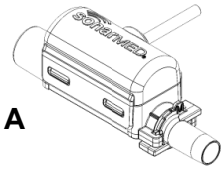


Instructions for Use – English

Model FG-A0001

AirWave™ Acoustic Airway Adapter



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

Indications for Use

The SonarMed AirWave Adapter Model FG-A0001 (Figure A) is for use with the SonarMed AirWave Monitor Model FG-M0001 (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 Adapter in an MRI environment.
- Do not use on a cuffless ETT. The AirWave Adapter is intended for use only with a cuffed ETT.
- Do not use on patients who require an ETT smaller than 6.5 mm ID or larger than 9.0 mm ID.
- Do not use the AirWave Adapter with a dual lumen ETT.
- Do not use the AirWave with any ETT adapter other than the AirWave Adapter; the system will not function.
- Do not use in a setting other than in-hospital.
- Do not attempt to re-use or sterilize the AirWave Adapter; infection and cross-contamination is possible. Sterilizing the Adapter may cause damage to the internal components which can cause the AirWave Monitor to produce erroneous results.

⚠ Warnings:

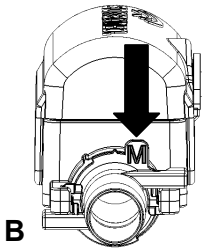
- The AirWave system is not to be used as a diagnostic tool; it is to be used as an adjunct to airway management only.
- The AirWave is to be used by properly trained personnel only.
- Only connect an ETT to an AirWave Adapter specified for that ETT ID. Failure to do so may result in an unsecure fit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

⚠ Cautions:

- Do not use a damaged Adapter. If the Adapter is damaged, discontinue use immediately and contact SonarMed for service.
- The Adapter is labeled for single use only. Dispose of the Adapter after use following hospital biohazard policies and local regulations.
- As with all medical patient equipment, carefully route patient cables to reduce the possibility of entanglement or strangulation.
- Factors that may shorten the acoustic sensor life of the AirWave Adapter include the following:
 - Environmental or patient biological factors such as rain-out and mucus.
 - Operating the Adapter in an orientation other than that indicated by the "This Side Down" text stenciled on the adapter body bottom.

Symbols:

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



Attaching the AirWave Adapter to an ETT

1. Select the correct Adapter size to match the ETT inner diameter. The size is found on the Adapter package label and also on the Adapter nozzle as shown in Figure B. Use the following table for reference:

ETT ID (mm)	AirWave Adapter Size
6.5 & 7.0	Small (S)
7.5 & 8.0	Medium (M)
8.5 & 9.0	Large (L)

2. While wearing clean gloves, remove the AirWave Adapter from the pouch and inspect it for visible damage. If the pouch is found to be torn or open, **DO NOT USE**. Return the Adapter 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** (Standard Adapter Removal Tool); 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 Adapter as shown in Figure C. Check that the ETT is securely affixed to the Adapter nozzle.

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

Connecting the SonarMed Adapter to the Monitor

1. Connect the end of the Adapter 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 Adapter and provides calibration options. Refer to the *AirWave System Operator's Manual* for further instructions on system calibration and use.

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:	-40 °C to +70 °C (-40°F to 158 °F)
Humidity	Operating:	10 % to 100 % non-condensing
	Storage/Transportation:	10 % to 100 % non-condensing

[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.

