Instructions for Use
Esophageal Stethoscope with Temperature Sensor

Thermistor: YSI 400 Series Equivalent

REF 4009-ES, 40012-ES, 40018-ES,40024-ES

⚠	Read Instructions for use
2	Single patient use
	Do not use if package is damaged
	Product does not contain natural rubber latex
STERILE EO	Sterilized with Ethylene Oxide
Rx only	Federal (U.S.A.) Law restricts this device to be sold by or on the order of a physician.

DESCRIPTION:

The Starboard Medical Esophageal Stethoscope with temperature sensor is designed for placement inside the esophagus for temperature measurement and auscultation of heart and lung sounds. The temperature sensor is placed inside of a PVC tube, with sensing tip placed at the tube's proximal end, which is beveled for atraumatic insertion. The tube at its proximal end has several side openings and is covered with a plastic cuff to facilitate heart and lung sound transmission. The tube is made of light weight, medical grade PVC materials. At the distal end a male Luer adaptor is attached to the tube for connection to any standard ear piece for listening to heart and lung sounds. The accuracy of the sensor is: ±0.1˚C at 37˚C and ±0.2˚C at 5˚C and 45˚C. The Starboard Medical Esophageal Stethoscope with temperature sensor is designed for use with patient temperature monitoring equipment compatible with YSI 400 Series or equivalent thermistors. The esophageal stethoscope with temperature sensor interfaces with Starboard Medical cables (C400MP-M, C400P-M, and C400MR) for connection to the temperature monitoring equipment. The esophageal stethoscope with temperature sensor is a disposable, single patient use item available in sizes 9, 12, 18, and 24 French.

INDICATIONS:

The Starboard Medical Esophageal Stethoscope with temperature sensor is indicated for continuous monitoring of patient temperature along with auscultation of the heart and lung sounds. The probe is designed for insertion into the esophagus.

CONTRAINDICATIONS:

The esophageal stethoscope with temperature sensor usage may be contraindicated in neonates and small infants during laser surgery, internal jugular artery catheterization, or tracheostomy procedures.

ADVERSE REACTIONS:

The following adverse reactions have been reported during clinical application of the esophageal stethoscope with temperature sensor:

- Accidental tracheal or bronchial placement accompanied with an airway obstruction.
- Esophageal abrasion and/or perforation
- Tissue burns due to aberrant electro-cautery radio-frequency current pathways.
- Epistaxis and/or trauma to the pharynx

WARNINGS:

If the esophageal stethoscope with temperature sensor is utilized during surgical procedures using electrocautery, the following may occur:

- Artificial fluctuations in temperature readings.
- Localized tissue burns due to the thermistor and lead wire acting as an alternate path for the radiofrequency current to return to ground.

The risk of localized tissue burns can be minimized by having the active and ground probes of the electro-cautery system in a close proximity to each other. All parts of the esophageal stethoscope with temperature sensor and cable shall be away from the electro-cautery probes and connecting cables and, therefore, outside of the radio-frequency current field.

- The Starboard Medical Esophageal Stethoscope with temperature sensor has not been evaluated for safety and compatibility in the MR environment.

DIRECTIONS FOR USE:

1. Verify the compatibility of the temperature probe, connecting cable, and temperature monitoring equipment.
2. Remove the esophageal stethoscope from its sterile package.
3. Lubricate probe with suitable water-soluble lubricant prior to insertion and place the probe in situ in accordance with currently accepted clinical practices.
   a. In patients requiring intubation, intubate the patient first and then insert the Esophageal Stethoscope into the esophagus.
4. Verify its location in accordance with currently accepted clinical practices.
5. Connect the esophageal stethoscope to the appropriate reusable temperature cable. Align the connectors and push firmly together. Misalignments and forced connections may cause sensor failure.
6. Connect the cable to the temperature cable receptacle on the temperature monitoring equipment. Secure the cable to avoid pulling the esophageal stethoscope.
7. For listening to heart and lung sounds, connect earpiece extension tubing to the stethoscope Luer connector.
8. Follow clinical best practices to reduce the risk of device related pressure injury. Do not place the device or cable directly under the patient.
9. Check location of device regularly.
10. Upon completion of temperature monitoring, carefully remove the esophageal stethoscope according to currently accepted clinical practice.
    a. If the patient was intubated, remove the esophageal stethoscope prior to endotracheal tube removal.
10. Disconnect the esophageal stethoscope from the cable by grasping both the cable connector and probe connector firmly and pulling apart.
11. Dispose of the probe according to facility protocol.

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