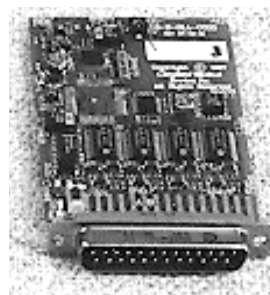
1994



1996



1997



1999



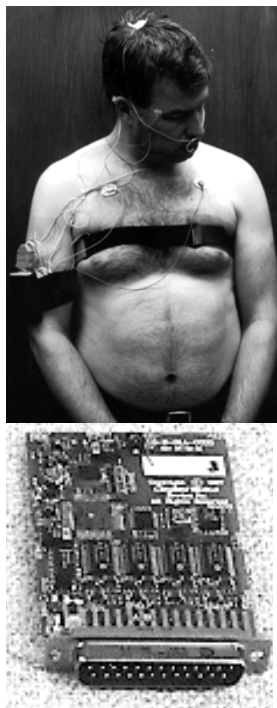
Auditory Evoked Response Epilepsy

Sleep

Non-Convulsive Seizures

Background -continued

1997



2002



2004



Research Sleep Device Crystal Monitor 16

Crystal Monitor 16-S

Crystal Monitor[®] Model 20-S Wireless Sleep Diagnostic Monitor



Crystal Monitor[®] Model 20-S Hardware

Crystal Monitor Model 20-S 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
- New 2- way radio for more robust radio link (ack-nak) with retransmission of packets

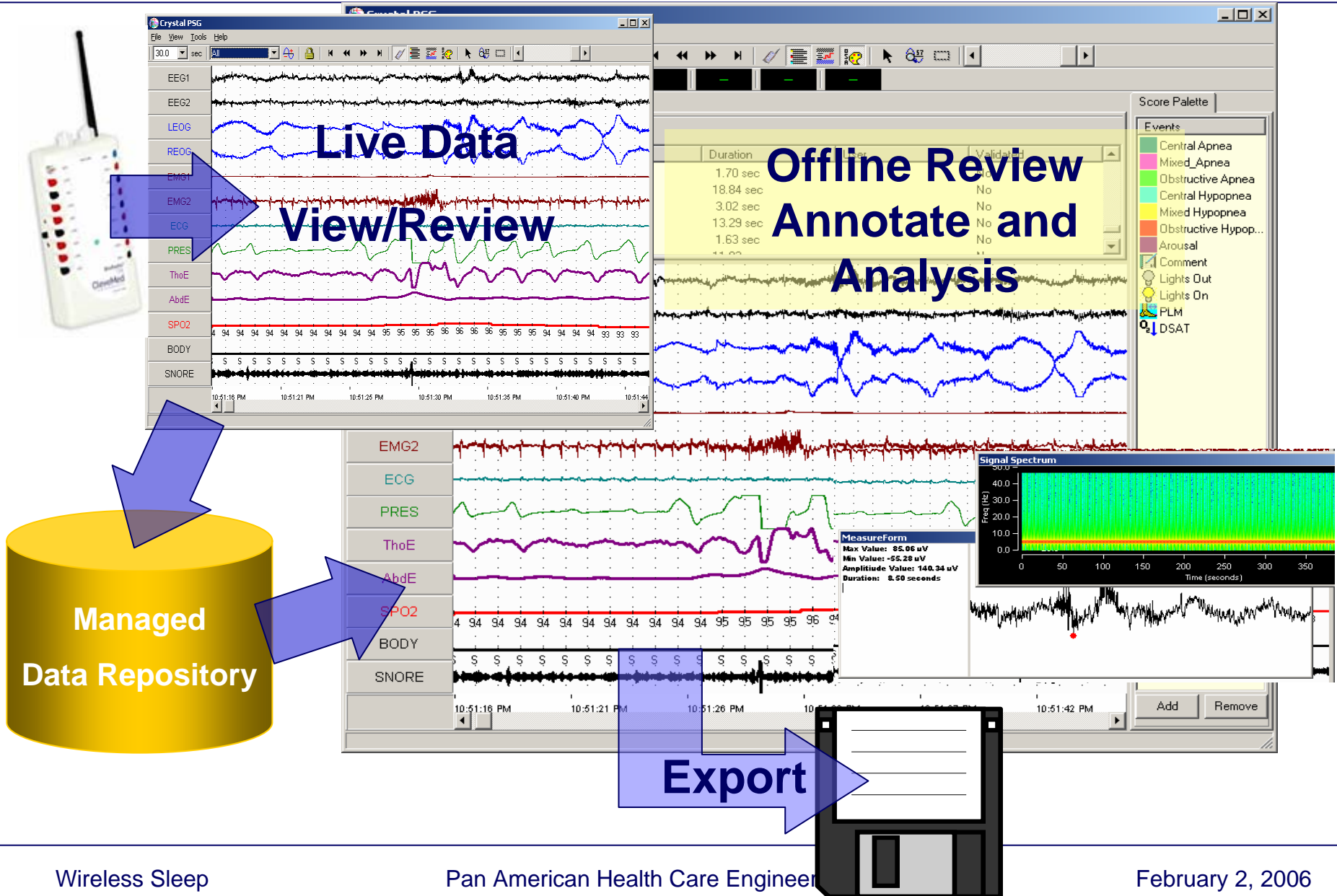


Crystal Monitor Model 20-S Specifications

- Dimensions: 135 mm x 63 mm x 25 mm (5.3" x 2.5" x 1") (not including 3" antenna)
- Weight: 210 grams (7.3 oz.) with batteries
- Radio Range: 80 feet (25 meters) through two walls
- Filter Input bandwidth 0.5 Hz - 250 Hz. 960 sps (-3dB attenuation); CMRR 100 dB
- Noise < 2 μ V peak-to-peak (< 1 μ V RMS) (0.5 Hz – 100 Hz)
- Input Impedance > 20 M Ω @ 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



Crystal Monitor[®] Model 20-S Software



Annotation Capability

A simple and complete interface will allow users to view and navigate through their collected data and make necessary annotations for later review by peers, or for report compilation

A highly configurable waveform display provides data visualization for virtually any clinical application

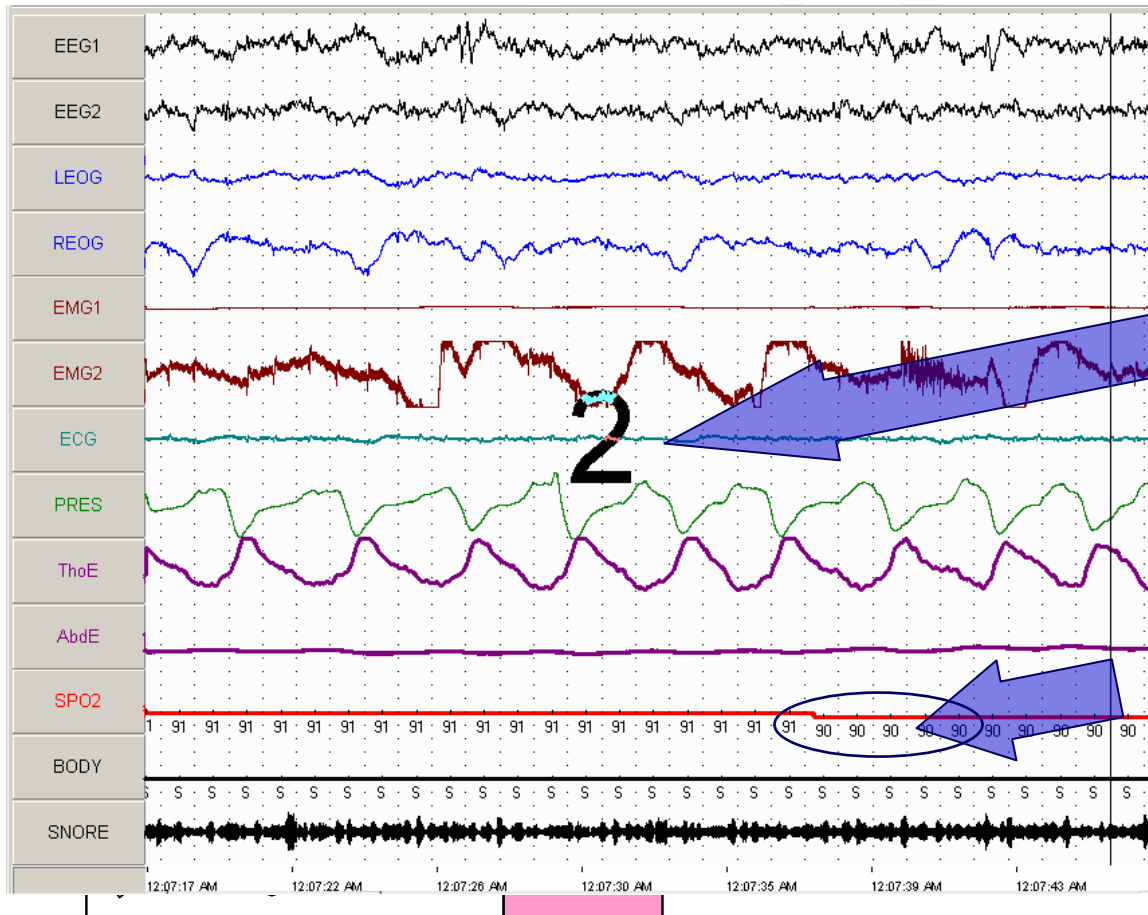
Configurable Multi-trace Waveform Viewer

Epoch	Event	Time	Duration	User	Validated
744	Arousal	5:01:12 AM	1.70 sec		No
745	C.Apnea	5:01:21 AM	18.84 sec		No
745	Arousal	5:01:41 AM	3.02 sec		No
749	C.Apnea	5:03:19 AM	13.29 sec		No
749	Arousal	5:03:33 AM	1.63 sec		No

Name	Color	Input	Range	Offset	Units	High-Cut	Low-Cut	Notch
EEG1	Black	EEG1	190.000	0.000	µV	(Off)	0.05 Hz	(Off)
EEG2	Black	EEG2	190.000	0.000	µV	(Off)	0.05 Hz	(Off)
LEOG	Blue	LEOG	190.000	0.000	µV	(Off)	0.05 Hz	(Off)
REOG	Blue	REOG	190.000	-14.461	µV	(Off)	0.05 Hz	(Off)
EMG1	Red	EMG1	190.000	0.000	µV	(Off)	0.05 Hz	(Off)
EMG2	Red	EMG2	190.000	0.000	µV	(Off)	0.05 Hz	(Off)
ECG	Green	ECG	7.000	0.000	mV	(Off)	0.05 Hz	(Off)
PRES	Green	PRES	19.002	0.000	mV	2.00 Hz	0.05 Hz	(Off)
ThoE	Purple	ThoE	43.339	0.000	mV	(Off)	(Off)	(Off)
AhrF	Purple	AhrF	4.000	0.000	mV	(Off)	(Off)	(Off)

CleveMed's Waveform Viewer component provides features you cannot buy

Multi-Channel display with shared screen area in order to mimic legacy paper stripcharts



On-page labeling

High-speed smooth scrolling operation with low CPU utilization

On-trace labeling

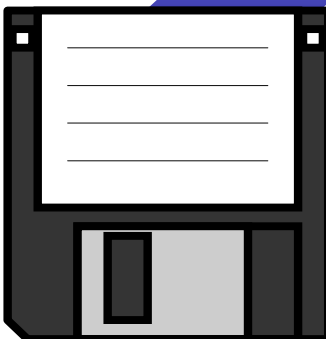
A dual-file storage architecture provides maximum flexibility and storage economy

A human-readable ASCII Layout file-format is capable of describing the encoding of the data taken from any system. Its separation from the raw data allows easily supplement information to be added to the record

A binary file provides efficient storage of the raw physiological data.

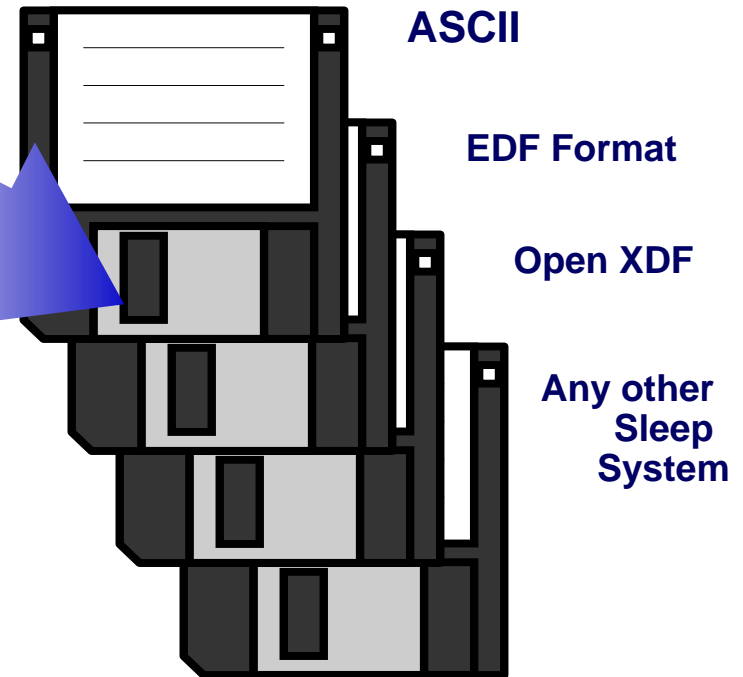
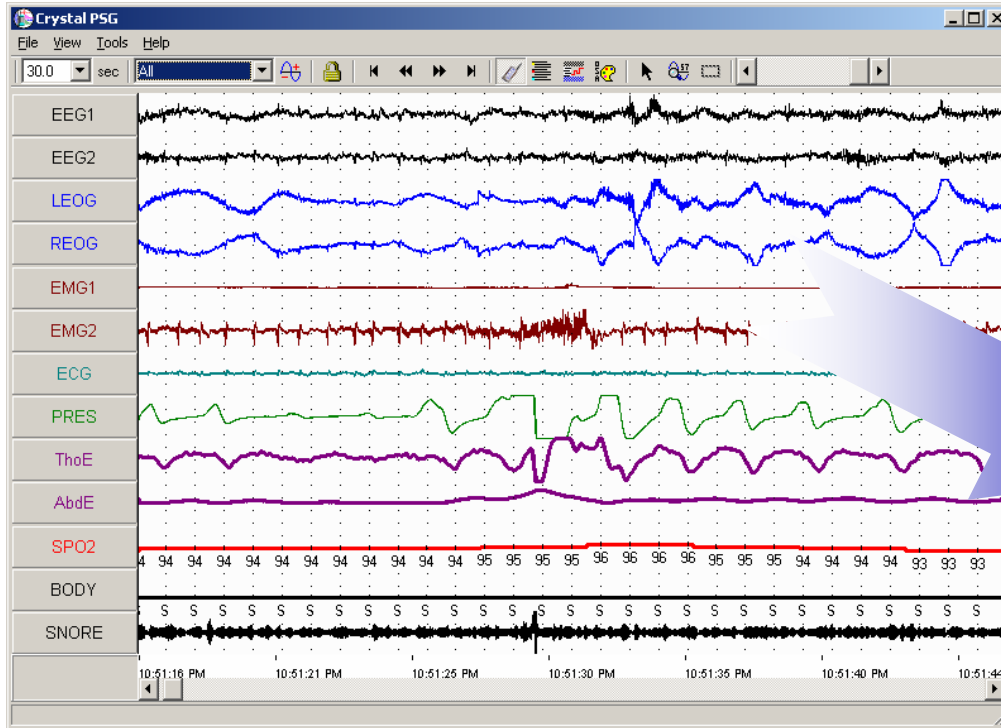
```
[FileInfo]
Version=1.0
Header=Test bed 1.0
FileType=Interleaved
DataFile=C:\CleveMed\CrystalPSG\MainProgram.exe\..\Data\Sample.psd
NumChannels=17
RecordDuration=0.00390625
Description=CPAP
TimeZone=0
[Study]
StartDate=6/8/2005
StartTime=82156.3990001846
[Channels]
Channel_0=InputName=EEG1,Units=uV,BitResolution=12,Index=0,SampleRate=256,Up
Channel_1=InputName=LEOG,Units=uV,BitResolution=12,Index=1,SampleRate=256,Up
Channel_2=InputName=EEG2,Units=uV,BitResolution=12,Index=2,SampleRate=256,Up
Channel_3=InputName=REOG,Units=uV,BitResolution=12,Index=3,SampleRate=256,Up
Channel_4=InputName=EMG1,Units=uV,BitResolution=12,Index=4,SampleRate=256,Up
Channel_5=InputName=AbdE,Units=mV,BitResolution=12,Index=5,SampleRate=256,Up
Channel_6=InputName=ThoE,Units=mV,BitResolution=12,Index=6,SampleRate=256,Up
Channel_7=InputName=EMG2,Units=uV,BitResolution=12,Index=7,SampleRate=256,Up
Channel_8=InputName=ECC,Units=mV,BitResolution=12,Index=8,SampleRate=256,Up
Channel_9=InputName=AUX,BitResolution=12,Index=9,SampleRate=256,UpperScale=8
Channel_10=InputName=PRES,BitResolution=12,Index=10,SampleRate=256,UpperScale=8
Channel_11=InputName=BPOX,BitResolution=12,Index=11,SampleRate=256,UpperScale=8
Channel_12=InputName=BPOSY,BitResolution=12,Index=12,SampleRate=256,UpperScale=8
Channel_13=InputName=BODY,BitResolution=12,Index=13,SampleRate=256,UpperScale=8
Channel_14=InputName=SPO2,BitResolution=12,Index=14,SampleRate=256,UpperScale=8
Channel_15=InputName=HR,BitResolution=12,Index=15,SampleRate=256,UpperScale=8
Channel_16=InputName=BATT,BitResolution=12,Index=16,SampleRate=256,UpperScale=8
Channel_17=InputName=,BitResolution=12,Index=17,SampleRate=256,UpperScale=8
```

ASCII Layout File



```
1d0h: 38 0D 0A 43 68 61 6E 6E 65 6C 5F 33 3D
1d4h: 2C 42 69 74 52 65 73 6F 6C 75 74 69
1f8h: 3D 32 35 36 2C 55 70 70 65 72 53 63
21ch: 30 2C 41 44 43 55 70 70 65 72 3D 34
240h: 30 0D 0A 43 68 61 6E 6E 65 6C 5F 32
264h: 56 2C 42 69 74 52 65 73 6F 6C 75 74
280h: 69 72 31 34 70 72 72 52 53
2a0h: 2C 41 44 43 55 70 70 65 72 3D 34 30
2c0h: 3D 0A 43 68 61 6E 6E 65 6C 5F 33 3D
2e0h: 69 74 52 65 73 6F 6C 75 74 69 6F
2f0h: 2 35 36 2C 55 70 70 65 72 53 63 61
310h: 2C 41 44 43 55 70 70 65 72 3D 34 30
360h: 0D 0A 43 68 61 6E 6E 65 6C 5F 34 3D
384h: 42 69 74 52 65 73 6F 6C 75 74 69 6F
```

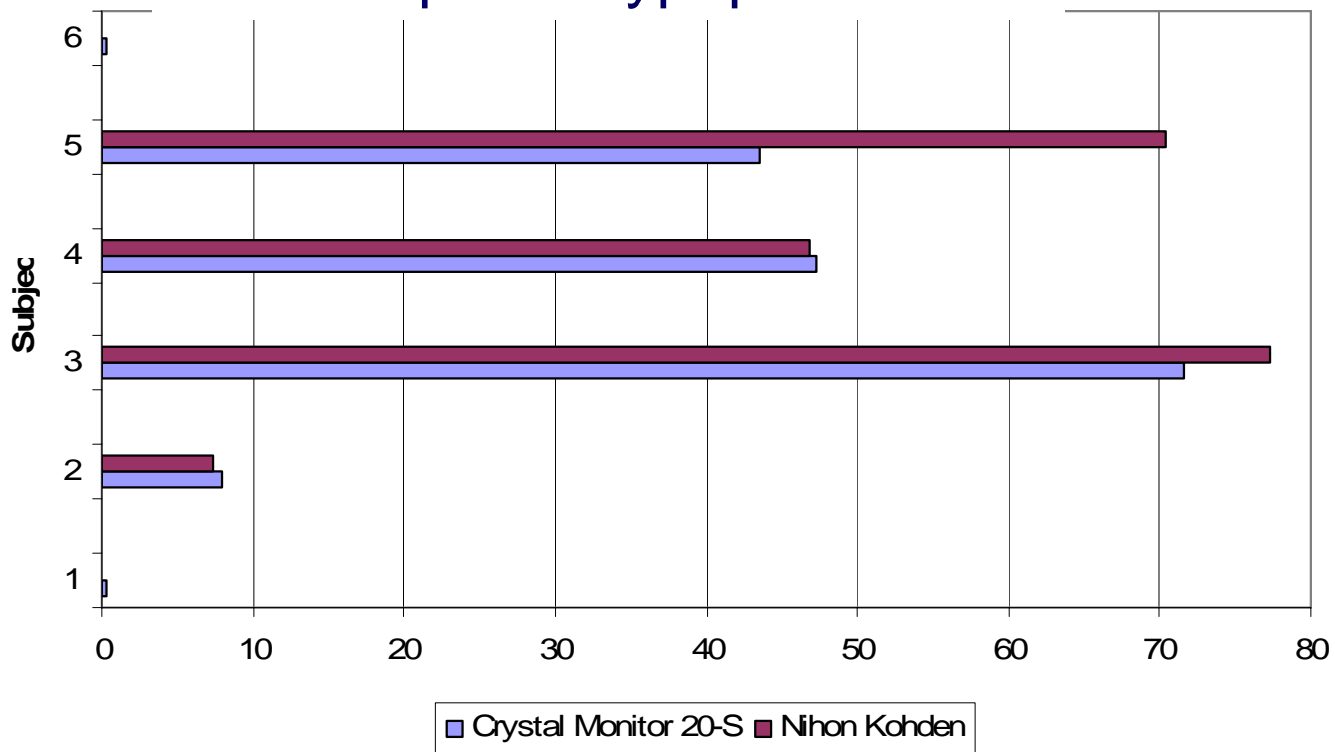
Binary Data File



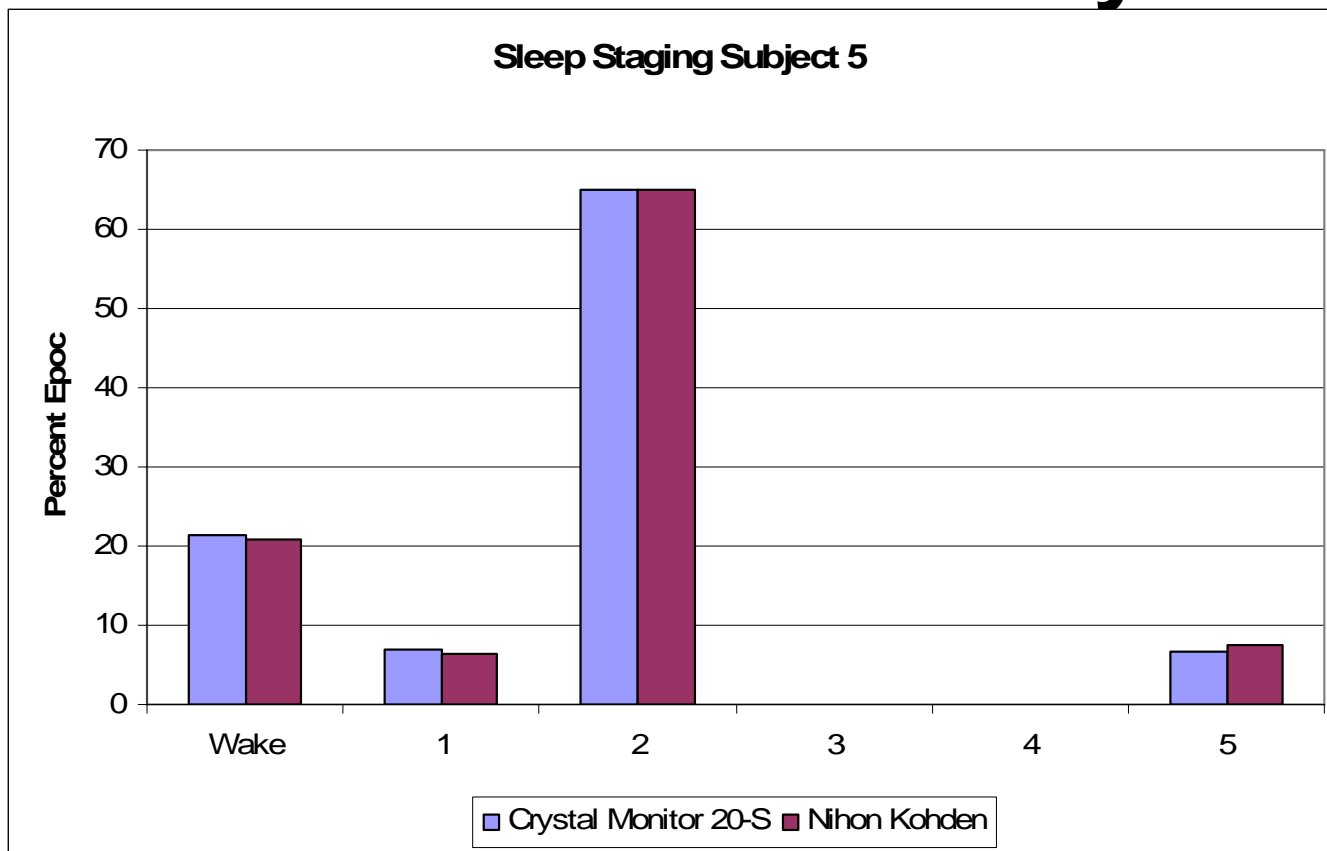
Export of data files to a variety of different other system formats will enhance the utility of the system for research collaboration

Comparison of CleveMed Crystal Monitor 20-S Versus a Nihon Kohden System

Apnea Hypopnea Index



Comparison of CleveMed Crystal Monitor 20-S Versus a Nihon Kohden System



Advantages over other traditional sleep systems

- Lower Cost
- Not on same frequency as other devices
 - 900 MHz., not 2.4 GHz.
 - Is not interfered with by computers
- Simple to use, but provides full reimbursement (CPT Code 95810)
- FDA approved

Crystal Monitor[®] Model 20-S Options:

Arrhythmia Analysis Software

NeuroCAP[™]



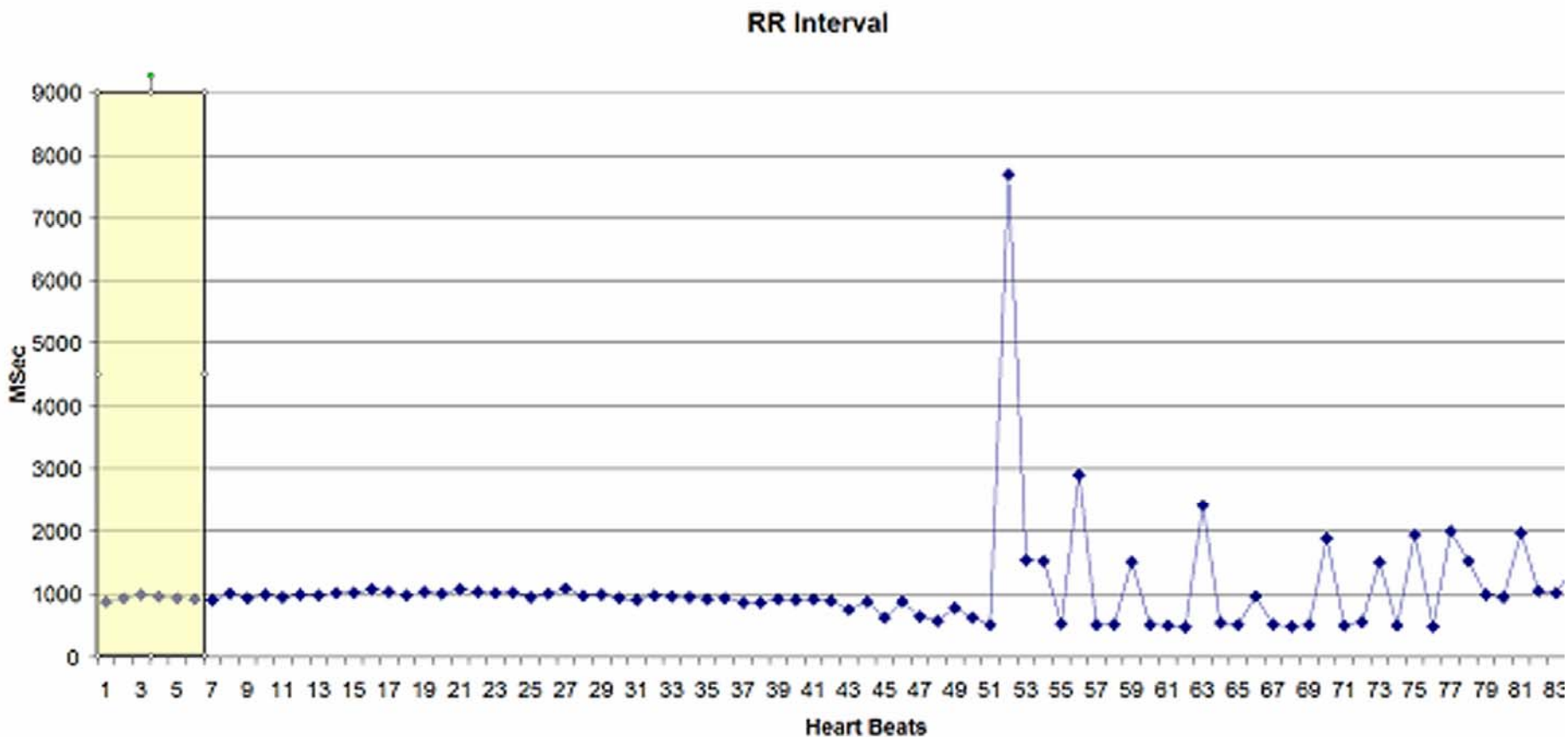
NeuroAD[™]



Arrhythmia Analysis Software

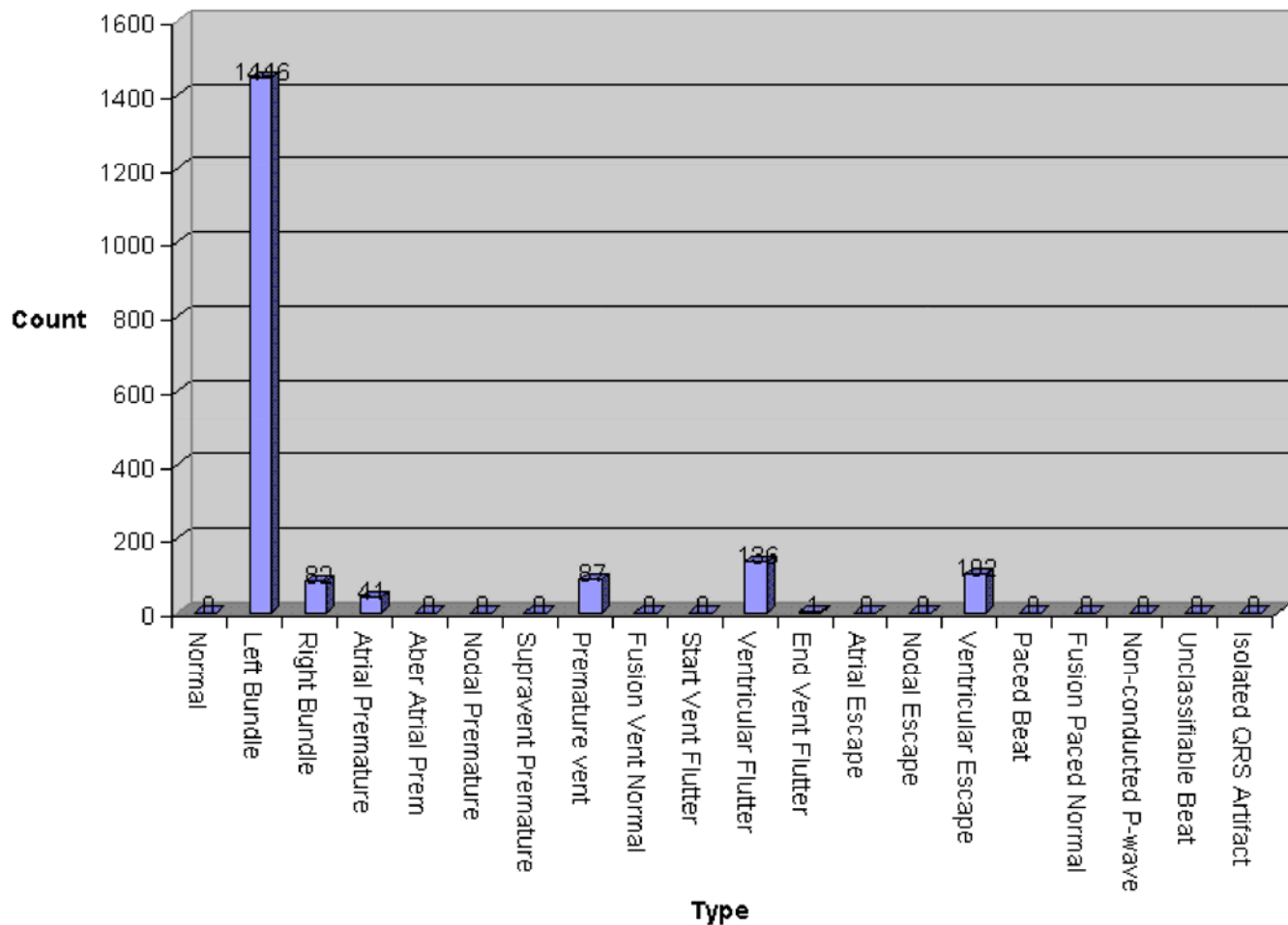
- Many studies have shown a strong link between cardiovascular disease and sleep disorders.
- A new, innovative, neural network based analysis software, capable of accurately detecting heart rate variability and many cardiac arrhythmias for the sleep specialist, was developed and tested against the MIT 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



NeuroCAP

- **Quantifiable and Rapid Test of Sleepiness is Needed for Sleep Medicine** (*2003 National Sleep Disorders Research Plan*)
- **To Address this Need, We Have Developed NeuroCAP™, Neuro Cognitive Assessment Package, an Ambulatory System for Fast/Objective Sleepiness Assessment**
- **NeuroCAP™ Measures are Based on Simultaneous Analysis of EEG and Behavioral Response to Auditory Cues**

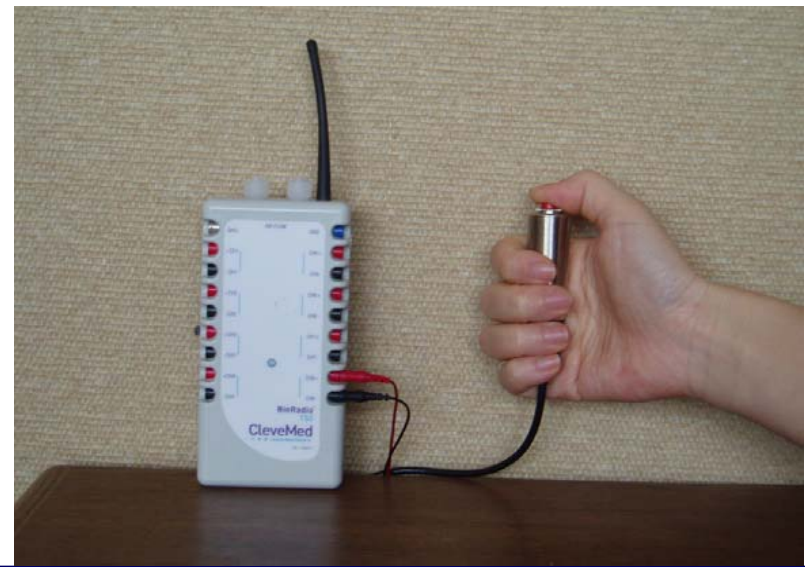
NeuroCAP Hardware

EEG and Subject's Response are Acquired by a Miniaturized Wireless Data Acquisition Unit

(1-7) EEG + Push-Button (Response Delay)

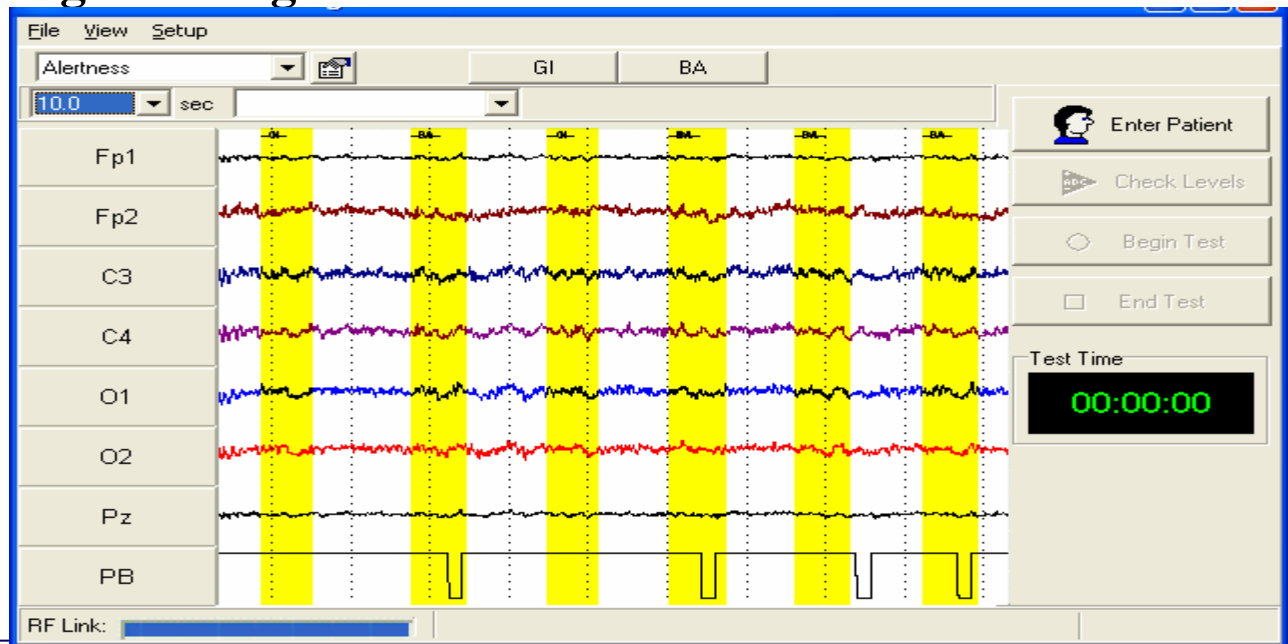
NeuroCAP™ System

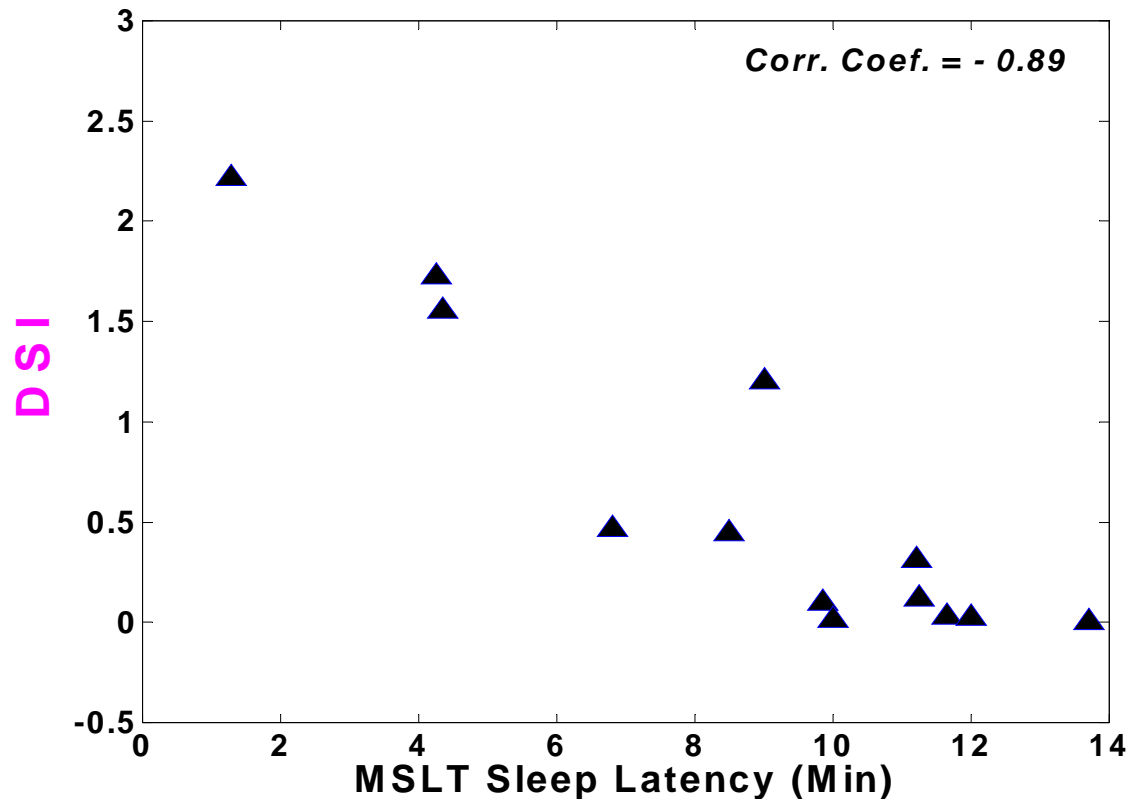
EEG Transmitter, Push-Button



NeuroCAP Test Protocol

- **Subjects are Instructed to Stay Awake/Alert While Being Challenged by a Sleep Conducive Environment**
- **A Nearby PC Randomly Delivers a Mixed Sequence of Target and Non-Target Auditory Tones every 2-5 Seconds for 15 Minutes**
- **Subjects Are Instructed to Press the Push Button as Quickly as Possible Upon Hearing the Target Tone**





DSI Provides Closer Agreement with MSLT Results:

- Stronger Correlation (-89%) with Mean Sleep Latencies (MSL)
- Better Differentiation of Clinically-Defined **Mild, Moderate, and Severe Sleepiness Conditions**

ANOVA Analysis on NeuroCAP Indices Grouped According to Patient's Mean Sleep Latency (MSL)

	MSL <5 Min (Severe Sleepiness)	5 < MSL <10 (Moderate Sleep.)	MSL >10 (Mild Sleep./Normal)	P- Value
Behav. Index	0.53 ± 0.23	0.22 ± 0.20	0.07 ± 0.07	0.013
EEG Index	3.89 ± 1.45	1.56 ± 0.62	1.14 ± 0.65	0.004
DSI	1.83 ± 0.34	0.41 ± 0.47	0.09 ± 0.13 *	0.0001

* DSI of Patients with MSL>10 Min is Statistically Similar to The Results of a Separate Study Evaluating **12 Normal Alert Volunteers** (DSI: **0.037 ± 0.04**)

NeuroAD

- A test similar to NeuroCAP, but with different algorithms
- Diagnoses Attention Deficit Disorder, can be used as a screener
- Not FDA approved, needs IRB approval

ACKNOWLEDGMENT

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For Questions Contact

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