sonarMED | airWAVE Airway Monitoring System

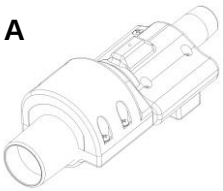
Instructions for Use – English

AirWave™ Acoustic Airway Sensor

Models AW-S0001 (ETT ID 6.5-7.0 mm)
AW-S0002 (ETT ID 7.5-8.0 mm)
AW-S0003 (ETT ID 8.5-9.0 mm)

Replace the AirWave Sensor when you change the ventilator circuit or after 14 days of use.

A



⚠ Caution:

Federal law (USA) restricts this device to sale by or on the order of a physician.

Indications for Use

The SonarMed AirWave Sensor Model AW-S0001, 2 and 3 (Figure A) is for use with the SonarMed AirWave Monitor Model AW-M0001 and reusable cable Model AW-S0007 (sold separately). The AirWave is used to assist in verifying placement of the ETT, to assist in detecting movement of the ETT tip, and to assist in detecting obstruction of the ETT. The AirWave is intended for use by qualified personnel to assist with artificial airway management for patients in an in-hospital setting (intensive care, operating room, emergency department settings, as well as intra-hospital transport). The AirWave is to be used as an adjunct to normal clinical practice, and is not to be used as a stand-alone diagnostic system. It is intended for use with patients who use ETT sizes from 6.5 mm to 9.0 mm inner diameter (ID), with a body weight of >35 Kg.

Contraindications:

- Do not use the AirWave Sensor in an MRI environment.
- Do not use on a cuffless ETT. These AirWave Sensor sizes (6.5-9.0) are intended for use only with a cuffed ETT.
- Do not use the AirWave Monitor with any ETT adapter other than the AirWave Sensor; the system will not function.
- Do not attempt to re-use or sterilize the AirWave Sensor; cross-contamination or damage to the internal components is possible.

⚠ Warnings:

- The AirWave system is not to be used as a diagnostic tool; it is to be used as an adjunct to airway management only.
- The AirWave is to be used by properly trained personnel only.
- Only connect an ETT to an AirWave Sensor specified for that ETT ID. Failure to do so may result in an unsecure fit between the Sensor and ETT.

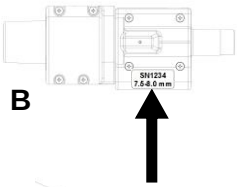
⚠ Cautions:

- Do not use a damaged Sensor. If the Sensor is damaged, discontinue use immediately and contact SonarMed for service.
- The Sensor is labeled for single use only. Dispose of the Sensor after use following hospital biohazard policies and local regulations.
- As with all medical patient equipment, carefully route patient cables to reduce the possibility of disconnection.

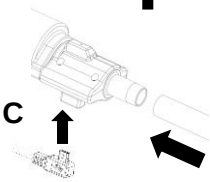
Symbols:

Symbol	Definition
	Consult Instructions for Use
	Do Not Reuse
	Defibrillation-proof type BF Applied Part
	Latex Free
	WARNING or Caution

B



C



Attaching the AirWave Sensor to an ETT

1. Select the correct Sensor size to match the ETT inner diameter. The supported ETT sizes are found on the Sensor package label and also on the Sensor serial number label as shown in Figure B.
2. While wearing clean gloves, remove the AirWave Sensor from the pouch and inspect it for visible damage. If the pouch is found to be torn or open, **DO NOT USE**. Return the Sensor to SonarMed for replacement.
3. Remove the standard adapter that is connected to the ETT leaving just the ETT. To assist with a difficult to remove adapter, SonarMed provides the StART (**St**andard **A**dapter **R**emoval **T**ool); please refer to the *StART Instructions for Use* packaged with the tool for information on its use.
4. Slide the proximal end of the ETT fully over the nozzle of the AirWave Sensor as shown in Figure C. Check that the ETT is securely affixed to the Sensor nozzle.
5. When using a closed system suction catheter, place the suction catheter on the machine end of the AirWave Sensor at the 15 mm connector.

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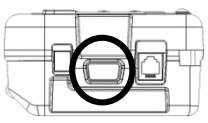
NOTICE! Prior to connecting the AirWave Sensor to an intubated ETT, it is necessary to calibrate the Sensor. Refer to the *AirWave System Operator's Manual* for Sensor calibration instructions.

For Best Results position the AirWave Sensor with the Serial Number/Size label (Figure B) facing upwards, toward the ceiling.

Connecting the SonarMed Sensor to the Monitor

1. Connect the micro-USB plug of the Sensor cable into the Sensor (see Figure C) and the serial plug of the Sensor cable (Figure D) to the matching port on the side of the SonarMed Monitor (indicated by the black circle in Figure E).
2. The Monitor automatically detects the Sensor and provides calibration options. Refer to the *AirWave System Operator's Manual* for further instructions on system calibration and use.

E



Specifications

Accuracy	**ETT Tip Movement (cm):**	± 1.9 cm
	ETT Obstruction (%):	± 15 % [1]
	Passageway Diameter [2] (mm):	± 25 % [3]
Temperature	**Operating:**	+10 °C to +40 °C (50 °F to 104 °F)
	Storage/Transportation:	- 25 °C to +50 °C (- 13°F to 122 °F)
Humidity	**Operating:**	10 % to 100 % non-condensing
	Storage/Transportation:	10 % to 95 %

[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 is of passageway diameter. For example, if actual diameter is 10.0 mm, then accuracy is 7.5 mm to 12.5 mm.

This product complies with ISO 5356-1:2004.

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