MaxVenturi - Suitability Assessment for the UK Market

The MaxVenturi device offers a solution for allowing the delivery of blended gases where a source of piped medical air is not available.

Discussions with potential customers revealed that there is a requirement within the NHS for a blending device that can operate in the absence of piped medical air.

The MaxVenturi is designed to operate with specific equipment, namely the Fisher & Paykel MR850 heated humidifier and the Hudson RCI Neptune heated humidifier.

Of these 2 devices, only Fisher & Paykel has any discernible presence in the NHS and the UK healthcare market.

A number of advantages and disadvantages were raised by potential customers and by Viamed sales and technical Staff, which have been summarised below:

<u>Advantages</u>

- The concept of a gas blending device that does not require a source of piped medical air is very relevant, as many lower risk medical departments do not have access to piped medical air, and cylinders can constitute a hazard.

- The device looks modern and appears well-engineered.

- The inclusion of a compact oxygen analyser adds to the functionality.

- Good battery life on the oxygen analyser.
- The controls are simple, allowing the flowrate and oxygen concentration to be adjusted independently.
- The option of an inlet muffler to reduce noise levels is a positive benefit.

Disadvantages

A number of concerns were raised by clinical Staff, which are detailed below:

The device does not indicate the true flowrate

The flowmeter has graduations marked in 10 LPM intervals, with a corresponding index letter from 'A' at 10 LPM to 'F' at 60 LPM. However, for some patient interfaces, the flowrate is not accurate.

For example, using a F&P humidifier with 22mm single heated limb and F&P Direct Connect (OPT570) accurately delivers 60 LPM at the 'F' marker, whereas when using a F&P Small Nasal Cannula (OPT542) on the same device, the flowrate at 'F' is 44 LPM. This represents an error of 26% in addition to the specified +/- 9% device accuracy at this flowrate.

Determining the correct flowrate introduces potential risk

To determine the delivered flowrate, the operator must refer to a user manual in order to do a conversion look-up. This introduces risk if the manual is not present as it does not clearly indicate on the device that a look-up must be performed.

Current NHS thinking strongly leans towards a mandate that devices should be able to be used safely without the need to refer to a user manual.

The device is designed to operate at 50 psi

The MaxVenturi is calibrated to operate at 3.5 bar / 50 psi, the UK uses 4 bar / 58 psi. Whilst the user manual states that the device can be operated at 4 bar, a further look-up must be performed in order to determine the correction factor.

Furthermore, the correction factor is given as a percentage, requiring the operator to perform a mathematical calculation in order to determine the true flowrate.

The look-up conversion process is device-led and not clinician-led

The user sets a flowrate on the device and then uses the look-up table to find the true flowrate that is actually being delivered to the patient. If a look-up must be performed, risk-reduction protocol would dictate this as being patient/clinician-led, ie the clinician decides the flowrate that they wish to give and then looks up the setting on the flowmeter required to deliver that flow.

There is no indication of how the clinician can adjust the device in order to deliver the flowrate that the patient requires.

The device is very limited in its application

There is a definite requirement for air entrainment mixing device to replace a blender in general applications, such as resuscitation. Unfortunately, these applications are not within the scope of the device and do not appear to be possible due to back-pressure destroying the venturi effect.

Summary

The MaxVenturi does seem to solve a niche problem but, in the highly regulated and risk-averse environment of the NHS, the compounded complications and observations detailed above continually prevent any sales progress.