MediByte / MediByte Jr
User Guide

For Version 9.0

BRAEBON

BRAEBON™ is an ISO 13485 (2016) certified company.

Legal Notices

Caution: United States Federal law restricts this device to sale by or on the order of a physician.

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BRAEBON Medical
1-100 Schneider Road
Kanata, Ontario,
Canada, K2K 1Y2

Technical Support: 1-888-462-4841 (9 am - 5 pm ET)

• E–mail: support@braebon.com

Customer Sales or Service: 1-888-462-4841 • E–mail: info@braebon.com

www.braebon.com

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Table of Contents

Table of Contents

Chapter 1: Introduction

This user guide describes how to use the MediByte, MediByte Jr and accompanying MediByte Software. The user guide has nine chapters:

1. Introduction
2. Specifications
3. Installing the Software
4. Preparing the MediByte for a Study
5. Preparing the Patient
6. Reviewing Data
7. Data Management
8. Passwords, Displays and Maintenance
9. File Transfer and Remote Scoring

In this chapter

This chapter describes the MediByte, MediByte Jr and their accessories. Included in this chapter:

- What's new in MediByte Software 9.0
- Intended Use
- Conventions used in this guide
- Warnings and cautions
- Contents of the MediByte Kit and MediByte Jr Kit
- Overview of the MediByte and MediByte Jr

What's New in MediByte Software 9.0

- One software program for both the MediByte and MediByte Jr.
- Windows 10 and 11 compatibility.
- Improved security and operational logging.
- Record a sleep channel which displays EEG, EOG and EMG waveforms on the data display.
- Sleep + EEG collection montage.
- Sleep + EKG collection montage.
- On-screen AHI, RDI.
- The ability to manually add sleep stage scoring tags to the data display.
- Sleep staging hypnogram drawn in real time as the data is sleep stage scored.
- Manual marking of Central Hypopneas and Cheynes Stokes events.
- Manual marking of arousals by dragging the mouse over the EEG waveform.
- Ten-minute display width option.
- View the Photoplethysmograph (PPG signal) at the bottom of the data display.
- Pulse rate variability marking and reporting.
- Metric measurements in the setup wizard.
- Ability to change Auto Scored RERAs to Auto Scored RERAs/Subhypopneas.
- The Studies Data Manager now has a sort feature. Sort by Patient Name, Study Date and Recorder Type.
- The Studies Data Manager shows the AHI, RDI and good data value in a study.
- Ability to edit and move waveforms.
- Reports no longer require Excel; updates include breathing rate; SpO_2 statistics with and without desaturations.
- View AHI, RDI and number of minutes of good data in the study status bar.
- MediByte and MediByte Jr can now work with Bi-level PAP devices.
- Study shown to be NON-VALIDATED (only scored by assisted scoring algorithms) or VALIDATED (scored by a trained individual).
- Events can only be scored in non-wake stages.
- The AI, AHI, RDI and Good Data values in the status bar are updated in real-time as the user scores the study.
- The user can mouse over any waveform and see the actual waveform data in the status bar.

Intended Use

The MediByte is a portable sleep data recorder used to record physiological signals during sleep while the patient is either at home or in a clinical environment. The data is downloaded after the recording is completed and the auto assist software enables the trained human professional - typically a Registered Sleep Technologist or Medical Doctor - to review and verify the results of the study and generate a report.

Target Population: Children and adult patients who are screened during sleep disorder studies.

Environment of Use: The majority of screenings occur either in the home or in a clinical setting (sleep laboratory).

Indications

The MediByte is a screener used to diagnose sleep disorders, such as sleep apnea, upper airway resistance, snoring, periodic limb movements, bruxism.

Contraindications

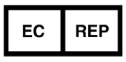
This product is for diagnostic purposes only and is not to be used as an apnea monitor or in life sustaining or life supporting applications.

Symbols Used On the Device and Guides

Symbols for the MediByte and MediByte Jr

These are the symbols used on the MediByte and MediByte Jr, or on its package labels. The table below lists the symbol, the name or meaning of the symbol.

	Type BF Applied Part: F-Type applied part complying with the specified requirements of the IEC 60601-1 to provide a higher degree of protection against electric shock than that provided by Type B applied parts. Type BF Applied Parts are not suitable for Direct Cardiac Application.
	Catalogue number/reference number.
	Serial Number of the device.
	Medical device.
	Made in Canada.
	Manufacturer information.
	Read operator’s manual.

	Consult instructions for use.
	In compliance with the European Directive on Waste of Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste
	Operating temperature limit.
	Operating humidity limit.
	Keep dry.
	Transport and storage temperature limit.
	Transport and storage humidity limit.
IP22	Ingress protection: IP22; as defined by IEC 60529 is protected from touch by fingers and objects greater than 12.5 mm diameter, and liquids from spray less than 15 degrees from vertical.
	Authorized representative in the European Community.
	UK Conformity Assessed marking.

Conventions for the User and Patient Guides

Following are document and safety conventions.

	**Warning:** This symbol flags a serious warning. It is vital that you heed all warnings to prevent injury to yourself or to your patient.
	**Caution:** This symbol flags a caution. Heed all cautions to prevent damage to your equipment.
	**Note:** This symbol flags a note. Notes provide important information about using the MediByte/MediByte Jr, its accessories and the software.
	Protect from heat and radioactive sources.
	Keep dry.
	No nail polish.

Warnings and Cautions

Warnings

This product is for diagnostic purposes only and is NOT to be used as an apnea monitor or in life sustaining or life supporting applications.

- MediByte/MediByte Jr record signals for use in assessing sleep disorders. Ensure all studies are reviewed by a qualified person. A licensed physician is required, by law, to diagnose sleep apnea because it is a medical condition.
- To protect the patient, never connect the MediByte/MediByte Jr to the computer while the patient is still hooked-up to the MediByte/MediByte Jr.
- Always use a new BRAEBON cannula and BRAEBON hydrophobic (safety) filter with each patient.
- Do NOT use or attempt to service damaged parts.
- Unauthorized opening of the MediByte/MediByte Jr will void both the safety of the MediByte/ MediByte Jr and the terms and conditions of the MediByte warranty. No modification of this equipment is allowed.
- Do not modify this equipment without authorization from the manufacturer.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- Keep the MediByte/MediByte Jr and its components away from flames.
- Do NOT use the MediByte/MediByte Jr in the presence of flammable compounds such as anesthetics.
- Do NOT immerse the MediByte/MediByte Jr in any liquids because damage will result. Advise all patients to keep the MediByte/MediByte Jr away from water. Water damage will void the warranty.
- Do NOT sterilize the MediByte/MediByte Jr.
- Do NOT perform unattended sleep studies on patients who are not physically able to use the MediByte and its accessories.
- To prevent strangulation, ensure all leads and wires are taped-down.
- Misapplication of an SpO_2 probe with excessive pressure for prolonged periods can induce pressure injury.
- Conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact other conductive parts including earth.
- MediByte should not be used along with HF surgical instruments.
- Ensure the SpO2 sensor is not too tight. Misapplication of a probe with excessive pressure for prolonged periods can induce pressure injury.

- The SpO2 sensor contains no alarms.
- Wear the MediByte or MediByte Jr over clothing to reduce the risk of allergic reaction.

Battery Warning Saft LS14250:

- Do not attempt to recharge the Saft LS14250 battery.
- Battery to be replaced by qualified personnel only.
- Remove the battery if the device is not to be used for an extended period of time.
- Fire, explosion and severe burn hazard. **Do not recharge**, short circuit, crush, disassemble, heat above 100 ^{O}C (212 ^{O}F), incinerate or expose contents to water.

Battery Warning BRAEBON Rechargeable:

- Battery to be replaced by qualified personnel only.
- Remove the battery if the device is not to be used for a long period of time.
- Fire, explosion and severe burn hazard. Do not short circuit, crush, disassemble, heat above 100 ^{O}C (212 ^{O}F), incinerate or expose contents to water.

Cautions

- Use *only* BRAEBON sensors and accessories.
- Use *only* the BRAEBON RIP Belts for MediByte (Models 8572, 8572PED, 8574). Other belts will NOT function with the MediByte.
- Always use a new cannula and BRAEBON hydrophobic (safety) filter with each patient.
- Sterilization of the MediByte is NOT required. Do NOT steam autoclave the MediByte or damage will occur and void the warranty.
- Do NOT immerse the MediByte in any liquids as damage will result. Advise all patients to keep the MediByte away from water; water damage will void the warranty.
- Do NOT drop the MediByte.
- Use only 3.6 V 1/2AA battery, Saft LS14250 (Model 0410) or 1/2AA Li-Ion Rechargeable Battery (Model 0412) supplied by BRAEBON.
- Do NOT recharge the Saft LS14250 (Model 0410) battery; it is non-rechargeable.
- Ensure the polarity of the battery is correct when inserting; otherwise, the device will not operate.
- Operate and store the MediByte under the following environmental conditions:

	Operating Conditions	**Storage and Transport Conditions**
Temperature	10°C–35°C	0°C–50°C
Relative Humidity	30%–95% (Without condensation)	10%–100%

Contents of the MediByte Kit

Verify that you have received the items listed in the MediByte Kit and that no items were damaged during shipping. If any items are damaged or missing, please contact BRAEBON immediately at 1.888.462.4841. Do NOT use damaged items.

MediByte Kit Contents

Quantity	Item
1	MediByte Recorder (Model MP-8)
2	RIP Belt for MediByte (Model 8572)
1	MediByte Electrode Prep Kit (Model 8128)
1	MediByte Electrode Prep Kit - five piece (Model 8128-5)
6	Self-Adhesive Electrodes, strip of 5 (Model 8501-5)
1	Ultima Snore Microphone for MediByte with Thermistor Input (Model 8541)
1	Electrode Box (Model 8611)
1	Leadwire Kit for MediByte (Model 8620)
1	cTherm Cannula Thermistor (Model 8514)
1	SpO_2 Cable for MediByte, Soft Fingertip (Model 8900)
1	MediByte Carrying case
1	USB Cable for MediByte (Model 8890)
1	MediByte Patient Guides (Model 8940)
1	MediByte/MediByte Jr User Manual (installed with software)
1	Hex Screwdriver for MediByte (Model 8870)
1	MediByte/MediByte Jr First Patient Setup Guide

Rechargeable Battery Kit is an available add-on. See page 1-12 for content list.

Contents of the MediByte Lite Kit

Verify that you have received the items listed in the MediByte Lite Kit and that no items were damaged during shipping. If any items are damaged or missing, please contact BRAEBON immediately at 1.888.462.4841. Do NOT use damaged items.

MediByte Lite Kit Contents

Quantity	Item
1	MediByte Recorder (Model MP-8)
2	RIP Belt for MediByte (Model 8572)
1	MediByte Patient Kit (Model 8110)
1	MediByte Patient Kit - five piece (Model 8110-5)
1	SpO_2 Cable for MediByte, Soft Fingertip (Model 8900)
1	MediByte Carrying case
1	USB Cable for MediByte (Model 8890)
1	MediByte Patient Guides (Model 8940)
1	MediByte/MediByte Jr User Manual (installed with software)
1	Hex Screwdriver for MediByte (Model 8870)
1	MediByte/MediByte Jr First Patient Setup Guide

Rechargeable Battery Kit is an available add-on. See page 1-12 for content list.

Contents of the MediByte Jr Kit

Verify that you have received the items listed in the MediByte Jr Kit and that no items were damaged during shipping. If any items are damaged or missing, please contact BRAEBON immediately at 1.888.462.4841. Do NOT use damaged items.

MediByte Jr Kit Contents

Quantity	Item
1	MediByte Jr Recorder (Model MBJR)
1	RIP Belt for MediByte (Model 8572)
1	SpO_2 Cable for MediByte, Soft Fingertip (Model 8900)
1	Patient Kit (Model 8110)
1	MediByte Jr Carrying case
1	USB Cable for MediByte (Model 8890)
1	Patient Guide to MediByte Jr (Model 8926)
1	MediByte/MediByte Jr User Manual (installed with software)
1	MediByte/MediByte Jr First Patient Setup Guide

Rechargeable Battery Kit is an available add-on.

Battery Charger Kit (Models 0444-N.A., 0445-E.U.)

Quantity	Item
1	1/2 AA Lithium Battery Charger Kit (Model 0429): contains 1/2 AA Battery Charger (Model 0422) and 1/2 AA Lithium Batteries - 2 pack (Model 0412-2)
1 of	AD/DC Power Adapter, 12 V, 0.5 A, Europe, Type C (Model 0426) AD/DC Power Adapter, 12 V, 0.5 A, North America, Type A (Model 0424)
Also available	AD/DC Power Adapter, 12 V, 0.5 A, United Kingdom, Type G (Model 0428)

Components and Accessories for MediByte (* available, not in kit)

Item	Device Name	Description
8572 8572PED* 8574*	RIP Belts for MediByte, Medium, small*, large* (MediByte/ MediByte Jr)	Plug into the chest and abdomen ports on the MediByte, used to detect respiratory effort.
8541	Ultima Snore Microphone for MediByte with Thermistor Input (MediByte only)	Plugs into the AUX port on the MediByte, used to detect snore sounds.
8611	Electrode Box (MediByte only)	Plugs into the AUX port on the MediByte, used to connect electrodes to the MediByte.
8612*	Electrode Box SE (MediByte only)	Plugs into the AUX port on the MediByte, used to connect electrodes to the MediByte for Sleep + EKG and Sleep + EEG montages.
8620	Leadwire Kit for MediByte (MediByte only)	Plugs into the Electrode Box on the MediByte, leadwires for connecting the self-adhesive electrodes. Contains nine leadwires: five 24” leadwires and four 60” leadwires.
8514	cTherm Cannula Thermistor for MediByte (MediByte only)	Plugs into the white input port on the snoring microphone or Electrode Box; used to measure airflow.
8896*	SpO_2 Cable for MediByte (MediByte/ MediByte Jr)	Plugs into the SpO_2 port on the MediByte, measures blood oxygen saturation and pulse (Flexiwrap style).
8898*	SpO2 Cable for MediByte, Large Soft Shell (MediByte/ MediByte Jr)	Plugs into the SpO_2 port on the MediByte, measures blood oxygen saturation and pulse.
8899*	SpO_2 Cable for MediByte, Earlobe (MediByte/ MediByte Jr)	Plugs into the SpO_2 port on the MediByte, measures blood oxygen saturation and pulse.
8900	SpO_2 Cable for MediByte, Soft Fingertip (MediByte/ MediByte Jr)	Plugs into the SpO_2 port on the MediByte, measures blood oxygen saturation and pulse (silicon finger pouch style).
8890	USB Cable for MediByte (MediByte/ MediByte Jr)	Connects the MediByte to the computer; used to program the MediByte for a study and for data download.
8110-25*	MediByte Patient Kit (MediByte/ MediByte Jr)	Package containing 25 of each: disposable 8597 Oronasal cannula, Paper Tape.

Item	Device Name	Description
8115-25*	MediByte Patient Kit (MediByte/ MediByte Jr)	Package containing 25 of each: disposable 8597 Oronasal cannula, 3.6V 1/2 AA Lithium battery. (North America only)
8119-25*	MediByte Patient Kit (MediByte/ MediByte Jr)	Package containing 25 of each: disposable 8597 Oronasal cannula, 3.6V 1/2 AA Lithium battery, Paper Tape. (North America only)
8120-25*	MediByte Patient Kit (MediByte/ MediByte Jr)	Package containing 25 of each: Nonin Flexiwrap Probe Tape, 3.6 V 1/2 AA Lithium battery, 8597 Oronasal cannula. For use with the 8896 SpO_2 cable for MediByte. (North America only)
8128-5	MediByte Electrode Prep Kit (MediByte only)	Package containing 5 of each: disposable 8597 Oronasal cannula, electrode prep pads and Paper Tape.
8128-20*	MediByte Electrode Prep Kit (MediByte only)	Package containing 20 of each: disposable 8597 Oronasal cannula, self-adhesive electrodes (20x5), electrode prep pads and Paper Tape. Not recommended for MediByte Jr.
8129-20*	MediByte Electrode Prep Kit (MediByte only)	Package containing 20 of each: disposable 8597 Oronasal cannula, self-adhesive electrodes (5x20), electrode prep pads, Paper Tape, 1/2 AA Lithium battery. Not recommended for MediByte Jr. (North America only)
8130-20*	MediByte Electrode Prep Kit (MediByte only)	Package containing 20 of each: disposable 8597 Oronasal cannula, self-adhesive electrodes (5x20), Paper Tape, 1/2 AA Lithium battery. Not recommended for MediByte Jr. (North America only)
8501-5	Vermed Self-Adhesive Electrodes (MediByte only)	Package containing 5 of each: disposable electrodes to apply to the patient for PLM, EKG, Brux and sleep studies.
8870	Hex Screwdriver for MediByte	Screwdriver for tightening the screw on the battery compartment.
	Carrying Case	Case to transport the MediByte or MediByte Jr.
8920	MediByte/MediByte Jr User Manual	User Guide for the clinician (downloaded with software).
8925/8940	Patient Guide	User Guide for the patient.
	MediByte/MediByte Jr First Patient Setup Guide	Quick-start guide for new users (clinician).

Overview of the MediByte and MediByte Jr

The Medibyte and MediByte Jr were designed for quick clinician-to-patient turnaround. The clinician prepares the recorder for data collection using the supplied MediByte Software. After the clinician prepares the MediByte (or MediByte Jr), the patient sleeps with the device and returns it to the clinician for data download and analysis. The data download and data analysis are performed using the MediByte Software. After reviewing the data, the clinician generates a report using the software.

Description of the MediByte and MediByte Jr

The MediByte and MediByte Jr are compact ambulatory devices designed to efficiently aid in the detection of a number of sleep disorders; such as apnea, upper airway resistance and snoring. Because of their small size and portability, clinicians are no longer limited to recording data in an artificial sleep environment. Data collection can occur in the patient's natural surroundings, over a more extensive period than might otherwise be practical in a sleep lab.

The MediByte is available in two models: the MediByte and the MediByte Jr.

The MediByte records up to 15 channels of physiological signals: oximetry; heart rate; photoplethysmography; pressure (flow); snore (derived from pressure); thermal flow; RIP chest effort; RIP abdominal effort; SUM (derived); event marker; body position; EEG, EOG, EMG and EKG (using AUX); or EKG, or EMG or snore audio (using AUX), sound level; CPAP flow and CPAP pressure.

The MediByte Jr records up to seven channels of physiological signals: oximetry; heart rate; pressure (flow); snore (derived from pressure); RIP chest effort; event marker; body position; CPAP flow and CPAP pressure. The MediByte Jr does not have an AUX port.

The MediByte and MediByte Jr consist of the following major components:

- the MediByte/MediByte Jr recorder
- the USB cable
- BRAEBON sensors
- MediByte Software.

The MediByte Recorder

The MediByte recorder has a plastic molded case with an Event button and Status LED on the front. On the top portion of the recorder, there is an auxiliary (AUX) port for snoring volume or EKG/EMG sensors, a pressure port and an SpO_2 port. On the bottom portion of the recorder,

there is a communication port, a chest port, an abdomen port and a collection on/off switch. See Figure 1.2 on page 1-17 for port locations.

The **Event button**, located on the front of the recorder, permits the patient to record an event by depressing the button. The event marker is defined by the clinician within the software. Common events are lights out, lights on and bathroom break.

The **Status LED** is a small light located on the front of the recorder; it flashes green or red to indicate the current state of the unit. For example, the LED flashes green once every six seconds to show that the recorder is waiting to collect; and it flashes green *twice* every six seconds to show that the recorder is collecting. Continuous red blinking indicates that the battery is too low to record a study, although it may have enough charge remaining to download data. See Displays and Indicators on page 2-5 for a complete list of Status LED indicators.

Figure 1.1: MediByte

The **Auxiliary Port (AUX)**, located on the top of the recorder, attaches either the snoring microphone (with or without thermistor) or either version of Electrode Box to the MediByte.

The **Pressure Port,** located on the top of the recorder, attaches the oral/nasal cannula to the recorder. You can also use this port to record CPAP pressure.

The **SpO_2 Port**, located on the top of the recorder, attaches the SpO_2 cable to the recorder.

The **Communication Port**, located on the bottom of the recorder, accepts the BRAEBON USB cable. Use this port to attach the recorder to the computer to configure a study and to download the data from the recorder. **Never attach the unit to the computer when it is already attached to the patient.**

The **Chest Port** attaches the RIP Belt for MediByte to the recorder.

The **Abdomen Port** attaches the RIP Belt for MediByte to the recorder.

The **Collection On/off Switch** sets the unit to record when in the manual mode. To start the recording, push the switch to the right (white dot). This switch only functions when the unit has been preset to manually record within the software. The collection on/off switch is disabled if

the unit is preset to automatically record within the software. It is also disabled when the unit is connected to the computer.

For optimized performance and ease-of-use, BRAEBON recommends the automatic mode.

Figure 1.2: MediByte port locations

BRAEBON Sensors

The **MediByte** uses the following BRAEBON sensors:

- Two RIP Belts for MediByte Belt (Model 8572). The RIP Belts for MediByte plug into the chest and abdomen ports on the MediByte. The belts detect the expansion and contraction of the abdomen and chest (effort) and contributes to the diagnosis of sleep apnea.
- One Ultima Snore Microphone for MediByte (Model 8541). The Ultima Snore Microphone for MediByte, which plugs into the AUX port on the MediByte, detects snore sounds.
- One Electrode Box (Model 8611). The Electrode Box, which plugs into the AUX port on the MediByte, attaches electrodes to the MediByte. Use this for Sleep, EKG, PLM and Bruxism studies.
- One (optional) Electrode Box SE (Model 8612). The Electrode Box SE, which plugs into the AUX port on the MediByte, attaches electrodes to the MediByte. Use this for Sleep + EKG or Sleep + EEG studies.
- One SpO_2 Cable for MediByte (Model 8900). The SpO_2 Cable for MediByte, which plugs into the SpO_2 port on the MediByte, measures blood oxygen saturation and pulse. It is used to aid in the diagnosis of sleep apnea. The status of the SpO_2 signal can be reviewed after the data has been downloaded.
- One oral/nasal cannula (Model 8597). The oral/nasal cannula, which plugs into the pressure port on the MediByte, measures airflow. It is used to aid in the diagnosis of sleep apnea.
- One cTherm cannula thermistor (Model 8514). The cTherm cannula thermistor, which plugs into the white input port on the snoring microphone (8541) or Electrode Box (8611), measures airflow using thermistors. It is used to aid in the diagnosis of sleep apnea.

The MediByte Jr Recorder

The MediByte Jr recorder has a plastic molded case with a Status LED on the front. On the top portion of the recorder, there is a pressure port and an SpO_2 port. On the bottom portion of the recorder, there is a communication port, a chest port and a collection on/off switch. See Figure 1.4 on page 1-20 for port locations.

The **Status LED** is a small light located on the front of the recorder; it flashes green or red to indicate the current state of the unit. For example, the LED flashes green once every six seconds to show that the recorder is waiting to collect; and it flashes green *twice* every six seconds to show that the recorder is collecting. Continuous red blinking indicates that the battery is too low to record a study, although it may have enough charge remaining to download data. See Displays and Indicators on page 2-5 for a complete list of Status LED indicators.

Figure 1.3: MediByte Jr

The **Pressure Port,** located on the top of the recorder, attaches the oral/nasal cannula to the recorder. You can also use this port to record CPAP pressure.

The **SpO_2 Port**, located on the top of the recorder, attaches the SpO_2 cable to the recorder.

The **Communication Port**, located on the bottom of the recorder, accepts the BRAEBON USB cable. Use this port to attach the recorder to the computer to configure a study and to download the data from the recorder. **Never attach the unit to the computer when it is already attached to the patient.**

The **Chest Port** attaches the RIP Belt for MediByte to the recorder.

The **Collection On/off Switch** sets the unit to record when in the manual mode. To start the recording, push the switch to the right (white dot). This switch only functions when the unit has been preset to manually record within the software. The collection on/off switch is disabled if the unit is preset to automatically record within the software. It is also disabled when the unit is connected to the computer.

Figure 1.4: MediByte Jr port locations

The **MediByte Jr** uses the following BRAEBON sensors:

- One RIP Belt for MediByte (Model 8572). The RIP Belt for MediByte plugs into the chest port on the MediByte Jr. The belt detects the expansion and contraction of the chest (effort) and contributes to the diagnosis of sleep apnea.
- One SpO_2 Cable for MediByte (Model 8900). The SpO_2 Cable for MediByte, which plugs into the SpO_2 port on the MediByte Jr, measures blood oxygen saturation and pulse. It is used to aid in the diagnosis of sleep apnea.
- One oral/nasal cannula (Model 8597). The oral/nasal cannula, which plugs into the pressure port on the MediByte Jr, measures airflow. It is used to aid in the diagnosis of sleep apnea.

MediByte Software

MediByte Software is the software designed to work exclusively with the MediByte/MediByte Jr. The software has a handy configuration wizard to help you quickly configure the recorder for a study. Enter the patient name, patient ID, patient weight and select the type of study you want to perform. The software sends this information to the recorder, telling it what types of channels are to be recorded and with whom to associate the data. After the patient has completed the study, download the data from the recorder onto the computer. The software will assist with data analysis. After you have reviewed the analysis and made any changes, you can enter more information into the Patient Info window and then generate and print a report.

BRAEBON Batteries

The MediByte/MediByte Jr uses a 3.6 V 1/2AA battery, Saft LS14250 (Model 0410-3) or a 1/2 AA Li-Ion Rechargeable Battery (Model 0412) supplied by BRAEBON. The Saft non-rechargeable battery can be used for a two-night study whereas the 1/2 AA Li-Ion Rechargeable Battery is good for a one-night study.

To recharge the rechargeable batteries, use the supplied 1/2 AA Lithium Battery Charger (Model 0422). Only charge rechargeable batteries; the Saft batteries **cannot** be recharged. Non-rechargeable batteries will cause the charger to overheat and may cause a fire or explosion.

The battery charger has an LED sequence as shown in the following table.

Table 1-1: Battery Charger LED Sequence

LED	Meaning
Red, always on	Battery is charging
Blue, always on	Battery is fully charged
Blue flash, red flash	Battery polarity is incorrect; reverse the direction of the batteries to continue.
Blue flash, red flash	If the battery polarity is correct, this indicates a voltage of less than 2.7V. Leave the batteries in the charger and after the voltage rises above 2.7V, the LED will change to red to indicate charging.

Chapter 2: Specifications

In this chapter

This chapter contains a number of tables which describe the MediByte and MediByte Jr. Also included are the manufacturer's declarations which show how the unit complies to the IEC Standard 60601-1. Included in this chapter:

- System requirements
- MediByte and MediByte Jr classification
- MediByte and MediByte Jr specifications
- Pulse oximeter specifications
- Displays and indicators
- Controls
- Manufacturer's declarations

System Requirements

The MediByte Software runs on a Windows computer.

Computer Processor	**Intel**: i5, i7 or higher or **AMD**: Zen Core Architecture, Ryzen 5 (or higher)
Hard drive	1/2 TB or larger with a minimum of 5 GB available space.
Minimum RAM	8GB
USB Port	2.0 (or higher)
Operating System	Windows 10 (or higher)
Software	Word 2016 (or higher)

MediByte and MediByte Jr Classification and Specifications

Table 2-1: MediByte and MediByte Jr Recorder Classification as per IEC 60601-1

Internally powered
Type BF
Ingress protection: IP22; as defined by IEC 60529 is protected from touch by fingers and objects greater than 12.5 mm diameter, and liquids from spray less than 15 degrees from vertical.
Sterilization not required, refer to cleaning methods
Category not anaesthetic proof, not suitable for such application
Continuous operation

Table 2-2: MediByte and MediByte Jr Specifications

Dimensions	2.5” x 2.25” x 0.75” (66 mm x 60 mm x 19 mm)
Weight	3.3 oz. with battery (93 g) MediByte 3.2 oz with battery (91 g) MediByte Jr
Case	Plastic (ABS)
Power	1/2 AA 3.6 V Saft LS 14250; max power 25 mA @ 3.6 VDC
Memory	Can store up to 18 hours of data (with audio) or 24 hours (with EMG-MediByte only)
MediByte and MediByte Jr contain no alarm systems.	

Table 2-3: Pulse Oximeter Specifications

Oxygen Saturation Range	0 to 100%
Pulse Rate Range	18 to 300 pulses per minute
Measurement Wavelengths Using Nonin Sensors	Red: 660 nanometers @ 3mW Nominal Infrared: 910 nanometers @ 3mW Nominal
Accuracy SpO_2 (70-100%) (± 1 SD)	No Motion - Adults, Pediatrics ± 2 digits; Neonates ± 3 digits Motion - Adults, Pediatrics ± 2 digits; Neonates ± 3 digits Low Perfusion- Adults, Pediatrics ± 2 digits; Neonates ± 3 digits
Accuracy Heart Rate	No Motion (18 - 300 BPM) - Adults, Pediatrics, Neonates ±3 digits Motion (40 - 240 BPM) - Adults, Pediatrics, Neonates ±5 digits Low Perfusion (40 - 240 BPM) - Adults, Pediatrics, Neonates ±3 digits
PULSE OXIMETER EQUIPMENT is calibrated to display FUNCTIONAL OXYGEN SATURATION.	
Device and accessories have been tested to EN ISO 80601-2-61:2019	
a) SpO_2 probes are designed for use with specific monitors; b) the OPERATOR is responsible for checking the compatibility of the monitor, probe and cable before use; and c) incompatible components can result in degraded performance. Note: Only BRAEBON-provided SpO_2 probes are compatible with MediByte and MediByte Jr.	

Displays and Indicators

Table 2-4: Displays and Indicators

LED	Status
At battery insertion, green/red alternating for four seconds	Unit functioning
Not flashing	Battery not inserted, battery dead
Flashing green once every six seconds	Recorder is waiting to collect
Flashing green twice every six seconds	Recorder is collecting
Flashing red once every six seconds	Low battery
Flashing red twice every six seconds	No SpO_2/Pulse signal
Blinking red continuously	Battery too low for a study; will not record data but may still work for data download
Solid green for up to one minute, then green twice every six seconds	MediByte/MediByte Jr is turned on using the ON/OFF switch

Table 2-5: Controls

Control	Function
Event button	When pressed, the event button records the button press. The event is predefined by the clinician. (MediByte only)
Collection on/off switch	The MediByte / MediByte JR will start collecting data when the switch is moved to the right (white dot). The switch is de-activated in the automatic mode.

Manufacturer's Declaration

Table 2-6: IEC 60601-1-2 Statements

Clause 6.8.2.201 a) 1)	Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
Clause 6.8.2.201 a) 2)	Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
6.8.3.201 a) 1)	The use of accessories, transducers, and cables other than those specified by the manufacturer, may result in increased Emissions or decreased Immunity of the System.
6.8.3.201 a) 4)	The System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.

Table 2-7: Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The MediByte is intended for use in the electromagnetic environment specified below. The customer or the user of the MediByte should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The MediByte uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The MediByte is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2-8: Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The MediByte is intended for use in the electromagnetic environment specified below. The customer or the user of the MediByte should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable. Battery powered.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable. Battery powered.	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Not applicable. Battery powered.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MediByte requires continued operation during power mains interruptions, it is recommended that the MediByte be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Table 2-9: Guidance and Manufacturer's Declaration - Electromagnetic Immunity - For Equipment and Systems that are not Life-Supporting

The MediByte is intended for use in the electromagnetic environment specified below. The customer or the user of the MediByte should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the MediByte, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	$d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Table 2-9: Guidance and Manufacturer's Declaration - Electromagnetic Immunity - For Equipment and Systems that are not Life-Supporting

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless), mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, a survey should be considered. If the measured field strength in the location in which the MediByte is used exceeds the applicable RF compliance level above, the MediByte should display normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MediByte.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the MediByte

The MediByte is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MediByte can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MediByte as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 2-10: Pulse Oximeter probes validated and tested for compliance with EN ISO 80601-2-61

8896	SpO_2 Cable for MediByte
8898	SpO_2 Cable for MediByte, Large Soft Shell
8899	SpO_2 Cable for MediByte, Earlobe
8900	SpO_2 Cable for MediByte, Soft Fingertip

Chapter 3: Installing the Software

In this chapter

This chapter describes how to install the MediByte software onto your computer. After you have installed the software, you can configure the MediByte/MediByte Jr and start collecting data. You cannot collect data until you have installed the software and configured the recorder. When you configure the recorder, you are telling it the name of the patient and the study parameters.

This chapter includes:

- Installing the MediByte software
- Connecting the MediByte/MediByte Jr to the computer
- Activating the MediByte software

Installing the MediByte Software

The MediByte software is installed from the Braebon.com website. After you have installed the software, a MediByte icon  will be placed on your desktop.

To install the software:

Installing the software is easy, an installation wizard will guide you through the process.

1. In your web browser (eg., Internet Explorer, Firefox), type braebon.com/setup.
2. Click MediByte.
   - Click the red **Download** link beside MediByte Software. The system is designed to start the installation process, but your web browser may not allow this. A new window may open asking whether you want to save the file, click **Save File**. The software will then download to your computer, usually in the *Downloads* folder.

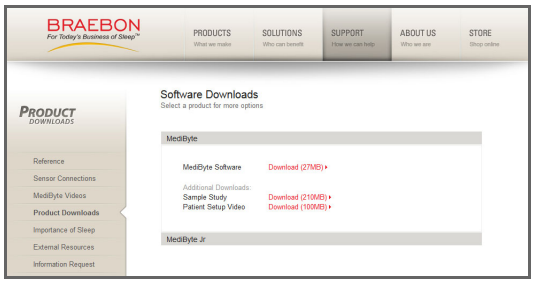


Figure 3.1: MediByte Software download

3. Double-click on the MediByte Installer File.
4. A security window may open asking you whether you want to run the file. Click **Run**. The MediByte Installation Wizard will open.
5. Click **Next** to open the Software License Agreement.
6. Review the software license agreement, and if you accept the terms, click the radio button beside *I accept the terms of the license agreement*, and click **Next**.
7. Click **Install**.

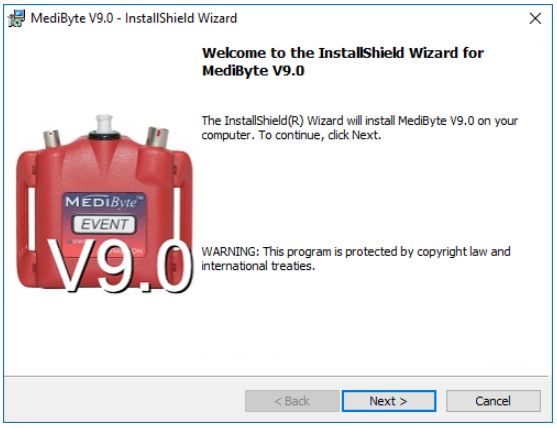


Figure 3.2: Installation Wizard

8. Click **Finish** to exit the Installation Wizard.
   The software installs in **C:\Program Files (x86)\MediByte v9.0** by default. You will find the MediByte icon  on your desktop.

Connecting the MediByte to the Computer

Install the software before you connect the MediByte to the computer.

1. Insert a battery into the MediByte.
2. Using the MediByte USB Cable, connect the large connector to your computer's USB port and connect the small connector to the MediByte communication port. The first time you connect a MediByte to the computer, the MediByte hardware drivers will automatically install.
3. Double-click the MediByte software icon  to start the MediByte Software.

Activating the MediByte Software

The first time you use the MediByte Software, you are required to authorize it. Authorizing the software consists of entering the serial number of your MediByte and an activation code into the BRAEBON on-line activation page. The page will generate an authorization code to be typed into the Software Activation page. If you do not have Internet access call 1.888.462.4841 (9-5 EST).

1. Double-click the MediByte software icon on the desktop. This action will open the Software Activation Page.
2. Using the dropdown menu, select the language you want to use. Select the language *before* activating the MediByte. You can also change the language within the Analysis screen in the MediByte Software.
3. Make a note of the ***Activation Code*** shown on the screen.
4. Select the **Click Here** button to open the BRAEBON on-line activation page.

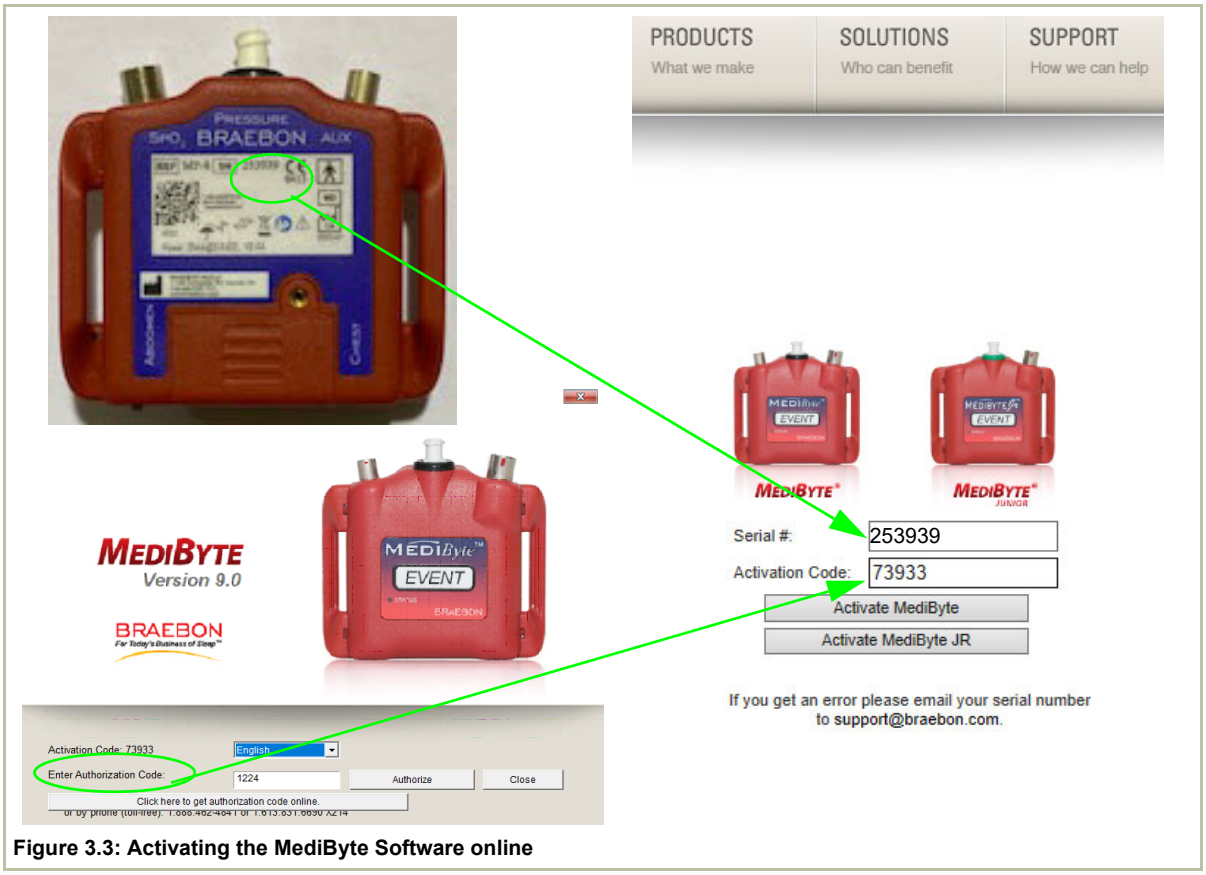
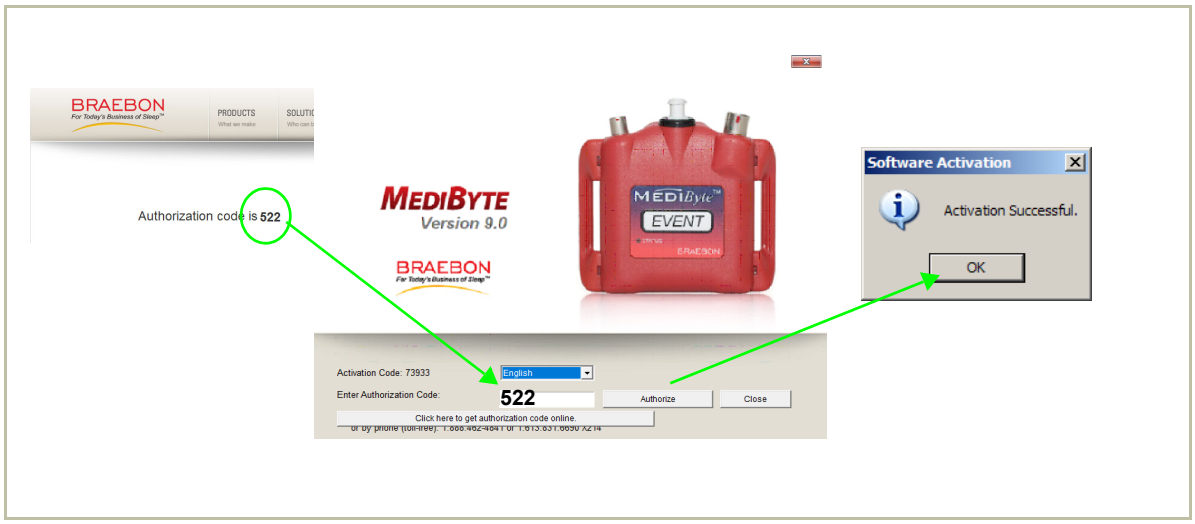


Figure 3.3: Activating the MediByte Software online

5. Type the **Activation Cod**e into the Activation Code field on the on-line activation page.

6. Type the serial number from the back of your MediByte/MediByte Jr into the Serial# field on the on-line activation page. You can also find the serial number on the packaging label.
7. Click **Activate MediByte**. You will receive an *Authorization Code*, enter it into the Enter Authorization Code field on the Software Activation screen, and click **Authorize**.
8. A pop-up window will notify you of your success. You are now ready to use the MediByte software.



Chapter 4: Preparing the MediByte

In this chapter

This chapter describes how to prepare the MediByte and MediByte Jr for a study. To prepare a recorder, you must connect it to the computer and use the MediByte wizard to program it.

This chapter includes information about how to:

1. Insert a new battery into the MediByte/MediByte Jr;
2. Connect the MediByte/MediByte Jr to the computer and start the software;;
3. Select an operation;
4. Enter patient information;
5. Select an auxiliary device (MediByte only);
6. Select the start time;
7. Review the settings and configure the MediByte/MediByte Jr;
8. Prepare a kit for the patient.

Preparing the MediByte for a Study

Before You Begin

1. Install the MediByte Software (see Chapter 3).
2. Insert a new battery into the MediByte/MediByte Jr.
3. Ensure the patient is not connected to the MediByte/MediByte Jr.

Preparing the MediByte/MediByte Jr for a study consists of the following steps:

1. Insert a new battery into the MediByte/MediByte Jr.
2. Use the USB cable to connect the MediByte/MediByte Jr to the computer and click on the MediByte Software icon to start the MediByte Software.
3. Select an operation in the MediByte wizard.
4. Enter the patient name, ID and weight.
5. Select an auxiliary device (MediByte only).
6. Select the start time.
7. Review the settings and configure the MediByte/MediByte Jr.

1. Insert a fresh Battery into the MediByte/MediByte Jr

The Saft LS14250battery, Model 0410-3, lasts for two over-night studies. To ensure that you don't lose power during a study, make it a habit to insert a fresh battery *before* you configure the MediByte/MediByte Jr. If you are using rechargeable batteries, you cannot run a two-night study without changing batteries between studies.

1. Using the hex screwdriver provided with your kit, remove the battery compartment screw.
2. Remove the battery compartment cover by pushing it down and away from you. Use the ribbon to extract the used battery.
3. With the ribbon on the bottom of the battery compartment, insert a new battery ensuring the polarity of the battery matches the diagram on the bottom of the compartment.
4. Replace the battery compartment cover, reinsert and tighten the screw. Do not over-tighten the screw as this may strip it.

2. Connect the MediByte/MediByte Jr to the Computer

Do NOT connect the MediByte/MediByte Jr to the computer while it is in contact with the patient. This could cause serious injury to the patient.

To connect the MediByte/MediByte Jr to the computer:

1. Connect the large end of the USB cable to the USB port of the computer and connect the other end of the USB cable to the MediByte/MediByte Jr.
2. Double-click the MediByte software icon 

on your desktop to start the software. The software will automatically detect whether the recorder is a MediByte or MediByte Jr.

3. Select an Operation in the wizard

The software features a MediByte wizard which guides you through the system settings. Here, you will choose whether to configure the MediByte/MediByte Jr for a study, download data or review an existing data file.

1. The MediByte wizard requires that you confirm that your patient is not connected to the MediByte/MediByte Jr by clicking the checkbox.
   - Click **Next** to continue.

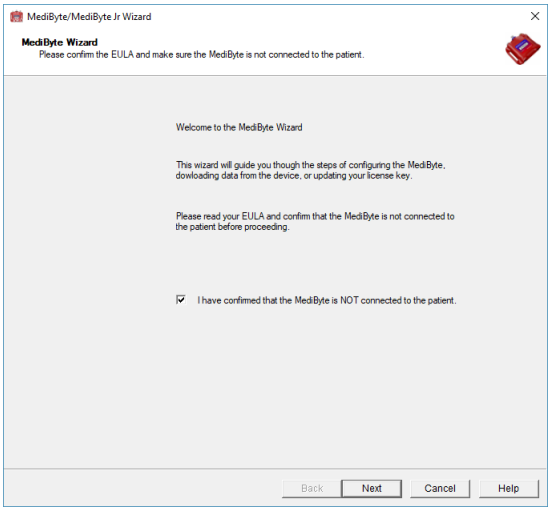


Figure 4.1: Opening screen

2. In the Operation Selection window, select from the list of activities.

- To prepare for a study, select *Configure the Medibyte for a Study* and click **Next** to move to the Patient screen.
- To retrieve data from the recorder, select *Download data from the MediByte* and click **Next** to start the data download.
- To review a data file stored on the computer, select *Review Existing Data File* and click **Next** to open the Load and Review window to select a data file.
- The Renew MediByte license (Unlimited-use device) is inactive because your device has an unlimited number of uses.

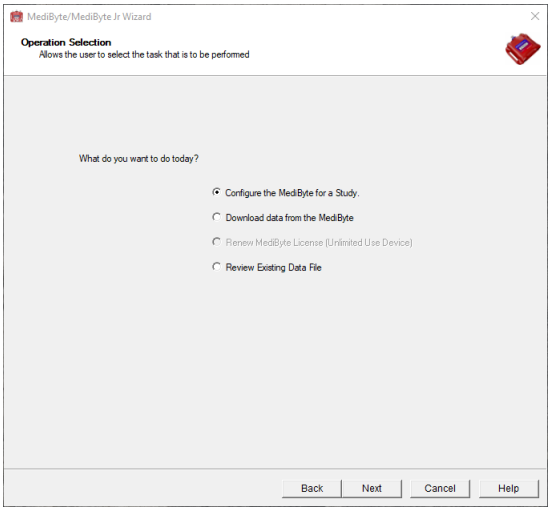


Figure 4.2: Operation Selection window

4. Enter Patient Information

In the Patient Information window, enter the patient's name, identification number and weight. Enter this information correctly as the patient file name is created using the patient's last name and ID.

1. Type the patient's last name in the *Last Name* field. This field is limited to 20 characters.
2. Type the patient's first name in the *First Name* field. This field is limited to 12 characters.
3. Type the patient's unique code in the *Patient ID* field. This field is limited to ten characters.
4. Type the patient's weight in either kilograms or pounds. The weight entered determines whether the patient is an adult or pediatric patient; i.e., greater than 55 pounds (25 kg) is considered adult. The default weight is 100 pounds (45 kg).
5. Click **Next** to move to the next screen. You cannot use the Next button to move forward until you have entered information into all of the fields.

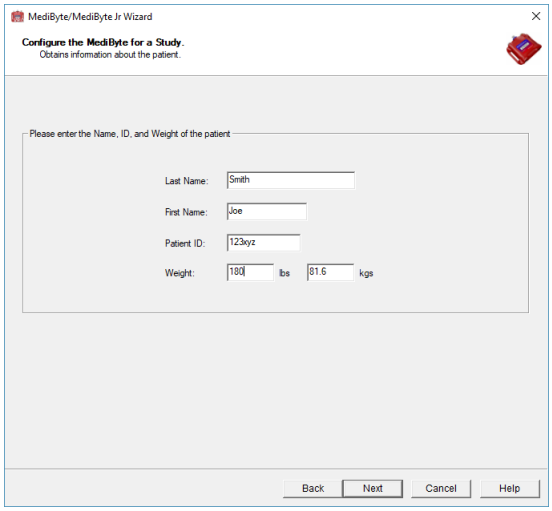


Figure 4.3: Patient information window

5. Select an Auxiliary Device (MediByte only)

The MediByte wizard prompts you to select the function of the auxiliary port. Use this screen to select the external accessory you want to use for the recording; this is the accessory that plugs into the AUX port.

If you select Do Not Use AUX, do not select Use Airflow Thermistor.

1. Select the auxiliary device from the list and click **Next** to move to the start time screen.

- Snore microphone
- EKG
- EMG Bruxism
- EMG PLM
- Sleep
- Sleep + EKG*
- Sleep + EEG*
- Do not use AUX channel

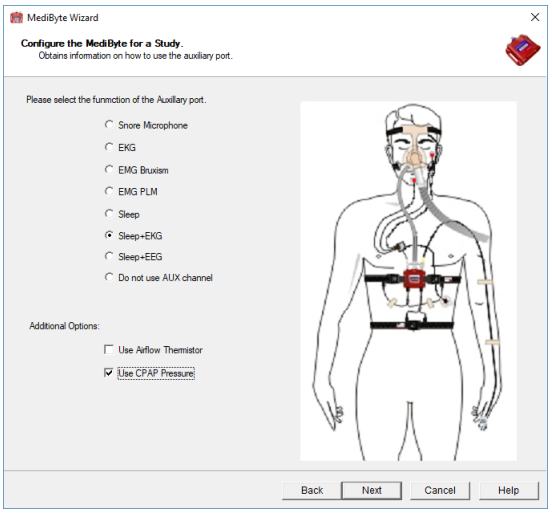


Figure 4.4: Auxiliary device window

Additional Options:

- Use Airflow Thermistor
- Use CPAP Pressure

As each item is selected, the picture corresponding to the selection changes.

*** These montages require the 8612 Electrode Box SE. You cannot use the thermistor with these montages.**

6. Select the Start Time

Select whether the recording will start automatically or manually. Automatically means the MediByte/MediByte Jr will start recording data at the time specified; the collection on/off switch is disabled. Manually means the collection on/off switch is enabled and the patient must start the data recording by pushing the collection on/off switch on the MediByte/ MediByte Jr to the right (white dot).

For a successful two-night recording, select automatic mode. This mode preserves battery power.

1. Select either the automatic or manual start. If you select automatic, you must select the start date and time.
2. Select either a one-night or two-night study and click **Next** to move forward to the summary screen. If you have opted to perform an EKG study, you will also have the option to select a 24-hour study.

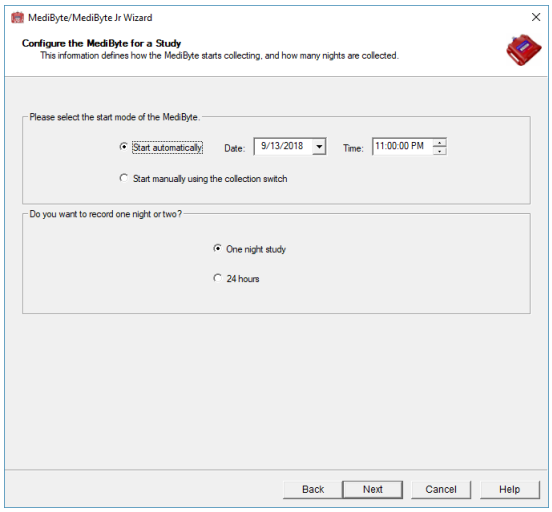


Figure 4.5: Select the start time

7. Review the Settings And Configure the MediByte

The Summary screen permits you to review the settings before you configure the MediByte/ MediByte Jr. If the settings are correct, start the configuration by clicking **Next**. If you need to change one of the settings, use the **Back** button to return to the previous screens.

When you configure the MediByte/MediByte Jr**,** the software sends the patient information and study settings to the recorder. You must configure the recorder before you start a study.

1. Review the summary screen. If the settings are correct, click **Next**. The software will confirm that you have finished and it is ready to configure the recorder.

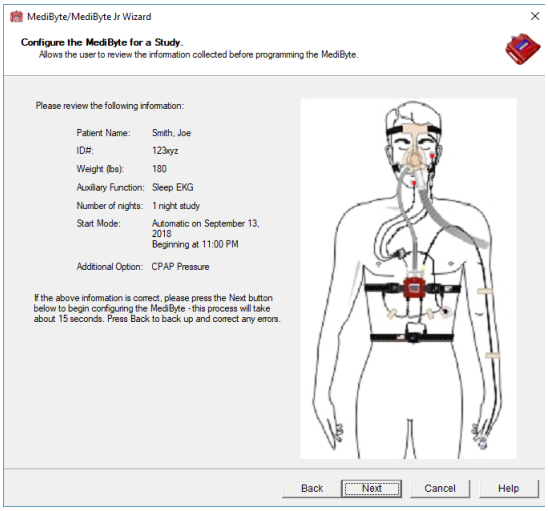


Figure 4.6: Summary screen

2. Select **Finish**. The software will send the patient information and study settings to the recorder. This action is called *configuring* the MediByte/ MediByte Jr. Once the recorder is configured, the software closes automatically and you can disconnect the recorder from the computer.

   The MediByte/MediByte Jr is now ready to record a study.

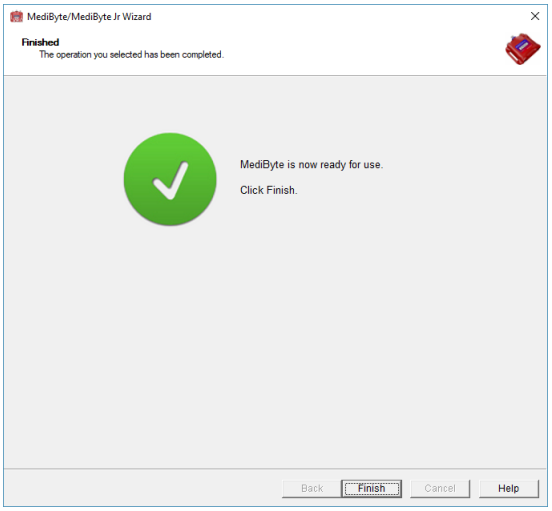


Figure 4.7: Final screen

8. Prepare a MediByte Kit for the Patient

The MediByte Jr Kit has all items required for a study. For the MediByte, pack the kit with only the sensors the patient requires to perform the study.

Study type	Requirements
No Aux (Cannula Study)	MediByte 2 RIP Belts with cables SpO_2 Cable Patient Kit
Snore	MediByte 2 RIP Belts with cables SpO_2 Cable Snore Microphone Patient Kit
EKG	MediByte 2 RIP Belts with cables SpO_2 Cable Electrode Box 3 EKG Leadwires (24”) Electrode Prep Kit
BRUX or SLEEP	MediByte 2 RIP Belts with cables SpO_2 Cable Electrode Box 4 EKG Leadwires (24”) Electrode Prep Kit
PLM	MediByte 2 RIP Belts with cables SpO_2 Cable Electrode Box 4 EKG Leadwires (60”) 1 EKG Leadwire (24”) Electrode Prep Kit
SLEEP + EKG or SLEEP +EEG	MediByte 2 RIP Belts with cables SpO_2 Cable Electrode Box SE 5 EKG Leadwires (24”) Electrode Prep Kit

Chapter 5: Preparing the Patient

In this chapter

This chapter describes how to place the sensors on the patient, where to plug the sensors into the MediByte/MediByte Jr, how to begin and how to end a study.

This chapter includes:

- MediByte Jr study
  - RIP Belt for MediByte
  - SpO_2 Cable for MediByte
  - Cannula
- CPAP pressure study (MediByte Jr)
- Snore study (MediByte)
  - Chest and abdominal RIP Belts
  - Snore microphone
  - Cannula placement or
  - Cannula with thermistor placement
  - SpO_2 Cable for MediByte
- Auxiliary channel electrode placement (MediByte)
  - EKG study
  - EMG Bruxism study
  - EMG PLM study
  - Sleep study
  - Sleep + EKG study
- Starting the study
- Ending the study

MediByte Jr Study

The MediByte Jr study uses a cannula, RIP Belt for MediByte and an SpO_2 Cable for MediByte.

Preparing for a MediByte Jr study is so easy the patient can usually do it at home.

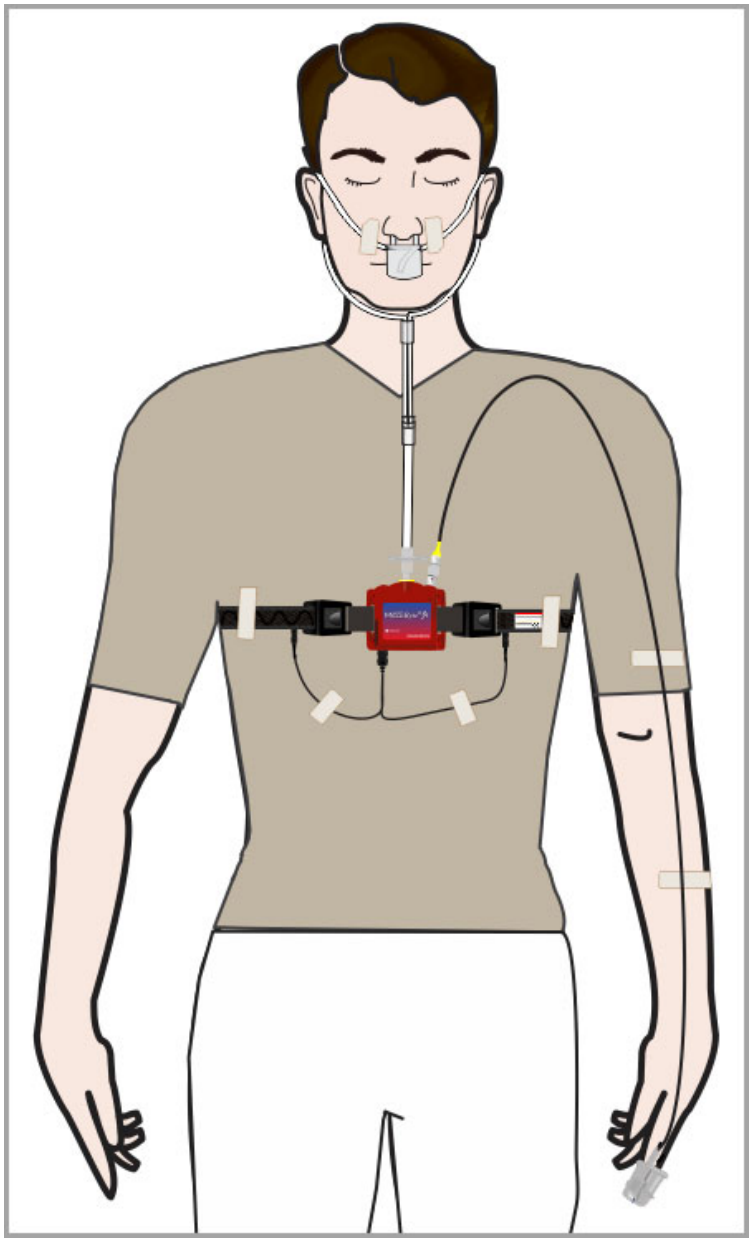


Figure 5.1: MediByte Jr study

1. Place the Chest RIP Belt

The chest RIP Belt clips onto the MediByte Jr, as illustrated.

1. With the MediByte Jr upright and facing you, clip the black belt onto the right MediByte Jr clip.
2. Tighten the belt as much as possible; it is much easier to loosen a tight belt on the body than to tighten a loose belt.
3. Wrap the belt around the chest and clip into the remaining MediByte Jr clip.

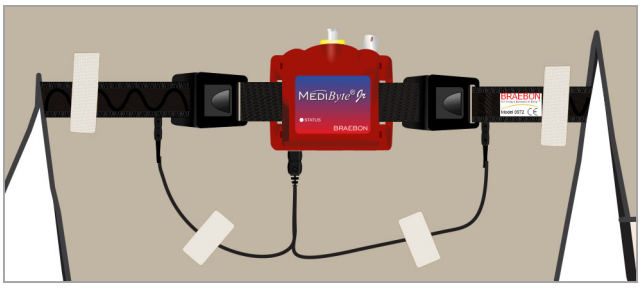
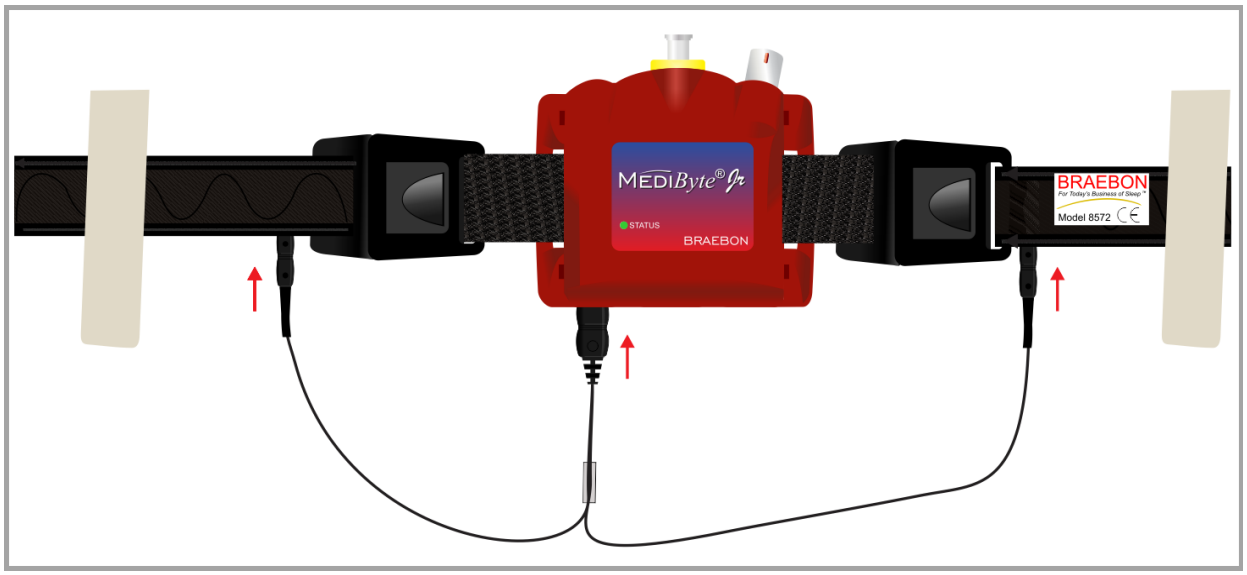


Figure 5.2: Placement of the chest RIP Belt

4. Ensure the belt is located above or below the patient's nipple line and loosen for a firm but comfortable fit.
5. Take the Y-shaped black cable and plug one safety pin connector into the left socket located on the belt and the other safety pin connector into the right socket.
6. Use medical tape to tape down the wires, if desired.
7. Plug the keyhole connector into the black keyhole input on the bottom right (when wearing) of the MediByte Jr, labelled **CHEST**.



Place the cannula (MediByte Jr):

1. Position the nasal prongs in the patient's nostrils and wrap the tubes over the ears and under the chin.
2. Using medical tape, secure the tubes to the patient's face.
3. Adjust the slider for a comfortable fit under the chin.
4. On the MediByte Jr, screw the filter on the end of the cannula to the input marked **PRESSURE**. Do NOT overtighten the filter.

Figure 5.3: Pressure cannula placement

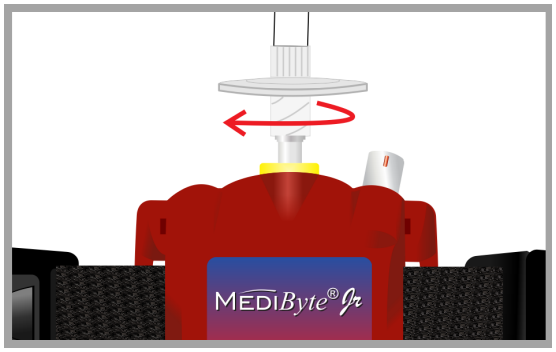


Figure 5.4: Connect the pressure filter to the Pressure cannula connection

Place the SpO_2 Cable for MediByte (MediByte Jr)

Remove artificial nails and nail polish from the chosen finger before you begin.

1. Place the cleaned middle finger (recommended) into the silicone pouch. Align the light-emitting sensor over the nail bed. The tip of the finger must not go through the end of the pouch.
2. Tape the sensor cable with medical tape after the second knuckle; ensure the finger can bend freely and movement is not restricted.
3. On the MediByte Jr, slide the sensor connector into the input marked SpO_2, ensuring the red dot on the connector aligns with the red dot on the SpO_2 input.

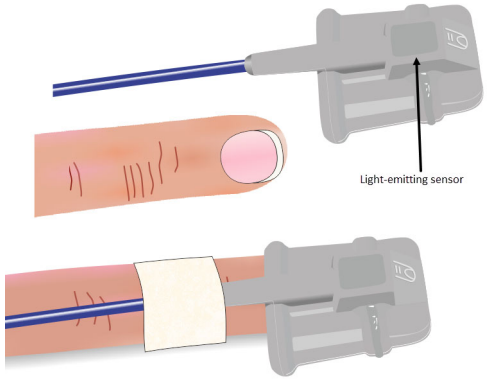


Figure 5.5: Using the SpO_2 Cable for MediByte

Ensure the red dot on the finger probe connector is aligned with the red dot on the MediByte Jr. Do NOT twist the connector; it will move easily in and out of the port once the dots are aligned. Give the connector a *light* tug to ensure that it is fully connected and will not come loose during the night.

Maximum application time for a site (finger) is nine hours.

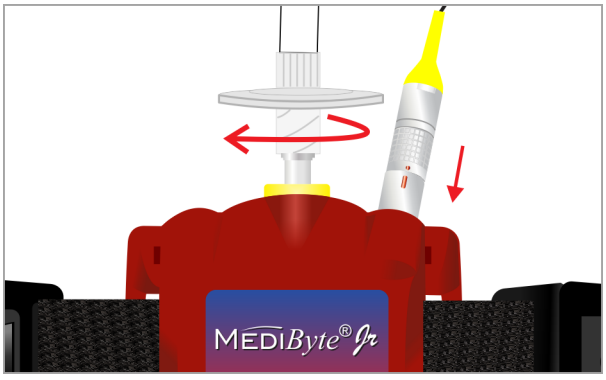


Figure 5.6: Connect the sensor to the SpO_2 port

CPAP Pressure Study (MediByte Jr)

For a CPAP Pressure study, the patient wears CPAP headgear attached to the MediByte Jr with CPAP pressure tubing and the SpO_2 sensor. The following page illustrates how to attach the MediByte to CPAP Adapter (Model 8552) to the CPAP headgear. To place the SpO_2 sensor onto the patient, see page 5-5.

Preparing for a CPAP Pressure study is so easy that usually the patient can do this at home.

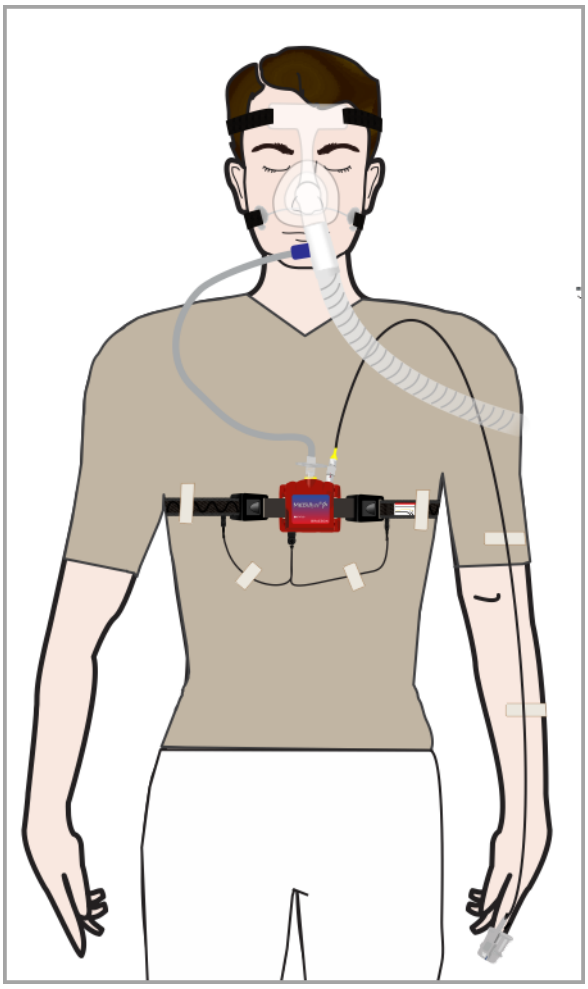


Figure 5.7: CPAP study

Attach the CPAP Pressure tubing:

1. Position the CPAP mask on the patient. The diagram illustrates a generic CPAP mask, your mask may look different.
2. Attach the MediByte to CPAP Adapter (Model 8552) to the CPAP output nozzle.
3. On the MediByte Jr, screw the filter end of the MediByte to CPAP Adapter (Model 8552) to the input marked **PRESSURE**. Do NOT overtighten the filter.

   Alternative attachment: attach pressure tubing to the nipple port on the CPAP mask (shown). Alternatively, you can attach the MediByte to CPAP Adapter (Model 8552) to an inline adapter.

Figure 5.8: Connect the MediByte to CPAP Adapter (Model 8552) to the CPAP output nozzle

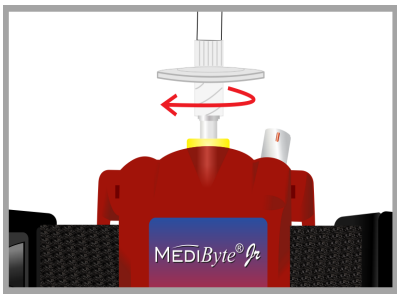


Figure 5.8: Connect the CPAP pressure tubing to the Pressure connection

Figure 5.8: Alternative attachment

Snore Study (MediByte)

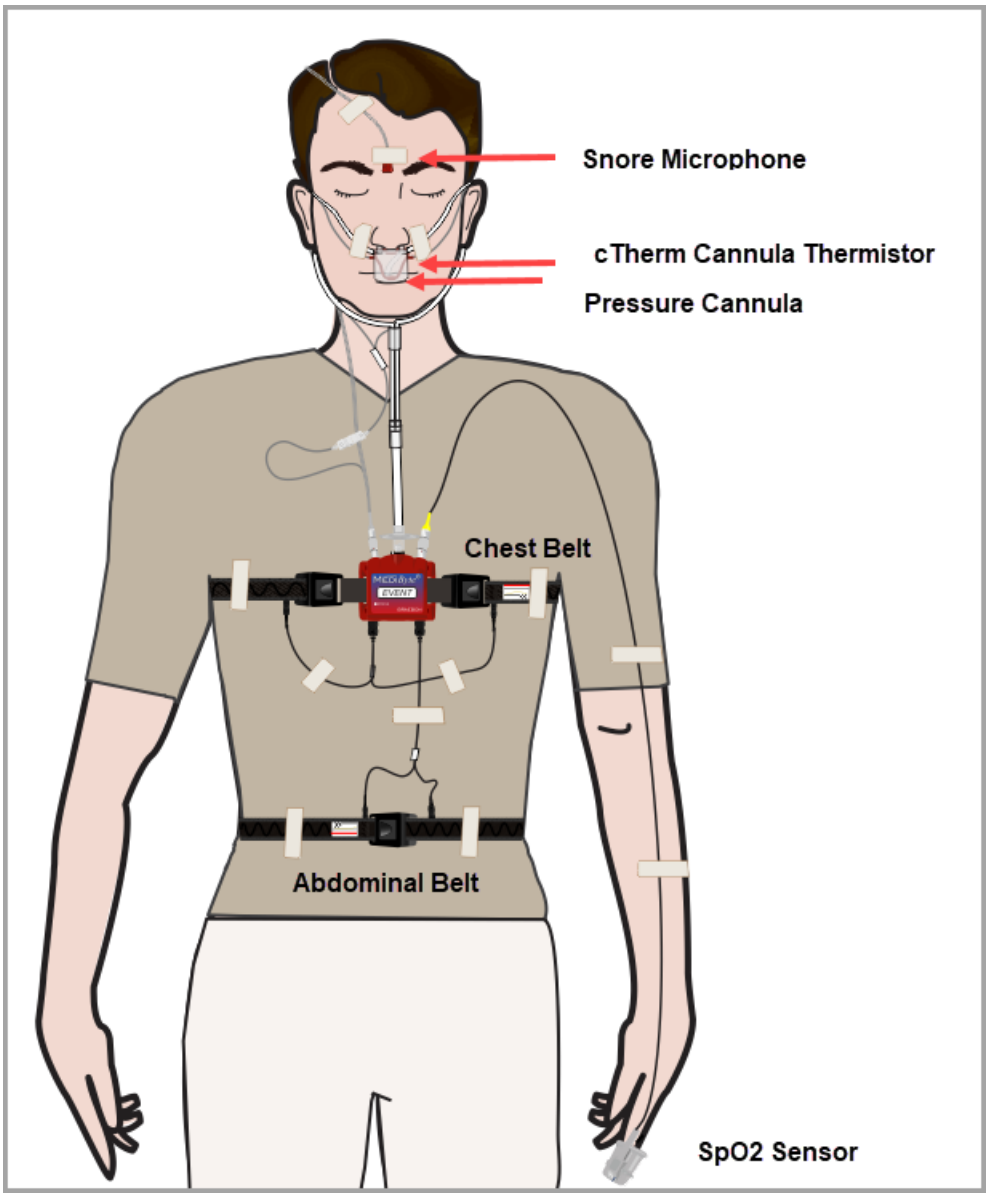


Figure 5.9: Snore study

Chest and Abdominal RIP Belts

The chest and abdominal RIP Belts record respiratory effort.

To place the chest RIP Belt

The chest RIP Belt clips onto the MediByte as illustrated.

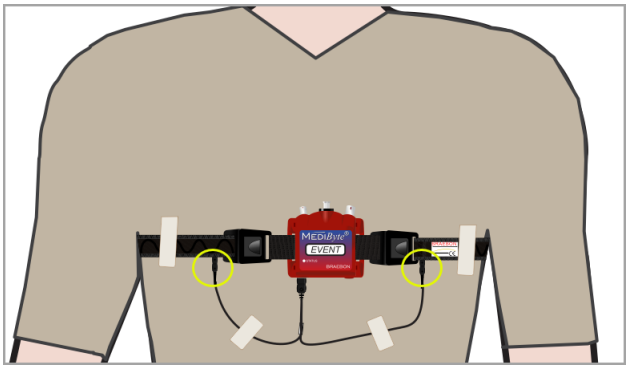
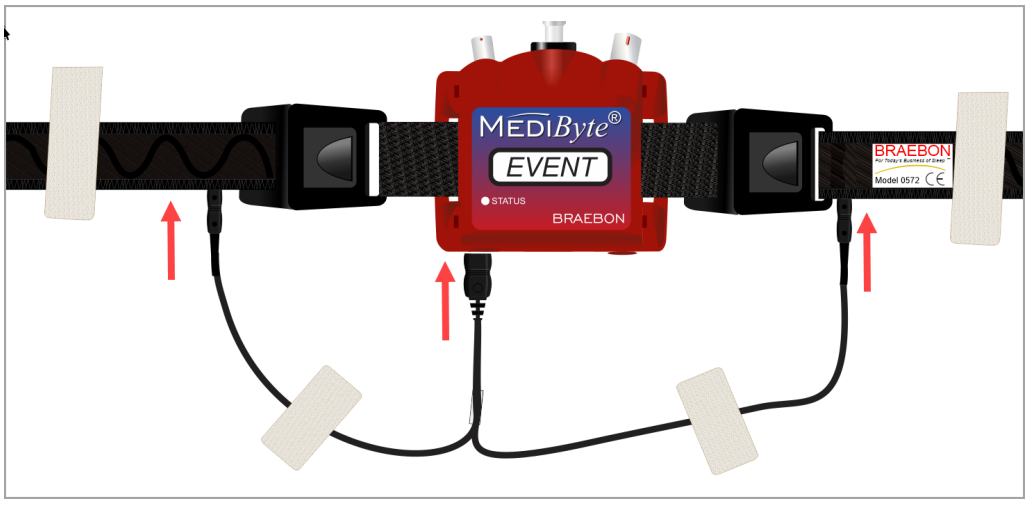


Figure 5.10: Placement of the chest RIP Belt

1. With the MediByte upright and facing you, clip the black belt onto the right MediByte clip.
2. Tighten the belt as much as possible; it is much easier to loosen a tight belt on the body than to tighten a loose belt.
3. Wrap the belt around the chest and clip into the remaining MediByte clip.
4. Ensure the belt is located above or below the patient's nipple line and loosen for a firm but comfortable fit.
5. Take one of the Y-shaped black cables and plug one safety pin connector into the left socket located on the belt (circled) and the other safety pin connector into the right socket (circled).
6. Use medical tape to tape down the wires, if desired.
7. Plug the keyhole connector into the black keyhole input on the bottom right of the MediByte labelled **CHEST**.



To place the abdominal RIP Belt

The abdominal RIP Belt is placed below the rib cage.

1. As with the chest RIP Belt, tighten the belt as much as possible before putting it on.
2. Wrap the belt around the patient's abdomen and snap closed. Loosen for a firm but comfortable fit.
3. Take the remaining black Y-shaped cable and plug one safety pin connector into the left socket located on the belt and the other safety pin connector into the right socket.
4. Use medical tape to tape down the wires, if desired.
5. Plug the keyhole connector into the black keyhole input on the bottom left of the MediByte labelled **ABDOMEN**.

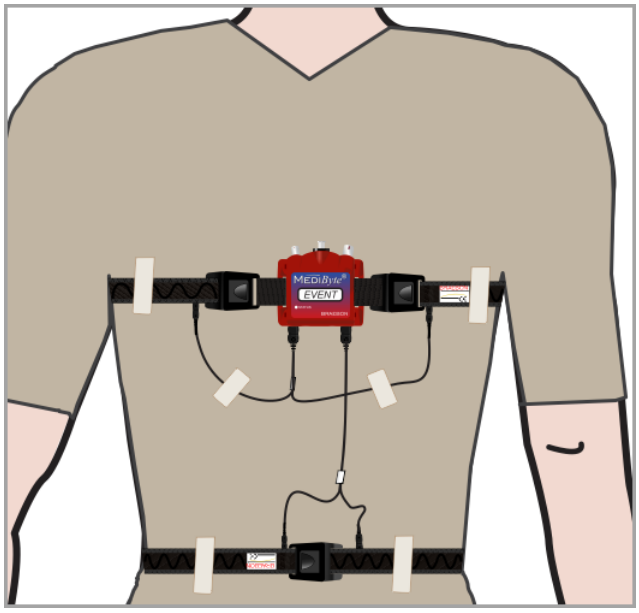


Figure 5.11: Placement of the abdominal RIP Belt

Snore Microphone

The Snore Microphone collects snoring sounds.

1. Position the Snore Microphone on the patient's forehead or cheek.
2. Secure the Snore Microphone with medical tape.
3. Plug the Snore Microphone into the **AUX** port on the MediByte, ensuring the red mark on the connector lines up with the red mark on the port (circled).
4. If you are using a cTherm cannula thermistor, plug the connector from the cTherm cannula thermistor into the white connector on the Snore Microphone. See page 5-13 for placing the cTherm cannula thermistor.

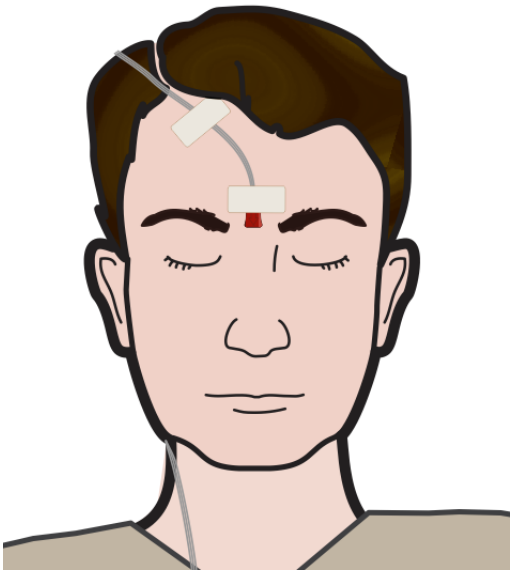


Figure 5.12: Snore Microphone placement

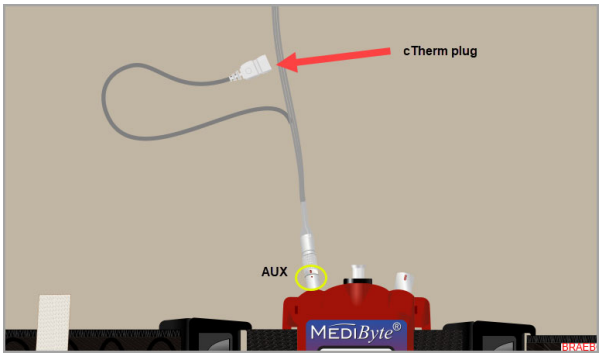


Figure 5.13: Connect the Snore Microphone to AUX.

Cannula Placement

The cannula measures airflow.

1. Position the nasal prongs in the patient's nostrils and wrap the tubes over the ears and under the chin.
2. Using medical tape, secure the tubes to the patient's cheeks.
3. Adjust the slider for a comfortable fit under the chin.
4. On the MediByte screw the filter on the end of the cannula to the input marked **PRESSURE**. Do NOT overtighten the filter.

Figure 5.14: Pressure cannula placement

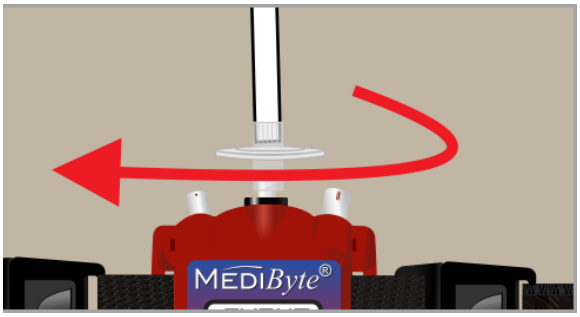


Figure 5.15: Connect the pressure filter to the Pressure cannula connection

Cannula with Thermistor Placement

The cannula and thermistor both measure airflow.

1. Position the cTherm cannula thermistor onto the cannula so that the cTherm cannula thermistor will be facing toward the patient. In other words, the cTherm cannula thermistor is behind the cannula when applied to the patient.
2. Position the nasal prongs in the patient's nostrils, the cTherm cannula thermistor mouth-piece is on the inside, closest to the mouth.
3. Gently grasp the cannula tubing and cTherm cannula thermistor wires together, and wrap them over the ears and under the chin.
4. Adjust the sliders on both the cannula and the cTherm cannula thermistor for a comfortable fit under the chin.
5. On the MediByte screw the filter on the end of the cannula to the input marked **PRESSURE**. Do NOT overtighten the filter.
6. The cTherm cannula thermistor plugs into the Snore Microphone.

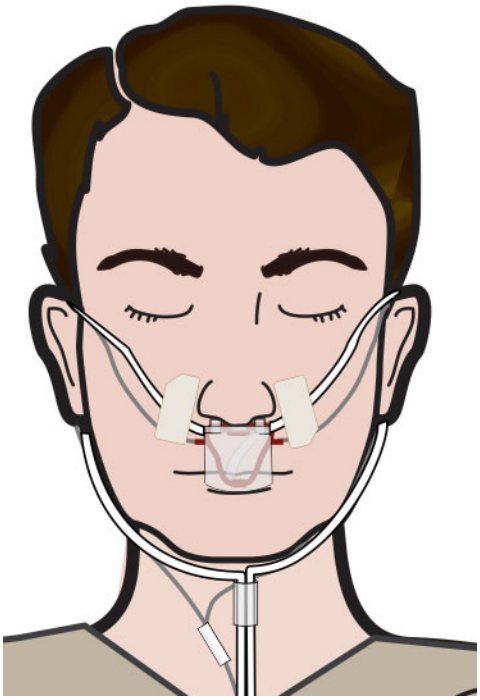


Figure 5.16: Pressure cannula with thermistor

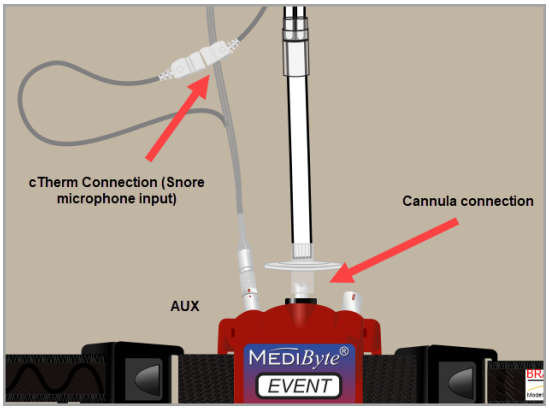


Figure 5.17: Connecting the pressure cannula and thermistor

Figure 5.18: cTherm placement on the cannula

SpO_2 Cable for MediByte

Remove artificial nails and nail polish from the chosen finger before you begin.

1. Place the cleaned middle finger (recommended) into the silicone pouch. Align the light-emitting sensor over the nail bed. The tip of the finger must NOT go through the end of the pouch.
2. Tape the sensor cable with medical tape after the second knuckle. Ensure the finger can bend freely and movement is not restricted.
3. On the MediByte, slide the sensor connector into the input marked SpO_2, ensuring the red dot on the connector aligns with the red dot on the SpO_2 input.

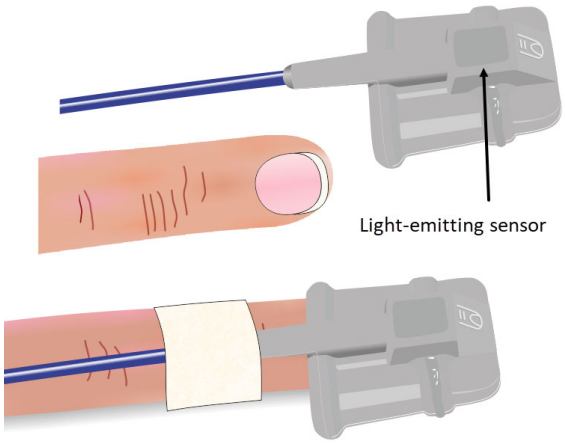


Figure 5.19: Using the SpO_2 Cable for MediByte

Ensure the red dot on the finger probe connector is aligned with the red dot on the MediByte. Do NOT twist the connector; it will move easily in and out of the port once the dots are aligned. Give the connector a **light** tug to ensure that it is fully connected and will not come loose during the night.

Maximum application time for a site (finger) is nine hours.

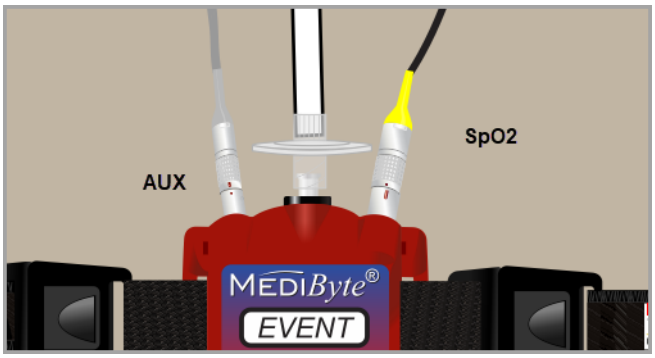


Figure 5.20: Connect the sensor to the SpO_2 port

Using a FlexiWrap SpO_2 Cable for MediByte

Do not wrap the FlexiWrap around the finger too tightly or you may restrict blood flow.

1. With the FlexiWrap face down on the table, pull up the tab and peel away the paper backing. The FlexiWrap has cutouts that fit over the finger sensor.
   - Insert the sensor into the cutouts in the FlexiWrap.

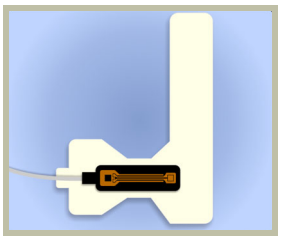


Figure 5.21: FlexiWrap and sensor

2. Place the index finger on the sensor so the dotted line on the FlexiWrap is at the tip of the finger.
   - Wrap the small side flaps around the side of the finger.

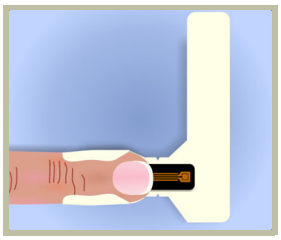


Figure 5.22: Finger on the sensor

3. Fold the FlexiWrap over the top of the index finger so the raised parts of the sensor are vertically aligned.
   - Wrap the small side flap around the side of the finger.

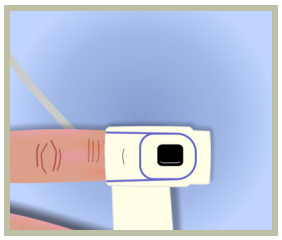


Figure 5.23: Fold and wrap

4. Wrap the long flap around the finger.
   - Around the base of the index finger, tape the sensor cable with medical tape.

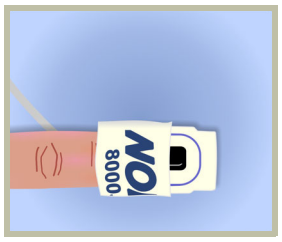


Figure 5.24: Wrap the long flap

5. Use medical tape to secure the leads on the patient's arm. If the patient is wearing a long-sleeve top, you can run the cable up the sleeve and out of the neck hole, foregoing the tape.

EKG Electrode Placement

The EKG electrode assembly uses peel and snap electrodes which plug into the Electrode Box (Model 8611). The Electrode Box is plugged into AUX on the MediByte.

To use peel and Snap electrodes:

1. Plug the leadwires, according to their color, into the Electrode Box.
2. Abrade the area with an alcohol wipe for ten seconds and allow the area to dry.
3. Peel the back off the adhesive pad and apply the pad to the abraded area.
4. Snap the electrode to the adhesive pad.

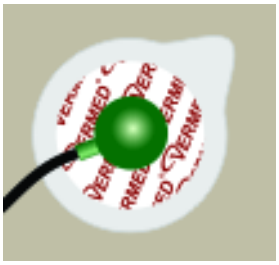


Figure 5.25: Peel and snap electrode

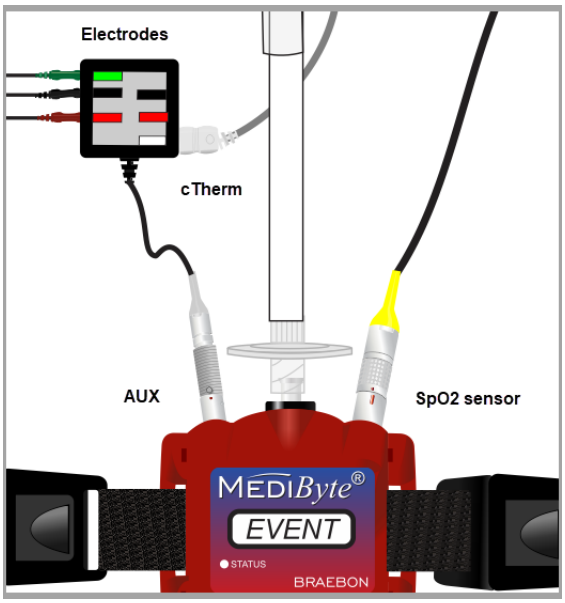


Figure 5.26: Electrode Box connected to AUX

To use the EKG electrode assembly

1. Place one adhesive pad on the left rib cage and attach the black electrode to the pad.
2. Place one adhesive pad on the right shoulder and attach the red electrode to the pad.
3. Place one adhesive pad on the left shoulder (this is the ground) and attach the green electrode to the pad.
4. Plug the leadwires according to their color into the Electrode Box.
5. Plug the lead of the Electrode Box into the **AUX** port on the MediByte ensuring the red dot on the connector is aligned with the red dot on the port.
6. If you are using the cTherm cannula thermistor, plug the connector from the cTherm into the white port located on the bottom of the Electrode Box.

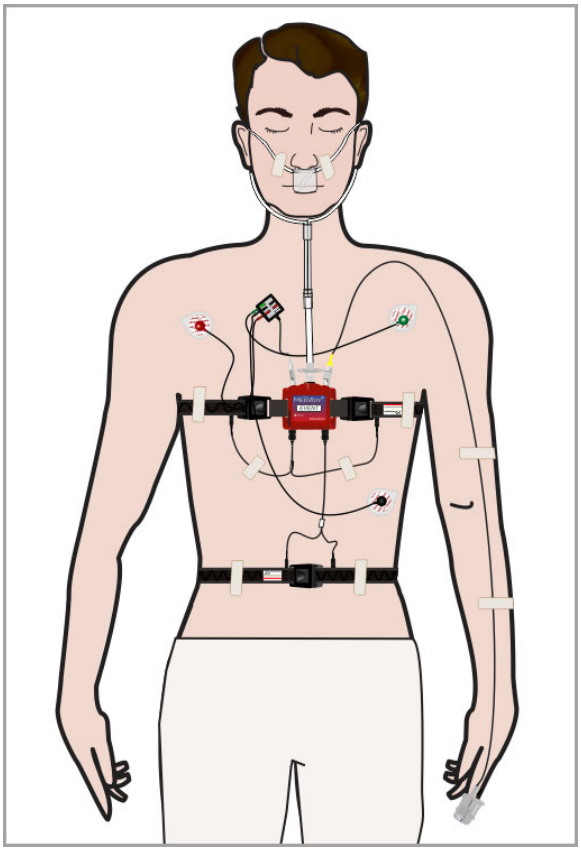


Figure 5.27: EKG electrode placement

Bruxism Electrode Placement

The Bruxism electrode assembly uses four peel and snap electrodes which plug into the Electrode Box (Model 8611). The Electrode Box is plugged into AUX on the MediByte. To use the peel and snap electrodes, see page 5-16.

To use the Bruxism assembly

1. To locate the temporalis, ask the patient to lightly clench the jaw and place an adhesive electrode pad at the peak of the muscle bulge; 1 on the diagram.
   - Attach a black electrode to the pad.
2. Attach an adhesive electrode pad to the Zygomatic arch (cheekbone); 2 on the diagram.
   - Attach a red electrode to the pad.
3. To locate the masseter, ask the patient to lightly clench the jaw and place an adhesive electrode pad at the peak of the muscle bulge; 3 on the diagram.
   - Attach a black electrode to the pad.
4. Attach an adhesive electrode pad to the Mastoid process; 4 on the diagram.
   - Attach the green electrode to the pad. This is ground.
5. Plug the leadwires according to their color into the Electrode Box.
6. Plug the lead of the Electrode Box into the **AUX** port on the MediByte ensuring the red dot on the connector is aligned with the red dot on the port.

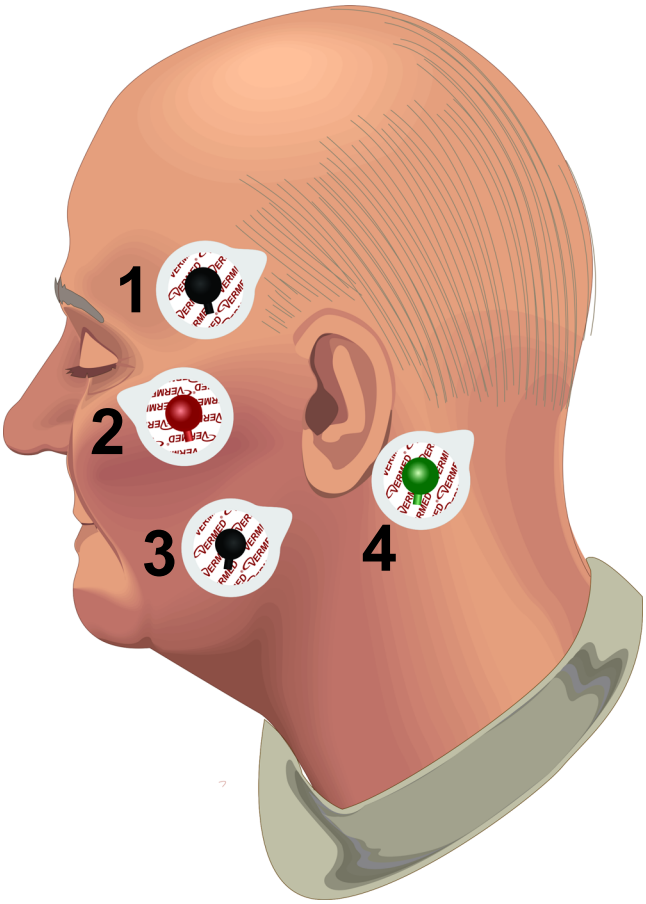


Figure 5.28: Bruxism assembly placement (leads not shown)

PLM Electrode Placement

The PLM electrode assembly uses peel and snap electrodes which plug into the Electrode Box (Model 8611). The Electrode Box is plugged into AUX on the MediByte. To use the peel and snap electrodes, see page 5-16.

To use the PLM electrode assembly:

1. On the right foreleg, place one adhesive pad and attach a red electrode to the pad.
2. Place a second adhesive pad 2” (5 cm) above the first, and attach a black electrode to the pad.
3. Repeat for the left leg.
4. Place the one adhesive pad on the left shoulder (this is ground) and attach the green electrode to the pad.
5. Plug the leadwires according to their color into the Electrode Box.
6. Plug the lead of the Electrode Box into the **AUX** port on the MediByte ensuring the red dot on the connector is aligned with the red dot on the port.
7. Tape down the loose leadwires.

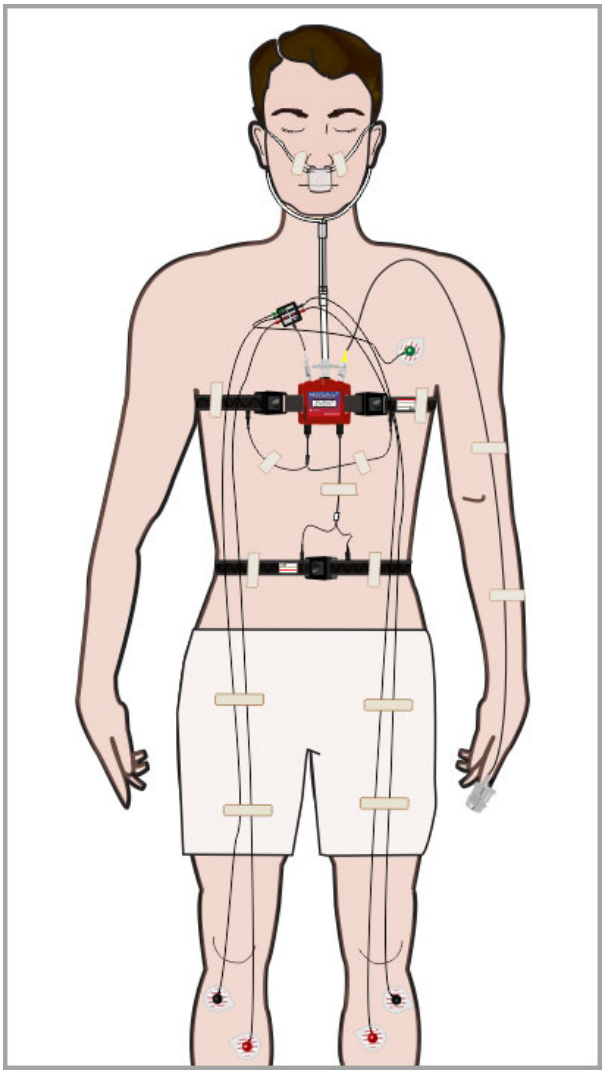


Figure 5.29: PLM study sensor placement; wires under shorts

Sleep Study Electrode Placement

The Sleep Study electrode assembly uses four peel and snap electrodes which plug into the Electrode Box (Model 8611). The Electrode Box is plugged into AUX on the MediByte. To use the peel and snap electrodes, see page 5-16.

To use the Sleep Study assembly

1. Place an adhesive electrode pad on FPz location of the center of the forehead.
   - Attach a black electrode to the pad.
2. Place an adhesive electrode pad on E1 (left eye 1 cm outer canthus, 1 cm inferior).
   - Attach a red electrode to the pad.
3. Place an adhesive electrode pad on the chin.
   - Attach a red electrode to the pad.
4. Attach an adhesive electrode pad on M1, the mastoid process.
   - Attach the green electrode to the pad. This is ground.
5. Plug the leadwires according to their color into the Electrode Box.
6. Plug the lead of the Electrode Box into the **AUX** port on the MediByte ensuring the red dot on the connector is aligned with the red dot on the port.

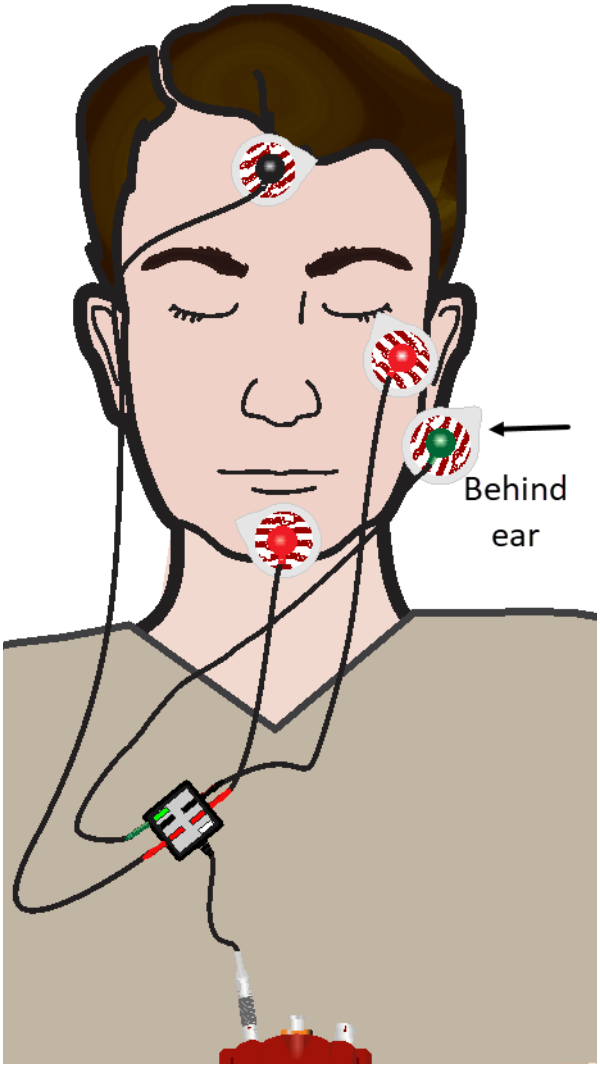


Figure 5.30: Sleep Study electrode placement

Sleep + EKG

The Sleep + EKG Study electrode assembly uses five peel and snap electrodes which plug into the optional Electrode Box SE (Model 8612). The Electrode Box SE is plugged into AUX on the MediByte. To use the peel and snap electrodes, see page 5-16.

To use the Sleep + EKG assembly

1. Place an adhesive electrode pad on the FPz location of the center of the forehead.
   - Attach a red electrode to the pad.
2. Place an adhesive electrode pad on E1 (left eye 1 cm outer canthus, 1 cm inferior).
   - Attach a black electrode to the pad.
3. Place an adhesive electrode pad on the chin.
   - Attach an red electrode to the pad.
4. Place an adhesive pad on M1, the mastoid process.
   - attach a green (ground) electrode to the pad.
5. Place an adhesive pad on the left or right rib cage.
   - attach the orange electrode to the pad.
6. Plug the leadwires according to their color into the Electrode Box SE.
7. Plug the lead of the Electrode Box SE into the **AUX** port on the MediByte ensuring the red dot on the connector is aligned with the red dot on the port.

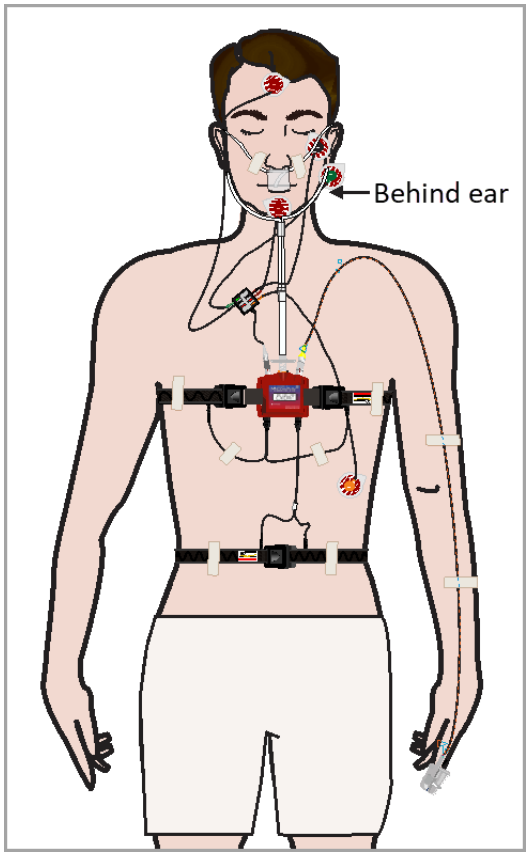


Figure 5.31: Sleep + EKG electrode placement

Sleep + EEG

The Sleep + EEG Study electrode assembly uses five peel and snap electrodes which plug into the optional Electrode Box SE (Model 8612). The Electrode Box SE is plugged into AUX on the MediByte. To use the peel and snap electrodes, see page 5-16.

Other 10-20 EEG electrode locations may be used, but will require use of different electrode application techniques.

To use the Sleep + EEG assembly

1. Place an adhesive electrode pad on the FPz location of the center of the forehead.
   - Attach a red electrode to the pad.
2. Place an adhesive electrode pad above the left eyebrow.
   - attach the orange electrode to the pad.
3. Place an adhesive electrode pad on E1 (left eye 1 cm outer canthus, 1 cm inferior).
   - Attach a black electrode to the pad.
4. Place an adhesive electrode pad on the chin.
   - Attach a red electrode to the pad.
5. Place an adhesive pad on M1, the mastoid process.
   - attach a green (ground) electrode to the pad.
6. Plug the leadwires according to their color into the Electrode Box SE.
7. Plug the lead of the Electrode Box SE into the **AUX** port on the MediByte ensuring the red dot on the connector is aligned with the red dot on the port.

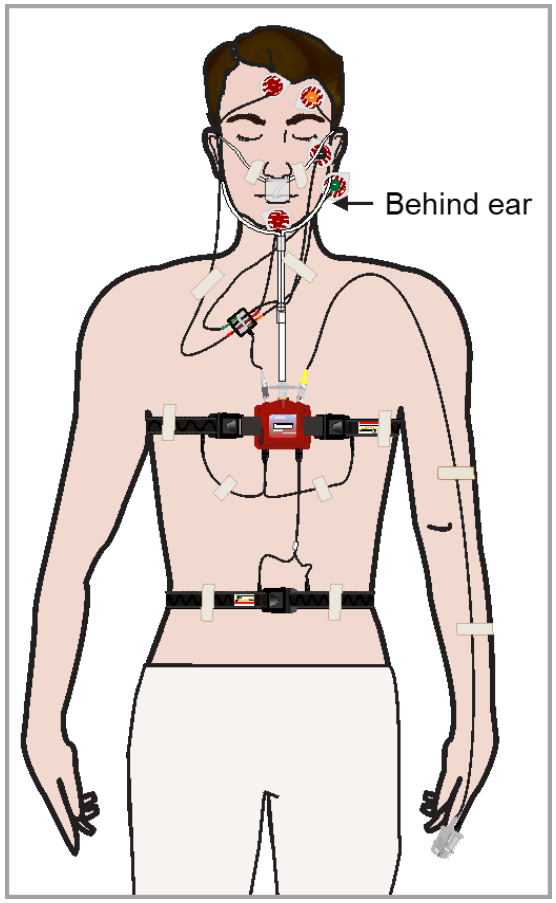


Figure 5.32: Sleep + EEG electrode placement

Starting the Study

Once the patient is wearing all of the sensors and the leads are connected to the MediByte/ MediByte Jr, the recorder is ready to collect data. If the recorder is set to automatic start (recommended), it will start on its own at the designated start time. If the recorder is set to manual start, instruct the patient to slide the collection on/off switch to the ON position (white dot) at bedtime. Manual start is not recommended.

The event button is used to mark significant events during the night. For example, instruct the patient to press the event button when turning off the lights, when getting up in the middle of the night, upon returning to bed, etc. The data will contain a button press marker which will display on the screen during data analysis.

Ending the Study

In the morning, instruct the patient to push the Event button, slide the collection on/off switch to the OFF position and remove the sensors.

The unit is now ready for data retrieval.

Chapter 6: Reviewing Data

In this chapter

This chapter describes how to download data from the MediByte/MediByte Jr, review the displayed data, mark it with event tags, mark it with scoring tags, adjust the event tags and scoring tags and print a report. You cannot open the data display screen without data either stored on your computer or downloaded from the MediByte/MediByte Jr.

This chapter includes:

- Downloading data from the MediByte/MediByte Jr
- Data display screen
- Changing the language used in the software
- Reviewing the data
- Assisted Scoring of events
- Manual Scoring of events
- Printing reports

Downloading Data from the MediByte/MediByte Jr

Do NOT connect the MediByte/MediByte Jr to the computer while it is in contact with the patient. This could cause serious injury to the patient.

1. If you have not already done so, disconnect the MediByte/MediByte Jr from the patient.
2. Ensure the battery is still functioning (the status LED will flash green once every six seconds).
3. Plug the USB cable into the computer and then into the MediByte/MediByte Jr.
4. Double-click the MediByte software icon on your desktop to start the software.
5. In the Operation Selection window, select **Download data from the MediByte**. An information window will appear to inform you that data has been found and the MediByte is downloading.
   - The scoring assist feature will process the data and generate scoring events.
   - The final screen of the wizard appears when the data download is finished. The screen displays the following: *Please ensure the data is reviewed by a qualified professional.*
6. Click **Finish**. The software will display the data on the computer screen.

Figure 6.1: Select Download data from the MediByte

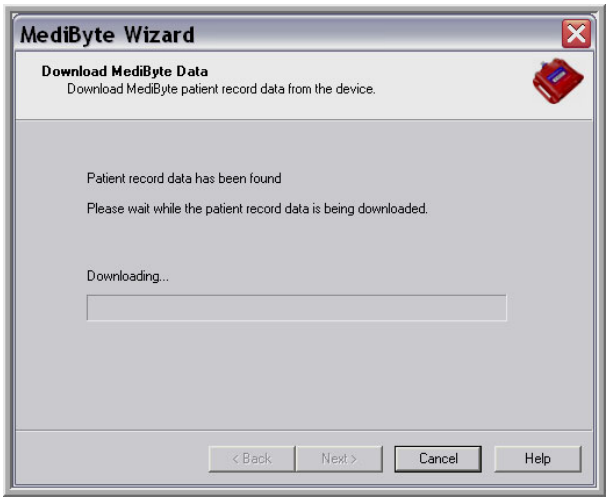


Figure 6.2: Downloading data window

Open a New Data File

You can open another data file from within the Data Display screen. When you open the new file, the current file is replaced. You cannot have two data files open at the same time.

To open a new data file:

1. Click **File>Open** to activate the Studies Data Manager. The Studies Data Manager displays the available files in the Default Tests Folder.
2. To select a different storage folder, click the dropdown button  and select a new folder.
3. Double-click the data file you wish to open; the new file opens in the Data Display screen.

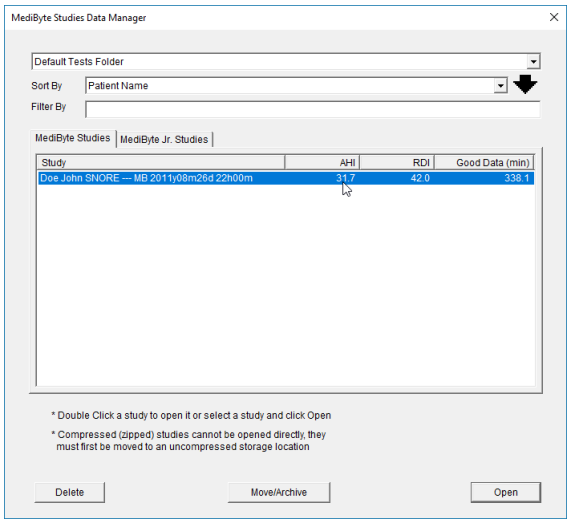


Figure 6.3: Studies Data Manager

Open a Study without the MediByte

You can open a study without connecting the MediByte to the computer.

To open a study:

1. Double-click the MediByte icon on the desktop.

2. Type the password **MASTER** into the Password field. The password is case-sensitive and must be typed in upper case (capitals).
3. Click the **Analyze a study** button to open the Load and Review window.
4. Double-click on the study you want to review. Alternatively, click to highlight the study and click **Finish**. The Data Display screen will open with the selected study displayed.

Figure 6.4: Opening screen

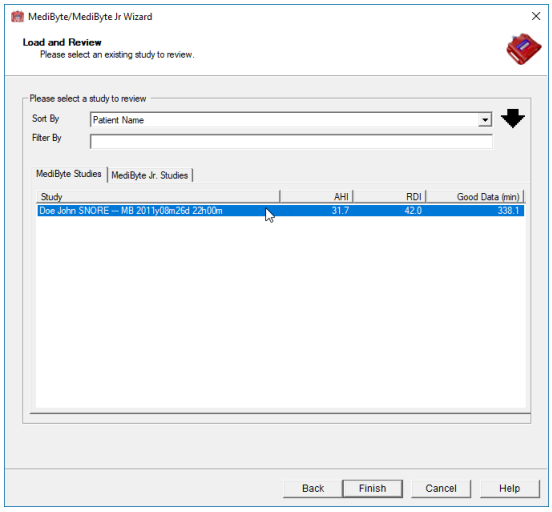


Figure 6.5: Load and Review window with a data file selected

Data Display Screen

MediByte software uses a standard Microsoft® Windows® graphical user interface (GUI) with a toolbar, status bar, and drop-down menus.

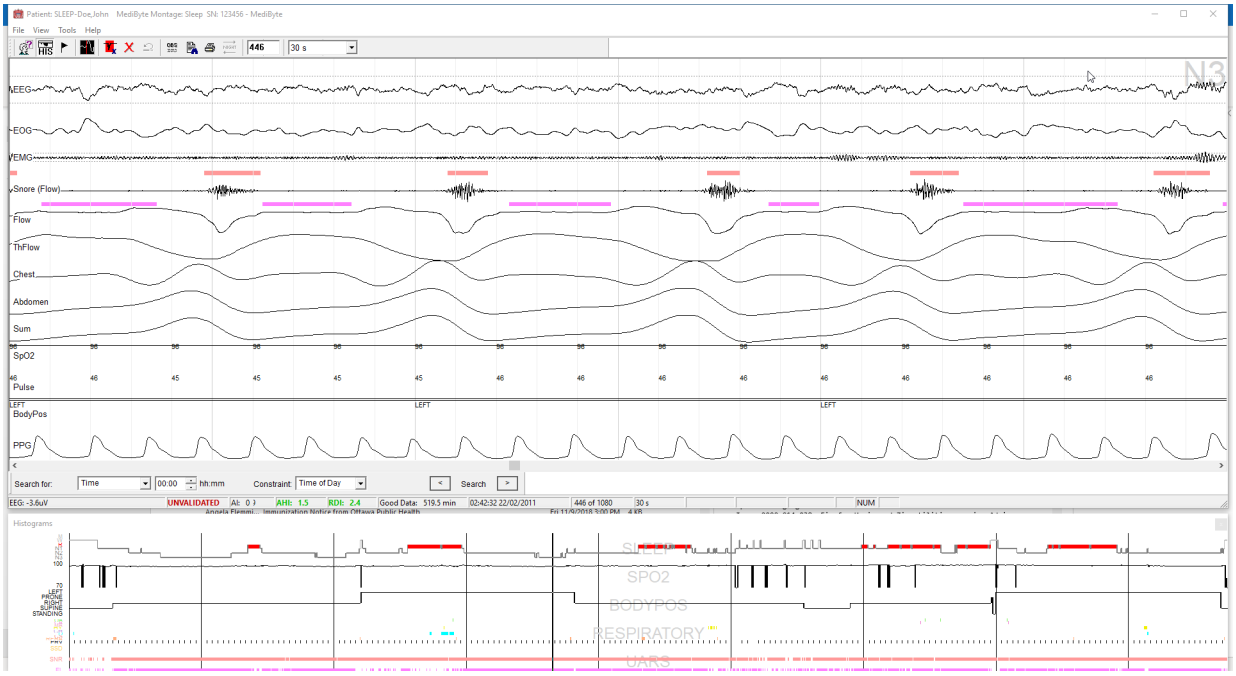
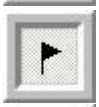


Figure 6.6: Data Display screen

On-screen buttons


Patient information

View the histogram


Open the event markers window


Scale the display


Mark bad data


Delete a scoring marker


Restore a deleted marker


Mark and play audio

Audio FFT Analysis

Record observations


Print a report


Print current screen

Changing the Language Used in the Software

You can change the language from within the Data Display Screen. The following languages are available within the software: Arabic, Chinese, German, English, Spanish, French, Italian, Dutch, Polish, Portuguese, Romanian and Russian.

To change the language used in the software:

1. Click Tools>Language to open the language selection menu.
2. Click on a language to change the language used in the software. It is best to restart the software to ensure all fields and windows are translated.

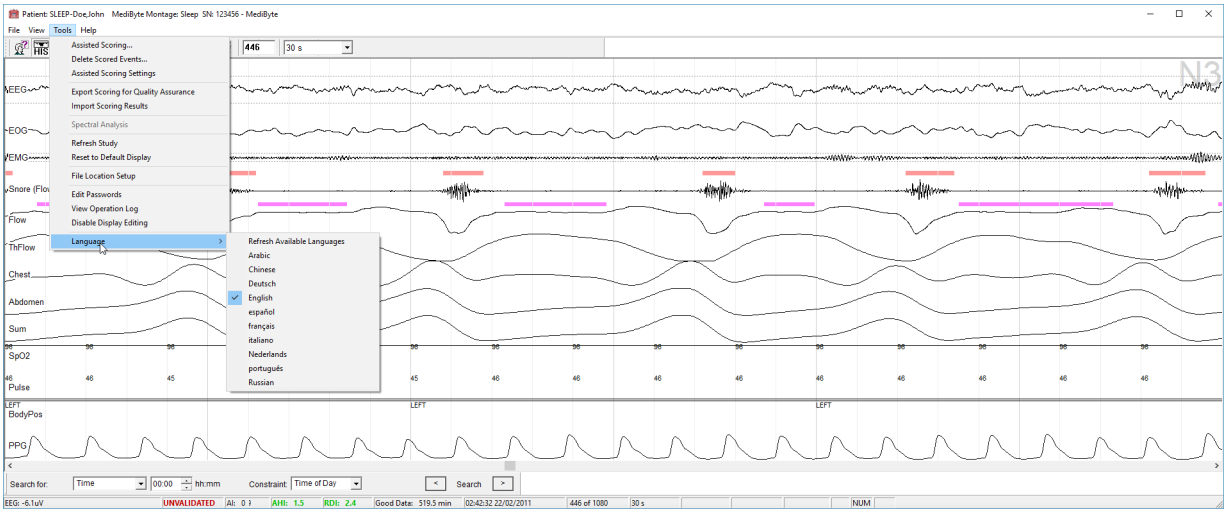
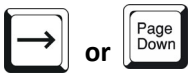
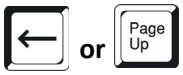


Figure 6.7: Language selection menu

Reviewing the Data

The MediByte software automatically tags the data with scoring events. Review the suggested scoring tags by paging through the data or by viewing the histogram.

To review screens of data:

-  move forward through the data by one full screen.
-  move forward through the data by half a screen.
-  move backward through the data by one full screen.
-  move backward through the data by half a screen.
-  moves to the first screen.
-  moves to the last screen.

Reviewing Data with the Histogram

You can review the data using the histogram.

Figure 6.8: Click on the histogram to view the data in greater detail

To jump to a screen of data from the histogram:

1. Expand the histogram by dragging the upper boundary of the histogram (circled).
1. Point to the section of the histogram you want to see in greater detail (as above) and click. The main data display shows the selected area of data.

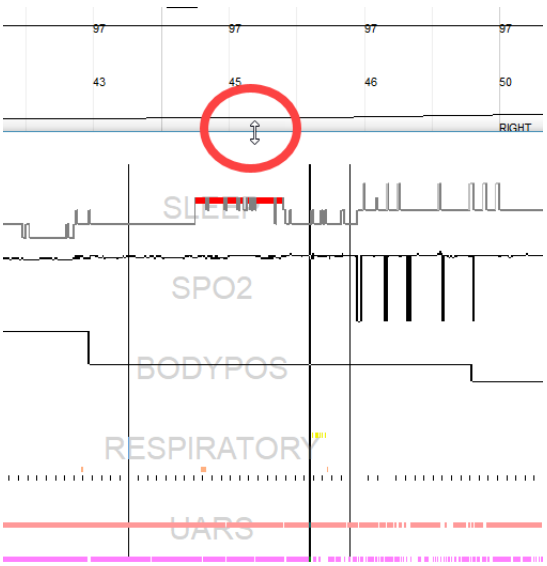


Figure 6.9: Drag the upper boundary of the histogram to expand it.

Changing the properties of the histogram

You can select the type of data you wish to see on the histogram using the Histogram Settings window.

To change the histogram properties:

1. Right-click on the histogram to activate the Histogram Info Properties button.
2. Click the **Histogram Info Properties** button to open the Histogram Settings window.
3. Select the Waveform Type, Signal, Lower and Upper Units and whether you want to see a Label.
4. Click **OK**.

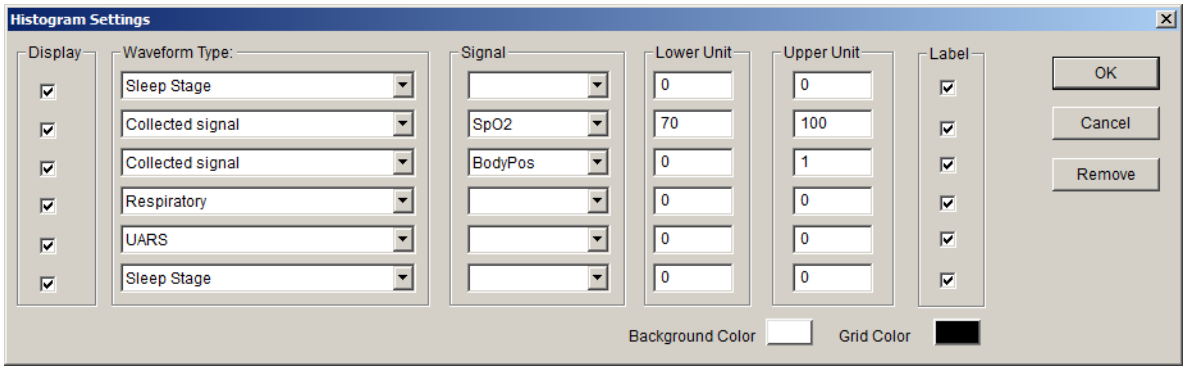


Figure 6.10: Histogram Settings window

Using the Study Navigator

The study navigator is located below the Data Display screen. Use it to search through the data using one of the following parameters: time, signal or scored event.

Navigating by Time

This function searches for a specific time in the study. You can set the constraint to *time of day* or *time into the study*.

Figure 6.11: Navigating by Time

1. Click the **Search for** button and select **Time**.
2. Click the hour section to highlight and press the arrows to change the hour.
3. Click the minute section to highlight and press the arrows to change the minutes.
4. Select the constraint; i.e., time of day or time into study.
5. Select the search forward or search backward button.

Navigating by Signal

This function searches for a specific signal in the study. You can set the constraint relative to a percentage value of the signal, the minimum value or the maximum value of the signal.

Figure 6.12: Navigating by Signal

1. Click the **Search for** button and select **Signal**.
2. Click the arrow to select the signal type.
3. Select the constraint . If you entered a relational constraint (for example, =), enter the percentage value.
4. Select the search forward or search backward button.

Navigating by Scored Event

This function searches for a specific scored event in the study.

Figure 6.13: Navigating by Scored Event

1. Click the **Search** for button and select **Scored Event**.
2. Click the arrow to select the scored event type.
3. Select the constraint.
4. Select the search forward or search backward button.

Study Status Bar

The study status bar is located below the study navigator. The study status bar provides the following information:

1. Signal measurement: shows the quantitative measure of a signal as you move the mouse over it.
2. Study status: For studies collected using version 9 software: UNVALIDATED means the study has been scored by the software, but not by a human. VALIDATED means that every epoch between lights off and lights on has been reviewed and at least one event has been altered. For studies collected from previous versions of the software, they will initially display as UNVALIDATED even if they had been reviewed in the previous version. After the Sleep Tech's name and observations have been entered into the study, the status will switch to VALIDATED.
3. Arousal Index (AI): average number of arousals per hour. AI is only reported on a study that recorded sleep; i.e., Sleep, Sleep + EEG or Sleep + EKG.
4. Apnea Hypopnea Index (AHI): average number of apnea and hypopnea events per hour of sleep. This number displays in green when the AHI is less than **15**, yellow between **15 and 30** and red when the AHI is greater than or equal to **30**.
5. RDI: average number of episodes of apneas, hypopneas and RERAs per hour of sleep. This number displays in green when the RDI is less than **20**, yellow between **20** and **40 and** red when the RDI is greater or equal to **40**.
6. Good Data: displays the number of minutes of good data in the study.
7. Epoch number: displays the epoch number as epoch number of total number of epochs.
8. Page Width: displays the page width in seconds.

Figure 6.14: Study Status Bar

Lights Out/Lights On Tags

The MediByte software automatically adds LIGHTS OUT/ LIGHTS ON tags during the initial downloading of the data from the MediByte. The software tags the data with a LIGHTS OUT tag after the first ten minutes of stable, non-standing data where the SpO_2 is also stable and valid.

The software tags the data with a LIGHTS ON tag by moving back from the end of the data set to the first five minutes of stable, non-standing data where the SpO_2 is also stable and valid.

Before you begin the data review, ensure that the data has been tagged with LIGHTS OUT and LIGHTS ON tags. If the patient pressed the Event button on the MediByte at bedtime and waking, there will be button press tags in the data. Insert the LIGHTS OUT and LIGHTS ON tags where button press tags are located and then remove the tags inserted by the software. See “Deleting Event Markers” on page 6- 20.

To tag the data:

1. At the beginning of the data set, double-click the data to activate the Select a User Event window.
2. Click the **LIGHTS OUT** button to place a Lights Out tag in the data.
3. At the end of the data set, double-click the data to activate the Select a User Event window.
4. Click the **LIGHTS ON** button to place a Lights On tag in the data.

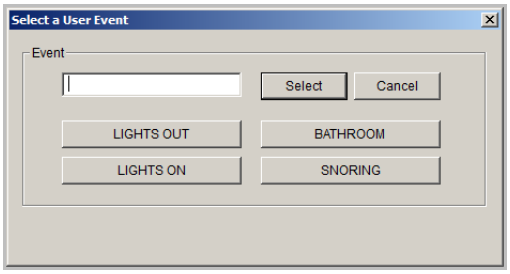


Figure 6.15: Select a User Event window

Patient Information

You can open the Patient Info screen and add additional information about the patient. Since the MediByte wizard only accepts the first name, last name, patient ID and weight, you will likely require more information about the patient.

To review and add patient information

1. Click  to open the Patient Info window.
2. In the **Code** field, type a unique patient code, as required.
3. In the **Last Name** and **First Name** field, verify the names are correct.
4. In the **SOC/SIN** field, type the patient's Social Security Number (SOC)/Social Insurance Number (SIN).
5. In the **DOB** (Date of Birth) field, click the part of the date you want to change, and then type the month, date or year of your choice.
6. In the **Height** field, type the patient's height in either feet (ft.) and inches (in.) or centimeters (cm) using whole numbers. The software calculates the corresponding value.
7. In the **Weight** field, type the patient's weight in either pounds (lbs.) or kilograms (kg) using whole numbers. The software calculates the corresponding value.
   Once you have entered the height and weight values, the MediByte software calculates the body mass index (BMI).
8. In the **Neck Circumference** field, enter the patient's neck circumference in either feet (ft.) and inches (in.) or centimeters (cm) using whole numbers. The software calculates the corresponding value.

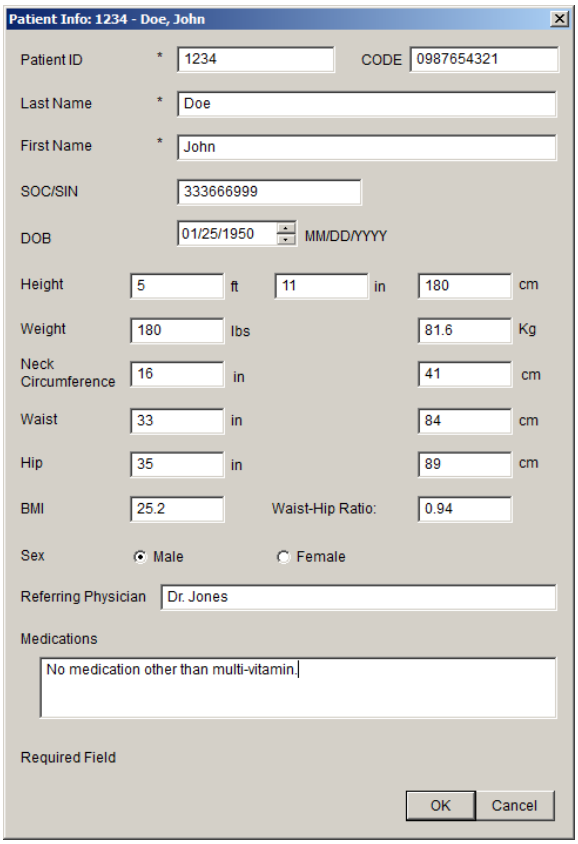


Figure 6.16: Patient Info Screen

9. In the **Waist** field, enter the patient's waist measurement either in inches (in.) or centimeters (cm) using whole numbers. The software calculates the corresponding value.
10. In the **Hip** field, enter the patient's hip measurement either in inches (in.) or centimeters (cm) using whole numbers. The software calculates the corresponding value. Once you have entered the waist and hip measurements, the MediByte Software calculates the waist-hip ratio.

Table 6-1: Waist to Hip Ratio Chart*

Male	Female	Health Risk Based Solely on WHR
≤ 0.95	≤ 0.80	Low risk
0.96 – 1.0	0.81 – 0.85	Moderate Risk
≥ 1.0	≥ 0.85	High Risk

11. Click **Male** or **Female**.
12. In the **Referring Physician** field, type the referring doctor's name, if required.
13. In the **Medications** field, type all the medications the patient uses.
14. Click **Save** and then click **OK** to save the patient file.

*Lancet, 2005 November; 366 (9497) 1640-9; *Obesity and the risk of myocardial infarction on 27,000 participants from 52 countries: a case-control study.* Yusuf, Hawken et al.

Scaling the Display

When the data is first displayed on the screen, the waveforms may appear flat. You can scale the display to improve the appearance of the waveforms. Scaling takes the maximum and minimum values of the waveforms and adjusts the upper and lower limits of the waveforms proportionally. Scaling changes the appearance of the display, it does not change the data.

To scale the display:

- Click  to scale the display. The figure at right shows the same data display before and after scaling.

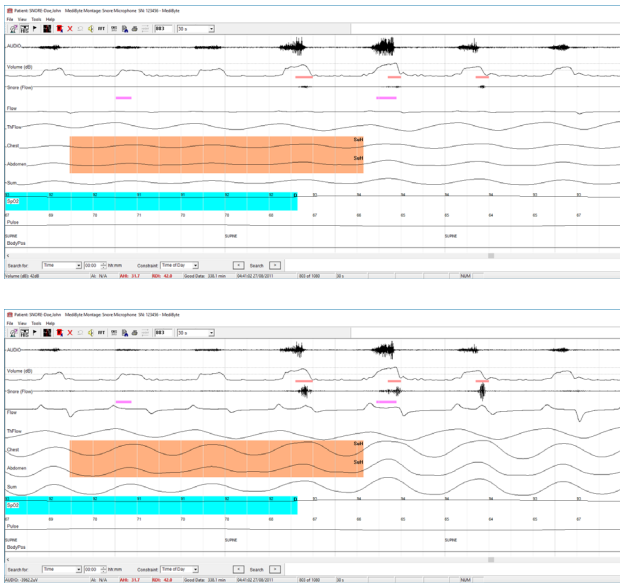


Figure 6.17: Data before and after scaling

Changing the Appearance of a Signal

You can change the way a signal is displayed on the screen using the signal properties menu. In the signal properties menu you can select scale, invert, digital and color. Changing the appearance of the signal using the signal properties menu does not change the data, only the way it is displayed on the screen.

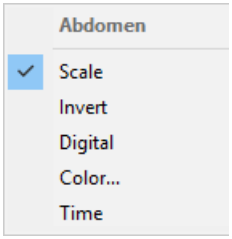


Figure 6.18: Signal properties menu of the Pulse channel

To scale a channel:

1. Right-click on a channel to open the signal properties menu.
2. Click Scale to select the channel for scaling.
3. Click  .

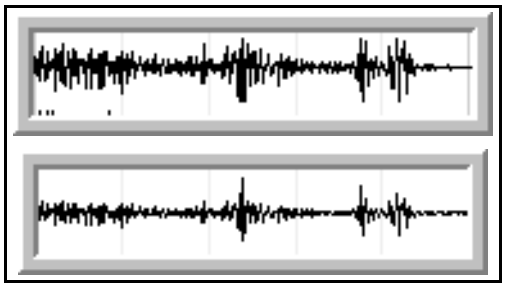


Figure 6.19: Signal before and after scaling

To invert a channel:

1. Right-click on a channel to open the signal properties menu.
2. Click **Invert** to invert the channel.

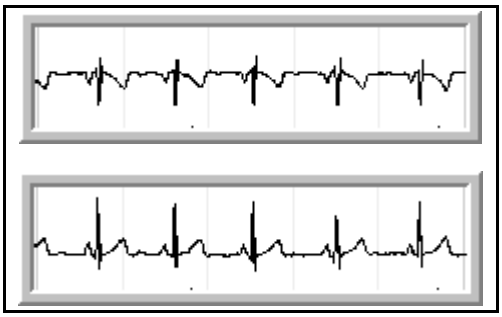


Figure 6.20: EKG before and after inverting

To display the digital readout of a channel:

1. Right-click on a channel to open the signal properties menu.
2. Click **Digital** to display the digital readout of the channel.

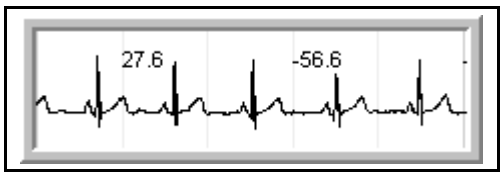


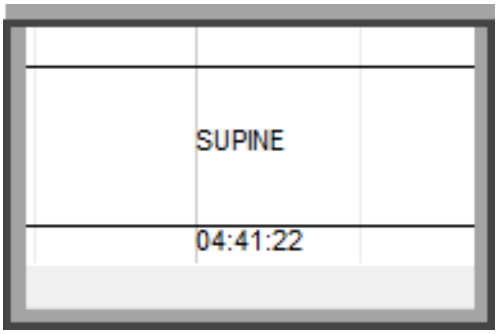
Figure 6.21: EKG digital readout

To change the color of the channel:

1. Right-click on a channel to open the signal properties menu.
2. Click **Color** to open the color menu.
3. Click on a color and select **OK**.

To see the actual time on the display

1. Right-click on a channel to open the signal properties menu.
2. Click **Time** and the actual time of the recording is shown at the bottom of the display.



To change the sensitivity of a channel:

1. Hold the control key and double-click the left mouse button. The signal will turn yellow.
2. Use the up and down arrow keys or your mouse wheel to change the amplitude of the signal. The data itself will not change, just how you see it on the screen.
3. When you are satisfied with the appearance of the signal, click the display and the signal will return to black.

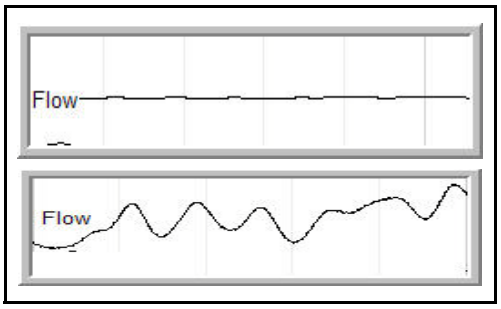


Figure 6.22: Flow before and after changing the sensitivity

Jumping to Event Markers

View a list of event markers in the Event Markers window. Double-click on an event marker to jump to the screen to view the event in greater detail.

To jump to an event marker:

1. Click  to open the Event Markers window.
2. Double-click the appropriate event marker in the list to jump to the epoch with the selected event marker.

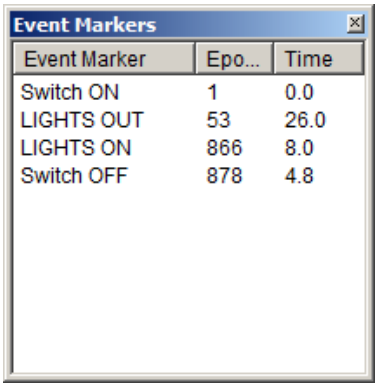


Figure 6.23: Event markers window

Inserting User Event Markers

While reviewing a study, you can insert additional event markers by double-clicking on the data and inserting a new user event. The MediByte Software inserts a vertical line and the user event tag in the data. If you have a CPAP study, you can insert a CPAP pressure tag.

To insert an event marker:

1. Go to the epoch where you want to insert a user event.
2. Position the mouse over an empty (white) part of the display and double-click to open the Select a User Event window.
3. Click to select the appropriate user event button or type a user event description and click **Select**.

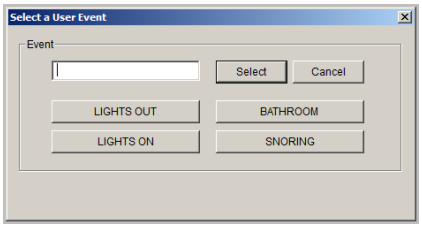


Figure 6.24: Select a user event window

To insert a CPAP pressure tag:

1. Go to the epoch where you want to insert a CPAP pressure tag.
2. Position the mouse and double-click to open the Select a User Event window.
3. Click the up and down arrows to select the appropriate pressure level. Click **CPAP**. CPAP tags are only available in studies where a CPAP signal was recorded.

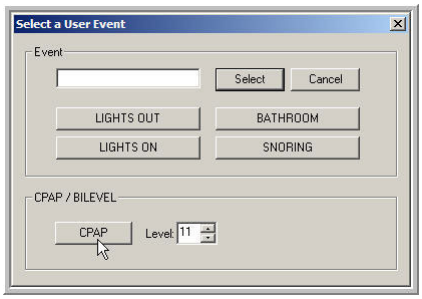


Figure 6.25: Select a CPAP user event

Deleting Event Markers

You can delete unwanted event markers from a study. Instead of searching through data to look for event markers you want to delete, use the event markers window to delete any event markers you don't want.

To delete an event marker:

1. Click  to open the Event Markers window.
2. Select the event you want to delete from the list.
3. Right-click on the event in the list to activate the event filter settings.
4. Click **Delete**.

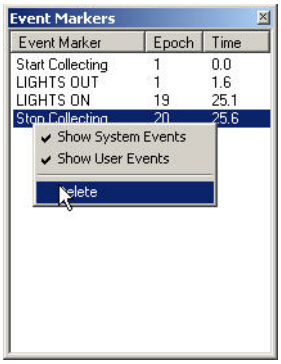


Figure 6.26: Deleting an event marker

Enter Observations

Use the Observations\Comments window to enter notes about the patient. The Night technician, Scoring technician and Physician can all add comments to the record.

To enter an observation:

1. Click 

to open the Observations\Comments window.
2. Use the tabs to select your job title.
3. Type in your observations and click **OK**.

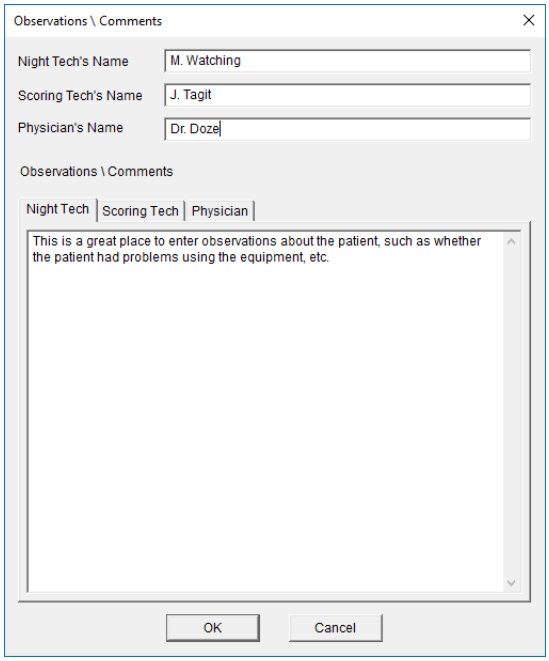


Figure 6.27: Observations\Comments window

View the Photoplethysmograph Signal

You can display the collected photoplethysmograph (PPG) signal by selecting photoplethysmograph signal from the View pull-down menu. The PPG signal is a volumetric measurement of the blood within the subcutaneous vessels of the finger tip or earlobe, depending on which site is used for the MediByte recording (i.e., fingertip SpO_2 Cable for MediByte or earlobe SpO_2 Cable for MediByte). The MediByte pulse oximeter collects the signal by illuminating the skin with infrared light. Blood is pumped throughout the body and to the periphery with each cardiac cycle. The pressure pulse, though dampened, is sufficient when it reaches the periphery to distend the subcutaneous vessels beneath the skin. As shown in Figures 6.28 and 6.29, premature ventricular contractions (PVCs) may be easily detectable within the PPG waveform and the PPG may be useful to detect some cardiac arrhythmias when not using the MediByte EKG montage.

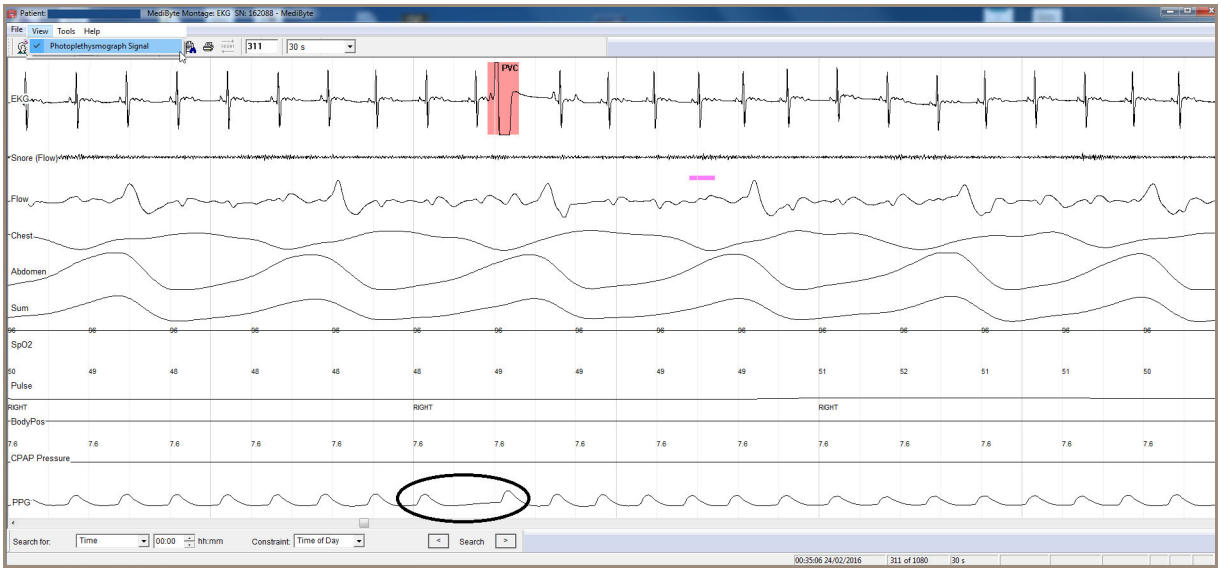


Figure 6.28: PVC on the PPG signal and the EKG

- To view the photoplethysmograph signal, click View>photoplethysmograph Signal.

  The signal is drawn at the bottom of the data display.

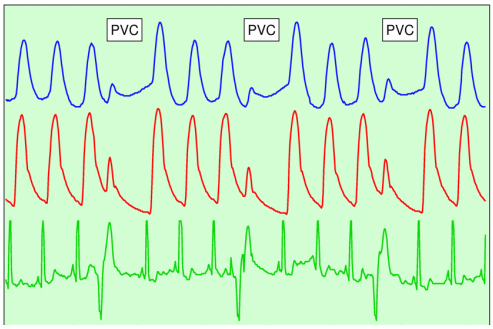


Figure 6.29: PVC on PPG, Pulse and EKG

Assisted Scoring of Events

The MediByte software has an assisted scoring tool for automatically tagging the data with bad SpO_2/pulse data, desaturation, respiratory, RERAs, and upper airway resistance. In addition, data collected with the MediByte may also display pulse rate variability, EKG, bruxism and limb movement event tags.

When the software downloads the data file, it automatically scores the events with scoring event markers. The scoring event markers are colored bars with scoring event abbreviations in the top right corners of the bars. If you have a CPAP study, the software will automatically tag CPAP pressure changes after downloading the data.

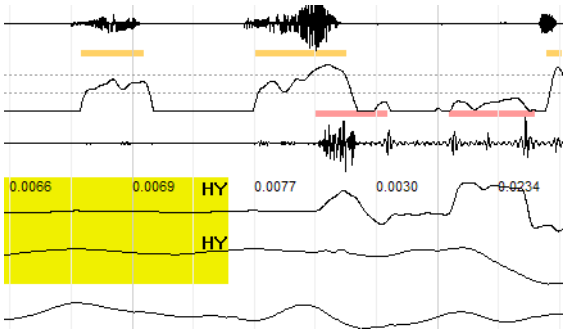


Figure 6.30: Scored events (SSD, SNR and hypopnea)

You can use the Tools menu to delete the scoring event markers, change the rules for scoring and rescore the data.

For information about marking bad SpO_2/pulse, see ***Marking Bad Data*** on page 6- 43.

Changing the Assisted Scoring Rules

Use the Assisted Rules Setup window to change the assisted scoring rules. If you are satisfied with the way the software scores the data, leave this window alone. You can change the parameters for desaturations, respiratory events, pulse rate variability, upper airway resistance events, and limb movements.

To change the assisted scoring settings:

1. Select **Tools>Assisted Scoring Settings** to open the Assisted Rules Setup screen.
2. Set the conditions for scoring events:

- For **Desaturation**, set the minimum decline in the signal required to score the event as a desaturation.
- For **Respiratory Events**, set the minimum duration of an event; the minimum flow reduction required to score an apnea and a hypopnea; and the minimum effort reduction required to score an apnea and a hypopnea. You can also select to autoscore RERA (respiratory effort related arousal).
- For **Pulse Rate Variability (MediByte only)**, set the minimum required change in beats per minute; the minimum and maximum duration of the event.
- For **Upper Airway Resistance Events: Snoring (Audio), Snoring (Flow) and Flow Limitation**, set the lower limit of the Snore volume in dB, set the Snore duration and use the slider to adjust the sensitivity of the threshold detector to score more or less events.
- For **Limb Movement (MediByte only),** set the maximum time between movements to score as both, select the channels to be used to detect limb movements and use the slider to adjust the sensitivity of the threshold detector to score more or less events.

3. Click **OK**.

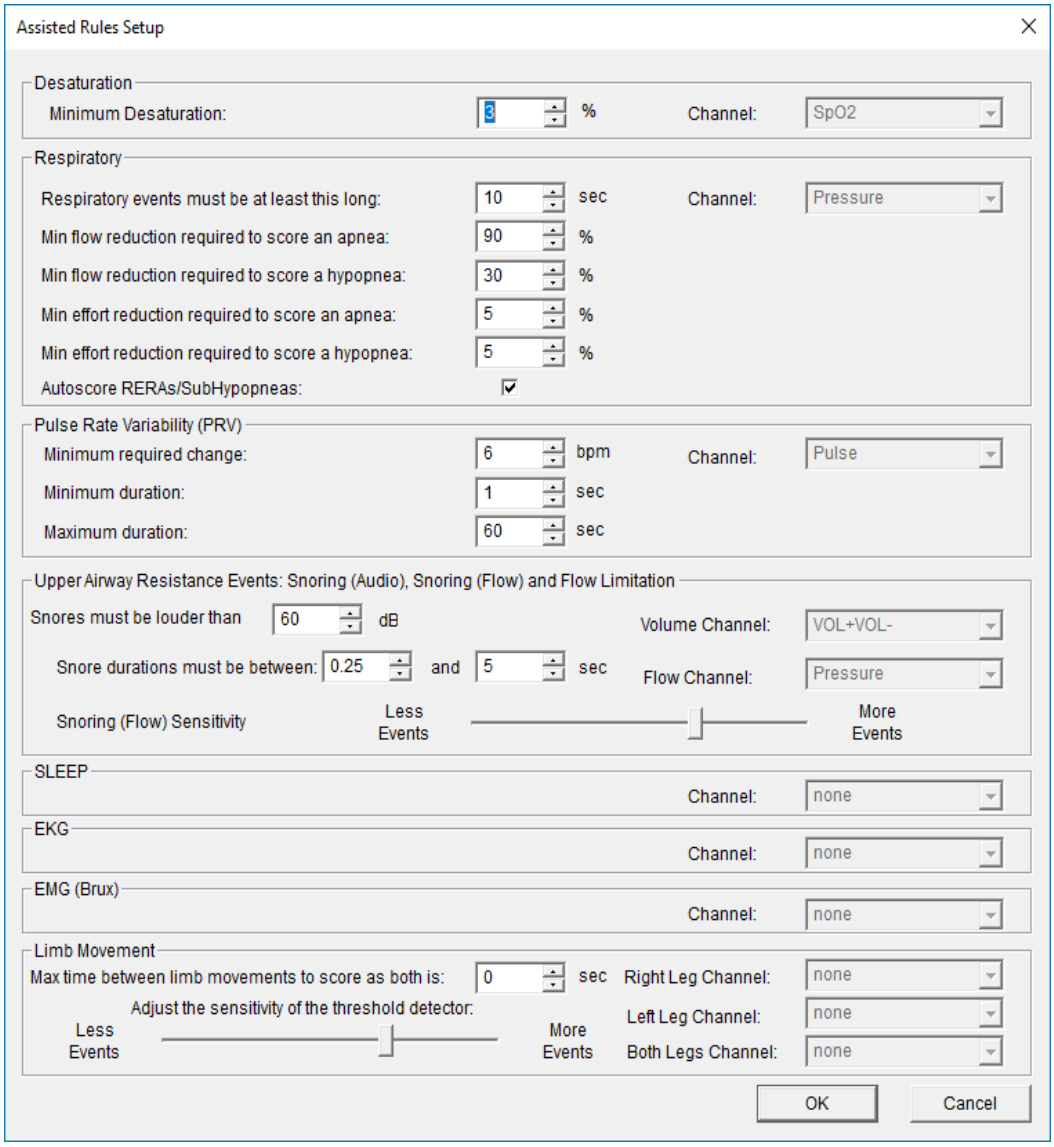


Figure 6.31: Assisted Rules Setup screen

Starting the Assisted Scoring

The assisted scoring tool will automatically tag the data with bad SpO_2/pulse data, desaturation, respiratory, RERAs, upper airway resistance. In additon, data collected with the MediByte may also display pulse rate variability, EKG, bruxism and limb movement event tags. You can select up to eight types of events for scoring and the portion of the study to be scored.

We recommend running the assisted scoring for respiratory if you have made changes to the desaturation scoring in the data.

The availability of assisted scoring is dependent upon the signals collected. For example, in the figure below, limb channels, EKG and Bruxism were not collected so they are unavailable.

1. Select **Tools>Assisted Scoring** to activate the Assisted Scoring screen.
2. Select the type of events you want the program to score.
3. Click **Go** to start the assisted scoring. A progress bar will appear on the screen as the software is calculating the locations of the events. When the automated scoring is finished, the progress bar will disappear.
4. Review the scored events using the histogram. You may want to manually modify the scored events, as discussed on page 6-28.

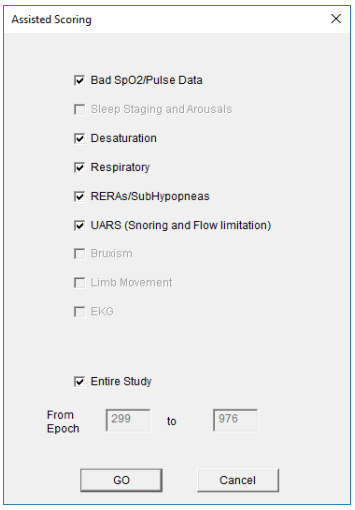


Figure 6.32: Assisted Scoring window

Figure 6.33: Histogram showing scored events

Deleting Scored Events

You can delete all or some of the scored events from a data set using the delete scored events function. The software only deletes scored events *between* the Lights Out and Lights On event markers, unless you select Entire Study. If there are no Lights Out and Lights On event markers, selecting the Entire Study will automatically delete all event markers from the entire data set.

If you want to remove one or two scored event markers, right click on a marker and select **Remove This Event.**

To delete all of the scoring event markers from the data set:

1. Click **Tools>Delete Scored Events** to open the Remove Scored Events screen.
2. Click on the type of events you want to remove from the data.
3. Click **Entire Study** if you want all of the events deleted, or deselect **Entire Study** and enter an epoch range.
4. Click **Go**. A warning window will ask you to verify that you want to delete the scored events, click **Yes** to continue. After the program has finished deleting the scored events, the histogram will show no scored events of the type you deleted.

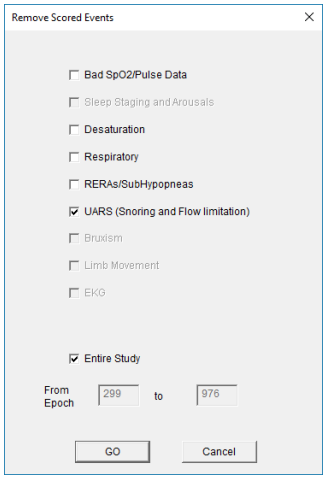


Figure 6.34: Remove Scored Events window

Figure 6.35: Histogram before deleting UARS events

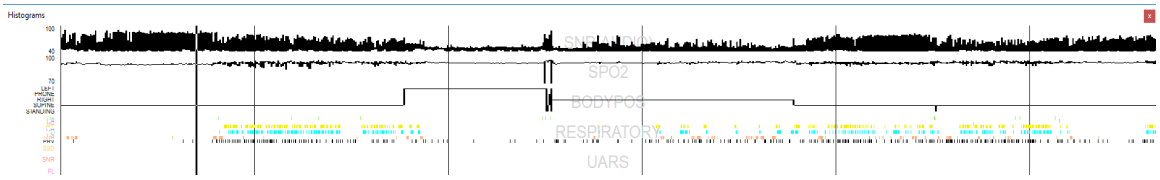


Figure 6.36: Histogram after deleting UARS events

Manual Scoring of Events

In the MediByte Software, scoring event markers are colored bars with scoring event abbreviations in the top right corners of the display. The table below shows all of the available scoring event marker abbreviations, their full names and the channel associated with each event. See the glossary for a description of each type of scored event.

Note: You cannot add scoring event markers to epochs scored as Wake. If an epoch's sleep stage is changed from a sleep stage to a wake stage, any marked events within the epoch will be hidden.

Table 6-2: Scoring Event Markers

Abbreviation	Full name	Type	Channel
CA	Central apnea	Assisted or Manual	Flow, ThFlow, Sum
OA	Obstructive apnea	Assisted or Manual	Flow, ThFlow, Sum
MA	Mixed apnea	Assisted or Manual	Flow, ThFlow, Sum
HY	Hypopnea	Assisted or Manual	Flow, ThFlow, Sum
CH	Central Hypopnea	Assisted or Manual	Flow, ThFlow, Sum
SuH	SubHypopnea	Assisted or Manual	Chest and Abdomen
RERA	Respiratory Related Arousal	Assisted or Manual	Chest and Abdomen
CS	Chenyne-Stokes	Manual only	Chest and Abdomen
D	Desaturation	Assisted or Manual	SpO_2
PRV	Pulse Rate Variability	Assisted or Manual	Pulse
A	Arousal	Manual only	EEG
RA	Respiratory Arousal	Manual only	EEG
SA	Snoring Arousal	Manual only	EEG
DA	Desaturation Arousal	Manual only	EEG
SSD	Snoring Sound	Assisted or Manual	Snore (Audio)

Table 6-2: Scoring Event Markers

Abbreviation	Full name	Type	Channel
SNR	Snoring Nasal Resistance	Assisted or Manual	Snore (Flow)
FL	Flow limitation	Assisted or Manual	Snore (Flow)
ASY	Asystole	Manual only	EKG
BRY	Bradycardia	Manual only	EKG
NTY	Narrow Complex Tachycardia	Manual only	EKG
WTY	Wide Complex Tachycardia	Manual only	EKG
STY	Sinus Tachycardia	Manual only	EKG
VFB	Ventricular Fibrillation	Manual only	EKG
AFB	Atrial Fibrillation	Manual only	EKG
PVC	Premature Ventricular Contractions	Manual only	EKG
PAC	Premature Atrial Contractions	Manual only	EKG
LM	Limb movement	Assisted or Manual	Legs (Both)
BRUX	Bruxism	Assisted or Manual	Brux
BAD_SPO2	Bad SpO_2 data	Assisted or Manual	SpO_2, Pulse
BAD_ALL	Bad data, all channels	Manual only	All

Scoring Apneas and Hypopneas

Apnea is defined as a cessation of breathing. Hypopnea is defined as breathing that is shallower or slower than normal. Hypopnea is distinct from apnea in which there is no breathing.

Score an apnea when the following occurs:

a. there is a drop in airflow amplitude ≥ 90% of baseline.

b. the duration is ten seconds or longer

c. at least 90% of the event duration meets the amplitude reduction criterion.

There are three types of sleep apnea: obstructive, central and mixed.

Obstructive apnea: A breathing disorder characterized by brief interruptions of breathing during sleep. In obstructive apnea, the muscles of the soft palate around the base of the tongue and the uvula relax, obstructing the airway. Obstructive sleep apnea is characterized by the presence of respiratory effort.

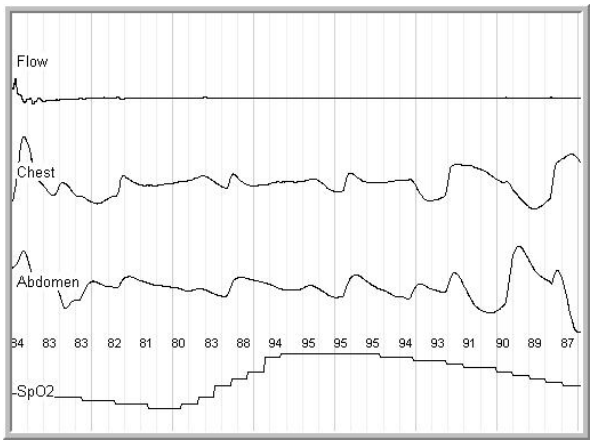


Figure 6.37: Obstructive apnea (90-second epoch size)

Central apnea: A breathing disorder characterized by brief interruptions of breathing during sleep. Central apnea occurs when the brain fails to send the appropriate signals to the breathing muscles to initiate respiration; hence, central sleep apnea is characterized by a lack of respiratory effort. Central sleep apnea is less common than obstructive sleep apnea.

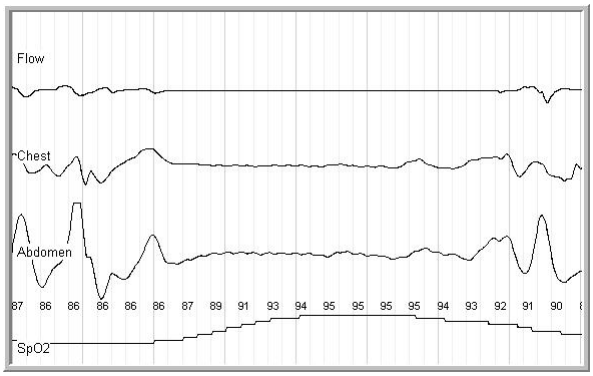


Figure 6.38: Central apnea (90-second epoch size)

Mixed apnea: A breathing disorder characterized by brief interruptions of breathing during sleep. Mixed sleep apnea consists of both central and obstructive sleep apnea.

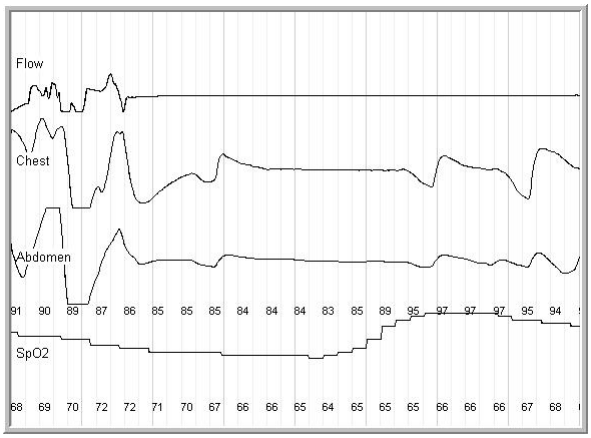


Figure 6.39: Mixed apnea (90-second epoch size)

Score a hypopnea when the following occurs:

a. airflow amplitude drops by ≥ 30% of baseline

b. the duration is ten seconds or longer

c. there is a ≥ 4% desaturation from pre-event baseline

d. at least 90% of the event duration meets the amplitude reduction criterion for hypopnea

OR

e. airflow amplitude drops by ≥ 50% of baseline

f. the duration is ten seconds or longer

g. there is a ≥ 3% desaturation from pre-event baseline OR the event is associated with an arousal

h. at least 90% of the event duration meets the amplitude reduction criterion for hypopnea.

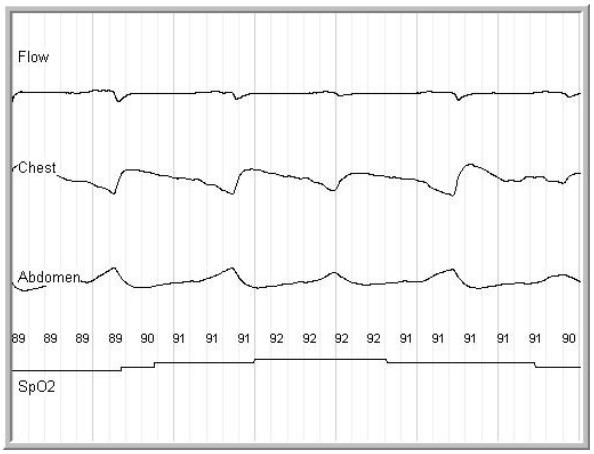


Figure 6.40: Hypopnea - note the accompanying desaturation

Flow Limitation: A flattening or plateau on the inspiratory waveform. This flattening indicates increased resistance of airflow through the upper airway and is often associated with snoring and upper airway resistance syndrome (UARS).

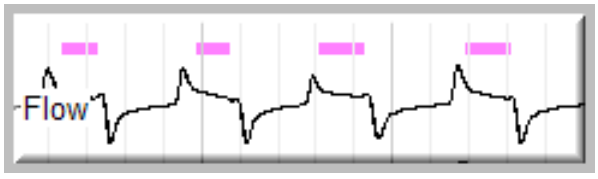


Figure 6.41: Flow Limitation

Respiratory Effort Related Arousal (RERA): Breaths lasting at least 10 seconds in length characterized by increasing respiratory effort or flattening of the nasal cannula pressure leading to an arousal from sleep when the sequence of breaths does not meet the criteria for either an apnea or an hypopnea. A RERA is a milder form of sleep disordered breathing than either apnea or hypopnea.

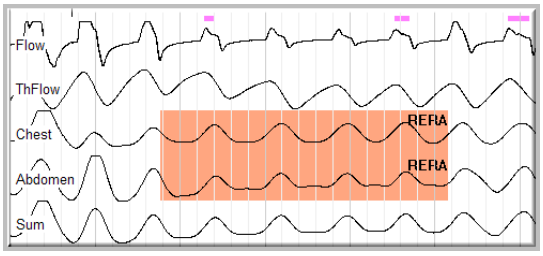


Figure 6.42: RERA

Pulse Rate Variability (PRV): Variation in time interval between heartbeats. You can set the rules for PRV in the Assisted Scoring Rules screen. The default setting for PRV is a minimum change of six beats per minute for a minimum duration of one second and a maximum duration of 60 seconds. The PRV is marked by a black bar above the pulse signal.

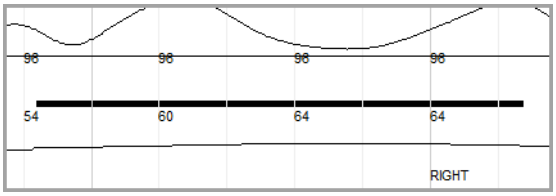


Figure 6.43: PRV

Inserting scoring event markers

Scoring event markers cannot be overlapped.

To insert a scoring event marker:

1. Point to the part of the waveform you want to score.
2. Hold down the left mouse button while moving the mouse over the waveform to the end of the area and release the left button — this action is called dragging. The shortcut menu will appear when you release the mouse button.
3. From the shortcut menu, click the appropriate scoring event.
4. For subsequent events on the same waveform, point to the part of the waveform you want to score and drag the mouse, the software will automatically tag the event with the same scoring event marker as the previous event.

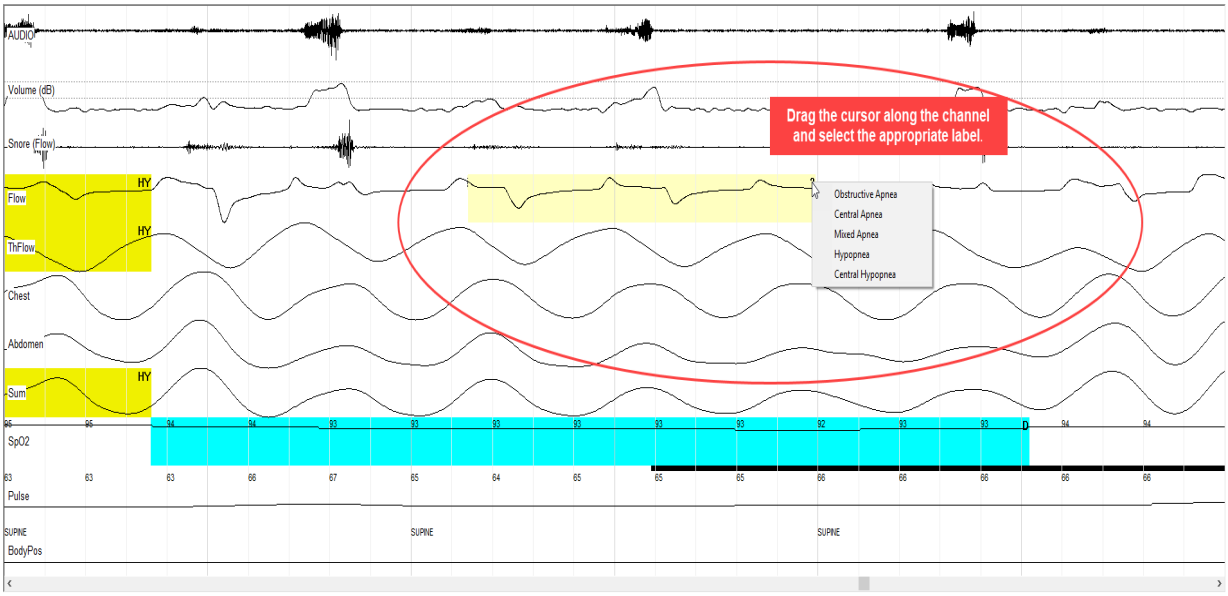


Figure 6.44: Shortcut menu

Deleting scoring event markers

You can delete scoring event markers using delete mode. Toggle delete mode by selecting and deselecting the Delete  button on the toolbar.

In delete mode, delete scoring event markers by clicking on them; restore deleted scoring markers by clicking the Undo button  . The software will stay in delete mode until you deselect the Delete button.

To delete a single scoring marker, right-click on the marker and select **Remove This Event** from the shortcut menu; however, you cannot undo deleted event markers when using the right-click method.

To delete scoring event markers:

1. Go to the epoch with the scoring event marker to delete.
2. Click  to turn on delete mode.
3. Click the scoring event marker(s) you want to delete.
4. When you are finished, click  to turn off delete mode.

Restoring deleted scoring event markers

You can only restore deleted scoring event markers if you deleted them using delete mode; you cannot restore events that were deleted by right-clicking on the marker and selecting **Remove This Event** from the shortcut menu.

As soon as you delete a scoring event marker in delete mode, the Undo button becomes available. Restore deleted scoring markers by clicking the Undo  button.

The Undo feature permits the restoring of scoring event markers starting from the last scoring event marker deleted up to the time delete mode was activated. When you cannot restore any more scoring event markers, the Undo button is unavailable.

To restore deleted scoring event markers:

- Click  as many times as required to restore the events you previously deleted.

Modifying scoring event markers

With all scoring event markers, change the scoring event at any time by right-clicking on the marker and selecting a new scoring event from the shortcut menu.

Scoring event markers cannot be overlapped.

To modify a scoring event marker:

1. Go to the epoch with the scoring event marker to change.
2. Right-click on the scoring event marker, and from the shortcut menu, click the appropriate scoring event.

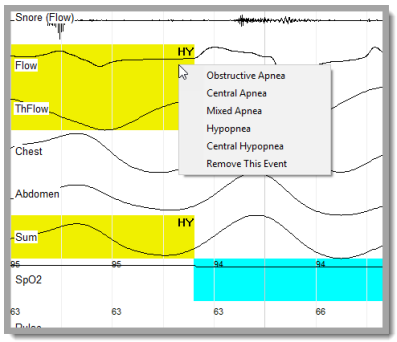


Figure 6.45: Modify a scoring event marker

Repositioning scoring event markers

Change the position of any scoring event marker at any time by clicking on the marker and dragging it to a new location.

To reposition a scoring event marker:

1. Go to the epoch with the scoring event marker you want to reposition.
2. Click the scoring event marker and drag it to the new location.

Lengthening or shortening scoring event markers

Change the length of any scoring event marker at any time by positioning the pointer over either the left or right border of the scoring event marker and dragging the border.

To lengthen or shorten a scoring event marker:

1. Go to the epoch with the scoring event marker you want to lengthen or shorten.
2. Point to either the right or left border of the scoring event marker and you will see a double-headed arrow [◄►].
3. Drag the border to lengthen or shorten the marker.

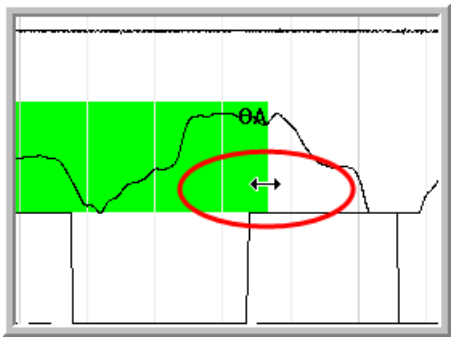


Figure 6.46: Double-headed arrow on the event

Sleep Stage Scoring (MediByte only)

You can manually score sleep stages on the display screen using the keyboard of your computer. To score sleep stages, set the screen width to 30 seconds. Press the shortcut key that corresponds to the sleep stage you are currently viewing. For example, score the REM stage by pressing the 5 key. Pressing the shortcut key for the sleep stage, inserts a watermark abbreviation of the sleep stage in the top right corner of the display.

The hypnogram will appear in the histogram as you score the data.

You can only add sleep stage scores to data that has been collected using the Sleep, Sleep + EKG or Sleep + EEG modes. The data will display EEG, EOG and EMG.

Table 6-3: Sleep Stage Keys

Sleep Stage	Keyboard	Displayed
Wakefulness	W, A or 0	W
Stage 1	1	N1
Stage 2	2	N2
Stage 3	3	N3
REM	4, 5 or R	R
Movement	M	M

To insert a sleep stage marker:

1. Set the display screen width to 30s.
2. Click the key corresponding to the sleep stage. The screen will advance to the next epoch so you can quickly score the data.
3. Click the back arrow to view the sleep stage score marker on the top right of the screen.

Manually Mark Arousals (MediByte only)

In data collected using the either of the three sleep modes, you can manually mark arousals on the EEG.

To mark an arousal:

1. Click and drag the mouse along the EEG signal to mark the arousal. An arousal menu will open.
2. Select the appropriate Arousal Tag by clicking your mouse.

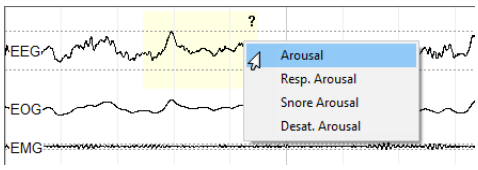


Figure 6.47: Arousal menu

To remove an arousal:

1. Right click on an arousal marker to open the Arousal menu.
2. Click on Remove This Event to delete the arousal from the data.

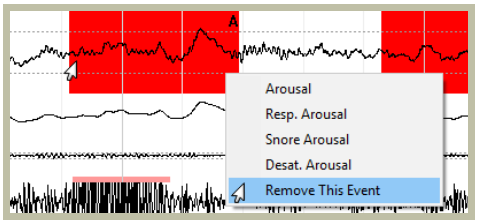


Figure 6.48: Removing an arousal

Mark and Play Audio

You can mark and play audio on the AUDIO channel using the Mark And Play Audio button. This button turns on the audio feature so that you can mark a segment of the AUDIO channel and listen to the sounds recorded. This feature is useful for distinguishing snoring from other noises that occur during the night. After the segment has finished playing, the yellow marker disappears; the data is not permanently marked. Refer to Table 6-4 on page 6-40 for a listing of the decibel levels of common sounds.

To mark and play audio:

1. Click to activate the audio function.
2. Click and drag the mouse along the AUDIO channel to listen to that segment of the data. If you click elsewhere on the data, the audio play-back will end.
3. Click again to turn off the audio function.

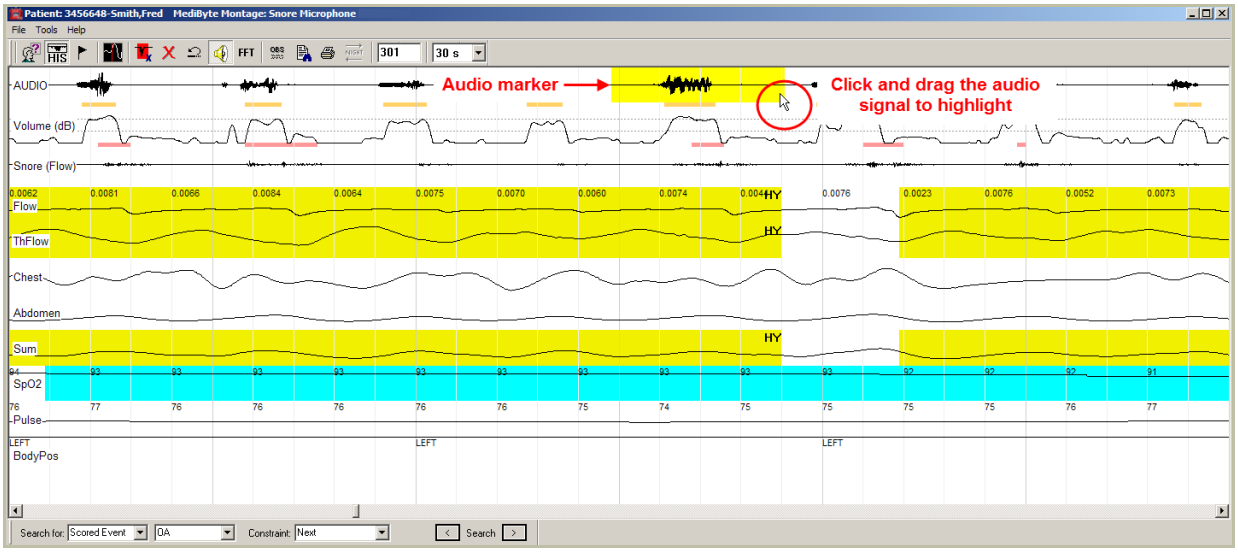


Figure 6.49: Using the audio feature

Table 6-4: Loudness Comparison Chart

Environmental Noise	Decibel Level (dB)
Whisper	40-45
Normal conversation	60-70
Telephone dial tone	80
City traffic (inside car)	85
Train whistle at 500’	90
Subway train at 200’	95
Level at which sustained exposure may result in hearing loss	90-95
Power mower	107
Power saw	110
Pain begins	125
Pneumatic river at 4’	125
Jet engine at 100’	140
Death of hearing tissue	180
Loudest possible sound	194

Mark and Play Audio with FFT Analysis

When you select the FFT Analysis button, you can mark a segment of the AUDIO channel for audio playback and FFT analysis. The software will first playback the segment and then display the FFT analysis of the segment in a graph. You can copy the graph to the clipboard for later use or print the graph.

To mark and play audio with FFT analysis:

1. Click FFT to activate the audio and FFT function.
2. Click and drag the mouse along the AUDIO channel to listen to that segment of the data. After the audio playback, the Audio-FFT Analysis window opens.
3. To copy the FFT graph to the clipboard, click **Copy to Clipboard**. You can paste the image into a document, but if you click **Copy to Clipboard** again, the first image will be over-written. You can only have one item in the clipboard at a time.
4. Click **Print** to print the Audio FFT graph.
5. Close the Audio-FFT Analysis window.
6. You can continue to highlight segments of the AUDIO channel to listen and review the FFT analysis graphs as long as the FFT button is depressed.
7. Click FFT again to turn off the audio and FFT analysis function.

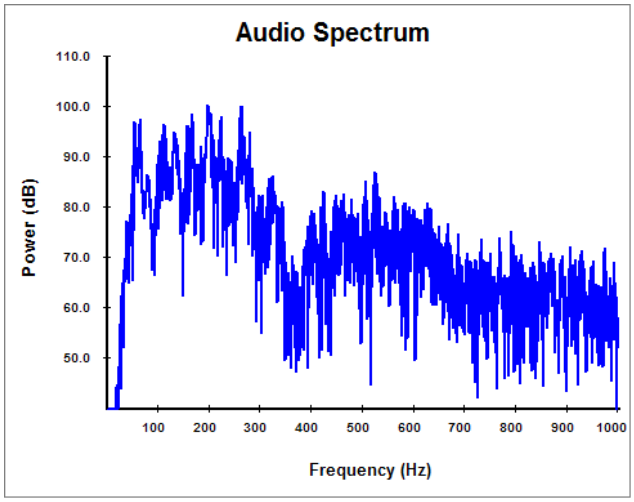


Figure 6.50: Sample Audio FFT graph pasted directly onto this page from the clipboard (sized to 90%)

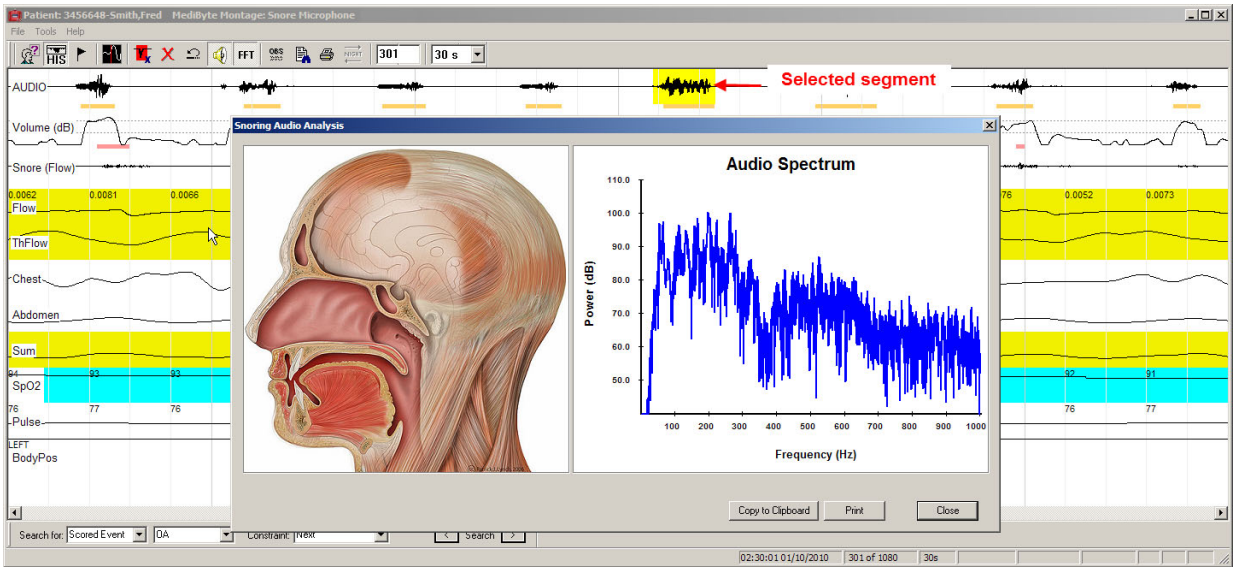


Figure 6.51: Audio - FFT Analysis Screen

Marking Bad Data

The software automatically marks bad data during the initial downloading of the data from the MediByte/MediByte Jr SpO_2 waveforms of less than 50% will be marked as bad data; pulse rate data occurring at the same time will also be marked as bad.

When data is marked as bad, that segment is removed from the statistical calculations by the report generator, but this does not affect the recording time statistics.

Bad data does not affect total recording time.

If your data set does not have automatically marked bad data because it was downloaded with an older version of the software, you can run the Assisted Scoring or manually mark the bad data. In addition, you can change the bad data markers, as required.

For information about Assisted Scoring, see **Starting the Assisted Scoring** on page 6-26.

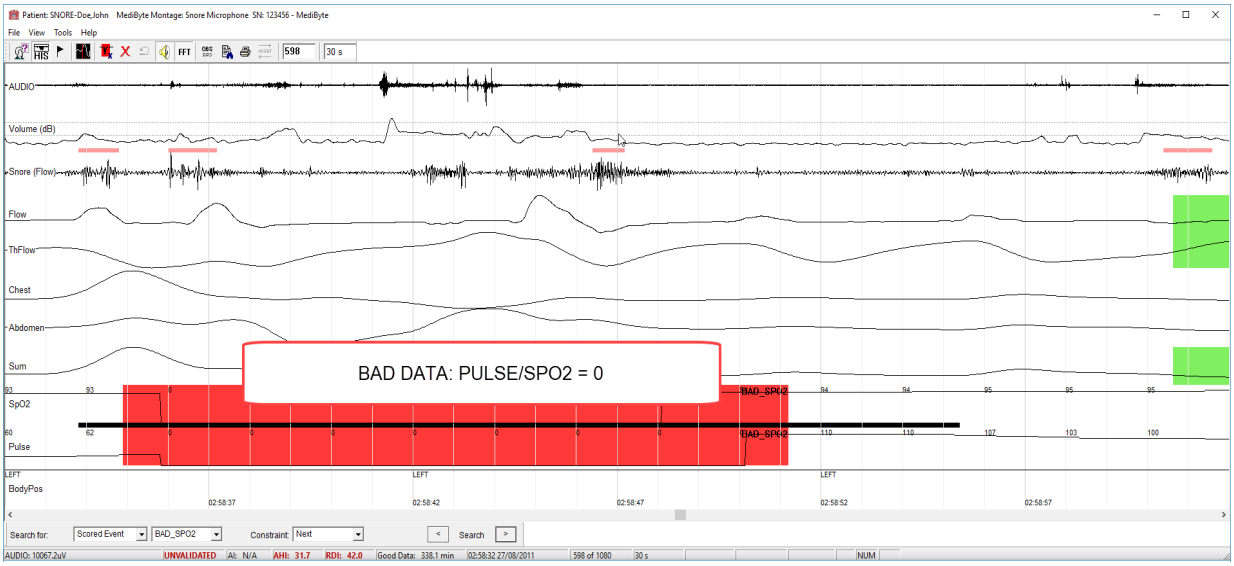


Figure 6.52: Bad pulse signal marked as bad data

Manually Marking Bad Data

Manually mark the SpO_2/Pulse signals or all of the channels as bad using , the Mark Bad Data button.

If you mark all channels as bad, you must re-run the assisted scoring to ensure that events associated with the bad data are completely removed. Deselect bad SpO2/Pulse data in the Assisted Scoring Screen before you run the assisted scoring.

Marking all channels as bad will affect total recording time; marking SpO_2/Pulse as bad will not affect total recording time.

To mark bad data:

1. Click to activate the bad data function.
2. Click and drag the mouse along the signal you want to mark. If you are dragging along the SpO_2 or Pulse signals, a pop-up will show Mark SpO_2/Pulse BAD or Mark All Channels BAD. If you are dragging on other signals, you will only have the option to mark all channels.
3. Select whether you want to mark all the channels as bad or only the SpO_2/Pulse.
4. Click to turn off the bad data function.

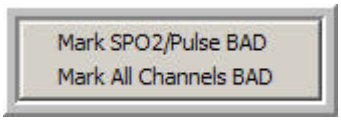


Figure 6.53: Bad data pop-up

Lengthening or shortening bad data event markers

Change the length of any bad data event marker at any time by positioning the pointer over either the left or right border of the event marker and dragging the border.

To lengthen or shorten a bad data marker:

1. Go to the epoch(s) with the bad data marker you want to lengthen or shorten.
2. Click  to activate the bad data function.
3. Point to either the right or left border of the red marker and you will see a double-headed arrow [◄►].
4. Drag the border to lengthen or shorten the marker.

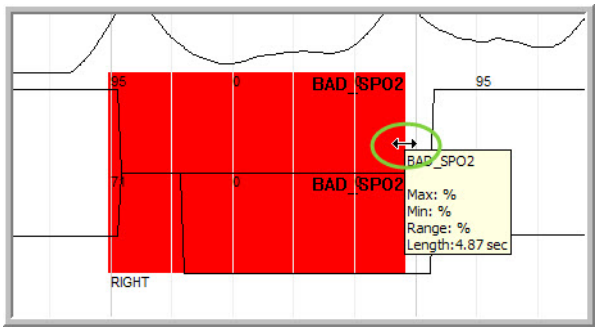


Figure 6.54: Changing the bad data marker

Deleting Bad Data Markers

You can delete all the bad data markers in a data set at once or one by one.

To delete all bad data markers from the data set:

1. Click **Tools>Delete Scored Events** to open the Remove Scored Events screen.
2. Click on Bad SpO2/Pulse Data.
3. Click **Entire Study** if you want all of the events deleted, or deselect **Entire Study** and enter an epoch range.
4. Click **Go**. A warning window will ask you to verify that you want to delete the scored events, click **Yes** to continue. After the program has finished deleting the scored events, the histogram will show no bad data.

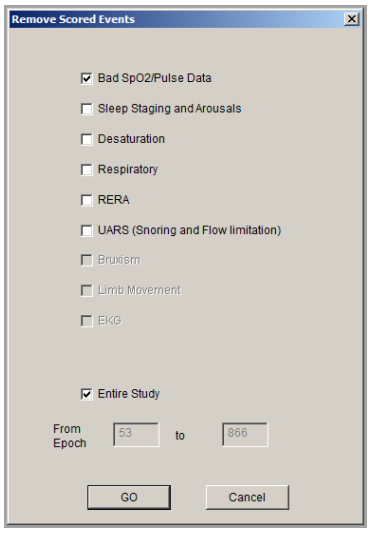


Figure 6.55: Remove All Bad Data Markers

To delete one bad data marker:

1. Go to the epoch(s) with the bad data marker you want to delete.
2. Click  to activate the bad data function.
3. Right-click on the bad data marker and select **Remove This Event**.

Viewing the Scoring Statistics

Point to a scoring event marker with the mouse cursor to view statistics about the scoring event, including:

- **Scoring event label:** indicates the abbreviated name for the scoring event.
- **Maximum physical unit:** indicates the highest physical unit for the scored event.
- **Minimum physical unit:** indicates the lowest physical unit for the scored event.
- **Range between the maximum and minimum physical units:** indicates the difference between the maximum and minimum physical units.
- **Length of the scoring event:** indicates the length in seconds of the scored event.

To view the scoring statistics for a scoring event marker:

- Use the mouse to point to the scoring event marker and the scoring statistics will display.

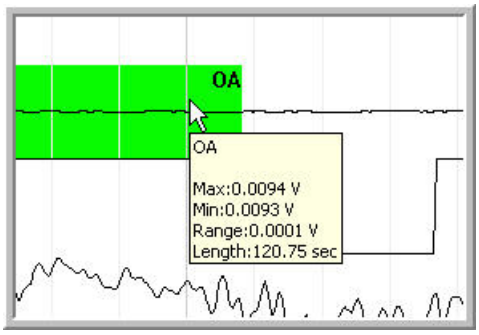


Figure 6.56: Scoring statistics

Printing Reports

There are two types of reports you can print: the print screen report and the generated reports. The print screen report is simply a picture of the data currently on your computer monitor. The generated reports use data from the entire study to create a report.

Studies should be reviewed by a qualified individual. You are required to acknowledge in a dialogue box that you have reviewed the study before generating a report.

To print the current screen:

1. Click  and then select the printer you will use to print the report.
2. Click **Print**.

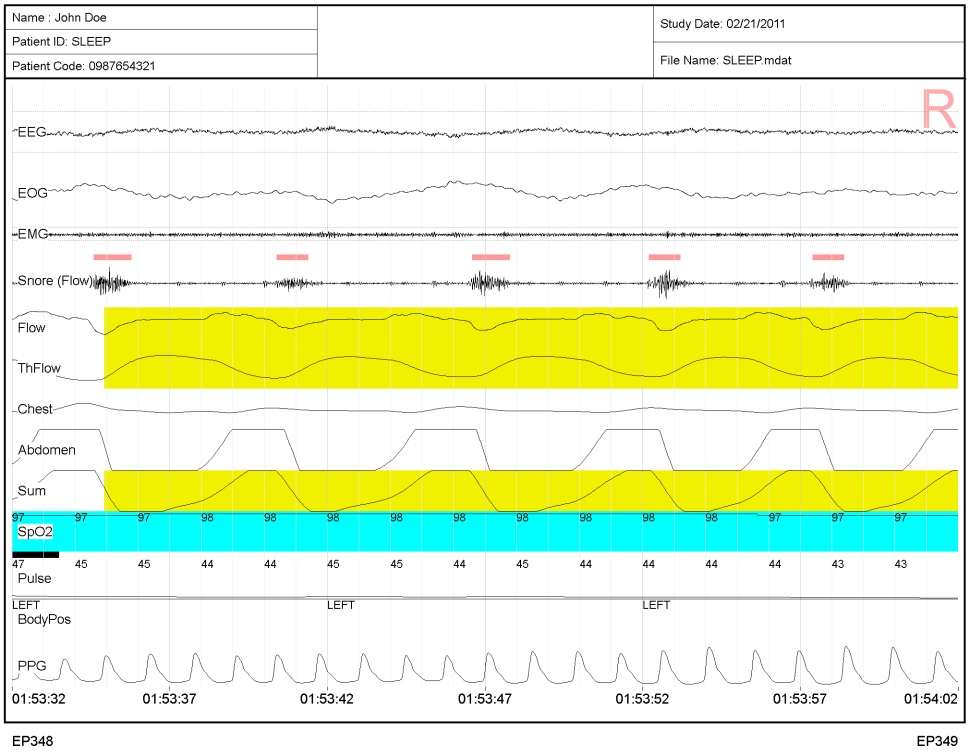


Figure 6.57: Print screen report

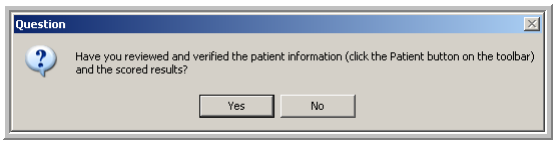
Printing a generated report

After viewing a data file, you can print a full report. Reports are previewed and printed using Microsoft Word®.

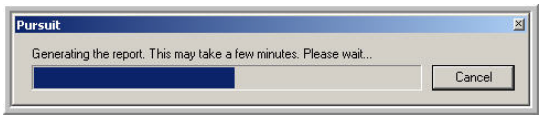
Note: Before generating the full report, click  and enter the patient information in the Patient Info window. In addition, ensure that you have entered a Lights Out tag at the beginning of the data and a Lights On tag at the end of the data.

To generate a full report:

1. Click  . A Select a Report to Create window opens.
2. Highlight the report you want to create and click **Create**. The available reports are dependent upon the type of study recorded. The report types are as follows:
   - **HST Report** (Snoring Report): A one page report that shows the respiratory and snoring events and oximetry recorded during the study. The report tabulates respiratory events for each body position.
   - **SpO2 Report**: A one page report showing blood oxygen saturation histograms for each one hour segment in the study.
   - **2018 HSAT Report:** A four page report that shows the sleep summary, sleep stage summary, arousal summary, respiratory events by body position and sleep stages, oximetry, respiratory events, breath stats and histogram. A sample of this report is at the end of this chapter.
   - **CPAP Report** (only available for studies configured for CPAP): This report shows the relationship between CPAP pressure and Apnea Hypopnea Index scores and SpO_2 nadirs.
3. A question box asks whether you have reviewed and verified the results. If you have reviewed the results and they are acceptable, click **Yes**. If you have not yet reviewed the results, click **No** and review the results before continuing.



4. If this is a new report, it will automatically generate.



5. If you have already made a report for this data, an information window will ask whether you wish to create a new report or view the existing report. If you have made changes to the data file, select **Create New**; otherwise, select **View Existing.** If you select **Create New**, a window will inform you that the system is generating the report (as per step 2) which can take a few minutes. The report will display on the screen.

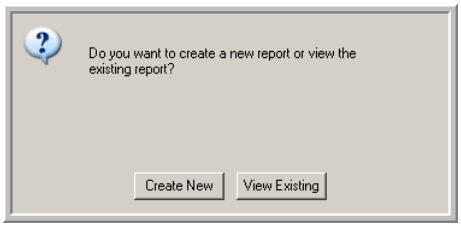


Figure 6.58: Confirmation window

6. Since the report is created in Microsoft® Word®, you can make changes to the text of the report, if required.
7. Print the report by selecting File>Print in Microsoft® Word®.

Sample MediByte Report

MEDIBYTE

HST & SLEEP BREATHING REPORT

PATIENT Doe, John

Patient ID:	SLEEP
Study Date:	02/21/11 (MM/DD/YY)
Date of Birth:	03/04/1965 (MM/DD/YY)
Age:	53
Sex:	Male
Height:	5' 11" (180 cm)
Weight:	175.0 lbs (79.6 kgs)
BMI:	24.6
Waist-Hip Ratio:	1.06 (W: 36", H: 34") (W: 91 cm, H: 86 cm)

AHI: 1.8

RDI: 2.9

ODI: 0.6

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

Chart Code:	0987654321
Referring Physician:	
Start Time:	23:03:35
End Time:	07:48:11
Total Recording Time:	524.6 minutes
Total Monitoring Time:	517.0 minutes
Total Good Study Time:	524.6 minutes

HOME SLEEP APNEA TESTING DEVICE

The MediByte®, 15-signal Type 2 home sleep apnea and snoring recorder (SN 123456), was used to evaluate sleep-disordered breathing. The following parameters were recorded for a duration of 524.6minutes: EEG, EOG, EMG, Snoring (high frequency vibrations in airflow), oronasal pressure Airflow, flow limitation, oronasal thermal Airflow, RIP Chest/Abdominal/Sum Effort, SpO_2, 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.

Total Good Monitoring Time = TRT less (Bad Data All + Bad Data SpO_2)
Total Good Study Time = TRT less Bad Data All

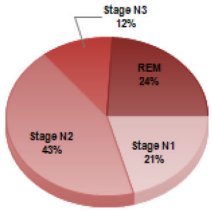
COMMENTS

This study has been VALIDATED.
Patient reports alcohol dependency, evening headaches.
70.1% of all breaths were associated either with flow limitation or with snoring. AHI & RDI were 1.8 and 2.9, respectively. Supine AHI was 0.0 and supine RDI was 1.4. REM sleep AHI was 1.8 and supine REM sleep AHI was 0. Oxygen Desaturation Index (ODI) was 0.6 and time below 88% SpO_2 was 0.9. Supine desaturation index was 1.4.

SLEEP SUMMARY

Lights Out Time:	23:03:35
Lights On Time:	07:48:11
Total Time in Bed:	524.6
Total Sleep Time:	501.0
Total Wake Time:	23.6
Sleep Latency:	12.94
Sleep Efficiency:	95.5%
Number of Awakenings:	10
Number of Stage Changes:	121

SLEEP STAGES (%TST)



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**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.*

Page 1 of 4

MEDIBYTE

HST & SLEEP BREATHING REPORT

PATIENT Doe, John Patient ID: SLEEP Study Date: 02/21/11

SLEEP STAGE SUMMARY

Stage	Latency	Time	% TST	% Norm
N1	12.94	104.0	20.8	7.5%
N2	26.94	218.0	43.5	53.0%
N3 (Delta)	41.44	58.0	11.6	10.0%
REM	80.94	121.0	24.2	24.0%
WASO	0.00	23.6		

AROUSAL SUMMARY

	NREM		REM		TOTAL	
Arousal Source	# Events	Index	# Events	Index	# Events	Index
Spontaneous	8	0.9	8	0.9	8	0.9
Apneas + Hypopneas	2	0.2	2	2	2	0.2
Snore	1	0.1	1	0.1	1	0.1
Desaturation	0	0.0	0	0	0	0.0

RESPIRATORY EVENTS BY BODY POSITION AND SLEEP STAGE SUMMARY

	NREM					REM				
Respiratory Events	Supine	Side (L/R)	Prone	Total	Index	Supine	Side (L/R)	Prone	Total	Index
Obstructive Apneas	0	2/2	0	4	0.5	0	2/2	0	4	0.5
Mixed Apneas	0	0/0	0	0	0.0	0	0/0	0	0	0.0
Central Apneas	0	1/1	0	2	0.2	0	1/1	0	2	0.2
Total Apneas	0	3/3	0	6	0.7	0	3/3	0	6	0.7
Central Hypopneas	0	0/0	0	0	0.0	0	0/0	0	0	0.0
Hypopneas	0	2/8	0	10	1.1	0	2/8	0	10	1.1
Apneas + Hypopneas	0	5/11	0	16	1.8	0	5/11	0	16	1.8
AHI	0.0	1.5/2.4	0.0	16	16	0.0	1.5/2.4	0.0	16	16
RDI	1.4	2.4/3.4	0.0	25	25	1.4	2.4/3.4	0.0	25	25

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Page 2 of 4

MEDIBYTE

HST & SLEEP BREATHING REPORT

PATIENT Doe, John Patient ID: SLEEP Study Date: 02/21/11

OXIMETRY

SpO2 Range	%	Minutes
98-100 %	44.1%	228.1
96-98 %	55.5%	287.5
94-96%	0.2%	0.9
92-94 %	0.0%	0.1
90-92 %	0.0%	0.0
90-100 %	99.8%	516.7
80-89 %	0.0%	0.3
70-79 %	0.0%	0.0
60-69 %	0.0%	0.0
50-59 %	0.0%	0.0
< 50%	0.1%	0.7
Total < 88 %	0.2%	0.9

	Total	Index (ODI)	NREM Index <R.D.NRI>	REM Index <R.D.RI>
Desaturations ≥ 3%	5	0.6		
	Mean	Min.	Max.	
SpO2% (No Desats)	97.3	80.0	100.0	
SpO2% (Desats Incl)	97.3	80.0	100.0	
Pulse (bpm)	47.0	40.0	104.0	

PULSE

Pulse Rate Range	% time	minutes
125-150	0.0%	0.0
100-125	0.0%	0.0
75-100	1.6%	8.3
50-75	14.2%	73.6
25-50	87.0%	450.3
PRV	Count	Index
Increases ≥ 6 bpm	208	23.8

RESPIRATORY

Duration (sec)	Total	Index	Mean	Min.	Max.
Breaths	5614	642.1	3.4	0.6	14.1
Central Apneas	2	0.2	11.6	10.4	12.7
Obstructive Apneas	4	0.5	13.0	10.3	18.7
Mixed Apneas	0	0.0	0.0	0.0	0.0
Central Hypopneas	0	0.0	0.0	0.0	0.0
Hypopneas	10	1.1	37.6	2.2	121.3
Apnea+Hypopnea	16	1.8	28.2	2.2	121.3
Snoring Flow (SNR)	4577	523.5	1.1	0.2	2.8
Flow Limitation (FL)	4672	534.4	1.5	0.6	6.0
Desaturations	5	0.6	86.2	0.8	201.8
Cheyne-Stokes	0	0.0	0.0	0.0	0.0
RERAs	9	1.0	36.0	10.4	103.9

EVENTS

BY BODY POSITION	Supine	Non-Supine	Right	Left	Prone
% Time in Position	8.2%	91.4%	53.5%	37.9%	0.1%
Total Breaths	507	5087	2948	2135	4
Snoring Flow (SNR)	204	4362	2438	1920	4
Flow Limitation (FL)	133	4539	2723	1816	0
Desaturations	1	4	0	4	0
Desaturation Index	1.4	0.5	0.0	1.2	0.0
RERAs	1	8	5	3	0
Cheyne-Stokes	0	0	0	0	0
Apneas + Hypopneas	0	16	11	5	0
Apnea Hypopnea Index	0.0	2.0	2.4	1.5	0.0
Resp Disturb Index	1.4	3.0	3.4	2.4	0.0

BREATH STATS

Total Breaths	5614
Mean Respiratory Rate (/min)	10.7
with FL	3934
% FL Breaths	70.1%

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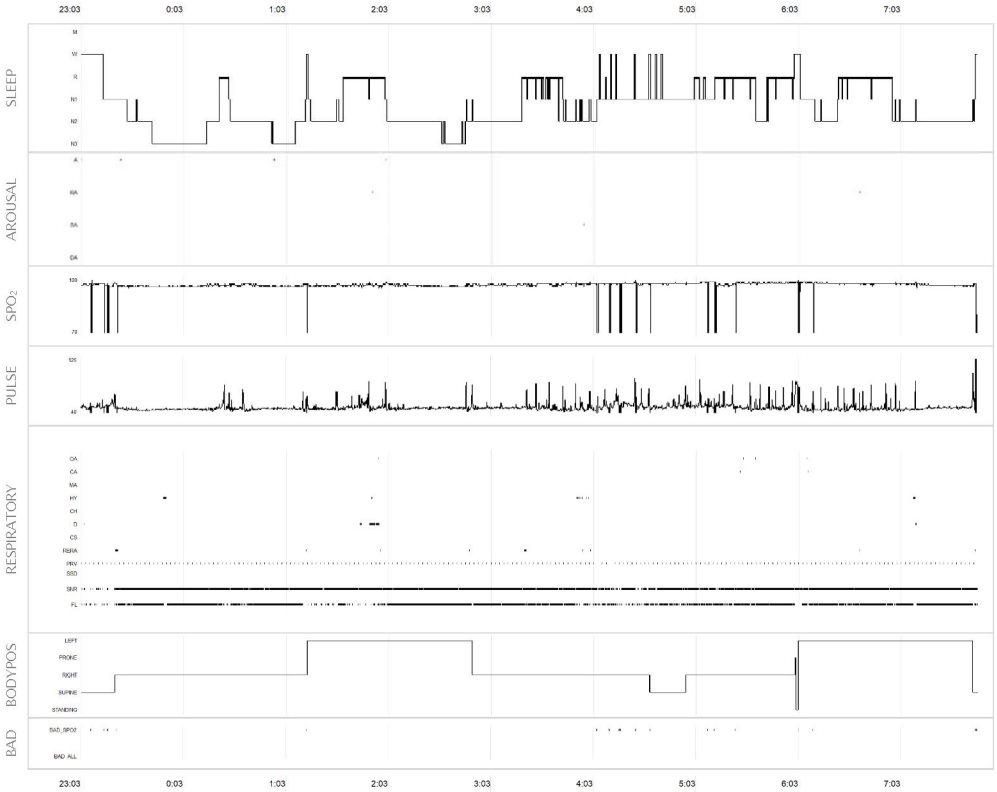
**Respiratory events are defined in the Assisted Scoring User Settings and in the User Guide. Final clinical decisions and degree of accuracy are the sole responsibility of the clinician using this software.*

MEDIBYTE

HST & SLEEP BREATHING REPORT

PATIENT Doe, John Patient ID: SLEEP Study Date: 02/21/11



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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.

Chapter 7: Data Management

In this chapter

This chapter includes:

- Assigning storage locations
- Moving/archiving study files
- Decompressing zipped files
- Manually moving studies

Data Management

The MediByte software controls file names and the directory structure for data management purposes.

All data management occurs within the Studies Data Manager window. You can use the Studies Data Manager window to delete study files, move/archive the study files to another folder or burn them to a CD/DVD. The software has a data compression feature for zipping the study data to save storage space.

Assigning Storage Locations

Before you can move/archive the study files, you need to assign a storage location using the File Location Setup window. The software provides four possible storage locations: Studies folder (default), two self-assigned folders and CD/DVD.

To assign a storage location

1. Select **Tools>File Location Setup** to open the File Location Setup window.
2. Type the name of the folder in Name. This name is used only to identify the folder in the Studies Data Manager window.
3. Browse to the location of the storage folder and select it; or type the name and location of the folder you want to create. If the folder does not already exist, a pop-up window will ask whether you want to create the new folder.
4. If you want the software to compress the study file, ensure the checkbox beside *Use Zip Compression* is selected (circled). Once compressed, a file cannot be opened; you must move it to an uncompressed storage location, such as the Studies folder, and the software will automatically decompress it.
5. Click **Save**.

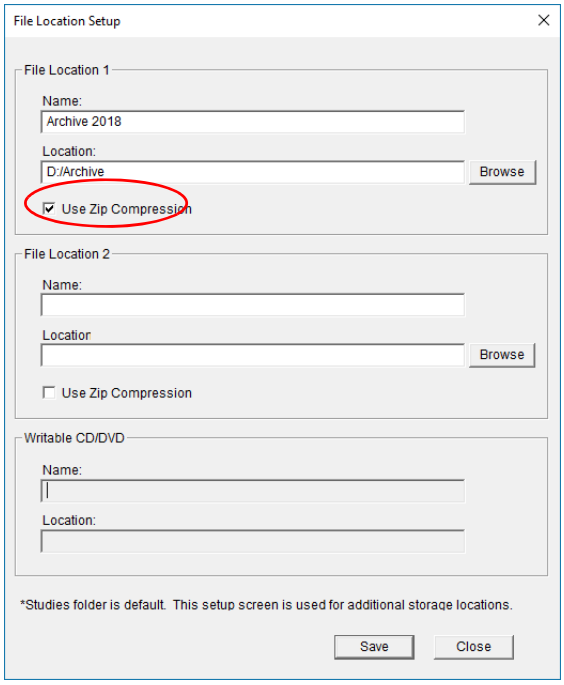


Figure 7.1: Assigning the storage locations. Data compression selected.

Moving/Archiving Studies Files

1. Select **File>Open** to open the Studies Data Manager window.
2. Click the button and select the file storage location. Here, the file storage location selected is Default Studies Folder. If you want to burn the data to a disc, select Writable CD/DVD Drive.

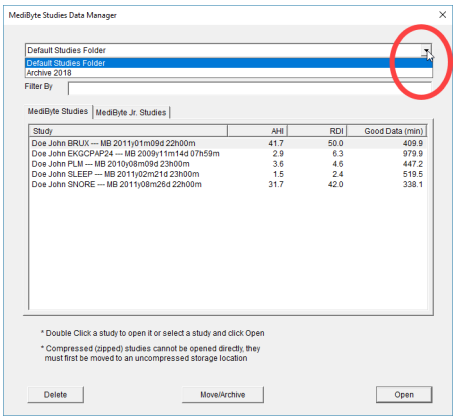


Figure 7.2: Select the location to move the test files

3. Select the studies you want to move/archive. If you want to move/archive more than one study file at a time, hold the Shift key while selecting the files.
4. Click **Move/Archive** to initiate the move/archive function.

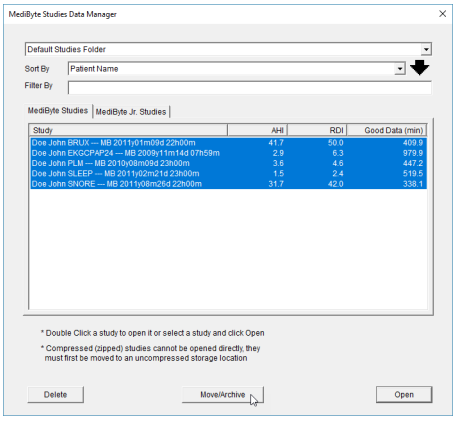


Figure 7.3: All test files selected using the Shift key

5. The Move/Archive Files window appears. This window shows the files you have chosen to move and the location of the storage folder. If this is what you want to do, click **OK**.
6. If you want to change the storage folder location, click and select a new folder location. To do this, you must have assigned other folder locations in the File Location Setup window; see *To assign a storage location* on page 7-2. You can cancel and assign more locations, if required.

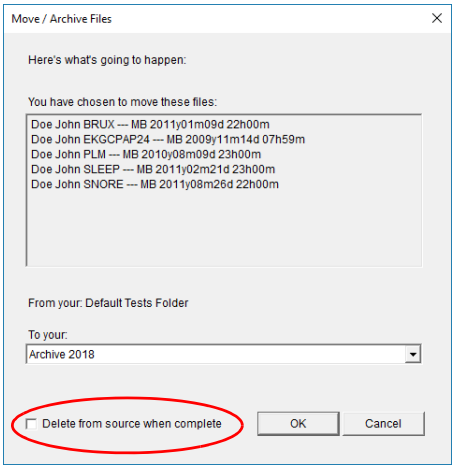


Figure 7.4: Move / Archive Files window showing the files to be moved and the destination

7. If you want the original studies files deleted from the source folder, ensure the *Delete from source when complete* checkbox is selected (circled in Figure 7.4).
8. Click **OK** to start the move/archive function. If you selected the zip compression function, the software will compress the data, and then copy it to the selected folder.

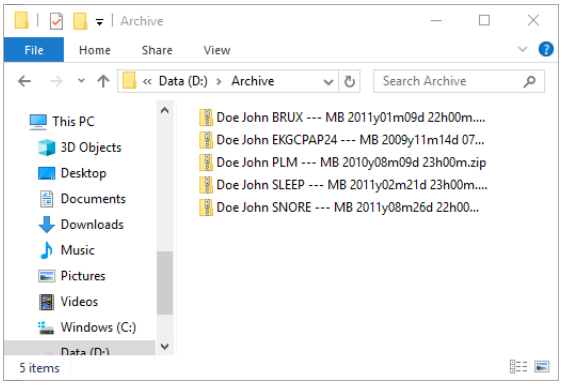


Figure 7.5: The zipped test files as they appear in the Archive folder

Decompressing Zipped Files

1. From the Studies Data Manager, click  and select the compressed data folder.
2. Click the file(s) you want to decompress and click **Move/Archive** to start the decompression.

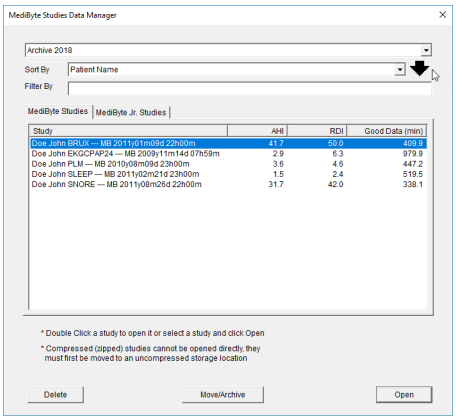


Figure 7.6: Selecting a compressed file to move and decompress

3. The Move/Archive Files window appears. This window shows the file(s) you have chosen to move and the location of the destination folder. Click and select the destination folder.
4. If you want the original file(s) deleted from the source folder, ensure the *Delete from source when complete* checkbox is selected (circled).
5. Click **OK**. A copying window will appear, showing the progress of the copy. After this window, you will see an unzip window, which will show the progress of the decompression.

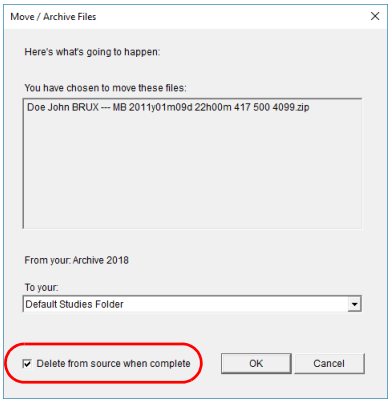


Figure 7.7: Move / Archive Files window showing the file to be moved and the destination folder.

Manually Moving Studies

Studies are located in the following directory:

C:/Users/Public Documents/Braebon/MediByte/Studies

All files and folders associated with a study are located here. Folders are labeled using the following structure:

Last Name First Name Patient ID

For example, Michael Jones who has a patient ID of 123456 will have a study folder named Jones Michael 123456.

Within each folder, there may be a number of folders representing more than one study for the patient. If you want to manually move a study, you must move the entire folder, otherwise information will be lost. We recommend you use the file management tool in the MediByte software to move studies.

Chapter 8: Passwords, Displays and Maintenance

In this chapter

This chapter describes how to set the administrator password and user passwords, how to change the way the channels are displayed and MediByte maintenance.

This chapter includes:

- Passwords and Security
- Display Edit
- Cleaning the MediByte
- Maintaining the MediByte and its accessories
- Troubleshooting
- Warranty

Passwords and Security

The MediByte software uses the initial password MASTER. For security, you can add an administrator password and five additional user passwords to the software.

If you are having difficulty with setting the passwords, please call Technical Support at 1.888.462.4841.

Change Administrator Password

1. Select Tools>Edit Passwords and enter the ADMIN Password (MASTER) to open the Password Editor screen.
2. Enter a new ADMIN password. The password must be 8-10 characters long with one each of upper case, lower case, a number and a special character.
3. Click OK.
4. Reenter the new ADMIN password.

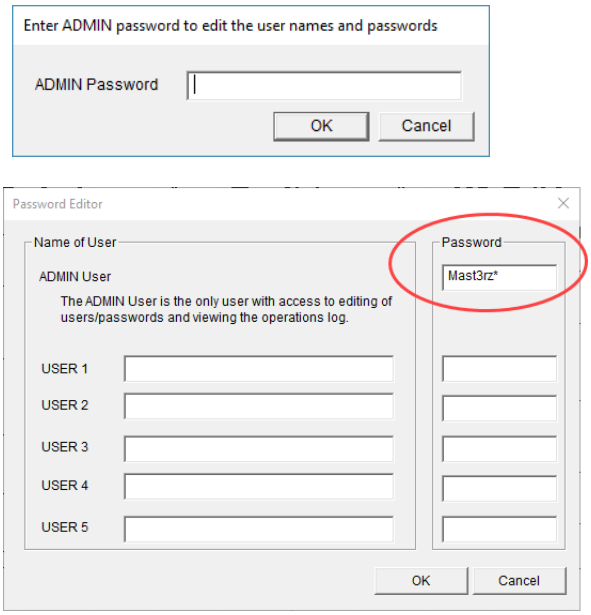


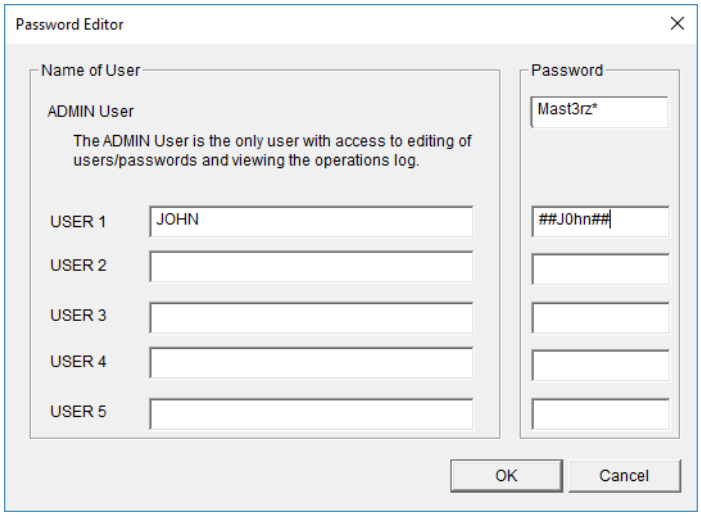
Figure 8.1: Create a new ADMIN password

Add Users and Passwords

You can add up to five unique users to the MediByte software. Once the users are set, the software will track all user operations with date, time, user name and operation performed in the User Operation Log.

Only the Administrator can add or edit users and passwords.

1. Select Tools>Edit Passwords and enter the ADMIN Password when prompted.
2. Enter a new user name and password. The password must be at least eight characters long with one each of upper case, lower case, a number and a special character.
3. Click OK.



User Operation Log

The User Operation Log is an encrypted text file showing all activity within the software. The entries are listed by Date, Time, user and description of the operation. All major operations, such as login, analyzing a study, generating a report, and changing passwords are recorded.

Only the Administrator can view the unencrypted content in the User Operation Log.

Open the User Operation Log

- Click Tools>View Operation Log and enter the ADMIN password when prompted.

The Operation Log opens on the screen.

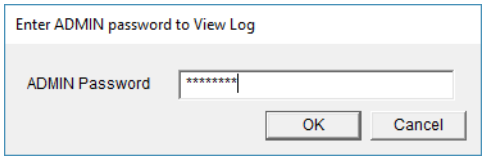


Figure 8.2: Enter ADMIN password

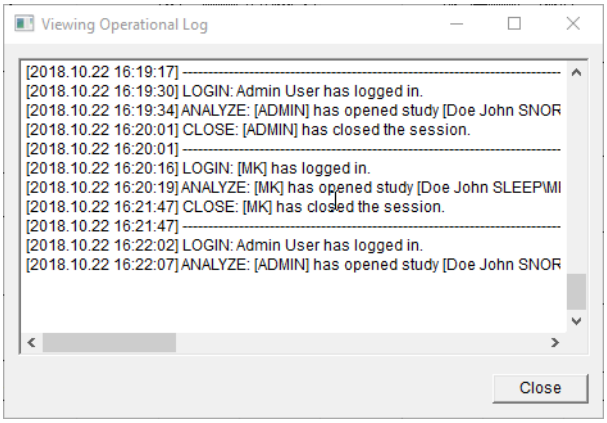


Figure 8.3: Sample Operation Log

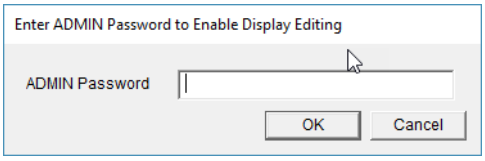
Display Edit

The Software Administrator can change and move the waveforms. Before you can change the waveforms, you must enable the waveform editing function.

Only the Administrator can enable the display editing function to change the waveforms. Once enabled, any user can modify the display. Be sure to disable the editing function to prevent unauthorized editing of waveforms.

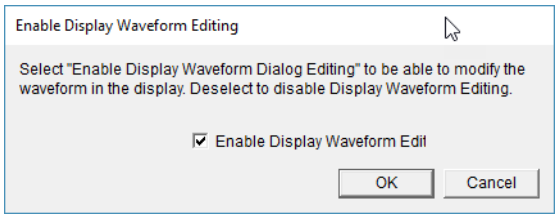
To enable waveform editing function

1. Select Tools>Enable Display Editing and enter the ADMIN password when prompted.



2. Click the checkbox beside Enable Display Waveform Edit to enable the waveform editing function and click OK.

   The waveform editing function is now available. You can disable the function by selecting Tools>Disable Display Editing.



To modify waveforms

1. Double left-click on the waveform label. The screen will change color and a bar will form across the waveform.
2. To move the waveform to a new position, click and drag the highlighted bar.
3. To increase the size of the displayed waveform, click and drag the upper and lower edges of the display.

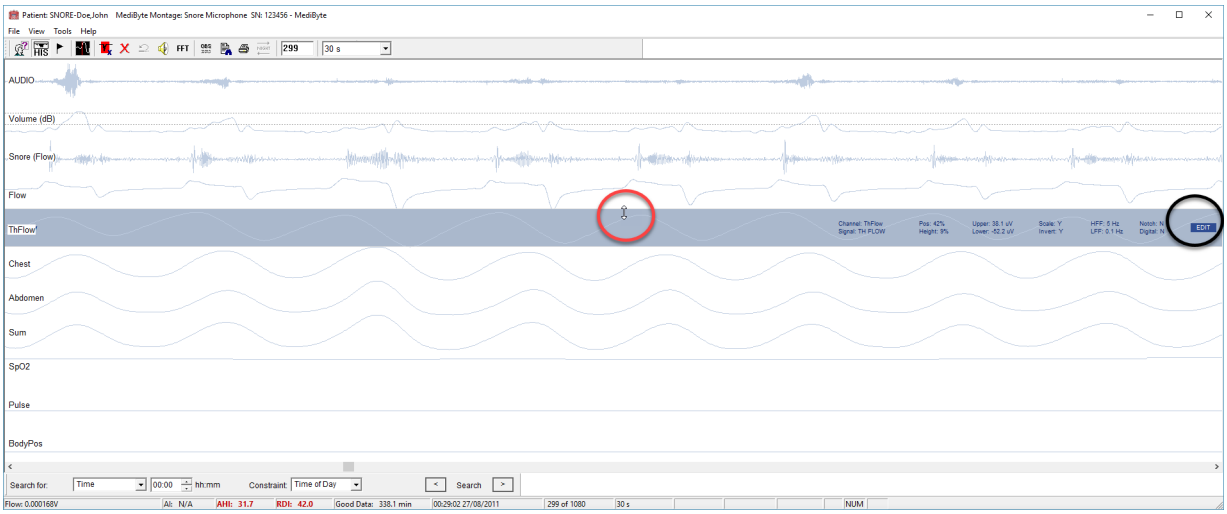


Figure 8.4: Click and drag the upper and lower edges of the display (red circle)

To change the waveform properties

1. Click Edit, located on the far-right of the waveform bar, to open the Display Channel Properties window. Here you can change any of the waveform parameters listed.
2. After changing the properties, click OK
3. To clear the current display properties, click New
4. To remove the waveform from the display, click Remove.

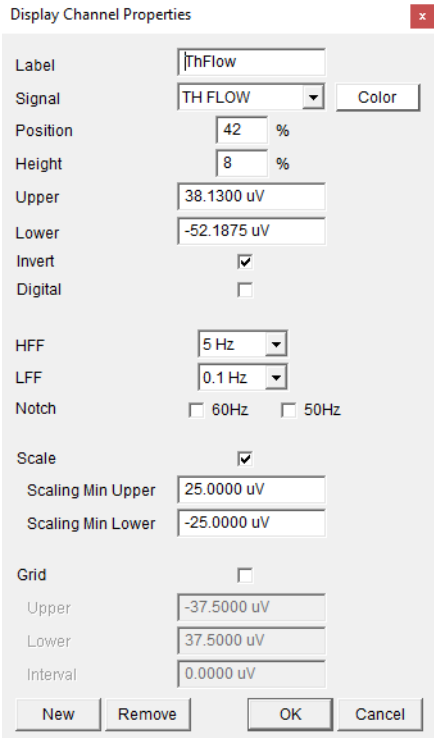
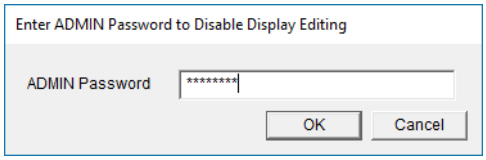


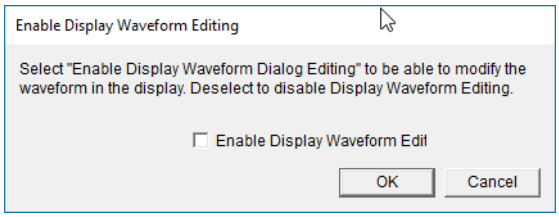
Figure 8.5: Display Channel Properties window

Label	On-screen name of a waveform.
Signal	Name of the collected signal used as input for the waveform.
Position	Percentage location of the midpoint of the waveform where 0% is the top of the display and 100% is the bottom of the display.
Height	The percentage height the waveform occupies on the display.
Upper/ Lower	Upper and lower range of the waveform expressed as units.
Invert	Upper and lower values are switched to invert the waveform on the display.
Digital	Digital values are placed periodically on the display. The display interval is dependent upon the the display width.
HFF	Digital low-pass filter; i.e., the high frequency filter, screens out amplitudes above the filter setting.
LFF	Digital hi-pass filter; i.e., the low frequency filter, screens out amplitudes below the filter setting.
Notch	60 Hz or 50 Hz band stop filter.
Scale	Permits the proportional adjustment of the upper and lower limits of the waveform to improve its appearance.
Grid	Places dashed grid lines on the display at the specified interval. If the interval is set to zero, only an upper and lower grid is drawn on the display.

To Disable Waveform Editing

1. Select Tools>Disable Display Editing and enter the ADMIN password when prompted.
2. Click the checkbox beside Enable Display Waveform Edit to disable the waveform editing function and click OK.
3. Click anywhere on the screen and the highlighted edit display bar on the display will disappear.





Reset to Default Display

After making changes to the displayed waveforms, you can quickly return to the default display. You can only use this feature when the highlighted edit display bar is off.

To reset the display

1. Click Tools>Reset to Default Display and the display will return to the factory default setting.

Cleaning the MediByte

Sterilization of the MediByte is NOT required. Do NOT steam autoclave the MediByte or damage will occur and void the warranty.

Do NOT immerse the MediByte in any liquids because damage will result. Water damage will void the warranty.

The MediByte is a non-sterile device that does not contact the patient.

Recommended:

- Disinfection wipes, such as Sono® Wipes[1] or Sani-Cloth® Wipes[2], which use quaternary ammonium (dimethyl ammonium chloride).
- Isopropyl alcohol.
- Damp cloth.

To clean the MediByte:

1. Gently wipe the MediByte with a disinfection wipe, isopropyl alcohol wipe or a damp cloth.
2. Ensure the MediByte is completely dry before using.

For additional information, refer to the Association for Professionals in Infection Control and Epidemiology (APIC) guidelines for selection and use of disinfectants (American Journal of Infection Control. Vol. 18, No. 2, April 1990).

To clean the Electrode Box and Communication Cable:

1. Gently wipe the Electrode Box and Communication Cable with a disinfection wipe, isopropyl alcohol wipe or a damp cloth.
2. Ensure the Electrode Box and communication cable are completely dry before using.

1. Registered trademark of Sono.
2. Registered trademark of PDI.

Maintaining the MediByte and Accessories

Unauthorized opening of the MediByte will void both the safety of the MediByte and the terms and conditions of the MediByte warranty.

Do NOT use or attempt to service damaged parts.

- The MediByte does not require any maintenance.
- The MediByte does not require calibration.

The MediByte is only repairable by BRAEBON– trained personnel. The opening of the MediByte by unauthorized individuals will void both the safety of the MediByte and the terms and conditions of the MediByte warranty.

If your MediByte or any of its accessories are damaged, please contact BRAEBON immediately at 1.888.462.4841.

Battery Disposal

Please dispose of used batteries responsibly. To locate a battery disposal sight near you, go to www.ehso.com.

Troubleshooting

If you have difficulty using this product, please verify the following:

Problem	Solution
No communication between the computer and the MediByte	• Ensure the battery is in the MediByte. • Change the battery. • Check that the MediByte USB cable is plugged into both the MediByte and the computer. • Restart the computer, and after it's started, plug the USB cable into an available USB port and *then* plug the other end of the cable into the MediByte. • Reinstall the MediByte Software.
Poor signals	• Check that all the sensors and electrodes were connected properly to the MediByte and that all sensors were correctly applied to the patient. Since the MediByte does not show real-time data collection, you cannot check sensor placement while the patient is connected to the unit. You must ensure that the patient understands correct placement of sensors before he or she leaves your site.
MediByte stops collecting data prematurely	• The memory is full, retrieve data from the MediByte and then re-program the unit. • Replace the standard 1/2 AA lithium battery.
Cannot retrieve data from MediByte	• Verify the communication between the computer and the MediByte. See "No communication between the computer and the MediByte," above.
MediByte was submerged in liquid	• Contact BRAEBON Medical Corporation at 1.888.462.4841 or 1.888.462.4844. Please have the product model and serial number available when you call.

If you still experience trouble with the product, contact technical support by **telephone at 1.888.462.4841** or by email at **support@braebon.com**. Visit our website for solutions to Frequently Asked Questions (FAQs): **www.braebon.com**.

Warranty

BRAEBON MEDICAL CORPORATION warrants to the first consumer that this MediByte, when shipped in its original container, will be free from defective workmanship, performance and materials and agrees that it will, at its option, either repair the defect or replace the defective MediByte or part thereof at no charge to the purchaser for parts or labor for a time period of one year from the date of purchase. The warranty described herein shall be the sole and exclusive warranty granted by BRAEBON MEDICAL CORPORATION and shall be the sole and exclusive remedy available to the purchaser. Use of the MediByte constitutes total and complete acceptance of this warranty. Correction of defects, in the manner and for the time period described herein, shall constitute complete fulfillment of all liabilities and responsibilities of BRAEBON MEDICAL CORPORATION to the purchaser with respect to the MediByte and shall constitute full satisfaction of all claims, whether based on contract, negligence, strict liability or otherwise. In no event shall BRAEBON MEDICAL CORPORATION be liable, or in any way responsible, for any loss of revenues or damage, direct, incidental, or consequential, including property damage, loss of profit, or personal injury resulting from the use or misuse of, or the inability to use this product. Nor shall BRAEBON MEDICAL CORPORATION be liable, or in any way responsible, for any damages or defects in the MediByte which were caused by abuse, misuse, tampering, neglect, incorrect battery type, or repairs or attempted repairs performed by anyone other than an authorized service person. This warranty covers the MediByte Model MP-8 and MBJR only. Accessories and consumables have separate warranties with different coverage periods.

Warning: Unauthorized opening of the MediByte will void both the safety of the MediByte and the terms and conditions of the MediByte warranty.

Caution: Failure to use the correct battery type as stated in this User Manual will void the warranty.

Specifications subject to change without notice.

Chapter 9: File Transfer and Remote Scoring

If you are interested in sending or moving files for remote scoring, BRAEBON offers a scoring service using Board Certified Sleep Technologists.

Please contact BRAEBON at **1.888.462.4841 x218** for more details.

Glossary

A

Abdominal effort port. Located on the bottom of the MediByte,® the abdominal effort port attaches the abdominal effort belt to the recorder.

AHI (Apnea + Hypopnea Index). The total number of apnea and hypopneas per hour during a test.

Apnea. Cessation of breathing for at least ten seconds.

Asystole. An absence of electromechanical activity within the heart.

Atrial Fibrillation. Rapid, uncoordinated firing of electrical impulses from multiple sites in the upper chambers, which causes ineffective contractions.

Auxiliary port. Located on the top of the MediByte, the auxiliary port accepts either the Snore microphone, or either Electrode Box for the EKG or EMG electrodes.

B

Body Mass Index (BMI). A measure of weight relative to height. A body mass index over 25 is considered overweight, over 30 is considered obese.

Body position. In the software, five sleep positions are identified: left, prone, right, supine and standing. The amount of time spent sleeping in each position and the occurrence of respiratory events in a particular position are tabulated.

Bradycardia. A slow heart rate (less than 60 beats per minute).

Bruxism. Grinding of the teeth during sleep.

C

Central apnea. A breathing disorder characterized by brief interruptions of breathing during sleep. Central apnea occurs when the brain fails to send the appropriate signals to the breathing muscles to initiate respiration; hence, central sleep apnea is characterized by a lack or respiratory effort. Central sleep apnea is less common than obstructive sleep apnea.

Chest effort port. Located on the bottom of the MediByte,® the chest effort port attaches the RIP Belt for MediByte to the recorder.

Cheyne-Stokes Breathing. An abnormal pattern of breathing characterized by a gradual increase in depth and sometimes in rate to a maximum depth, followed by a decrease resulting in apnea.

Communication port. Located on the bottom of the MediByte,® the communication port accepts the BRAEBON communication cable. Use this port to attach the recorder to the

computer to program the recorder and to download data from the recorder.

D

Desaturation. Less than normal amount of oxygen carried by hemoglobin in the blood. A value below 90% is considered abnormal.

E

EKG. Electrocardiogram, a graphical recording of the cardiac cycle

Electrodes. Small devices that transmit brain waves or other biological electrical signals from a patient to a recorder, where the signal is amplified and displayed.

EMG. Electromyogram, a graphical record of electric currents associated with muscle contractions.

Epoch. A standard 30-second page of a sleep recording.

EULA. End user licence agreement.

Event button. The event button, located on the front of the MediByte,® permits the patient to record an event by depressing the button.

F

Flow limitation. A flattening or plateau on the inspiratory waveform. This flattening indicates increased resistance of airflow through the upper airway and is often associated with snoring and upper airway resistance syndrome (UARS).

H

Histogram. A graphical display of tabulated frequencies. In the MediByte software, the histogram displays the selected channels and scored events in the study.

Hypopnea. A reduction of >30% amplitude in airflow followed by an SpO_2 desaturation of 4% OR a reduction of >50% amplitude in airflow followed by an SpO_2 desaturation of 3%.

M

Mixed apnea. A breathing disorder characterized by brief interruptions of breathing during sleep. Mixed sleep apnea consists of both central and obstructive sleep apnea.

O

Obstructive apnea. A breathing disorder characterized by brief interruptions of breathing during sleep. In obstructive apnea, the muscles of the soft palate around the base of the tongue and the uvula relax, obstructing the airway. Obstructive sleep apnea is characterized by the presence of respiratory effort.

Obstructive hypopnea. An episode of diminished breathing during sleep, caused by a partial airway obstruction, usually accompanied by oxygen desaturation.

Oximeter. A medical device used to provide estimates of arterial oxygen saturation by using selected wavelengths of light to determine the saturation of oxyhemoglobin (SpO_2).

Oxygen saturation. A measure of oxygen carried by hemoglobin in the blood. Normal values range from 90% to 100%. An important indicator of sleep disordered breathing that is directly affected by the degree of throat closure and its duration.

P

PLM. Periodic Limb Movement Disorder. Characterized by periodic episodes of repetitive limb movements during sleep. The movements are often associated with a partial arousal or awakening; however, the patient is usually unaware of the limb movements or frequent sleep disruption.

Pressure port. Located on the top of the MediByte,® the pressure port accepts the oral/ nasal cannula.

Premature arterial contractions. Extra heartbeats originating from the atrial chambers.

Premature ventricular contractions. Extra heartbeats originating from the ventricles. PVCs interrupt the normal heart rhythm and cause an irregular beat. This is often felt as a *missed beat* or a *flip-flop* in the chest.

R

RDI (Respiratory Disturbance Index. An index used to assess the severity of sleep apnea based on the total number of complete cessations (apnea) and partial obstructions (hypopnea) of breathing occurring per hour of sleep. These pauses in breathing must last for ten seconds and are associated with a decrease in oxygen saturation of the blood.

RERA (Respiratory Effort Related Arousal). Breaths lasting at least 10 seconds in length characterized by increasing respiratory effort or flattening of the nasal cannula pressure leading to an arousal from sleep when the sequence of breaths does not meet the criteria for either an apnea or an hypopnea. A RERA is a milder form of sleep disordered breathing than either apnea or hypopnea.

S

Scale. Scaling the display improves the appearance of the waveforms, but does not change the data. Scaling takes the maximum and minimum values of the waveforms and adjusts the upper and lower limits of the waveforms proportionally.

Scoring tags. In the MediByte software, respiratory, PLM and snoring events markers are colored bars with scoring event

abbreviations in the top right corners of the display.

Sinus tachycardia. A fast rhythm (more than 100 beats per minute) originating at the sinus node.

Snoring. Sounds made during sleep caused by breathing vibrations in the pharynx. In the diagnosis of obstructive sleep apnea, snoring volume and frequency of occurrence often correlate with the severity of the condition.

SpO_2 port. Located on the top of the MediByte,® the SpO_2 port attaches the SpO_2 sensor to the recorder.

U

User event. A note placed in the data to mark a significant event, such as lights on, lights off, bathroom break.

V

Ventricular Fibrillation. Uncoordinated contraction of the cardiac muscle of the ventricles in the heart, making them quiver rather than contract properly. Ventricular fibrillation is the most commonly identified arrhythmia in cardiac arrest patients

W

Waist-to-hip ratio (WHR). A calculation comparing waist circumference to hip circumference; a simple measure of where fat is stored in your body. Most people store their body fat in two places: around their waist and around their hips. Storing extra weight around your waist (apple shaped) puts a person at a higher health risk than someone carrying extra weight around their hips and thighs (pear shaped). According to a study published in The Lancet, WHR is a better predictor of heart attack risk than BMI.*

Table 1-1: Waist to Hip Ratio (WHR) Chart

Male	Female	Health Risk Based Solely on WHR
≤ 0.95	≤ 0.80	Low risk
0.96 - 1.0	0.81 - 0.85	Moderate Risk
≥ 1.0	≥ 0.85	High Risk

*Lancet, 2005 November; 366 (9497) 1640-9 *Obesity and the risk of myocardial infarction on 27,000 participants from 52 countries: a case-control study.* Yusuf, Hawken et al.

Index

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BRAEBON Medical
1-100 Schneider Road
Kanata, Ontario,
Canada, K2K 1Y2

Customer Sales, Technical Support: 1-888-462-4841 (9 am - 5 pm ET)

• E–mail:support@braebon.com

www.braebon.com

EU Notice: Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

EC REP

CEpartner4U BV
Esdoornlaan 13
3951 DB Mearn
The Netherlands
www.cepartner4u.eu

CE 0413

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