COMPARING THE FREQUENCY RESPONSE OF DEROYAL ESOPHAGEAL STETHESCOPES WITH TEMPERATURE MONITORING AGAINST SMITHS' AND MALLINKRODT'S

Testing Performed by:
Benny Tanhehco, Ph.D.
Product Development Engineer
DeRoyal Industries, Inc.

Testing Performed at:
DeRoyal Industries, Inc.
Department of Research and Development
300 DeBusk Lane
Powell, TN 37849

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OBJECTIVE

The objective of this analysis is to compare the frequency response of the *DeRoyal Esophageal Stethoscope with Temperature Monitoring* (EST) with those of the *Mallinckrodt (Tyco) MAT* and *Smith's (SIMS) Level 1 ESTs.* In particular, this study was conducted to determine if *DeRoyal's* ESTs allowed for a better frequency response during normal use.

As a primary purpose of the EST is to monitor and listen to both heart and respiratory (lung) sounds, it is critical that the EST provide high quality audio responses so that the clinician can diagnose and treat problems with the patient as they occur.

PRODUCT DESCRIPTION

Product Use

Esophageal Stethoscopes with Temperature Sensors (ESTs) are designed for use in the surgical settings to monitor heart and respiratory (lung) sounds and measure core body temperature of anesthetized patients.

Temperature measured in the lower esophagus approximates cerebral temperature. The ideal location for the esophageal temperature probe is in the lower one-third to one-fourth of the esophagus. In adults, 45 cm from the nostril gives a good approximation of cerebral temperature. Placing an esophageal temperature probe at the point where heart sounds are most prominent gives good results and works well in patients of all ages.

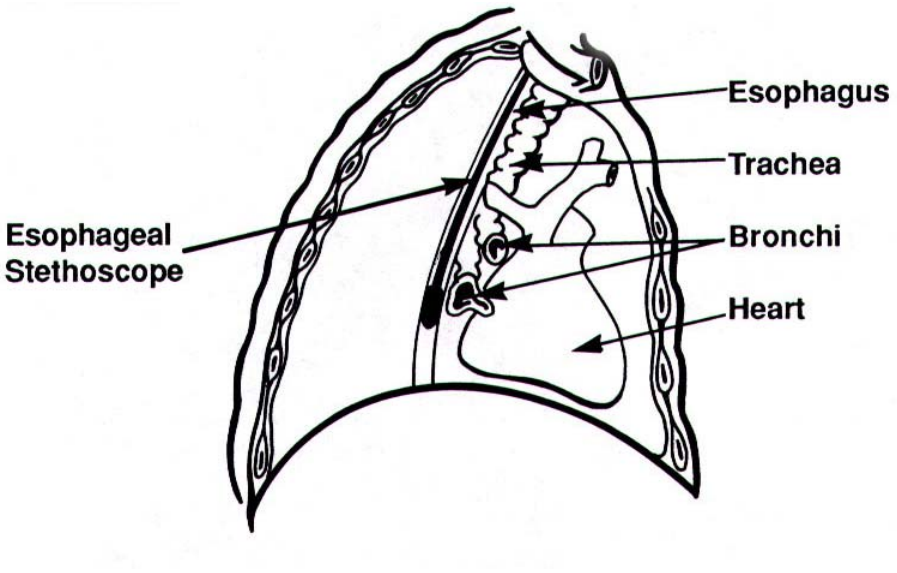


Figure 1: Placement of the EST

Product Construction

The EST is comprised of several components:

1) A single lumen tube, open at both ends and “punched” with a series of lateral holes at the distal end. The tubes are available in different diameters (9 Fr, 12 Fr, 18 Fr, 24 Fr), with the 18 Fr as the most common, as well as longer lengths to accommodate different patient sizes. The tubes are also available in varying durometers based on clinician preference.
2) A plastic (PVC) membrane cuff (opaque blue in the case of the DeRoyal brand) adhered to the distal end of the tube, covering the laterally punched holes.

3) An earpiece attached to the proximal end of the tube, which is then attached to the clinician's stethoscope, which in turn is used to listen to the heart and lung sounds.
4) A wire set inside the tube. The wire set has a thermistor at the distal end, placed adjacent to the cuff and a plug at the proximal end. The plug is inserted into an interface cable, which is plugged into a temperature-monitoring unit with a temperature read-out display. Note that the wire set is for temperature monitoring only and is an optional feature in Esophageal Stethoscopes (i.e., Esophageal stethoscopes are available with or without temperature monitoring capabilities.).

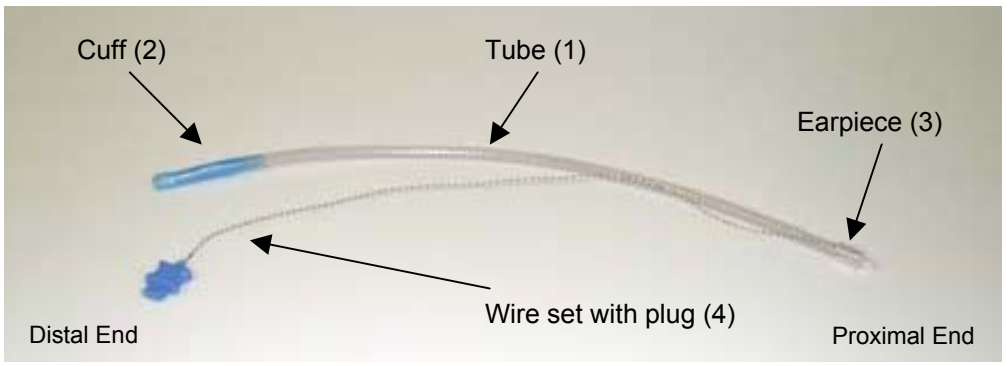


Figure 2: Esophageal Stethoscope with Temperature Monitoring Components

TEST SAMPLE DESCRIPTION

The following products were compared for the purposes of this study:

DeRoyal:

- 18 French, YSI 400 Series, Regular Tube, Part #81-040418 Qty = 3

Mallinckrodt:

- 18 French, YSI 400 Series, Regular Tube, Part #90042 Qty = 3

Smith's (SIMS):

- 18 French, YSI 400 Series, Regular Tube, Part #ES400-18 Qty = 3

TEST METHODOLOGY

Sample Preparation / Condition

The required test samples were off-the-shelf sterilized product. The set-up and preparation are shown below:

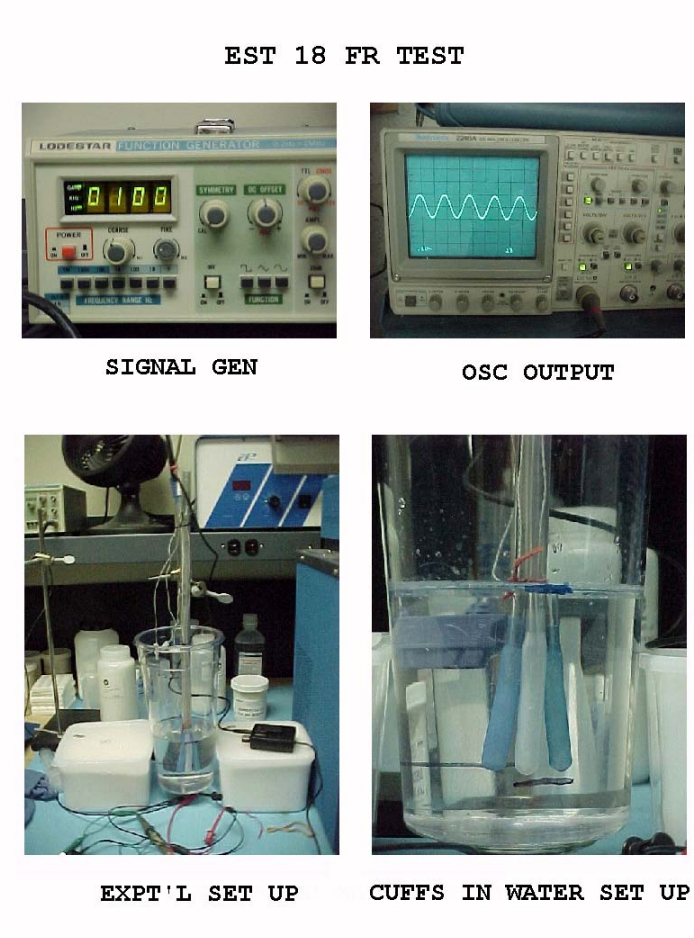


Figure 3: Test Equipment Set-Up and Preparation

Test Equipment

Following is a listing of the equipment used to conduct the test:

- Canister, 15 Liters
- Stand and fixtures (to hold the test ESTs)
- Adapter tubing (to adapt the EST ear piece to the pen microphone)
- Loudspeaker, 2” (8 ohms, Optimus, fits under the canister)
- Signal generator (Lodestar Function Generator FG-2102AD)
- Pen microphone (MM pen mic)
- Preamp (MM microphone pre-Amp)
- Oscilloscope (Tektronix 2246A, 100 mHz)

Test Procedures

General considerations and preparation

1) A large canister is filled with water. The cuff at the distal end of the ESTs are submerged into the water such that the water level is one (1) inch above the cuff of the EST.
2) The canister / EST apparatus is situated on top of the speaker centrally. The site is level and free of vibration and extraneous noises.
3) The pen microphone is attached to the plastic tubing adapter. The adapter fits the pen microphone at one end and the earpiece at the other end (proximal) of the EST.
4) The output of the pen microphone is attached to the input of the preamp.
5) The output of the signal generator is attached to the speaker. The signal generator is set-up to provide the lowest possible sinusoidal waveform that can be detected by the oscilloscope.
6) The oscilloscope is set-up to monitor the output from the preamp. The preamp is set to a gain that provides undistorted output for the frequencies of interest.

Test procedure

1) Attach a set of three ESTs (one from each company) onto a stand such that the ESTs can be suspended vertically and centrally inside the canister.
2) Immerse the ESTs to a depth such that the water level is one (1) inch above the cuff.
3) Attach the earpiece of the target EST to the pen microphone via the tubing adapter.
4) Power up the signal generator, the oscilloscope and the preamp.
5) Verify and adjust if necessary the output voltage of the signal generator to a constant value. Record this voltage as the input signal to the cuff for the test.
6) Start the signal generator at 50 Hz frequency.
7) Record the preamp output voltage using the oscilloscope. This is the output signal or response from the cuff.
8) Repeat from step 6 for frequencies of 100 Hz, 300 Hz, 500 Hz, 750 Hz, 1 kHz, and 2 kHz.
9) Remove the set of three ESTs, re-assemble the next set of three and repeat from step 1.

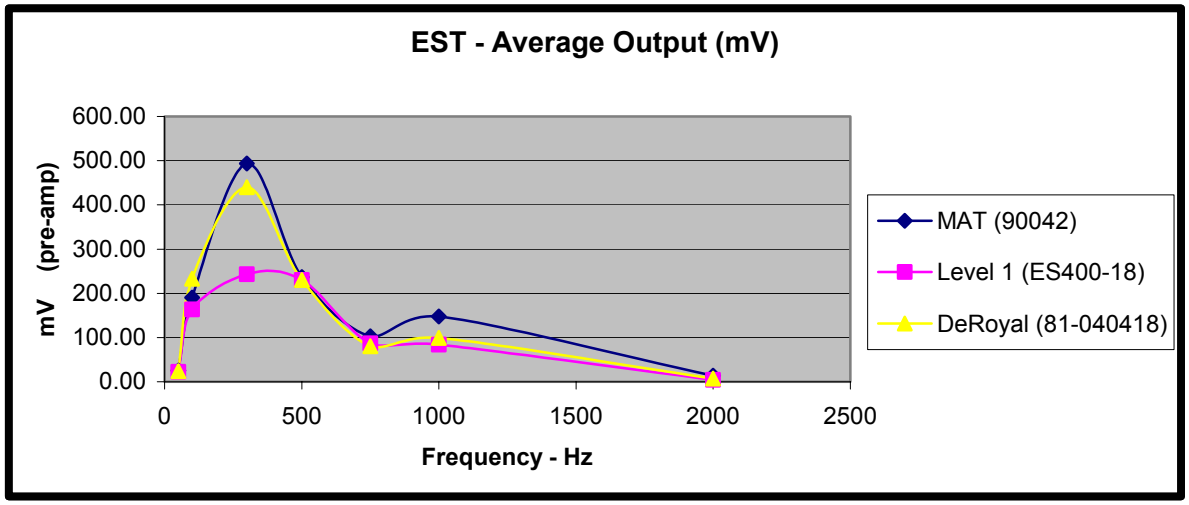
TEST RESULTS

Data

All pk-pk voltages		Sample #	Amplifier Output mV		
			Mallickrodt MAT	SIMS Level 1	DeRoyal
Freq. Hz	Gen. Out		(#90042)	(#ES400-18)	(#81-040418)
50	310 mV	1	24	24	24
		2	36	24	24
		3	16	20	24
100	310 mV	1	200	160	180
		2	250	140	260
		3	120	190	260
300	310 mV	1	400	240	350
		2	660	210	480
		3	420	280	490
500	310 mV	1	240	220	360
		2	300	280	170
		3	170	190	160
750	310 mV	1	88	76	104
		2	120	112	56
		3	100	72	80
1000	310 mV	1	124	80	120
		2	140	96	68
		3	180	75	110
2000	310 mV	1	10	6	6
		2	16	4	6
		3	16	4	10

Analysis

Freq. Hz	Mallinckrodt 90042	SIMS Level I ES400-18	DeRoyal 81-040418	DeRoyal vs. Mallinckrodt	DeRoyal vs. SIMS
	Average Output (mV)			Ratio (dB)	
50	25.33	22.67	24.00	-0.47	0.50
100	190.00	163.33	233.33	1.78	3.10
300	493.33	243.33	440.00	-0.99	5.15
500	236.67	230.00	230.00	-0.25	0.00
750	102.67	86.67	80.00	-2.17	-0.70
1000	148.00	83.67	99.33	-3.46	1.49
2000	14.00	4.67	7.33	-5.62	3.92



CONCLUSIONS

The EST is used by the anesthesiologists to listen to the respiratory and heart sounds of patients under anesthesia. These sounds usually have fundamental frequencies lower than 100 Hz. Even with harmonics considered, the range of frequencies of interest would be in the range of a few hundred Hertz.

For these lower frequencies of interest, it could be noted that the DeRoyal EST had a substantially better audio response than SIMS (43% at 100 Hz and 81% at 300 Hz) and about the same response as Mallinckrodt.