### 1- Not all data is available:

Please check that you have downloaded all latest packages as we regularly update the information available. Ensure you have requested "update" to the device specification when requesting your license.

### 2- We can't match the material description from the component's drawings:

We do not take responsibility for any deviation to the design released. It's down to the license owner to ensure any deviations to the design is approved by the local medical authority.

### 3- We can't source silencer material (Vyon F):

Silencer material definition is critical to the device performance. Running without a silencer actually reduces flow performance.

The intent of the material choice was to let oxygen through (at flow up to 80L/min) but without too much pressure drop.

Our testing suggests that pressure drop across the silencer should be maximum 1 bar when flowing 80L/min of oxygen.

### 4- We have the correct spec silencer material but the pressure drop is too high:

There's a couple of potential root cause to this:

- Only the diameters should be machined, the end faces should be left untouched (as per raw material)
- We have noticed some variations in material quality. As such, every sheet of material get an initial sample cut in each corner so we can test and validate each new sheet ahead of ordering a new batch of silencers

### 5- Can the supplier details be made available?

We do not plan to share the supplier details as those are already very busy supporting our efforts. As this becomes easier, we might be able to share those details.

## 6- Standard catalogue parts:

When we refer to standard catalogue parts, those are parts that we don't have to manufacture specifically for the assembly as they are commonly available.

### 7- What should happen to the device once it's assembled?

As specified in the "Value Stream Map" released in phase 3.0, the device should go through a "CPAP Inspection Pass-off Test" which will confirm that it's fit for use.

As always, you sure ensure this final test is approved by your local medical authority as part of the design certification.

## 8- Can you recommend which component you use for patient circuit?

We are not able to recommend any specific make of components for filters, peep valves, hose or mask.

Within "schematic – CPAP" we have specified the maximum pressure drop characteristics for the system to deliver best performance and patient comfort. Local component supply and availability should be taken into account when selecting components for the patient circuit.

## 9- Do I need official approval before sending the drawings to external suppliers?

When you have been granted the manufacturing license for the UCL-Ventura, we agree for you to use the drawings as it suits your supply requirements and there is no need to seek any further approval.

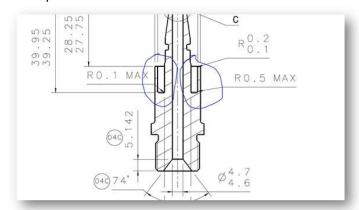
# 10- What does "CPAP Back Pressure" refers to on the system characteristics on page 2 of the CPAP schematic (Phase 1 bundle), bottom left figure?

The graph shows the acceptable back-pressure onto the flow generator output port. This includes the pressure drop from the sensors, filter and the full patient circuit.

### 11- Is there a specific tool used to manufacture the deep groove detail on GIN1756?

We turned this detail using a "Horn" grooving tool:

Tool holder: RAH25A.20.1520.02
Tool tip: S25A.0200.12 TH35



### 12- Can you share contacts for your raw material supplier?

Vyon material:

Porvair Sciences Limited.

Clywedog Road South, Wrexham Industrial Estate, Wrexham, LL13 9XS, United Kingdom

Tel: 01978 661144

Stainless steel tube and needles:

STAINLESS TUBE & NEEDLE CO LTD

 $\label{thm:continuous} \textit{Tube Stockists \& Manipulators-Hypodermic Needle Manufacturers}.$ 

66 Fazeley Road, Tamworth, Staffs, B78 3JN

Telephone: (01827) 51162

Email: stainlesstube@outlook.com

Website: www.stainlesstubeandneedle.co.uk

# 13- Can you share details of your test equipment (and cost)?

There are many ways to assemble a test rig as per "CPAP\_Inspection\_Pass-off\_Test\_v3" or "CPAP\_benchtesting\_Characterisation\_v1" and there is a long list of kit suitable for this application:

- Two pressure sensors or gauge (reading 4 barg)
- One oxygen sensor (0 to 100% O2)
- One flow meter (0 to 200L/min)

Therefore, the choice of kit will be influenced by stock availability rather than by specific models.

### 14- Is it possible to purchase build tooling?

Sorry, there is no spare build tooling available to purchase at this stage

# 15- Is it possible to purchase sub-components from UCL?

Sorry, it is not possible to purchase specific sub-components at this stage

### 16- Is it possible to purchase a fully built UCL-Ventura?

Sorry, it is not possible to purchase fully assembled UCL-Ventura CPAP flow generators at this stage

### 17- Is there a specific contact for further technical support?

You can send your requests to:

UCL.IHE.Covid19Response < ihecovid19response@ucl.ac.uk >

From there, the relevant people will be contacted function of the topic of the request.