BRAEBON

For Today's Business of Sleep™

Home Sleep Testing – Common Questions and Answers

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What is sleep apnea?

Sleep apnea is a cessation of airflow during sleep for at least ten seconds or longer and is considered a type of sleep-disordered breathing (SDB) which may also include snoring, flow limitation, and hypopnea. There are three types of sleep apnea: central, obstructive, and mixed. Treatment for mixed sleep apnea is generally the same as obstructive sleep apnea. Obstructive sleep apnea is broken down as mild, moderate, severe, and usually measured as an index or number of stoppages per hour of sleep or per hour of recording. New research suggests sleep apnea is an epidemic and some type of sleep-disordered breathing occurs in about 15% of the general population worldwide.

What are some facts about sleep apnea?

Causes of sleep apnea may include obesity, age (i.e., loss of muscle tonus with increasing age), craniofacial morphology, macroglossia, nasalpharyngeal problems, narrow dentition. Increasing global obesity rates are linked with growing rates of sleep apnea. Common symptoms of sleep apnea include snoring, daytime sleepiness, morning headaches, morning irritability, depression, frequent night-time urination, erectile dysfunction, hyperactivity in children, bedwetting in children. Research has found that, for certain patients, both the diagnosis and treatment of sleep apnea may be done just as well at home as done within a hospital environment. Treatment options include continuous positive airway pressure (CPAP), oral appliance therapy (OAT), nasal and / or oral surgery, implantable pacemaker, and mouth exercises may also help.

I thought BRAEBON was a sleep sensor company? How can BRAEBON help me with Home Sleep Testing (HST)?

Yes, we started with sleep sensors but over the past 20 years BRAEBON has been doing much more than just sleep sensors. In fact, we've been in the Home Sleep Testing business much longer than most other companies. We took our famous sleep sensor technology and adapted it to work with our own portable recorders in the home. The result is BRAEBON now sells a complete range of top-notch Level 2 & 3 Home Sleep Testing equipment.

What are the BRAEBON HST devices called?

BRAEBON offers two HST devices for recording snoring and sleep apnea: the BRAEBON MediByte® is our 15-channel Level 2 / 3 HST device and the MediByte® Junior is the 7-channel Level 3 HST version.

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

The MediByte is a complete 15-channel Level 2 / 3 recorder which exceeds all new home sleep apnea testing guidelines. The MediByte Junior is a 7-channel Level 3 recorder. This entry-level Home Sleep Testing device complies with all CMS requirements for Level 3 Home Sleep Testing.

The MediByte records everything the MediByte Junior does, but adds an additional effort channel, a sum channel, an oronasal thermal airflow channel, and an Auxiliary port which means you have the option to record more information when using the thermal airflow sensor: ECG, or EMG, or Audio (snoring) and Volume in dB.

What exactly does the MediByte and MediByte Junior record?

	MEDIBYTE® Junior 7 Channels	MEDIBYTE® 15 Channels
Airflow (OroNasal Pressure Cannula)	●	●
Snoring (OroNasal Pressure Cannula)	●	●
SpO2	●	●
Pulse Rate	●	●
Body Position	●	●
CPAP Pressure	●	●
Event Marker	●	●
Chest Effort Respiratory Inductive Plethysmography (RIP)	●	●
Abdominal Effort (RIP)		●
SUM (RIP)		●
Airflow (OroNasal Thermistor)		●
Audio (Microphone)		●
Volume (dB)		●
EEG		●
EKG		●
EMG (PLMs, Bruxism)		●
Number of software installations per recorder	1	1
Size	World's Smallest Type 3 2.5”x2.25”x0.75” 63x57x19mm	World's Smallest Type 3 2.5”x2.25”x0.75” 63x57x19mm
Weight in grams (including battery)	91	93
Location worn during recording	Chest	Chest

What are the benefits of these signal parameters?

- SpO2 = saturation of peripheral blood oxygen obtained from the finger probe (optional ear lobe probe) and is used to see how often and how much oxygen drops during sleep
- Pulse rate = obtained from the finger probe (optional ear lobe probe) and used to see if the heart is racing during sleep (i.e., brady-tachycardia)
- Airflow pressure (flow)= obtained from the oronasal cannula and used to see if the patient snores, has limited airflow during sleep (i.e., flow limitation), and under breathes during sleep (i.e., hypopneas). This technology is required by the American Academy of Sleep Medicine to separate normal breathing from hypopneas for best scoring results.
- Airflow thermistor = obtained from the oronasal thermistor and used to see if the patient stops breathing during sleep (i.e., has apnea) and to separate hypopneas from apneas. This technology is required by American Academy of Sleep Medicine to separate apneas from hypopneas for best scoring results.
- Flow limitation = obtained from the oronasal cannula to detect mild breathing problems during sleep associated with upper airway resistance syndrome (UARS).
- Snore vibration = obtained from the oronasal cannula to see if airflow shows mild snoring.
- Snore sounds = obtained from the microphone to see how loud in dB the person snores and we can also play back the audio and listen. Snoring is the number one complaint from bedpartners.
- RIP Chest effort = obtained from the chest RIP band to see if the chest keeps moving during apneas / hypopneas to separate obstructive apnea from central apnea.
- RIP Abdominal effort = obtained from the abdominal RIP band to see if the diaphragm (abdomen) keeps moving during apneas / hypopneas to separate obstructive apnea from central apnea. Two belts help us look at paradoxical effort which helps to confirm obstructive vs. central.

- Body position = obtained from a sensor inside the MediByte and used to see if breathing is worse or limited to only when the patient sleeps on their back. Sleep disordered breathing is often worse when sleeping on the back (i.e., supine)
- EEG, EOG, EMG = obtained from electrodes placed on the face and head to determine wakefulness vs sleep and the type of sleep stages
- EKG = obtained from electrodes placed on the chest to look for heart problems (i.e., cardiac arrhythmias)
- CPAP = obtained from the CPAP to MediByte adapter to determine the effectiveness of autoPAP therapy for the patient

What do I get when I buy it?

You get everything you need right out of the box. Simply add your own Windows 10, Windows 8, or Windows 7 computer with a USB port and you are good to go. When you buy the complete MediByte kit you receive a convenient, durable carrying case which includes the MediByte recorder, all needed software with a software license, all sensors, USB communication cable, six patient kits and a one-year MediByte warranty. The MediByte Junior comes in a carrying pack about the size of a shaving kit and includes one patient kit.

MediByte carrying case

MediByte Junior carrying pack

How big is the MediByte?

The MediByte is the smallest in its class. The small size means better patient comfort and compliance.

How easy is it to use the MediByte?

The MediByte is one of the easiest Home Sleep Testing devices to use. Simplicity and ease of use is the key to its success. For example, all connectors are unique. This means the patient training and hook-up

is much simpler with no likelihood to plug the wrong sensor into the wrong connector on the MediByte. Attaching the MediByte to the computer is simple and uses a standard USB connection just like your digital camera. The software uses a wizard to prepare the MediByte for a patient recording, and to download the data. The oversized event button makes it easy for the patient to use during the recording. After the recording, the data is automatically analyzed and ready for review within our full disclosure software. Quite literally, if you can use a computer mouse you can use the MediByte!

How long has the MediByte been on the market?

BRAEBON has been selling the MediByte since 2006 and today it is used on six continents.

Are patient instructional videos available?

Yes, go to http://braebon.com/support/downloads.php and videos are available for both MediByte and MediByte Junior.

Can the MediByte record multiple nights?

Yes, you can record up to two consecutive 9-hour recordings. In fact, you can choose one 9-hour night, two nights, or one continuous 24-hour recording for EKG. You can also choose to start the recording automatically or manually use the On / Off switch. The ability to record two nights minimizes the first-night effect, and is also useful for evaluating oral appliance treatment with a baseline night and treatment night.

Does the MediByte permit full disclosure?

Yes, MediByte software fully complies with new guidelines and permits both full data disclosure and manual scoring.

Can I install the software anywhere I like?

Yes, you receive one software license with your purchase and you can install a copy on any Microsoft Windows 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, because BRAEBON has been selling sleep sensors to sleep laboratories for over fifteen years, we use the exact same sensors and technology within our family of Home Sleep Testing devices as we supply to world leading sleep laboratories. This means you meet published Home Sleep Testing guidelines when using the MediByte. It also means the test results can be exchanged and easily understood by any doctor, dentist, or laboratory. With the MediByte, you are practicing medicine at the state-of-the-art.

Can I use sensors from other companies with the MediByte?

No, to achieve optimal performance with the MediByte you must use genuine BRAEBON sensors. Remember, BRAEBON started in the sleep sensor business and is a recognized leader in this field – why use something else?

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

The cost to do a test with the MediByte can be around $5 to $7

Do I need to hook up the patient and send them home?

No, because the MediByte is so easy to use most patients hook themselves up at night in the comfort of their own bedroom. Prior to the test, a sleep technologist or dental assistant would prepare the MediByte for the patient before the patient arrives at the laboratory or office. Once the patient arrives, a brief five to ten-minute training session is recommended to demonstrate the recorder to the patient and answer any questions. It is also recommended the patient watch the ten-minute MediByte video prior to the actual test. Some sleep laboratories also provide their phone number in case the patient has any questions during the evening of the test. On the night of the test, the patient takes the MediByte carrying case home, uses the MediByte and returns the unit the next day where the technologist or assistant downloads the data for analysis.

Can I use rechargeable batteries with the MediByte?

Yes, BRAEBON offers a rechargeable battery kit as a standard feature. You may record one study night using the rechargeable battery and two nights or 24 continuous hours of recording using a disposable battery.

How often can the MediByte study be downloaded after it is recorded?

The study data is downloaded onto a local PC (Windows 7, 8, 10) with a usb cable and may be optionally uploaded to the BRAEBON BridgeBuilder Cloud Portal. The MediByte study may be downloaded again and again until the MediByte is reprogrammed for the next patient because the data is stored in nonvolatile flash memory just like what is used on a standard usb stick. MediByte software automatically analyzes the study data and then a human sleep technologist scores and validates the data. After the technologist has verified data integrity a sleep physician over-reads the study and makes a diagnosis. Note, however, some physicians may choose to review the data themselves rather than have a technologist review the data.

Can I change the reports?

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

Has the MediByte been validated?

Yes, studies have found both high sensitivity and high specificity when using the MediByte compared to full PSG in a sleep laboratory.

Can the patient re-apply sensors at home?

Yes, the patient can both apply and re-apply sensors at home by themselves. The BRAEBON MediByte uses the identical technology as used in sleep laboratories worldwide, thus, re-applying leads is not an issue. Sensors will not disconnect from the MediByte because they lock in place. Using tape to apply the sensors to the patient's body will minimize the likelihood of sensors dislodging from the patient.

Does MediByte need to be calibrated or is there any maintenance?

No, there are no user-calibrated or user-serviced parts after MediByte leaves the factory. However, you must use BRAEBON sensors and cannula or the warranty is null and void.

What disposable sensors are used?

The battery is rechargeable and most sensors are reusable. The only single-patient use sensor is the oronasal cannula but it may be used by the same patient again and again. The cost for the cannula varies by type used and the top of the line BRAEBON oronasal cannula is only a few dollars. Ventilatory effort

bands, oronasal thermistor, snore sensor, and SpO2 finger probe are reusable but disposable options are available for most sensors.

Where to find more Information:

1- BRAEBON Website www.braebon.com
2- BRAEBON Product Guide. https://www.braebon.com/docs/BraebonCatalog_M_0500_80101_2.pdf
3- BRAEBON videos: go to https://www.braebon.com/support/videos.php videos are available for both MediByte and MediByte Junior.
4- YouTube. Search "Braebon" or "Medibyte" and you will find many informative videos.
5- MediByte, MediByte JR and Sensors Studies available upon request.

What if I still have more questions?

Call us at +01.613.831.6690 extension 218 or toll-free in North America at 1-888-462-4841 x218. We're here to help.

What does a sample MediByte report look like?

MEDIBYTE
SNORE REPORT

PATIENT Doe, John

Patient ID:	SNORE
Study Date:	08/26/11 (MM/DD/YY)
Date of Birth:	06/14/1960 (MM/DD/YY)
Age:	57
Sex:	Male
Height:	5' 10" (178 cm)
Weight:	222.0 lbs
BMI:	31.8
Waist-Hip Ratio:	0.95 (W: 38", H: 40")

AHI/REI:	32.4
RDI:	43.2
ODI:	28.2
Chart Code:	11223344
Referring Physician:	Dr. Jones
Start Time:	00:29:13
End Time:	06:10:54
Total Recording Time:	333.6 minutes

Severe >30
Moderate 15-30
Mild 5-15
Normal <5

HOME SLEEP APNEA TESTING DEVICE

The MediByte®, 12-channel Type 3 home sleep apnea and snoring recorder (SN 123456), was used to evaluate sleep-disordered breathing. The following parameters were recorded for a duration of 333.6minutes: Snoring Audio, Volume in decibels, Snoring (high frequency vibrations in airflow), oronasal pressure Airflow, thermal Airflow, RIP Chest/Abdominal/Sum Effort, SpO2, Pulse Rate, Body Position, and User Events.

Note: Respiratory events were scored using the following rules: Apneic events required a 90% or more reduction in airflow, Hypopneic events required a 30% reduction in airflow along with an accompanying 3% oxygen desaturation.

COMMENTS

85.5% of all breaths were associated either with flow limitation or with snoring. AHI & RDI were 32.4 and 43.2, respectively. Supine AHI was 45.8 and supine RDI was 56.9. Oxygen Desaturation Index (ODI) was 28.2 and time below 88% SpO2 was 0.4 minutes. Supine desaturation index was 40.0.

OXIMETRY	SpO_2 Range % Time	minutes
98-100 %	0.1%	0.3
96-98 %	6.5%	21.8
94-96 %	50.7%	170.4
92-94 %	35.6%	119.8
90-92 %	6.5%	22.0
90-100 %	99.5%	334.3
80-89 %	0.5%	1.8
70-79 %	0.0%	0.0
60-69 %	0.0%	0.0
50-59 %	0.0%	0.0
< 50%	0.0%	0.0
Total <88 %	0.1%	0.4
Total >95%	22.2%	74.5

	Total	Index
Desaturations ≥3%	157	28.2

	Mean	Min.	Max.
SpO_2 (%)	93.6	85.0	98.0
Pulse (bpm)	70.4	56.0	145.0

PULSE	Pulse Rate Range % Time	minutes
125-150	0.4%	1.3
100-125	0.5%	1.6
75-100	20.6%	69.3
50-75	78.5%	263.9
25-50	0.0%	0.0
PRV Increases ≥ 6 bpm	288	

**Respiratory events are defined in the Assisted Scoring User Settings and in the User Guide. Final clinical decisions and degree of accuracy are the sole responsibility of the clinician using this software.*

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MEDIBYTE
SNORE REPORT

RESPIRATORY

	Total	Index	Duration (sec) Mean	Min.	Max.
Breaths	5268	947.5	3.1	0.7	13.0
Central Apneas	1	0.2	13.9	13.9	13.9
Obstructive Apneas	8	1.4	17.2	12.8	23.7
Mixed Apneas	1	0.2	14.8	14.8	14.8
Hypopneas	170	30.6	27.8	10.2	96.3
Apnea+Hypopnea	180	32.4	27.2	10.2	96.3
Snoring Sounds (SSD)	1732	311.5	0.7	0.3	1.6
Snoring Flow (SNR)	2904	522.3	0.7	0.2	2.8
Flow Limitation (FL)	3413	613.9	1.2	0.6	4.9
Desaturations	157	28.2	28.3	6.3	85.1
RERAs	60	10.8	32.1	11.9	81.0

SNORING VOLUME

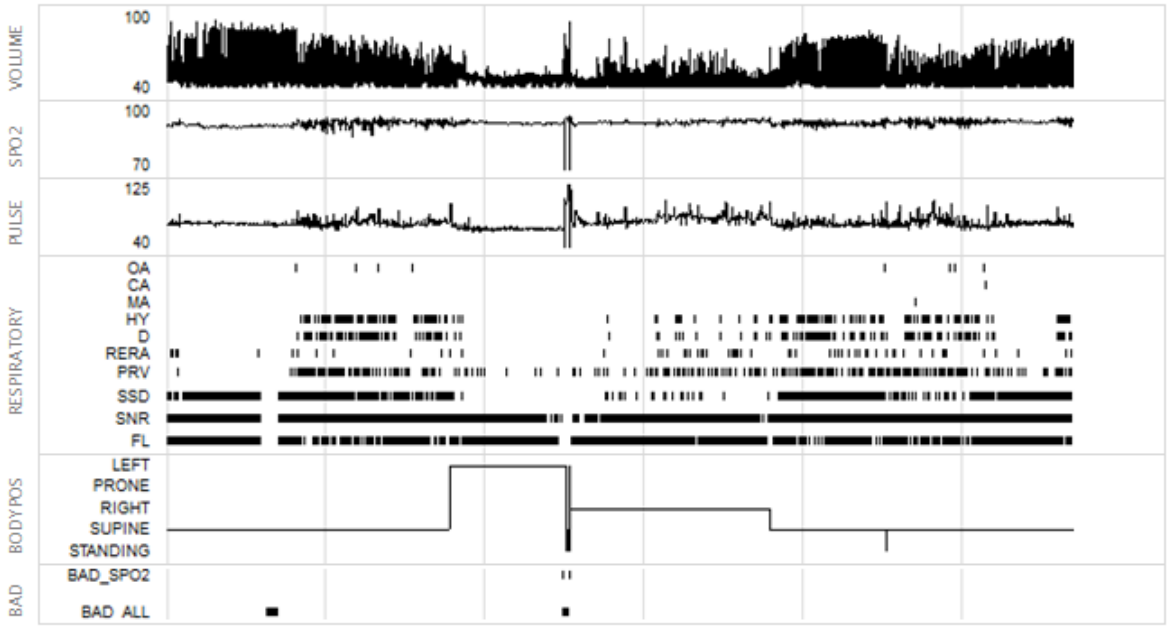
RANGE	% Time
90–100 dB	0.0%
80–90 dB	0.9%
70–80 dB	2.1%
60–70 dB	4.0%
50–60 dB	13.1%
40–50 dB	79.9%
Mean Snore ≥60dB	69.9

EVENTS

BY BODY POSITION	Supine	Non-Supine	Right	Left	Prone
% Time in Position	64.8%	35.1%	22.3%	12.8%	0.0%
Total Breaths	3365	1891	1229	662	0
Snoring Sounds (SSD)	1687	45	40	5	0
Snoring Flow (SNR)	2119	782	494	288	0
Flow Limitation (FL)	1823	1588	990	598	0
Desaturations	144	13	11	2	0
ODI	40.0	6.7	8.9	2.8	0.0
RERAs	40	20	18	2	0
RDI	56.9	17.9	24.1	7.0	0.0
Apneas + Hypopneas	165	15	12	3	0
AHI/REI	45.8	7.7	9.7	4.2	0.0

BREATH STATS

Total Breaths	5268
with FL	3801
with FL or SSD	4505
% FL Breaths	72.2%
% FL Breaths or SSD	85.5%



PATIENT Doe, John Patient ID: SNORE Study Date: 08/26/11

**Respiratory events are defined in the Assisted Scoring User Settings and in the User Guide. Final clinical decisions and degree of accuracy are the sole responsibility of the clinician using this software.*

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What does a sample MediByte Junior report look like?

MEDIBYTE JR
HOME SLEEP TEST REPORT

PATIENT Doe, John

Patient ID:	123456
Study Date:	05/29/09 (MM/DD/YY)
Date of Birth:	06/14/1960 (MM/DD/YY)
Age:	58
Sex:	Male
Height:	6' 1" (185 cm)
Weight:	229.0 lbs
BMI:	30.3
Waist-Hip Ratio:	1.07 (W: 38", H: 36")

AHI/REI:	50.7
RDI:	51.8
ODI:	37.2
Chart Code:	0987654321
Referring Physician:	Dr. Johns
Start Time:	22:12:49
End Time:	05:24:56
Total Recording Time:	432.1 minutes

Severe >30
Moderate 15-30
Mild 5-15
Normal <5

HOME SLEEP APNEA TESTING DEVICE

The MediByte Jr®, a 6-channel Type 3 home sleep respiratory recorder (SN N/A), was used to evaluate sleep-disordered breathing. The following parameters were recorded for a duration of 432.1minutes: Snoring (high frequency vibrations in airflow), oronasal pressure Airflow, RIP Chest Effort, SpO2, Pulse Rate, Body Position, and User Events.

Note: Respiratory events were scored using the following rules: Apneic events required a 90% or more reduction in airflow, Hypopneic events required a 30% reduction in airflow along with an accompanying 3% oxygen desaturation.

COMMENTS

42.6% of all breaths had flow limitation which is associated with upper airway resistance. AHI & RDI were 50.7 and 51.8, respectively. Supine AHI was 51.4 and supine RDI was 52.6. Oxygen Desaturation Index (ODI) was 37.2 and time below 88% SpO2 was 6.3 minutes. Supine desaturation index was 38.5.

OXIMETRY	SpO_2 Range % Time	Minutes
98-100 %	7.8%	33.7
96-98 %	38.3%	165.2
94-96%	32.3%	139.3
92-94 %	13.0%	55.8
90-92 %	5.5%	23.6
90-100 %	96.9%	417.6
80-89 %	3.0%	13.1
70-79 %	0.0%	0.1
60-69 %	0.0%	0.0
50-59 %	0.0%	0.0
< 50%	0.1%	0.3
Total <88 %	1.5%	6.3

	Total	Index
Desaturations ≥ 3%	268	37.2

	Mean	Min.	Max.
SpO_2 (%)	94.9	78.0	99.0
Pulse (BPM)	85.0	55.0	132.0

PULSE	Pulse Rate Range % Time	minutes
125-150	0.1%	0.3
100-125	8.4%	36.1
75-100	72.1%	311.0
50-75	19.3%	83.4
25-50	0.0%	0.0

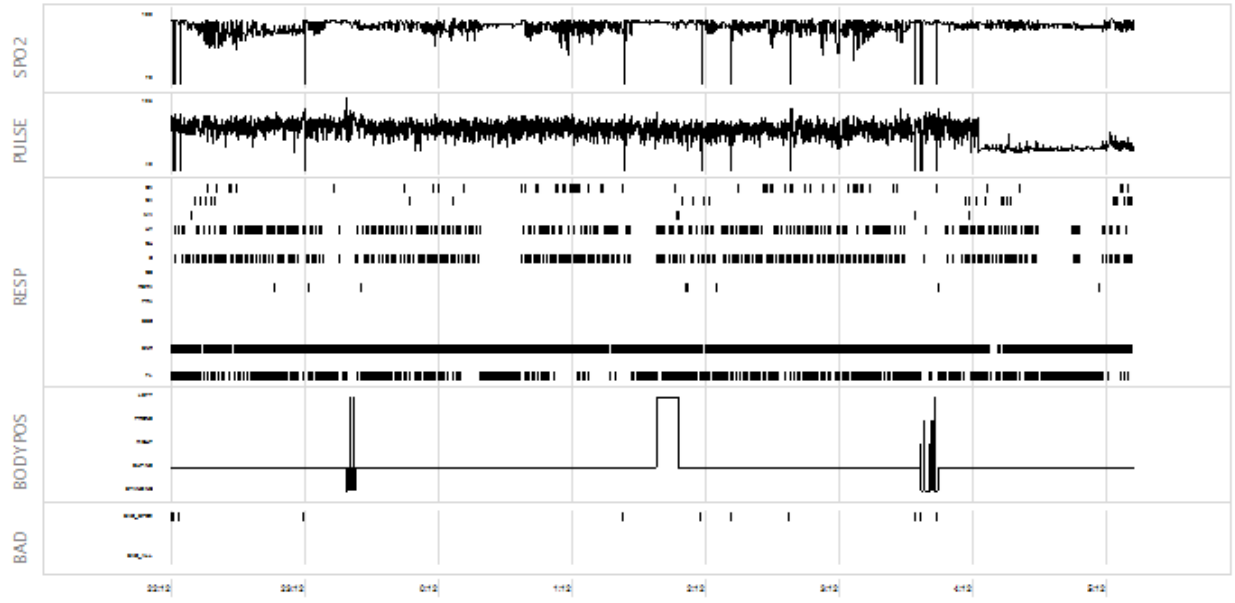
RESPIRATORY	Total	Index	Duration (sec) Mean	Min.	Max.
Breaths	3734	518.5	3.9	0.6	13.4
Central Apneas	26	3.6	25.7	11.6	63.9
Obstructive Apneas	57	7.9	36.3	10.1	105.4
Mixed Apneas	5	0.7	27.1	14.8	59.4
Hypopneas	277	38.5	33.4	10.1	118.9
Apnea+Hypopnea	365	50.7	33.2	10.1	118.9
Snoring (Flow)	2857	396.7	1.1	0.2	3.2
Flow Limitation (FL)	1407	195.4	1.2	0.6	4.4
Desaturations	268	37.2	49.9	13.4	276.6
RERAs	8	1.1	31.2	19.7	42.5

BREATH STATS

Total Breaths	**3734**
with FL	1590
% FL Breaths	42.6%

EVENTS

BY BODY POSITION	Supine	Non-Supine	Right	Left	Prone
% Time in Position	95.3%	2.5%	0.1%	2.2%	0.2%
Total Breaths	3505	103	5	88	10
Snoring (Flow)	2742	47	2	38	7
Flow Limitation (FL)	1358	42	0	42	0
Desaturations	264	3	0	3	0
ODI	38.5	16.8	0.0	18.8	0.0
RERAs	8	0	0	0	0
RDI	52.6	61.5	0.0	68.8	0.0
Apneas + Hypopneas	353	11	0	11	0
AHI/REI	51.4	61.5	0.0	68.8	0.0



PATIENT Doe, John Patient ID: 123456 Study Date: 05/29/09