



UCL VENTURA FLOW GENERATOR

Continuous Positive Airway Pressure Device System Kit
For COVID-19

User Manual



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IMPORTANT REMINDERS

- **The UCL Ventura is for emergency use during COVID-19 pandemic only.**
- **Do not use on confirmed or suspected COVID-19 patients without the appropriate PPE.**
- **All hospitals must work with their oxygen engineering teams to ascertain their vacuum insulated evaporator (VIE) outflow, and downstream flows and pressures to specific ward areas, before deploying this device.**
- **The UCL Ventura flow generator is recommended to be used with the patient circuit provided and set-up as described in this section. The components were selected to provide minimal back pressure to achieve high efficiency oxygen usage and patient comfort, as well as provide safety for healthcare practitioners. Any circuit modification, use of unapproved replacement parts, or set-up and operation not in accordance to this manual may cause high oxygen wastage, loss of CPAP support function and therapeutic benefit, as well as harm to both patient and healthcare practitioner.**



Introduction

The **UCL Ventura** is a non-invasive ventilation (NIV) system specifically developed to aid COVID-19 patients with breathing difficulties. It is an improved design of the continuous positive airway pressure (CPAP) system that optimizes oxygen consumption.

Although the **UCL Ventura** is not a direct replacement for invasive mechanical ventilation (IMV), this NIV system can serve as supportive therapy for COVID-19 patients experiencing moderate to severe symptoms and may be used to prevent patients from progressing to the point of needing IMV, or as a bridging therapy for cases where IMV is unavailable. This may help improve patient outcomes while reducing the strain on hospital resources.

The **UCL Ventura** flow generator uses a high-velocity oxygen supply to entrain room air into the flow stream. At typical operating range, it allows varied generated flow from 7.5L/min to 60 L/min, and oxygen concentrations from 35% to 80%, enabling the clinician to attend to a wide range of patient needs. At device peak operations, the device can provide oxygenation up to 95% FiO₂ at up to 120 L/min flow rate.

The device is designed to be used with preset CPAP valves at 5, 10, or 15 cmH₂O and a variety of mask sizes.

Since transmission reduction is a central issue for any healthcare facility dealing with COVID-19, the **UCL Ventura** system was developed to reduce the spread of aerosols, with features such as a patient mask that completely covers the nose and mouth, as well as HEPA filters for output gas filtration for bacterial and viral protection of healthcare practitioners. Tests from the original design team show that SARS-CoV-2 was not detectable within one meter away from patients being treated with the system.

When combined with the use of proper personal protective equipment (PPE), the **UCL Ventura** delivers an effective oxygen therapy while keeping healthcare workers safe from infection.

Its effectivity is evident with the observational data from Italy and China showing that it can prevent up to 50% of patients from progressing to MIV.

Although the high flow nasal cannula (HFNC) is also used to provide oxygen therapy for COVID-19 patients, there is not enough clinical data to prove its superiority over the CPAP NIV. The **UCL Ventura** also offers other advantages over HFNC, including an improved cost of ownership due to the optimized oxygen consumption, as well as its affordability.

The system is easy to set up and use. It is compact in size and can easily be integrated into any ICU or COVID-19 ward. The flow generator device does not require a power source or medical air and can be used in conjunction with any standard medical oxygen tank that supports the 4-bar (400 kPa or 58 psi) oxygen requirement. It is portable and may be used outside the hospital, in an ambulance or any remote setting allowing a timely intervention for critical COVID-19 care.

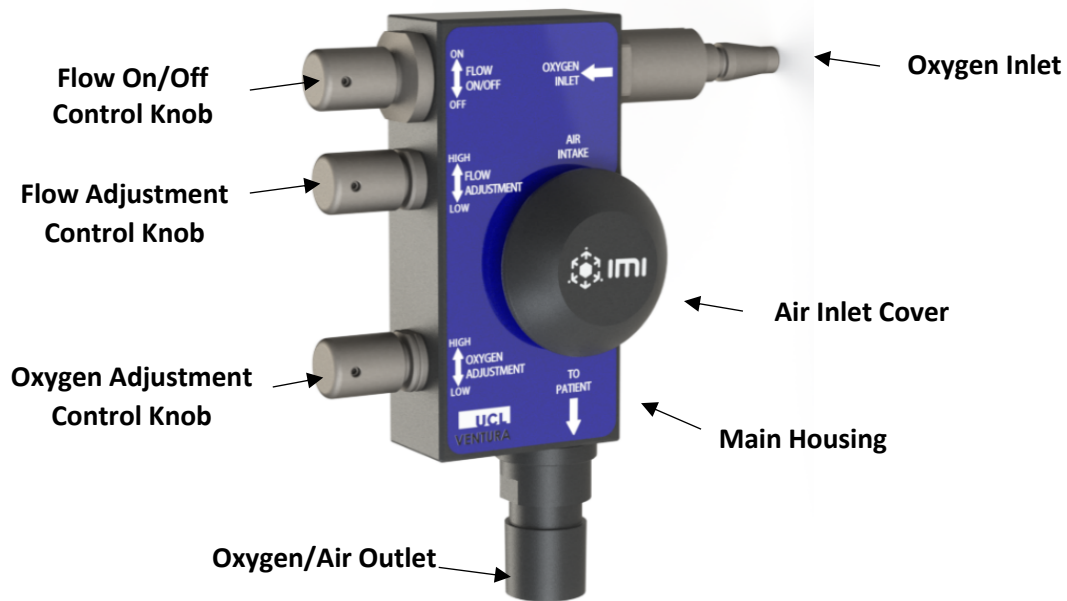


Fig. 1. UCL Ventura Flow Generator Main Parts

Features

- Provides effective oxygen therapy for COVID-19 patients
- Supports patients with COVID-19 with breathing difficulties, including:
 - Hypoxemic patients;
 - Tachypnoeic patients;
 - Patients with difficulty breathing after use of supplemental face mask oxygen therapy; and
 - Patients recovering from IMV.
- More affordable than other oxygen therapy solutions, including HFNC
- Simple to set up and use; requires less specialized training
- Compact and highly portable, ready for ambulant use or in remote locations
- Fully mechanical flow generator, no electricity or medical air required
- Powered by a 4-bar oxygen (± 0.25 -bar) (400 ± 25 kPa or 58 ± 3.6 psi)
- Allows oxygenation from 35% to 80% FiO₂ at 7.5L/min to 60L/min, up to 95% FiO₂ and 120L/min
- Wide ambient temperature and humidity operating range
- Clinician configurable CPAP levels at 5, 10, or 15 cmH₂O

Contraindications

The **UCL Ventura** may be contraindicated in any of these conditions:

- Infant patients;
- Unconscious patients;
- Patients with anxiety, claustrophobia;
- Unstable cardiorespiratory status or respiratory arrest;
- Patients with severe trauma or burns on the face;
- Patients with pneumothorax;
- Facial, esophageal, or gastric surgery patients;
- Patients suffering from copious vomiting, severe nausea; and
- Patients with chronic pulmonary disease.

Oxygen Supply Guidelines

CAUTION: All hospitals must work with their oxygen engineering teams and ascertain their Vacuum Insulated Evaporator (VIE) outflow, downstream flows and pressures to specific ward areas before deploying this device.

- Healthy patient evaluation data indicates O₂ flow rates of 11L/min, 14L/min, 17L/min for inhaled oxygen (FiO₂) levels of 30%, 40%, 60%, respectively for calm breathing and O₂ flow rates of 14L/min, 25L/min and 46L/min at FiO₂ of 30%, 40%, 60%, respectively for heavy breathing. More information for consumption estimation and risk assessment can be found in the Reference for Oxygen Supply Assessment on p.21 of this manual.
- Only medical-grade, oil-free and contaminant-free oxygen of at least 82% purity should be used with the **UCL Ventura** system.
- The **UCL Ventura** system is compatible with wall oxygen sources for hospitals, whether generated on-site, from bulk liquid oxygen storage, or oxygen cylinder banks that can support the 4-bar (400 kPa or 58 psi) requirement.
- The oxygen inlet of the **UCL Ventura** flow generator has a British Standard (BS) Schrader male probe connection which can be plugged directly to a compatible wall oxygen source or via available oxygen hose adaptors such as: BS Schrader to DISS Hand-tight nut and BS Schrader to Ohmeda Probe. Ensure that the wall oxygen connection standard and the supplied oxygen hose adaptor are compatible.
- Oxygen gas cylinders may also be used to supply the **UCL Ventura** system with limited operation time depending on the cylinder size and fill level. Ensure that each oxygen gas cylinder is used with gas pressure regulators that support the 4-bar (400 kPa or 58 psi) requirement and a compatible oxygen hose adaptor, such as the BS Schrader to DISS Hand-tight Nut. For user safety, ensure that the cylinder valve is closed before connecting and disconnecting the device hose adaptor.

Mounting the UCL Ventura System

CAUTION: Ensure that all control knobs on the UCL Ventura flow generator are fully turned clockwise (OFF) before setup and before dismantling for user safety and to avoid oxygen wastage.

1. Check the completeness of the **UCL Ventura** flow generator, supplied Oxygen Analyzer, and mounting accessories from the packaging box. Refer to the packing list and Parts List section on p.25 of this document. For any issues on completeness, please contact the distributor and indicate the **UCL Ventura** flow generator serial number which is located on the device, as shown in Fig. 2.
2. On the **UCL Ventura** flow generator, remove the oxygen inlet and outlet rubber caps shown in Fig. 2. Safekeep these caps and reattach them only when storing the device to avoid entry of contaminants.

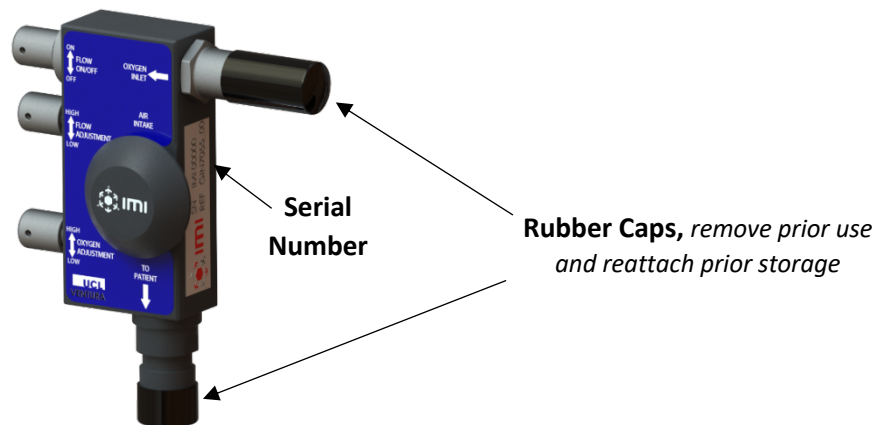


Fig. 2. Rubber Caps and Serial Number Location

3. If the wall oxygen terminal conforms to BS 5682:2015, the user may mount the **UCL Ventura** flow generator directly to it by plugging the oxygen inlet into the wall terminal. Ensure that the **UCL Ventura** flow generator is securely inserted before proceeding to the next step.



Fig. 3. Flow generator direct mounting installation (BS Schrader-compatible wall oxygen terminal only)

- Slide the IV pole clamp onto the IV pole as shown in Fig. 3 such that the V-shape banks against the pole at the desired height. The two slots on the IV pole clamp should be facing upward, as shown.

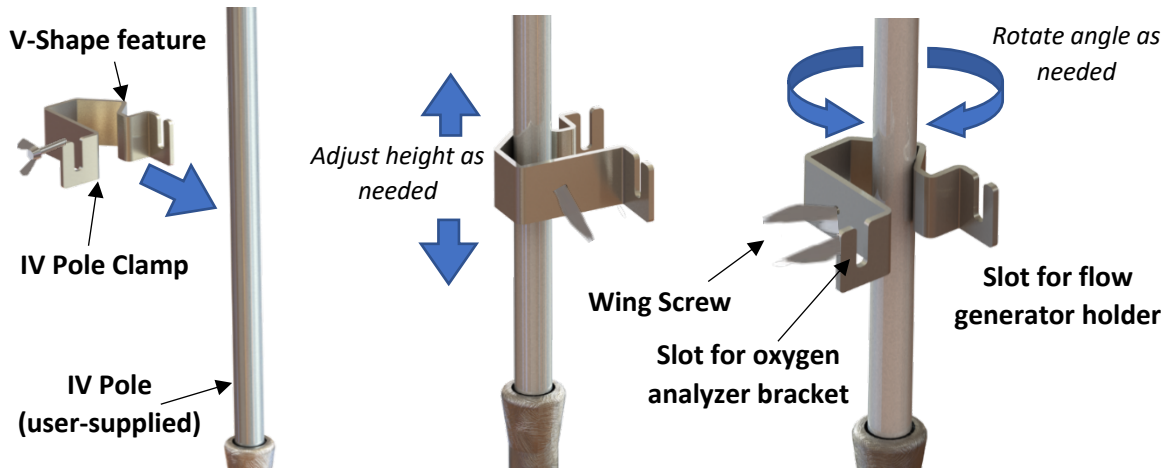


Fig. 4. IV Pole Clamp Setup

- Secure the IV pole clamp by hand-tightening the wing screw clockwise. The user may also adjust the rotation of the clamp around the IV pole at a later time to improve visibility of the oxygen analyzer display and access to the **UCL Ventura** control knobs. Ensure that the wing screw is tightened after any adjustment.

Skip Steps 6, 7, and 10 if the **UCL Ventura** flow generator is already connected directly to the wall oxygen terminal in Step 3. Otherwise, proceed to the next step.

- Clip in the **UCL Ventura** flow generator into the holder by pressing it perpendicularly firmly into the slot, as shown in Fig 5. Ensure that all clips have engaged before proceeding.

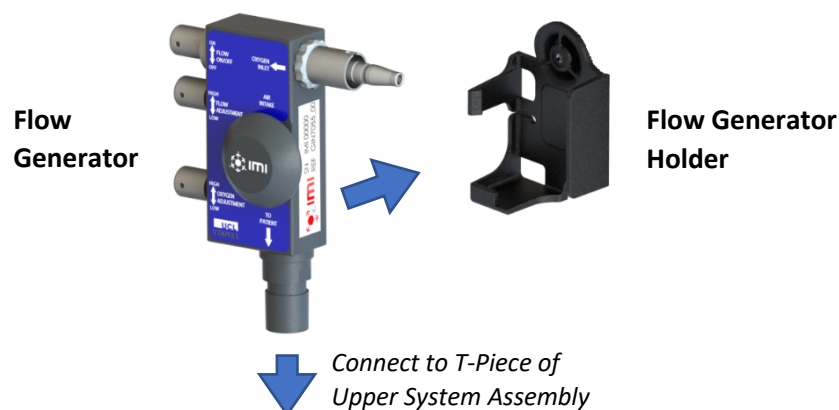


Fig. 5. . Flow generator installation to holder

7. Install the flow generator holder to the IV pole clamp by sliding the screw head into the slot of the IV pole clamp, adjacent to the V-shape feature. Note the orientation of the flow generator holder as shown in Fig. 6.

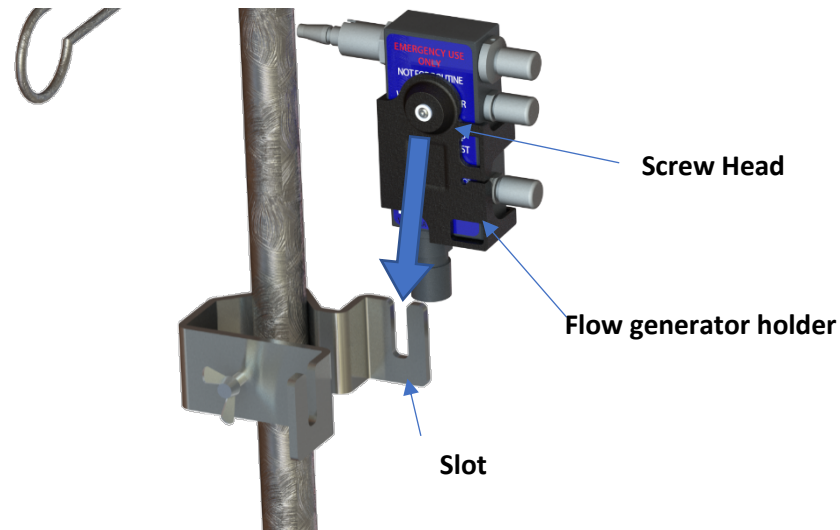


Fig. 6. Flow generator IV pole installation

8. Install the mounting bracket provided at the back of the oxygen analyzer with the shoulder screw head facing out by sliding it upward into the slot at the back of the oxygen analyzer, refer to Fig. 7. Attach the oxygen sensor cable and the oxygen sensor as shown in Fig. 7. *Note: The parts and connections may be different depending on the supplied oxygen analyzer.*

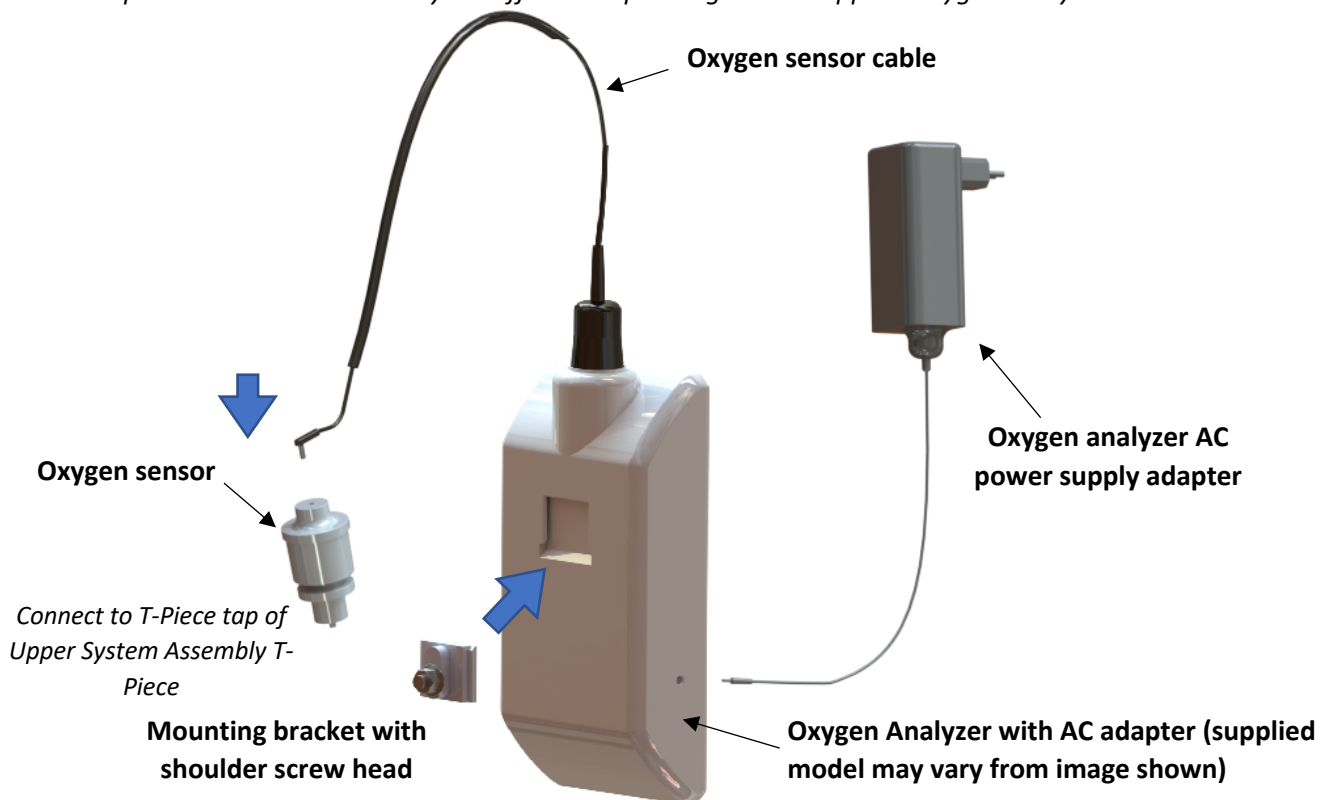


Fig. 7. Oxygen analyzer connection diagram

- Mount the oxygen analyzer onto the IV pole clamp by sliding the mounting bracket shoulder screw head into the slot as shown in Fig. 8. Plug the oxygen analyzer to a power source and power on. The oxygen analyzer may be operated with its internal battery. Refer to the oxygen analyzer user manual included in the kit. The set-up should have the oxygen analyzer display and **UCL Ventura** control knobs accessible.

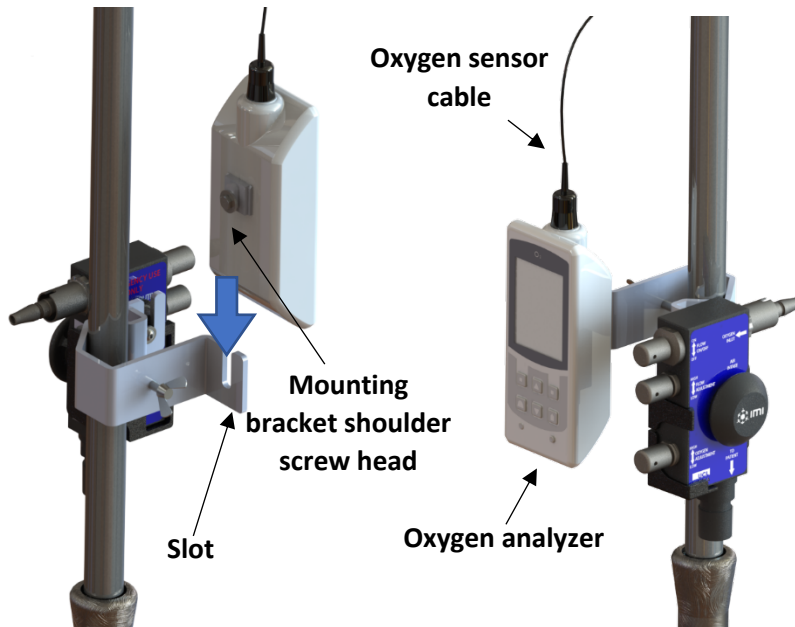


Fig. 8. Oxygen analyzer mounting

- Connect the oxygen supply to the **UCL Ventura** flow generator by using an appropriate oxygen hose adaptor for the standard wall oxygen terminal, connecting the supply side of the hose first, then pressing the BS Schrader connector of the hose into the **UCL Ventura** flow generator until a click is heard. Reverse the sequence when disconnecting the oxygen hose.

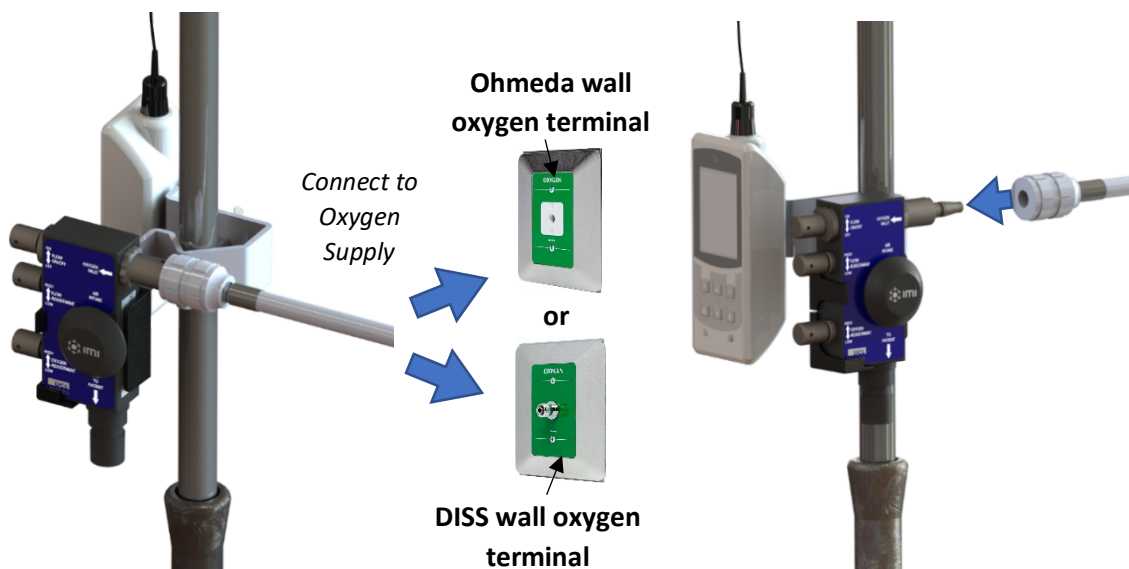


Fig. 9. Oxygen supply hose connection

Setting up the UCL Ventura System

1. Check the completeness of the **UCL Ventura** flow generator and patient circuit set. The patient circuit set is kitted into separate packages: the upper system assembly, lower system assembly and spare peripherals. Refer to the packing list and Parts List section on p.25 of this document
2. Select the appropriate face mask size for the patient. Two sizes are available in the kit. Ensure that the mask will fit snugly around the patient's nose and mouth to form an airtight seal.
3. Select the appropriate fixed PEEP valve rating to provide the target CPAP level for the patient. The target CPAP level is to be defined by the attending physician. Three fixed PEEP valves of 5cmH₂O, 10cmH₂O, and 15cmH₂O are included in the kit, with the 10cmH₂O included in the lower system assembly kit and the other two are in the spares kit. In the succeeding setup, an appropriate safety valve needs to be selected according to Table 1.

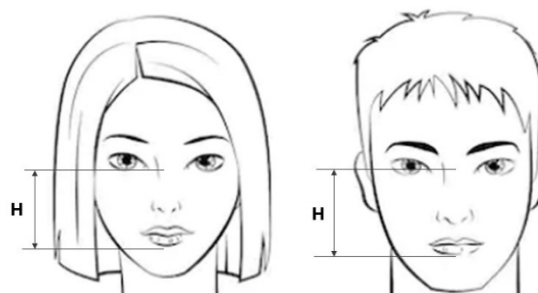
Recommended PEEP valve rating combinations.

PEEP Valve Combination	Lower System Assembly Patient PEEP Valve		
	15	10	5
Upper System Assembly Safety PEEP Valve			
20	✓	✓	X
15	X	✓	✓
10	X	X	✓

Table 1. PEEP Valve Combination (units are in cmH₂O)

CAUTION: Ensure the installation location of the safety PEEP valve and patient PEEP valves are not interchanged to avoid loss of function of the system circuit.

4. Assemble the lower system accessories as shown in Fig. 11 using the selected patient PEEP valve rating. Set aside the mask harness for later use. The sub-assembly comprising the patient PEEP valve, flow flag indicator and breathing filter may be rotated to the right or left from the downward orientation to avoid interference with the patient's chest as needed. *Note: Appropriate patient mask size must be chosen according to Fig. 10.*



H (mm)	Size
80 < H < 90	Small
90 < H < 100	Medium-Large

Fig. 10. Patient Mask Selection Guide

LOWER SYSTEM ASSEMBLY

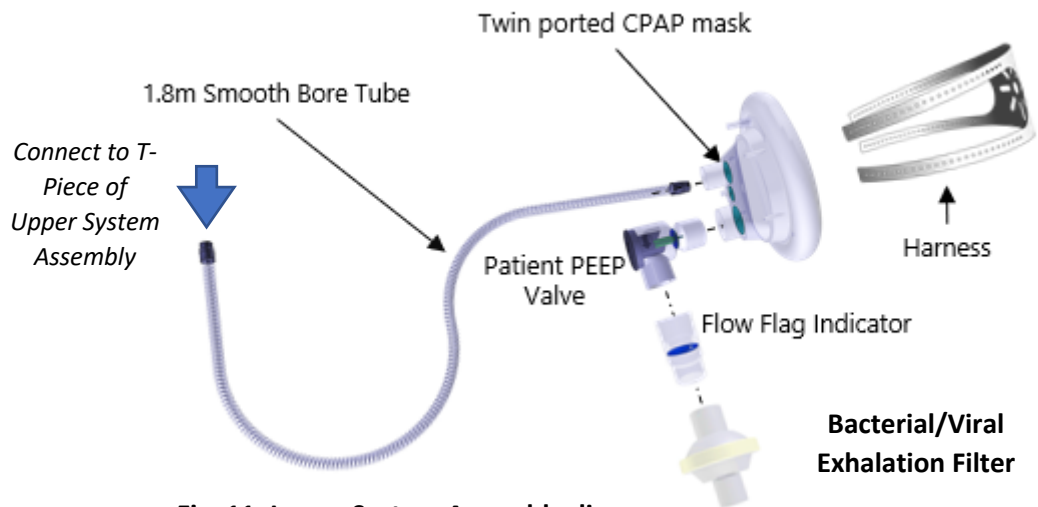


Fig. 11. Lower System Assembly diagram

- Assemble the upper system accessories as shown in Fig. 12, ensuring that the safety PEEP valve rating is 5 cmH₂O to 10 cmH₂O greater than the patient PEEP valve per Table 1 for the recommended patient PEEP valve and safety PEEP valve combinations.

CAUTION:

Ensure the installation location of the safety PEEP valve and patient PEEP valves are not interchanged to avoid loss of function of the system circuit.

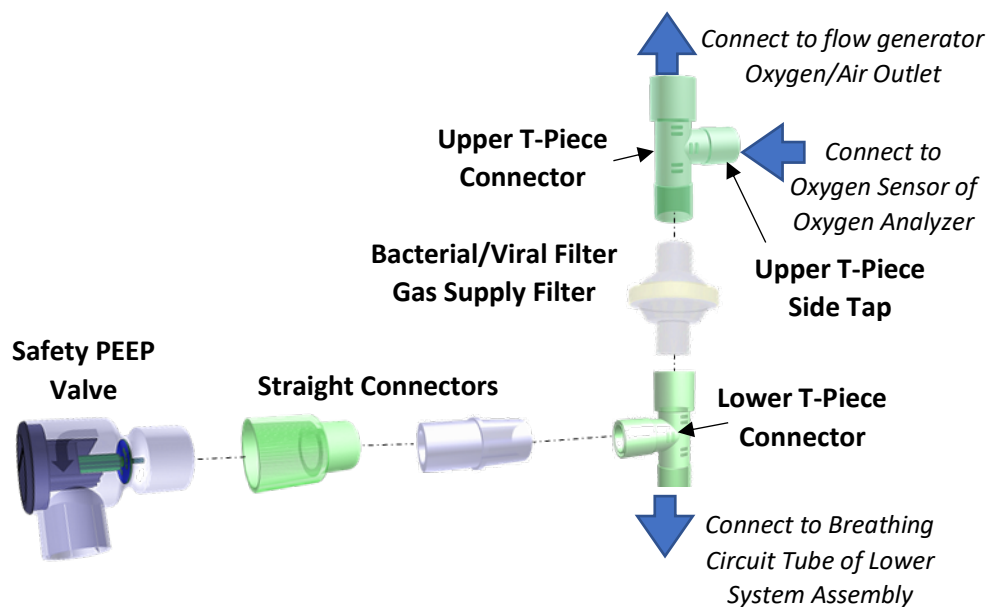


Fig. 12. Upper System Assembly diagram

CAUTION: Ensure that all control knobs on the UCL Ventura flow generator are turned fully clockwise (OFF) before setup and before dismounting for user safety and to avoid oxygen wastage.

6. Connect the UCL Ventura flow generator and the oxygen analyzer to the assembled lower and upper system accessories as shown in Fig. 13.

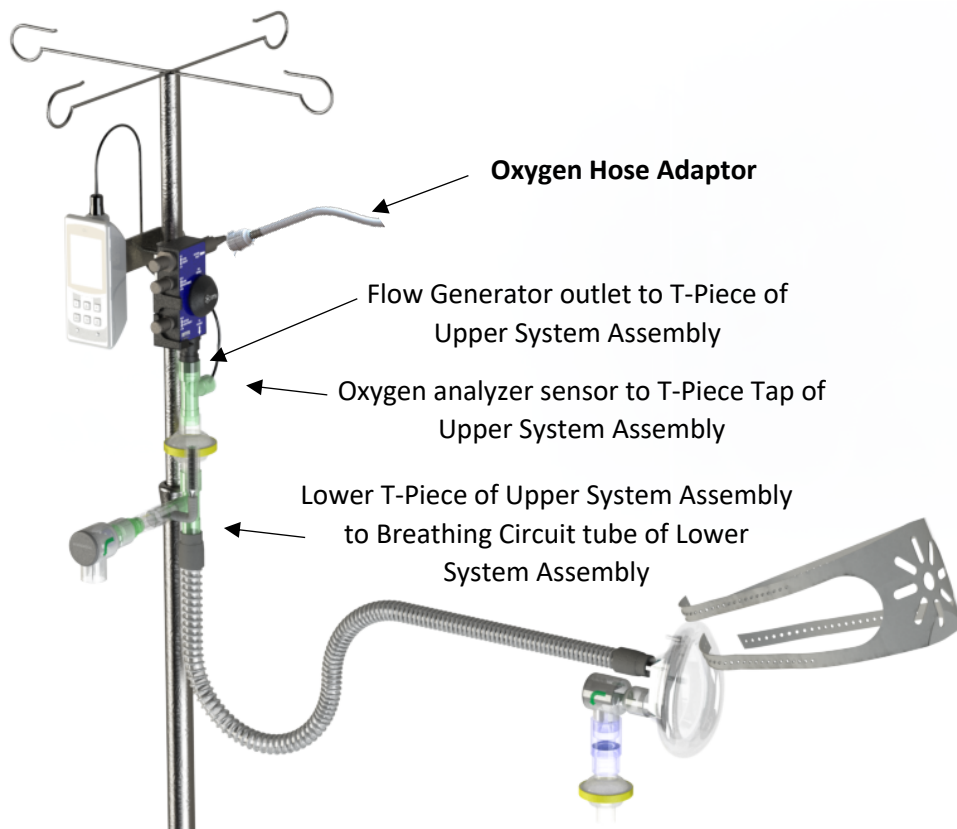


Fig. 13. Complete System interconnect diagram

7. Connect the upper T-Piece connector of the assembled upper system to the UCL Ventura flow generator oxygen/air outlet. Refer to Fig. 12 and Fig. 13. Ensure the flow generator outlet is securely inserted in the T-Piece connector.
8. Connect the oxygen sensor to the Upper T-Piece side tap. Refer to Fig. 12 and Fig. 13.
9. Connect the breathing circuit tube of the assembled lower system to the lower T-Piece connector of the assembled upper system. Refer to Fig. 11 and Fig. 13. Ensure that the end of the breathing circuit tube is securely fits onto the lower T-Piece connector. Route the lower system assembly to the patient's head to minimize risk of unintended disconnection or occlusion in preparation for the next steps.

Operating the UCL Ventura System

1. Turn the **ON/OFF** control knob **(A)** fully counter-clockwise to the ON position.
2. Open the **FLOW ADJUSTMENT** knob **(B)**. This is typically open after 3-4 complete counter-clockwise rotations, towards the HIGH position. The **UCL Ventura** flow generator will make a whooshing sound that increases in volume with the flow.

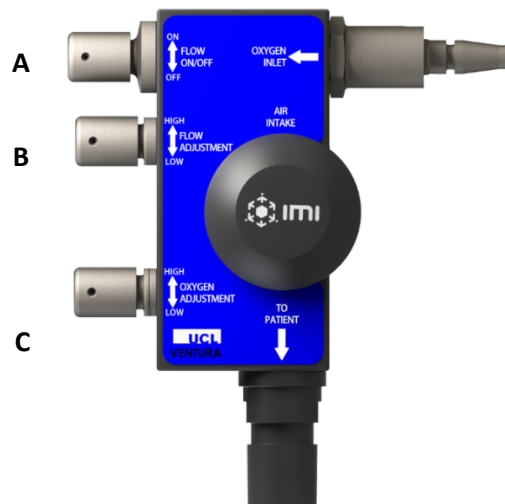


Fig. 14. UCL Ventura Flow Generator Control Knobs

3. Increase the oxygen concentration by turning the **OXYGEN ADJUSTMENT** control knob **(C)** counter-clockwise to the target level specified by the clinician based on the oxygen analyzer readout. Take note of any response delay to avoid prolonging the setup from repetitive overshoot or undershoot.
4. Set the oxygen analyzer alarm according to the oxygen analyzer manual included in the kit, or based on the recommendation from the clinician while considering the patient's oxygen needs.

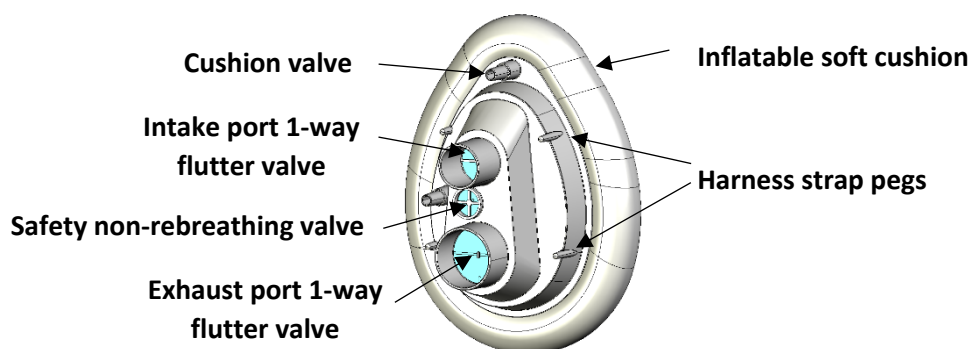


Fig. 15. Two-port mask diagram

5. To improve patient comfort or fit it may be necessary to adjust the inflatable mask cushion pressure by inflating or deflating it through the cushion valve using an unused syringe with

its hypodermic needle removed, before affixing it to the patient face. Refer to Figure 16 for illustration. Repeat all steps if necessary.

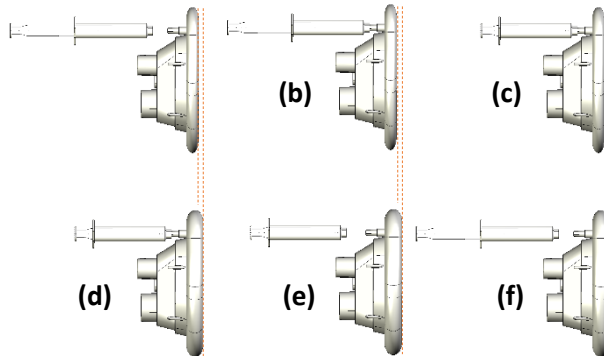


Fig. 16. Air Inflation of Patient Mask Cushion. Repeat all steps until intended air volume is attained.

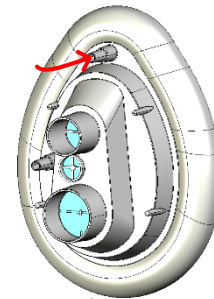


Fig. 17. To deflate, use any tiny round-tip object to push the valve inside and let the air out of the patient mask cushion

6. Put the mask over the patient's nose and mouth, ensuring a snug fit and a tight seal. Wrap the harness around the back of the patient's head to secure the mask. Attach the strap onto the pegs of the mask to secure the fit. It is recommended that this procedure is performed by two personnel.
7. Check for air leaking out from around the mask, and adjust the strap as needed.

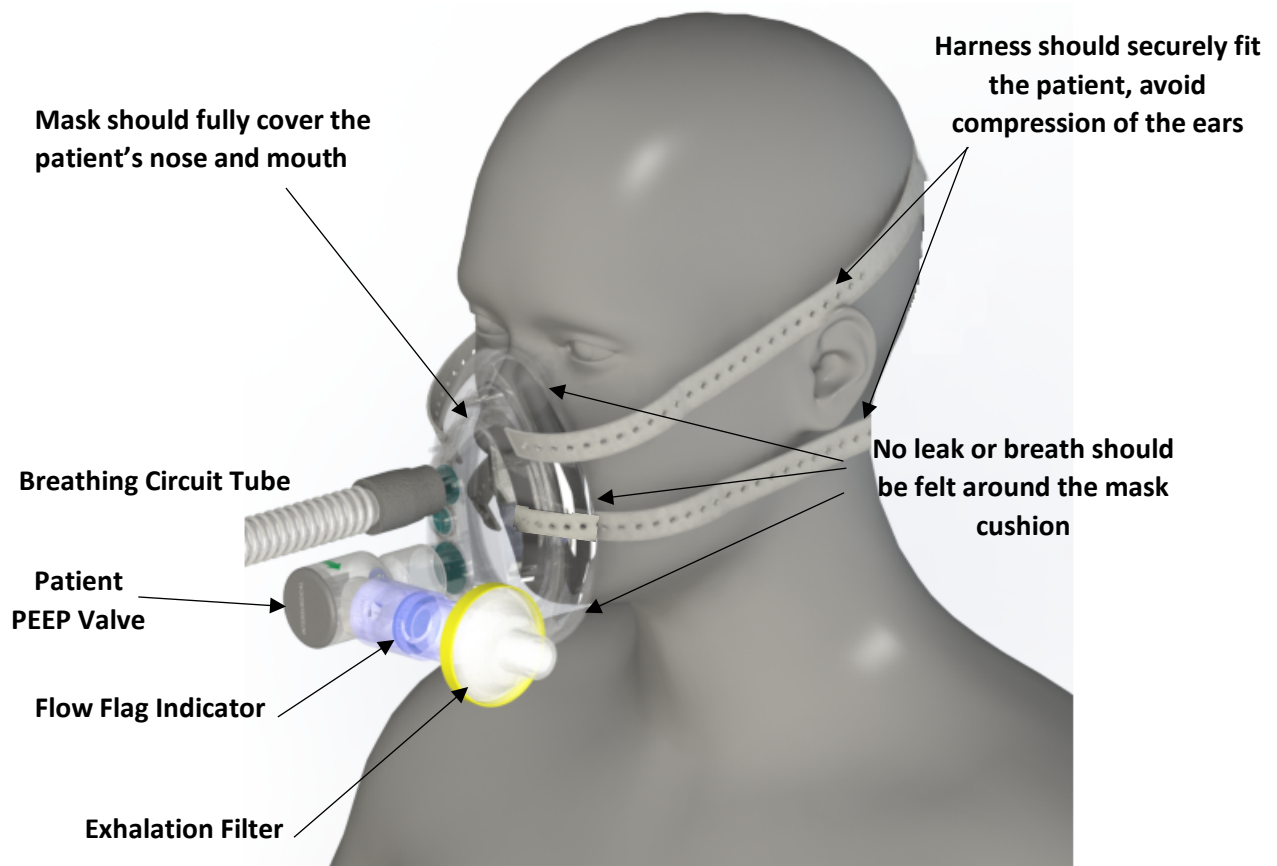


Fig. 18. Patient Circuit diagram

8. Adjust the **FLOW ADJUSTMENT** control knob **(B)** to ensure optimal flow. Observe the following indicators that appear when the flow is already optimized:

- The mask exhaust flutter valve on Fig. 15 must flutter throughout the respiratory cycle, with a smaller flutter during inspiration.
- The blue flow flag indicator must remain horizontal or just below horizontal on inspiration and below horizontal on expiration, as shown in Fig. 19

An almost continuous flow should be felt by the back of a gloved hand at the exhalation filter of the patient PEEP valve throughout the respiratory cycle.

Minimal gas flow may be felt or heard from the safety PEEP valve. If excessive gas escapes causing discomfort to the patient, the flow may be too high and should be reduced by turning the flow adjustment knob **(B)** clockwise.

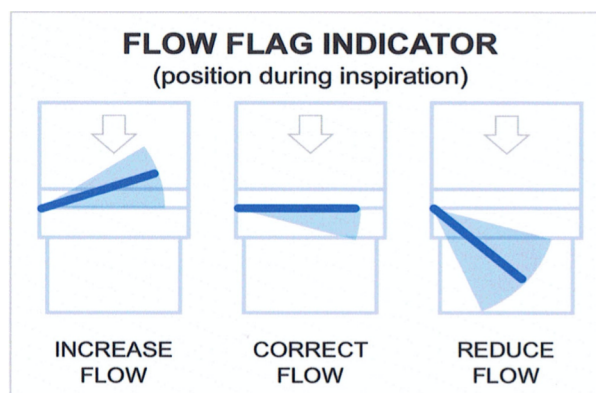


Fig. 19. Flow Flag Appearance and Recommended Action

9. Alter the **OXYGEN ADJUSTMENT** control knob **(C)** if the oxygen concentration changes. Adjust the upper and lower limits of the oxygen analyzer as recommended by the clinician.

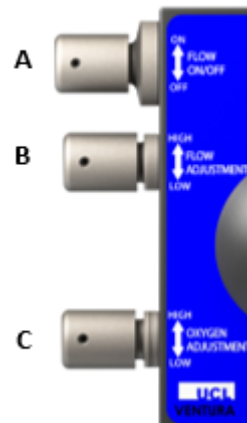
Ongoing Patient Care

Closely monitor every hour. If the patient becomes uncomfortable or distressed, ensure that:

1. Patient flow is sufficient:
 - The mask outlet port valve flutters throughout the respiratory cycle;
 - The blue flow-indicator flag is at near horizontal to just below horizontal (not pointing upwards) during inspiration; and
 - A continuous flow is felt from the mask outlet filter on the back of a gloved hand.

Otherwise, increase flow by turning the flow adjustment knob **(B)** counter-clockwise.
2. Patient flow is not excessive:
 - There is no flow or sound of flow from the safety PEEP valve; and that
 - The blue flow-indicator flag is at horizontal to just below horizontal (not pointing downwards) during inspiration.

Otherwise, decrease the flow by turning the flow adjustment knob **(B)** clockwise.
3. The desired oxygen concentration based on target remains constant. Otherwise, adjust the knob **(C)**.
4. The patient is comfortable and the patient mask remains snug. Any leak will waste oxygen and cause a loss in CPAP. Check the patient for mask-related pressure injuries. Replace patient mask when there are visible fluids or oversized particles inside.



Some reminders:

- Altering the target CPAP pressure is done by changing the mask PEEP valve, NOT by changing flow.
- Patients need to be observed and monitored closely as any patient on CPAP can rapidly deteriorate.
- Be attentive and alert to determine if the CPAP is failing and have an escalation plan in advanced.
- This is a high-flow device and therefore inappropriate use (e.g. excessive flow), or use of multiple devices, may have a negative impact on hospital oxygen supply or pipeline pressure. Discuss CPAP needs with the hospital's facilities personnel and be aware of any oxygen supply issues.
- Switch off if not in use to avoid oxygen wastage.
- Like many high-flow systems, the gas is not humidified. Ensure that the patient is taking in fluid regularly or set up IV fluids. Patients will dehydrate quickly with these systems.
- Change the exhalation filter in the lower assembly every 24 hours or if there are visible fluids or oversized particles inside. Use only the filters supplied with the device.
- The **UCL Ventura** flow generator, including the oxygen analyzer, and oxygen sensor are reusable. Do not dispose. Refer to the Parts List indicated on p. 25 for the recommended frequency replacement of each part. Refer to the Maintenance, Storage, and Handling section on p. 18 for other details.

Maintenance, Storage, and Handling

BEFORE USE:

Under normal conditions, the **UCL Ventura** flow generator does not require any special maintenance or sterilization. However, the device may be gas-sterilized using ethylene oxide (EtO) or wiped down with any disposable wet towels containing Chlorhexidine or 70% alcohol. Sterilization of the **UCL Ventura** flow generator may be done in between COVID-19 patients' use or according to your hospital's protocol for cleaning reusable equipment. After sterilization, open all the control knobs fully, connect to an oxygen supply for five minutes, and verify performance before reuse. Safe-keep the oxygen inlet and oxygen outlet rubber caps for reuse.

Caution: Do not autoclave or immerse the UCL Ventura flow generator or any of its components in any solution. The upper and lower circuit system is for single patient use.

AFTER USE:

1. Disconnect the **UCL Ventura** flow generator and oxygen analyzer from the circuit.
2. Clean the oxygen analyzer according to its User Manual.
3. Clean the flow generator by gas-sterilization with ethylene oxide (EtO) or by wiping down with any disposable wet towels containing Chlorhexidine or 70% alcohol.
4. Cover both oxygen inlet and oxygen outlet using the rubber caps provided.
5. Put back **UCL Ventura** flow generator in its box.
6. Store in a room at 0-40°C temperature with 0-95% RH conditions.

Follow these steps to test the **UCL Ventura** flow generator's minimum FiO_2 annually:

1. Set-up a simple pass-off test circuit as shown in Fig. 18.
2. Tap the oxygen analyzer through a t-piece between the flow generator and the filter.
3. Attach a 10 cmH₂O PEEP valve at the end by using straight connectors.
4. Set the flow generator flow adjustment to its maximum, and the oxygen adjustment knob to its minimum.
5. The FiO_2 at a circuit pressure of 10 cmH₂O should not exceed 31%.
6. If exceeded, do not use the flow generator.

For the supplied oxygen analyzer, refer to the instruction manual provided by the manufacturer as regards the specific replacement part number for the custom Li-ion rechargeable battery, and other replacement parts like the oxygen sensor and cable.

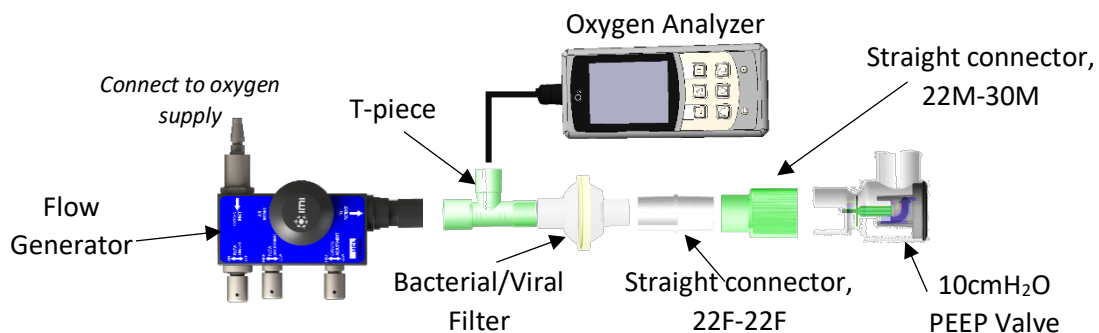


Fig. 18. Setup for Annual check for Flow Generator Performance

Flow Generator Specifications

Device reference	GIN7055_02
Dimensions	158x140x48 mm
Mass	495 g
Operating Range	0 to 40°C (Temperature) 0 to 95% RH (Humidity)
Storage Condition	0 to 40°C (Temperature) 0 to 95% RH (Humidity)
Inlet Connection	Schrader male probe (BS 5682:2015)
Input Pressure	4 bar ± 0.25 bar (400 ± 25 kPa / 58 ± 3.6 psi)
Outlet Connection	22 mm male taper (BS 5356:2015)
CPAP	5, 10, or 15 cmH ₂ O (±20% of rating)

Materials	
Main Body	Tecaform AH MT Black (Acetal Polyoxymethylene)
Control Valves and Oxygen Probe	316S11 Stainless Steel
O Rings	FKM (fluorocarbon rubber)
Lubricant	Fomblin-OT20

Table 2. Flow Generator Specification

Flow Generator Functional Properties

Device Typical Operating Range •Flow Rate, LPM •Oxygen Fraction, FiO ₂ %	7.5 LPM to 60 LPM (±5% of setpoint) ¹ 35% - 80% (±5%)	<u>Test Method:</u> O ₂ Supply = 4 bar (400 kPa) Safety PEEP Valve = 20 cmH ₂ O Patient PEEP Valve = 10 cmH ₂ O Patient Flow Rate - Flow Adjustment Knob adjusted to set flow rate from 5 LPM to full opening (~120 LPM) FiO ₂ - O ₂ Adjustment Knob opened from shut-off until >95% FiO ₂ is reached
Device Peak Values •Flow Rate, LPM •Oxygen Fraction, FiO ₂ %	120 LPM (±5% of setpoint) ¹ 95% (±5%)	<u>Test Method:</u> O ₂ Supply = 4 bar (400 kPa) Safety PEEP Valve = 20 cmH ₂ O Patient PEEP Valve = 10 cmH ₂ O Patient Flow Rate - Flow Adjustment Knob full opened (~120 LPM) FiO ₂ - O ₂ Adjustment Knob opened until >95% FiO ₂ is reached

¹ Device has no feature to display these values. Correct flow will be adjusted based on the visual indicators available as part of the accessories. Refer to Operating the UCL Ventura or Patient Ongoing Care.

Table 3. Flow Generator General Functional Properties

Device Operating Range

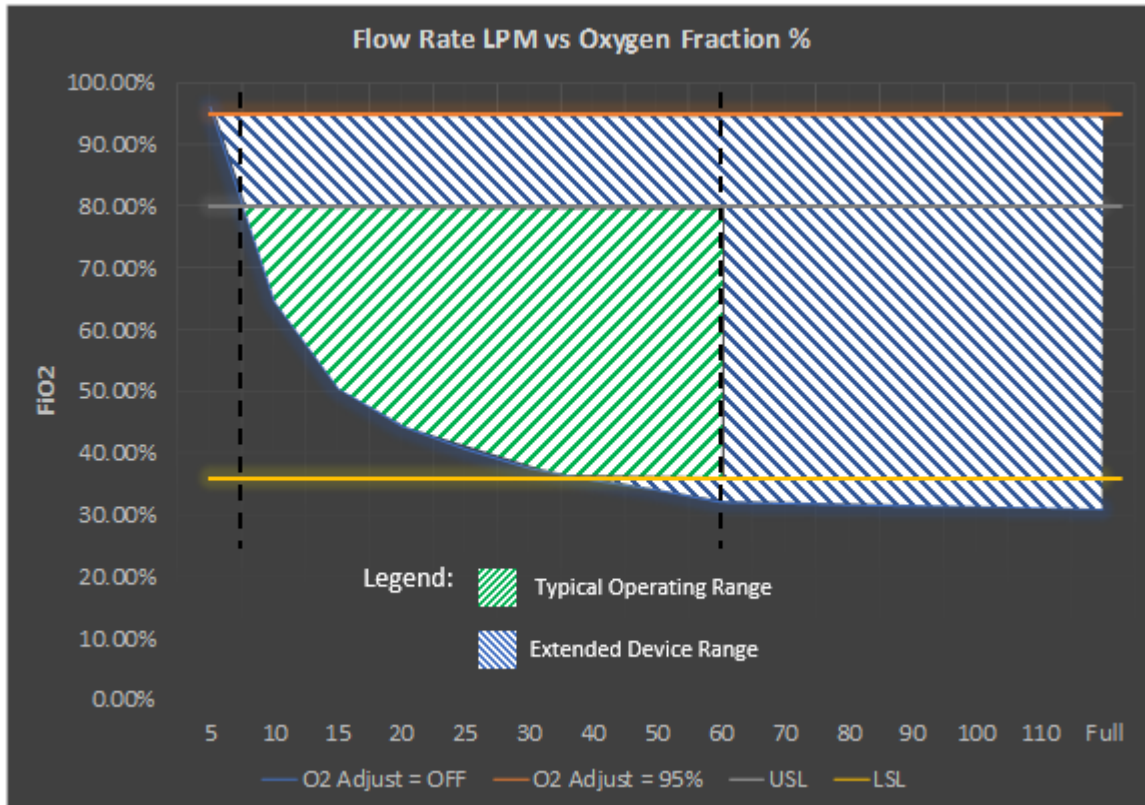


Fig. 19. Device Operating Range using a 10cmH₂O CPAP valve

Personnel Training Video

Training video on the use of the UCL Ventura system is available here:

<https://youtu.be/o6WkHwUI4U8>



Re-supply of Consumable Accessories

The breathing circuit configuration is designed to minimize pressure drop and oxygen consumption when used with the UCL Ventura flow generator.

To re-order consumables, contact your distributor.

Reference for Oxygen Supply Assessment

Additional guidance for oxygen sources and distribution for COVID-19 treatment centers from World Health Organization (WHO) for health facility administrator, clinical decision makers, procurement officers, planning officers, biomedical engineers, infrastructure engineers and policy-makers is available at:

<https://www.who.int/publications/i/item/oxygen-sources-and-distribution-for-covid-19-treatment-centres>



Additional guidance for hospital oxygen supply assessment from the UK Medicines & Healthcare products Regulatory Agency (MHRA) and National Health Service (NHS) Central Alert System (CAS) regarding use of high flow oxygen therapy devices during the COVID-19 pandemic for medical directors, critical care directors and respiratory and acute medicine director is available at:

<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103013>



Reference Materials

Background materials on the clinical guidance as regards the use of CPAP systems to treat COVID-19 patients with respiratory complications are available for reference.

<p>Reference on practicalities of a CPAP strategy in the COVID-19 pandemic by Dr. Ronan Astin: https://www.global-imi.com/sites/default/files/UCL%20Reference%20%20-%20Ronan%20Astin%20Pres.pdf</p>	
<p>COVID-19: the role of CPAP by Prof. Mervyn Singer, and international guidance on the UCL-Ventura: https://www.global-imi.com/sites/default/files/UCL%20Reference%20%20-%20Mervyn%20Singer%20Pres.pdf</p>	
<p>Reference on how to use CPAP to treat COVID-19 patients, webinar conducted by the University College London: https://youtu.be/2Go0h4UkQwM</p>	
<p>Guidance for the role and use of non-invasive respiratory support in adult patients with COVID-19 (confirmed or suspected) published by the UK NHS: https://www.global-imi.com/sites/default/files/UK%20NHS%20Reference%20%20-%20specialty-guide-NIV-respiratory-support-and-coronavirus-v3_.pdf</p>	
<p>International Guidance on the use of UCL Ventura from University College London: https://www.global-imi.com/sites/default/files/UCL%20References%20%20-%20International%20Guidance%20for%20UCL_Ventura%20v4.0.pdf</p>	

UCL Ventura Flow Generator Outline Drawing

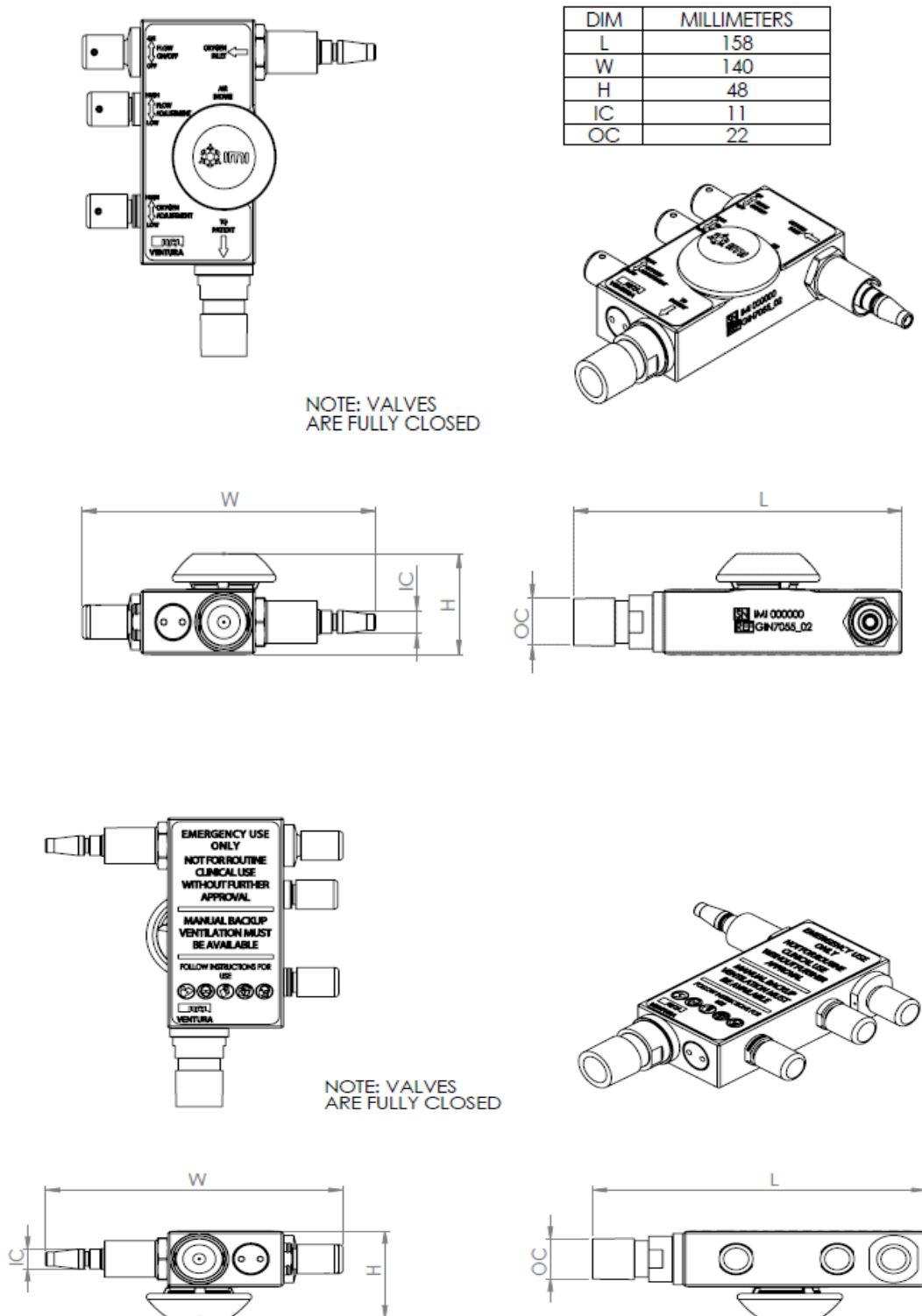
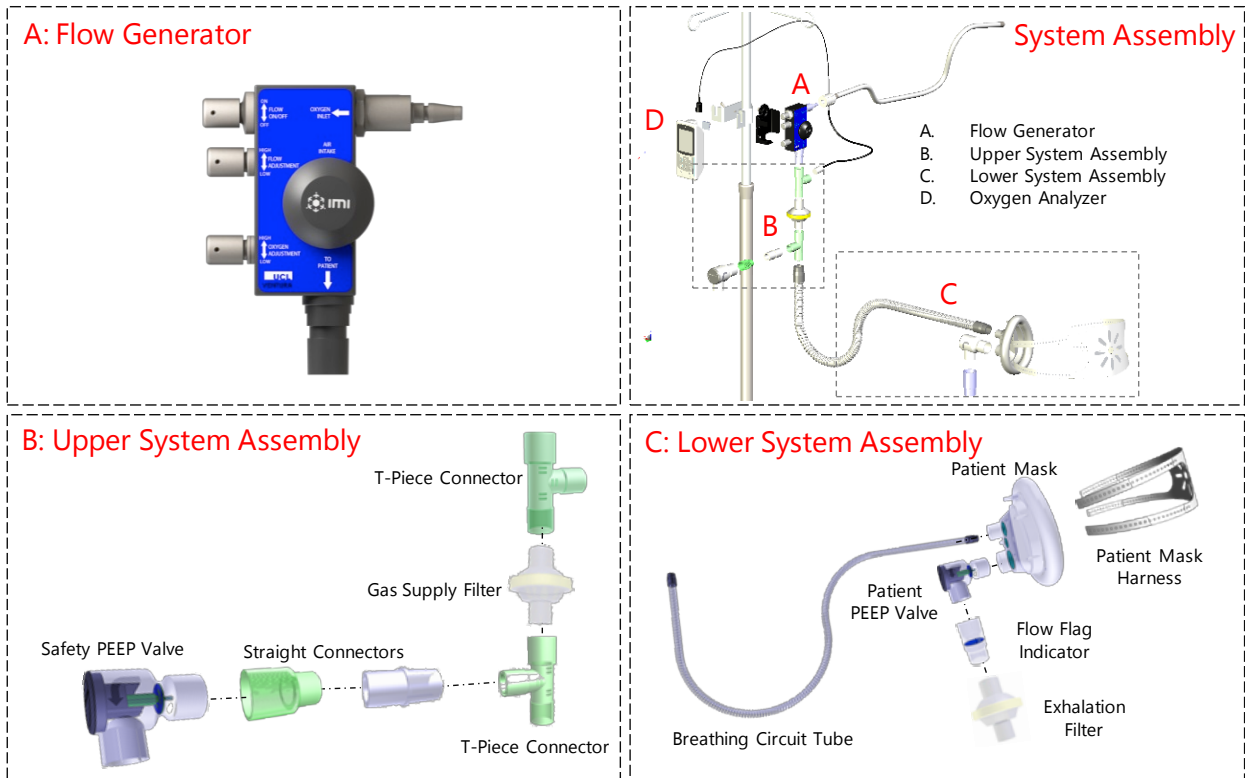


Fig. 20. UCL Ventura Flow Generator Outline Drawing

Patient Circuit Guide



Note: IV Pole is not included, and should be provided by the user. See the following Parts List section on p.25 for the detailed list.

Fig. 21. Patient Circuit Guide

Parts List

Item	Item Description	Quantity	Recommended Frequency of Change
Flow Generator¹			
1	UCL Ventura Flow Generator	1	As necessary
Accessories¹			
2	Flow Generator Holder	1	As necessary
3	IV pole clamp + wing screw	1	As necessary
4	Oxygen Analyzer mounting bracket	1	As necessary
5	Oxygen hose, BS Schrader to DISS, Hand-tight nut	1	As necessary
	Oxygen hose, BS Schrader to Ohmeda Probe		
6	Oxygen Analyzer	1	As necessary
Patient Circuit: Upper System Accessories Kit²			
7	T-piece connector, 22F-22M/15F-22F	2	Per Patient / As necessary
8	Bacterial and viral filter, 22F-22M (Gas Supply Filter)	1	Per Patient / As necessary
9	Straight connector, 22F-22F	1	Per Patient / As necessary
10	Straight connector, 22M-30M	1	Per Patient / As necessary
11	Safety PEEP valve, 20 cmH ₂ O, 30F-30M (Option 1)	1	Per Patient / As necessary <i>*See Table 1, "Recommended PEEP Valve rating combinations" matrix for reference.</i>
Patient Circuit: Lower System Accessories Kit²			
12	Breathing circuit tube, smooth bore 1.8m, 22M	1	Per Patient / As necessary
13	Twin ported mask, medium-large	1	Per Patient / As necessary
14	Mask harness, medium-large	1	Per Patient / As necessary
15	Patient PEEP valve, 10 cmH ₂ O, 30F-30M (Option 1)	1	Per Patient / As necessary <i>*See Table 1, "Recommended PEEP Valve rating combinations" matrix for reference.</i>
16	Flow flag indicator, 30F-22F	1	Per Patient / As necessary
17	Bacterial and viral filter, 22F-22M (Exhalation Filter)	1	Every 24 hours
Patient Circuit: Spare Accessories Kit²			
8/17	Bacterial and viral filter, 22F-22M	6	Every 24 hours / As necessary
11	Safety PEEP valve, 15 cmH ₂ O, 30F-30M	1	Per Patient / As necessary
13	Twin ported mask, small	1	Per Patient / As necessary
14	Mask harness, small	1	Per Patient / As necessary
15	Patient PEEP valve, 5 cmH ₂ O, 30F-30M	1	Per Patient / As necessary

Table 4. Detailed Parts List

¹ Reusable

² Non-Sterile and Single Use

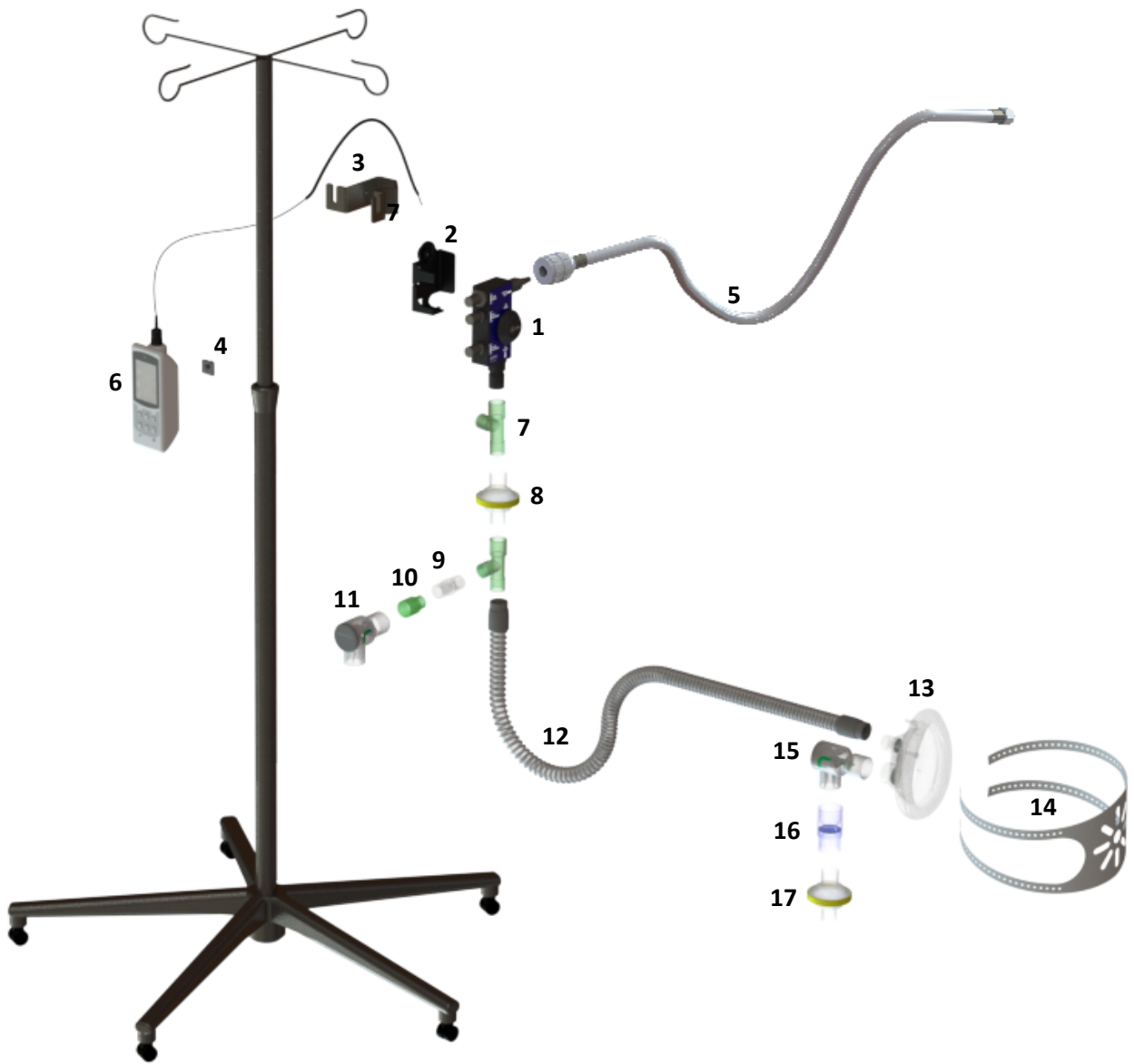


Fig. 22. Parts List Overview

Risk Analysis on the Use of UCL Ventura in the COVID-19 Pandemic

Area Affected	Potential Risk	Risk Management
Environmental Safety	COVID-19 healthcare worker transmission	<ul style="list-style-type: none"> Ensure that all staff caring for COVID-19 patients are provided with personal protective equipment. Attach a suitable viral filter at the expiratory limb of the circuit.
	Aerosolizing the virus	<ul style="list-style-type: none"> Perform procedures in an airborne infection isolation room. Seek collaboration with local infection control expertise. (Tests in the UK have shown that exhaled air from Ventura show zero instances of bacteria).
	Patient cross-infection	<ul style="list-style-type: none"> All COVID-19 patients receiving CPAP treatment should be placed in the same area with other COVID-19 patients. Follow guidelines for decontamination of equipment that has come into contact with COVID-19 patients, particularly the non-disposable parts..
Patient Safety	Patient CO2 rebreathing	<ul style="list-style-type: none"> Specified patient mask (accessory) has a fail-safe valve.
	Inspired oxygen fraction	<ul style="list-style-type: none"> Place an oxygen analyzer in the inspiratory limb of the circuit to allow oxygen to be accurately titrated according to individual patient needs.
	Over-pressure and barotrauma	<ul style="list-style-type: none"> Add a second safety valve, rated at 5-20 cmH₂O above CPAP, in the inspiratory limb to release the pressure.
	Hospital oxygen supply depletion	<ul style="list-style-type: none"> Monitor for any pressure drop across the pipe network and monitor oxygen utilization. Work closely with the hospital engineering team to monitor and evaluation supply and demand.
	Device failure	<ul style="list-style-type: none"> Monitor every patient using the device (continuous oxygen saturations and other vitals) and in an appropriate environment where staff are trained to look out for and respond to deterioration. Report any device failure immediately through trust reporting mechanisms and to the manufacturer. Quarantine all failed devices immediately and cease the use of that device until the failure is addressed. Central reporting mechanism will initially collect safety concerns from the testing sites . Following a wider deployment, a similar reporting mechanism will identify common issues that may lead to urgent advisories or withdrawal of device.

Administration and Management	Inappropriate use	<ul style="list-style-type: none"> • Use the device only in suitable and appropriate settings. • Train staff in the use of the CPAP and the UCL Ventura in his patient population. • Provide hands-on training to all staff, providing deployment scales up. This will use a train-the-trainer approach as there is still an institutional memory for the device. • Provide instruction manuals and visual aids. • Provide pre-assembled disposable circuits to reduce the risk of inappropriate assembly.
	Clinical deterioration	<ul style="list-style-type: none"> • Provide staff with a clear escalation pathway, escalating concerns to the Critical Care team and the Critical Care Outreach team. • Provide staff with regular monitoring and clear pathways for step up and step down.

Table 5. Risk Analysis on the Use of UCL Ventura in the COVID-19 Pandemic



Risk, Warranty, and Liability Information

Additional Risks Associated with Use of UCL Ventura. After training has been conducted for the benefit of the User and has accepted the UCL Ventura, User assumes all risks associated with the use or misuse thereof. As such, User is fully responsible for ensuring that the UCL Ventura is used only in a safe and proper manner, by properly trained and licensed individuals, and in full compliance with all specifications and instructions for use provided by IMI. IMI does not provide or make any assurances regarding the efficacy of medical treatment using UCL Ventura.

Warranty and Liability Provisions

Limited Warranty. IMI warrants that this UCL Ventura is free from defects in materials and workmanship under normal usage and in accordance with the prescribed instructions in this Manual. This Limited warranty shall continue for a period of 12 months (the “Warranty Period”). During the warranty period, User’s exclusive remedies (and IMI’s exclusive liabilities) for a warranty claim are limited to repair, replacement or refund, at the option of IMI.

IMI shall not be liable for any alleged defect arising from or in relation to: (i) the use of UCL Ventura in combination with any software, tools, hardware, equipment, supplies, accessories or any other materials not recommended in writing by IMI; (ii) the normal wear and tear of the UCL Ventura; (iii) shipping, storage or working conditions after delivery of the UCL Ventura by IMI to User; (iv) User’s failure to follow IMI’s usage restrictions, recommendations and instructions; (v) any alteration, modification, repair or enhancement of the UCL Ventura by any party; (vi) any misuse of the UCL Ventura or any use of the UCL Ventura not in accordance with IMI’s specifications; and (vii) a force majeure event.

A UCL Ventura replaced under this warranty shall be warranted for the remaining unexpired period of warranty only.

Exclusions. All other warranties as to quality, condition, description, fitness for purpose, merchantability or non-infringement are hereby expressly excluded and disclaimed by IMI. IMI hereby expressly disclaims and User hereby expressly waives any warranty regarding the effectiveness of the UCL Ventura to achieve specific results. Results may vary based on factors beyond the control of IMI.

IMI’s warranty excludes the repair or replacement of any accessories, or consumable items or parts needed for the normal operations of the UCL Ventura.

User’s Indemnification Obligation. User agrees to indemnify and defend IMI (including its parent, subsidiaries, and related companies and its and their officers, directors, employees, agents, and consultants) from and against all losses, expenses, damages, demands, claims, suits, and other liabilities (including, without limitation, reasonable attorneys’ fees) arising out of (i) any bodily injury, death, or property damage which occurs, either directly or indirectly, in connection with User’s handling or use of the UCL Ventura in a manner or environment, or for any purpose, for which IMI did not design it, or in violation or deviation of IMI’s written recommendations or instructions.

Limitations on IMI’s Liability. IMI shall be liable (i) only for the actual cost of the repair or replacement of products which do not conform to specifications, or (ii) at IMI’s sole option, to refund the amount paid by User for the UCL Ventura.



IN NO EVENT SHALL IMI BE LIABLE FOR ANY INDIRECT, CONSEQUENTIAL, EXEMPLARY, SPECIAL, INCIDENTAL OR PUNITIVE DAMAGES OF ANY KIND HOWEVER CAUSED (INCLUDING FAULT OR NEGLIGENCE) ARISING OUT OF, OR IN CONNECTION WITH THE USE OF THE UCL VENTURA, INCLUDING WITHOUT LIMITATION, LOSS OF PROFITS, GOODWILL OR BUSINESS INTERRUPTION.