An introduction to Dental Sleep Medicine

Innovative products in a simple business workflow.







For Today's Business of Sleep.[™]

Who we are

Over the past 15 years, BRAEBON has evolved into a single-source provider of PSG

sensors, accessories, Home Sleep Testing (HST) systems, and software solutions for sleep medicine.

In Dental Sleep Medicine, our mission is to be **the** company to provide valued alternatives. We are committed to providing exactly what you need - products of the highest quality that are easy to use, more reliable and better-supported.

We have developed a unique combination of products at the forefront of technology for today's busy environment of dental sleep medicine. We continue to evolve so that our products will be positioned to solve new problems the dental sleep medicine community may face in the future.

In addition to our high-quality products, BRAEBON offers clients unparalleled aftersales support with industry-leading warranties, technical support and our helpful Rapid Replacement Program.

BRAEBON is an ISO 13485 and CE compliant company with an international customer

base – our products are used on six continents.

Our technological advancements include:



Home Sleep Apnea Testing Recorders

2

Sensors

Powerful Workflow Management Software



DENTAL SLEEP MEDICINE



Enter the mainstream.

Many sleep professionals often consider dentists who treat sleep apnea to be on the periphery. Technology that uses processed signals and algorithms will only reinforce this view. BRAEBON offers dentists mainstream technology and overcomes this challenge by helping dentists use the same technology used in a sleep lab - real waveforms directly measuring physiological signals to meet new guidelines.

As easy as 1,2,3...

Clinical Workflow

1. Home Sleep Test (Baseline) Perform a MediByte[®] study to get a baseline of the patient's snoring and apnea. Get a diagnosis from an M.D.

2. Fit / Adjust Oral Appliance

If the results of the baseline MediByte[®] study indicate room for improvement, fit the patient with an oral appliance. BRAEBON offers a temporary oral appliance for patients waiting for their permanent solution.

Perform a follow-up MediByte[®] test to monitor the effectiveness of your oral appliance therapy and to make any adjustments needed. Repeat as needed.

3



3. Home Sleep Test



MAINSTREAM **PRODUCTS AND SERVICES OVERVIEW**



The MediByte[®] Jr.

Powerful. Easy. Compact.

The MediByte[®] Jr uses the same technology as a sleep lab in the comfort of the home. Readily provides AHI for titrating oral appliances.





4



We've teamed with leading dentists around the world to help you receive the best education so you are comfortable using the MediByte[®] with the most advanced oral appliances available.





The SnoreByte[®] Kit

Initial. Interim. Immediate.

Ideal to help determine a patient's suitability for an oral appliance, the SnoreByte® Patient Kit is the perfect low-cost temporary oral appliance solution for initial, interim or immediate use.



Issue

Many view dental sleep apnea treatment to be on the periphery.

Solution

Don't let your recorder technology be another barrier.



The MediByte[®]

Advanced. Innovative. Unique. The 12-channel MediByte® enables you to titrate both AHI and snore volume in dB. This powerful product exceeds new guidelines. Bruxism, combination therapy with CPAP, multiple nights – MediByte® efficiently does it all.

Our turnkey workflow process business solution software is sophisticated, yet simple. EasyHST integrates with our MediByte® family to seamlessly manage patient intake, process questionnaires, generate reports, create interpretation letters and manage your patients' MediByte® data.

Optional Home Delivery Simple. Cost-Effective. Fast. BRAEBON has teamed with a leading home sleep apnea testing company to provide direct MediByte® delivery right to the patient's door. Medical interpretation and scoring, provided by Board Certified Sleep Physicians and Board Registered Sleep Technologists, is a snap! For more information, call 1-888-462-4841.

Free Provinces inclusions in the part in the			
	Automation (
A REAL PROPERTY AND	100 B		

Optional Scoring Service Convenient. Efficient. Reliable. BRAEBON provides a sleep scoring service using Registered Sleep Technologists to provide MediByte[®] scoring to MediByte[®] Dental users. If you are interested in using this service, please call 1-888-462-4841 x 218 or email info@braebon.com.

Robust. Reliable. Accurate.

The world's smallest recorder just got simpler. A reliable and cost-effective alternative to the 12-channel MediByte[®] now comes in a Type 3, six-channel recorder – the MediByte[®] Junior.

This six-channel device features all the benefits of a full-scale Type 3 recorder in the same small package. Using the MediByte[®] Junior and its analysis software is as easy as a few mouse clicks. The included software meets guidelines for full disclosure and contains simplified tools for manually scoring or editing automated results.

For your convenience, the MediByte[®] Junior is also designed for two-night studies and CPAP-compatibility for hybrid therapy. Go beyond the single nine-hour recording with the option to capture two consecutive nights: one for oral appliance treatment and one for baseline.

MediByte[®] Jr Recorder,

To produce the most reliable results, the patent-pending MediByte® Junior uses the same technology found in sleep laboratories. Rock-solid components, cuttingedge technology and innovative products combine to deliver a home sleep apnea Oximetry finger probe Oral + Nasal Cannula

Patient Kits: Model 8115: Oronasal cannula, battery, finger probe wrap Model 8119: Oronasal cannula, battery, tape

MediByte[®] Software Setup & Download Wizard Full disclosure Assisted and manual scoring Event editing

testing solution like no

other.

6

Titrate AHI

The MediByte[®] Jr empowers you to titrate your oral appliance to the optimum apnea and hypopnea index using the same biosensors and technology found in the best sleep laboratories. Moreover, you can combine your oral appliance therapy with CPAP for patients in need of combination therapy.

Record Multiple Nights

Go beyond the single nine-hour recording with BRAEBON's products and solutions. The MediByte[®] family of devices offers you the option to capture two consecutive nights: one for oral appliance treatment and one for baseline.

Exchange Data with Healthcare Professionals

Results from studies can be shared among dentists and other healthcare professionals. Use BRAEBON's HST software to manage data and offer advanced analysis and reporting technology, streamlining the steps to interpretation.

Use with CPAP

The MediByte[®] Jr can be used with CPAP to record CPAP pressure, CPAP flow and snoring. This is useful in cases where oral appliances are combined with CPAP.

Body Position

Accurately record body position to effectively manage positional apnea.

Central, Obstructive, Mixed Apneas

True Type 3 recorders use RIP respiratory effort belts on the chest, abdomen, or both.

Powerful. Easy. Compact.

MediByte[®] Junior Type 3 Recorder

Using patent-pending technology, this next generation MediByte[®] Junior Home Sleep

Testing (HST) device provides simple, cost-effective and reliable oral appliance monitoring for sleep apnea. Constructed of smooth ABS plastic with an extra-strength lockable LEMO^{$^{\text{M}}$} connector, the MediByte[®] Junior was designed for durability and reliability. Weighing less than three ounces, it is ideal for both adult and pediatric studies. Side wings attach the unit to the chest effort belt so a holding vest or pouch is not required.

On-board oximetry and an internal accurate pressure sensor eliminate external transducers. An oversized, tactile push-button allows the patient to indicate specific events during a recording. Studies are stored on the internal memory and downloaded via a USB computer connection.

This recorder is the next generation of screening devices. CPAP/AutoPAP compatible, the MediByte[®] Junior may be used during titration studies or for follow-up evaluations.

MediByte[®] Junior Software

A miniature

6-channel Home Apnea Tester that records up to two nights on a single

battery.

8

The MediByte[®] Junior software is easy to use, yet flexible enough to analyze a number of user-selected signals. DIY or use our optional

The MediByte[®] Junior Software is an exclusive application that simplifies every step of a study, from setup to analysis to reporting. It is extremely easy to use, yet provides accurate assisted scoring and quality reports. Patient preparation uses a quick setup wizard to eliminate user error. You can program the unit to remain dormant for up to seven days and then start and stop recording at any time for one to two nights on the same patient.

Software Features

- Guided device configuration with user-defined options
- Auto start/stop date and time
- Computer-assisted scoring marks all desaturations, respiratory and snoring events
- Powerful event editing capabilities
- Print any part of the recording with a user-selected epoch size
- Export recordings to EDF
- Microsoft Word[®] templates specific to dental sleep medicine.

System Requirements

PC with a USB 2.0 port, 5 GB of hard disk space Windows 7, Windows Vista SP2 or Windows XP SP3

The Evolution of HST.

9

Recorder

- 1. Oximetry
- 2. Heart rate
- 3. Pressure/flow
- 4. Snore from pressure

Available Channels

(6 Total)

- 5. RIP Chest effort
 6. Event marker
 - 7. Internal body position sensor
 8. CPAP Flow

9. CPAP Pressure

Oversized sealed tactile push-button marks events on recording Event Marker 24-bit ADC with fixed sample rates for each channel Signal Quality Bi-color LED with color-coded legend Status Indicator Single 1/2 AA lithium battery Power Source Up to two continuous nights of data Recording Time Dormant Mode Programmable to remain in a dormant state for up to seven days Internal Memory 128 MB internal memory Communication cable for data downloads Computer Interface 2.8 x 3 x 0.75 inches, 3.1 ounces with battery (71 x 76 x 19 millimeters, 89 grams) Physical Size

Software

Auto SetupExtremely easy to use sequential patient setup screens with user-defined optionsAuto StartSet the recorder to automatically start and stop at a specified date and time

Assisted ScoringComputer-assisted scoring marks all desaturations, respiratory and snoring eventsEvent EditingAdjust, delete, rename or add eventsFull DisclosurePrint any part of the recording with a user-selected epoch sizeEDF FormatDownload recordings in EDF for research applicationsReport TemplatesMicrosoft® Word templates specific to dental sleep medicine

MEDIBYTE®

Powerful Software Made Simple.

Using the MediByte[®] and its analysis software is as easy as a few mouse clicks. The included software meets guidelines for full disclosure and contains simplified tools for manually scoring or editing automated results.

For your convenience, the MediByte[®] is also designed for two-night studies. Go beyond the single nine-hour recording with the option to capture two consecutive nights: one for oral appliance treatment and one for baseline.

Approximately 8 percent of the population has sleep bruxism and the association between sleep bruxism and sleep apnea

is well-documented in scientific literature. With the MediByte®, you can practice dentistry and manage sleep bruxism.

To produce the most reliable results, the patentpending MediByte® exceeds guidelines for home evaluation of snoring and sleep apnea. Rock-solid components, cutting-edge technology and innovative products

Software Features

- Guided device configuration with user-defined options
- Auto start/stop date and time

combine to deliver a

10

home sleep apnea testing solution like no other.

• Computer-assisted scoring marks all desaturations, respiratory, PLM and snoring events

Powerful event editing capabilities

- Print any part of the recording with a user-selected epoch size
- Export recordings to EDF

• Microsoft Word[®] templates specific to dental sleep medicine.

System Requirements

PC with a USB 2.0 port, 5 GB of hard disk space Windows 7, Windows Vista SP2 or Windows XP SP3

Titrate Snoring Volume Using Snoring Audio Playback

Hear every single snore with the precise audio playback capabilities of Pursuit Sleep software. With the ease of a mouse drag, quickly identify key snoring and respiratory characteristics as if you were in the room.

Practice Dentistry, Manage Bruxism

Designed specifically for dental sleep medicine, the MediByte[®] enables you to evaluate the known association between sleep bruxism and sleep apnea within the scope of everyday dental practice.

Simple Interpretation Clean, concise and easy-to-read data. Every report

is designed to make finding information effortless.

Titrate AHI

The MediByte[®] empowers you to titrate your oral appliance to the optimum apnea and hypopnea index using the same biosensors and technology found in the best sleep laboratories.

Use with CPAP

11

The MediByte[®] can be used with CPAP to record CPAP pressure, CPAP flow and snoring. This is useful in cases where oral appliances are combined with CPAP.

Central, Obstructive, Mixed Apneas

True Type 3 recorders use RIP respiratory effort belts on the chest, abdomen or both.

MEDIBYTE®

Home Sleep Testing Advancement.

MediByte[®] Type 3 HST Recorder

Using patent-pending technology and designed to exceed new guidelines, this next

generation screener overcomes the many limitations of current devices. Constructed of smooth ABS plastic with extra-strength lockable LEMO[™] connectors, the MediByte[®] was designed for durability and reliability. Weighing less than three ounces, it is ideal for both adult and pediatric studies. Side wings attach the unit to the chest effort belt so that a holding strap is not required. On-board oximetry, pressure and body position sensors eliminate external transducers.

An auxiliary (AUX) port provides a high sample rate channel for a variety of applications, including sound, EKG and EMG. Use the sensitive snore microphone for high-frequency snoring analysis and a quantitative dB sound level. Use EKG electrodes for 24-hour holter monitoring or EMG electrodes to record bruxism or other movement events.

An oversized, tactile push-button allows the patient to indicate specific events during a recording. Studies are stored on the internal memory and downloaded via a USB computer connection.

This recorder represents a new generation screening device that can be used for a

number of different applications.

This miniature device can record 12-channels of sleep apnea data up to two nights or 24 hours on a single battery.

Complete with biosensors and software, the MediByte® package includes everything you need to provide reliable patient testing in a variety of scenarios. DIY or use

MediByte[®] Software

The MediByte[®] Software is an exclusive application that simplifies every step of a study, from setup to analysis to reporting. It is extremely easy to use, yet provides accurate assisted scoring and quality reports. Patient preparation uses a quick setup wizard to eliminate user error. You can program the unit to remain dormant for up to seven days and then start and stop recording at any time for one to two nights on the same patient.

Everything you need
MediByte[®] Kit
1) Oximetry finger probe
2) Snore microphone
3) Two RIP Respiratory effort belts
4) Six oronasal cannulae
5) EKG/EMG lead yoke adapter
6) Prep. accessories
7) Leg EMG
8) Airflow Thermistor

our optional outsourcing

services.

12

13

Recorder

- 1. Oximetry
- 2. Heart Rate
- 3. Pressure Flow
- 4. Snore from Pressure
- 5. Thermal Flow
- 6. RIP Chest Effort

8. Sum – from RIP

- 7. RIP Abdomen Effort
- Available Channels

(12 Total)

- 9. Event Marker
 - Internal Body Position Sensor
 Snoring Audio, EKG, EMG (Bruxism), EMG (PLMs)
 - 12. Sound Level
 - 13. CPAP Flow

14. CPAP Pressure

Quantitative snoring sampled at 2000 Hz or EKG/EMG at 250 Hz AUX Channel Oversized sealed tactile push-button marks events on recording Event Marker Signal Quality 24-bit ADC with fixed sample rates for each channel Bi-color LED with color-coded legend Status Indicator Single 1/2 AA lithium battery Power Source Up to 24 hours of continuous data Recording Time Programmable to remain in a dormant state for up to seven days Dormant Mode Internal Memory 128 MB internal memory Computer Interface Communication cable for data downloads Physical Size 2.8 x 3 x 0.75 inches, 3.3 ounces with battery (71 x 76 x 19 millimeters, 93 grams) Sampling Rates Exceeds new guidelines

Software

Auto Setup Extremely easy to use sequential patient setup screens with user-defined options

Auto StartSet the recorder to automatically start and stop at a specified date and timeAssisted ScoringComputer-assisted scoring marks all desaturations, respiratory, PLM and snoring eventsEvent EditingAdjust, delete, rename or add eventsFull DisclosurePrint any part of the recording with a user-selected epoch sizeEDF FormatDownload recordings to EDF for research applications or to share with any clinicianReport TemplatesMicrosoft® Word templates specific to dental sleep medicine

Genuine MediByte[®] Accessories No one knows sensors and accessories better than BRAEBON - that's how we made our mark. We only use the best

sensor technology to collect your valuable

data.

Reusable or Disposable SpO₂ Finger Probes Choice is always nice. With the MediByte[®] Jr. / MediByte[®], the reusable finger probe is a standard feature, but the disposable-type version is an available option.

14

RIP Effort Belt

New guidelines require RIP technology and prohibit signals based on processed data algorithms. Use only the best. Get RIP!

MediByte High
Energy LithiumMediByte Standard
Lithium BatteryBatteryStandard replacementHigh energybatteries for MediBytereplacement batteriesJr. and MediByte.for MediByte Jr. andJr. and MediByte.

Helping MediByte® Users

Software solutions don't get any simpler. EasyHST offers the simplest turnkey Home Sleep Testing Solution to help manage your workflow from intake to interpretation. Manage your patients, your questionnaires, organize your MediByte[®] data,

and re-order MediByte[®] supplies.

Reliable Data Storage

Much more than a limited Access database, EasyHST uses the same robust database technology found in much more expensive applications. This technology ensures excellent performance with any patient load. Use the power of EasyHST to reliably store, manage and report your patient data and manage your home sleep testing business.

Trend Reporting

Track patient progress by comparing key characteristics of a set of sleep studies in a single report. Launch a single report to monitor the effectiveness of treatment, helping you decide on further adjustments.

Questionnaires

Record a wide range of data from patient history to the Epworth Sleepiness Scale. Fill out as many questionnaires as needed per patient, or none at all. Flexibility to streamline your workflow.

15

Interpretation Letters

Save time when creating interpretation letters by using a built-in letter that summarizes the sleep study data. Time saved means more time with patients and building a more successful practice.

1-888-462-4841

16

PATIENT Smith, Joe

Date of Birth: 07/01/1939 Age: 70 Sex: Male Height: 6' 1" (185 cm)

Patient ID: 1234 Chart Code: 0987654321

Weight:	215.0 lbs	Referring Physician:	Dr. Bronson
BMI:	28.6	Study Date:	06/30/09
Waist-Hip Ratio:	0.90 (W: 36", H: 40")	Total Recording Time:	467.8 minutes

			Du	ration (se	ec.)			
ESPIRATORY	Total	Index	Mean	Min.	Max.	OXIMETRY		
entral Apneas	16	2.1	19.8	13.5	34.2	SpO2 Range	Mi	nutes
Obstructive Apneas	175	22.4	33.3	12.2	118.1	90-100%	8	9.5%
/ixed Apneas	1	0.1	39.5	39.5	39.5	80-89%	10	0.3%
Hypopneas	106	13.6	30.3	11.1	70.3	70-79%	0	.2%
Apnea+Hypopnea	298	38.2	31.5	11.1	118.1	60-69%	0	.0%
Snoring	1272	163.1	0.7	0.2	2.8	50-59%	0	.0%
Desaturations $\geq 4\%$	262	33.6	34.3	6.2	90.2	< 50%	0	.0%
RERAs	0	0.0	0.0	0.0	0.0			
							Mean	Min.
	S	NS	R	L	Ρ	SpO ₂ (%)	92.1	76.0
%Time in Position	99.2%	0.2%	0.2%	0.0%	0.0%	Pulse (BPM)	67.1	52.0

BODYPOS	PRONE RIGHT SUPINE STANDING								
BAD	BAD SPO2 BAD ALL								
	23:59	0:59	1:59	2:59	3:59	4:59	5:59	6:59	

FOLLOW-UP ORAL APPLIANCE TREATMENT

PATIENT Smith, Joe

Date of Birth: 07/01/1939 Age: 70 Sex: Male Height: 6' 1" (185 cm)

AHI: 11.2

Patient ID: 1234 Chart Code: 0987654321

Weight:	215.0 lbs	Referring Physician:	Dr. Bronson
BMI:	28.6	Study Date:	07/02/09
Waist-Hip Ratio:	0.90 (W: 36", H: 40")	Total Recording Time:	384.2 minutes

			Du	ration (se	ec.)				
ESPIRATORY	Total	Index	Mean	Min.	Max.	OXIMETRY			
Central Apneas	11	1.7	18.6	13.4	26.3	SpO2 Range	Mir	nutes	
Obstructive Apneas	20	3.1	29.7	11.7	116.7	90-100%	97	7.2%	
Mixed Apneas	0	0.0	0.0	0.0	0.0	80-89%	2	.8%	
Hypopneas	41	6.4	35.6	15.0	109.1	70-79%	0	.0%	
Apnea+Hypopnea	72	11.2	31.4	11.7	116.7	60-69%	0	.0%	
Snoring	1344	209.9	0.6	0.2	2.6	50-59%	0	.0%	
Desaturations $\geq 4\%$	61	9.5	33.6	9.3	89.2	< 50%	0	.0%	
RERAs	0	0.0	0.0	0.0	0.0				
							Mean	Min.	
	S	NS	R	L	Р	SpO ₂ (%)	93.3	81.0	
%Time in Position	98.7%	1.3%	1.3%	0.0%	0.0%	Pulse (BPM)	69.1	54.0	

AHI 11.4 0.0 0.0 0.0 0.0

1-888-462-4841

17

REPORT BREAKDOWN

Patient Identification – Patient's name, physical characteristics, referring physician.

PATIENT Smith, Joe

Date of Birth: 07/01/1939 Age: 70 Sex: Male Height: 6' 1" (185 cm) Weight: 215.0 lbs BMI: 28.6

Respiratory and Snoring Events – The first column is the total number of events recorded during the study; the second column is the number of respiratory events recorded per hour.

Waist-Hip Ratio: 0.90 (W: 36", H: 40")

Duration (sec.)

RESPIRATORY	Total	Index	Mean	Min.	ľ
Central Apneas	16	2.1	19.8	13.5	
Obstructive Apneas	175	22.4	33.3	12.2	1
Mixed Apneas	1	0.1	39.5	39.5	
Hypopneas	106	13.6	30.3	11.1	4
Apnea+Hypopnea	298	38.2	31.5	11.1	1
Snoring	1272	163.1	0.7	0.2	
Desaturations $\geq 4\%$	262	33.6	34.3	6.2	9
RERAs	0	0.0	0.0	0.0	
	S	NS	R	L	
%Time in Position	99.2%	0.2%	0.2%	0.0%	(
AHI	38.5	0.0	0.0	0.0	

Snoring Volume – This table reports the snoring volume in decibel ranges as a percentage of the recording. Compare this data at baseline to your follow-up study data.

Pulse rate throughout the study.

18

Body position throughout the study.

Hypopnea – Breathing that is shallower or slower than normal by \geq 30% for at least 10 seconds.

Desaturation – A drop of $\ge 4\%$ SpO₂ (oxygen carried by hemoglobin in the blood). A value below 90% is considered abnormal.

уүр	SUPINE				
BOL	STANDING				
BAD	BAD SPO2 BAD ALL				
	23:59	0:59	1:59	2:59	

AHI: **38.2**

Patient ID: 1234 Chart Code: 0987654321 Referring Physician: Dr. Bronson AHI – Apnea + Hypopnea Index is the total number of apnea and hypopneas per hour during the test. An AHI of <5 is normal; 5 to 15 is mild; 15 to 30 is moderate; \geq 30 is severe. Compare this number at baseline to your follow-up MediByte Jr / MediByte test.

Study Date: 06/30/09 Total Recording Time: 467.8 minutes

(sec.)

Max.	OXIMETRY				
34.2	SpO ₂ Range	Mir	nutes	%	
118.1	90-100%	89	9.5%	418.8	
39.5	80-89%	10).3%	48.2	
70.3	70-79%	0	.2%	0.9	
118.1	60-69%	0	.0%	0.0	
2.8	50-59%	0	.0%	0.0	
90.2	< 50%	0	0.0%		
0.0					
		Mean	Min.	Max.	
Р	SpO ₂ (%)	92.1	76.0	97.0	
0.0%	Pulse (BPM)	67.1	52.0	92.0	

Oxygen Saturation Statistics – Blood oxygen saturation recorded throughout the study. This chart displays the saturation levels and amount of time for each SpO_2 range. Clinically significant desaturations of 4% or greater are shown as the total number of desaturation events scored and the index number of desaturation events per hour.

Cardiac – Pulse rates in beats per minute (average, minimum and maximum) recorded during the study.

Body Position – This chart shows body position with time spent in each position as a percentage of the study, the total number of apnea + hypopnea events scored in each position, and the apnea

hypopnea index (AHI) scored for each position. Use body position to diagnose positional apnea – in the chart, the patient has an AHI of 38.5 supine and it is significantly lower in non-supine positions. This result shows the patient has apnea only when supine.

Oxygen saturation throughout the study.

Respiratory, desaturation and snoring events scored throughout the study. Events listed in order are Obstructive Apnea (OA), Central Apnea (CA), Mixed Apnea (MA), Hypopneas (HY), SpO₂ Desaturations (D), Respiratory Effort Related Arousals (RERA), and Snoring Events (SNR).

Bad Data marked in the study. This bad data is excluded from all calculations but the sleep summary.

Apnea – A cessation of breathing lasting for ten seconds or longer whereby the drop in airflow amplitude is \geq 90% of the baseline.

19

1-888-462-4841

QUESTIONS & ANSWERS

What's the difference between the MediByte[®] and its sibling, the MediByte[®] Junior?

The MediByte[®] is a complete 12-channel Type 3 recorder that exceeds all new home sleep apnea testing guidelines. The MediByte[®] Junior is a six-channel Type 3 device. The MediByte[®] records everything the MediByte[®] Junior can, but adds an additional effort channel, a sum channel, an oronasal thermal airflow channel and an Auxilary port; meaning you have the option to record more information when using the thermal airflow sensor: ECG, or EMG, or Audio (snoring).

What do I get when I buy it?

You get everything you need right out of the box – simply add your own Windows 7, XP or Vista computer with USB port. The

complete MediByte[®] kit includes the MediByte[®] recorder, all needed software with three software licenses, all sensors, USB communication cable, six patient kits and a one-year MediByte[®] warranty packed into a convenient, durable carrying case. The MediByte[®] Junior comes in a carrying pack about the size of a shaving kit and includes one patient kit.

How easy is it to use the MediByte®?

Simplicity and ease of use is the key to the MediByte[®]'s success. All connectors are unique and lock in place, meaning the patient training and hook-up is much simpler – there is no chance of plugging the wrong sensor into the wrong connector. The MediByte[®] attaches to the computer with a standard USB connection, just like a digital camera. The software uses a wizard to prepare the MediByte[®] for a patient recording and to download the data. The oversized event button is easy for the patient to use during the recording. After recording, data is automatically analyzed and ready for manual review within our full disclosure software.

Can I install the software anywhere I like?

Yes, you receive three software licenses with your purchase and you can install a copy on any Microsoft Windows 7, XP or Vista computer. Additional software licenses are available for a small fee.

Is the MediByte[®] compatible with CPAP?

Yes, both the MediByte[®] and MediByte[®] Junior can be connected to any CPAP for recording flow, snoring and CPAP pressure.

Is the technology used in the MediByte[®] the same technology used in sleep laboratories?

Yes. BRAEBON has been selling sleep sensors to sleep laboratories for over 12 years. We include the same sensors and technology from within our family of Home Sleep Apnea Testing devices that we supply to world-leading sleep laboratories. When using the MediByte[®], you meet the new Home Sleep Testing guidelines and your test results can be exchanged and easily understood by any doctor, dentist or laboratory.

What is the per use cost of running a test with the MediByte[®]?

The average cost of running a test with the MediByte[®] is around \$7 to \$8.

Are scoring services available?

Yes, a variety of outsourcing service options are available. These options include scoring services by a Registered Sleep Technologist, a medical interpretation by a Board Certified Sleep Physician, or a complete turnkey solution where the product is sent via courier directly to the patient and returned to the sleep scoring experts and physician for a professional interpretation. All you need to do is request the service and the patient and/or their insurance will pay the bill for the home sleep apnea test.

Can I change the reports?

20

You can change the header and footer on the report templates and add your company information, but we generally do not recommend altering the reports.

Has the MediByte® been validated?

Yes, studies have found both high sensitivity and high specificity and have concluded that more than four out of five patients are diagnosed identically when using the MediByte[®] or when using full PSG in a sleep laboratory.

VORKFLOW PROCESS

Marketing Tools

21

A GLOSSARY OF TERMS

Apnea – Cessation of airflow during sleep for at least ten seconds or longer. There are three types: central, obstructive, and mixed. Treatment for mixed is generally the same as obstructive. Obstructive is broken down as mild, moderate, severe, and usually measured as an index.

Apnea/Hypopnea Index (AHI) – A measurement of the number of apneas plus the number of hypopneas per sleep hour. Mild apnea + hypopnea index (AHI) is defined as 5 to 15 per sleep hour, moderate as 15 to 30, and greater than 30 as severe. An AHI of less than 5 is considered within normal limits.

Arousal – To abruptly awaken from a deeper level of sleep to a lighter level of sleep.

Auto-CPAP (APAP) – A type of CPAP machine that changes pressures automatically to manage detected apneas and/or

hypopneas.

22

Bi-Level – Positive Pressure Therapy delivered through inspiratory pressure and expiratory pressure.

Body Position – The different body positions identified during sleep to identify movement: supine, left, right, prone, standing. May effect severity of sleep apnea.

Bruxism – Teeth grinding while sleeping. Awake bruxism is found in about 20 percent of the population and associated with stress and nervous tics. Sleep bruxism is found in about 8 percent of the population and is often associated with sleep apnea.

Central Apnea – The absence of breathing and respiratory effort caused by the failure of the respiratory centers of the brain. Cheyne-Stokes Respiration (CSR) – A periodic breathing pattern observed with an increasing and decreasing in respiratory rate and tidal volume. Usually seen in patients with congestive heart failure.

Complex Sleep Apnea – A classification of sleep apnea characterized by the manifestation of central sleep apnea after the treatment of obstructive sleep apnea using PAP.

Compliance – Adhering to or conforming to treatment such as CPAP therapy or oral appliance therapy.

Continuous Positive Airway Pressure (CPAP) – A continuous positive airway pressure device used to pneumatically open the airway. The primary treatment option to manage severe obstructive sleep apnea.

CPAP Pressure – Positive pressure required to maintain an open airway in patients with sleep apnea using a CPAP machine and measured in cm of H_2O .

Delta Sleep – Characterized by a high voltage, low frequency EEG activity, and indicative of NREM Stage 3 deep sleep (N3) observed during a polysomnogram.

Electro-oculogram (EOG) – In sleep medicine, it is the method of measuring the eye movements to identify if an individual has rapid eye movements (REMs) or slow eye movements (SEMs).

Electrocardiography (EKG or ECG) – A measurement of the electrical heart rhythm.

Electroencephalogram (EEG) – Electrical activity of the brain used to identify the different stages of sleep.

Electromyogram (EMG) – Electrical muscle activity of the brain used to help identify sleep stage, REM sleep muscle atonia and bruxism.

Epoch – Usually a 30-second period of time during sleep studies representing one page of displayed waveform data.

Epworth Sleepiness Scale – A widely-used series of questions to quantify an individual's daytime sleepiness. With a scale ranging from 0 to 24, a score of > 8 indicates excessive daytime sleepiness.

Expiratory Positive Airway Pressure (EPAP) – The pressure delivered upon expiration during Bi-level therapy.

Flow Limitation – The partial closure and restriction of the upper airway which prevents efficient flow of air into the lungs.

Gastroesophageal Reflux Disease (GERD) – Flow of stomach acid upwards into the esophagus causing arousals and sleep disruption.

Habitual Snorers – Individuals who snore nightly. Snoring is a common clinical complaint and may be the primary reason for sleep disturbance and it may also be indicative of apnea.

High Upper Airway Resistance Syndrome (HUARS) – A sleep-disordered breathing syndrome characterized by complaints of daytime fatigue and/or sleepiness, increased upper airway resistance during sleep, frequent arousals and no significant drop in oxygen levels.

Hypopnea – A reduction in air flow of 30 to 50 percent or greater in combination with arterial oxygen desaturations of 4 to 3 percent, respectively, or with an obvious sign of arousal. New AASM guidelines require hypopneas to be scored using only nasal airflow pressure transducers in combination with RIP technology.

Hypoventilation – Reduced rate and depth of breathing resulting in a low movement of air volume to the lungs.

```
Hypoxemia – Low oxygen content in the blood.
```

Inspiration (Inspiratory Phase) – Part of the breathing cycle which involves taking air into the body.

Inspiratory Positive Airway Pressure (IPAP) – The pressure that is delivered upon inspiration during Bi-level therapy.

K-complex – A sharp negative (upward) deflection followed immediately by a positive (downward) deflection in EEG during sleep. Most common during Stage 2 sleep (N2).

Light Sleep – Stages 1 and 2 NREM sleep identified during sleep studies via polysomnogram.

Mandibular Advancement Device (MAD) – Also known as an oral appliance, it is a treatment option for snoring and obstructive sleep apnea that requires a device that moves the jaw (and preferably the tongue) to a forward protrusive position to increase the size of the upper airway.

Mixed Sleep Apnea – A sleep-disordered breathing event comprised initially of a central apnea component that changes immediately into an obstructive apnea. Treatment is the same as for obstructive apnea.

Motor Atonia – Absence of muscle activity during sleep normally observed during REM sleep. Multiple Sleep Latency Test (MSLT) – An assessment of excessive daytime sleepiness and narcolepsy consisting of four or five 20-minute daytime naps.

Nasal Airflow/Nasal Ventilation – Measuring inspiratory and expiratory airflow.

Obstructive Sleep Apnea – Cessation of airflow for at least 10 seconds in the presence of continued ventilatory effort due to a physical obstruction of the upper airway. Paradoxical effort is often observed during such events.

Oximeter – A device that measures the saturation of oxygen in the blood.

Periodic Limb Movement (PLM) Disorder – Also known as periodic leg movements syndrome. A disorder characterized by periodic episodes of repetitive limb movements occurring during sleep that cause arousal in sleep. Sometimes will appear

following CPAP therapy.

Polysomnogram (PSG) – A study conducted in a sleep laboratory with a sleep technologist in attendance. Also known as a Type 1 recording.

Q-RIP – Respiratory Inductive Plethysmography biosensor system to detect respiratory effort during sleep and manufactured by BRAEBON Medical Corporation.

REM Motor Atonia – Muscle paralysis during REM sleep.

REM Sleep – Rapid eye movement sleep characterized by low voltage desynchronized brain waves, rapid eye movements, and muscle paralysis. This stage accounts for about 20 to 25 percent of adult sleep. Most dreams are recalled upon awakening from REM sleep; however, dreaming also occurs during other stages of sleep. Respiratory Disturbance Index (RDI) – Pertains to all respiratory-related events per hour measured via portable monitor or

PSG.

Respiratory Inductive Plethysmography (RIP) – A respiratory effort technology used to differentiate central from obstructive apneas and now required by new AASM guidelines.

Restless Legs Syndrome (RLS) – A sleep disorder characterized by a deep creeping (or crawling) sensation in the legs that tends to occur when an individual is not moving. There is an almost irresistible urge to move the legs; these sensations are

relieved by movement and are associated with periodic limb movements that occur during sleep.

Snoring – Unwanted sound (noise) associated with vibration of upper airway tissue during sleep. Reported in up to 50 percent of the general population, snoring is a common symptom of obstructive sleep apnea.

Tidal Volume – Volume of air that passes in and out of the lungs in an ordinary breath.

Titration – Progressive adjustment of CPAP pressure or oral appliance to achieve an optimum adjustment setting to effectively manage a person's obstructive sleep apnea.

Type 3 Recording – Airflow, ventilatory effort, oximetry, and pulse rate or ECG.

Oral Appliance Monitoring.

Sleep apnea science by an industry leader.

braebon.com

888.462.4841

