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Respiratory Care Products

Catalog & Technical Guidance

2020-2021

for sales & technical support, please contact:

Michael Lombardi
Lombardi Undersea LLC
sales@oxygentreatmenthoods.com

Covid-19 Pandemic Response

Dear colleagues,

In March 2020, Subsalve USA was called upon to contribute to the emergent need for much needed respiratory assistance products given supply shortfalls associated with the Covid-19 pandemic.

With 40 years of experience in the field of high performance engineered inflatable products, Subsalve set out to rapidly design, prototype, and bring to market its first medical device, the Subsalve Oxygen Treatment Hood. This call to action was met without hesitation, speaking to the company's long standing reputation of integrity, willingness to invest in the future, and commitment to its community.

The device went on to receive emergency use authorization by the US Food and Drug Administration (FDA EUA) in August 2020, making it the first US domestically manufactured device of this type authorized for the treatment of respiratory distress.

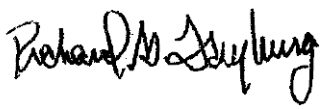
Within a few short months, the Subsalve Oxygen Treatment Hood reached more than 20 countries, and has become widely recognized as an impactful tool for respiratory care, as well as a frontrunner for related research and development through a variety of academic and institutional collaborations.

Respiratory therapies via oxygen hood is a rapidly emerging field, and Subsalve is committed to advancing its position as a market leader in the US and internationally by continuing to introduce innovative solutions, and promoting information exchange within the medical community.

The enclosed information highlights the company's current product offerings, including a variety of accessory items, as well as technical guidance towards effective implementation of this technique.

The entire Subsalve team thanks you for considering our products, and we look forward to supporting you through the Covid-19 pandemic and beyond.

Respectfully,



Richard Fryburg
Founder & Chief Growth Officer

Contents

Overview

The enclosed product and accessory component information is provided to help guide informed purchase decisions. None of the enclosed information should be construed as a medical protocol or prescription for treatment, and is presented solely as technical guidance to configure the Subsalve Oxygen Treatment Hood for use.

Contents

Important Safety Notes

- Review the IFU for the Subsalve Oxygen Treatment Hood before use.
- Review the medical literature for the current state of the art and best practices for hooded/helmet non-invasive ventilation techniques.
- The end-user must recognize that minimum flows are required for this treatment technique. The addition of any number of in-line circuit components adds resistance and can reduce flow. Review best practices to understand how to gauge and monitor flows, pressures, and delivered FiO2.

Acknowledgements

We express our sincerest thanks to practitioners at the University of Chicago Medical Center, Boston Medical Center, VA Boston Healthcare System, and Children's Hospital Colorado Anschutz for their technical advising and contributions to the enclosed guidance.

Subsalve Oxygen Treatment Hood

FDA authorized for emergency use (EUA) during the Covid-19 pandemic

The **Subsalve Oxygen Treatment Hood** (SS-TH) is a patient interface for the administration of respiratory care[1] using oxygen and positive pressure.

Benefits

•Establish positive airway pressure
•Deliver therapeutic oxygen
•Reduce virus aerosolization within healthcare worker environment

Features

•One-piece, no required assembly
•All soft materials for increased patient comfort
•Raised interior port stems to reduce fluid backflow
•Two 22mm port connections
•Service port for drinking, patient suction
•Adjustable under arm straps
•Latex and silicone neck seal options
•Single patient use
•FDA compliant raw materials

Versatility

Can be configured for use with CPAP, BiPAP, high flow, blenders, venturi, ventilators w/pressure support, and wall gasses.

Neck Seal Options (specify at time of purchase)

Material	Size	Neck circumference (inches)	Neck circumference (cm)	Note
Latex	S	8.5” - 11”	21cm – 28cm	Trim for comfort
Latex	M	9” - 13”	23cm – 33cm	Trim for comfort
Latex	L	11” - 13”	28cm – 33cm	Trim for comfort
Latex	XL	13” – 17+”	33cm – 43cm+	Trim for comfort
Silicone	Universal - L	11” – 17+”	28cm – 43cm+	Trim for comfort
Silicone	Universal - S	9 – 13+”	23cm – 33cm+	Trim for comfort

1 Respiratory Care using Oxygen Hoods is referred to NIPPV, Hooded/Helmet NIV, Hooded/Helmet CPAP, H-CPAP, hCPAP, helmet based ventilation, and other terms.

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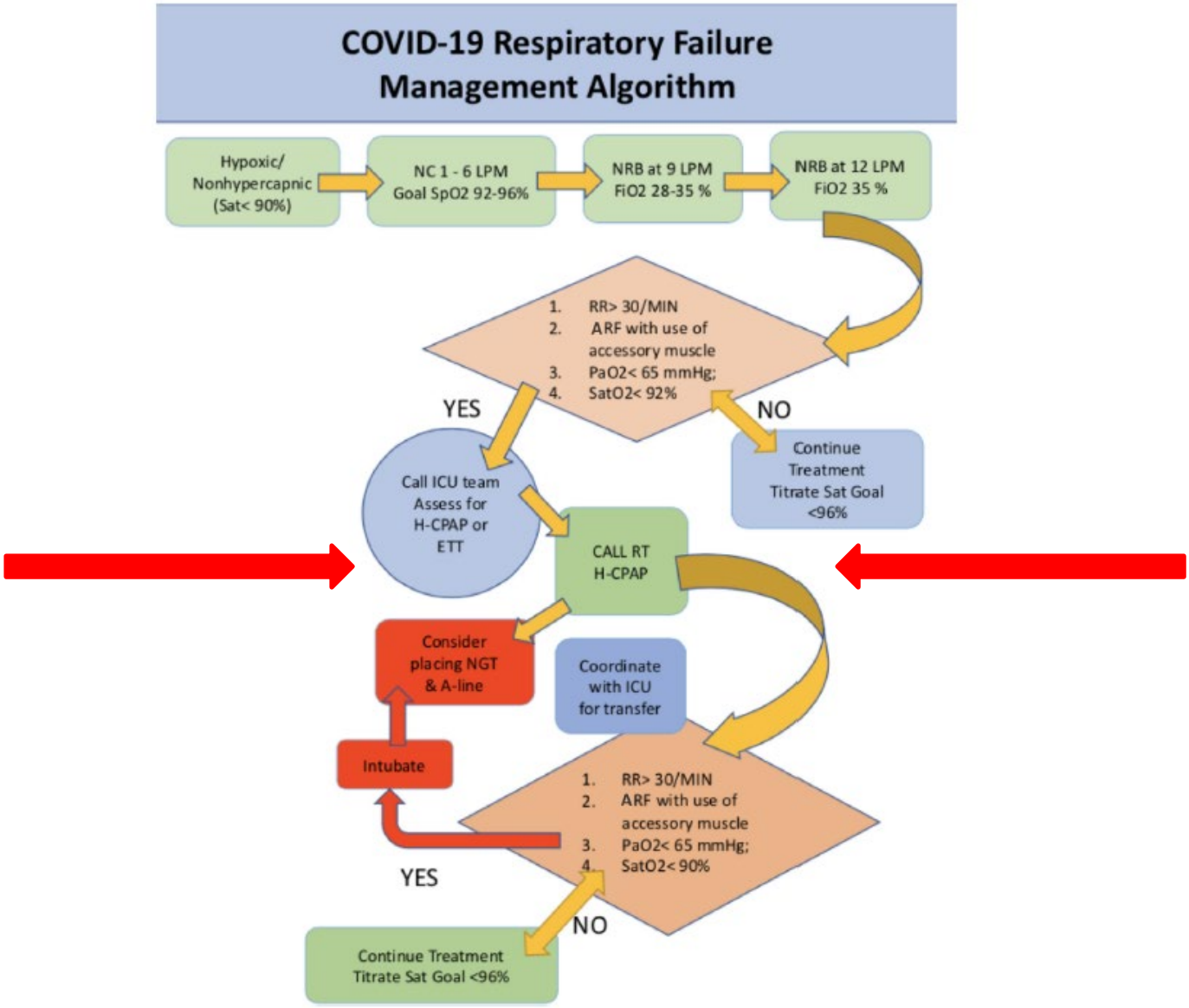
When to Use

Respiratory therapies using the Subsalve Oxygen Treatment Hood are being used for both CPAP and bilevel pressure support. These therapies can be implemented with many different configurations.

The most recent research[1] in the area suggests the below treatment algorithm:



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1 H. Amirfarzan, M. Cereda, T.G. Gaulton, K.B. Leissner, A. Cortegiani, R. Schumann, C. Gregoretti. Use of Helmet CPAP in COVID – A practical review. Pulmonology, 2021, ISSN 2531-0437. https://doi.org/10.1016/j.pulmoe.2021.01.008. (https://www.sciencedirect.com/science/article/pii/S2531043721000404)

Getting Started

To get started, at a minimum, a flow source is needed to drive the Subsalve Oxygen Treatment Hood. The limb circuit configuration to connect the flow source to the hood will vary somewhat depending on the source device type. A variety of configurations are presented throughout this guide for use with the following:

- Wall-gasses only (both air and oxygen)
- CPAP devices
- High flow oxygen venturi
- BiPAP v60 or equivalent devices
- Dual-limb ventilators

Delivery of oxygen as a supplement to the flow source may enhance the therapeutic benefits of treatment by boosting FiO2. Oxygen requirements should be considered in advance since it may be a limiting resource in some settings. The below chart provides expected cylinder durations for each of the commonly found medical oxygen cylinders across varying flow rates.

The oxygen flow volumes required to achieve desired FiO2 varies depending on the flow source and setup configuration. Review the enclosed charts with each technique for further guidance.

Medical Oxygen Cylinder Durations for HPAP treatment

common cylinders	fluid capacity (L)	fill pressure (bar)	fill pressure (psi)	free liters of O2	cylinder duration (minutes)			
					60lpm flow	30lpm flow	15lpm flow	10lpm flow
M265	46.4	153	2249	7503	125	250	500	750
M150	28.9	139	2043	4248	71	142	283	425
M122	21.4	153	2249	3455	58	115	230	346
M90	15.7	153	2249	2549	42	85	170	255
M60	10.5	153	2249	1699	28	57	113	170
ME	4.6	139	2043	680	11	23	45	68
M22	3.9	153	2249	623	10	21	42	62
MD	2.9	139	2043	425	7	14	28	43
M90	1.7	139	2043	255	4	9	17	26
M7	1.4	139	2043	198	3	7	13	20
ML6	1.2	139	2043	170	3	6	11	17
M6	1	153	2249	170	3	6	11	17
M4	0.7	153	2249	113	2	4	8	11
M2	0.3	153	2249	45	1	2	3	5

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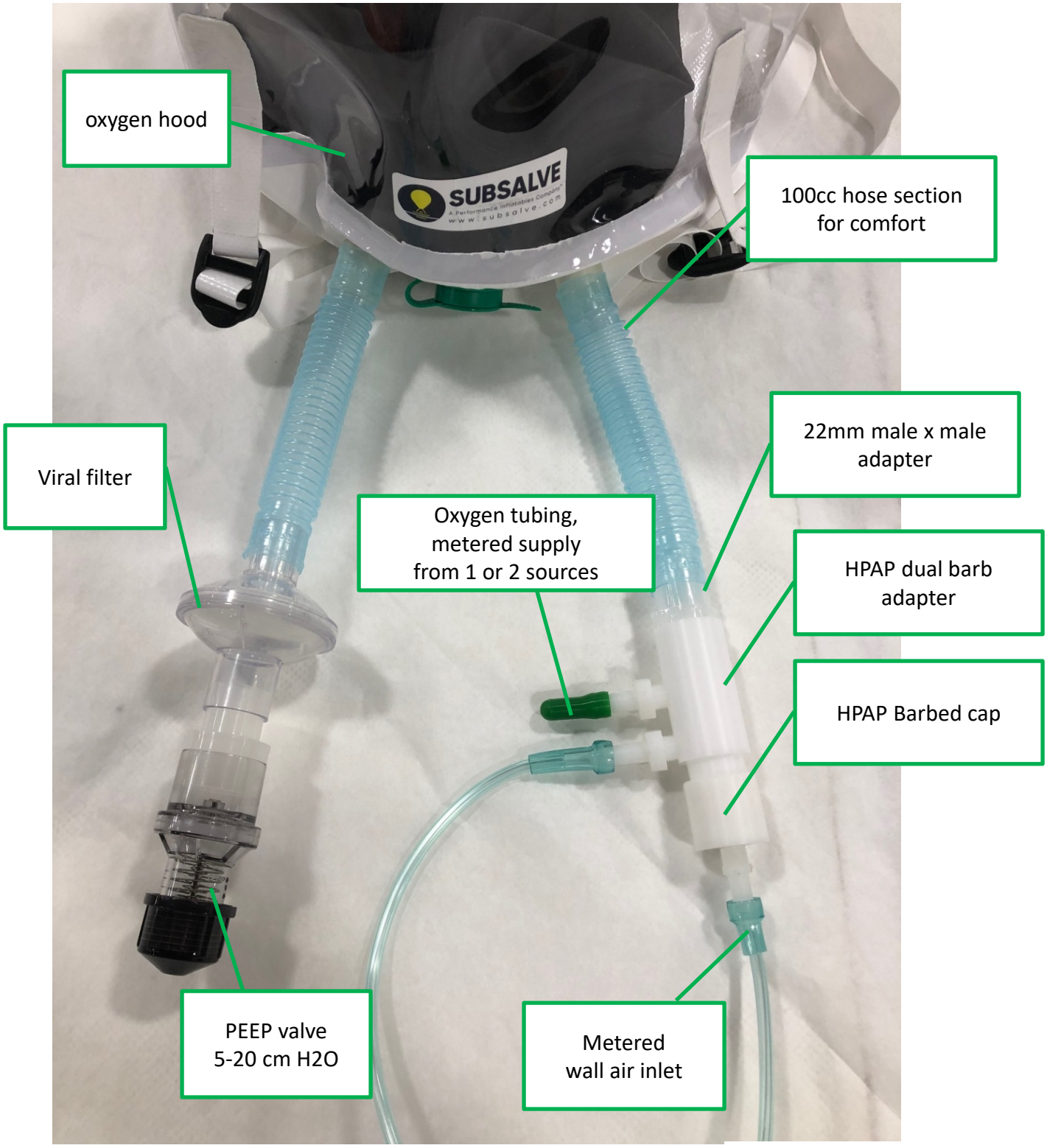
Configuration Guidance

The enclosed materials present considerations for respiratory therapy using oxygen and positive pressure. The actual setup used should be determined by the implementing clinician based on the high flow source.

Note: follow clinical guidance for implementing treatment using Pressure, Flow, and FiO2 adjustments.

Wall Gas Titration Configuration Guide

The below presents a simplified circuit for titrating wall gasses (air and oxygen) to deliver positive pressure and elevated FiO2.



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Wall Gas Titration Configuration Guide

High Flow Air & Oxygen Titration (wall gas only)

Flow introduced in to HPAP system				Total Flow (LPM)	FiO2
Air supply (LPM)	Oxygen supply 1 (LPM)	Oxygen supply 2 (LPM)	Oxygen supply 3 (LPM)		
120				120	0.21
100	0			100	0.21
100	5			105	0.25
100	10			110	0.28
100	20			120	0.34
60	0			60	0.21
60	5			65	0.27
60	10			70	0.32
60	20			80	0.41
60	30			90	0.47
60	30	5		95	0.50
60	30	10		100	0.53
60	30	20		110	0.57
60	30	30		120	0.61
30	30			60	0.61
30	30	5		65	0.64
30	30	10		70	0.66
30	30	20		80	0.70
30	30	30		90	0.74
30	30	30	5	95	0.75
30	30	30	10	100	0.76
30	30	30	20	110	0.78
30	30	30	30	120	0.80
15	30	20		65	0.82
15	30	30		75	0.84
15	30	30	5	80	0.85
15	30	30	10	85	0.86
15	30	30	20	95	0.88
15	30	30	30	105	0.89
10	30	30		70	0.89
10	30	30	5	75	0.89
10	30	30	10	80	0.90
10	30	30	20	90	0.91
10	30	30	30	100	0.92
5	30	30		65	0.94
5	30	30	5	70	0.94
5	30	30	10	75	0.95
5	30	30	20	85	0.95
5	30	30	30	95	0.96
	30	30		60	1.00
	30	30	5	65	1.00
	30	30	10	70	1.00
	30	30	20	80	1.00
	30	30	30	90	1.00

Assumptions

FiO2 is calculated; analytical results may vary
120 LPM max gas flow
30 LPM max O2 flow per supply
60 LPM required to mitigate CO2 rebreathing

Color Legend

minimum to prevent CO2
total flow
oxygen
sufficient flow alone
insufficient flow alone

Notes

•>60LPM total flow is required for mitigating CO2 rebreathing.

•This flow can be made up from multiple wall-gas sources with known flow rates.

•It is recommended to humidify one of the oxygen supplies.

Instructional Guidance

Configuration

•Configure hood as pictured. Change filter every 8 hours or as needed.

Flow

•Establish flow to >60LPM. Flow is gauged as the sum from all wall flowmeters.

Pressure

•Use the PEEP valve (5-20 cmH2O) to regulate positive pressure at the patient.

Oxygen/FiO2

•Select desired FiO2 using the table and adjust flow sources (blending of air and oxygen).

•If adjusting FiO2, maintain at least the flow columns in yellow while transitioning to ensure adequate flow.

Monitor

•Monitor PEEP pressure using a manometer in the circuit if desired.

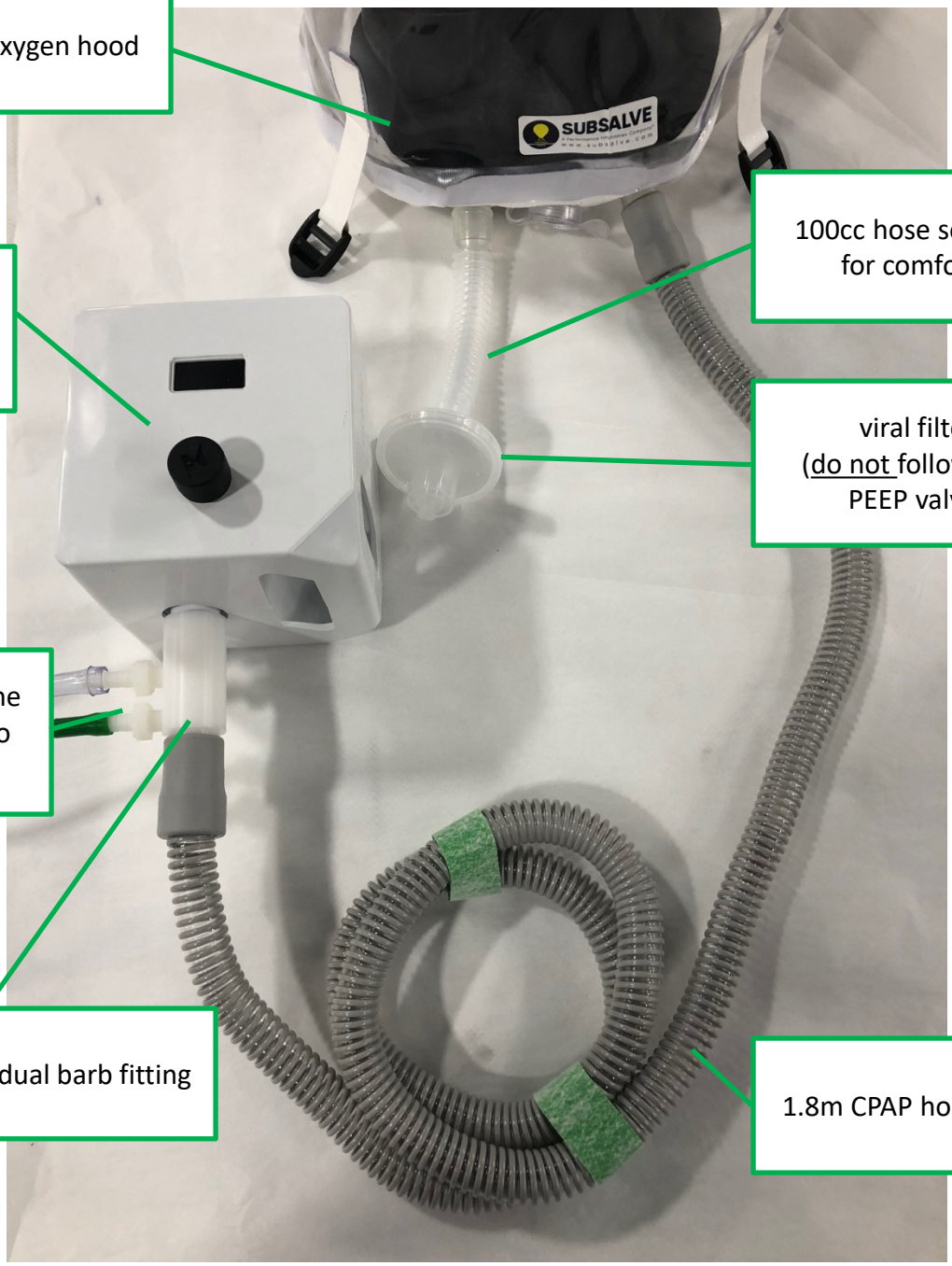
•Monitor patient vitals and oxygen saturation.

Treatment

•Implement treatment and monitor patient according to clinical best practices.

Hood+CPAP Configuration Guide for nHale

The below circuit allows delivery of positive pressure with elevated FiO2 using the nHale CPAP device.



Important Safety Note:
DO NOT use this circuit setup or guidance for other makes/models of CPAP devices. Configuration may vary. Contact us for assistance.

Hood+CPAP Configuration Guide for nHale

Instructional Guidance

Configuration

- •Read IFU documents for both the Subsalve Oxygen Treatment Hood and Nanotronics Health nHale (**15vdc power supply**).
- •Set-up complete circuit as pictured, including 1 or 2 oxygen flow sources (user provided). DO NOT DEVIATE SETUP.
- •If only one oxygen flow source is used and a barb is left unused on the titration valve, cap off the unused barb.

Flow & Pressure

- •Reference below chart for the 4 step operation sequence.
- •Set nHale to operate in 'CPAP mode' and preset desired pressure setting (device PEEP). Default is 8 cm H2O.

Oxygen/FiO2

- •Adjust FiO2 as desired by increasing or decreasing oxygen flow from your flowmeter.
- •Two oxygen sources may be used (one to each barb on the dual barb fitting) to elevate FiO2.

Monitor

- •Continuously monitor patient vitals and oxygen saturation.
- •Periodically verify system flow is >60LPM after the viral filter using digital Peak Flow Meter.
- •Change out viral filter as needed. Three are provided to afford two replacements during treatment.

Treatment

- •Implement treatment and continue to monitor patient according to clinical best practices.

Hood+CPAP Technique using nHale (CPAP mode)

	treatment PEEP (+/- 1 cm H2O)					
	3	5	7	8	9	11
device PEEP setting	4	6	8	10	12	14
O2 flow rate (LPM)		FiO2				
0	21	21	21	21	21	21
0.5	21	22	22	22	22	22
1	22	22	22	22	22	22
2	23	23	23	23	23	23
4	26	24	25	24	24	24
6	29	26	26	26	25	25
8	31	29	28	27	27	26
10	34	31	30	28	28	27
12	38	34	31	30	29	28
15	41	38	34	32	32	30
20	49	44	38	36	36	33
25	61	55	46	43	41	39
30	71	59	53	48	45	43
40		70	63	56	52	50

Step 1: choose patient PEEP

Step 2: set CPAP device PEEP

Step 3: choose desired FiO2

Step 4: set corresponding O2 flow rate

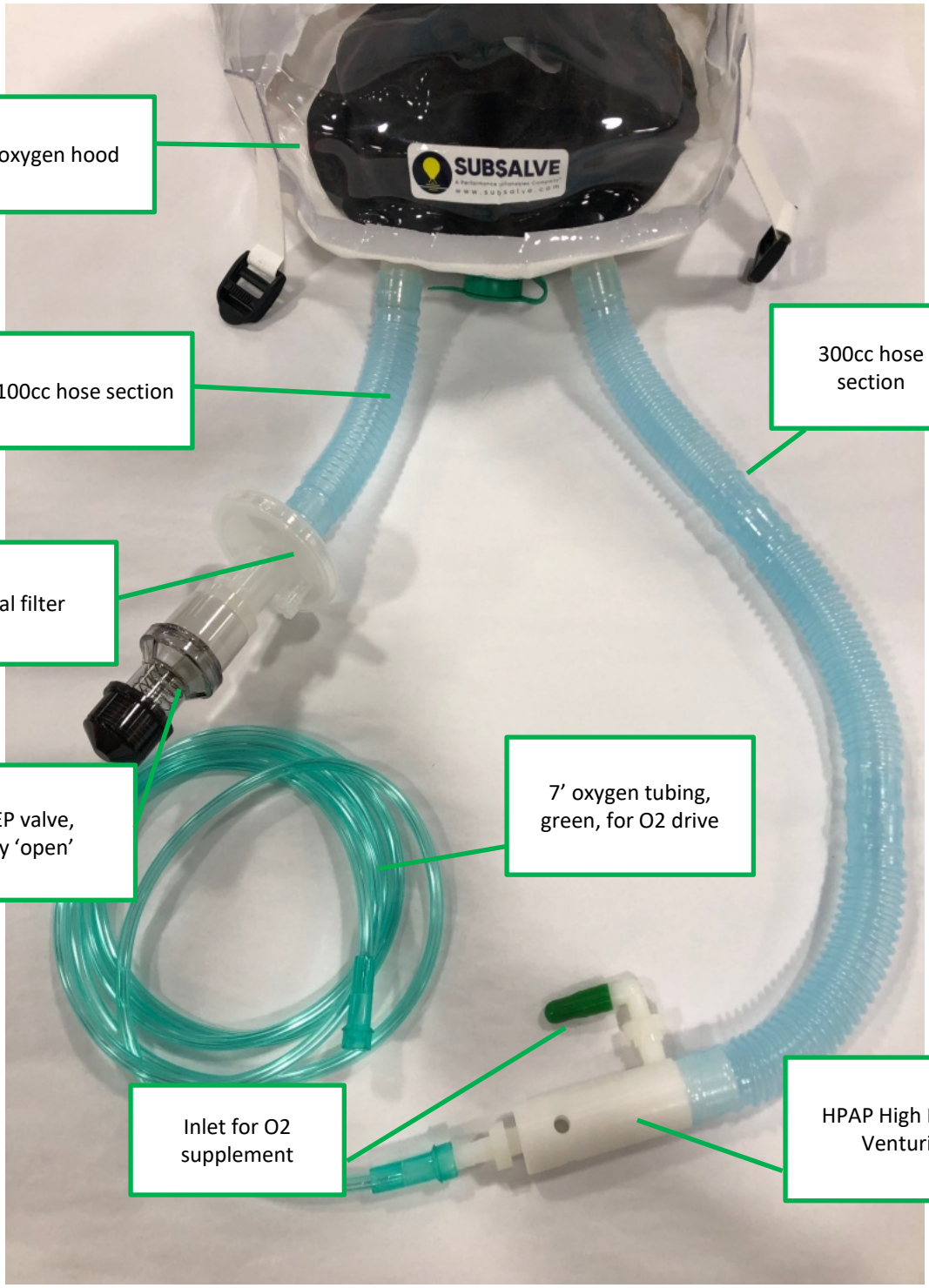
generated for educational purposes only

nHale in CPAP mode with 110vac to 15vdc power adapter
table developed analytically with specific circuit configuration
deviation from the tested circuit configuraiton may yield unverified results
FiO2 measured using Maxtec O2 sensor, error +/- 0.6 bar
all values were verified at >60LPM flow

Important Safety Note: DO NOT use this chart or guidance for other makes/models of CPAP. Only applies to nHale w/15vdc supply.

Configuration Guide | HPAP High Flow Oxygen Venturi

The below circuit allows delivery of positive pressure and elevated FiO2 using the venturi method.



Configuration Guide | HPAP High Flow Oxygen Venturi

Instructional Guidance

Configuration

•Configure hood as pictured. Change filter every 8 hours or as needed.

Flow

•Establish drive flow using oxygen to 10LPM. Flow is gauged from the oxygen supply regulator.

Pressure

•Use a PEEP valve in the full OPEN position to provide minimal resistance. Pressures of 8-12 cm H2O are achieved with flow adjustment only.

Oxygen/FiO2

•Select desired FiO2 using the table and adjust flow sources (blending of entrained air and supplemental oxygen).

Monitor

•Monitor PEEP pressure using a manometer in the circuit (optional), or reference the chart as a guide.

•Monitor patient vitals and oxygen saturation.

Treatment

•Implement treatment and monitor patient according to clinical best practices.

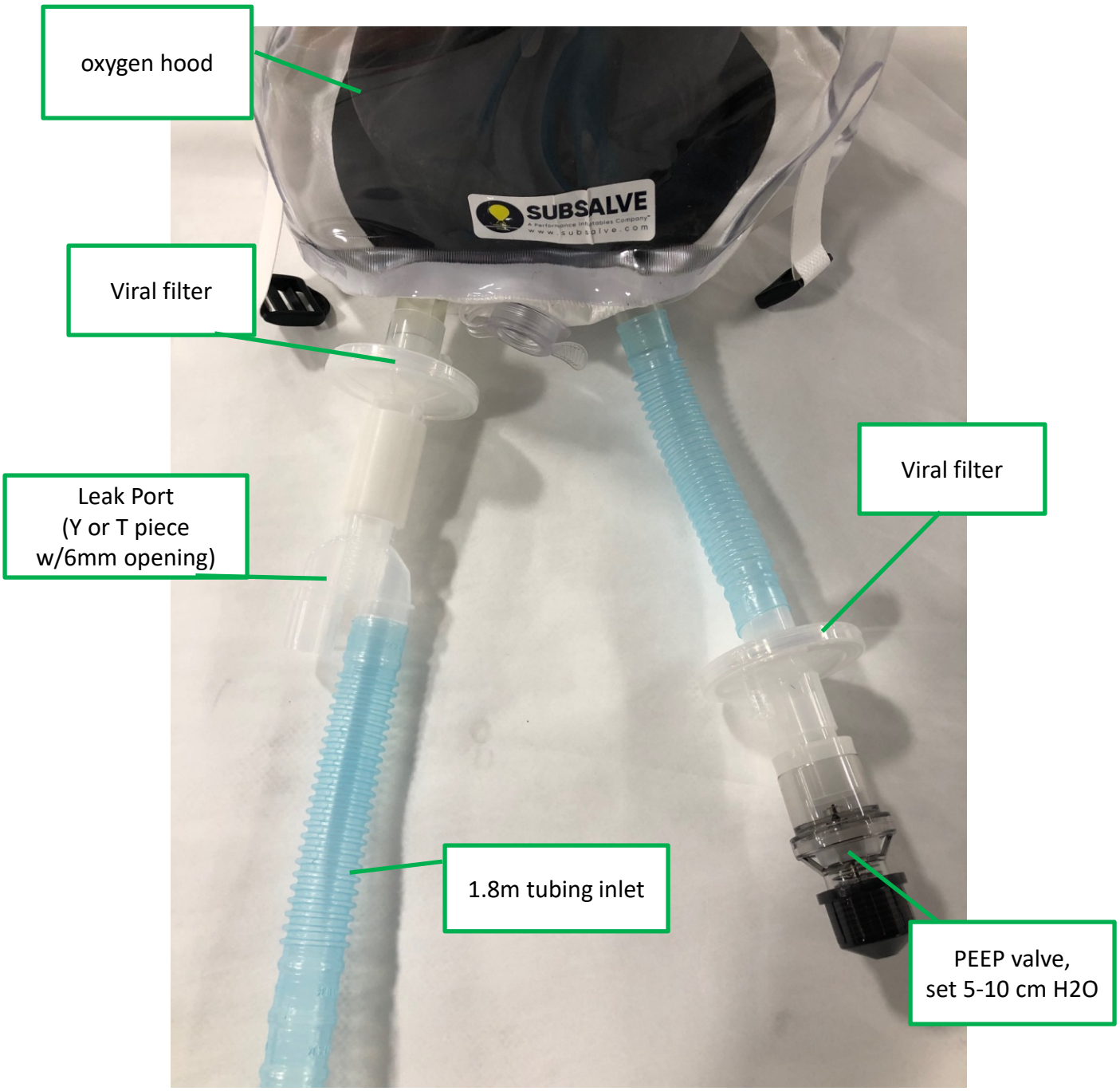
HPAP Oxygen Venturi - with PEEP valve in OPEN position

O2 drive LPM	O2 supplement LPM	delivered high flow (LPM)	delivered FiO2	Patient PEEP (cm H2O)
10	0	50	38	8
10	5	53	39	9
10	8	54	43	9
10	10	55	44	10
10	15	57	51	10
10	25	62	62	12

Table of flow, pressure, and delivered FiO2 values developed analytically with pictured circuit configuration.
Deviation from the tested circuit configuration may yield unverified results.
FiO2 measured using Maxtec O2 sensor, error +/- 0.6 bar.

BiPAP v60 or Equivalent Configuration Guide

The below circuit allows bilevel pressure support with the v60 BiPAP or device with comparable functionality.



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Configuration Guide | BiPAP v60 or Equivalent

Instructional Guidance

Configuration

•Configure hood as pictured. Use circuits and circuit accessories recommended for the v60 when available.

Flow

•Flow rates required for mitigating CO2 rebreathing are defined by the indicated 'Total Leak' from the v60.

Pressure

•Set the PEEP valve in the 5-10 cmH20 range. This allows for a small amount of resistance to flow necessary for the ventilator to function correctly.

•Turn on your ventilator. While in Standby mode, select "Menu" and then choose "Mask/Port". Select "Other" for mask and "DEP" for the port.

•Enter the desired mode/settings and adjust the alarm parameters accordingly.

Oxygen/FiO2

•If providing supplemental oxygen, reference the v60 user manual for appropriate delivery.

Monitor

•Monitor ventilator for normal function and alarms.

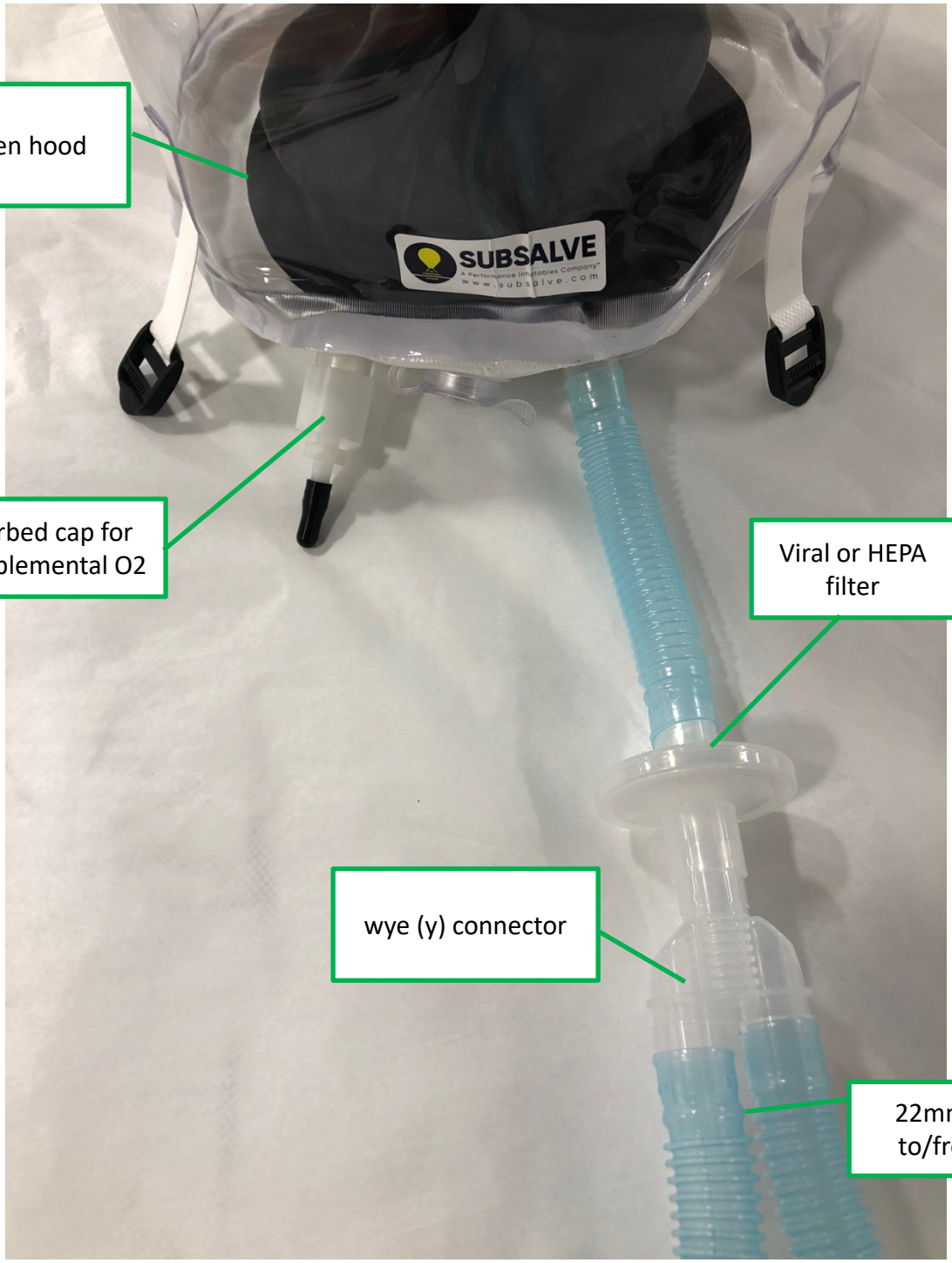
•Monitor patient vitals and oxygen saturation.

Treatment

•Implement treatment and monitor patient according to clinical best practices.

Hamilton Ventilator or Equivalent Configuration Guide

The below circuit allows bilevel pressure support with Hamilton Ventilators or devices with comparable functionality.



Configuration Guide | Hamilton Ventilators or Equivalent

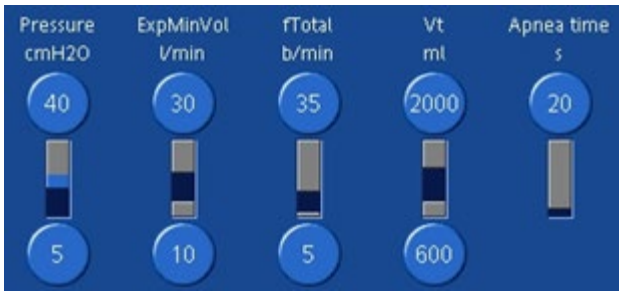
Instructional Guidance

Configuration

- •Configure hood as pictured. Do not use coaxial circuits.
- •Insert a bacterial/viral filter at the inspiratory and expiratory port of the ventilator.

Mode selections

- •If available, select NIV mode.
- •If there is no NIV option, consider using PCV+/PCMV.



Alarm settings

- •Adjust the alarm limits to avoid unnecessary alarming.

Mode controls

Note: Two ventilated compartments in sequence = hood + lungs.

•Pressure ramp	Set to the fastest speed possible
•PEEP	Target PEEP + 30%–50% Minimum PEEP 10 cmH2O to increase helmet stiffness
•P support	Target P support + 30% – 50% Minimum P support 12 cm H2O
•Inspiratory trigger	Start with 2 l/min and maintain as low as possible
•ETS	Start with default ETS of 25%, monitor for cycling asynchronies and adapt accordingly
•TI max	Set to 1.5 s to avoid late cycling
•Oxygen	Start with Oxygen = 60% and titrate based on SpO2. *Note: Single gas source (100% oxygen) may limit peak flow capacities*

Monitoring

•Tidal volume	Between 1,000 and 1,500 ml Note: ~ 50%–75% of the VT delivered is distributed to the helmet! (12)
•ExpMinVol	> 25 l/min to have sufficient CO2 washout. Efficiency can be monitored with PCO2 monitoring inside the hood.

Tips

- •Measure partial pressure of CO2 inside the helmet (PCO2h) in a "silent" part of the hood (e.g., place the sensor directly above the neck seal) to detect CO2 rebreathing. Use a mainstream or sidestream CO2 sensor from the ventilator or the monitoring system. PCO2h should not be above 5 mmHg/0.6 kPa.
- •If CO2 rebreathing is suspected, add a supplemental flow of > 10 l/min via the barbed cap placed on the unused port on the hood.
- •Increase pressurization by activating TRC (100%)

Treatment

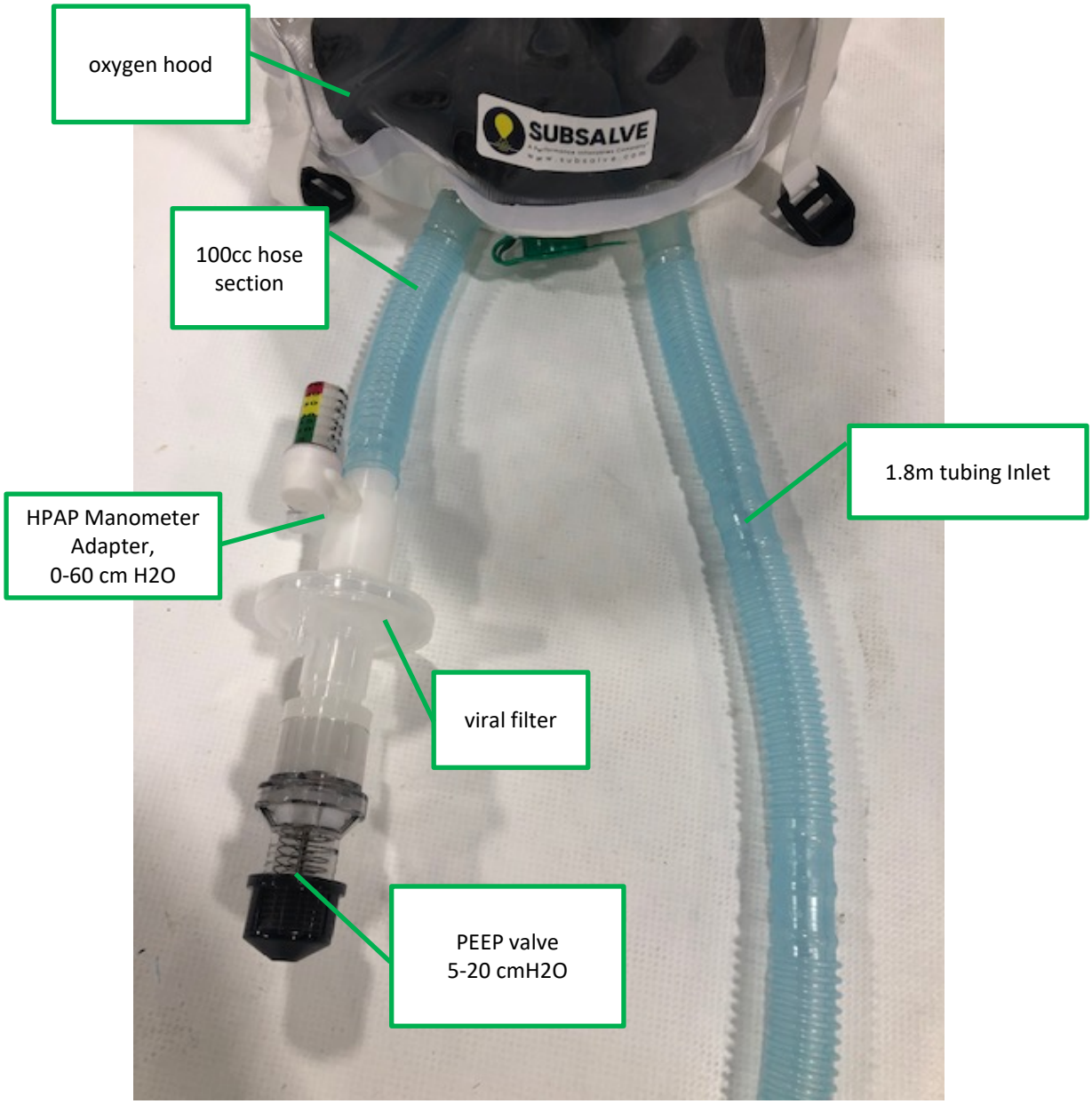
- •Implement treatment and monitor patient according to clinical best practices.

Adapted from: https://www.hamilton-medical.com/en_US/E-Learning-and-Education/Knowledge-Base/Knowledge-Base-Detail~2020-04-22~Helmet-NIV-%28NIPPV%29-ventilation-on-adult-COVID-19-patients~ad615df8-e219-412c-bbd2-61b5390ab736~.html. Accessed 02/23/2021.

Configuration Guide | addition of Analog Manometer

An analog manometer may be added to the breathing circuit on the expiratory limb when additional verification of delivered PEEP is desired.

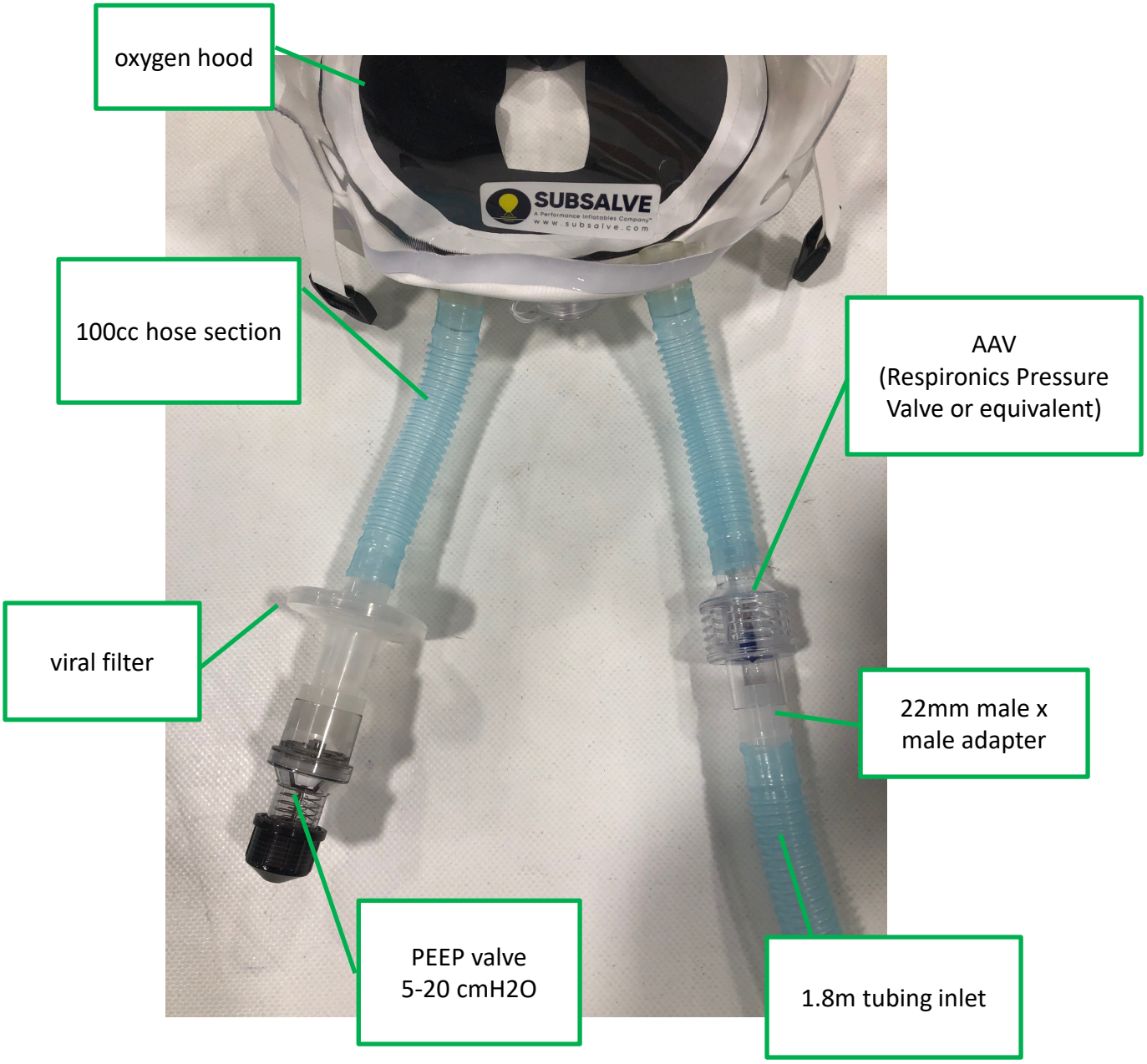
This is most useful when delivering pressure with devices that do not electronically control for pressure, such as wall-gas titration or venturi techniques.



Configuration Guide | addition of Anti-asphyxia valve (AAV)

An AAV may be added to the respiratory circuit on the inspiratory limb. The component should fail 'open' to permit fresh air exchange if the primary flow source fails.

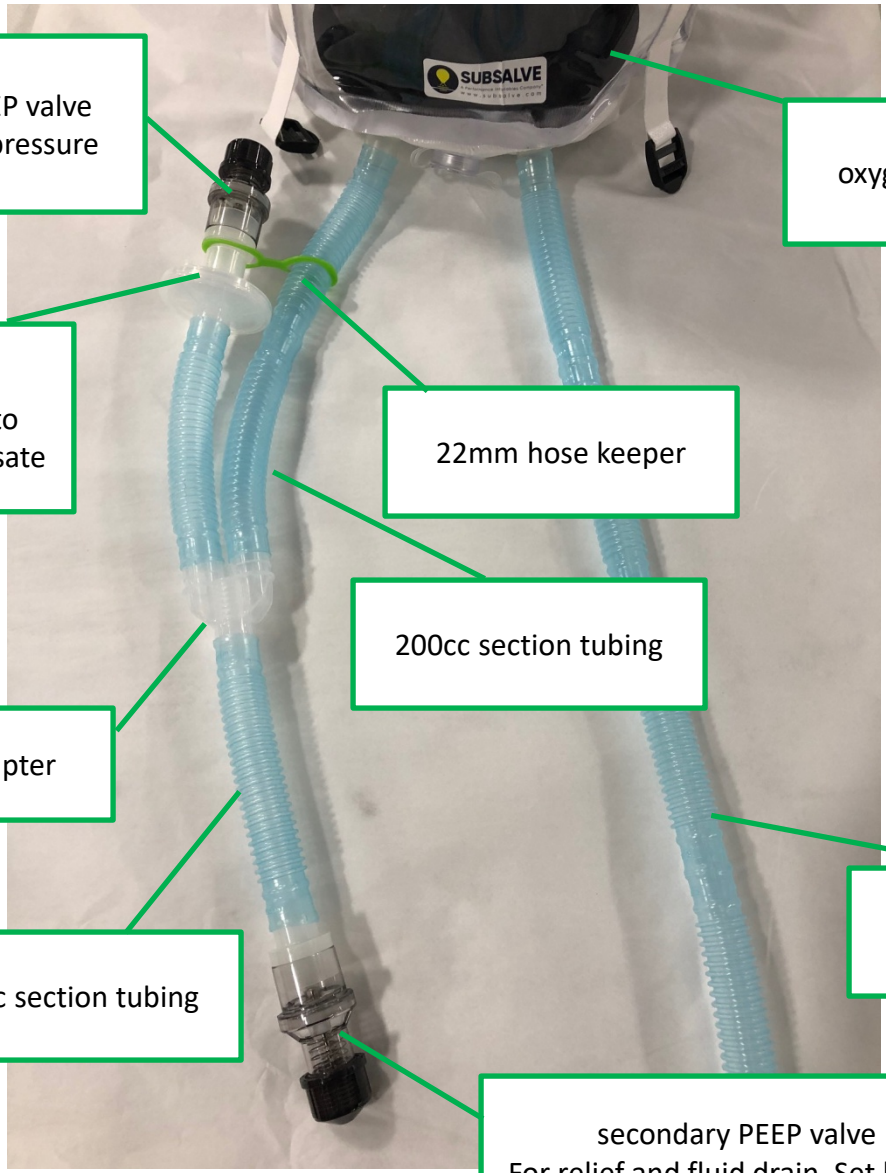
This is most useful when delivering therapies in circumstances where direct ICU-level patient oversight and monitoring may not be available, and when using circuit configurations that are substantially restricted with a flow failure, such as when titrating wall gasses.



Configuration Guide | addition of Over-Pressure Relief

Pressure relief may be added to a breathing circuit by using two PEEP valves on the expiratory limb as configured below. The primary pressure control is the high positioned PEEP valve. The low positioned PEEP valve is set to a higher pressure to serve as over-pressure relief.

This is most useful when using wall-gas titration methods that do not include a leak port, or in environments with high humidity or when encountering fluid build-up in the hood. The high positioned filter reduces occlusion from moisture. In the event it did clog, the secondary PEEP valve would actuate to prevent over-pressurization.



primary PEEP valve
Set patient pressure

oxygen hood

viral filter
high position to
prevent condensate

22mm hose keeper

200cc section tubing

Y-adapter

inlet tubing

100cc section tubing

secondary PEEP valve
For relief and fluid drain. Set higher than primary.

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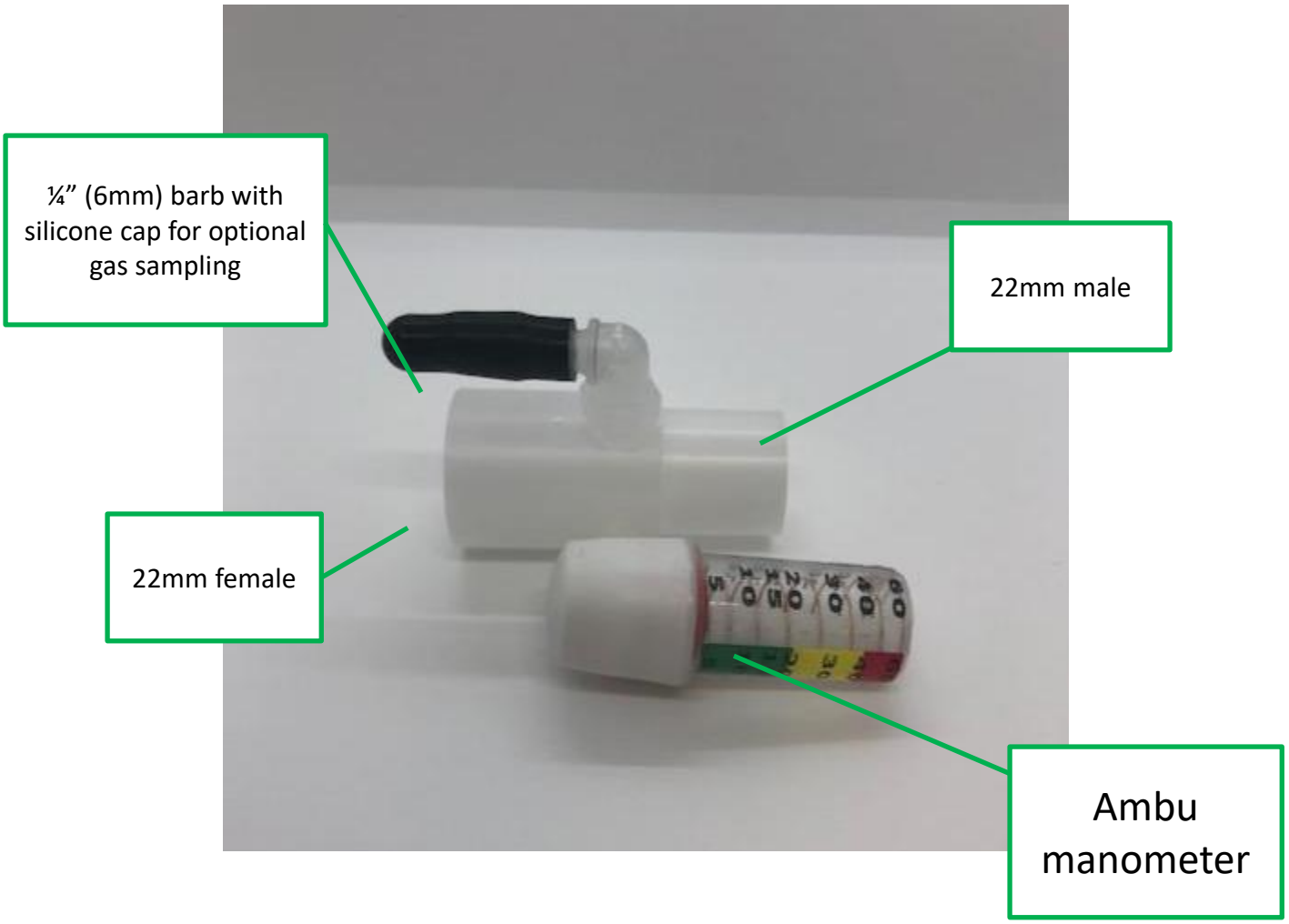
HPAP Analog Manometer Adapter (HPAP-001)

Adapter to fit analog manometer to a respiratory circuit. Fits standard 22mm male and female fittings. The manometer reads 0-60 cm H2O and can be used as a general indication of hood pressure and indicates elevating pressures due to filter occlusion. Additional ¼" (6mm) gas sampling port for oxygen or CO2 monitoring devices.

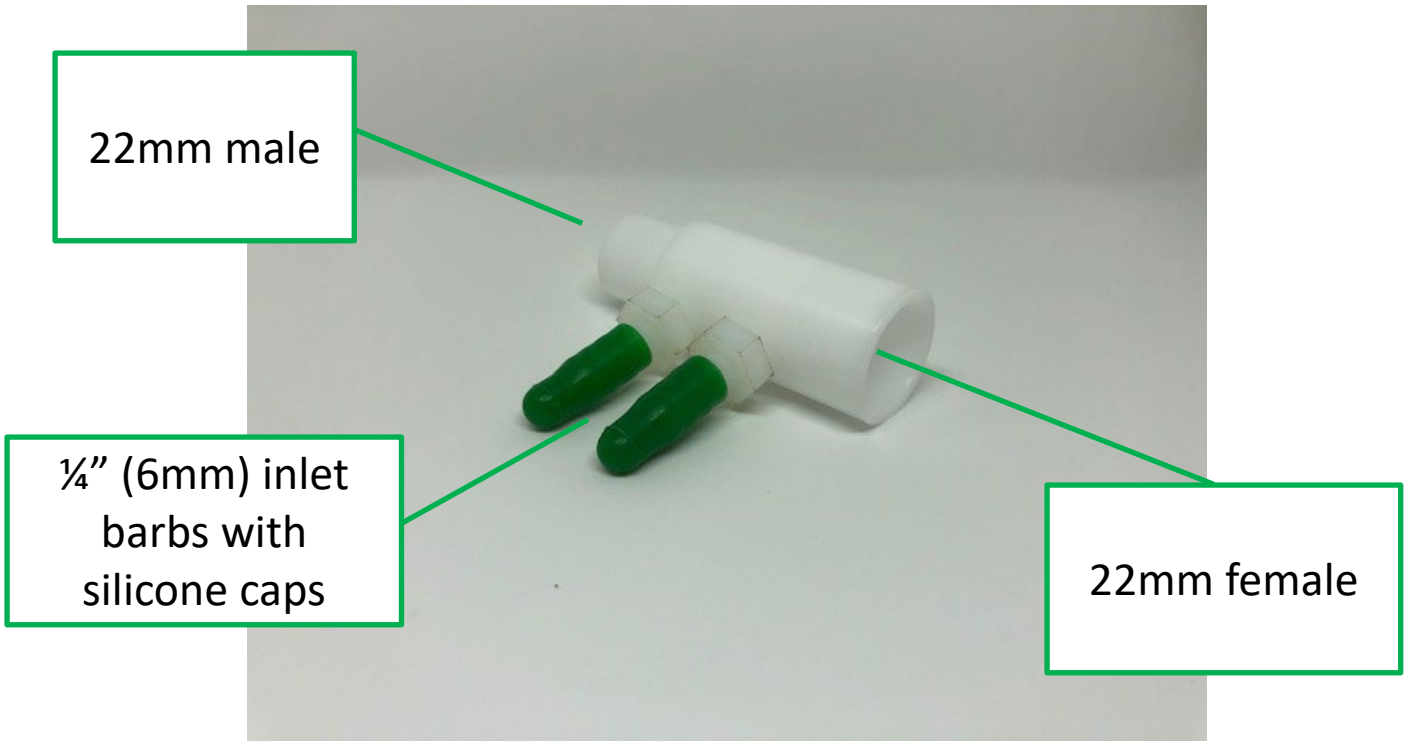
•Component is designed to meet ISO5356 and ISO5367 specifications.
•Main tube is manufactured to ISO9001:2008.
•Uses FDA compliant materials.
•Shipped clean/non-sterile.



HPAP Dual Barb Titration Fitting (HPAP-002)

Dual barb fitting for tee-in connection of one or two oxygen supply tubings to a respiratory circuit. When used with CPAP devices, one port may be uncapped as a breather vent /leak port when needed. Fits standard 22mm male and 22mm female mating components and accepts ¼" (6mm) push-on oxygen supply tubing.

•Component is designed to meet ISO5356 and ISO5367 specifications.
•Main tube is manufactured to ISO9001:2008.
•Uses FDA compliant materials..



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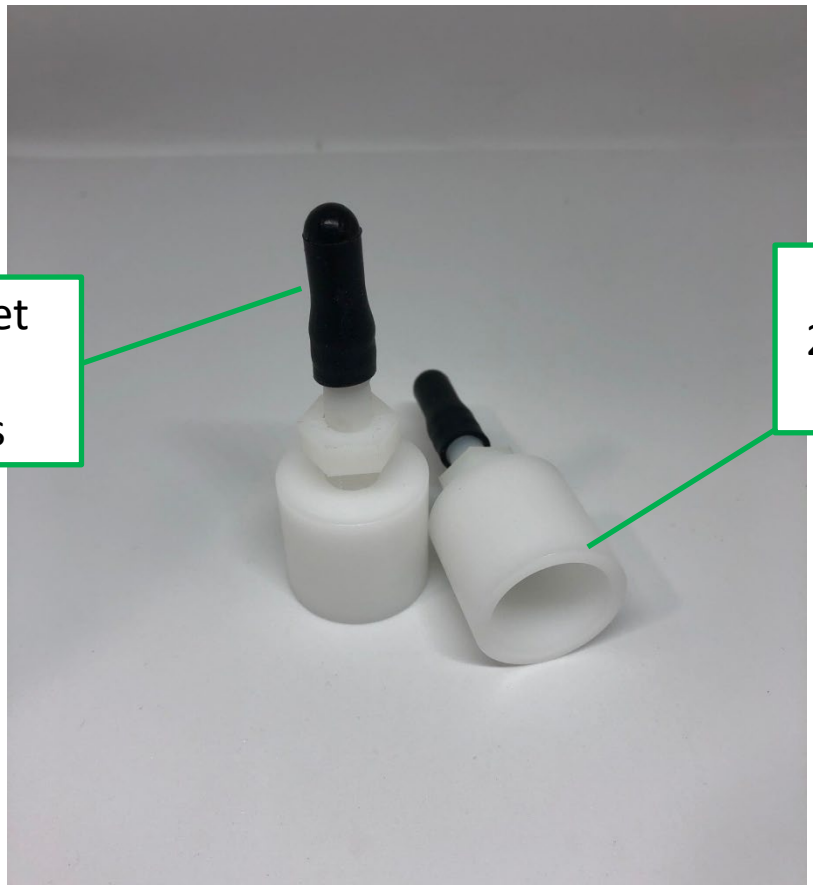
HPAP Barbed Cap (HPAP-003)

Barbed cap for supplemental air or oxygen. Fits standard 22mm male fittings and/or directly to the Subsalve Oxygen Hood when used with oxygen only. Accepts ¼" (6mm) push-on supply tubing.

•Component is designed to meet ISO5356 and ISO5367 specifications.
•Main tube is manufactured to ISO9001:2008.
•Uses FDA compliant materials.
•Shipped clean/non-sterile.



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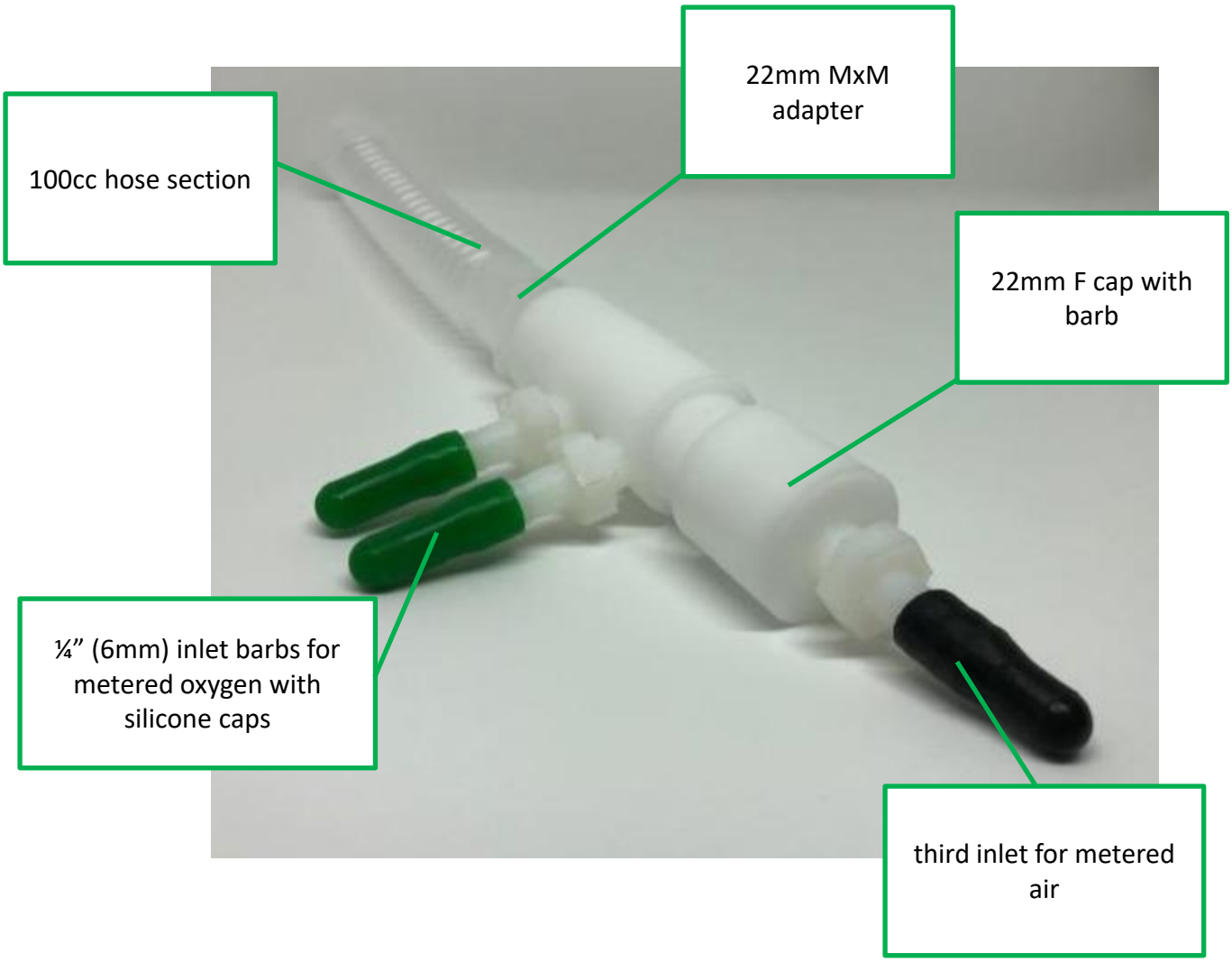
HPAP Wall Gas Titration Assembly (HPAP-004)

Wall gas titration assembly which includes the dual barb fitting plus a barbed cap. This is ideally suited for wall gas titration methods where 1, 2, or 3 air/oxygen sources may be required. Fits standard 22mm male and 22mm female mating components and accepts ¼" (6mm) push-on supply tubing.

•Component is designed to meet ISO5356 and ISO5367 specifications.
•Main tube is manufactured to ISO9001:2008.
•Uses FDA compliant materials.
•Shipped clean/non-sterile.



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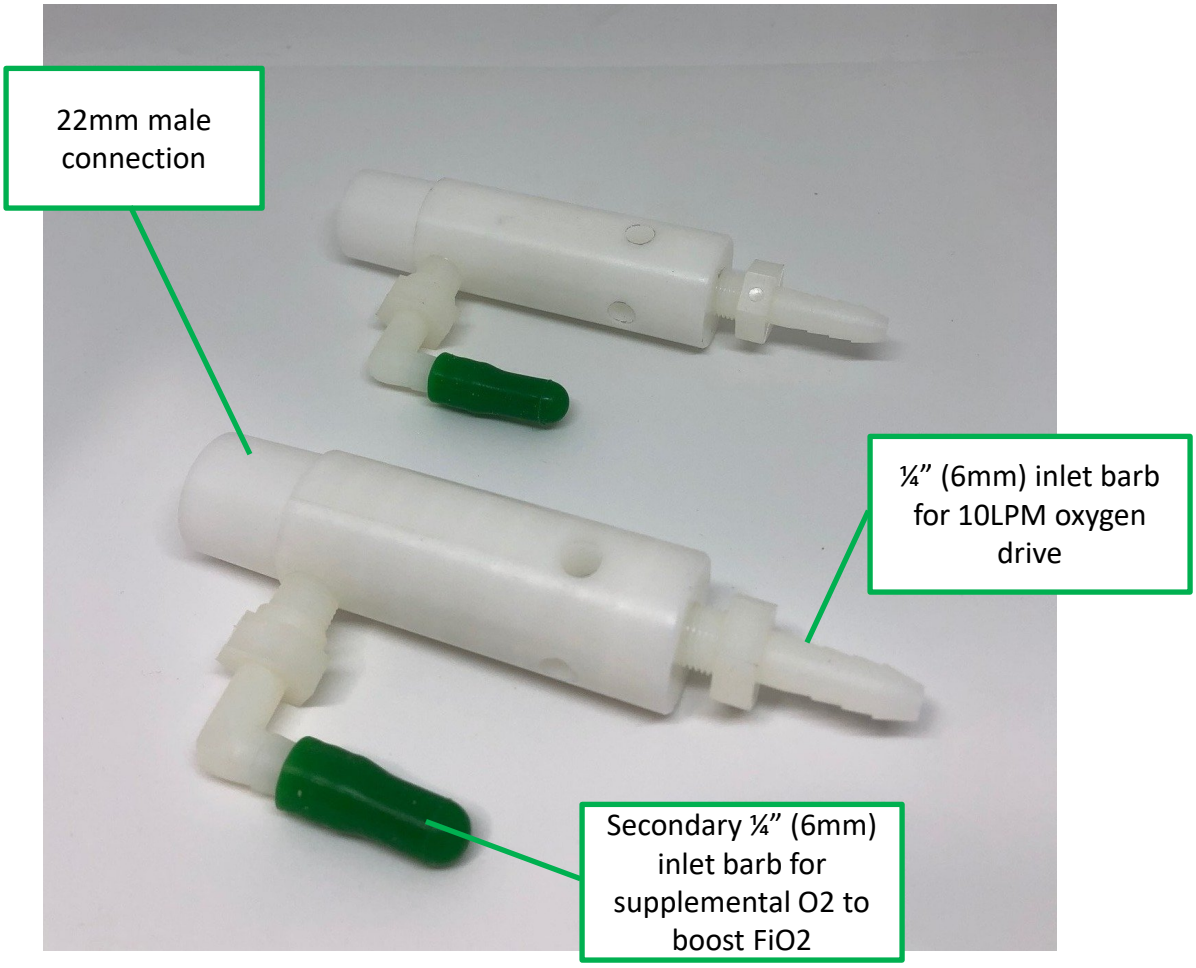
HPAP High Flow Oxygen Venturi (HPAP-005)

Venturi valve utilizing the Bernoulli Principle to boost low flow oxygen to a high flow rate via air entrainment. Provides flow rates suitable for maintaining a hooded positive airway pressure with PEEP. This device eliminates the need for electrical supply devices such as CPAP, BiPAP, or ventilators, however requires significant volumes of available oxygen.

•Device is driven using oxygen supply at 10 LPM.
•FiO2 can be increased using supplemental oxygen.
•22mm male connection is designed to meet ISO5356 and ISO5367 specifications.
•Barbed connections fit to standard ¼" (6mm) oxygen supply tubing.
•Main tube is manufactured to ISO9001:2008.
•Uses FDA compliant materials.
•Shipped clean/non-sterile.



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Scalable Triage Configuration

Scalable Triage Configuration

Allows management of respiratory distress for large patient populations using Hood+CPAP technique.

With hospital overburdens, respiratory distress patients can be managed outside of conventional settings using hooded respiratory therapy techniques. Hood+CPAP methods are particularly well suited to be implemented at scale in a manor which allows careful monitoring by dedicated staff within a specific area. This cost effective solution can be scaled to 10x, 100x, or even 1000x for patient care in field hospitals while significantly reducing virus spread.

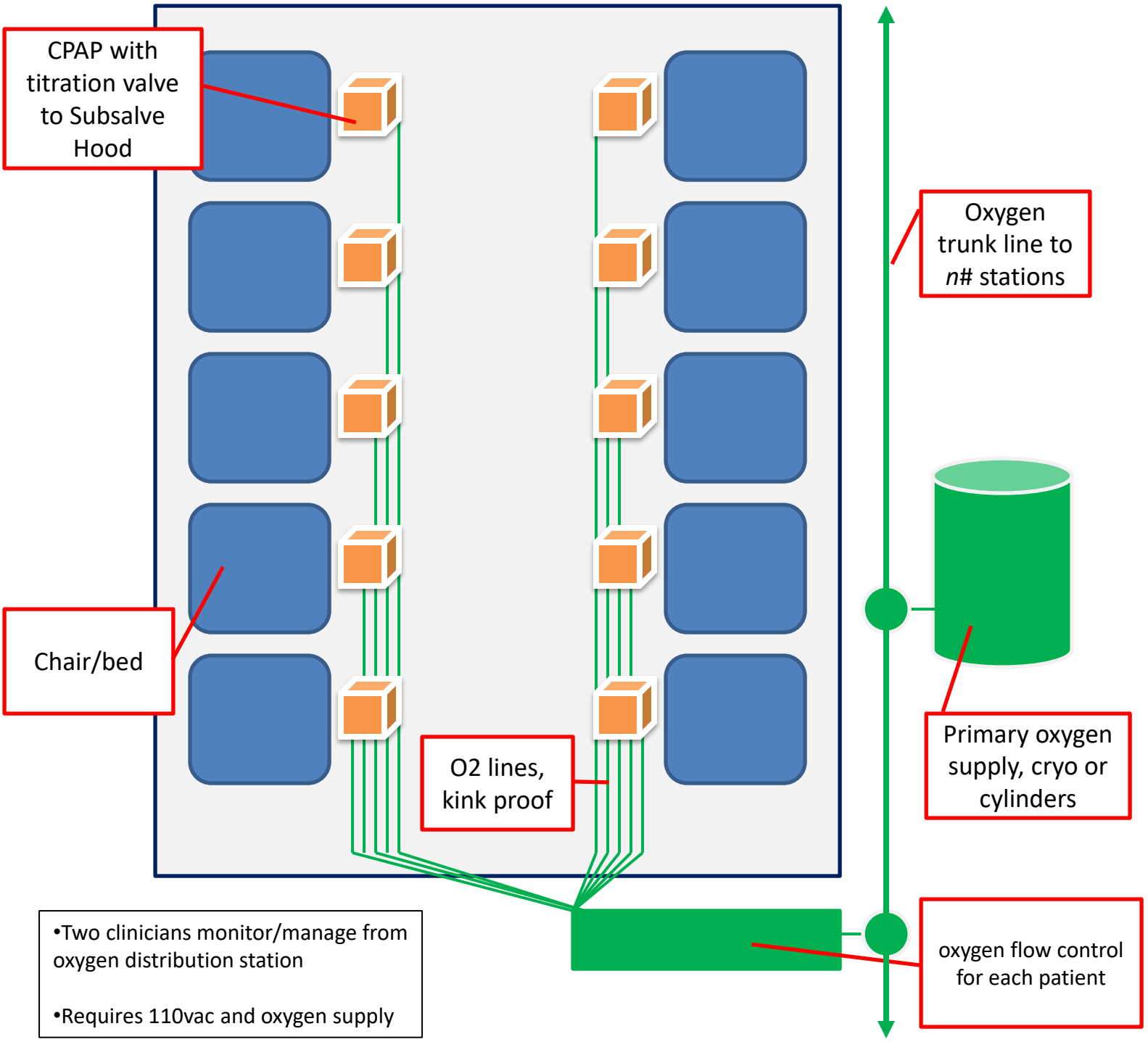
Scalable Triage Configuration Layout

Allows management of respiratory distress for large patient populations using Hood+CPAP technique.

10 Patient C19 Triage, Outside of ICU

•Each patient CPAP 4-14 cm H2O, FiO2 21-60%.

•Reduce virus aerosolization for HCWs.



•Two clinicians monitor/manage from oxygen distribution station

•Requires 110vac and oxygen supply

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Resources & FAQs

Resources

Protocols for Use from Medical Community

Protocol for Use with CPAP devices - the 'CircumVent Protocol' is in active use among a multi-country study to validate use of CPAPs with the Subsalve Hood. The protocols for multiple CPAP units and brief instruction are open-sourced and available here:

- **Circum Vent Protocol**

Very important safety note: DO NOT use the hoods with just any make/model of CPAP. There are multiple nuances between makes/models that result in differing procedures required to ensure adequate flow for treatment.

Protocol for use with ventilators and BiPAP - Physicians in Saudi Arabia have developed a protocol provided through their Ministry of Health:

- **MOH Protocol**

Publications

Munshi L, Hall JB. Respiratory Support During the COVID-19 Pandemic: Is It Time to Consider Using a Helmet? *JAMA.* Published online March 25, 2021. doi:10.1001/jama.2021.4975

H. Amirfarzan, M. Cereda, T.G. Gaulton, K.B. Leissner, A. Cortegiani, R. Schumann, C. Gregoretti (2021). Use of Helmet CPAP in COVID-19 – A practical review.

Alharthy et al. (2020). Helmet Continuous Positive Airway Pressure in the Treatment of COVID-19 Patients with Acute Respiratory Failure could be an Effective Strategy: A Feasibility Study.

Armirfarzan et al. (2020). Helmet CPAP: how an unfamiliar respiratory tool is moving into treatment options during COVID-19 in the US.

Bourrianne et al. (2020). Inexpensive multi-patient respiratory monitoring system for helmet ventilation during COVID-19 pandemic.

Khan et al. (2020). A low-cost, helmet-based, non-invasive ventilator for COVID-19.

FAQs

FAQs (1 of 4)

Q: Is the Subsalve hood reusable?

A: The hood is single patient use. It can be taken off and re-applied with the same patient multiple times during the course of treatment, however should not be repurposed for multiple patients. It is more cost effective to use and dispose of this hood, than sterilize and reassemble (with risks of errors) competitor makes/models.

Q: What are the advantages of the one-piece design?

A: There are no parts requiring assembly. With other makes/models, there have been documented instances of assembly error by the clinician, and even missing component parts, which can result in device failure. The Subsalve hood is ready for immediate use right out of the box.

Q: Can we prone a patient with the hood?

A: The FDAs EUA review resulted in their recommendation to not be prone with the hood. This was not a device specific recommendation, and applied to helmets generally at the time of review. However, we are aware of patients being prone with the hoods at the clinician's discretion. It is their recommendation to apply the hood with the ports to the side of the head, rather than in front, to ensure the hoses and fittings are unobstructed.

Q: What flow is required?

A: The Subsalve hood is recommended for use at a minimum flow of 60 LPM. This is based on the research of Taccone et al. (2004) with predicate devices in order to mitigate risks of CO2 rebreathing. The Subsalve hood is of comparable volume, shape, and port positions as the predicate devices that are well studied.

Q: How much oxygen is required?

A: When using our venturi device, 10LPM flow is required to drive the high flow air entrainment. For all other techniques, oxygen is used to supplement air flow and boost FiO2. 10LPM minimum is a good benchmark, however when titrating wall-gasses 30LPM or more can be useful.

Q: How do I ensure adequate flow to the hood, are there any alarms?

A: Alarming features are incorporated into air supply devices such as ventilators, BiPAP v60s, and other electronic supply devices and are not a function of the hood itself. These supply devices should be well understood before using helmet ventilation techniques. When using wall gasses, the total flow is the cumulative flow from each wall-gas flowmeters.

Q: Can we use hoods with CPAP (sleep apnea) devices?

A: Yes, however with caveats. Not all makes/models are suitable for hooded respiratory care, and each further has nuances relative to the appropriate circuit configuration. We offer a kitted solution with the Nanotronics Health nHale which pairs exceptionally well with our hood. Please contact us to discuss considerations for using alternate CPAP devices.

FAQs (2 of 4)

Q: What hoses and fittings do I need for helmet ventilation?

A: The inspiratory and expiratory limb circuits will vary depending on your high flow source. All setups will require a viral filter on the expiratory limb. Very generally, electronically driven systems (ventilators, BiPAPs, CPAPs) may not require a PEEP valve after this filter since pressure regulation occurs at the device. High flow gas driven systems (wall gas and HF blenders) may likely require the PEEP valve to regulate pressure. The inspiratory side may include one or multiple fittings for oxygen titration, depending on the high flow supply source. Refer to current protocols and the medical literature for specific guidance.

Q: Is the hood FDA approved?

A: The Subsalve Oxygen Treatment Hood is cleared under an FDA EUA (Emergency Use Authorization) for the purpose of treating respiratory distress during the Covid-19 pandemic. The hood is additionally registered with multiple international health ministries and has been accepted for use by numerous individual hospitals.

Q: How do I purchase hoods, and what is the supply situation?

A: Contact sales@oxygentreatmenthoods.com to request a quote for hoods. You will be directed to the appropriate reseller or distributor. Hoods are maintained in inventory and smaller orders (up to 100 units) typically ship within one business day. Larger orders are placed in the production queue in the order they are received. Most orders ship in not more than 3-5 business days. Large institutional orders (several thousands of units) are placed on a batch delivery schedule.

Q: We are in a low-resource setting and do not have ventilators, are the hoods useful?

A: Yes! Though a high flow gas supply is still required. CPAP may be an inexpensive and viable solution. Contact sales@oxygentreatmenthoods.com to discuss CPAP options that work well with the hoods.

Q: What are the outcomes like?

A: Hooded based respiratory therapies are is still relatively new in many parts of the world, and is still quite new for Covid-19 specific treatment. Research is actively underway and we will share results with the community once published and available. In the meantime, we are hearing lots of success stories. Visit www.oxygentreatmenthoods.com for up to date information.

Q: Are hoods an alternative to intubation?

A: No, not necessarily. Hooded respiratory therapies are being used proactively to alleviate more severe respiratory distress and thus reduce the need for intubation, or even the need for bilevel pressure support altogether. Early research suggests that patients are well managed with this treatment modality, and intubation may be avoided in some cases. If a patient does not improve via hood, they may still require intubation. The most important benefits come from early and proactive use, immediately following lack of improvement from 6L NC. The early hooded option may be an alternative to HFNC. Most importantly, hoods provide the opportunity to free up ventilators for those who need them most.

FAQs (3 of 4)

Q: What are the advantages of helmet ventilation?

A: Hoods/helmets allow the clinician to provide positive airway pressure from 3 to 20 cm H2O, deliver therapeutic oxygen, and mitigate aerosolized virus exhaled by the infected patient from reaching the healthcare worker environment. This is all achieved non-invasively. Mitigating virus aerosolization is a huge benefit when considering high patient density in Covid wards.

Q: We need help at a field hospital that does not have negative pressure space. Can the hoods help?

A: Yes! The hoods significantly reduce aerosolized virus exposure since the expiratory flow is filtered. These are perfectly suited for field hospitals and will make a huge impact. Contact us at sales@oxygentreatmenthoods.com to assist with logistics and guidance to manage large patient populations. We have complete systems that are scalable to manage 10x, 100x, 1000x patient volumes.

Q: Which viral filters can be used with the hoods?

A: The Subsalve hood has two standard 22mm male ports that are compatible with most respiratory care fittings and hoses. Conventional viral filters can be friction-fit directly to one of the ports. These should be changed out according to their instructions for use, typically once every 8 hours. The filter must remain free of debris, moisture/dampness, and otherwise remain unclogged. An occluded filter will impact the desired flow and pressure for the hood.

Q: Can I use the hood with [enter XYZ device]?

A: Hoods are an interface for high flow techniques. There are literally dozens, or more, of makes/models of various device types that can supply the hoods with adequate flow. Consult the instructions for the device you have to ensure it can supply continuous high flow >60 LPM even with the resistance of a viral filter in-line - *this is very important*. Generally, hoods can be used with ventilators, BiPAPs, CPAPs, venturi devices, HF blenders, or even wall gasses only. Each device may have its own nuances for use with hoods/helmets. New guidelines are emerging within the medical field in real-time and this literature should be consulted directly.

Q: Can you explain the neck size options and how to adjust them?

A: The Subsalve hood is available in latex in sizes S, M, L, and XL. The seals are very elastic and can accommodate a wide range of patient neck sizes out of the box. Sizing is not an exact science. Some patients may be more or less comfortable with a different size. Choose the closest match for the patient using the supplied sizing chart, allow the patient to try it, and adjust for comfort as needed. Every seal is marked with scored ribs which can be cut from the seal to make it larger. Patient tolerance to the neck seal varies greatly from patient to patient. Each rib removed opens the seal circumference about ½". A silicone version neck seal is also offered. This is available in just one size, and may additionally be trimmed for comfort.

FAQs (4 of 4)

Q: Is it loud?

A: The high flow nature of the hood does create some noise. The pitch and volume will vary based on the hose type you are using, the flow velocity, and the size of the patient's head (resulting in varied dead space for resonance). Patients may wear earplugs, or even a headset for music if desired.

Q: Can we run NG tubes or other lines using the hood?

A: Yes. Any required lines should be run alongside the neck and can be taped in place while the hood is donned. The lines will run under the neck seal. Adjust their position for patient comfort once the hood is properly positioned.

Q: My patient is experiencing redness and irritation on their neck. How can I prevent this?

A: The neck seal makes an elastic fit over a wide area. Sweat is the primary culprit for any irritation. Use talcum powder under the seal before placement, and/or apply by hand during treatment. Alternatively, a mepilex barrier can be used under the neck seal. If the seal is too tight, trim for comfort.

Q: The under arm straps loosen over time. How can I prevent this?

The under arm straps can loosen over a period of time. This is a function of the patient's body shape, their orientation in the hospital bed, and any humidity/condensate that causes some slippage. Position the strap where desired, then place a quick wrap of medical tape over the buckle to prevent any slippage.

Q: How do I reduce discomfort under the arms?

A: Some stress will be placed under the arms from the hood being inflated. If this causes patient discomfort, place a rolled towel or pillow under the arms, and then the strap. In some instances, at the clinician's discretion, the straps may be secured to the bed rails.

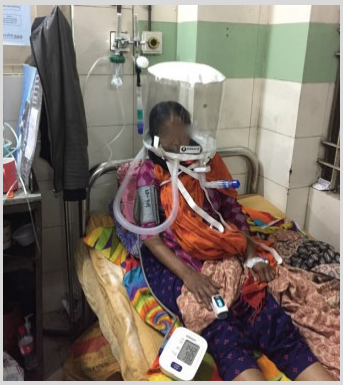
Q: Can the hoods be used as PPE for workers?

A: The manufacturer has produced variant hood designs that may be suitable for various types of PPE including with PAPR devices. Very generally, the ventilation rates for use in a PPE application would be the same as for use in patient care. However, this type of use may be subject to other local or national regulatory requirements. Contact us to discuss interest and needs further.

Covid-19 Social Responsibility

Subsalve USA, in cooperation with Lombardi Undersea LLC have pledged recurring contributions of equipment and financial assistance to Ocean Opportunity Inc., a 501(c)3 not for profit organization, for the duration of the Covid-19 pandemic.

Ocean Opportunity has facilitated aid relief to multiple countries including Bolivia, Guatemala, Honduras, Haiti, Nigeria, Iraq, Bangladesh, and others by introducing respiratory therapy techniques via The Subsalve Oxygen Treatment Hood as a viable technique for managing respiratory distress in low and middle income communities and other resource constrained circumstances.



Those interested in supporting this organization's humanitarian mission are encouraged to visit www.oceanopportunity.com/donate, or mail a contribution to:

Ocean Opportunity Inc.
21 Sixth Street
Barrington, RI 02806
USA
explore@oceanopportunity.com

Ocean Opportunity is a 501(c)3 Guidestar registered charity. Donations are tax-deductible to the extent allowable by law.

Regulatory Notice

WARNING

The pictured breathing circuits are for technical guidance and educational purposes only. It is up to the managing practitioner to determine the most suitable breathing circuits for delivering therapeutic treatments. Use of alternate components to those presented may alter system performance and present considerable risks.

Ensure patients are appropriately monitored during any hooded respiratory treatment. Use of the pictured breathing circuits may not be considered a traditional means of patient care under all circumstances and in all locations or treatment environments.

CAUTION

The charts and tables provided throughout are for reference only and were developed using the specific components pictured and within the described settings. These may or may not be suitable for all makes/models of alternate components.

REGULATORY NOTICE

The US FDA has authorized the Subsalve Oxygen Treatment Hood and the Nanotronics Health nHale independently for emergency use (EUA) in healthcare settings to treat patients during the COVID-19 pandemic, and have been added to Appendix B of the FDA's Emergency Use Authorization (EUA).

- The devices have not been FDA cleared or approved
- The devices have been authorized by FDA under an EUA
- The devices are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use.

DISCLAIMERS

The integrated kitted systems or breathing circuits described are in no way standalone medical devices and present only methodologies for administering treatment using the integrated primary and accessory components.

The provided guidance offers specific technical know-how for assembly and operations of the integrated components and are not a medical protocol or prescription for treatment.

Use of this pictured components and associated treatment methodologies must only be done by or under the direction of the physician prescribing the afforded treatment.





2020-2021 Order Request

Subsalve maintains limited inventory of the component parts pictured throughout this guidance document to facilitate ease of hooded respiratory therapy adoption by our customers. Availability and pricing are subject to change based on supply chain constraints during the Covid-19 pandemic. Please submit order requests to sales@oxygentreatmenthoods.com for a quote.

Qty requested	SKU	component name
	SS-TH	Subsalve Oxygen Treatment Hood
		specify latex in S, M, L, XL
		specify silicone, one size
hoses		
	LUM-021	CPAP hose 1.8m
	LUM-001-100	100cc hose section
	LUM-001-200	200 cc hose section
	LUM-001-300	300cc hose section
	LUM-001-1800	22mm, 1.8m length corrugated tubing
other consumables		
	LUM-002	viral filter
	LUM-003	PEEP valve, 5-20 cm H2O
	LUM-004	22mm wye connector
	LUM-005	22mm male x male connector
	LUM-010	O2 tubing, 7' length (ships green or white)
	LUMC-005	22mm hose keeper
specialty components		
	HPAP-001	HPAP Analog Manometer Adapter
	HPAP-002	HPAP Dual Barb Titration Fitting
	HPAP-003	HPAP Barbed Cap
	HPAP-004	HPAP Wall-Gas Titration Assembly
	HPAP-005	HPAP High Flow Oxygen Venturi (valve only)
	LUM-009	Anti-asphyxia valve (AAV)
	LUM-011	Digital Peak Flow Meter
	LUM-012	Pulse Oximeter
kitted systems		
	HPAP-005-venturikit	Hood+Venturi Kit = hood, venturi, tubing/filters
	HPAP-006-ecokit	Hood+nHaleCPAP Kit = hood, nHale15vdc, tubing/filters
	HPAP-006-prokit	Above+DigitalPFM+pulsox+ruggedized case

for sales & technical support:

Lombardi Undersea LLC
21 Sixth Street
Barrington, RI 02806
USA
sales@oxygentreatmenthoods.com

to visit the manufacturer:

Subsalve USA
51 Circuit Drive
North Kingstown, RI 02852
USA
www.subsalve.com