

Response to FDA

9 April 2020

- 1) Regarding the clamping of corrugated tubing, we performed a durability test on the material that consisted of 45 full clamp / unclamp cycles. In each cycle, we used a power screwdriver to tighten the clamp such that the tubing became completely shut. This simulates the worst-case scenario for the material, in which a doctor uses the clamp to completely stop flow, maximally deforming the tubing. The results of our test are as follows: after 45 full clamp / unclamp cycles, the tube appears to have retained its integrity. Based on a visual inspection of the tubing, we identified no discernible cracks or creases. It would be difficult to distinguish between the tube that underwent the clamping cycles and a new tube.

To ensure that the structural integrity of the tubing remained unaffected by the clamping cycles, we performed a leak test of the tubing in a bath of water. We clamped one end of the tube and blew air through it, effectively pressurizing the inside of the tube. Through this test, we saw no air bubbles escaping from the tubing; this precludes the possibility of micro cracks in the material.

- 2) The table referred to is reiterated below:

1 L total tidal volume	Measured tidal volumes (mL)				
	Left patient	Right patient	Actual ratio	Ideal ratio	Error
80 L/m (40/40)	514	486	1.057	1	5.7%
100 L/m (50/50)	514	479	1.073	1	7.3%
100 L/m (60/40)	570	398	1.432	1.5	4.5%
120 L/m (60/60)	520	478	1.087	1	8.7%
120 L/m (80/40)	650	339	1.917	2	4.1%

The ventilator we performed this test on had a maximum flow rate of 120 L/m; since our device has a minimum measurement capability of 40 L/m, the highest ratio we could test at was 2:1. However, based on this test we have identified that error levels decrease as the ratio moves farther away from unity. This leads us to believe that for ratios higher than 2, the error rate would be below 4.1%.