

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.

The aim should be to match the strength for each components. The critical one is the material for the flow needle (we started with a low strength material but the needle snapped very easily, so we increased the spec of the material)

Also, the valve bodies benefit from being low hardness (~25HrC as the seat is machined at the end of deep bore).

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 (at room pressure) 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.

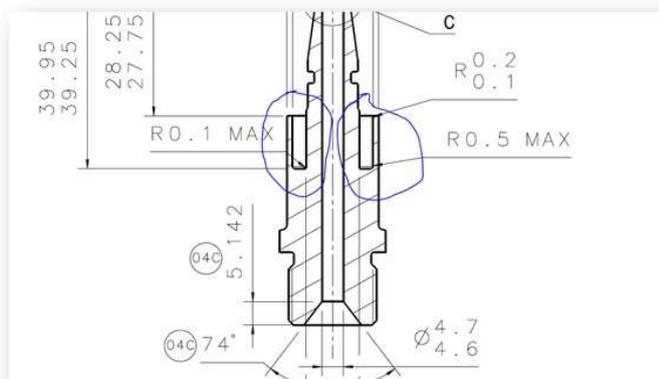
10- **What does “CPAP Back Pressure” refers to on the system characteristics on page 2 of the CPAP schematic (Phase 1 bundle), bottom left figure?**

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
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 we fit a standard filter to the inlet of the UCL-Ventura (instead of the inlet cap GIN1805)?**

The Ventura was designed without a filter on the inlet. This is to reduce the requirement of useful stock of filter as well as removing the risk of the inlet being blocked by a foreign body due to the suction of the device. The geometry is not suitable to fit a standard filter.

14- **Does GIB2211 need to be made from PEEK material?**

This tool is for help during assembly process, which is used to rotate the needles prior to fitting the circlip.

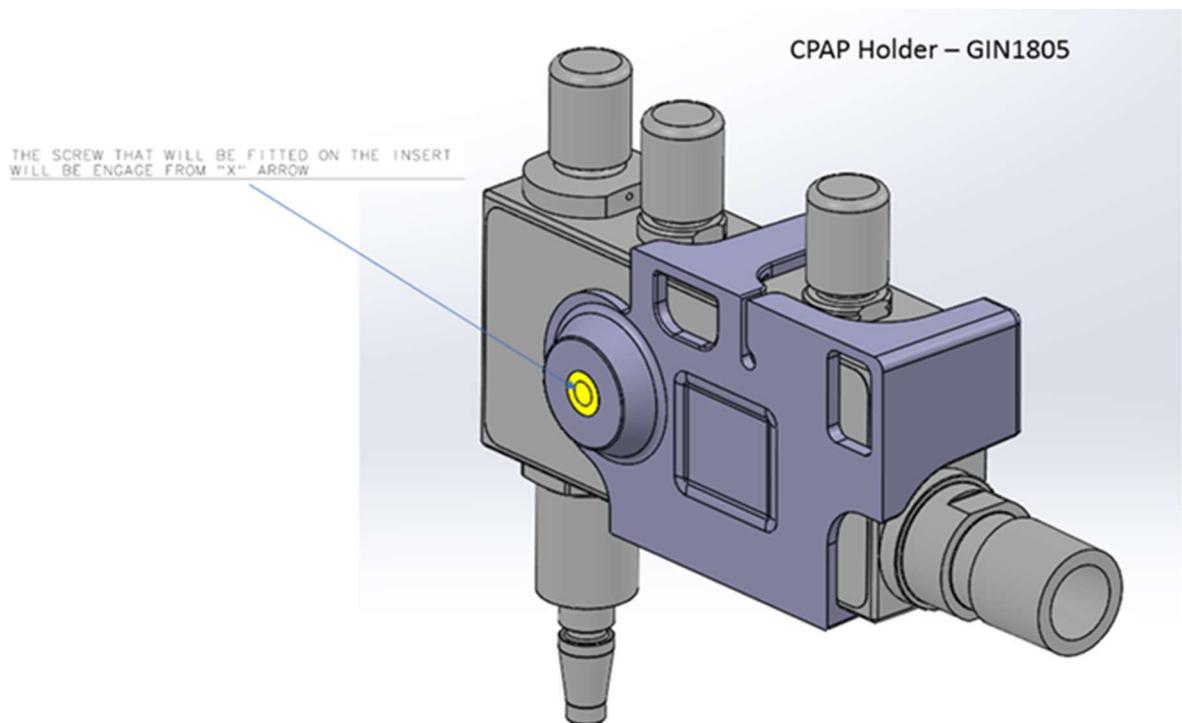
The material for this needs to be chosen to be strong enough to carry the torque load but soft enough not to damage / mark the needle.

Our assumption would be that even a soft aluminium could cover this application (Aluminium 6082 for example)

15- **What is GIN1805 used for?**

GIN1805 "CPAP holder" is a bracket designed to allow for the UCL-Ventura to be positioned closer to the patient in case the oxygen supply is too far, or not solidly mounted.

Any "standard" ¼" screw fitting will be suitable bolt into the holder (and be fitted onto an IV pole for example).



17- 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.

18- Is it possible to purchase build tooling?

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

19- Is it possible to purchase sub-components from UCL?

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

20- 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

21- 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.

22- What is “Elma ultrasonic wash line” line mentioned in the “CPAP Assembly Instructions Iss2.9”?

This is the cleaning process we use for all our components.

For more information, see their website “<https://www.elma-ultrasonic.com/en/>”

23- Where can I find more information about “Keyence” products as mentioned in the “CPAP Assembly Instructions Iss2.9”?

We’ve setup one of our existing vision machines to check the valves where assembled properly.

For more information, see their website “<https://www.keyence.co.uk/>”

24- There are no drawings for GIK8783_01 / GIK8784_01 /GIK8785_01 mentioned in the build instructions?

Those parts numbers are used for the “top level” kit of parts for each sets of tooling.

For example, GIK8783_01 FLOW ADJUSTMENT VALVE TOOL KIT includes the following components:

	GIK8783_01	Flow Adjustment Valve Tool Kit	
	GIN7058_01	Flow Adjustment Valve	
	Tool List		
Assembly No.	Part No.	Description	Qty
	BIF3431_01	1.5mm A/F Allen Key Bit	1
	BIF3432_01	Snap-on 1/4" to 1/4" hex magnetic	1
	GIB2152_01	O Ring Seating Tool	1
	GIB2168_01	Bullet	1
	GIB2211_01A	C-PAP Actuation Handle	1
GIB7325_01		Circlip Fitting Taper Tooling	1
	GIB2150_01	Circlip Taper Sleeve	1
	GIB2151_01	Circlip Push Tool	1
GIB7326_01		Valve Support Plate	1
	FXB1389_01	Cleco Ground Dowel Using BIP2470	2
	GIB2158_01	Support Block	1