sonarMED

airWAVE
Airway Monitoring System

Setup and Maintenance Manual

June2013 Edition

The foundation of airway management has just changed…
at the speed of sound.

This Set-up and Maintenance Manual is an addendum to the Operator's Manual supplied with the Airwave system and focuses on technical aspects of the system. For information regarding the use of the AirWave in a clinical setting, refer to the Operator's Manual.

WARNING: The instructions in this addendum will allow the user to change the default settings of the Airwave Monitor.

Because improvements to this manual and the products it describes will occur, please check that you are using the most current version of this document by visiting www.sonarmed.com.

SP0621_D

Table of Contents

A. System Description

The SonarMed AirWave acoustic airway monitoring system consists of an AirWave Monitor (Monitor) which is used in conjunction with a single-use AirWave Adapter and cable (Sensor).

The Monitor contains signal-generating and echo-processing circuitry that uses proprietary software to monitor the position and patency of an endotracheal tube (ETT) via the AirWave Sensor. The Monitor is powered from an external power supply and has a battery backup that will allow the device to function for approximately 120 minutes without external power. The Monitor has a color display which is used to present information about the ETT status. This information can be used in an adjunctive manner to assist with management of the patient's artificial airway.

The Sensor replaces the standard 15-mm connector (also known as the "hub") that typically comes with each ETT.

AirWave Monitor

**AirWave Sensor
and Cable**

B. Warnings and Precautions

♦ **The SonarMed AirWave (Monitor and Sensor) is not to be used as a diagnostic tool; it is to be used as an adjunct to airway management only.**

♦ **The SonarMed AirWave is to be used by properly trained personnel only.**

♦ **Do not use an AirWave Sensor if its pouch is open or damaged.**

♦ **Only the SonarMed AC/DC power supply may be used with the SonarMed Monitor. Use of another power supply may put the patient at risk of an electrical hazard.**

♦ **When the Alarm Silence button is pressed, the Monitor speaker is disabled for two (2) minutes even if a new alarm should occur during that period. Pressing the Alarm Silence button a second time does not reactivate the speaker.**

♦ **Some AirWave alarms may be manually disabled by the user. The Monitor will display the message "An Alarm is Off" when this is the case. All alarms that have been disabled are reactivated to their previous settings if the Monitor is powered off and back on.**

♦ **Only connect the Firmware Upgrade Cable to the Monitor when the AirWave system is not connected to a patient.**

♦ **Calibration of the AirWave Sensor must be performed on a clean, unintubated ETT. Failure to do so may cause the AirWave to provide erroneous results.**

♦ **Do not use abrasive cleaning products on the Monitor as this will damage the clear screen cover and degrade visibility of system information.**

♦ **This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and voids the warranty.**

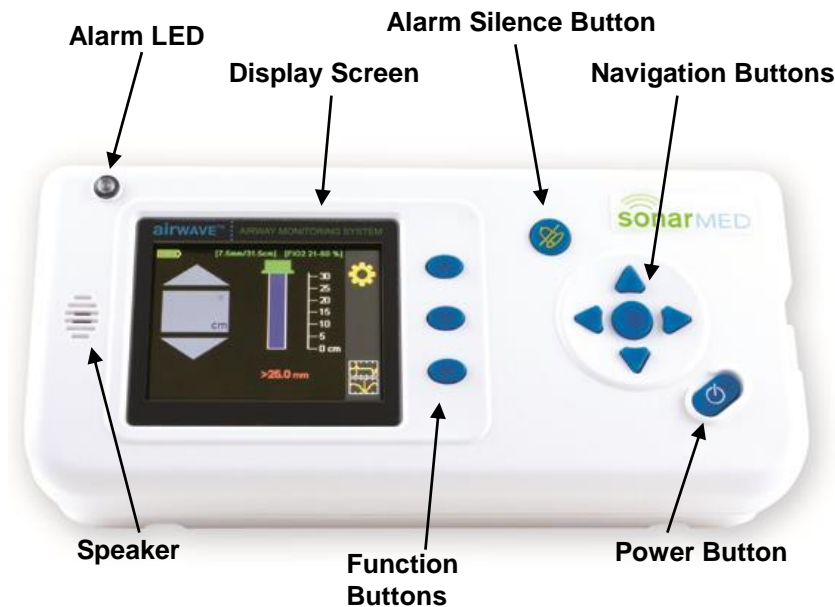## C. Airwave Monitor Package Contents

(1) AirWave Monitor

(1) Carrying strap

(1) AC/DC Power Supply

(1) Hospital Grade Power Cord

(1) Firmware Upgrade Cable (RS232 Connection)

(1) USB-to-RS232 Converter Cable

(1) Software and Documentation CD

D. Displays, Indicators, and Controls

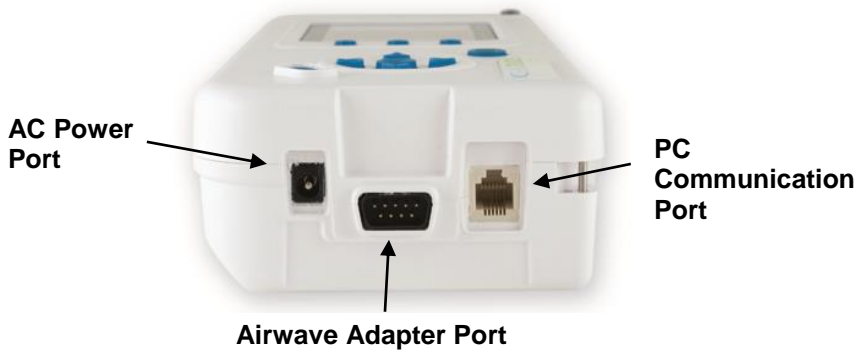This section describes the displays, indicators, and controls for the SonarMed AirWave Monitor.

1. AirWave Monitor Controls – Front Panel

Control	Description
Alarm LED	This LED flashes red when and alarm condition is present. The LED flashes even if the audible alarms are silenced
Display Screen	The display screen of the AirWave Monitor is a color LCD.
Alarm Silence Button	This button is used to temporarily silence audible alarms. Once pressed, the Monitor silences alarm sounds for two minutes (including if a new alarm is triggered during that time). If an alarm condition still exists after two minutes, the audible signal resumes. **Note:** Pressing the Alarm Silence button a second time DOES NOT reactivate audible alarms.
Navigation Buttons	The navigation arrows are used to move between user-selectable options on the screen and to change user-editable values and parameters. The center button (also referred to as the **Enter** button) selects and locks in changes.
Speaker	The speaker plays audible alarm tones when an alarm condition exists. The speaker is also used to play the real-time signals sensed by the AirWave Sensor microphones.
Function Buttons	The function buttons provide specific contextual functionality as indicated by the currently display screen icons. Icons appear to the left of these buttons to indicate their current function.
Power Button	Pressing the power button once turns on the AirWave Monitor. Pressing and holding the power button for one (1) second turns the AirWave Monitor off, discontinuing all monitoring functions. After turning the Monitor off, if the Monitor is plugged into AC power and the battery is not fully charged, the Monitor screen powers back on with a message that the battery is

Control	Description
	charging. The monitor can be turned off completely by pressing the power button one more time.

2. *Airwave Connections – Right Side*

AC Power Port

PC Communication Port

Airwave Adapter Port

Port	Description
AC Power Port	This connector accepts the SonarMed AC/DC power supply.
	Only the SonarMed AC/DC power supply may be used with the SonarMed Monitor. Use of another power supply may put the patient at risk of an electrical hazard.
	Note: To begin charging the battery, the Monitor must be connected to the AC power source, and the Monitor must be turned on. Plugging in the AC power source to a Monitor that is turned off **will not** charge the battery.
AirWave Sensor Port	This connector accepts the SonarMed AirWave Sensor.
	Only connect the SonarMed AirWave Sensor to this port. The system will not function if another adapter is connected.
PC Communication Port	This connector accepts the Firmware Upgrade Cable supplied with the SonarMed AirWave Monitor which is used to upgrade system firmware.
	Only connect the Firmware Upgrade Cable to the Monitor when the AirWave system is not connected to a patient.
	Only use the Firmware Upgrade Cable supplied by SonarMed.

3. *AirWave Monitor Screens*

System Start-up Screens

These screens appear when the unit is first powered on. If no AirWave Sensor is connected to the Monitor, the system prompts to connect one. Once a Sensor is connected, the user is guided through the calibration process to the **Patient Monitoring Screen**.

Patient Monitoring Screen ("Home" screen)

This is the primary monitoring screen for the AirWave Monitor. It provides icon-graphical and numerical representation of the status of the ETT including indicators for ETT tip movement, passageway size, and tube obstruction.

Waveform Screen

This screen provides an alternative visual representation of the information displayed on the **Patient Monitoring Screen** in the form of the acoustic waveforms being analyzed by the AirWave.

System Set-Up Screens

These screens, accessed through the **Main Menu**, provide the interface for editing system parameters. These parameters include alarm limits for ETT tip movement, passageway size, and obstruction, a patient identification number, an ETT length setting, and sound speed correction settings.

4. *AirWave Monitor Indicators and Icons*

Indicators (if applicable) are presented on all screens. Icons appear next to the function keys to provide specific functionality depending on the current screen or action being performed.

Indicator/ Symbol	Description
	Battery Indicator – located in the upper left corner of the screen; the number of bars indicates charge level, and the bars blink during charging.
	External Power Indicator – when this symbol is present near the upper left corner of the screen, the AirWave monitor is plugged into AC power
	Alarm Silence Indicator – when this symbol is present near the upper left corner of the screen, the alarms on the AirWave Monitor have been muted using the Alarm Silence button. The symbol begins to flash ten seconds prior to the alarms becoming unmuted.
UNCALIBRATED	**Uncalibrated Indicator** – located in the upper center of the screen, this indicates that a connected Sensor-ETT pair has not yet been calibrated for use with this Monitor.
[7.5mm/31.7cm]	**Calibrated Indicator** – located in the upper center of the screen, this indicator appears once a connected Sensor-ETT pair has been calibrated for use with the Monitor. The left value is the ID of the ETT, the right value is the calibrated length of the ETT.
[FiO2 21-60 %]	**Sound Speed Correction Indicator** – located in the upper right corner of the screen, this indicator shows the current user defined setting that the AirWave is using to compensate for changes in the speed of sound caused by high oxygen concentrations (FiO_2) or the presence of anesthesia gases.
	LCD Brightness Symbol
	Time/Date Symbol

Button Icon	System Action When Pressed
	[Accept Changes] / [Yes] Icon

Button Icon	System Action When Pressed
X	**[Cancel Changes] / [No] Icon**
	Screen Pixel Test Icon – when pressed, sets all LCD pixels to white to allow examination for dead pixels
	Main Menu Icon – enters the **Main Menu** to make changes to user-defined parameters
	Previous Screen Icon – returns to the last screen that was displayed
	Next Screen Icon – moves to the next screen in a sequence
	Return to Defaults Icon – resets the Monitor's alarm settings to the default values (default values are selected during initial Monitor set-up, typically by the hospital's Biomedical Engineering Department).
	System Memory Erase Icon – erases any data stored in system memory as a result of data logging activity

5. General Symbols

Symbol	Definition
	WARNING – Refer to this user manual for specific warnings and precautions.
	Prohibited – Refer to the **Contraindications** Section of this manual for a complete list of system limitations
	Single Use Only – the SonarMed AirWave Sensor may not be reused due to risk of infection and/or cross-contamination
	The SonarMed Sensor is a defibrillation-proof type BF applied part
	"Use By" date in the format: YYYY-MM
	Manufacturer symbol

6. *Basic Navigation and Editing*

a. Navigation from screen to screen of the AirWave Monitor occurs in one of two ways:
   ♦ Using the **Function Buttons** – These buttons provide specific contextual functionality for the current screen and as indicated by the icons displayed to the left of the buttons.
   ♦ Selecting from a list – On the **Main Menu Screen**, item are selected from a list by using the **Navigation Arrows** and pressing the **Enter** button to enter that screen.

b. Certain screens of the AirWave Monitor contain fields that can be edited.
   ♦ Navigation between these fields occurs by using the navigation arrows. The active field is designated by a yellow highlight:

   ♦ To edit the field, press the **Enter** button, which turns the highlight from yellow to white:

   ♦ Modify the field value by using the up and down navigation arrows. In some cases, individual digits of a value are modified separately and the left and right arrows navigate between the digits.
   ♦ To lock in the new value, press the **Enter** button again. This turns the highlight back to yellow. At this point, the navigation arrows move the focus to different fields to make changes.
   ♦ When exiting the screen (usually by using the **Return Arrow** function button), the system prompts to accept or cancel any changes.

Selecting the green checkmark confirms all modifications made on the screen; the Monitor also plays a confirmatory tone. Selecting the red X returns all values on the screen to their previous values.

E. System Set-up

This section describes how to access and modify the AirWave Monitor system settings (screen brightness, date/time, default alarm thresholds, alarm tone, and patient data requirements).

1. Powering On the AirWave Monitor

    a.   Press the power button to turn on the Monitor.

    b.   The Monitor emits an audible tone to test its sound circuitry. The alarm LED flashes red once.

    c.   If any errors are detected during start-up diagnostics, refer to **Section H – Troubleshooting**.

2. Modifying System Settings

    a.   Access the **Main Menu** by pressing the top function key as shown below.
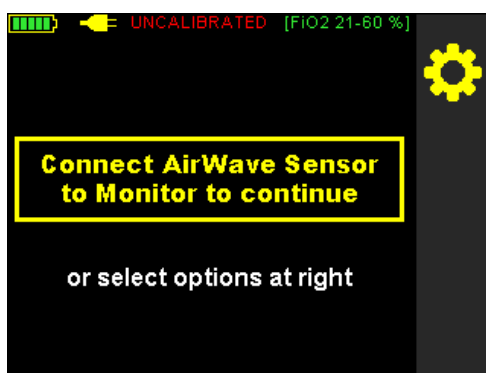
    b.   From the **Main Menu** select **System Settings** as shown below to advance to the **Password Screen**. Note that the options displayed in the **Main Menu** may differ from those shown depending on the selected settings and whether a Sensor is present or not.

    c.   In the **Password Screen**, enter the password using the **Navigation Arrows** in the following order: left – up – right.
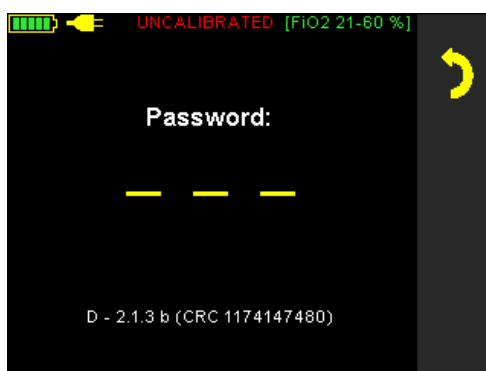
d. In the **System Setting Screen** shown below, the following settings can be modified:
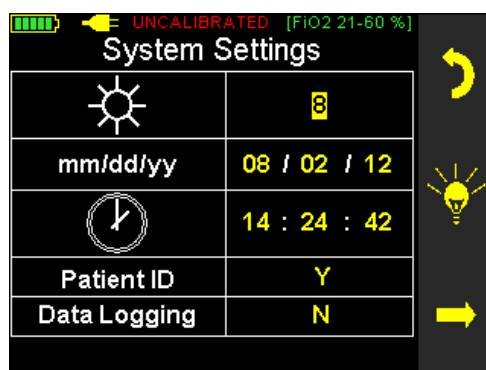
- ♦ Screen Brightness: 1 (low) to 10 (high)

- ♦ Date: MM/DD/YY format

- ♦ Time: 24-hour time format (12:00-11:59 PM represented as 12:00 -23:59).

- ♦ Patient ID: Enables access from **Main Menu** to **Patient Info Screen**. If this option is enabled (set to "Y"), then all data collected within the Monitor are stamped with a patient identification number which is accessible from the **Patient Info Screen**.

- ♦ Data Logging: Enables access from **Main Menu** to the **Data Logging Screen**. If this option is enabled (set to "Y"), the monitor can be set up for various data collection operations to facilitate troubleshooting (see **Section H – Troubleshooting** for details).

e. When modifications are complete, return to the **Main Menu** by pressing the **Previous Screen Icon** or advance to the **Default Alarm Settings Screen** by pressing the **Next Screen Icon**. If changes were made, the system prompts to confirm or cancel the changes before moving to the next screen.

f. In the **Default Alarm Settings Screen** shown below, the default alarm values can be modified as follows:

- ♦ ETT Tip Movement: High and low thresholds may be set separately in increments of 0.1 cm

- ♦ Passageway Diameter: High and low thresholds may be set separately in increments of 5%

- ♦ ETT Obstruction: This threshold may be set in increments of 5%

- ♦ Main Alarm Tone: To provide a distinct alarm tone that will differentiate the AirWave alarm from nearby alarms, the alarm tone is selectable from four sequences (A through D). While editing this field, pressing the up/down arrow buttons plays each alarm tone.

Note that these are the <u>default</u> alarm settings to which the system will revert if the user presses the **Restore Defaults** button in the **Alarm Settings Screen**.

g. When modifications are complete, return to the **System Setting Screen** by pressing the **Previous Screen Icon** or advance to the **Main Menu** by pressing the **Next Screen Icon**. If changes were made, the system prompts to confirm or cancel the changes before moving to the next screen.

3. *Powering Off the Monitor*

a. Press and hold the power button for at least one second.

b. The Monitor displays "Power Down In Progress" for one second and then the screen goes black.

c. If the internal battery is not fully charged and the AC/DC Power Supply is still connected, then the Monitor screen powers back on into the battery charging mode. For new units, it is recommended to fully charge the battery before placing the device into service.
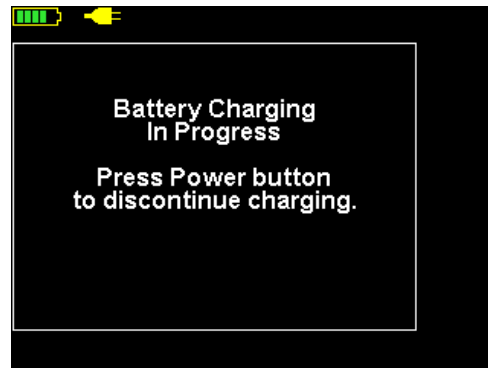
d. Pressing the power button while in battery charging mode stops charging and powers down the Monitor.

e. While in battery charging mode, the Monitor automatically powers down when either the internal battery is fully charged or the AC/DC Power Supply is disconnected.

Note: To charge the battery, the Monitor must be connected to the AC/DC Power Supply, and the Monitor must be turned on either in normal mode or battery charging mode. Connecting the AC/DC Power Supply to a Monitor that is turned off **will not** charge the battery.

F. Updating Monitor Firmware

In an effort to continually improve the performance of the AirWave system and provide new system features, SonarMed will periodically release new versions of the Monitor firmware. This section provides instructions for upgrading the Monitor firmware.

Note: The Monitor firmware version and its unique CRC number is displayed at the bottom of the **Password Screen** when **System Settings** is selected in the **Main Menu**.
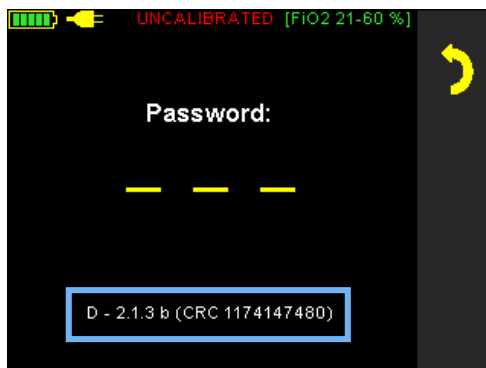
1. Necessary items

a. Firmware Update Cable (DB-9 to RJ-11).

b. USB-to-RS232 Converter Cable (connected to Firmware Update Cable).

   Note: If necessary, refer to the **Parts and Accessories** section of this manual for ordering information.

c. Software and Documentation CD.

d. Firmware Image File **X.ldr** (e.g. **M_1.2.1_CRC149712653.ldr**).

2. Windows Software Installation

a. Insert the Software and Documentation CD into PC drive.

b. Open the **Firmware Updater** folder, and execute **setup.exe** to install software on the PC.

c. After installation is complete, if the drivers for the USB-to-RS232 Adapter haven't previously been installed then install them by going to **Start►All Programs►SonarMed►USB-RS232 Drivers** and selecting the appropriate installation file (WIN98/XP/2000 or Vista/Win7).

d. Allow driver to install.

e. Connect the USB-to-RS232 Converter Cable to PC and allow driver to finish installing.

f. Connect Firmware Update Cable to USB-to-RS232 Converter Cable if not already done.

3. Firmware Upgrade

a. Connect RJ-11 side of Firmware Update Cable to the Airwave Monitor. This is the connector that looks like a telephone jack.

b. To place Monitor in firmware update mode, start with Monitor turned off and hold down speaker mute button while pressing power button. The alarm LED rapidly blinks yellow and the LCD remains off. If this does not occur, power down the Monitor and retry.

c. It is ok to run the Monitor off battery power while updating the firmware. Even if the Monitor loses power while updating, the previous firmware version will remain intact.

d. Run **Start► All Programs►SonarMed► AirwaveFirmwareUpdater** on PC.

e. Select the **Upload Firmware** button.

f.   Select the firmware image **X.ldr** and select **Open**.

g.   The status window and progress bar shows programming progress. Programming is complete when the Monitor reboots and executes the new firmware image. If the cable accidently becomes disconnected during programming, power down the Monitor by holding down the power button, quit the **AirwaveFirmwareUpdater** program, and repeat from step b.

h.   Go to the **System Setting Password Screen** on the Monitor to verify that the system has been updated to the correct firmware version. The version number and CRC should match the firmware image filename.

G. <u>Cleaning, Maintenance and Disposal</u>

The Monitor enclosure and AC/DC power supply may be cleaned by lightly rubbing their surfaces with a standard hospital cleaning wipe or a soft cloth dampened with 70% isopropyl alcohol, and then allowed to dry. The Monitor enclosure should be cleaned per the above method between each use from one patient to the next. Do not use any other cleaning solutions as they may degrade the plastic.

WARNING: Do not use abrasive cleaning products as this will damage the clear screen cover and degrade visibility of system information.

The Monitor contains two batteries: one lithium ion rechargeable battery pack and one coin cell battery used to power the internal clock. These batteries are not user replaceable; contact SonarMed for service. The Monitor must be disposed of in accordance with facility standards and local laws.

The Sensor is labeled for single use only. Dispose of the Sensor after use following hospital biohazard policies and local regulations.

There are no user serviceable parts in the Monitor. Repairs must be made by SonarMed authorized personnel only.

H. Troubleshooting

1. Error Messages

When the AirWave system experiences a failure, it displays informational/error messages to assist the user in pinpointing the cause of the problem and determining how to resolve it. The table below lists possible system failures modes, the associated system message (if applicable), if the failure is associated with an audible alarm, and the recommended user action. If the user action doesn't remedy the problem, please contact SonarMed technical support for assistance.

System Message	Alarm	Description	User Action
Calibration/Monitoring Messages and Alarms			
Unable to Calibrate		The AirWave cannot obtain a proper calibration signal.	Follow the on-screen prompts to correct the condition causing the failure. If failure persists, replace the AirWave Sensor.
ETT Too Low	1	The ETT tip has migrated low in the trachea beyond the "ETT Movement – Low" alarm threshold.	Verify condition using alternate airway management techniques; error will clear when condition is corrected.
ETT Too High	1	The ETT tip has migrated high in the trachea beyond the "ETT Movement – High" alarm threshold.	Verify condition using alternate airway management techniques; error will clear when condition is corrected.
Obstruction Detected	1	An obstruction in the ETT has exceeded the "ETT Obstruction – High" alarm threshold	Verify condition using alternate airway management techniques; error will clear when condition is corrected.
Small Passageway (Prior to setting baseline)	2	The ETT is in a passageway smaller than the ETT ID. This alarm is intended for use during intubation to provide feedback if the ETT tip is placed in a small passageway such as the esophagus.	Verify condition using alternate airway management techniques; error will clear when condition is corrected.
Small Passageway (After setting baseline)	1	The ETT is in a passage smaller than the "Passageway Size – Low" alarm threshold.	Verify condition using alternate airway management techniques; error will clear when condition is corrected.
Large Passageway	1	The ETT is in a passage larger than the "Passageway Size – High" alarm threshold	Verify condition using alternate airway management techniques; error will clear when condition is corrected.
Analyzing…		This message displays routinely as the Monitor is waiting to receive a clean microphone signal (i.e. between breaths)	None required
An Alarm is Off		At least one of the AirWave monitoring alarms is disabled.	Re-enable the alarms in the **Alarm Settings Screen** or cycle the Monitor power.
Sensor Cable Disconnect	3	AirWave Sensor cable is disconnected from Monitor during patient monitoring.	Reconnect Sensor cable to Monitor.
ETT Disconnected		The ETT is disconnected from the AirWave Sensor.	Reconnect the ETT.
Excessive Noise		Excessive noise detected in microphone signals which is preventing collection of data. It is normal for this message to be displayed occasionally. If it occurs continuously for more than one minute then the Monitor is unable to collect data. This is most likely due to excessive ventilator noise, high ventilation rates, or excessive secretions in the airway. Refer to **Section F.10** of the *AirWave Operator's Manual* for more information.	To determine the noise source, listen to the microphone signals via the **Monitor AirWave Microphones** option in the **Main Menu Screen** (see **Section F.3.c** of the *AirWave Operator's Manual*). If the source is identified, attempt to reduce the noise level from the source. If this is not feasible, then monitoring on this patient may not be possible.
Poor Signal Quality		The airway echo amplitude is insufficient for accurate tracking. It is normal for this error to occur occasionally for a few seconds. **WARNING! While this error is present, the ETT movement indicator may provide inaccurate readings.**	It is possible that a small percentage of patients may exhibit an airway echo of inadequate amplitude that the system may have difficulty tracking accurately. In these patients, it may be necessary to turn off the ETT position tracking alarm.
Microphone Monitor On		The system is playing the microphone signals directly over the Monitor speaker. Patient monitoring is disabled while this message is on.	Exit **Monitor AirWave Microphones Screen**.

System Message	Alarm	Description	User Action
Power and Battery Failures			
N/A		Monitor does not power on.	Connect Monitor to AC/DC power supply and press on button. If Monitor powers on, leave connected until battery is fully charged. If Monitor doesn't power on, contact SonarMed technical support
N/A		Battery takes longer than 4 hours to charge.	Contact SonarMed technical support.
Battery Failure	3	Battery exceeded normal temperature or voltage during charging, or it exceeded the time during which it should have fully charged.	Power down Monitor and contact SonarMed for service.
Charge Battery		System is running on battery and 20% or less charge is remaining.	Connect Monitor to AC/DC power supply to recharge internal battery. The Monitor can remain connected to a SonarMed Sensor and collect data during battery charge.
Low Battery	2	System is running on battery and 15% or less charge is remaining. System will automatically shutdown in 60 seconds.	Connect Monitor to AC/DC power supply to recharge internal battery. The Monitor can remain connected to a SonarMed Sensor and collect data during battery charge.
AirWave Sensor Failures			
Heater Failure	3	Heater circuit inside AirWave Sensor is not operating properly.	Cycle Monitor power. If error reoccurs try replacing AirWave Sensor. Report error to SonarMed if it persists.
Sx/Change Sensor	3	AirWave microphone(s) and/or speaker are not operating correctly due to electrical malfunction or mucus/water deposition over protective microphone or speaker membranes. It is normal for this error to occur occasionally for a few seconds.	If error persists, suction protective membranes inside AirWave Sensor lumen to remove mucus. If this does not clear the error then replace AirWave Sensor.
System Failures			
N/A		AirWave Sensor is not automatically detected when connected to the Monitor.	Contact SonarMed technical support.
System Error	3	Internal circuit or software error.	Power cycle Monitor and contact SonarMed for service if error persists.
Button Stuck		One or more buttons on the keypad are stuck in the pressed position.	Power down Monitor and contact SonarMed for service if error persists.
Data Flash Error	3	Internal memory to which data is being stored has malfunctioned.	If this error persists, power down monitor and contact SonarMed for service.
Alarm Speaker Failure	3	Test failed during power up that verifies proper operation of alarm speaker.	Power down Monitor and contact SonarMed for service.
Entry Error		Incorrect value entered in system setup.	Retry entry using correct value.
Internal Clock Fail		Internal clock malfunction.	Power down Monitor and contact SonarMed for service.
Use Up/Down Keys to Edit		The wrong button was used to edit a parameter	Use the up and down keys only.
Invalid Date or Time		An inappropriate value was entered for one of the parts of the date or time (e.g. month = 13 or hour = 26)	Correct the entry in question.

1 – User selectable alarm sound sequence (see *AirWave System Set-up and Maintenance Manual* for details on selecting alarm type)
2 – Urgent alarm (short, high-pitched tones)
3 – User Action Required alarm

2. *AirWave Sensor Health Metric*

When the AirWave Sensor is placed in the breathing circuit, it is probable that secretions will occasionally occlude the acoustic components of the Sensor. Such occlusions can degrade the performance of the System and eventually result in erroneous feedback to the user. To avoid this, the AirWave System continually checks the quality of the acoustic signals and suspends patient monitoring if signal quality drops too much. In this situation, the System displays the error message **"Sx /Change Sensor"**.

To provide further guidance, the System also provides a troubleshooting graphic to assist in determining where within the sensor to focus the suctioning/cleaning efforts. This visual aide looks as follows:
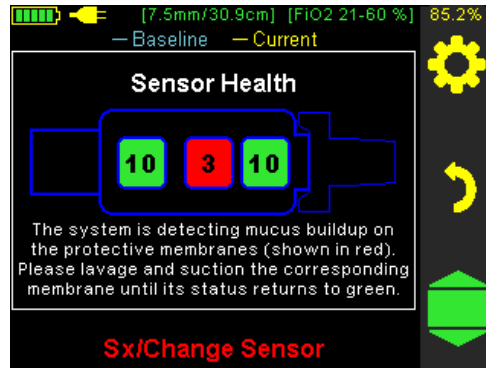
When the **"Sx/Change Sensor"** error is active, this graphic will automatically be overlaid onto the **Patient Monitoring Screen** to further alert the user to the condition of the Sensor. It will only go away after the Sensor health has returned to an acceptable level to resume monitoring. The Sensor Health graphic is also accessible at any time from the **Waveform Screen** by selecting the **Sensor Health icon** (center function button). Since the waveforms may still provide useful troubleshooting information even while monitoring is suspended, the Sensor Health graphic will not automatically appear on the Waveform Screen.

The Sensor Health graphic depicts a representation of the AirWave Sensor when seen through the lumen from below. The three boxes show locations of the speaker and the two microphones within the Sensor along with a numeric representation of the performance of each. When all three numbers are green, the Sensor is functioning within acceptable limits. When one or more of the numbers are red, the Sensor requires cleaning. Knowing which of the three components is affected allows the user to specifically target the lavage and suctioning to the correct component, which should make the cleaning process more effective. Once the affected component is clean, its number should return to green.

It is possible that cleaning/suctioning will not allow the Sensor health numbers to recover sufficiently to resume monitoring. If this is the case, it will be necessary to replace the Sensor.

3. *Data Logging*

The AirWave contains nonvolatile memory into which monitoring data can be logged at selected intervals. Data logging provides a means for SonarMed technical service personnel to remotely troubleshoot AirWave operation. If the AirWave is frequently displaying error messages or is not performing as expected, it is recommended that data logging be activated and the data be periodically downloaded from the AirWave and sent to SonarMed for analysis. The data logging feature is enabled in **System Settings** (See Section E.2).

    a. To access the **Data Logging Screen** to set the logging parameters, select **Data Logging** from the **Main Menu**.
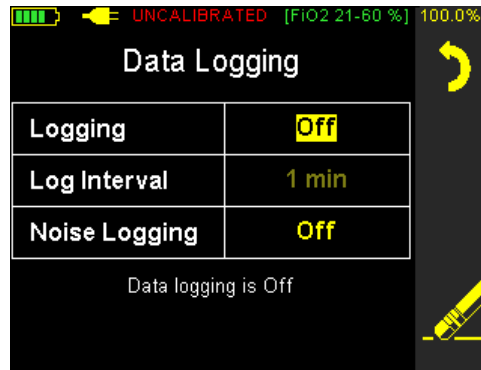
b. The **Logging** mode can be set to one of three options:

Off	No logging takes place
Periodic	The system records individual measurements at pre-set intervals
Continuous	The system records every measurement; note that memory will fill up quickly in this mode

c. If using the **Periodic** logging mode, the user can choose from a selection of time intervals ranging from 5 seconds to 3 minutes. Based on the logging period and the amount of free memory, the text below the parameter box will provide an estimate of the time remaining until the memory becomes full.

d. If the **Noise Logging** feature is turned on, the system will automatically record noise-related data (data stream) when the "Excessive Noise" message is encountered. This can assist SonarMed technical personnel in identifying the cause of the message since noise can originate from a number of sources both inside and outside the patient. Since a data stream uses a large amount of memory (~10%), only one automatic recording is taken in a 12-hour period (unless the Monitor is powered down, which resets the clock).

e. The system memory can be erased by pushing the bottom function key. The system prompts the user to confirm prior to erasing,

    WARNING! Erasing the system memory causes a permanent loss of the data. Any data stored in the system should be downloaded prior to erasing (see Section H.4 for additional details).

    Note: The amount of memory remaining is displayed in the Monitor's upper right corner while data logging is enabled. This number will be yellow if **Logging** is set to **Off** and green if it is set to **Periodic** or **Continuous**. The Monitor will alarm when the system memory is almost full. If the memory becomes full then data logging will stop.

f. Once **Data Logging** parameters are set, exit to the **Main Menu** by selecting the **Return Arrow**. The system will prompt the user to confirm changes.

4. *Downloading Data*

In order for SonarMed technical personnel to analyze logged data, the data must be downloaded from the Monitor and sent to SonarMed.

a. **Necessary Items**

    ♦ Firmware Update Cable (DB-9 to RJ-11).

    ♦ USB-to-RS232 Converter Cable (connected to Firmware Update Cable).
       Note: If necessary, refer to the **Parts and Accessories** section of this manual for ordering information.

    ♦ Software and Documentation CD.

b. Windows Software Installation

♦ Insert the Software and Documentation CD into PC drive.

♦ Open the **AirWave Downloader** folder, and execute **setup.exe** to install software on the PC.

♦ After installation is complete, if the drivers for the USB-to-RS232 Adapter haven't previously been installed then install them by going to **Start►All Programs►SonarMed►USB-RS232 Drivers** and selecting the appropriate installation file (WIN98/XP/2000 or Vista/Win7).

♦ Allow driver to install.

♦ Connect the USB-to-RS232 Converter Cable to PC and allow driver to finish installing.

♦ Connect Firmware Update Cable to USB-to-RS232 Converter Cable if not already done.

c. Data Download Procedure

♦ Connect RJ-11 side of Firmware Update Cable to the Airwave Monitor. This is the connector that looks like a telephone jack.

♦ Power on the Monitor if it is not already on.

♦ It is ok to run the Monitor off battery power while downloading data. However, large amounts of data may take several minutes to download, so connecting the power cord may be desirable if the battery is very low.

♦ Run **Start► All Programs►SonarMed► AirwaveDownloader** on PC.

♦ Select the **Download Patient History** button.

♦ Select a location to save the data file, and hit "OK".

♦ The status window and progress bar show downloading progress, and the Monitor screen will show "Log download in progress…". The download is complete when the file name (.bin) is displayed over the progress bar. If the cable accidently becomes disconnected during programming, quit the **AirwaveDownloader** program, and repeat this procedure.

♦ Select the **Download Error Log** button.

♦ Select a location to save the data file, and hit "OK".

♦ The download is complete when the file name (.txt) is displayed over the progress bar.

d. Sending Data to SonarMed

♦ Compress data files (.bin and .txt) into a zip file (.zip)

♦ Email the data file to support@sonarmed.com along with a description of the reason for logging the data.

I. <u>Service, Support, and Warranty</u>

WARNING: This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.

A return authorization number is required before returning any product to SonarMed. To obtain this return authorization number, contact SonarMed Customer Support:

<p align="center">SonarMed, Inc.
12220 N. Meridian Street, Suite 150
Carmel, Indiana 46032
USA</p>

<p align="center">Phone: (855) 240-0553
Fax: (866) 853-3684</p>

<p align="center">support@sonarmed.com</p>

<p align="center">www.sonarmed.com</p>

<p align="center"><u>Warranty</u></p>

SonarMed, Incorporated, (SonarMed) warrants to the purchaser, for a period of one year from the date of purchase, each <u>AirWave Monitor battery pack</u>.

SonarMed warrants to the purchaser that the <u>AirWave Sensor</u> will calibrate on a clean unused endotracheal tube a minimum of one (1) time when used before the expiration date listed on the package and if the original packaging is not damaged.

SonarMed warrants the <u>AirWave Monitor</u> for a period of three years from the date of purchase from an authorized SonarMed distributor as follows:

SonarMed shall repair or replace any AirWave Monitor found to be defective in accordance with this warranty, free of charge, for which SonarMed has been notified by the purchaser by serial number that there is a defect, provided said notification occurs within the applicable warranty period. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any AirWave delivered to the purchaser which is found to be defective in any manner, whether such remedies be in contract, tort, or by law.

This warranty excludes cost of delivery to and from SonarMed. All repaired units shall be received by the purchaser at SonarMed's place of business.

SonarMed reserves the right to charge a fee for a warranty repair request on any AirWave that is found to be within specifications.

The AirWave is a precision electronic instrument and must be repaired by qualified technical professionals. Accordingly, any sign or evidence of opening the AirWave, field service by non-authorized personnel, tampering, or any kind of misuse or abuse of the AirWave, shall void the warranty in its entirety. All non-warranty work shall be done according to SonarMed standard rates and charges in effect at the time of delivery to SonarMed.

<u>Disclaimer/Exclusivity of Warranty</u>:

The express warranties set forth in this manual are exclusive, and no other warranties of any kind, whether statutory, written, oral, or implied, including warranties of fitness for a particular purpose or merchantability, shall apply.

J. Parts and Accessories

The following parts and accessories are available for use with AirWave airway monitoring system. Please contact your distributor representative for pricing and to place an order.

Part Description	Part Number
AirWave Sensor – Small (box of 10)	AW-S0001
AirWave Sensor – Medium (box of 10)	AW-S0002
AirWave Sensor – Large (box of 10)	AW-S0003
AC/DC Power Supply with Power Cord	AW-X0007
Firmware Upgrade Cable	AW-X0005
RS232 to USB Converter Cable	AW-X0006
Monitor Carrying Strap	AW-X0004
Standard Adapter Removal Tool (StART)	AW-X0001
Monitor Post/Rail Mount (Swivel/Tilt)	AW-X0008
Monitor Post/Rail Mount (Gooseneck)	AW-X0009

K. Specifications

1. AirWave Monitor

Characteristics	Functional Specification
Size	9.625" x 4.5" x 2.25"
Weight	1.9 lb (863 g)
Power	AC line and battery operation.
AC/DC Adaptor Input	100 - 250 VAC 50/60Hz
AC/DC Adaptor Output	5 A, 5 V DC
Battery Type	Single cell lithium ion
Battery Run Time	2 hours on fully charged battery
Battery Charge Time	1.5 hours typical
Mode of Operation	Continuous
Water Ingress Protection[1]	IPX-1
Enclosure Leakage Current	< 300 µA at 240 VAC
Applied Part Classification	Type BF, Defibrillation proof
Power Classification	Monitor: Internally powered or powered from specified supply Power Supply: Class II

2. AirWave Sensor

Characteristics	Functional Specification
Single use	Do not re-sterilize or re-use
Latex free	NA
Size	3.5" x 1" x 1.25" / 8.9 x 2.5 x 3.2 cm (with airway connectors) 2.125" x 1" x 1.25" / 5.4 x 2.5 x 3.2 cm (without airway connectors)
Weight	4.2 oz / 119 g (with cable) 1.1 oz / 32 g (without cable)

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[1] IPX-1 Water Ingress Protection rating is for the Monitor only.

3. *System Accuracy*

Indicator	Accuracy (95% Confidence)
ETT Tip Movement (cm)	± 1.9 cm
ETT Obstruction (%)	± 15%[1]
Passageway Diameter[2] (mm)	± 25%[3]

1 – Percentage is absolute. For example, if actual obstruction is 50% of ETT cross-sectional area, then accuracy is 35% to 65%.
2 – Passageway cross-sectional area is represented as effective passageway diameter. Actual passageway geometry may not have a circular cross-section.
3 – Percentage of passageway diameter. For example, if actual diameter is 10.0 mm, then accuracy is 7.5 mm to 12.5 mm.

4. *Storage & Operating Conditions*

When not in use, the SonarMed AirWave is to be stored under the following conditions:

- Temperature: -40 to +70 °C
- Relative Humidity: 10% to 100%
- Atmospheric Pressure: 50 to 106 kPa

The Monitor may be used under the following conditions:

- Temperature: +10 to +40 °C
- Relative Humidity: 30% to 75%
- Atmospheric Pressure: 70 to 106 kPa

5. *Electromagnetic Compatibility*

The information contained in this section (such as separation distances) is in general specifically written with regard to the SonarMed AirWave. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the remainders of the instructions for use of this device.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Cables and accessories not specified within the instructions for use are not authorized. Using other cables and/or accessories may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity).

Care should be taken if the equipment is used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the equipment should be observed to verify normal operation in the configuration in which it will be used.

It is intended for all qualified personnel using the SonarMed AirWave to leave the plastic surround installed around the Monitor's perimeter at all times.

Electromagnetic Emissions

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in the specified environment.

Emissions	Compliance according to	Electromagnetic environment
RF emissions (CISPR 11)	Group 1	The equipment 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.
CISPR Emissions Classification	Class A	The SonarMed Airway Monitoring System is suitable for use in all establishments other than domestic 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)	Not applicable	
Voltage fluctuations / flicker (IEC 61000-3-3)	Not applicable	

Electromagnetic Immunity

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in the specified environment.

Immunity against	IEC 60601-1-2 test level	Compliance level (of this device)	Electromagnetic environment
electrostatic discharge, ESD (IEC 61000-4-2)	contact discharge: $\pm$ 6 kV air discharge: $\pm$ 8 kV	$\pm$ 6 kV $\pm$ 8 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be kept at levels to reduce electrostatic charge to suitable levels.
electrical fast transients / bursts (IEC 61000-4-4)	power supply lines: $\pm$ 2 kV longer input / output lines: $\pm$ 1 kV	$\pm$ 2 kV $\pm$ 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
surges on AC mains lines (IEC 61000-4-5)	Common mode: $\pm$ 2 kV differential mode: $\pm$ 1 kV	$\pm$ 2 kV $\pm$ 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	3 A/m	3 A/m	Equipment which emits high levels of power line magnetic fields (in excess of 3A/m) should be kept at a distance to reduce the likelihood of interference
voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	dip >95%, 0.5 periods dip 60%, 5 periods dip 30%, 25 periods dip >95%, 5 seconds	>95%, 0.5 per. 60%, 5 per. 30%, 25 per. >95%, 5 sec.	Mains power should be that of a typical commercial or hospital environment. If user requires continued operation during power mains interruptions ensure that batteries are installed and charged. Ensure that battery life exceeds longest anticipated power outages or provide and additional uninterruptible power source.

Electromagnetic Environment

This equipment is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in the specified environment.

Portable and mobile RF communications equipment should be used no closer to any part of the SonarMed Airway Monitoring System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below.

Immunity test	IEC 60601-1-2 test level	Compliance level	Recommended separation distance
Conducted RF coupled into lines (IEC 61000-4-6)	150 kHz – 80 MHz	3 V	$d=1.2\sqrt{P}$
Radiated RF (IEC 61000-4-3)	80 MHz – 2.5 GHz	3 V/m	$d=1.2\sqrt{P}$ 80 MHz to 800MHz $d=2.3\sqrt{P}$ 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 meters (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:

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. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

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

d. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitters in meters		
	150 kHz – 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
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 meters (m) can be determined 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 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz;

13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

L. Principles of Operation

The AirWave System

The SonarMed AirWave system, as shown in the Figure below, consists of an AirWave Sensor connected to the proximal end of an ETT, and a Monitor to which the Sensor is connected via a cable.

Inside the AirWave Sensor are embedded a miniature speaker, for emitting sound waves into the ETT, and microphones, for sensing the returning echoes. The amplitudes and timing of the echoes are analyzed by the Monitor to provide the following information:

- location and size of ETT obstructions
- size of the passageway around the ETT tip
- relative movements of the ETT tip within the trachea

SonarMed AirWave System
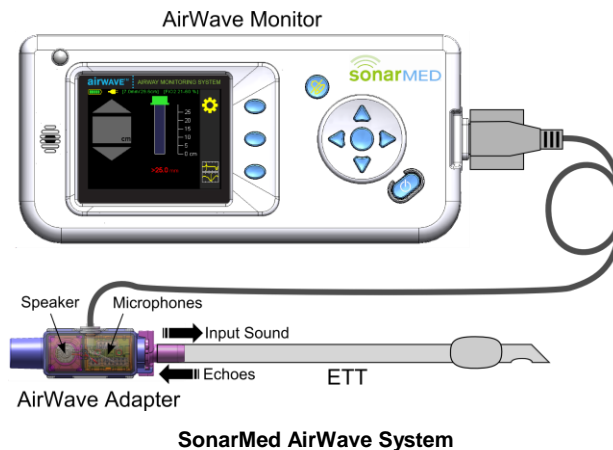
During use of the AirWave, an option is provided via the **Patient Monitoring Waveform Screen** to view the echo signal to provide a means to the user to verify that the signal is free of artifact and that the algorithm is properly identifying and tracking the ETT and the patient's airway echoes (refer to the *AirWave System Operator's Manual* for further information). This primer is intended to help the user to better understand and interpret the AirWave echo signals.

Acoustic Reflectometry

The SonarMed AirWave employs the technique of acoustic reflectometry which consists of emitting acoustic waves into an unknown object (or in this case, an intubated ETT), detecting the returning acoustic reflections (echoes), and examining their timing and amplitudes to infer characteristics of the object in question.

As mentioned above, the AirWave Sensor contains a speaker, for generating acoustic waves which travel into the ETT and airways, and two microphones (separated by a small distance), for converting the reflected waves into an echo signal which is input into the Monitor's proprietary algorithms. This echo signal consists of positive and negative deflections that represent positive and negative sound pressure waves, respectively.

The use of two microphones to sense the acoustic waves allows the system to determine the direction from which echoes arrive. As a result, the system can selectively filter all echoes that arise from devices on the ventilator side of the Sensor, such as closed-circuit suction catheters, y-connectors, $ETCO_2$ sensors, filters, etc. This selective filtering is critical for obtaining a clean echo waveform from the ETT and airways that is free of ventilator circuit echoes.

Origin of Echoes inside Tubes

A key property of an acoustic wave propagating in a tube is that a fraction of the wave's energy will undergo a reflection each time it encounters a change in cross-sectional area (A). If the changing A is from larger to smaller (as depicted in (a) of the Figure below), a positive pressure wave is reflected (showing up as a positive deflection in the echo signal). Conversely, if the changing A is from smaller to larger (see (b) in Figure below), a negative pressure wave is reflected (showing up as a negative deflection in the echo signal). The delay time of each echo identifies the

distance of the changing A that caused the echo. The amplitude of each echo identifies approximately how much the corresponding A changed.


(a)   (b)
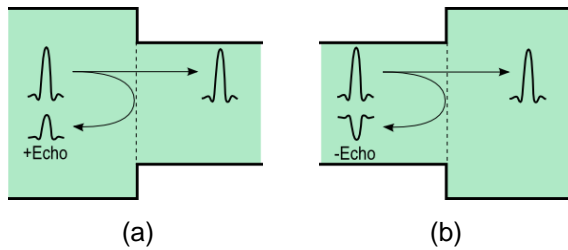
Reflection or echo signals that arise from a tube with (a) changing A from large to small and (b) changing A from small to large.

Echoes in the ETT and Airways

The human airways consist of a network of bifurcating branches that start at the trachea and terminate at the alveoli—small sacs where oxygen-carbon dioxide exchange takes place. An interesting property of the airways is that even though the A of each individual segment decreases as the branching depth increases, the total A (adding As of all parallel segments) undergoes a rapid increase after several generations of airway branching. Considering this morphology, the airways behave acoustically like a horn with a bell at the end. Therefore, acoustic waves traveling down the airways, or the analogous horn model, will be reflected at the rapid increase in total A. The negative pressure wave from this bell-shaped region is used as a reference to which changes in ETT tip position are tracked. The bell begins around the 6th branching generation which is approximately 5 cm past the carina in adults. It is worth noting that there are no echoes of significance that arise from the carina, since the additive A of the two mainstem bronchi is approximately equal to the trachea A.

To illustrate the relationships between cross-sectional area, amplitude, and time delay, refer to the Figure below depicting an intubated ETT with a corresponding echo signal (pressure amplitude on y-axis and time delay on x-axis). For each deflection in the echo signal, an arrow denotes the corresponding region in the ETT and airways from which that echo arises.
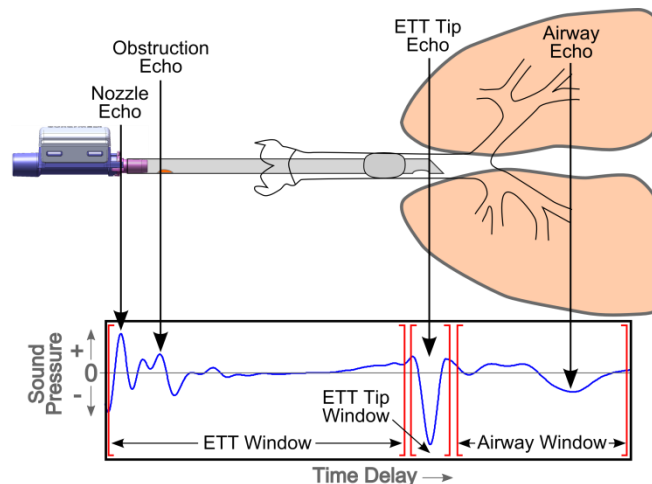
Relationship of AirWave Sensor and intubated ETT (top) to the corresponding echo signal recorded by the AirWave system (bottom).

The first (leftmost) nozzle echo is a positive deflection (positive pressure) which indicates an A change within the nozzle from larger to smaller. This corresponds to the diameter change within the nozzle from 9 to 8 mm ID.

The second echo is a positive deflection immediately followed by a negative deflection which indicates an A change from larger to smaller and then back to larger. This echo could be from a small obstruction within the ETT, a kink in the ETT, or a patient biting on the ETT. If the echo amplitude were larger, this would correspond to a larger obstruction. The AirWave system estimates the obstruction size from the echo amplitude and the obstruction location from the echo delay time.

The third echo is a negative deflection which indicates an A change from smaller to larger. This echo, referred to as the ETT tip echo, is analyzed by the AirWave system to estimate the passageway size (effective diameter) around the ETT. A negative deflection echo indicates that the ETT is located within a passageway that has a larger A compared to the ETT (this would be the case for an ETT in the trachea).   If this echo were to change to a positive deflection,

then this would indicate that the ETT is located within a passageway that has a smaller A compared to the ETT. This may correspond to an ETT that is in the esophagus or bronchus, or that is clogged at the tip, such as from mucus.

The last echo, referred to as the airway echo, arises from the aforementioned bell-shaped region in the airways. The AirWave system tracks the time delay of the airway echo to estimate relative changes in the distance between the ETT tip and the airway echo region. For example, if the time delay between the ETT tip echo and the airway echo is decreasing (airway echo moves to the left), then this indicates that the ETT tip is getting closer to the airway echo region, or that the ETT is migrating down the trachea.

All Lungs Are Not the Same

Accurate tracking of the airway echo by the system assumes that the echo shape remains consistent over the duration of patient monitoring. Significant changes in the echo shape may result in the system reporting a change in ETT position when the actual position has not changed. It is possible that the airway echo shape may change due to airway changes that affect the geometry of the airway echo region. Some examples of airway changes that may affect the airway echo shape include mucus plugs in a bronchus, or a significant change in middle airway *A* due to bronchoconstriction or dilation. Therefore, when the system indicates ETT movement, it is recommended that the user enter the **Patient Monitoring Waveform Screen** (refer to the *AirWave System Operator's Manual* for further information) to compare the baseline and present airway echoes to confirm the current echo has shifted in time (moved left/right compared to the baseline echo) and that the baseline and current airway echoes have similar shapes.

AirWave Sounds are Audible

While a majority of medical devices that employ acoustics do so in the ultrasonic frequency range, the AirWave operates in the audible range below 8 kHz due to reasons related to the frequencies at which tubes behave as waveguides. Operating in these frequencies creates a challenge for collecting echo signals that are not corrupted by the sounds typically found within a ventilator circuit, such as respiratory sounds, secretion sounds, cuff leak sounds, etc. As a result, the AirWave system uses a variety of data collection strategies to collect a clean echo signal during ventilation. When connected to a patient, the system collects a majority of its measurements during the quiet period of ventilation between end-expiration and inspiration. Therefore, the AirWave Monitor provides updates to the ETT status approximately every patient breath depending on the level of noise present between breaths. For cases where excessive noise interferes with acoustical measurements such that the ETT status is not updating, it is recommended that the user enter the **Listen to AirWave Microphones Screen** to listen directly to the Sensor microphones via the Monitor speaker (refer to the *AirWave System Operator's Manual* for further information). This assists the user in determining the noise source so they can rectify it if possible. Examples of noise sources may include: a leaky ETT cuff, secretions in the airway and/or ETT, a high respiratory rate, a nebulizer, and patient coughing.