

## Cuff Sentry™ FAQ's

**Q - What happens if the flow meter is turned off or the CuffSentry itself is turned off?**

A – As with any cuff that is not routinely checked, maintained, or has a leak, it will deflate and a ventilator alarm will sound. This occurs just as it would if the cuff or the pilot balloon check valve fails and deflates if CuffSentry were not used.

Once the alarm sounds, following standard practice for a cuff leak is recommended: the situation is assessed and it can be determined that the cuff is deflated due to the flow meter or CuffSentry being turned off. Unlike typical cuff leaks where clinicians “jerry-rig” a fix or are required to re-intubate the patient, once the flow meter or CuffSentry is turned on again at the original flowrate, the cuff will inflate to set pressure and the alarm condition will cease. There is a notification label located on top of the CuffSentry stating not to turn off the device or the flow meter.

**Q – What happens if the flow meter is adjusted upward and above 2 lpm?**

A – Excess flow and pressure over and above the clinician set point is vented via the device pressure relief valve and the cuff will not be exposed to excess pressure above the set point.

**Q – I have noticed a hum or vibration creating an annoying sound from the CuffSentry. What causes this?**

A – This is completely avoidable with proper adjustment. We have found the valve used to vent excess flow from the system may at times vibrate and create a humming sound. This sound will go away once the flow is reduced to a level between 0.5 and 1.5 LPM. This flow rate is easily sufficient to properly fill and maintain clinician set cuff pressures.

**Q – I notice if the ET tube is disconnected from CuffSentry after the set pressure has been attained and the cuff is inflated, there will still be pressure displayed on the manometer dial. Why does this happen and how do I determine if Cuff Sentry is properly connected to the ET tube?**

A – If CuffSentry is disconnected as described above, yes there will still be a pressure reading on the manometer dial. This is because there is still flow

coming from the flow meter and the spring tension in the relief valve is effectively pressurizing the system. Quite simply, when CuffSentry is connected to the pilot balloon flow will normally escape continuously out of the pressure relief valve - while cuff pressure is being maintained. If CuffSentry is disconnected from the pilot balloon, the relief valve remains under tension from the compressed spring. So disconnected, flow is now venting through a) the narrow tubing which is the path of least resistance and b) from the pressure relief valve – two paths are established for flow rather than one.

The size and type of tubing used with CuffSentry is narrow and stiff (the same used for invasive blood pressure monitoring) which by using these properties assures that accurate pressure transmission occurs between the cuff of the artificial airway and CuffSentry's pressure gauge.

Proper connection of CuffSentry to the ET tube can be determined by a series of 2 or more quick compressions and immediate releasing of the ET tube pilot balloon. You will see a slight change in cuff pressure displayed on the manometer dial which verifies communication with CuffSentry.

**Q – Where should cuff pressure be set when using CuffSentry?**

A – Cuff pressure between 20 cm H<sub>2</sub>O and 30 cm H<sub>2</sub>O has historically been a long standing goal. Today there is a significant body of published work that suggests 5 cm H<sub>2</sub>O above PIP or between 26 to 28 cm H<sub>2</sub>O as the recommended cuff pressure range. Maintaining this range minimizes the migration of secretions around the cuff while avoiding tracheal injury resulting from high pressure.

CuffSentry operates at any set pressure range a clinician prefers within the scale displayed on the dial. CuffSentry does allow the ability to set and maintain cuff pressures described in the current body of published work to minimize secretions migrating around the cuff.

**Q – How do I avoid the CuffSentry tubing from getting in the way of the patient or clinician?**

A – CuffSentry tubing can be inserted into the clips along the ventilator breathing circuit creating a clean and uncluttered field.

**Q – Can the tubing used on Cuff Sentry be hooked to an IV line?**

A – No, CuffSentry has a male luer connection and it cannot be connected to the male luer connection of an IV line. A male luer connector requires a female luer receiver and as with other devices it can theoretically be connected to an IV catheter. To guard against this we have placed a red connector on the patient line to draw attention to the appropriate connection as well as a warning label at the connection point reading **“Warning For Cuff Inflation Only”**.

**It should also be considered that if there is an intravenous line disconnect, blood will be flowing back from the intravenous catheter. In addition, there will be fluid flowing from the IV line - or a cause and effect situation - followed immediately by a disconnect alarm from the IV pump.**

**The ‘perfect storm’ of 1) CuffSentry being disconnected, 2) an IV line being disconnected, 3) ignoring an alarming IV pump, and 4) connecting CuffSentry to an IV catheter in the face of a Warning label - coupled with a unique color coded luer connector - all at the same time - is improbable and highly unlikely.**

**Q – Why does the manometer pointer appear to be jumpy at times when adjusting pressures with the CuffSentry pressure relief/adjustment valve?**

A – It is possible to see the pointer jump slightly when adjusting and setting pressure with the pressure relief/adjustment valve. This does not indicate a defective manometer. Fine tuning and smoother operation of the pointer/indicator can be attained via slight adjustment using the flow meter - after reaching the target range with the pressure relief/adjustment valve.

**Q – What should the flow meter setting be to fill the cuff?**

A – We have found the optimum range for the flow meter setting to be between 0.5 and 1.5 lpm. This allows enough flow to easily fill and maintain cuff pressure while avoiding annoying humming or vibration from the pressure relief / adjustment valve.

**Q – Can CuffSentry be sterilized?**

A – No. CuffSentry is a single patient use disposable device.

**Q – Can CuffSentry be used on trach tubes?**

A – CuffSentry can be used on any air filled cuff.

**Q- Why is intermittent cuff checking inadequate?**

A - Numerous evidence-based articles report significant cuff pressure (CP) variation with current cuff management practice(s) leaving CP outside of the recommended range of 25-28 cm H<sub>2</sub>O before and after routine cuff checks.

- MOV starts with deflating the cuff and creating a cuff leak. This allows contaminated secretion migration to the lower airways.
- Syringe inflation method during MOV (or intra-op, EMS intubation, and ED intubation) does not measure CP. Palpation of the pilot balloon has been found to be unpredictable/unreliable indicator of CP using these techniques.
- Excessive CP (the direct cause of tracheal damage) and inadequate CP (resulting in secretion migration to the lower airways) has been reported extensively as being common consequences associated with the current devices and practices of cuff management.

**Q - Is the pressure gauge on CuffSentry accurate?**

A - Yes, CuffSentry pressure gauge has been independently validated for accuracy. It is the same FDA approved gauge manufactured for manual resuscitation devices used with premature neonates, pediatric, and adult patients.