

Frequently Asked Questions for COVID-19 Emergency Response with VOCSN

General FAQ

How can I purchase VOCSN for myself or a loved one impacted by COVID-19?

The five therapies provided by VOCSN require a physician prescription for use in the home. VOCSN is not available for sale to individuals and can only be sold to hospitals, home medical equipment providers (DME companies), long term care facilities, medical transport, and government organizations who are licensed to purchase medical equipment.

How can my hospital or government access VOCSN?

If you are a hospital or government representative, please <u>contact us here.</u> We are processing and shipping orders as quickly as possible as they are placed, and we encourage you to plan ahead for your anticipated needs so we can best support your response.

What is the status of the Ventec supply chain?

VOCSN is manufactured in the United States and Ventec continues to work closely with our supply partners to ensure access to parts and supplies. Increased production in response to COVID-19 continues to impact areas of the supply chain and we are managing accordingly.

Throughout the COVID-19 pandemic, Ventec Life Systems remains fully operational and our team is working hard to aid in the supply of additional ventilators. We have implemented additional cleaning, limited visitors, masks and social distancing for all employees, and additional protective procedures to ensure the health and safety of team members, and we continue to track local and federal health recommendations and guidelines.

How can I learn how to use VOCSN?

If you are a respiratory therapist or medical professional wanting to learn more about using VOCSN, please visit our <u>training section</u>. Respiratory therapists can also sign up for a free online training course to earn 2.0 credit hours of CEU credit.



How can I get access to VOCSN if I am impacted by COVID-19?

Your physician and medical professionals will determine the best course of treatment if you are impacted by COVID-19. We are not able to provide VOCSN on an individual basis or provide direct care.

What is the difference between the different VOCSN configurations?

VOCSN is one model with multiple configurations, including seven hardware configurations (V+O+C+S+N+Pro, V+O+C+S+N, V+C+S+N+Pro, V+C+Pro, V+C, V+Pro, and V+Pro Emergency). Each VOCSN device can also be customized to the patient using the software by enabling or disabling prescribed therapies in Clinician Access Mode. The +Pro configurations are capable of connecting external high pressure oxygen and include an on-board oxygen blender.

All VOCSN configurations are FDA cleared to provide continuous or intermittent ventilatory support for the care of pediatric through adult patients weighing at least 5 kg who require mechanical ventilation. All VOCSN configurations may be used in invasive and non-invasive applications across a variety of modes and settings including pressure and volume ventilation and include high flow therapy functionality. All VOCSN configurations are intended for use in home, hospital, institutional, and transport settings, including portable applications.

Is VOCSN subject to an EUA or FDA cleared?

The VOCSN Multi-Function ventilator was <u>FDA 510(k)</u> cleared in April, 2017. The 510(k) cleared VOCSN ventilator can be provided in a number of configurations with optional integrated functions, such as an oxygen generator or a suction pump (these options are highlighted on pages 7, 9, and 11 in the <u>VOCSN 510(k) Summary</u>). Note: The nebulizer function is a Class 1 device, exempt from 510(k) clearance, thus not included in the 510(k) letter. The V+Pro Emergency configuration with certain alternate components is subject to an EUA, but to date no V+Pro Emergency units have been distributed under the EUA.



Clinical FAQ

How can I filter the exhaled gas from the Ventec One-Circuit (single limb)?

Some versions of the Ventec One-Circuit™ include a cuff around the exhalation valve that can be used to attach a bacterial filter. If your patient circuit does not include this cuff, it is recommended that you place a filter inline after the exhalation valve.

Is the travel suction canister filtered?

Yes. The travel suction canister and the external suction canister adapter are equipped with a hydrophobic filter that offers a high filtration efficiency.

Can VOCSN measure static or plateau pressures?

Yes. VOCSN configurations with software version 4.09R and later include an <u>Inspiratory Hold</u> feature that provides static compliance and plateau pressure measurements.

What is the PEEP range on VOCSN?

- With an Active circuit, PEEP can be set between 0 and 25 cmH2O.
- With a Passive or Valveless circuit, PEEP can be set between 4 and 25 cmH2O.

How much oxygen can be delivered with VOCSN?

- With a high-pressure oxygen source, oxygen can be delivered from 21% 100% FiO2.
- With a low-pressure oxygen source, oxygen can be bled-in up to 20 L/min .
- With the VOCSN internal oxygen concentrator, oxygen from 0.5 to 6.0 L/min O2 Flow Equivalent can be
 delivered with the Oxygen Direct system (through a patient circuit O2 tube). In an average-sized adult,
 6.0 L/min O2 Flow Equivalent delivers approximately 40% FiO2.



Can you use the internal oxygen concentrator and bleed-in additional low-pressure oxygen at the same time?

Yes. Oxygen via bleed-in from an external low-pressure source is additive, and can be used in conjunction with the internal oxygen concentrator or external high-pressure source.

If you are using the internal oxygen concentrator and want to add additional oxygen via bleed-in from an external, low-pressure source, leave the internal oxygen concentrator running (as shown on the Oxygen therapy screen) and then simply add the low pressure source to the back of VOCSN, and turn the oxygen source on.

Does bleed-in of external, low-pressure oxygen affect delivered tidal volumes and/or flow triggers?

No. Adding external, low-pressure oxygen will not affect ventilation delivery.

What ventilation modes can VOCSN provide?

Please refer to the Comparable Ventilation Modes document, available by clicking here.

Does VOCSN offer High Flow oxygen therapy?

Yes. VOCSN offers High Flow therapy on devices with software version 4.06 and compatible hardware. To determine if your VOCSN has access to High Flow therapy, look at the "V" icon in the status bar.

• Devices **with** High Flow therapy display a "V" icon with a white background.



• Devices **without** High Flow therapy display a "V" icon with a blue background.



VOCSN devices with High Flow therapy offer the following Flow setting ranges:

- When Patient Type is set to Adult, the Flow range is 15 to 60 L/min.
- When Patient Type is set to Pediatric, the Flow range is 4 to 25 L/min.

For more information about using High Flow Therapy with VOCSN V+Pro Emergency including accessories and supplies, please <u>click here</u>.

For information on setting up High Flow therapy please refer to page 26 of the Clinical and Technical Manual, available at VentecLife.com/VOCSNmanual.



How much leak can VOCSN compensate for?

At minimum, all VOCSN devices provide leak compensation up to 75 L/min at 20 cmH2O. VOCSN devices with software version 4.06 and compatible hardware provide extended leak compensation up to 175 L/min @ 20 cmH2O. To determine if your VOCSN has access to the extended Leak+ performance, look at the "V" icon in the status bar.

• Devices with Leak+ performance display a "V" icon with a white background.



• Devices **without** Leak+ performance display a "V" icon with a blue background.



What circuits are compatible with VOCSN?

VOCSN has been tested and validated using the Ventec One-Circuit. The Ventec One-Circuit is available in several different circuit configurations, most of which can be ordered as adult or pediatric, and heated or non-heated:

- Active
- Passive
- Valveless
- Active with Oxygen
- Passive with Oxygen

Can VOCSN run off of a generator?

Yes. Refer to the Clinical and Technical Manual, page 191 for external power requirements, available at <u>VentecLife.</u> <u>com/VOCSNmanual</u>.

How long does it take to recharge the batteries if they are completely depleted?

Approximately 13 hours. A separately available Quick Charger can be used to charge the external batteries in 5 hours.

Does VOCSN offer a stand-by mode?

VOCSN does not offer a stand-by mode.

Can VOCSN be used with gloves and typical COVID-19 personal protective equipment?

Yes. The VOCSN touchscreen can still be easily navigated with gloves and typical personal protective equipment.