

Baylis Medical

V4C-560™ Ventilator



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The warranty period for the V4C-560™ Ventilator is one(1) year from the shipment date.

Purchaser covenants not to use the Equipment with any unauthorized products, items, consumables, disposables, equipment and parts.

Purchaser specifically agrees that Baylis Medical shall not be liable for damages, personal injury or death if the Equipment is used with any unauthorized products, items, consumables, disposables, equipment, and parts.

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Preface

Purpose of This Manual

This manual contains important information regarding the safe operation of your V4C-560™ ventilator. Your ventilator is an electrical device that can provide years of useful service with the proper care, as described in this manual.

Ensure that you read and understand the instructions contained in this manual before operating the ventilator.



WARNING:

Before operating the ventilator, read, understand, and strictly follow the information contained in Chapter 1, [Safety Information](#).

Qualification of Personnel

Installation and maintenance of the device must be made by authorized and trained personnel. In particular, training for the handling of products sensitive to electrostatic discharges must include the use of electrostatic discharge (ESD) protection devices and knowledge of the meaning of the symbol at left, as well as using original spare parts and respecting quality assurance and traceability rules approved by Baylis Medical Technologies.



Warranty

Information regarding your Product warranty is available from your sales representative or Baylis Medical Technologies.

Manufacturer




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1 Safety Information

1.1 Definitions

This manual uses three indicators to highlight critical information: warning, caution, and note. They are defined as follows:

	WARNING Indicates a condition that can endanger the patient or the ventilator operator.
	Caution Indicates a condition that can damage the Equipment.
	Note Indicates points of particular emphasis, that make operation of the ventilator more efficient or convenient.

It is essential to read, understand and follow these instructions before using the V4C-560™ ventilator.

In order to use the ventilator correctly and efficiently and to help prevent incidents, please pay particular attention to section [1.2, Warnings](#), as well as all warnings and cautions contained throughout this manual.



Note:

Many ventilator functions are not accessible when the Locking key  is enabled.

For additional assistance contact your clinician or Equipment representative.

1.2 Warnings

1.2.1 General Warnings Regarding Use of Equipment



WARNING:

Install air inlet filter prior to operation. Do not use or store the ventilator without an air inlet filter installed.



WARNING:

The ventilator must be used only under the responsibility and on the prescription of a doctor.



WARNING:

The ventilator must be used according to its intended use. Refer to section [2.1, *Indications for Use*](#).



WARNING:

Be aware this manual describes how to respond to the ventilator, but does not tell you how to respond to the patient.



WARNING:

While the ventilator is in use, an alternative means of ventilation should always be available in the event of a ventilator problem. This is particularly true for ventilator-dependent patients. Supplementary observation, appropriate for the patient's condition, is also recommended.



WARNING:

To ensure that ventilation continues uninterrupted, ensure alternative power sources are available (AC power source, extra batteries, or an auxiliary DC car adapter). Be prepared for the possibility of power failure by having an alternative means of ventilation ready for use—particularly for ventilator-dependent patients.



WARNING:

Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of exhalation gas, primarily carbon dioxide, may be inhaled by the patient. In some circumstances, inhaling carbon dioxide may lead to under-ventilation, suffocation, and serious injury or death.














WARNING:

Always have immediate access to an alternative means of ventilation, which is ready for use, to avoid patient death or serious injury.



WARNING:

The ventilator must not be used with flammable anesthetic substances.

-  **WARNING:**
Do not start ventilation until you ensure that the device is suitably assembled, that the air inlet filter is properly installed and is not obstructed, and that there is proper clearance all around the Unit. Also ensure that the patient circuit is suitably connected to both the ventilator and the patient and that the patient circuit, including all hoses, is not damaged or obstructed.
-  **WARNING:**
A ventilator-dependent patient should always be monitored by trained and competent medical personnel. Ensure that the patient's caregiver is able and prepared to take suitable action in the event the ventilator identifies an alarmed condition or experiences a problem.
-  **WARNING:**
Do not use a patient circuit with a leak accessory for ventilator-dependent patients.
-  **WARNING:**
Refer to this manual for equipment compatible with this ventilator. It may be unsafe to interconnect this equipment with other equipment not described in this manual.
-  **WARNING:**
Before dispensing the ventilator to caregivers or the patient for home use, ensure the Locking Key  is activated so that critical ventilator settings are not modified.
-  **WARNING:**
Do not perform ventilator alarm tests while the patient is connected to the ventilator. Provide the patient with an alternate means of ventilation before conducting these tests.
-  **WARNING:**
Verify the functionality of the alarms before connecting the patient to the ventilator. Refer to Appendix [E, Alarms Tests](#).
-  **WARNING:**
If the ventilator fails the alarm tests or if you cannot complete the tests, refer to Chapter [3, Alarms and Troubleshooting](#) or call your Equipment supplier or Baylis Medical Technologies.
-  **WARNING:**
When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.
-  **WARNING:**
A continuous alarm condition will be activated if the ventilator power switch is turned off while ventilation is in progress. When the power switch is turned back on again, ventilation will resume without having to press the VENTILATION ON/OFF button.

**WARNING:**

To reduce the risk of infection, wash your hands thoroughly before and after handling the ventilator or its accessories.

**WARNING:**

A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated Equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet (TO PATIENT) port—or both ports if a double-limb circuit is used—is recommended. Refer to Chapter 7, [Cleaning](#).

**WARNING:**

Handle the ventilator with care during and after use, particularly when ambient temperatures are high. Some ventilator surfaces may become hot, even if safety specifications are not exceeded.

**WARNING:**

Do not connect the ventilator to any device other than a PC with a dedicated compatible Puritan Bennett™ software package. Contact your Product representative for further information.











**WARNING:**

The ventilator system is not intended to be a comprehensive monitoring device and does not activate alarms for all types of conditions. For a detailed understanding of ventilator operations, be sure to thoroughly read this manual before attempting to use the ventilator system.

1.2.2 Warnings Regarding Installation and Environment of Use

**WARNING:**

Even though the V4C-560™ ventilator meets current safety standards, the internal Lithium-ion battery of the device exceeds the 100Wh threshold and is therefore considered to be Dangerous Goods (DG) Class 9 – Miscellaneous, when transported in commerce. As such, the V4C-560™ ventilator and/or the associated Lithium-ion battery are subject to strict transport conditions under the Dangerous Goods Regulation for air transport (IATA: International Air Transport Association), International Maritime Dangerous Goods code for sea and the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) for Europe. Private individuals who transport the device are excluded from these regulations although for air transport some requirements apply. For air transport; the V4C-560™ ventilator is permitted as checked-in or carry-on baggage. Two spare batteries per person may be taken on board as carry-on luggage only, with the prior approval of the airline. This classification and regulatory requirements may vary depending upon the country and mode of transport. Therefore it is recommended that users verify with the carrier / airline as to which measures to take before the voyage.

-
-  **WARNING:**
The ventilator should never be immersed in any liquid, and any liquid on the surface of the device should be wiped away immediately.
-  **WARNING:**
To avoid damage to the ventilator, in particular the batteries or electrical components, fluids must not be allowed to enter the device, particularly through the air inlet filter, cooling vents, or side exhaust port located in the side, rear, and bottom panels of the ventilator.
-  **WARNING:**
To ensure correct and lasting operation of the device, ensure that the ventilator is installed and operated in the environmental conditions recommended in Appendix [A, Specifications](#).
-  **WARNING:**
Do not leave power cables lying on the ground where they may pose a hazard.
-  **WARNING:**
Do not operate the ventilator in a magnetic resonance imaging (MRI) environment. Doing so could cause a ventilator malfunction.
-  **WARNING:**
Do not operate the ventilator in the presence of active high frequency (HF) surgical equipment. Doing so could cause a ventilator malfunction.
-  **WARNING:**
Do not operate the ventilator in direct sunlight, near heat sources, outdoors, or near installations where liquid may pose a risk without first providing adequate protection for the device.
-  **WARNING:**
Avoid using the ventilator, if possible, in dusty environments. Dusty environments may require more vigilant monitoring, cleaning, and/or replacement of air intake and other filters.
-  **WARNING:**
Ensure that the ventilator's immediate surroundings allow for the proper operational connection of the device without folding, pinching, or damaging any of the required cables or tubes, and that the connection of the patient circuit to the patient provides for a secure, comfortable fit.
-  **WARNING:**
Ensure that the ventilator is not positioned or located such that the AC and DC connections at the back of the ventilator are difficult to access.



WARNING:

Do not cover the ventilator or place in a position that affects proper operation, e.g., blocking a front or lateral opening.



WARNING:

Place the ventilator in a safe place when ventilating and according to the recommendations in this manual.



WARNING:

Do not place the ventilator in a position where a child, pet or pest can reach it, or in any position that might cause it to fall on the patient or someone else.



WARNING:

To ensure correct and lasting operation of the ventilator, ensure that its air circulation holes (air inlet filter, cooling vents, and side exhaust port) are never obstructed. Place the device in an area where air can freely circulate around the ventilator and avoid installing it near floating fabrics, such as curtains.



WARNING:

If the ventilator has been transported or stored at a temperature that differs more than $\pm 20^{\circ}\text{C}$ ($\pm 36^{\circ}\text{F}$) from the temperature in which it will be operating, the ventilator should be allowed to stabilize in its operating environment for at least 2 hours prior to use. When the ambient temperature is 20°C , 2 hours are required to warm the ventilator from the minimum storage temperature or to cool the ventilator from the maximum storage temperature prior to use.



WARNING:

If the ambient temperature where the device is operated is greater than 35°C (95°F), the temperature of the patient circuit or the flow supplied at the device outlet may exceed 41°C (106°F), and the patient circuit may reach up to 60°C (140°F). This may lead to undesirable side effects for the patient. To avoid injury to the patient move the patient and the ventilator to a cooler location. For more information, contact Baylis Medical Technologies.



WARNING:

The default setting for altitude compensation is YES. Altitude compensation should always be set to YES for accurate volume delivery calculations at all elevations.




WARNING:


To reduce the risk of a fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (such as flammable anesthetics and/or heaters) away from the ventilator and oxygen hoses.




WARNING:


Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. If necessary, replace the filter before the recommended replacement period is over (see Chapter 8, [Routine Maintenance](#)).


 **WARNING:**
Handle the ventilator with care during and after use, particularly when ambient temperatures are high. Some ventilator surfaces may become hot, even if safety specifications are not exceeded.


 **WARNING:**
Exercise care to avoid any potential significant risks of reciprocal interference posed by the ventilator and accessories during specific investigations or treatments.


1.2.3 Warnings Regarding Electrical Power Supplies


 **WARNING:**
The operator should connect the ventilator to an AC power source whenever available, for safer operation.


 **WARNING:**
The maximum recommended shelf life of the internal battery is 2 years. Do not use a battery that has been stored for 2 years prior to its first use.

 **WARNING:**
Periodic recharging is important to help maximize useful life of the battery. Do not store the internal battery for extended periods, without recharging, as this may reduce the maximum life.

 **WARNING:**
For the AC (“mains”) power cable to be properly secured, the attachment located on the power cable must be fitted into the power cable holder incorporated in the battery access cover and located under the AC (mains) power socket. Refer to section [4.2, *Connecting to External AC Power*](#).

 **WARNING:**
The power supply to which the ventilator is connected (both AC and DC) must comply with all applicable standards and provide electrical power corresponding to the voltage characteristics inscribed on the rear of the ventilator to ensure correct operation. Refer also to the electrical specifications found in [Appendix A, *Specifications*](#).

 **WARNING:**
Ensure that the ventilator’s internal battery is fully charged before connecting the ventilator to an external DC power source. Powering the ventilator using an external 12–30 VDC power source (via the DC power cable) does not enable its internal battery to recharge.

 **WARNING:**
Due to the internal battery’s limited reserve capacity, the ventilator should only be operated on the internal battery when no other power source is available. Ensure that the internal battery never becomes fully discharged.



WARNING:

When using a car auxiliary adapter (cigarette lighter) ensure the car has been started prior to plugging in the ventilator's DC adapter. Refer to section [4.3, *Connecting to an External DC Power Source*](#).



WARNING:

Even if the internal battery charging indicator is off, charging of the battery may sometimes be incomplete if the ambient temperature is above 40°C (104°F) because of the battery's internal heat safety device.



WARNING:

When the Low Battery alarm is triggered, immediately connect the ventilator to an AC power supply to maintain ventilation and recharge the internal battery.



WARNING:

Batteries should be disposed of according to environmental legislation in your country and locality.



WARNING:

Never expose any batteries to direct flame.



WARNING:

Ensure that the AC power cable is in perfect condition and not compressed. The device should not be turned on if the AC power cable is damaged.

1.2.4 Warnings Regarding Hoses and Accessories



WARNING:

Do not use an air inlet filter with resistance higher than indicated in Table A-16.



WARNING:

The ventilator must not use, nor be connected to, any anti-static or electrically conductive hoses, tubing, or conduits.



WARNING:

Minimum and maximum VTE alarm parameters must be properly set to warn in the event of patient disconnection.














WARNING:

Before opening the packaging for the patient circuit, ensure that no damage is evident to the packaging or its contents. Do not use if evidence of damage exists.



WARNING:

The patient circuit should not be changed during ventilation.

-  **WARNING:**
On a DAILY basis, inspect the patient circuit to ensure that it shows no signs of damage, is properly connected, and is operating correctly without leakage.
-  **WARNING:**
Single use accessories should not be reused.
-  **WARNING:**
The exhalation block is intended for single use by a single patient . It may periodically be cleaned, but it cannot be disinfected or sterilized. To maintain good measurement quality when used continuously, clean the exhalation block periodically (refer to section 7.3, *Cleaning the Exhalation Block*). The exhalation block should be changed every 4 months and cannot be reused with any other patient.
-  **WARNING:**
During invasive ventilation (when an artificial airway bypasses the patient's upper respiratory system), the patient's upper respiratory system cannot humidify the incoming gas. For this reason, a humidifier, to minimize drying of the patient's airway and subsequent irritation and discomfort, must be used.
-  **WARNING:**
If exhaled tidal volume measurements are required to ensure correct patient ventilation a double-limb patient circuit configuration must be used in order to detect leaks. In this case, both the minimum and maximum VTE alarm parameters must be properly set to warn in the event of patient disconnection.
-  **WARNING:**
Failing to replace a dirty air inlet filter or operating the ventilator without a filter may cause serious damage to the ventilator.
-  **WARNING:**
Before cleaning the ventilator, first disconnect the ventilator and the patient circuit.
-  **WARNING:**
If the ventilator is used indoors, the condition of the air inlet filter should be checked every two weeks. If the ventilator is used outdoors or in a dusty environment, the filter should be checked every one week and replaced as necessary.
-  **WARNING:**
The air inlet filter is not reusable; do not attempt to wash, clean, or reuse it.
-  **WARNING:**
The patient circuit should always be positioned to avoid hindering the patient's movements, to prevent accidental disconnection or leakage, and to minimize the risk of patient strangulation.



WARNING:

For pediatric use, ensure that the patient circuit type fits, and, in all respects, is suitable for use with a child. Use a pediatric circuit for patients that weigh under 53 lb. (23 kg). To ensure proper performance of the ventilator, use a recommended patient circuit; see [Table F-2](#).



WARNING:

Resistance of the exhalation valve and accessories (water traps, filters, HMEs, etc.) must be as low as possible.



WARNING:

Adding attachments to the ventilator breathing system can cause the pressure during exhalation at the patient connection port to increase.



WARNING:

The exhalation valve must allow rapid discharge of the circuit pressure. Ensure that the exhalation valve is always clean and its evacuation aperture (exhaust port) is never obstructed.



WARNING:

Users must always possess an additional breathing circuit and exhalation valve while using the V4C-560™ ventilator.



WARNING:

Always ensure that the humidification device is positioned lower than both the ventilator and the patient. Use water traps, if necessary, to limit water in the patient circuit and periodically empty these water traps. Take precautions when discarding the fluid in the water trap. Discard per local ordinance for proper disposal.



WARNING:

Use of a nebulizer or humidifier can lead to an increase in the resistance of inspiratory and exhalation filters. Monitor the filters frequently for increased resistance or blockage.




WARNING:


If a heated humidifier is used, you should always monitor the temperature of the gas delivered to the patient. Gas delivered from the ventilator that becomes too hot may burn the patient's airway.





WARNING:


Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.

 **WARNING:**
The level of inspiratory resistance of the circuit and accessories (bacteria filter, humidifier, HMEs, etc.) must be as low as possible. Settings—particularly the Patient Disconnection alarm, maximum inspired volume (Max VTI), and minimum inspired volume (Min VTI) settings—must be periodically adjusted according to changes in the patient circuit resistance—especially when filters are replaced.


 **WARNING:**
To ensure proper performance of the ventilator, use a patient circuit recommended by Baylis Medical Technologies in this manual; refer to Chapter 4, *Installation and Assembly* and Appendix F, *Parts and Accessories*. The total specified length of the patient circuit tubing as measured from the ventilator outlet to the ventilator inlet is 1.1 meters (3.6 feet) to 2.0 meters (6.6 feet). The tubing must conform to all applicable standards and must be fitted with Ø 22 mm terminals that also conform to all applicable standards. Ensure that both the length and the internal volume of the patient circuit are appropriate for the tidal volume: a corrugated tube of Ø 22 mm for adult patients, and a corrugated tube of Ø 15 mm for pediatric patients with a tidal volume lower than 200 ml.


 **WARNING:**
To ensure proper performance of the ventilator, use only accessories (including oxygen accessories) approved and recommended by Baylis Medical Technologies. See Appendix F, *Parts and Accessories* or contact your customer services.


 **WARNING:**
To reduce the likelihood of disconnection and to prevent adverse ventilator performance, use only accessories compatible with the ventilator. Compatibility is determined by reviewing the instructions for use of either the ventilator or the accessories.


 **WARNING:**
When using non-invasive ventilation (NIV) without an exhalation valve, use a vented nose or face mask or a non vented combined with a leak accessory. When using non-invasive ventilation (NIV) with an exhalation valve, use a non-vented mask.


1.2.5 Warnings Regarding Settings


 **WARNING:**
Before starting ventilation, always verify that all settings are properly set in accordance with the required prescription.


 **WARNING:**
Before starting ventilation, ensure that the device is properly assembled and that the air inlet filter, cooling vents, alarm sound diffusion holes, and side exhaust port are not obstructed. Ensure also that the patient circuit is of the proper configuration (double or single limb), properly connected to the ventilator, and that the circuit hoses are neither damaged nor compressed and contain no obstructions or foreign bodies.


 **WARNING:**
The CPAP mode does not provide a set respiratory rate. Do not use this mode for ventilator-dependent patients.


 **WARNING:**
Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of exhalation gas, primarily carbon dioxide, may be inhaled by the patient.


 **WARNING:**
Alarm volume should be adjusted with respect to the ventilator's operating environment and so that the patient's caretakers can hear the alarms. The audible alarm vents located at the front of the device should never be obstructed. The alarm can be paused with the Alarm Pause function by pressing the ALARM CONTROL key twice once the alarm has been declared.











 **WARNING:**
Ensure that the I Sens setting is not set to OFF when ventilating patients capable of triggering spontaneous breaths.

 **WARNING:**
The ventilator offers a variety of breath delivery options. Throughout the patient's treatment, the clinician should carefully select the ventilation mode and settings to use for that patient, based on clinical judgment, the condition and needs of the patient, and the benefits, limitations, and characteristics of the breath delivery options. As the patient's condition changes over time, periodically assess the chosen modes and settings to determine whether those are best for the patient's current needs.

 **WARNING:**
In adult or pediatric use ensure that the adjusted tidal volume is compatible with the needs of the patient.

 **WARNING:**
When changing the mode during ventilation, significant transitions of pressure, flow or cycling rate might occur, depending on the difference between the modes. Before setting the new mode, first ensure that the settings between the different modes are compatible. This reduces the risk of discomfort and harm to the patient.

 **WARNING:**
Do not conduct the ventilator alarm test while the patient is connected to the ventilator. Switch the patient to an alternate means of ventilation before testing.

-
-  **WARNING:**
The Min PIP alarm setting must be adjusted for the patient, but must also be set high enough to allow the Patient Disconnection alarm to trigger properly. Perform the low pressure test to ensure the alarm is properly set.
-  **WARNING:**
The Max Leak alarm setting must be adjusted for the patient, but must also be set low enough to allow the High Leakage alarm to trigger properly. Perform the max leak test to ensure the alarm is functioning properly. This alarm only applies to leak configuration (NIV).
-  **WARNING:**
If Apnea Time is set to a value higher than 60/Control R then the Apnea alarm will not activate.
-  **WARNING:**
If an Apnea alarm is required, set the Apnea setting to YES in the Preferences Menu.
-  **WARNING:**
The Apnea alarm should be set to YES for ventilator dependent patients.
-  **WARNING:**
Setting any alarm limits to OFF or extreme high or low values can cause the associated alarm not to activate during ventilation, which reduces its efficacy for monitoring the patient and alerting the clinician to situations that may require intervention.
-  **WARNING:**
Ensure the Insp Time setting is compatible with the physiological requirements of the patient.
-  **WARNING:**
Adjustable alarms should not be systematically canceled; instead, they should be adjusted according to the needs and condition of the patient.
-  **WARNING:**
Do not pause, disable, or decrease the volume of the ventilator's audible alarm if patient safety could be compromised.
-  **WARNING:**
A continuous alarm condition will be activated if the ventilator power switch is turned off while ventilation is in progress. When the power switch is turned back on again, the ventilation will resume without having to press the VENTILATION ON/OFF button.



WARNING:

In the SIMV mode the use of a double-limb circuit is recommended. The Min VTE setting should remain active in the event that pressure losses are present on the patient circuit downstream from the proximal pressure link. In such cases the Patient Disconnection alarm would not be systematically activated in case of a disconnection of the circuit.



WARNING:

The inspiration trigger threshold should be carefully modified in order to avoid the risk of false triggering or “autotriggering” of the ventilator. For example, Level 0P, the most sensitive mode, is recommended for pediatric use. However, for an adult, this setting may result in autotriggering.



WARNING:

The sound level of the alarms should be adjusted according to the installation environment and the size of the area monitored by the patient’s caregiver. Ensure that the alarm sound apertures at the front of the device are never obstructed.

1.2.6 Warnings Regarding PC Connection and USB Memory Devices



WARNING:

Do not connect the ventilator to any device other than a PC with a dedicated compatible Puritan Bennett™ software package. Contact your Product representative for further information.



WARNING:

Always verify the file ID before using a USB memory device to transfer data between the ventilator and a PC.



WARNING:

USB connections are not intended for connection to any devices other than the specified USB flash storage (see section [5.2.1, USB Memory Device Specifications](#)).

1.2.7 Warnings Regarding Maintenance














WARNING:

Never use a ventilator or any components or accessories that appear to be damaged. If any signs of damage are evident, contact your Equipment supplier or Baylis Medical Technologies.



WARNING:

To ensure proper servicing and avoid the possibility of physical injury to personnel or damage to the ventilator, only personnel authorized and qualified by Baylis Medical Technologies should attempt to service or make authorized modifications to the V4C-560™ ventilator.

-  **WARNING:**
If you cannot determine the cause of a problem with your ventilator, contact your Equipment supplier. Do not use the ventilator until the problem has been corrected.
-  **WARNING:**
To ensure proper performance of the ventilator, the preventative maintenance schedule should be followed. For further information contact Baylis Medical Technologies.
-  **WARNING:**
On a daily basis, ensure the proper connection and operation of the patient circuit.
-  **WARNING:**
If a problem with the ventilator is suspected, **FIRST CHECK THAT THE PATIENT IS NOT IN DANGER.** If necessary, remove the patient from the ventilator and provide an alternative means of ventilation.
-  **WARNING:**
After assembling, cleaning, or reassembling the patient circuit, and on a daily basis, inspect the hoses and other components to ensure that there are no cracks or leaks and that all connections are secure.
-  **WARNING:**
Use all cleaning solutions and products with caution. Read and follow the instructions associated with the cleaning solutions you use to clean your ventilator. Use only those solutions listed in [Table 7-1](#).
-  **WARNING:**
Never use a liquid cleaner inside the patient circuit, or on any component of a gas pathway. Clean the patient circuit only as specified by the manufacturer's instructions.
-  **WARNING:**
Do not attempt to open, repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, or void your warranty. Only personnel authorized and qualified by Baylis Medical Technologies should repair, open or service the ventilator.
-  **WARNING:**
If the ventilator is damaged, or its external housing is not correctly closed, or it behaves in a way that is not described in this manual (excessive noise, heat emission, unusual odor, alarms not triggered during the start-up procedure), the oxygen and power supplies should be disconnected and use of the device stopped immediately.
-  **WARNING:**
The exhalation block is intended for single use by a single patient . It may periodically be cleaned, but it cannot be disinfected or sterilized. To maintain good measurement quality when used continuously,

clean the exhalation block periodically (refer to section 7.3, [Cleaning the Exhalation Block](#)). The exhalation block should be changed every 4 months and cannot be reused with any other patient.


**WARNING:**

Ensure that the exhalation block is completely dried after cleaning and prior to use.

**WARNING:**

When an exhalation block is set up, each time it is removed, or after installing a new exhalation block on the machine, it is essential that the exhalation flow sensor be recalibrated before the exhalation block is used. Refer to section 8.2, [Calibrating the Exhalation Flow Sensor](#).

**WARNING:**

The patient circuit is intended for single use by a single patient  and should be changed according to the manufacturer's recommendations and according to the patient circuit lifetime. Refer to the instructions for use supplied by the manufacturer of the patient circuit and Chapter 4, [Installation and Assembly](#).

**WARNING:**

A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated Equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet (TO PATIENT) port—or both ports if a double-limb circuit is used—is recommended. Refer to Chapter 7, [Cleaning](#).

**WARNING:**

Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. If necessary, replace the filter before the recommended replacement period is over (see Chapter 8, [Routine Maintenance](#)).

**WARNING:**

For environmental protection, the ventilator and its components, whatever their respective conditions of operation, cannot be disposed of with household waste and must be submitted for suitable selective collection and possible recycling. Observe all applicable regulations when disposing of the ventilator and any of its components.

**WARNING:**

Before using the ventilator's internal battery, ensure that the battery is fully charged and that the charge holds. Back up ventilators should be connected to an AC power source to protect the integrity of the battery.

**WARNING:**

The maximum recommended shelf life of the internal battery is 2 years. Do not use a battery that has been stored for 2 years prior to its first use. Periodic recharging is important to help maximize useful life

of the battery. Do not store the internal battery for extended periods, without recharging, as this may reduce the maximum life.



WARNING:

To connect the ventilator to an external power source, first ensure the ventilator's I/O (power) switch is off (O). Then, connect the desired power cable to the ventilator. Finally, connect the power cable to the external power source.



WARNING:

To disconnect the ventilator from an external power source, first power down the ventilator. Then, disconnect the power cable from the external power source and, finally, the ventilator.



WARNING:

Connect the external DC power source by first connecting the power cable to the ventilator and then to the external DC source. Follow the reverse procedure to disconnect the device from the external DC power source.



WARNING:

Connect the external electrical power source by first connecting the power cable to the ventilator and then to the external power source. Follow the reverse procedure to disconnect the device from electrical power sources.

1.2.8 Warnings Regarding Oxygen



WARNING:

The ventilator must not be used with flammable anesthetic substances.



WARNING:

Oxygen therapy for patients with respiratory failure is a common and effective medical prescription. However, be aware that inappropriate oxygen use may potentially lead to serious complications, including, but not limited to, patient injury.




WARNING:


Strictly follow the instructions provided in section [4.8.2, *Connecting the Oxygen Supply*](#), which include the use of a flow regulator and special oxygen connector.





WARNING:


To avoid injury to the patient and/or possible damage to the ventilator: before connecting the ventilator to the oxygen supply, ensure a flow meter (flow regulator) is connected to the ventilator to regulate the oxygen supply to the required specification.


 **WARNING:**
The V4C-560™ ventilator can be used with an optional oxygen analyzer with minimum and maximum concentration alarms. Always measure the delivered oxygen with a calibrated oxygen analyzer (FiO₂ kit) that features a minimum and maximum concentration alarm in order to ensure that the prescribed oxygen concentration is delivered to the patient.


 **WARNING:**
The FiO₂ sensor must be securely installed on the T-connector. Failure to correctly install the FiO₂ sensor can cause air to escape the patient circuit, preventing the ventilator from detecting occlusions. Always make sure the FiO₂ sensor is securely installed on the T-connector.


 **WARNING:**
The V4C-560™ ventilator is designed to deliver a percentage of oxygen equal or lower than 50%. Do not exceed this value as this may cause the ventilator to malfunction and put the patient at risk.


 **WARNING:**
Ensure that the oxygen supply pressure to the machine never exceeds 7 psi (50 kPa) or a flow of 15 lpm. For volume and sensitivity tolerances, refer to [Table A-7](#).







 **WARNING:**
In the event of an oxygen leak, shut down the supply of oxygen at its source. In addition, remove and/or keep any incandescent source away from the device, which may be enriched with oxygen. Circulate fresh air into the room to bring the oxygen level down to normal.

 **WARNING:**
The hose connecting the ventilator to the oxygen source must be designed exclusively for use with medical-grade oxygen. Under no circumstances should the oxygen hose be modified by the user. In addition, the hose must be installed without the use of lubricants.




 **WARNING:**
Ensure that the only gas supplied to the ventilator through the dedicated oxygen supply connector is medical-grade oxygen.

 **WARNING:**
The coupler must not remain connected to the oxygen inlet unless it is also connected to a leakproof, external oxygen gas source. When an oxygen supply is not being used with the ventilator, disconnect the oxygen source completely from the ventilator.

 **WARNING:**
To prevent any interference with the internal sensors of the ventilator, do not install a humidifier upstream of the ventilator.

-  **WARNING:**
The oxygen supply hose ages even when it is not in use and should be replaced periodically. Follow the expiration date, if any.
-  **WARNING:**
The oxygen supply must be regulated using a flow meter connected to the source gas outlet.
-  **WARNING:**
The oxygen supply must be shut off when ventilation is interrupted. Before disconnecting the oxygen hose, allow the ventilator to continue for a few cycles without oxygen to flush the patient circuit of excess oxygen.
-  **WARNING:**
Before connecting the oxygen supply, ensure that the stud on the oxygen inlet is protruding outwards.
-  **WARNING:**
Inspect the oxygen coupler before use to ensure it has its black O-ring attached and in good condition. Do not use an oxygen coupler with a missing, damaged, or worn O-ring.
-  **WARNING:**
Ensure the O₂ exhaust port on the side of the ventilator is not blocked while the ventilator is in use.

1.2.9 Warnings Regarding Electromagnetic Interference

-  **WARNING:**
The V4C-560™ ventilator requires special precautions for electromagnetic compatibility and should be installed and started according to the recommendations found in Appendix A, *Specifications*. In particular, the use of nearby mobile and portable communications equipment using radio frequencies, such as mobile telephones or other systems exceeding the levels set in the IEC 60601-1-2 standard, may affect its operation. Refer to section A.10, *Manufacturer's Declaration*.
-  **WARNING:**
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ventilator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this Equipment could result.
-  **WARNING:**
The use of any accessory other than those specified, with the exception of the power supplies or cables approved by Baylis Medical Technologies, may lead to an increase in electromagnetic emissions or a decrease in the Equipment protection against electromagnetic emissions. If the ventilator is used

adjacent to such accessories or stacked with such devices, the ventilator’s performance should be monitored to verify normal operation.

1.3 Symbols and Markings

Table 1-1. Ventilator Symbols






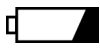




Symbols	Descriptions
	It is essential to read, understand, and follow these instructions before using the V4C-560™ ventilator (ISO 7000-0434A). This symbol appears on the ventilator’s back panel, see item 5 in Table 1-2 .
	It is mandatory to read, understand, and follow these instructions before using the V4C-560™ Ventilator (ISO 7010-M002). This symbol appears on the ventilator’s air inlet label, see item 5 in Table 1-2 .
	Type BF applied part (IEC 60417-5333). A regulatory standard classification for protection against electrical shock for the part of the device that contacts the patient. This symbol appears on the ventilator’s back panel; see item 5 in Table 1-2 .
	Direct current, DC (IEC 60417-5031). This symbol appears on the ventilator’s front panel and back panel; see Figure 1-1 , and item 9 in Figure 1-3 .
	Alternating current, AC (IEC 60417-5032). This symbol appears on the ventilator’s front panel and back panel; see item 8 in Figure 1-3 , and item 10 in Figure 2-3 (page 2-7).
	Internal battery. This symbol appears on the ventilator’s front panel; see item 10 in Figure 2-3 (page 2-7).
	Insulation class II equipment (IEC 60417-5172). A regulatory standard classification for protection against electric shock. Class II equipment relies on double insulation rather than protective earthing. This symbol appears on the ventilator’s back panel; see item 5 in Table 1-2 .
IP32	Index of Protection rating for the ventilator’s enclosure, defined in IEC 60529 (BSEN60529). The first digit, 3, indicates protection against the intrusion of small foreign bodies (including fingers, tools, wires, etc. with a diameter greater than 2.5 mm) into the ventilator. The second digit, 2, indicates protection against water dripping or falling vertically when the enclosure is tilted at an angle up to 15° from its normal position, as well as an environment featuring water vapor condensation and/or light rain. This rating appears on the ventilator’s back panel; see item 5 in Table 1-2 .
	This combined symbol appears on the ventilator’s UP/UNFREEZE key; see item 4 in Figure 2-3 (page 2-7). This key is used to: move the LCD display’s cursor upwards, line-by-line; increase the value of displayed and selected parameter settings; restart (“unfreeze”) waveforms tracing.
	This combined symbol appears on the ventilator’s DOWN/FREEZE key; see item 6 in Figure 2-3 (page 2-7). This key is used to: move the LCD display’s cursor downwards, line-by-line; decrease the value of displayed and selected parameter settings; stop (“freeze”) waveforms tracing.
	This symbol appears on the ventilator’s ENTER key; see item 5 in Figure 2-3 (page 2-7). This key is used to confirm command actions.

Table 1-1. Ventilator Symbols (Continued)





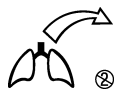
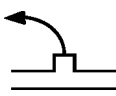
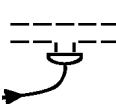

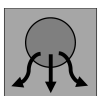




Symbols	Descriptions
	This combined symbol appears on the ventilator's ALARM CONTROL key; see item 2 in Figure 2-3 (page 2-7). This key is used to: cancel the audible portion of alarms for 60 seconds at a time; cancel an alarm. For more information, see Appendix E, Alarms Tests.
	This symbol appears on the ventilator's MENU key; see item 7 in Figure 2-3 (page 2-7). This key is used to access the ventilator's menus via the ventilator's front panel LCD display.
	This symbol (IEC 60417-5009) appears on the ventilator's VENTILATION ON/OFF button; see item 8 in Figure 2-3 (page 2-7). This button is used to start and stop ventilation.
	TO PATIENT port. This symbol appears on the front right of the ventilator, adjacent to the TO PATIENT port; see item 1 in Figure 1-1.
	FROM PATIENT port (double-limb option). This symbol appears on the front left of the ventilator, adjacent to the FROM PATIENT port; see item 4 in Figure 1-1.
	Patient proximal pressure port. This symbol appears on the front right of the ventilator, adjacent to the proximal pressure and TO PATIENT ports; see Figure 1-1, and item 3 in Figure 1-4.
	Exhalation valve pilot port. This symbol appears on the front right of the ventilator, adjacent to the exhalation valve and TO PATIENT ports, indicating the connection of the tubing between the patient circuit exhalation valve; see Figure 1-1, and item 3 in Figure 1-4.
	Oxygen inlet. This marking appears on the back panel of the ventilator, adjacent to the oxygen inlet port; see item 2 in Figure 1-3.
	Oxygen exhaust: do not obstruct.
	Nurse call connection. This symbol appears on the back panel of the ventilator, adjacent to the nurse call receptacle; see item 12 in Figure 1-3. Note: Nurse call is not intended for use in the home environment.
	Switch in "Off" position (IEC 60417-5008). This symbol appears on the I/O (power on/off) switch on the back panel of the ventilator to indicate the switch's "Off" position. See item 2 in Figure 2-2 (page 2-6).
	Switch in "On" position (IEC 60417-5007). This symbol appears on the I/O (power on/off) switch on the back panel of the ventilator to indicate the switch's "On" position. See item 2 in Figure 2-2 (page 2-6).
	Software lock enabled. This symbol appears at upper left in the ventilator's LCD display when the keyboard Locking key is enabled.

Table 1-1. Ventilator Symbols (Continued)


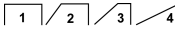
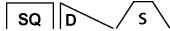











Symbols	Descriptions
	<p>Internal battery.</p> <p>This symbol appears at top center in the ventilator’s LCD display to indicate that the ventilator is being powered by its internal battery. See item 1 in Figure 2-4 (page 2-8), and Chapter 6, Internal Battery, for more information.</p>
	<p>Pressure rise times (inspiratory phase) parameter.</p> <p>These symbols appear on the ventilation mode menu screens. In pressure ventilation modes, you can select one of four rise times with setting 1 representing the fastest rise time and setting 4 representing the slowest.</p>
	<p>Flow shape (“flow distribution shape”, inspiratory phase) parameter.</p> <p>These symbols appear on the ventilation mode menu screens; selectable for V A/C mode only. In volume ventilation mode you can select between Square (SQ), Descending (D) or Sinusoidal (S) flow patterns.</p>
	<p>Selected line (filled square).</p> <p>When making menu choices, this graphic indicates the line on which the cursor is currently positioned.</p>
	<p>Non-selected line (empty square).</p> <p>When making menu choices, this graphic indicates a line on which the cursor is currently not positioned.</p>
	<p>Locked parameter line.</p> <p>When making menu choices, this graphic indicates a line that cannot be selected (the Locking key is enabled).</p>
	<p>Active parameter line.</p> <p>When making menu choices, this graphic indicates that the current parameter is selected and can be changed. See Chapter 5, Operating Procedures.</p>
	<p>Inspiratory effort detected.</p> <p>This symbol appears in the front panel display’s Status window when the patient triggers a breath.</p>
	<p>Parameter adjustment bar.</p> <p>This graphic shows the current setting for parameters such as display contrast and alarm volume in the Preferences menu.</p>
	<p>Year of manufacture.</p>
	<p>Manufacturer.</p>
	<p>Audio paused (ALARM CONTROL key pressed once).</p> <p>This symbol means the sounding of audible alarms is currently disabled. This period lasts 60 seconds. For more information, see section 3.5, Pausing the Audible Portion of Alarms.</p>
	<p>Alarm paused (ALARM CONTROL key pressed twice).</p> <p>This symbol means one or more alarms have been paused, or reset/canceled. The alarm is paused until the alarm condition is corrected and the condition reoccurs. For more information, see section 3.6, Pausing and Resetting Alarms.</p>
	<p>Alarm off (Apnea off).</p> <p>This symbol means that the Apnea alarm has been set to OFF in the Preferences menu. For more information, see section 3.6, Pausing and Resetting Alarms.</p>

Table 1-1. Ventilator Symbols (Continued)







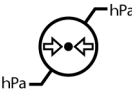










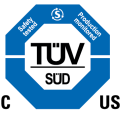
Symbols	Descriptions
	Exhalation valve detected. This symbol means that an exhalation valve has been detected during ventilation.
	No exhalation valve detected. This symbol means that no exhalation valve has been detected during ventilation.
	Single patient use only (ISO 7000-1051). This symbol means that the labeled device is for use by a single patient only.
	Freeze waveforms. This symbol means the tracing of patient pressure and flow waveforms is currently paused or "frozen."
	USB port. This symbol indicates a communications port for interfacing with a USB connector. See item 11 in Figure 1-3 .
	PC connection. This symbol indicates a port that can be used by authorized Baylis Medical Technologies Product service personnel or Baylis Medical Technologies service personnel for software maintenance. See item 10 in Figure 1-3 .
	Atmospheric pressure limitations. See section A.7 for specifications.
	Humidity limitations. See section A.7 for specifications.
	Temperature limitations. See section A.7 for specifications.
	Fragile.
	Keep dry.
	Keep away from direct sunlight.
	This side up.

Table 1-1. Ventilator Symbols (Continued)

Symbols	Descriptions
	<p>Stacking limitation.</p> <p>The number shown (represented by "n") indicates the maximum number of additional identical packages that may be stacked on top of a package containing this device, when this device is correctly packaged.</p> <p>For the V4C-560™ Ventilator, n = 2.</p>
	<p>Lithium battery.</p> <p>This symbol Indicates that the contents of the package contain lithium batteries.</p>
	<p>Air inlet: do not obstruct.</p>
	<p>O2E accessory port.</p>
	<p>TÜV SÜD certification marking</p>

1.4 Labels (Identification and Instruction Information)

Various labels or specific markings are affixed to the ventilator that describe precautions to be taken for the correct use of the ventilator and contribute to the traceability of the Product. See Table 1-2 and the figures on the following pages for illustrations of these labels and markings and their locations on the ventilator. Use the item numbers in Table 1-2 to locate the labels in Figures 1-1 through 1-4.

Table 1-2. Ventilator Labels and Markings

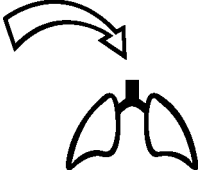

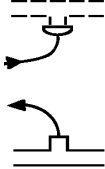
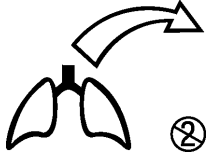

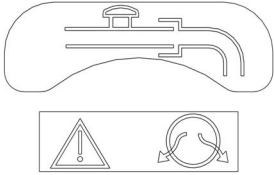
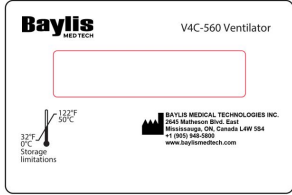
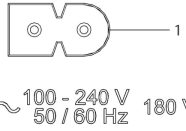
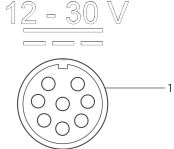
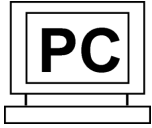



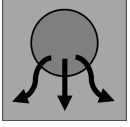

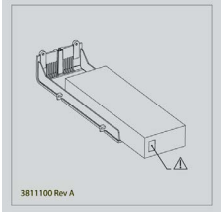

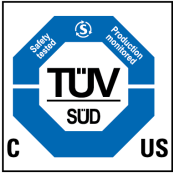

			
<p>1. TO PATIENT port label (Figures 1-1 and 1-4)</p>	<p>2. Oxygen inlet marking and label (Figure 1-3)</p>	<p>3. Exhalation valve and patient pressure connection label (Figures 1-1 and 1-4)</p>	<p>4. FROM PATIENT port, exhalation limb connection of patient circuit—single use exhalation block label (Figures 1-1, 1-2, and 1-4)</p>
			 <p>1—Location of AC power cable receptacle</p>
<p>5. Air inlet label (Figure 1-3)</p>	<p>6. Exhaled gas outlet label (Figure 1-2)</p>	<p>7. Identification label (Figure 1-4)</p>	<p>8. AC power (mains) cable receptacle marking (Figure 1-3)</p>
 <p>1—Location of DC power cable receptacle</p>			
<p>9. External DC cable receptacle marking (Figure 1-3)</p>	<p>10. PC connection marking (Figure 1-3)</p>	<p>11. USB port marking (Figure 1-3)</p>	<p>12. Nurse call cable receptacle marking (Figure 1-3)</p>

Table 1-2. Ventilator Labels and Markings (Continued)

			
<p>13. FiO₂ label (Figures 1-1 and 1-4)</p>	<p>14. O₂ exhaust port label</p>	<p>15. O₂ exhaust port warning label</p>	<p>16. Internal battery cover label</p>
			
<p>17. O₂E accessory port marking (Figure 1-3)</p>	<p>18. TÜV SÜD certification marking label (Either TÜV SÜD certification marking label OR SPE-3000 label will be present)</p>	<p>19. SPE-3000 label (Either TÜV SÜD certification marking label OR SPE-3000 label will be present)</p>	



Note:

The item number callouts in the following figures correspond to those listed in [Table 1-2](#).

Figure 1-1. Locations of Labels—Top-Front View



Figure 1-2. Locations of Labels—Front-Left View

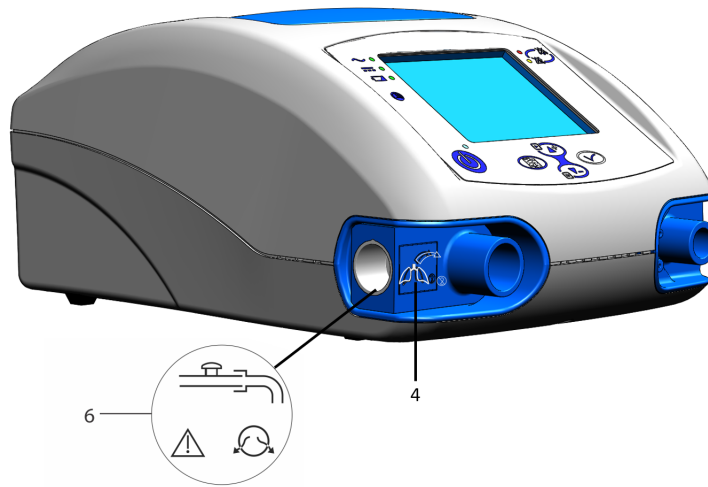


Figure 1-3. Location of Labels and Markings—Rear View

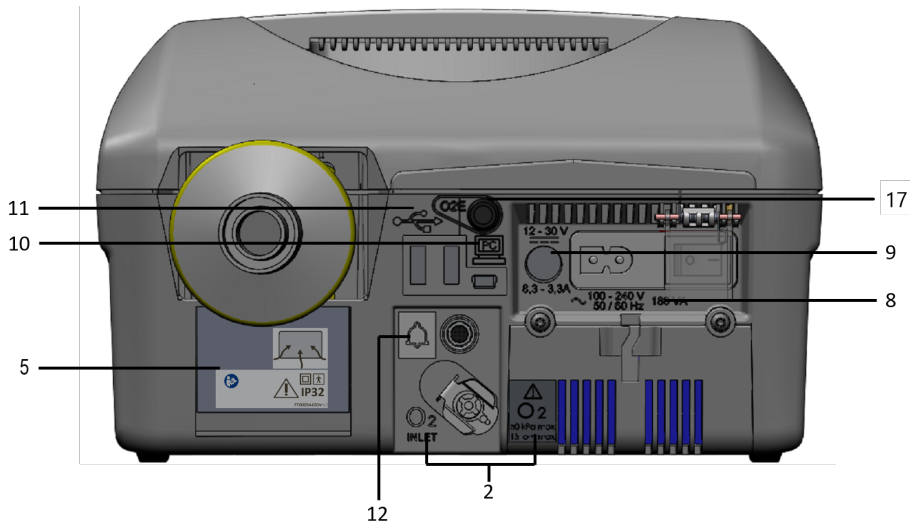


Figure 1-4. Location of Labels—Bottom View

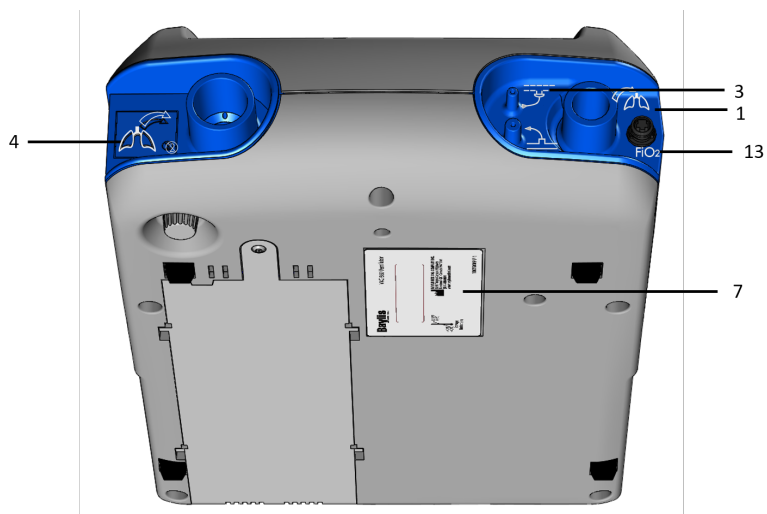


Figure 1-5. Location of Labels—Right Side View

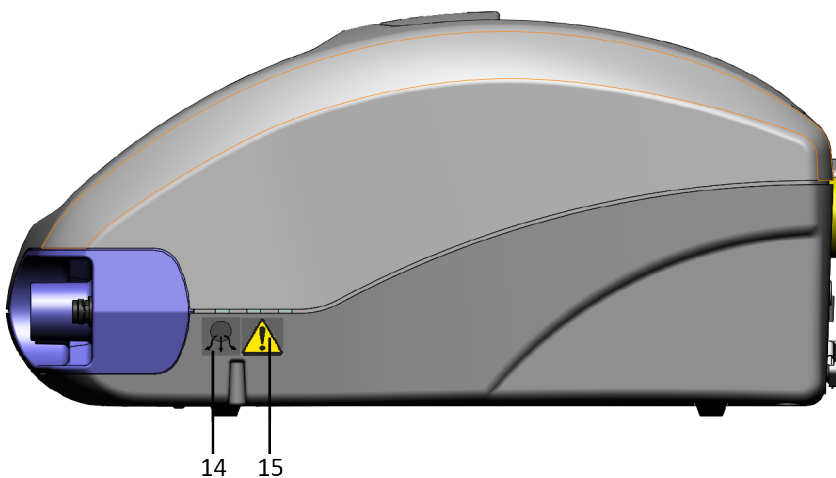
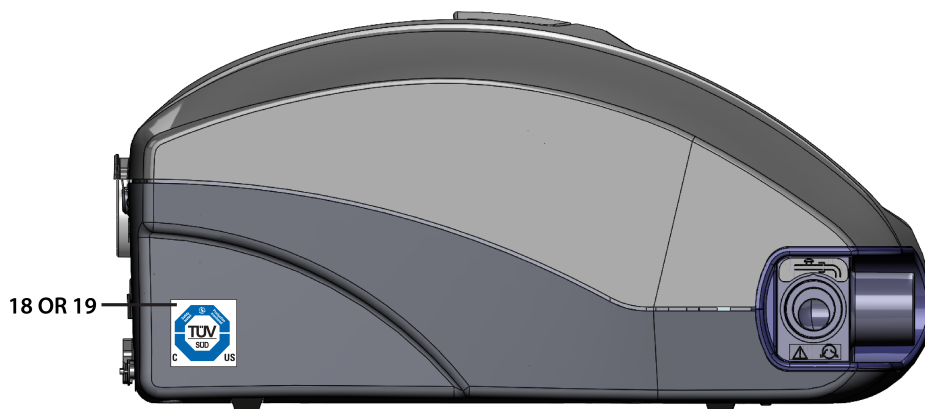


Figure 1-6. Location of Labels—Left Side View



2 Ventilator Overview

2.1 Indications for Use

The V4C-560™ Ventilator is indicated for the continuous or intermittent mechanical ventilatory support of patients weighing at least 11 lb (5 kg) who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a doctor. It is essential to read, understand, and follow these instructions before using the V4C-560™ Ventilator.

2.1.1 Target Patients

Specifically, the ventilator is applicable for adult and pediatric patients who require the following general types of invasive or non-invasive ventilatory support, as prescribed by an attending doctor:

- Positive Pressure ventilation
- Assist/Control, SIMV, or CPAP modes of ventilation
- Breath types including Volume Control, Pressure Control, and Pressure Support

2.1.2 Target Environments

The ventilator is suitable for use in institutional and home settings. It is not intended for use in Emergency Medical Service (EMS) such as an emergency transport.

2.1.3 Target Operators



WARNING:

This ventilator must be used only under the responsibility and on the prescription of a doctor.

The ventilator may be operated by the following caregivers:

- Respiratory therapists
- Doctors
- Nurses

- Homecare providers
- Patient and patient's families

For more details on knowledge and skill requirements for operating the V4C-560™ ventilator, please consult your clinician.

It is the responsibility of the clinician or clinical educator to ensure that both the patient and the caregiver fully understand the topics necessary for operation of the ventilator.

2.2 **Contraindications**

This ventilator is not for use with anesthetic gases, and is not intended for use as an emergency transport ventilator.

2.3 Operational Use

The V4C-560™ ventilator uses a micro-turbine to provide ventilatory support to patients. Clinicians may use a variety of interfaces to connect patients to the ventilator for continuous or intermittent ventilatory support. Some examples include mouthpieces; nasal masks or full face masks; endotracheal tubes or tracheotomy tubes. User-selectable ventilation modes are:

- Assisted Controlled Volume (V A/C)
- Assisted Controlled Pressure (P A/C)
- Volume Synchronized Intermittent Mandatory Ventilation (V SIMV)
- Pressure Synchronized Intermittent Mandatory Ventilation (P SIMV)
- Continuous Positive Airway Pressure (CPAP)
- Pressure Support Ventilation with apnea ventilation (PSV/ST)

2.3.1 Safety Net

Incorporated in the ventilator design is an alarm system that continuously monitors both patient and machine for signs of specific errors or faults that could lead to an unsafe condition. Should any of these errors or faults be detected, the alarm system announces the specific alarm condition both audibly and visually. The machine-related alarm conditions are factory set, whereas the patient-related alarm conditions are defined by alarm-threshold values selected by an operator (a clinician or a caregiver). For more information, see Chapter [3, Alarms and Troubleshooting](#).

2.3.2 Settings



A software key, known as the Locking key, restricts access to ventilation parameter settings and ventilation mode changes in order to distinguish between clinician usage and patient usage.

2.3.3 Oxygen Enrichment

Oxygen may be supplied from an external, low pressure source, but the oxygen flow must be limited to 15 lpm (50 kPa, 500 mbar). The ventilator automatically compensates for the extra flow created by the external oxygen supply (see Chapter [4, Installation and Assembly](#).)

2.3.4 Breathing Circuit

The ventilator can be used with a single- or double-limb patient circuit. If exhaled volume monitoring is required (such as ventilator dependent patients), use the double-limb circuit for exhaled tidal volume monitoring. For more information, see section [4.4, Patient Circuit](#).



WARNING:

Users must always possess an additional breathing circuit and exhalation valve while using the V4C-560™ ventilator.

2.4 Device Classification

The ventilator's IEC/EN 60601-1 classification is as follows:

- Protection/insulation class (electric shock): Class II
- Protection index of enclosure: IP32
- Degree of protection against risk of electric shock: BF
- Power: External (AC–mains, or DC–adapter) or internal (DC–battery)
- Operation mode: Continuous operation

For additional information, see Appendix [A, Specifications](#).

2.5 Front Panel

Figure 2-1. Front Panel

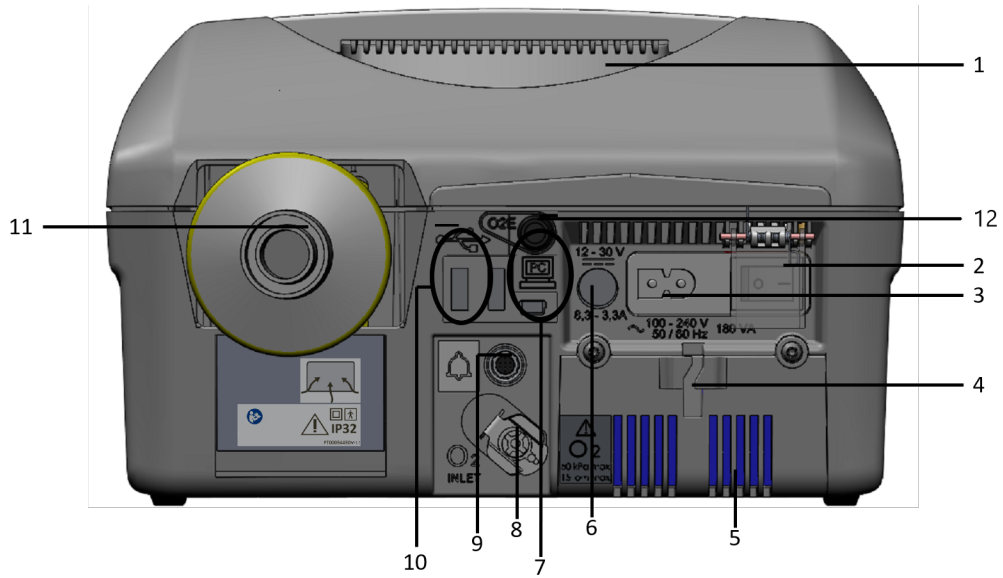


<p>1 LCD display—Shows information about the ventilator, including patient hours and software version, ventilation modes and settings, and monitored and calculated patient data and waveforms. The display also allows the user to view and, using the control panel, adjust the ventilator's operating and alarm configuration settings.</p>	<p>6 Exhalation valve port—Nipple for providing piloting pressure to the exhalation valve. Controls the open-closed position of the exhalation valve.</p>
<p>2 Control panel—Features the controls for setting up and operating the ventilator, and LEDs to indicate the ventilator's power source, ventilation on/off status, and alarm priority level. Control functions include turning on and off the ventilation, configuring ventilation modes, pausing audible alarms, canceling alarms, and setting device and alarm parameters.</p>	<p>7 Lateral and front openings—Vents that allow for air circulation to cool the ventilator's internal components. In addition, these openings function as sound ports for audible alarms.</p> <p>WARNING: Do not cover or obstruct these openings.</p>
<p>3 FiO₂ sensor connection—Connection for FiO₂ sensor, which monitors the amount of oxygen in the patient circuit.</p>	<p>8 From patient port—Exhaled volume measurements are taken from this port, through which a portion of the exhaled gas is diverted to the exhalation flow sensor. VTE is calculated from this flow measurement.¹</p>
<p>4 Patient connection port—Provides an outlet for the gas to be delivered to the patient via the patient circuit.</p>	<p>9 Exhaled gas outlet—Exhalation valve connects here.</p>
<p>5 Patient pressure monitoring port—Nipple for monitoring proximal patient pressure.</p>	

1. If exhaled tidal volume monitoring is required, use the double-limb circuit.

2.6 Back Panel

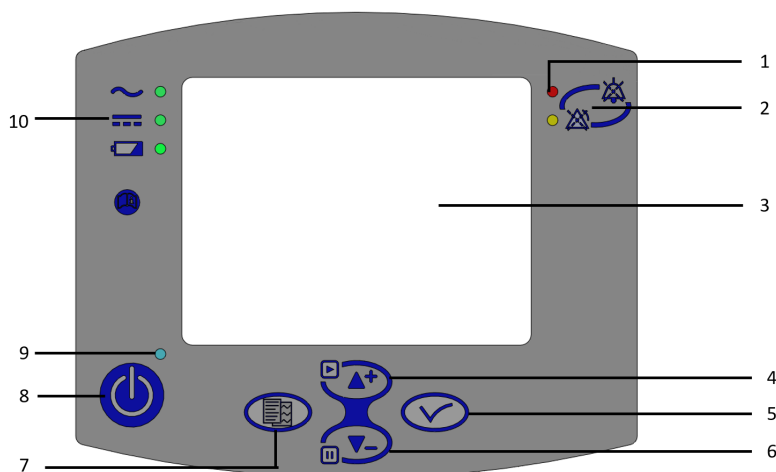
Figure 2-2. Back Panel



<p>1 Ergonomic carrying handle.</p>	<p>7 PC cable connector: USB mini-B connector used for Puritan Bennett™ ventilator test software. WARNING: Do not connect the ventilator to any device other than a PC with a dedicated compatible Puritan Bennett™ software package. Contact your Product representative for further information.</p>
<p>2 I/O (power) switch with protective cover: Device powered on in position I; device switched off in position 0.</p>	<p>8 O₂ inlet port: Connects the ventilator to a low pressure oxygen source via an adapter connected to the O₂ inlet (see section 4.8, Oxygen).</p>
<p>3 AC power (mains) cable connector.</p>	<p>9 Nurse call output connector: Used to connect the ventilator to the nurse call system. Note: Nurse call is not intended for use in the home environment.</p>
<p>4 AC power (mains) cable holding system: Secures AC power cable to avoid accidental disconnection.</p>	<p>10 USB memory device connection: USB connection to be used with the Puritan Bennett™ Respiratory Insight software package. Contact your Product representative for further information. There are two USB type A ports. WARNING: USB connections are not intended for connection to any devices other than the specified USB flash storage (per section 5.2.1, USB Memory Device Specifications).</p>
<p>5 Access cover for the internal battery.</p>	<p>11 Air inlet filter: Filters air as it enters the ventilator.</p>
<p>6 DC power cable connector with key.</p>	
	<p>12 O₂E accessory port</p>

2.7 Control Panel

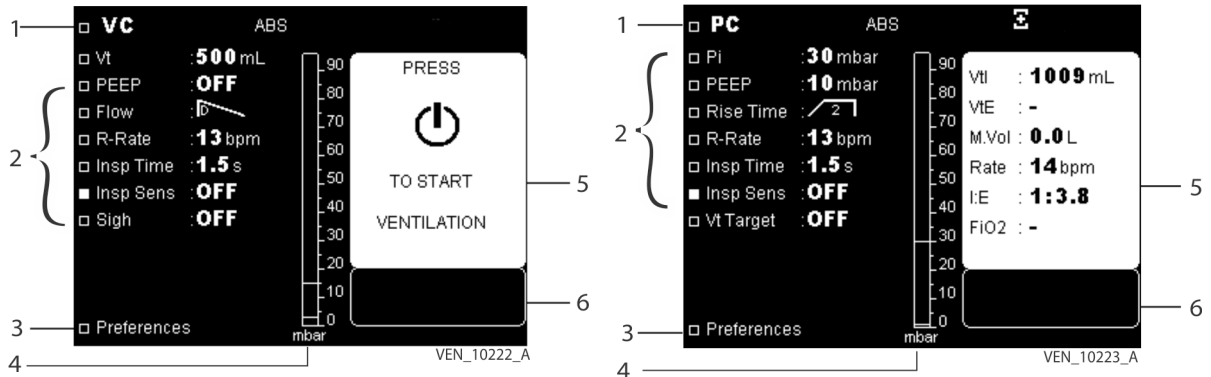
Figure 2-3. Control Panel



<p>1 Alarm indicators (two LEDs):</p> <p>Red indicator:</p> <ul style="list-style-type: none"> • Continuous: Very high priority (VHP) alarm activated. • Flashing: High priority (HP) alarm activated. <p>Yellow indicator:</p> <ul style="list-style-type: none"> • Flashing: Medium priority (MP) alarm activated. • Continuous: Low priority (LP) alarm activated. 	<p>6 DOWN/FREEZE key:</p> <ul style="list-style-type: none"> • Moves the cursor down and decreases parameter values. • During ventilation, freezes the waveform shown in the Waveform menu.
<p>2 ALARM CONTROL key:</p> <ul style="list-style-type: none"> • Press once to pause an audible alarm for 60 seconds. • Press twice to halt visual and audible alarms. If alarm is remedied, the alarm is canceled (other than the high pressure alarm). 	<p>7 MENU key:</p> <p>Changes the menu shown. From the Ventilation menu screen, press this key to show the Alarm menu screen.</p> <p>When a USB memory device is inserted into the ventilator, press this key to show the USB memory device screen.</p>
<p>3 Display screen:</p> <p>Shows modes, ventilation settings, patient data and waveforms, configuration of the ventilator, and alarm management.</p>	<p>8 VENTILATION ON/OFF button:</p> <ul style="list-style-type: none"> • ON: Press briefly and release to start ventilation. • OFF: Press and hold for 3 seconds, then press again to stop ventilation.
<p>4 UP/UNFREEZE key:</p> <ul style="list-style-type: none"> • Moves the cursor up and increases parameter values. • During ventilation, reactivates waveform tracing in the Waveform menu. 	<p>9 Ventilation status indicator:</p> <ul style="list-style-type: none"> • Blue indicator illuminated: Device is turned on and ventilation is off (on standby). • Blue indicator off: Ventilation is on.
<p>5 ENTER key:</p> <ul style="list-style-type: none"> • Access to a setting value and validation of the modification of this setting. • Access to a sub-menu. 	<p>10 Electrical power source indicators:</p> <ul style="list-style-type: none"> • AC power indicator lit: AC power source connected. • DC power indicator lit: DC power source connected. • Internal battery indicator lit continuously: Internal battery in use (no external power source connected.) • Internal battery indicator flashing: Battery charging.

2.8 Ventilation Menu

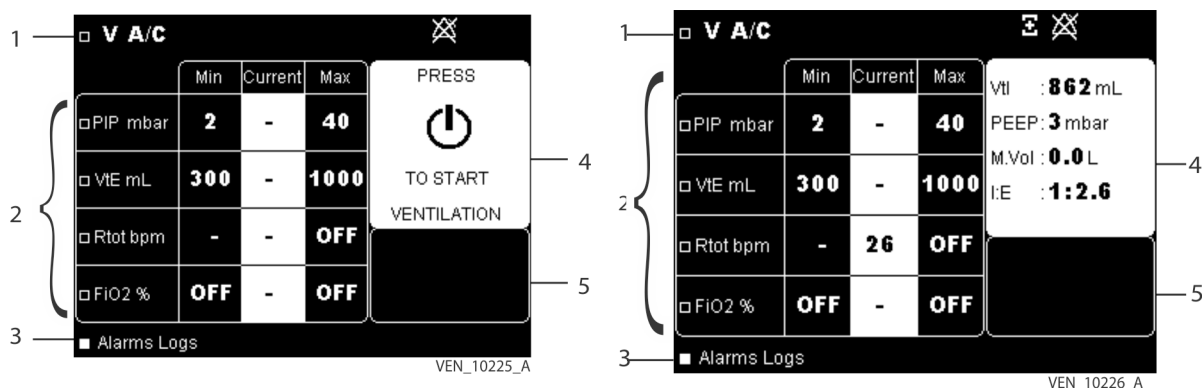
Figure 2-4. Ventilation Menu Display (on standby at left; during ventilation at right)



<p>1 General information line: Shows the current ventilation mode, along with the following:</p> <ul style="list-style-type: none"> : Battery symbol if the ventilator is powered by the internal battery. : Audio paused symbol if an alarm is currently inhibited. : Alarm paused symbol if an alarm has been canceled manually and the cause of the alarm remains. : Apnea alarm deactivation symbol. : Exhalation valve symbol. : No exhalation valve symbol. <p>ABS: Absolute symbol. REL: Relative symbol.</p>	<p>2 Ventilation settings: Shows the specific ventilation parameter values for the currently selected ventilation mode.</p>	<p>3 Preferences menu access line: Highlight this line and press the ENTER key to show the Preferences menu.</p>
<p>4 Bargraph: Shows pressure generation during ventilation.</p>	<p>5 Status/monitored data window:</p> <ul style="list-style-type: none"> • Ventilation stopped (standby): Shows the message, "PRESS TO START VENTILATION." • Ventilation on: Parameters are monitored and shown. • The Inspiratory effort detected symbol appears adjacent to the monitored I:E ratio when the patient actively triggers a breath. 	<p>6 Alarm conditions window:</p> <ul style="list-style-type: none"> • For active alarms, scrolls through active alarm messages in flashing reverse video. • For inactive alarms, shows the last alarm along with its trigger date and end-of-event time. <p>See Chapter 3, Alarms and Troubleshooting for details.</p>

2.9 Alarm Menu

Figure 2-5. Alarm Menu (on standby at left; during ventilation at right)

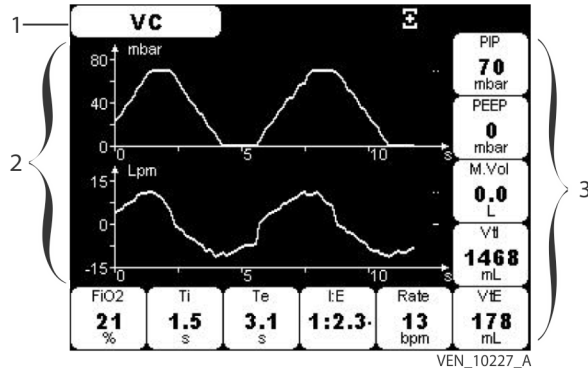









<p>1 Title line:</p> <p>Shows ventilation mode and the following symbols:</p> <p>: Battery symbol if the ventilator is powered by the internal battery.</p> <p>: Audio paused symbol if an alarm is currently inhibited.</p> <p>: Alarm paused symbol if an alarm has been canceled manually and the cause of the alarm remains.</p> <p>: Apnea alarm deactivation symbol.</p> <p>: Exhalation valve symbol.</p> <p>: No exhalation valve symbol.</p>	<p>2 Alarm settings:</p> <p>Shows the specific alarm parameter values for the currently selected ventilation mode, which are:</p> <ul style="list-style-type: none"> • Minimum and maximum alarm threshold settings • Current monitored patient readings, or hyphen (-) when ventilation is in standby 	<p>3 Access line to Alarm Logs menu.</p> <p>Highlight this line and press the ENTER key to show the Alarm Logs menu. See section 3.4, Alarm Logs Menu.</p>
<p>4 Status/monitored data window:</p> <ul style="list-style-type: none"> • Ventilation stopped (standby): Shows the message, "PRESS TO START VENTILATION." • Ventilation on: Parameters are monitored and shown. • The Inspiratory effort detected symbol appears adjacent to the monitored I:E ratio when the patient actively triggers a breath. 	<p>5 Alarm message window:</p> <ul style="list-style-type: none"> • For active alarms, scrolls through active alarm messages in flashing reverse video. • For inactive alarms, shows the last alarm along with its trigger date and end-of-event time. <p>See Chapter 3, Alarms and Troubleshooting for details.</p>	

2.10 Waveforms Menu

- The display of waveforms (see Figure 2-6) is optional and can be selected using the Menu key. The Waveform menu is only accessible when ventilation is active.

Figure 2-6. Waveforms Menu



<p>1 Title line: Shows ventilation mode and the following symbols:</p> <ul style="list-style-type: none"> : Battery symbol if the ventilator is powered by the internal battery. : Audio paused symbol if an alarm is currently inhibited. : Alarm paused symbol if an alarm has been canceled manually and the cause of the alarm remains. : Apnea alarm deactivation symbol. : Freeze waveforms symbol if the tracing of patient waveforms has been halted during ventilation. : Exhalation valve symbol. : No exhalation valve symbol. 	<p>2 Graphic zone: Shows the patient's pressure and flow waveforms as a function of time.</p>	<p>3 Numeric zone: Shows monitored data.</p>
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2.11 USB Memory Device Menu

Figure 2-7. USB Memory Device Menu



- | | | | |
|---|--------------------------|---|------------------------|
| 1 | Title line | 3 | USB Memory Device menu |
| 2 | Ventilator serial number | 4 | Dialogue box |

2.12 If Ventilator Failure Occurs

If a problem with the ventilator is suspected, **first check that the patient is not in danger**. If necessary, remove the patient from the ventilator and provide an alternate means of ventilation.

Keep in mind that troubleshooting information is available in this manual to assist you in the event of a problem. See Chapter [3, Alarms and Troubleshooting](#).

If you cannot determine the cause of a problem, contact your Equipment supplier or Baylis Medical Technologies. See section [8.6, Service Assistance](#).

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3 Alarms and Troubleshooting

3.1 Overview

The alarms or faults generated by the V4C-560™ ventilator are classified into two categories:

- Ventilation (or utilization) alarms
- Technical faults

Alarms indicate events likely to affect the ventilation in the short term and necessitate rapid intervention (see section [3.9, Troubleshooting](#)).

Some of the ventilator alarms are adjustable, depending on ventilation modes. Automatic, non-adjustable alarms also exist to create a safety net for safer patient ventilation.

Technical faults do not directly affect machine operation. Therefore, the user is not alerted to technical faults. Only authorized and trained technicians may consult the maintenance menu (see the service manual).



WARNING:

Setting any alarm limits to OFF or extreme high or low values can cause the associated alarm not to activate during ventilation, which reduces its efficacy for monitoring the patient and alerting the clinician to situations that may require intervention.



WARNING:

When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.




WARNING:

Do not pause, disable, or decrease the volume of the ventilator's audible alarm if patient safety could be compromised.



Note:

Many ventilator functions are not accessible when the Locking key  is enabled. For additional assistance contact your clinician or Equipment representative.



Note:

Default alarm setting preferences should be entered prior to using the ventilator.



Note:

All configurable alarm settings are recorded in the ventilator's nonvolatile internal memory, and are retained when powering down or in the event of a total loss of power.

3.2 Alarm Level of Priority

The alarm hierarchy for signaling the level of alarm criticality is listed as follows:

- **Very high priority (VHP): Immediate critical situation; ventilation is impossible:** Continuous sound signaling / with or without continuous red LED illumination / with or without message / with or without display lighting (it is possible for an alarm condition to occur that may not have both a message and lighting)
- **High priority (HP): Critical situation in the short term; ventilation is potentially compromised:** High speed intermittent sound signaling / flashing red LED illumination / with message / with display lighting
- **Medium priority (MP): Critical situation in the long term; ventilation is not affected in the short term:** Medium speed intermittent sound signaling / flashing yellow LED illumination / with message / with display lighting
- **Low priority (LP): Ventilation is not affected in the short term, but potential for delayed minor injury or discomfort:** Medium speed intermittent sound signaling / continuous yellow LED illumination / with message / with display lighting



Note:

If there is no corrective action and if the audible alarm is not inhibited (Audio Paused) or reset (Alarm Reset) within 60 seconds, high priority alarms will sound at the maximum level.

3.3 Alarm Display



Note:

The alarm indicator LEDs to the left of the ALARM CONTROL key on the V4C-560™ ventilator are designed to be visible to the operator at any position where the ventilator is visible to the operator. Specific alarm detail (shown in the alarm message area) is designed to be readable from up to four meters from the screen, at a viewing angle of up to 30°.

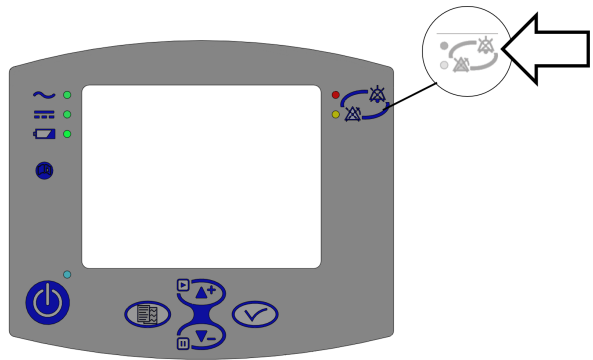
The ventilator is constructed to meet the compliance requirements of the IEC 60601-1-8 alarm standard.

During operation, when an alarm is activated, the following events occur:



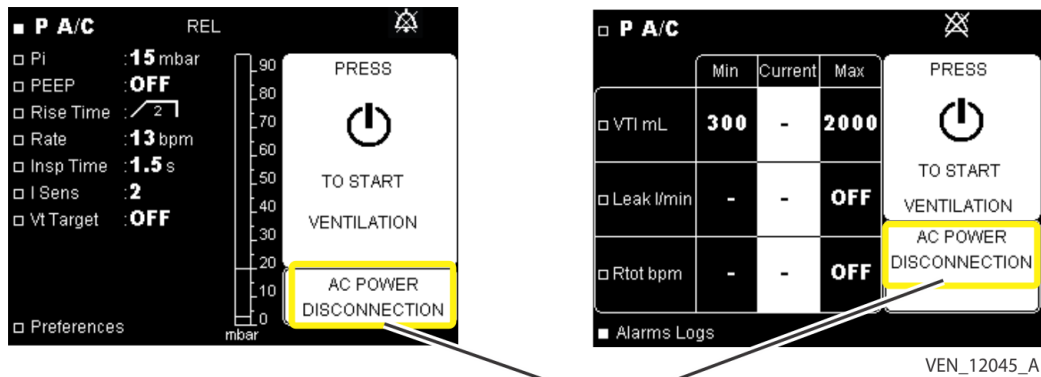
- One of the red or yellow alarm indicators to the left of the ALARM CONTROL key illuminates and possibly flashes.
- An alarm tone sounds.
- A message is shown and flashes in reverse video at the bottom of the Ventilation menu or Alarm menu.

Figure 3-1. Front Panel (Alarm Control Key)



1 Alarm Control key

Figure 3-2. Alarm Messages (in Ventilation menu at left, in Alarm menu at right)



1 Alarm messages



Note:

When an alarm is triggered, if the current menu shown is not the Ventilation parameters or Alarm menu, the display automatically switches to one of these menus to show the alarm message.



Note:

In the event several alarms are activated at the same time, the highest priority audible and visual alarm is highlighted; however, all active messages are shown, in the sequence in which they occurred.

3.4 Alarm Logs Menu

All alarms are recorded in the ventilator’s nonvolatile internal memory at the time of activation, and are retained when powering down or in the event of a total loss of power.

The Alarm Logs menu shows the last eight alarms activated, along with their date and time of activation.

To access the Alarm Logs menu:

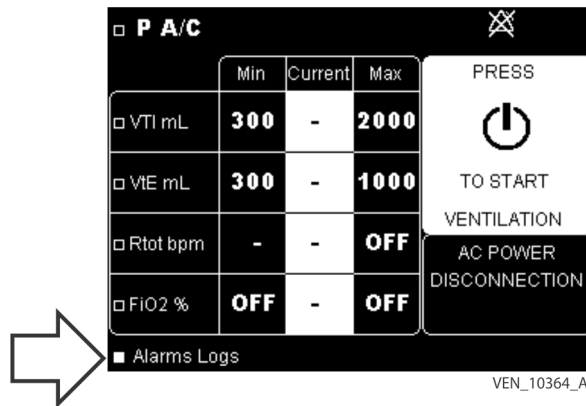


1. Press the MENU key to access the alarm setting menu (if this is not the menu currently shown).



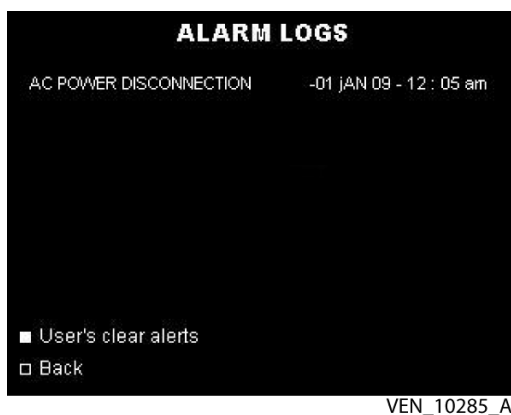
2. Press the DOWN key until the cursor is on the Alarm Logs line at the bottom of the page. The display appears as shown in Figure 3-3:

Figure 3-3. Accessing the Alarm Logs Menu



3. Press the ENTER key. The Alarm Logs screen is shown.

Figure 3-4. Alarm Logs Screen

**Note:**

When no alarm has been activated, the message "NO DATA" is shown on the screen (see Figure 3-5).

Figure 3-5. Alarm Logs Screen (no alarm activated)



For more information on the User's clear alerts line, see section 3.7, [Reactivating Alarms](#).

To dismiss the Alarm Logs screen manually:

1. Ensure that the cursor is on the Back line.
2. Press the ENTER key.

The Alarm Logs screen is dismissed automatically:

- After 15 seconds if no keyboard action is detected
- When a high priority alarm is triggered

**Note:**

Only qualified service personnel may access all alarms and events recorded by the ventilator. Qualified personnel should see the service manual for further information.

3.5 Pausing the Audible Portion of Alarms



WARNING:

Do not pause, disable, or decrease the volume of the ventilator’s audible alarm if patient safety could be compromised.

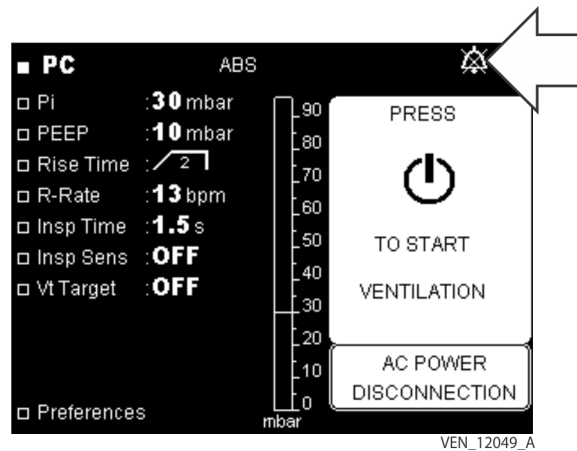


To pause the audible portion of activated alarms for 60 seconds at a time, press the ALARM CONTROL key. This causes the following:

- The audible portion of all activated alarms is paused.
- The visual portions (light indicator and message) of activated alarms remain visible.
- The audio paused symbol is shown at the top right of the screen while the audio pause function is active.



Figure 3-6. Pausing the Audible Portion of Alarms



If several alarms are activated at the same time, pressing the ALARM CONTROL key affects all current alarms.

The audible portion of activated alarms is automatically reactivated if the following occurs:

- After 60 seconds, if the cause or causes of the alarm or alarms persist
- Whenever a new alarm is activated



Note:

If a key is stuck or held down for 45 seconds, a keypad alarm will occur.

3.6 Pausing and Resetting Alarms



WARNING:

Alarm volume should be adjusted with respect to the ventilator's operating environment and so that the patient's caretakers can hear the alarms. The audible alarm vents located at the front of the device should never be obstructed. The alarm can be paused with the Alarm Pause function by pressing the ALARM CONTROL key twice once the alarm has been declared.



WARNING:

When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.

Some alarms are not automatically canceled when the condition causing the alarm clears (for example, high pressure). Some alarms can be paused manually even if the cause or causes of their activation remain.



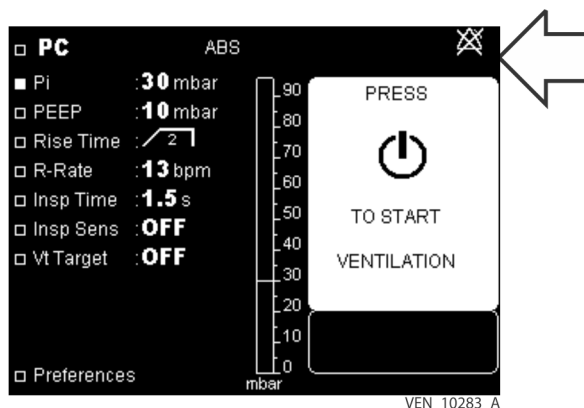
To manually pause an alarm, press the ALARM CONTROL key twice.

- The alarm is paused until the alarm condition is corrected and the condition reoccurs: the audible portion, light indicator, and message are all halted (for alarms that can be paused manually).



- The alarm paused symbol is shown at the top right of the Ventilation, Alarms, and Waveforms screens. See [Figure 3-7](#).

Figure 3-7. Ventilator Screen (alarm paused indicator)



When no other alarms are currently activated, the last alarm canceled is shown continuously in the alarm message window in the Alarms menu, along with the date and time of its activation. The High Pressure alarm must be manually reset. See section [3.8, Overview of Alarms](#).



To manually reset the High Pressure alarm, press the ALARM CONTROL key twice. The visual alarms will be reset.

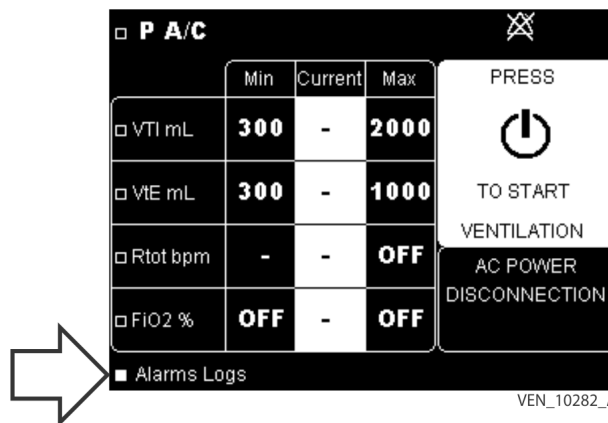
3.7 Reactivating Alarms

Alarms that have been paused and whose activation conditions continue to exist can be reactivated.

To reactivate alarms, proceed as follows:

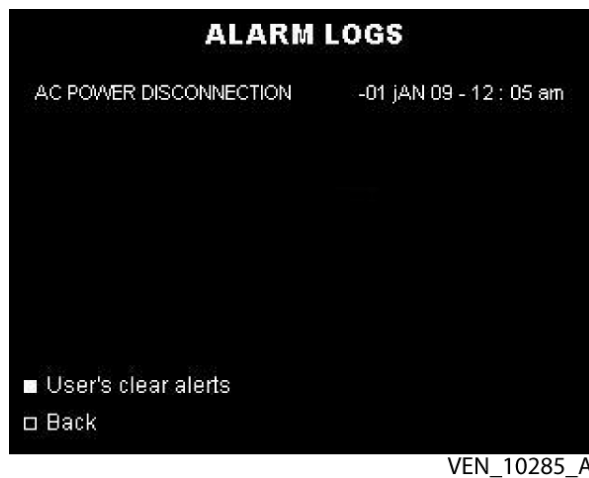
1. Press the MENU key to access the alarm setting menu, if this is not the menu currently shown.
2. Press the DOWN key to position the cursor on the Alarm Logs line, if this is not already the case. See [Figure 3-8](#).

Figure 3-8. Reactivating Alarms



3. Press the ENTER key, to confirm access to the Alarm Logs menu.
4. Press the UP key to position the cursor on the User's clear alerts line. See [Figure 3-9](#).

Figure 3-9. Alarm Logs



5. Press the ENTER key for at least 3 seconds. The following events occur:
 - A beep sounds.
 - An audible alarm sounds.
 - An alarm indicator illuminates.

- The messages of all active alarms are shown in a loop in the Ventilation and Alarm menus.
- The audio paused symbol disappears (if it was shown).
- The alarm paused symbol disappears.

3.8 Overview of Alarms



Note:

The message: “*IF PERSISTS RESTART/SRVC” will occur only if the alarm condition continues for longer than 30 seconds.



Note:


Many ventilator functions are not accessible when the Locking key  is enabled. For additional assistance, contact your clinician or Equipment representative.

Table 3-1. Overview of Alarms

Alarm message	Cause/ventilator response	Priority	Audio Paused available	Alarm Paused available
AC POWER DISCONNECTION	Cut-off of the AC (mains) power supply. Alarm activation occurs: <ul style="list-style-type: none"> • Immediately if the Power Fault alarm is OFF • After 5 seconds if the Power Fault alarm is ON and ventilation is stopped • After two breath cycles when ventilation is in progress Consequence: Switchover to external DC power supply if present; if not, to the internal battery.	If the Power Fault alarm is active: MP Otherwise: LP	Yes	Yes
APNEA	NOTE: The Apnea alarm is equivalent to a hypoventilation alarm. No inspiratory trigger detected by the ventilator after the apnea time set in PSV, CPAP, P SIMV, and V SIMV modes. Automatically clears itself after three successive patient breaths.	MP	Yes	Yes (except for CPAP)
BATTERY FAULT1 RESTART/SRVC	Ventilator has detected an internal battery fault. Consequence: The internal battery is disabled from use.	MP	Yes	Yes
BATTERY FAULT2 RESTART/SRVC	No internal battery detected.	MP	Yes	No
BUZZER FAULT1 RESTART/SRVC	Defective operation of the buzzers.	MP	Yes	No
BUZZER FAULT2 RESTART/SRVC	Failure detected in the very high priority buzzer. Consequence: No audible alarm in case of Power Supply Loss alarm.	MP	Yes	Yes

Table 3-1. Overview of Alarms (Continued)

Alarm message	Cause/ventilator response	Priority	Audio Paused available	Alarm Paused available
BUZZER FAULT3 RESTART/SRVC	Battery charge failure due to incorrect voltage. Contact your service representative for assistance.	HP	Yes	No
BUZZER LOW BATTERY	Buzzer battery failure. The battery buzzer voltage is too low. Internal technical problem that prevents the battery sounding the Power Supply Loss alarm.	MP	Yes	Yes
CALIBRATE FiO ₂	An FiO ₂ sensor is detected and has not been calibrated.	MP	Yes	Yes
CALIBRATION FAIL	Failure of one calibration point of the internal exhaled flow sensor. Consequence: Failed calibration point is replaced by the default point.	MP	Yes	Yes
CHECK BATTERY CHARGE *IF PERSISTS RESTART/SRVC	Internal battery charging failure. Consequence: Charging of the internal battery impossible.	MP	Yes	No
CHECK EXH VALVE* *IF PERSISTS RESTART/SRVC	Inspired tidal volume during exhalation <20% of Inspired tidal volume and inspired tidal volume >20 mL. Exhalation valve obstructed. Alarm activation occurs after two breath cycles or after 5 seconds, whichever is greater.	HP	Yes	No
CHECK EXH VALVE PRESSURE	Internal ventilation fault related to exhalation valve detection sensor (pressure sensor).	HP	Yes	Yes
CHECK FiO ₂ SENSOR	FiO ₂ measurement is less than 18%. Recalibrate or change FiO ₂ sensor.	HP	Yes	No
CHECK PROXIMAL LINE1* *IF PERSISTS RESTART/SRVC	NOTE: The Check Proximal Line 1 alarm is equivalent to a continuous positive pressure alarm. Loss of signal from the proximal pressure sensor. Consequence: Switch to internal pressure sensor for the pressure measurement. Alarm activation occurs in the event of signal loss, and under the following conditions (time is in seconds): <ul style="list-style-type: none"> • Disconnection time +2 or (60/R-Rate +2), whichever is greater, in P A/C and V A/C mode • Disconnection time +2 or (Apnea time +4), whichever is greater, in CPAP and PSV mode • Disconnection time +2 or (60/R-Rate + Insp time +2), whichever is greater, in P SIMV and V SIMV mode 	MP	Yes	No
CHECK REMOTE ALARM	No activation of nurse call or remote alarm system when an alarm is in progress.	MP	Yes	Yes

Table 3-1. Overview of Alarms (Continued)

Alarm message	Cause/ventilator response	Priority	Audio Paused available	Alarm Paused available
CHECK SETTINGS	Alarm activation occurs: <ul style="list-style-type: none"> • Systematically after software versions have changed. • Loss of memorized parameters Consequence: <ul style="list-style-type: none"> • Locking key disabled • Out-of-range settings are replaced by their default values 	MP	Yes	Yes
CONNECT VALVE OR CHANGE PRESS	<ul style="list-style-type: none"> • No exhalation valve connected with PEEP set to less than 4 mbar • Pi set to more than 30 mbar when relative pressure is set to OFF. 	HP	Yes	No
CONTROLLED CYCLES	The ventilator is delivering apnea ventilation at set back up rate.	N/A	N/A	N/A
COOLING FAN RESTART/SRVC	Ventilator cooling fan operating speed not suited to the internal ambient temperature of the device.	MP	Yes	Yes
DC POWER DISCONNECTION	Cut-off of the external DC power supply. Consequence: Switchover to the internal battery.	LP	Yes	Yes
DEVICE FAULT3 RESTART/SRVC	Failure in the 24 V power supply.	HP	Yes	No
DEVICE FAULT5 RESTART/SRVC	Detection of a fault in the electrical power supply system. Alarm activation occurs once the ventilator is on for at least 3 seconds, and a power supply fault is detected for at least 5 seconds thereafter. Consequence: The internal battery capacity is not shown beside the battery symbol.	MP	Yes	Yes
DEVICE FAULT7 RESTART/SRVC	Detection of a fault in internal voltage measurement.	HP	Yes	No
DEVICE FAULT9 RESTART/SRVC	POST RAM error. RAM read/write does not match memory setting.	VHP	No	No
DEVICE FAULT10 RESTART/SRVC	POST FLASH checksum error. Startup FLASH computed checksum does not match memory setting.	VHP	No	No
DEVICE FAULT11 RESTART/SRVC	POST EEPROM error. Startup EEPROM does not match memory setting.	VHP	No	No
DEVICE FAULT12 RESTART/SRVC	POST reference voltage error. 5V or 10V reference voltage error.	VHP	No	No
DEVICE FAULT13 RESTART/SRVC	Software version error.	VHP	No	No
E SENS FAULT OR CIRC LEAK	At least four of the last six breaths within the last minute are terminated by time.	MP	Yes	No

Table 3-1. Overview of Alarms (Continued)


Alarm message	Cause/ventilator response	Priority	Audio Paused available	Alarm Paused available
EMPTY BATTERY	Internal battery capacity <10 minutes or 3%. (battery voltage <22.5 V) Consequence: Ventilation comes to a halt.	If AC power is not connected: HP If AC power is connected: LP	No	No
EXH VALVE LEAKAGE	Abnormally high expired flow during the inspiratory phase of three consecutive breaths (in double-limb setup). Alarm activation occurs after three consecutive breaths.	MP	Yes	No
FI _O ₂ SENSOR MISSING	No FI _O ₂ sensor detected and the FI _O ₂ alarm is active.	HP	Yes	Yes
HIGH / LOW BATTERY TEMP* *IF PERSISTS RESTART/SRVC	Battery temperature out of tolerance. Consequence: Battery charging stops.	MP	Yes	Yes
HIGH FI _O ₂	The level of oxygen delivered by the ventilator exceeds the Max FI _O ₂ level set for 45 seconds.	MP	Yes	No
HIGH INT TEMP COOL VENT* *IF PERSISTS RESTART/SRVC	Device internal ambient temperature out of tolerance range.	MP	Yes	Yes
HIGH LEAKAGE	The leak estimated by the ventilator exceeds the Max leak alarm threshold.	HP	Yes	No
HIGH PRESSURE	Alarm activation occurs after three consecutive breaths, under the following conditions: <ul style="list-style-type: none"> • In V A/C or V SIMV modes, if inspiratory pressure is higher than Max PIP during three consecutive cycles. • In PSV, CPAP, P A/C, or P SIMV modes, if inspiratory pressure is higher than (P Support or P Control + PEEP) + 5 mbar up to 29 mbar or + 10 mbar over 30 mbar during three consecutive cycles. • In PSV or CPAP mode and P Support is set to off, if inspiratory pressure is higher than PEEP + 10 mbar during three consecutive cycles. Consequence: Switch to exhalation phase.	HP NOTE: When alarm condition clears, alarm priority indicator must be manually reset by pressing  . Automatically resets upon activation of lower priority alarm.	Yes	No (The visual portion of the alarm may be paused)
HIGH RATE	Rate measured greater than Max Rtot set during three consecutive breaths. Alarm activation occurs after three consecutive breaths.	MP	Yes	No
HIGH VTE	Exhaled tidal volume greater than Max VTE set during three consecutive breaths (in double-limb setup). Alarm activation occurs after three consecutive breaths.	MP	Yes	No
HIGH VTI	Inspired tidal volume greater than Max VTI set during three consecutive breaths in PSV, CPAP, P A/C, P SIMV, and V SIMV modes. Alarm activation occurs after three consecutive breaths.	HP	Yes	No

Table 3-1. Overview of Alarms (Continued)

Alarm message	Cause/ventilator response	Priority	Audio Paused available	Alarm Paused available
INSP FLOW RESTART/SRVC	Inspiratory flow is constant (± 1 lpm) with normal turbine temperature and speed conditions. Contact your service representative for assistance.	HP	Yes	No
INTENTIONAL VENT STOP	Ventilation has been stopped voluntarily by the caregiver or patient.	HP	Yes	Yes
KEYPAD FAULT RESTART/SRVC* *IF PERSISTS RESTART/SRVC	Keyboard key held down for more than 45 seconds.	HP	No	No
LOW BATTERY	Internal battery capacity <30 minutes or 8%.	If AC power is not connected: HP If AC power is connected: LP	Yes	No
LOW FiO ₂	The level of oxygen delivered by the ventilator is below the Min FiO ₂ level set for 45 seconds.	MP	Yes	No
LOW VTE	Exhaled tidal volume less than Min VTE set during three consecutive breaths (in double-limb setup). Alarm activation occurs after three consecutive breaths.	MP	Yes	No
LOW VTI	Inspired tidal volume less than Min VTI set during three consecutive breaths in PSV, CPAP, P A/C, P SIMV, and V SIMV modes. Alarm activation occurs after three consecutive breaths.	MP	Yes	No
NO BATTERY DETECTED	Immediately detected when no battery is installed.	MP	Yes	No
OCCLUSION CHECK CIRCUIT* *IF PERSISTS RESTART/SRVC	Occurs in valve configuration when measured tidal volume is less than 20 ml for PSV, P A/C, and P SIMV modes. Alarm activation occurs after two breath cycles or after 5 seconds, whichever is greater, if the tidal volume is less than 20 mL.	HP	Yes	No
OCCLUSION CHECK CIRCUIT	Occurs in leak configuration when the leak level is not sufficient to flush the CO ₂ from patient exhalation. The built-in leak in the mask may be obstructed. The built-in leak for the mask is not sufficient for the settings.	HP	Yes	No

Table 3-1. Overview of Alarms (Continued)

Alarm message	Cause/ventilator response	Priority	Audio Paused available	Alarm Paused available
PATIENT DISCONNECTION* *IF PERSISTS RESTART/SRVC	Alarm activation occurs under the following conditions (time is in seconds): <ul style="list-style-type: none"> • Disconnection time or 60/R-Rate, whichever is greater, in P A/C and V A/C mode • Disconnection time or (Apnea time +2 sec), whichever is greater, in CPAP and PSV mode • Disconnection time or (60/R-Rate + Insp time), whichever is greater, in P SIMV and V SIMV mode. If the flow is greater than 130 lpm during the inspiratory phase. In V A/C and V SIMV modes, if patient pressure is lower than Min PIP. In PSV, CPAP, P A/C modes and P SIMV if patient pressure is lower than (P Support + PEEP) –20% or (Pi + PEEP) –20%.	HP	Yes	No
POWER FAULT RESTART/SRVC	Detection of a fault in the electrical power supply system.	MP	Yes	Yes
POWER SUPPLY LOSS (no message)	<ul style="list-style-type: none"> • Electrical power supply to the machine is interrupted with the I/O (power) switch when ventilation is in progress. • Battery fully discharged when it was the only source of power to the ventilator. Consequence: Ventilation stops immediately. Ventilation restarts immediately when the switch is pressed or after restoration of the AC or DC supply.	VHP	No—Alarm cancel only	No—Alarm cancel only
PRES SENS FLT1 RESTART/SRVC	Faulty internal pressure sensor signal. Alarm activation occurs after 15 seconds.	HP	Yes	No
PROX SENS FLT2 RESTART/SRVC	Faulty proximal pressure sensor signal. Alarm activation occurs after 15 seconds.	MP	Yes	Yes
REMOVE VALVE CPAP MODE	The ventilation settings are not compatible with the type of patient circuit used. Remove exhalation valve to start CPAP ventilation.	HP	Yes	No
REMOVE VALVE OR CHANGE PRES	The ventilation settings are not compatible with the type of patient circuit used. With a valve circuit, the difference between Pi and PEEP should not be less than 5 mbar.	HP	Yes	No
SOFTWARE VERSION ERROR	Detection of a wrong software version.	N/A	N/A	N/A
TURB OVERHEAT RESTART/SRVC	Turbine speed too low and temperature too high. Consequence: Ventilation stops immediately and O ₂ supply stops.	HP	No	No
UNKNOWN BATTERY	The internal battery is not recognized as a Baylis Medical approved battery.	MP	Yes	No

Table 3-1. Overview of Alarms (Continued)

Alarm message	Cause/ventilator response	Priority	Audio Paused available	Alarm Paused available
VALVE MISSING CONNECT VALVE	Connect exhalation valve to start ventilation in V A/C or V SIMV / P SIMV modes.	HP	Yes	No
VTI NOT REACHED* *IF PERSISTS RESTART/SRVC	Measurement and calculation of tidal volume do not match Vt set during six consecutive breaths in VOL inspired and V SIMV modes. Alarm activation occurs after six consecutive breaths—once the ventilator has reached its performance limits.	HP	Yes	No

3.9 Troubleshooting



WARNING:

This manual tells you how to respond to ventilator alarms, but it does NOT tell you how to respond to the patient.



WARNING:

To ensure proper servicing and avoid the possibility of physical injury to personnel or damage to the ventilator, only personnel authorized and qualified by Baylis Medical Technologies should attempt to service or make authorized modifications to the V4C-560™ ventilator.

3.9.1 Alarms

Table 3-2 offers a guide to the most likely ventilator alarms, possible reasons for the alarms, and corrective actions.



WARNING:

Do not attempt to open, repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only personnel authorized and qualified by Baylis Medical Technologies should repair, open or service the ventilator.



WARNING:

When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.



Note:

The ventilator screen must be unlocked before settings and parameters can be changed.



Note:


Many ventilator functions are not accessible when the Locking key  is enabled. For additional assistance, contact your clinician or Equipment representative.

Table 3-2. Alarms and Corrective Actions

Alarm message or symptom	Possible reason for the alarm event	Corrective action
AC POWER DISCONNECTION	AC ("mains") power source cut off.	Cancel the alarm, and then check the supply cable and the effective availability of a voltage on the AC power ("mains") port.
	Starting with 12–30 VDC external power supply.	Cancel the alarm.
	Current-limiting fuse of the device blown.	Replace the ventilator. Contact your customer service representative for assistance.
APNEA Note: The Apnea alarm is equivalent to a hypoventilation alarm.	Patient's breathing effort less than the sensitivity control setting.	Ensure the patient is breathing. Contact your customer service representative for assistance.
	Patient apnea.	Examine the patient for breathing effort and stimulate if necessary. If patient status has changed, contact your customer service representative for additional assistance.
	Defective sensors.	Contact your customer service representative to arrange for a qualified technician to replace the defective component or components.
BATTERY FAULT1 RESTART/SRVC	Battery problem that prevents operation.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
BATTERY FAULT2 RESTART/SRVC	Internal battery missing or not detected.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
BUZZER FAULT1 RESTART/SRVC	Defective operation of the buzzers. Consequence: no audible tone when an alarm is activated.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
BUZZER FAULT2 RESTART/SRVC	Internal technical problem that prevents the very high priority Power Supply Loss alarm from triggering.	Ensure that the protective cover over the I/O (power) switch located on the rear of the device is intact and functioning properly. This cover helps prevent accidental pressing of the switch and stoppage of ventilation. Ensure that the device is stabilized. Contact your customer service representative for additional assistance.
BUZZER FAULT3 RESTART/SRVC	Internal technical problem that prevents the battery from correctly charging.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
BUZZER LOW BATTERY	Internal technical problem that prevents the battery warning buzzer from sounding a Power Supply Loss alarm.	Connect the ventilator to an AC power source and power on using the I/O (power) switch located on the rear of the ventilator. Allow the ventilator to charge for a minimum of 15 minutes and up to 2 hours. If alarm persists, restart ventilator to see if alarm clears. If not, contact your customer service representative for assistance.
CALIBRATE FiO ₂	An FiO ₂ sensor is detected and has not been calibrated.	Calibrate FiO ₂ sensor. Contact your customer service representative for assistance.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm message or symptom	Possible reason for the alarm event	Corrective action
CALIBRATION FAIL	Too large a difference between a calibration point and its tolerance range.	There may be a leak in the circuit. Ensure an approved circuit is in use (see circuit documentation). Contact your customer service representative for assistance.
	Incorrect circuit type selected in the Preferences menu.	Verify the circuit selection matches the circuit in use. Contact your customer service representative for assistance.
	Exhalation block defective or not properly aligned.	Reset alarm message and ensure all connections are secure, verify circuit integrity, and verify the exhalation block is properly seated.
	Defective exhalation flow sensor.	Contact your customer service representative to arrange for a qualified technician to replace the defective component or components.
CHECK BATTERY CHARGE	Battery charging impossible.	Do not disconnect the ventilator from the AC power supply. Ensure that the power cable is installed according to the instructions in Chapter 4, <i>Installation and Assembly</i> , so that the power cable cannot be involuntarily disconnected. In the event the internal battery capacity is low, use an alternate device to ventilate the patient. Contact your customer service representative for assistance.
CHECK EXH VALVE	Obstruction or abnormal damage of the exhalation valve.	Contact your customer service representative for assistance.
	Excessive moisture in the exhalation block.	Verify exhalation valve is seated properly. Reduce temperature of the humidifier. Contact your customer service representative for additional assistance.
	Defective connection or defective exhalation valve tubing.	Reconnect the valve or replace the exhalation valve, the exhalation valve pilot pressure tube, or both.
	Defective inspiratory flow sensor.	Contact your customer service representative to arrange for a qualified technician to replace the defective component or components.
CHECK EXH VALVE PRESSURE	The exhalation valve may not be detected by the ventilator when ventilation is started. The exhalation valve may be falsely detected when ventilation is started.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
CHECK FiO ₂ SENSOR	FiO ₂ measured is less than 18%.	Contact your customer service representative for assistance.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm message or symptom	Possible reason for the alarm event	Corrective action
CHECK PROXIMAL LINE1* *IF PERSISTS RESTART/SRVC Note: The Check Proximal Line 1 alarm is equivalent to a continuous positive pressure alarm.	No connection of the proximal pressure tube when ventilation starts.	Reconnect the proximal pressure line.
	Proximal pressure line disconnected or obstructed.	Reconnect the connection line or replace it if obstructed. Check for moisture or occlusion of the proximal line. Reduce humidifier temperature. Switch to a heated wire circuit. Contact your customer service representative for additional assistance.
	Defective proximal pressure sensor or internal leak of the machine.	Restart ventilator to see if alarm clears. If not, contact your customer service representative to arrange for a qualified technician to replace the defective component or components.
CHECK REMOTE ALARM	Nurse call or remote alarm system is disconnected.	Contact your customer service representative for assistance.
	Relay control voltage problem.	Carefully monitor the patient to detect possible alarm triggering. Contact your customer service representative to arrange for maintenance.
CHECK SETTINGS	Loss of memorized parameters.	Contact your customer service representative for assistance.
	Software versions have changed.	Contact your customer service representative for assistance.
CONNECT VALVE OR CHANGE PRESS	The ventilation settings are not compatible with the type of patient circuit used. No exhalation valve connected with PEEP set to less than 4 mbar. Pi set to more than 30 mbar when relative pressure is set to OFF.	Connect exhalation valve. Contact your customer service representative for additional assistance. NOTE: Always consult the clinician before changing PEEP, FiO ₂ , pressure, volume, or Rate settings.
CONTROLLED CYCLES	The ventilator is delivering apnea ventilation at set back up rate.	Check that the patient circuit is correctly attached and the patient is correctly ventilated.
COOLING FAN RESTART/SRVC	Operating speed of the cooling fan not properly adjusted for the internal ambient temperature of the device.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
DC POWER DISCONNECTION	12–30 VDC power supply cut off when there is no AC (“mains”) power supply.	Cancel the alarm, and then check the supply wiring and the effective availability of voltage on the external source.
	Ventilator’s current-limiting fuse blown.	Replace the ventilator. Contact your customer service representative for assistance.
DEVICE FAULT3 IF PERSISTS RESTART/SRVC	24V supply failure.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
DEVICE FAULT5 IF PERSISTS RESTART/SRVC	Internal problem in the electrical power supply.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm message or symptom	Possible reason for the alarm event	Corrective action
DEVICE FAULT7 IF PERSISTS RESTART/SRVC	Internal technical problem.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
DEVICE FAULT9 IF PERSISTS RESTART/SRVC	POST RAM error. RAM read/write does not match memory setting.	If patient has been disconnected, reconnect patient to reset the fault. If the error persists, restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
DEVICE FAULT10 IF PERSISTS RESTART/SRVC	POST FLASH checksum error. Startup FLASH computed checksum does not match memory setting.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
DEVICE FAULT11 IF PERSISTS RESTART/SRVC	POST EEPROM error. Startup EEPROM does not match memory setting.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
DEVICE FAULT12 IF PERSISTS RESTART/SRVC	POST reference voltage error. 5V or 10V reference voltage error.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
DEVICE FAULT13 IF PERSISTS RESTART/SRVC	Incorrect software version detected.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
EMPTY BATTERY	Internal battery capacity is less than 10 minutes (or 3%)—battery operation overextended.	Reconnect the device to an AC power outlet, connect it to an external DC power source, or replace the battery. NOTE: The internal battery can be charged only when the ventilator is connected to an AC power supply.
E SENS FAULT OR CIRC LEAK	Leak in the patient circuit, leak in patient artificial airway or vented mask interface.	Check and properly connect the patient circuit connections. Minimize the leak. Ensure O ₂ connector is removed. Check tracheotomy cuff. Refit mask. Use non-vented mask. Contact your customer service representative for additional assistance. NOTE: Always consult the clinician before changing PEEP, FiO ₂ , pressure, volume or Rate settings.
	E sensitivity setting not properly adjusted.	Contact your customer service representative for assistance. NOTE: Always consult the clinician before changing PEEP, FiO ₂ , pressure, volume or Rate settings.
EXH VALVE LEAKAGE	Large leakage detected on the patient circuit return limb during the inspiratory phase.	Replace the exhalation valve, its control tube, or both.
	Contaminated or defective exhalation flow sensor.	Restart ventilator to see if alarm clears. If not, contact your customer service representative to arrange for a qualified technician to replace the defective component or components.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm message or symptom	Possible reason for the alarm event	Corrective action
FiO ₂ SENSOR MISSING	There is no FiO ₂ sensor, and FiO ₂ alarms are active.	Contact your customer service representative for assistance.
HIGH FiO ₂	The level of oxygen being delivered to the patient is higher than the Max FiO ₂ limit set.	Contact your customer service representative for assistance. Recalibrate sensor, ensuring it is removed from the T-connector and exposed to ambient air. NOTE: Always consult the clinician before changing PEEP, FiO ₂ , pressure, volume or Rate settings.
HIGH INT TEMP COOL VENT	Internal ambient temperature of the device out of the tolerance ranges.	If the ambient temperature is too low, place the device in a warmer environment. If the ambient temperature is too high, place the ventilator in a cooler environment. For example, ensure the ventilator is not in direct sunlight or next to an air conditioning vent. WARNING: In case of operation in a high ambient temperature, handle the ventilator with care; some portions of the device may have high surface temperatures. WARNING: In the case of high ambient temperatures, it may take a significant period of time to cool the internal temperature of the ventilator to the proper operating range. To avoid injury to the patient, ensure that the air inspired by the patient does not exceed 41°C (106°F). If in doubt, replace the ventilator. NOTE: The temperature fault alarm does not interfere with the operation of the ventilator. NOTE: Ensure that you are operating the ventilator within the proper temperature range (see Appendix A, <i>Specifications</i>).
	Defective internal temperature probe or any other technical anomaly.	Replace the ventilator. Contact your customer service representative for assistance.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm message or symptom	Possible reason for the alarm event	Corrective action
HIGH/LOW BATTERY TEMP* *IF PERSISTS RESTART/SRVC	Battery temperature out of the tolerance ranges. Defective internal temperature probe or any other technical anomaly inside the battery.	<p>If the ambient temperature is too low, place the device in a warmer environment.</p> <p>If the ambient temperature is too high, place the ventilator in a cooler environment.</p> <p>For example, ensure the ventilator is not in direct sunlight or next to an air conditioning vent.</p> <p>Restart ventilator to see if alarm clears. If the alarm message persists, please contact technical services.</p> <p>WARNING: In case of operation in a high ambient temperature, handle the ventilator with care; some portions of the device may have high surface temperatures.</p> <p>CAUTION: Do not attempt to charge a defective battery; such a battery cannot be charged.</p> <p>NOTE: The temperature fault alarm does not interfere with the operation of the ventilator.</p> <p>NOTE: Ensure that the ventilator is being used according to the operating instructions found in Appendix A, Specifications.</p>
HIGH LEAKAGE	The leak estimated by the ventilator exceeds the Max Leak alarm threshold.	<p>Readjust mask to reduce leakage.</p> <p>Contact your customer service representative for additional assistance.</p>
HIGH PRESSURE	Adjustment of Max PIP too low (only for V A/C and V SIMV modes).	<p>Contact your customer service representative for assistance.</p> <p>NOTE: Always consult the clinician before changing PEEP, FiO₂, pressure, volume or Rate settings.</p>
	Airway obstruction.	Check patient's trachea and clear the obstruction. If the filter is obstructed, replace the filter.
	Proximal pressure tube or patient circuit obstructed.	Clean the proximal pressure tube or the patient circuit or replace them.
	Coughing or other high-flow exhalation efforts.	<p>Treat patient's cough.</p> <p>Pause the audible alarm, if necessary.</p>
	Patient inspiratory resistance or compliance changes.	Have physician determine if ventilator settings are appropriate for the patient.
	Defective internal circuits of the machine or pressure sensor.	Replace the ventilator. Contact your customer service representative for assistance.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm message or symptom	Possible reason for the alarm event	Corrective action
HIGH RATE	Adjustment of the Max Rtot level too low.	Contact your customer service representative for assistance.
	Adjustment of the I Sens level too low.	Contact your customer service representative for assistance.
	Patient hyperventilating.	Pause the audible alarm, and call for a medical team if the symptoms persist. Manage leaks. Drain condensation from patient circuit. Contact your customer service representative for additional assistance
	Defective inspiratory flow sensor.	Contact your customer service representative to arrange for a qualified technician to replace the defective component or components.
HIGH VTE	Adjustment of the Max VTE level too low.	Contact your customer service representative for assistance. NOTE: Always consult the clinician before changing PEEP, FiO ₂ , pressure, volume or Rate settings.
	Inappropriate patient circuit.	Replace the patient circuit. Ensure there is not excessive airflow near the exhalation block (such as a fan).
	Exhalation flow sensor not calibrated properly.	Contact your customer service representative for assistance.
	Defective exhalation flow sensor.	Contact your customer service representative for assistance.
HIGH VTI	Adjustment of the Max VTI level too low (for PSV, CPAP, P A/C, P SIMV, and V SIMV modes).	Contact your customer service representative for assistance. NOTE: Always consult the clinician before changing PEEP, FiO ₂ , pressure, volume or Rate settings.
	Adjustment of the pressure level too high for the volume required (for PSV, CPAP, P A/C, P SIMV, and V SIMV modes).	Contact your customer service representative for assistance. NOTE: Always consult the clinician before changing PEEP, FiO ₂ , pressure, volume or Rate settings.
	A leak in the patient circuit causing increased bias flow.	Check and properly connect the patient circuit.
	Inappropriate patient circuit.	Replace with an appropriate circuit.
	Defective flow sensor or internal leak in the machine.	Contact your customer service representative to arrange for a qualified technician to replace the defective component or components.
INSP FLOW RESTART/SRVC	Inspiratory flow is constant (± 1 lpm) with normal turbine temperature and speed conditions.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
INTENTIONAL VENT STOP	The user/caregiver has stopped ventilation using the VENTILATION ON/OFF button. Ventilation is in standby.	Check that the ventilation was switched off on purpose.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm message or symptom	Possible reason for the alarm event	Corrective action
KEYPAD FAULT RESTART/SRVC	Pressing a key for more than 45 seconds.	Press and release keys in the normal, prescribed manner. Do not press keys for 45 seconds or more.
	A key on the keyboard is stuck.	If unsuccessful in releasing the stuck key or keys, restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
LOW BATTERY	Internal battery capacity is less than 30 minutes (or 8%)—battery operation overextended.	Immediately connect the ventilator to an AC power outlet or to an external DC power source. NOTE: The internal battery can be charged only when the ventilator is connected to an AC power supply.
LOW FiO ₂	The level of oxygen being delivered to the patient is below the Min FiO ₂ limit set.	Contact your customer service representative for assistance. NOTE: Always consult the clinician before changing PEEP, FiO ₂ , pressure, volume or Rate settings.
LOW VTE	Patient circuit obstructed.	Clean, unblock, or properly connect the patient circuit.
	Leak in the patient circuit.	Check and properly connect the patient circuit connections. May be caused by increased resistance across exhalation filter (such as excessive moisture).
	Exhalation block missing or disconnected.	Contact your customer service representative for assistance.
	Adjustment of a Min VTE threshold when the patient circuit is in a single-limb configuration.	Contact your customer service representative for assistance. WARNING: If exhaled tidal volume monitoring is required, use the double-limb circuit.
	Inappropriate patient circuit.	Replace with an appropriate circuit.
	Exhalation flow sensor not properly calibrated.	Contact your customer service representative for assistance.
	Defective exhalation flow sensor.	Contact your customer service representative for assistance.
	Adjustment of the Min VTE level too high.	Contact your customer service representative for assistance.
LOW VTI	Adjustment of the Min VTI level too high (for PSV, CPAP, P A/C, P SIMV, and V SIMV modes)	Contact your customer service representative for assistance.
	Adjustment of the pressure level not enough to reach the volume required (for PSV, CPAP, P A/C, P SIMV, and V SIMV modes).	Contact your customer service representative for assistance.
	Patient circuit obstructed or disconnected.	Clean, unblock, or reconnect the patient circuit.
	Inappropriate patient circuit.	Replace with an appropriate circuit.
	Defective flow sensor or internal leak in the machine.	Check patient and replace the ventilator. Contact your customer service representative for assistance.
NO BATTERY DETECTED	Immediately detected when no battery is installed.	Contact an authorized service representative for battery installation.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm message or symptom	Possible reason for the alarm event	Corrective action
OCCLUSION CHECK CIRCUIT *IF PERSISTS RESTART/SRVC	Patient circuit obstructed.	Clean, unblock, or properly connect the patient circuit.
OCCLUSION CHECK CIRCUIT	A non-vented configuration is being used or the built-in leak in the mask or in the circuit may be obstructed or insufficient for the settings. Note that a high patient or backup respiratory rate may not sufficiently flush out CO ₂ in some vented pediatric masks.	Replace the nonvented circuit with a vented one. Clean, unblock the mask or the circuit of the vented system, or switch to a vented system with a larger leak configuration. Contact your customer service representative for additional assistance.
PATIENT DISCONNECTION *IF PERSISTS RESTART/SRVC	Adjustment of Min PIP too high.	Contact your customer service representative for assistance.
	Leak or loose connection in the patient circuit. Circuit disconnection from patient or ventilator.	Check the patient circuit connections to the ventilator; examine all connections for leakage and tightness. Replace the patient circuit if necessary.
	Inspiratory flow exceeds 130 LPM.	Contact your customer service representative for assistance.
	Inappropriate patient circuit.	Replace with an appropriate circuit.
	Defective internal circuits of the machine or pressure sensor.	Restart ventilator to see if alarm clears. If not, contact your customer service representative to arrange for a qualified technician to replace the defective component or components.
POWER FAULT RESTART/SRVC	Internal problem in the electrical power supply.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
POWER SUPPLY LOSS (without message)	Electrical power supply cut off by the main switch when ventilation is in progress.	Press the I/O (power) switch to restore electrical power to the ventilator and allow ventilation to continue. To stop ventilation, press the VENTILATION ON/OFF button for 3 seconds, then release it. Press the VENTILATION ON/OFF button again to confirm stop (see Chapter 5, <i>Operating Procedures</i>).
	The internal battery that supplies the ventilator is entirely discharged.	Immediately connect the ventilator to an AC power outlet or an external DC power source; otherwise, use an alternate device to ventilate the patient.
PRES SENS FLT1 RESTART/SRVC	Defective internal pressure sensor.	Restart ventilator to see if alarm clears. If not, contact your customer service representative to arrange for a qualified technician to replace the defective component or components.
PROX SENS FLT2 RESTART/SRVC	Defective proximal pressure sensor or internal leak of the machine.	Restart ventilator to see if alarm clears. If not, contact your customer service representative to arrange for a qualified technician to replace the defective component or components.
REMOVE VALVE OR CHANGE PRES	The ventilation settings are not compatible with the type of patient circuit used.	Remove exhalation valve. Contact your customer service representative for additional assistance.
REMOVE VALVE CPAP MODE	The ventilation settings are not compatible with the type of patient circuit used.	Remove exhalation valve to start CPAP ventilation.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm message or symptom	Possible reason for the alarm event	Corrective action
SOFTWARE VERSION ERROR	Incorrect software version detected.	Contact your customer service representative.
TURB OVERHEAT RESTART/SRVC	Turbine overheated because of blockage during operation.	Ensure lateral and front openings are not obstructed. Check air inlet filter. Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
UNKNOWN BATTERY	Internal battery not recognized as a Baylis Medical approved battery.	Contact your customer service representative.
VALVE MISSING CONNECT VALVE	The ventilation settings are not compatible with the type of patient circuit used.	Connect exhalation valve.
VTI NOT REACHED *IF PERSISTS RESTART/SRVC	Defective inspiratory flow sensor or internal leak of the machine.	Restart ventilator to see if alarm clears. If not, replace the ventilator. Contact your customer service representative for assistance.
	I time is not long enough to deliver set VT.	Contact your customer service representative.

3.9.2 Additional Troubleshooting

Table 3-3 provides other possible ventilator problems, causes, and corrective actions.



WARNING:

If the device is damaged, its external housing is not correctly closed, or it behaves in a way that is not described in this manual (excessive noise, heat emission, unusual odor, alarms not triggered during the start-up procedure), the oxygen and power supplies should be disconnected and use of the device stopped immediately.



WARNING:

If you cannot determine the cause of the problem, contact your Equipment supplier. Do not use the ventilator until the problem has been corrected.



Note:

Buzzer and battery alarms may occur when the Unit is first powered on after the internal battery has been completely drained. Connect to an AC power source and recycle power.



Note:


Many ventilator functions are not accessible when the Locking key  is enabled. For additional assistance, contact your clinician or Equipment representative.

Table 3-3. Additional Troubleshooting and Corrective Actions

Conditions	Possible causes	Corrective actions
No access to the waveforms	Display waveform set to OFF in Preferences menu.	Contact your customer service representative for assistance.
The screen backlight never switches off during ventilation	Backlight set to YES in Preferences menu.	Contact your customer service representative for assistance.
Alarm sound level too low or too high	Adjustment of the alarm sound level is incompatible with the patient's environment.	Contact your customer service representative for assistance.
Poor visibility of the displays	Contrast adjustment is incompatible with the luminosity of the environment.	Contact your customer service representative for assistance.
Unusual display on the screen	Problem with the display unit.	Ensure that the ventilator is not exposed to direct radiation from the sun. Contact your customer service representative if the problem persists.
The ventilator does not operate after pressing I/O (power) switch	No external power source and the internal battery is completely discharged.	Connect the ventilator to the AC power source.
Light noise	Turbine noise.	Replace the ventilator. Contact your customer service representative for assistance.
Whistling noise or vibrations	Filter, turbine silencer, or both have deteriorated.	Replace the ventilator. Contact your customer service representative for assistance.
	Valve membranes damaged.	Replace the ventilator. Contact your customer service representative for assistance.
Excessive heat emitted	Obstruction of main or secondary air inlets of the casings.	Remove obstructions from all blocked ventilator air inlets and outlets.
Condensation inside the device	Liquid entered the device.	Replace the ventilator. Contact your customer service representative for assistance.

4 Installation and Assembly



WARNING:

Before operating the ventilator, read, understand, and strictly follow the information contained in Chapter 1, [Safety Information](#).



WARNING:

A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated Equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet (TO PATIENT) port—or both ports if a double-limb circuit is used—is highly recommended. Refer to Chapter 7, [Cleaning](#).

4.1 Ventilator Startup Procedure

To set up the V4C-560™ ventilator and start ventilation:

1. Choose an area where air can circulate freely. Avoid proximity to loose fabrics, such as curtains, and direct exposure to sunlight.
2. Set the ventilator on a flat and stable surface so that its feet are all in contact with the surface. The ventilator may operate in any position, provided that the air inlets are not obstructed and the device cannot fall and possibly cause damage, personal injury, or both.
3. Assemble and connect the patient circuit (see section 4.4.2, [Installing the Patient Circuit](#)), including the following:
 - a. Air inlet filter (see section 4.5.1)
 - b. Bacteria filter (see section 4.5.2)
 - c. Humidifier (if used) (see section 4.6)
 - d. Oxygen sensor (connection to O₂ supply) (see section 4.8.3)
4. Connect the oxygen supply to the ventilator. See section 4.8.2, [Connecting the Oxygen Supply](#).
5. If the battery is packaged outside the ventilator, contact an authorized service representative for battery installation.

6. For instructions on switching to and operating from the internal battery, see section [6.2, Battery Operation](#). For instructions on connecting to DC power, see section [4.3, Connecting to an External DC Power Source](#).
7. Confirm proper functioning of alarms. For testing instructions, see Appendix [E, Alarms Tests](#).
8. Turn on the ventilator. See section [5.1, Turning on the Ventilator](#).
9. Begin ventilation. See section [5.3, Starting Ventilation](#).



WARNING:

The operator should connect the ventilator to an AC power source whenever available, for safer operation.



WARNING:

To ensure correct and lasting operation of the ventilator, ensure that its air circulation holes (main inletfilter, cooling vents, and side exhaust port) are never obstructed. Place the device in an area where air can freely circulate around the ventilator and avoid installing it near floating fabrics, such as curtains.



WARNING:

Do not place the ventilator in a position where a child, pet or pest can reach it or in any position that might cause it to fall on the patient or someone else.



WARNING:

Ensure that the ventilator's immediate surroundings allow for the proper operational connection of the device without folding, pinching, or damaging any of the required cables or tubes, and that the connection of the patient circuit to the patient provides for a secure, comfortable fit.



WARNING:

Do not operate the ventilator in direct sunlight, near heat sources, outdoors, or near installations where liquid may pose a risk without first providing adequate protection for the device.



WARNING:

If the ambient temperature where the device is operated is greater than 35°C (95°F), the temperature of the patient circuit or the flow supplied at the device outlet may exceed 41°C (106°F), and the patient circuit may reach up to 60°C (140°F). This may lead to undesirable side effects for the patient. To avoid injury to the patient move the patient and the ventilator to a cooler location. For more information, contact Baylis Medical.



WARNING:

To reduce the risk of a fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (such as flammable anesthetics and/or heaters) away from the ventilator and oxygen hoses.

**WARNING:**

Even if the internal battery charging indicator is off, charging of the battery may sometimes be incomplete if the ambient temperature is above 40°C (104°F) because of the battery's internal heat safety device.

**WARNING:**

The use of any accessory other than those specified, with the exception of the power supplies or cables approved by Baylis Medical, may lead to an increase in electromagnetic emissions or a decrease in the Equipment protection against electromagnetic emissions. If the ventilator is used adjacent to such accessories or stacked with such devices, the ventilator's performance should be monitored to verify normal operation.

**WARNING:**

The V4C-560™ ventilator requires special precautions for electromagnetic compatibility and should be installed and started according to the recommendations found in Appendix A, *Specifications*. In particular, the use of nearby mobile and portable communications equipment using radio frequencies, such as mobile telephones or other systems exceeding the levels set in the IEC/EN 60601-1-2 standard, may affect its operation. Refer to section A.10, *Manufacturer's Declaration*.

**WARNING:**

The ventilator must not use, nor be connected to, any anti-static or electrically conductive hoses, tubing, or conduits.

4.2 Connecting to External AC Power

The ventilator can use any of the following power sources:

- AC power from a suitable wall outlet
- DC power (12 to 30 volts)
- Internal battery power
- DC adapter

The ventilator will automatically select AC power for operation whenever AC power is available.

**WARNING:**

The power supply to which the ventilator is connected (both AC and DC) must comply with all current and applicable standards and provide electrical power corresponding to the voltage characteristics inscribed on the rear of the ventilator to ensure correct operation.

**WARNING:**

Ensure that the AC power cable is in perfect condition and not compressed. The device should not be turned on if the AC power cable is damaged.



WARNING:

Connect the external electrical power source by first connecting the power cable to the ventilator and then to the external power source. Follow the reverse procedure to disconnect the device from electrical power sources.

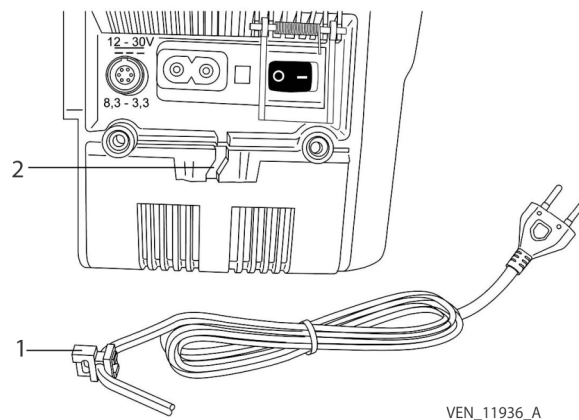


WARNING:

Do not leave power cables lying on the ground where they may pose a hazard.

To prevent accidental disconnection of the AC power cable, use the power cable holder that is inserted into the notch on the battery cover. See Figure 4-1.

Figure 4-1. The Power Cable Holder



VEN_11936_A

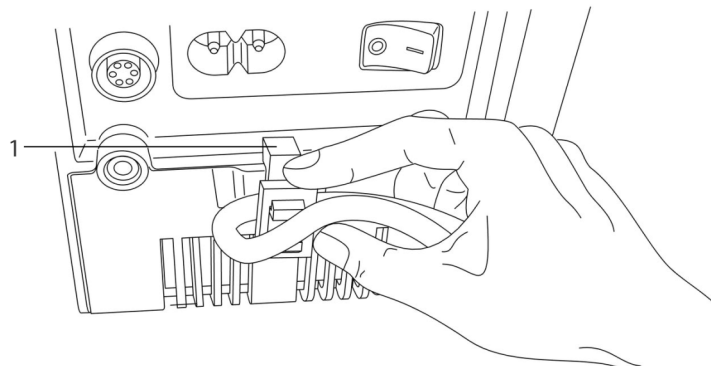
1 Power cable holder

2 Notch on battery cover

To secure the AC power cable:

1. Insert the power cable holder into the notch on the battery cover. See Figure 4-2.

Figure 4-2. Inserting the Power Cable Holder into the Notch

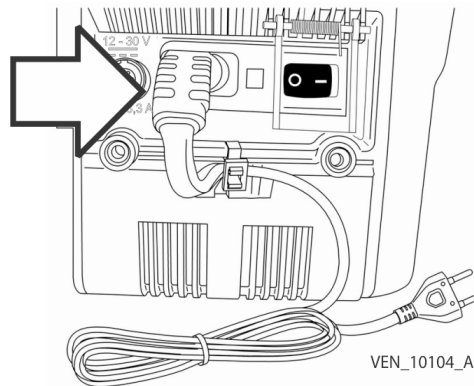


VEN_11937_A

1 Power cable holder

2. Connect the female end of the ventilator's AC power cable to the AC connector on the back of the ventilator.

Figure 4-3. Power Cable Connected to the Ventilator



3. Connect the male end of the AC power cable to the AC power outlet.



- The AC power indicator on the top left corner of the ventilator illuminates.



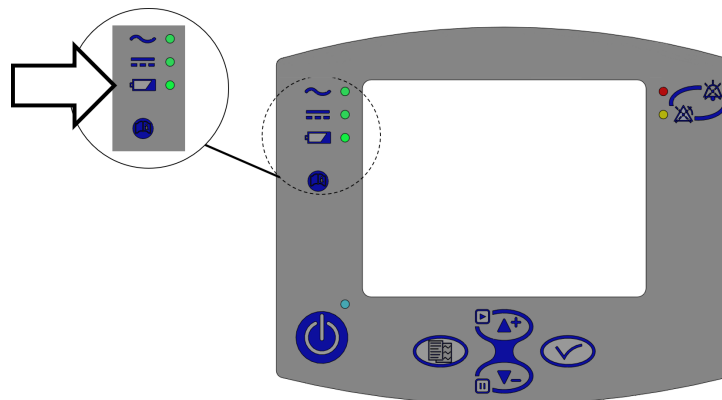
- The indicator flashes while the battery charges and then turns off when the battery is fully charged.

See Figure 4-4 on page 4-5.

If the AC power cable becomes disconnected or the AC power source fails, an AC Power Disconnection alarm signals an automatic switch to the external DC power source (if the DC power cable is connected) or to the ventilator's internal battery.

One of three power indicators, located on the upper left of the ventilator's front panel, illuminates to signal which of the possible power sources are currently in use by the device (see Figure 4-4).

Figure 4-4. Power Indicators



Note:

The only time the AC power indicator and other indicators are illuminated at the same time is when the ventilator is connected to an AC supply and the battery is charging (indicator is flashing).

To disconnect the AC power cable:

1. Disconnect the AC power cable from the AC power outlet.
2. Disconnect the AC power cable from the ventilator's AC connector at the rear of the device.
3. Grasp the AC power cable at the level of the power cable holder and turn the cable clockwise while lifting it upwards and out of the holder.

4.3 Connecting to an External DC Power Source



WARNING:

Ensure that the ventilator's internal battery is fully charged before connecting the ventilator to an external DC power source. Powering the ventilator using an external 12–30 VDC power source (via the DC power cable) does not enable charging of its internal battery.



WARNING:

When using a car auxiliary adapter (cigarette lighter) ensure the car has been started prior to plugging in the ventilator's DC adapter.



Note:

An alternative means of ventilation should always be available, particularly when the patient is away from wall power.



Note:

While using the ventilator on external battery power it is vital that a qualified caregiver (capable of providing necessary corrective actions in the event of alarm conditions) is present.



Note:

When AC power is not available use an external DC power source prior to using internal battery power.



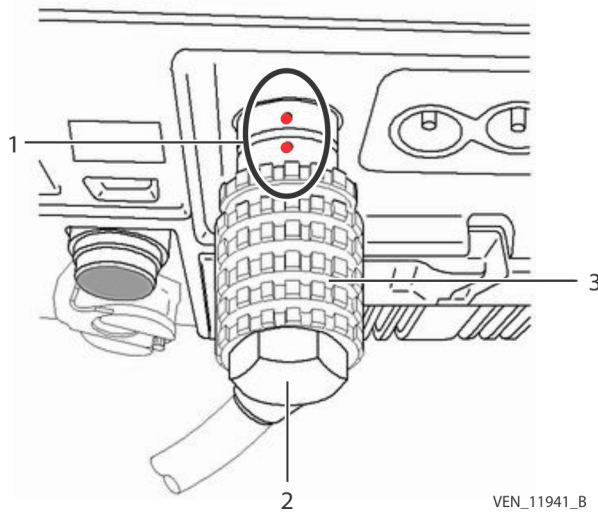
Note:

The DC power cable is optional; see Appendix [F, Parts and Accessories](#), for more information.



WARNING:

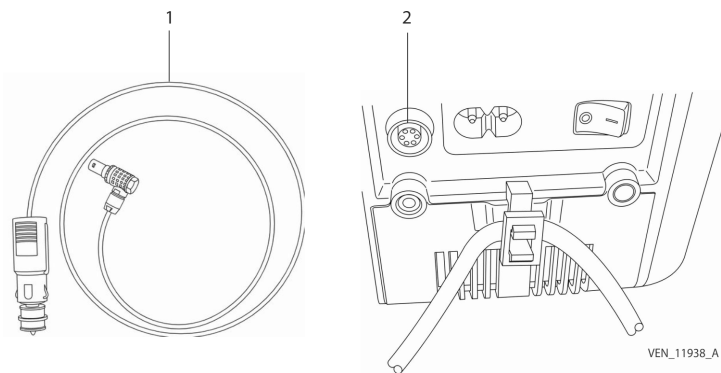
Connect the external DC power source by first connecting the power cable to the ventilator and then to the external DC source. Follow the reverse procedure to disconnect the device from the external DC power source.

Figure 4-5. Connecting the DC Power Cable to the Ventilator

- | | | | |
|---|--------------------------|---|------------------------|
| 1 | Red alignment dots | 3 | Connector locking ring |
| 2 | DC power cable connector | | |

To connect the DC power cable to the ventilator (see Figure 4-5):

1. Line up the red alignment dots on the ventilator's DC power receptacle and on the DC power cable.
 2. Push the DC power cable into the ventilator's DC power receptacle.
 - You will hear a locking click.
- ☐☐☐ • The DC power indicator on the top left corner of the ventilator illuminates (see Figure 4-4).

Figure 4-6. Connecting the Ventilator to an External DC Power Source

- | | | | |
|---|----------------|---|---------------------------|
| 1 | DC power cable | 2 | DC power input receptacle |
|---|----------------|---|---------------------------|

To connect the ventilator to an external DC power source (see Figure 4-6):

1. If using the DC auxiliary receptacle, ensure that the power source is on prior to connecting the ventilator.

2. Connect the smaller connector on the DC power cable into the DC power input receptacle on the rear of the ventilator.
3. Connect the larger connector on the DC power cable into the power source's DC auxiliary receptacle.

To disconnect the DC power cable from the ventilator (see Figure 4-5):

1. Slide the locking ring back, away from the ventilator.
2. Pull the DC power cable connector out from the input receptacle to disengage it.

A DC Power Disconnection alarm signals an automatic switch to the internal battery if the external DC power source fails or becomes disconnected.

4.4 Patient Circuit



WARNING:

Before opening the packaging for the patient circuit, ensure that no damage is evident to the packaging or its contents. Do not use if evidence of damage exists.



WARNING:

For pediatric use, ensure that the patient circuit type fits, and, in all respects, is suitable for use with a child. Use a pediatric circuit for patients that weigh under 53 lb. (23 kg). For a list of recommended patient circuits, see [Table F-2](#).



WARNING:

If exhaled tidal volume measurements are required to ensure correct patient ventilation, a double-limb patient circuit configuration must be used in order to detect leaks. In this case, both the minimum and maximum VTE alarm parameters must be properly set to warn in the event of patient disconnection.



WARNING:

The patient circuit should always be positioned to avoid hindering the patient's movements, to prevent accidental disconnection or leakage, and to minimize the risk of patient strangulation.




WARNING:

Ensure that the ventilator's immediate surroundings allow for the proper operational connection of the device without folding, pinching, or damaging any of the required cables or tubes, and that the connection of the patient circuit to the patient provides for a secure, comfortable fit.



WARNING:

The patient circuit is intended for single use by a single patient  and should be changed according to the manufacturer's recommendations and according to the patient circuit lifetime. Refer to the instructions for use supplied by the manufacturer of the patient circuit (included with the ventilator) and Chapter 4, [Installation and Assembly](#).

**WARNING:**

After assembling, cleaning, or reassembling the patient circuit, and on a daily basis, inspect the hoses and other components to ensure that there are no cracks or leaks and that all connections are secure.

**WARNING:**

To ensure proper performance of the ventilator, use a patient circuit recommended by Baylis Medical in this manual; refer to Chapter 4, [Installation and Assembly](#) and Appendix F, [Parts and Accessories](#). The total specified length of the patient circuit tubing as measured from the ventilator outlet to the ventilator inlet is 1.1 meters (3.6 feet) to 2.0 meters (6.6 feet). The tubing must conform to all applicable standards and must be fitted with Ø 22 mm terminals that also conform to all applicable standards. Ensure that both the length and the internal volume of the patient circuit are appropriate for the tidal volume: a corrugated tube of Ø 22 mm for adult patients, and a corrugated tube of Ø 15 mm for pediatric patients with a tidal volume lower than 200 ml.

**WARNING:**

Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.

**WARNING:**

Users must always possess an additional breathing circuit and exhalation valve while using the V4C-560™ ventilator.

4.4.1 Choosing the Patient Circuit Type

Single-limb circuits are used with breathing modes where spirometry measurements are not required, and double-limb circuits are used with breathing modes where spirometry is required. Be sure to choose the appropriate circuit in the menu preferences; in particular, ensure that Pediatric Circuit Yes/No is set to YES when using a pediatric circuit (refer to Appendix F, [Parts and Accessories](#)).

For information regarding validated circuits contact your customer representative.

4.4.2 Installing the Patient Circuit

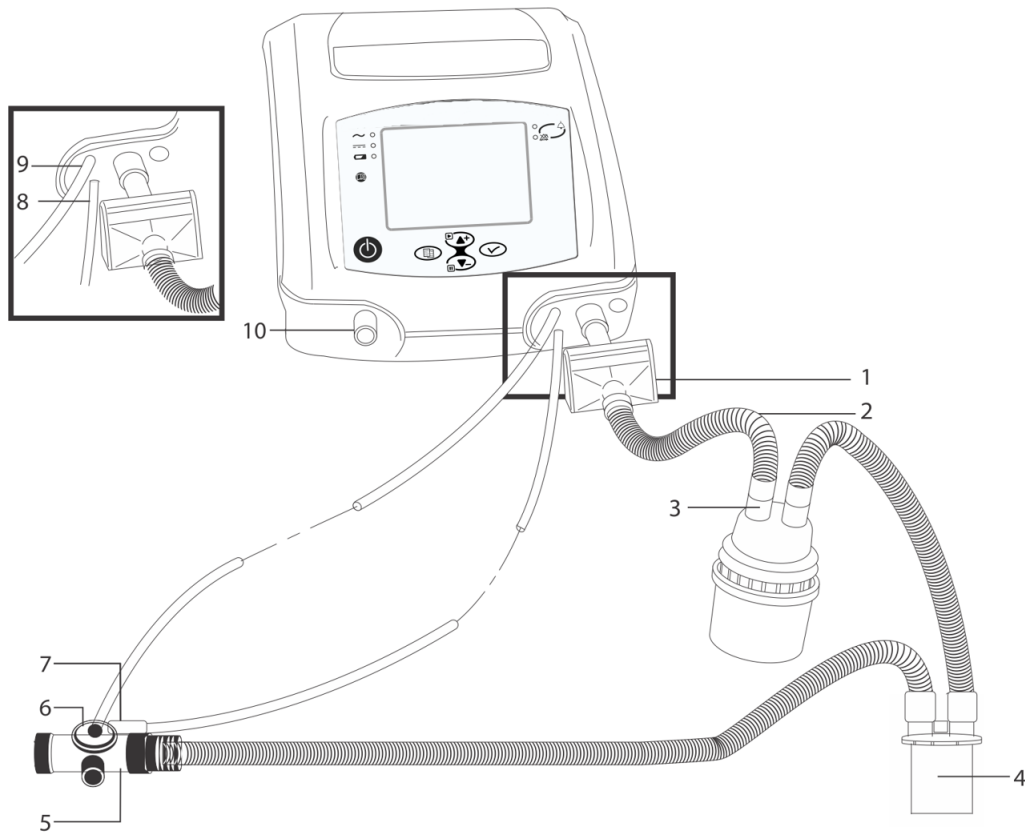
The patient circuit is mounted depending on the setup of the circuit used and the accessories used.

**Note:**

The following procedures describe the installation of the patient circuit with a humidifier, which is an optional accessory. To add other optional accessories not shown here, see the installation instructions for the specific accessories used.

Single-Limb Circuit (With Exhalation Valve)

Figure 4-7. Single-Limb Patient Circuit With Exhalation Valve (including accessories)




- | | | | |
|---|---------------------------------|----|--------------------------------|
| 1 | Inspiratory bacteria filter | 6 | Exhalation valve tubing |
| 2 | Short circuit tubing | 7 | Proximal pressure tubing |
| 3 | Humidifier (optional accessory) | 8 | Patient proximal pressure port |
| 4 | Water trap | 9 | Exhalation valve port |
| 5 | Exhalation valve | 10 | FROM PATIENT port |



Note:

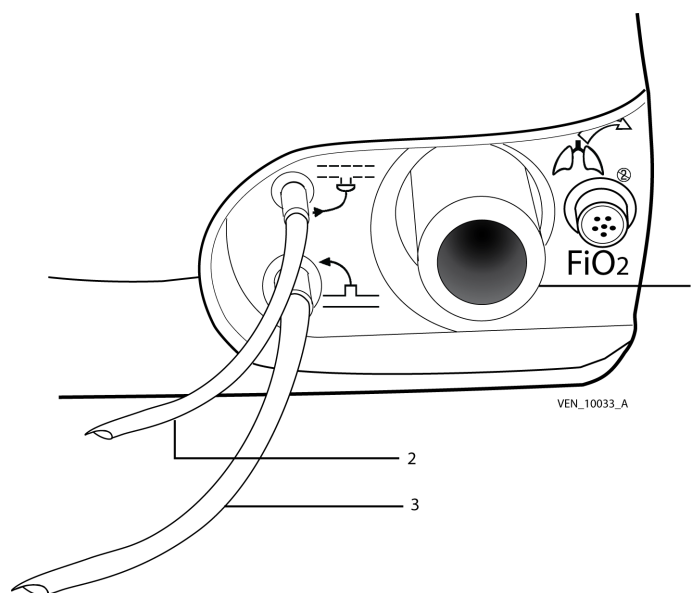
Some breathing circuits include water traps that are already connected. If so, simply verify that the connection is secure and the tube shows no signs of damage, kinks, or obstructions.

To connect a single-limb circuit with an exhalation valve (see Figure 4-7):



1. Inspect the components of the patient circuit for any signs of damage, such as cracks (which might cause leakage). Do not use damaged components to assemble the patient circuit.
2.  Connect the proximal pressure tubing to the patient proximal pressure port on the ventilator. See Figure 4-8 for a detailed view.

-  3. Connect the exhalation valve tubing to the exhalation valve port on the ventilator. See Figure 4-8 for a detailed view.

Figure 4-8. Closeup of Exhalation Valve Tube and Proximal Pressure Tube

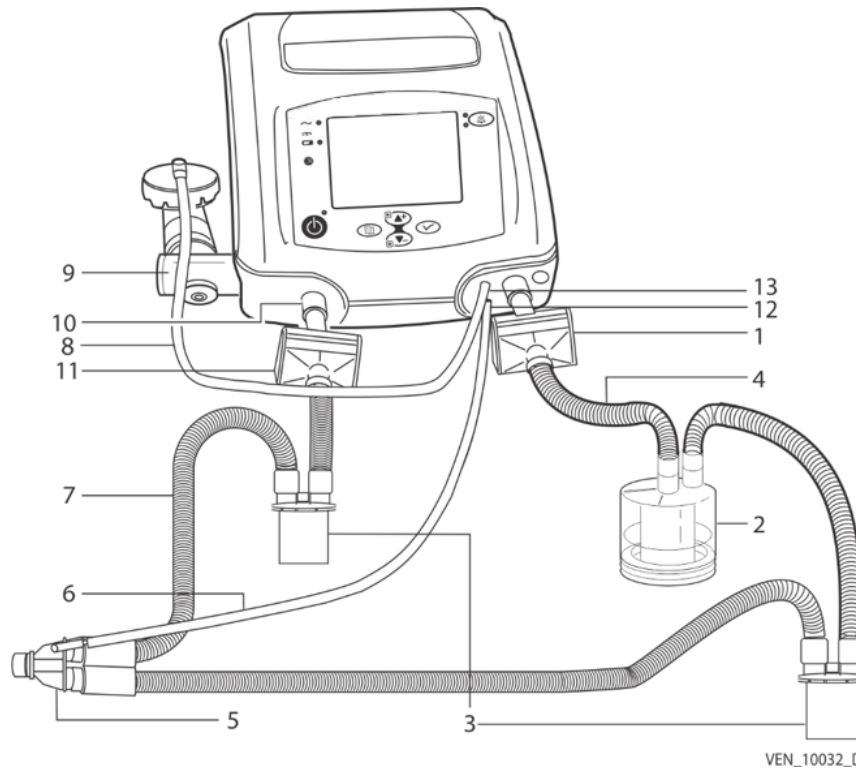


- 1** TO PATIENT port **3** Proximal pressure tube
2 Exhalation valve tube

-  4. Connect the inspiratory bacteria filter to the TO PATIENT outlet port on the ventilator.
5. Connect one end of the short circuit tubing to the inspiratory bacteria filter.
6. Connect the other end of the short circuit tubing to the inlet port of the humidifier.
7. If it is not already in place, connect a water trap to the outlet port of the humidifier and to the patient circuit tubing.
8. Ensure the exhalation valve is placed as close as possible to the patient.
-  9. To protect the FROM PATIENT inlet port, as it is not used in this configuration, place the cap (if provided with the breathing circuit) over the port opening.

Double-Limb Circuit

Figure 4-9. Double-Limb Patient Circuit (including accessories)



- | | | | |
|---|---------------------------------|----|--------------------------------|
| 1 | Inspiratory bacteria filter | 8 | Exhalation valve tubing |
| 2 | Humidifier (optional accessory) | 9 | Exhalation valve assembly |
| 3 | Water traps | 10 | Exhalation (FROM PATIENT) port |
| 4 | Short circuit tubing | 11 | Exhalation bacteria filter |
| 5 | Patient wye | 12 | Patient proximal pressure port |
| 6 | Proximal pressure tubing | 13 | Exhalation valve port |
| 7 | Double-limb circuit tubing | | |



Note:

When shipped, the proximal pressure tube may already be connected to the patient wye. If so, simply verify that the connection is secure and the tube shows no signs of damage, kinks, or obstructions.



Note:

Some breathing circuits include water traps that are already connected. If so, simply verify that the connection is secure and the tube shows no signs of damage, kinks, or obstructions.

To connect a double-limb circuit (see Figure 4-9):

1. Inspect the components of the patient circuit for any signs of damage, such as cracks (which might cause leakage). Do not use damaged components to assemble the patient circuit.



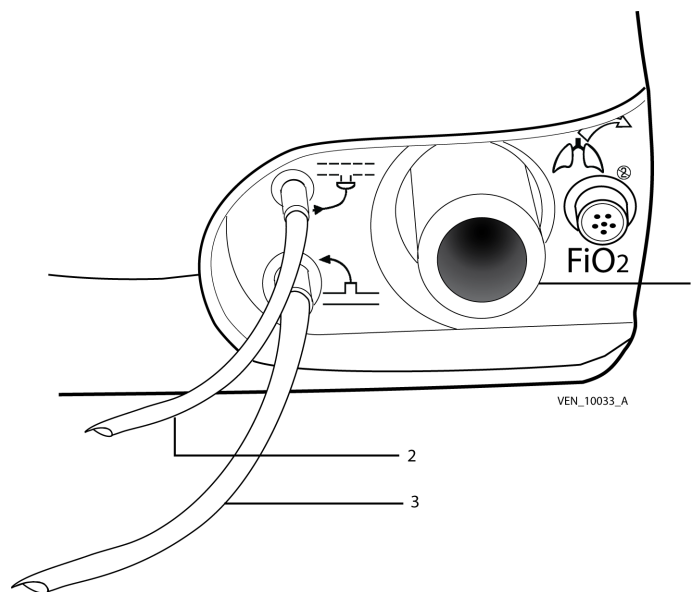

- 
 2. Connect the proximal pressure tubing to the patient proximal pressure port on the ventilator. See Figure 4-10 for a detailed view.
3. Connect the exhalation valve assembly to the exhaled gas outlet on the left side of the ventilator, near the left front corner.
- 
 4. Connect the exhalation valve tubing from the exhalation valve assembly to the exhalation valve port on the ventilator. See Figure 4-10 for a detailed view.

Figure 4-10. Closeup of Exhalation Valve Tube and Proximal Pressure Tube



- | | | | |
|----------|-----------------------|----------|------------------------|
| 1 | TO PATIENT port | 3 | Proximal pressure tube |
| 2 | Exhalation valve tube | | |

- 
 5. Connect the inspiratory bacteria filter to the TO PATIENT outlet port on the ventilator.
6. Connect one end of the short circuit tubing to the inspiratory bacteria filter.
7. Connect the other end of the short circuit tubing to the inlet port of the humidifier.
8. If it is not already in place, connect a water trap to the outlet port of the humidifier and to one tube from the patient wye.
9. If it is not already in place, connect a second water trap to the other tube from the patient wye and to the inlet port of the exhalation bacteria filter.



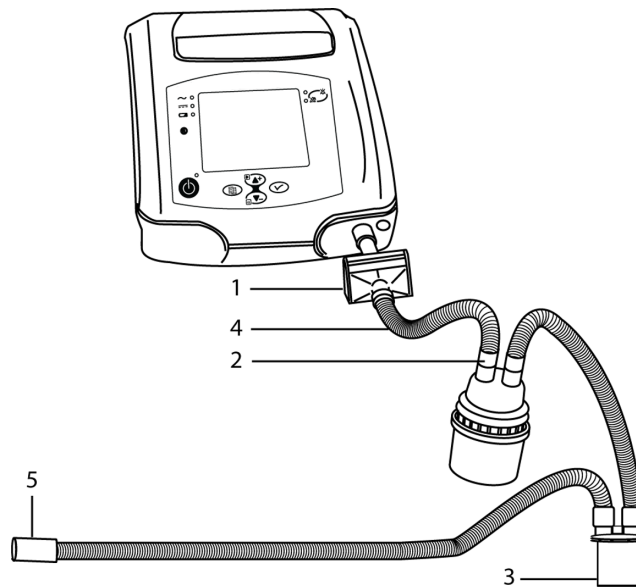
- Using a circuit adapter, connect the exhalation bacterial filter to the FROM PATIENT inlet port. See Figure 4-11.

Figure 4-11. Close-up of Exhalation Bacteria Filter Connection



Single-Limb Circuit (Without Exhalation Valve)

Figure 4-12. Single-Limb Patient Circuit Without Exhalation Valve



- | | | | |
|---|---------------------------------|---|------------------------|
| 1 | Inspiratory bacteria filter | 4 | Short circuit tubing |
| 2 | Humidifier (optional accessory) | 5 | Patient circuit tubing |
| 3 | Water trap | | |

To connect a single-limb circuit without an exhalation valve (NIV only) (see Figure 4-12):

- Inspect the components of the patient circuit for any signs of damage, such as cracks (which might cause leakage). Do not use damaged components to assemble the patient circuit.



2. Connect the inspiratory bacteria filter to the TO PATIENT outlet port on the ventilator.
3. Connect one end of the short circuit tubing to the inspiratory bacteria filter.
4. Connect the other end of the short circuit tubing to the inlet port of the humidifier.
5. If it is not already in place, connect a water trap to the outlet port of the humidifier and to the patient circuit tubing.
6. Connect a mouthpiece or vented (NIV) interface to the end of the patient circuit.

For both types of circuits, connect the end of the proximal pressure tube as close as possible to the patient (at the mouthpiece, mask or cannula entry, if possible) so that the ventilator can account for all load losses due to the circuit and its potential accessories. If this is not possible, it is best to modify the patient disconnection triggering threshold by doing one of the following: Set a Max VTI alarm limit for pressure modes, or a Min VTE alarm limit for all ventilation modes if using a dual limb circuit.

**Note:**

Ensure that the length and the internal volume of the patient circuit are compatible with the tidal volume: Ringed tube Ø 22 mm for adults and ringed tube Ø 15 mm for pediatric patients with tidal volumes lower than 200 ml. Use, if necessary, a 22F-15M link on the outlet and a 15M-22M link on the exhalation block for a double-limb circuit.

**WARNING:**

When using non-invasive ventilation (NIV), without an exhalation valve, use a vented nose or face mask or a non vented combined with a leak accessory. When using non-invasive ventilation (NIV), with an exhalation valve, use a non vented mask.

**WARNING:**

The level of inspiratory resistance of the circuit and accessories (bacteria filter, humidifier, and so on) must be as low as possible. Settings—particularly the Patient Disconnection alarm, high inspired volume (High VTI), and low inspired volume (Low VTI) settings—must be periodically adjusted according to changes in the patient circuit resistance—especially when filters are replaced.

**WARNING:**

Resistance of the exhalation valve and accessories (water traps, filters, HMEs, etc.) must be as low as possible.

**WARNING:**

The exhalation valve must allow rapid discharge of the circuit pressure. Ensure that the exhalation valve is always clean and its evacuation aperture (exhaust port) is never obstructed.

**WARNING:**

Do not start ventilation until you ensure that the device is suitably assembled, that the air inlet filter is properly installed and is not obstructed, and that there is proper clearance all around the Unit. Also ensure that the patient circuit is suitably connected to both the ventilator and the patient and that the patient circuit, including all hoses, is not damaged or obstructed.



WARNING:

Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.

4.5 Filters



WARNING:

Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. If necessary, replace the filter before the recommended replacement period is over (see Chapter 8, *Routine Maintenance*).

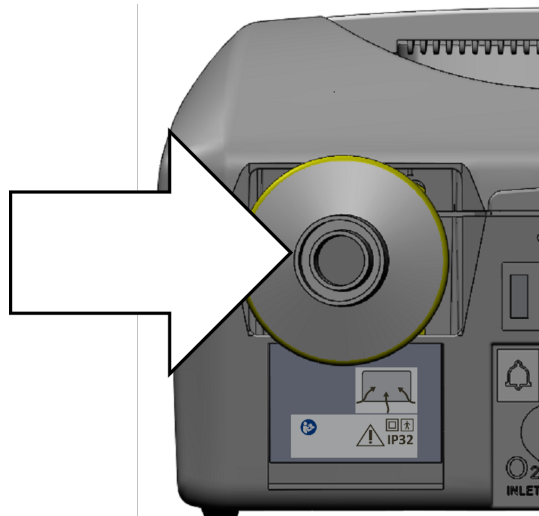
The ventilator features two filter types:

- Air inlet filter
- Bacteria filter

4.5.1 Air Inlet Filter

Consisting of fine particle filter media and located at the rear of the ventilator, this filters the air as it enters the ventilator.

Figure 4-13. Air Inlet Filter



WARNING:

The air inlet filter is not reusable; do not attempt to wash, clean, or reuse it.

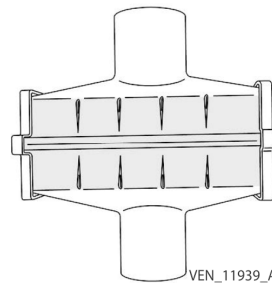
**WARNING:**

Failing to replace a dirty air inlet filter, or operating the ventilator without a filter, may cause serious damage to the ventilator.

4.5.2 Bacteria Filter

It is highly recommended that you install a bacteria filter (see Figure 4-14) on both single- and double-limb circuits.

Figure 4-14. Bacteria Filter



A single-limb configuration uses one bacteria filter, at the TO PATIENT port. A double-limb configuration uses two bacteria filters, one at the TO PATIENT port, and the other at the FROM PATIENT port.



- Connected to the TO PATIENT port: The filter protects the ventilator from contamination by the patient (primarily, rebreathed gas). See Figure 4-7 (item 1), Figure 4-9 (item 1), and Figure 4-12 (item 1). When connected here, the filter is called the inspiratory bacteria filter.



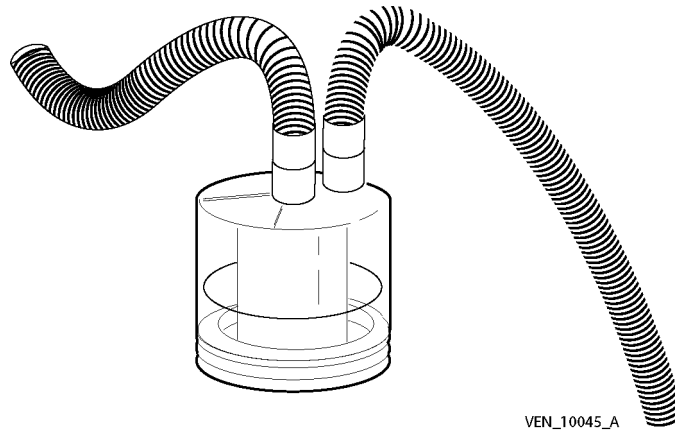
- Connected to the FROM PATIENT port: The filter protects the internal exhalation flow sensor from the gases exhaled by the patient. See Figure 4-9 (item 11). When connected here (using a circuit adapter), the filter is called the exhalation bacteria filter.

See the manufacturer's instructions for more information about the use and maintenance of bacteria filters.

4.6 Humidifier

The humidifier (Figure 4-15) adds moisture (water vapor) and warms the gas in the patient circuit. It is inserted into the patient circuit between the TO PATIENT outlet port and the patient (see Figures 4-7, 4-9, and 4-12).

Figure 4-15. Humidifier



WARNING:

During invasive ventilation (when an artificial airway bypasses the patient's upper respiratory system), the patient's upper respiratory system cannot humidify the incoming gas. For this reason, the use of a humidifier, to minimize drying of the patient's airways and subsequent irritation and discomfort, must be used.



WARNING:

Always position a humidification device so that it is lower than both the ventilator and the patient. Use water traps, if necessary, to limit water in the patient circuit and periodically empty these water traps. Take precautions when discarding the fluid in the water trap. Discard per local ordinance for proper disposal.



WARNING:

If a heated humidifier is used, you should always monitor the temperature of the gas delivered to the patient. Gas delivered from the ventilator that becomes too hot may burn the patient's airway.



WARNING:

Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.

When a humidification device is used, any condensation that forms in the patient circuit is collected in the water trap (or traps). If you notice any moisture in the patient circuit, you need to replace the wet circuit components with dry ones.


See the humidification device's instructions for information on operating, cleaning, and sterilizing the humidifier.

**Note:**

It is the user's responsibility to verify that any humidification system selected for use is compatible with the V4C-560™ ventilator.

4.7 Exhalation Block

**WARNING:**

The exhalation block is intended for single use by a single patient . It may periodically be cleaned, but it cannot be disinfected or sterilized. To maintain good measurement quality when used continuously, clean the exhalation block periodically (see section 7.3, [Cleaning the Exhalation Block](#)). The exhalation block should be changed every 4 months and cannot be reused with any other patient.

**WARNING:**

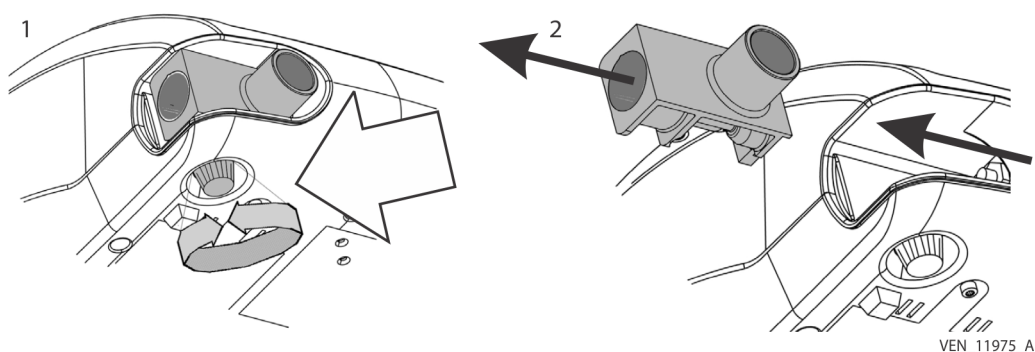
Ensure that the exhalation block is completely dried after cleaning and prior to use.

**WARNING:**

When an exhalation block is set up, each time it is removed, or after installing a new exhalation block on the machine, it is essential that the exhalation flow sensor be recalibrated before the exhalation block is used.

The exhalation block requires calibration and should only be removed or cleaned by qualified personnel. See section 7.3, [Cleaning the Exhalation Block](#) for more information.

Figure 4-16. Removing the Exhalation Block



4.8 Oxygen

4.8.1 Administering Oxygen



WARNING:

The ventilator must not be used with flammable anesthetic substances.



WARNING:

Oxygen therapy for patients with respiratory failure is a common and effective medical prescription. However, be aware that inappropriate oxygen use may potentially lead to serious complications, including, but not limited to, patient injury.



WARNING:

To avoid injury to the patient and/or possible damage to the ventilator: before using the ventilator, use a flow meter (flow regulator) to regulate the oxygen supply to specifications before connecting the ventilator to the oxygen supply.



WARNING:

Ensure that the oxygen supply pressure to the machine never exceeds 7 psi (50 kPa) or a flow of 15 lpm. Refer to Table A-7 for volume and sensitivity tolerances.



WARNING:

The V4C-560™ ventilator can be used with an optional oxygen analyzer with minimum and maximum concentration alarms. Always measure the delivered oxygen with a calibrated oxygen analyzer (FiO₂ kit) that features a minimum and maximum concentration alarm in order to ensure that the prescribed oxygen concentration is delivered to the patient.



WARNING:

The FiO₂ sensor must be securely installed on the T-connector. Failure to correctly install the FiO₂ sensor can cause air to escape the patient circuit, preventing the ventilator from detecting occlusions. Always make sure the FiO₂ sensor is securely installed on the T-connector.

Oxygen administered to the patient is introduced from an external source into the machine through the oxygen connector at the rear of the ventilator. It is then integrated into the total volume of delivered gas. Remove the oxygen connector from the back of the ventilator when external oxygen is not in use.

The specific oxygen flow to the patient depends on the physiological characteristics of the patient and the ventilator settings.

The oxygen flow setting should be adjusted for each patient and established in relation to a calibrated oxygen monitor measurement. As the factors that affect administered oxygen flow may change over time, you must ensure that these settings always correspond to the current oxygen therapy objectives specified by the physician.

4.8.2 Connecting the Oxygen Supply



WARNING:

Ensure that the only gas supplied to the ventilator through the dedicated oxygen supply connector is medical-grade oxygen.

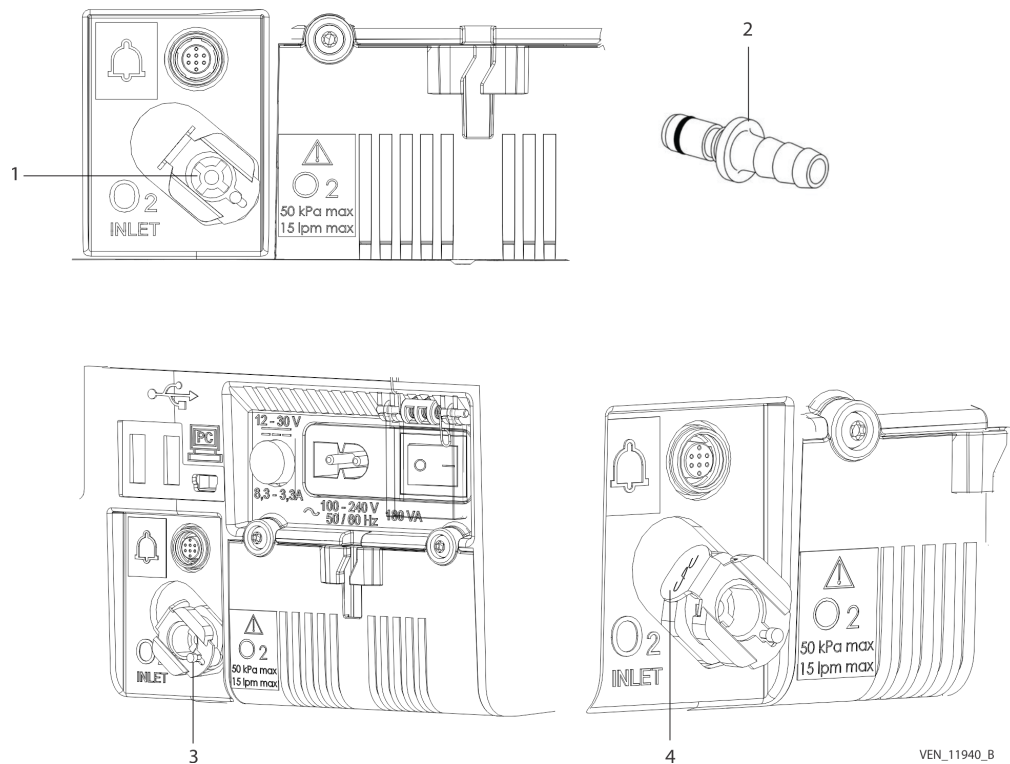


WARNING:

The hose connecting the ventilator to the oxygen source must be designed exclusively for use with medical-grade oxygen. Under no circumstances should the oxygen hose be modified by the user. In addition, the hose must be installed without the use of lubricants.

Refer to Figure 4-17. An inlet port for an external low pressure oxygen source is available at the rear of the ventilator. It is essential to also use the special coupler supplied with the ventilator to connect the external low pressure oxygen source to the ventilator. The inlet port is also fitted with a non-return airtight valve system, which includes a stud and a locking tab.

Figure 4-17. Rear Panel Oxygen Inlet Port and Coupler



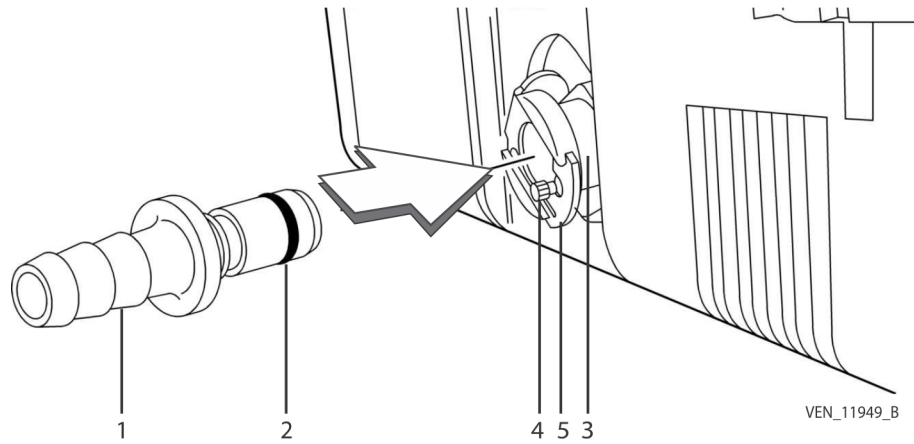
- | | | | |
|---|--------------------------------|---|--|
| 1 | O ₂ inlet port | 3 | O ₂ inlet port locking stud |
| 2 | External oxygen supply coupler | 4 | O ₂ inlet port locking tab |

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WARNING:
 Before connecting the oxygen supply, ensure that the stud on the oxygen inlet (Figure 4-17, item 3) is protruding outwards.

WARNING:
 Inspect the oxygen coupler (Figure 4-17, item 2) before use to ensure it has its black O-ring (Figure 4-18, item 2) attached and in good condition. Do not use an oxygen coupler with a missing, damaged, or worn O-ring.

Figure 4-18. Connecting the Oxygen Supply



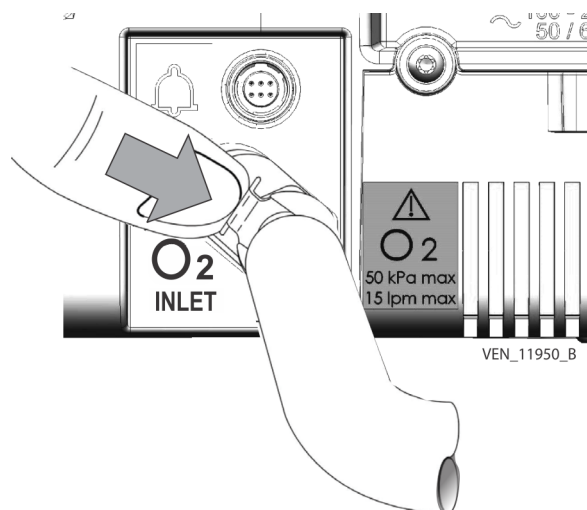
- | | | | |
|---|--------------------------------|---|--------------|
| 1 | External oxygen supply coupler | 4 | Locking stud |
| 2 | Coupler O-ring | 5 | Locking tab |
| 3 | O ₂ inlet port | | |

To connect the oxygen supply to the ventilator (see Figure 4-18):

1. Inspect the oxygen supply coupler to ensure that the black O-ring is not missing.
2. Push the coupler into the O₂ inlet port on the ventilator. Ensure that the following occurs:
 - The locking stud on the inlet port retracts.
 - The locking tab on the inlet port is released, ensuring that the oxygen supply connection is locked and secured in place.

To disconnect the oxygen supply from the ventilator:

1. Ensure that the oxygen source is turned off prior to placing the ventilator in standby or turning off the ventilator.
2. Stop the oxygen flow from the oxygen supply.
3. Press the locking tab on the ventilator’s O₂ inlet port to unlock the oxygen connection.

Figure 4-19. Disconnecting the Oxygen Supply

4. Disconnect the oxygen supply by pulling the coupler out from the inlet port.

The locking stud on the inlet port (Figure 4-18, item 4) will then extend outwards, which is required before the oxygen connector can be reconnected.

**WARNING:**

The coupler must not remain connected to the oxygen connector unless it also connected to a leak-proof, external oxygen gas source. When an oxygen supply is not being used with the ventilator, disconnect the oxygen source completely from the ventilator.

**WARNING:**

In the event of an oxygen leak, shut down the supply of oxygen at its source. In addition, remove and/or keep any incandescent source away from the device, which may be enriched with oxygen. Circulate fresh air into the room to bring the oxygen level down to normal.

**WARNING:**

To prevent any interference with the internal sensors of the ventilator, do not install a humidifier upstream of the ventilator.

4.8.3 Connecting the FiO₂ Sensor

When administering oxygen, it is recommended to use a FiO₂ oxygen sensor that can be connected by means of a FiO₂ measurement kit.

**WARNING:**

The FiO₂ sensor must be securely installed on the T-connector. Failure to correctly install the FiO₂ sensor can cause air to escape the patient circuit, preventing the ventilator from detecting occlusions. Always make sure the FiO₂ sensor is securely installed on the T-connector.



Note:

The FiO₂ sensor requires calibration and should only be removed or cleaned by qualified personnel. Home users need to be trained by qualified personnel to perform these tasks.



Note:

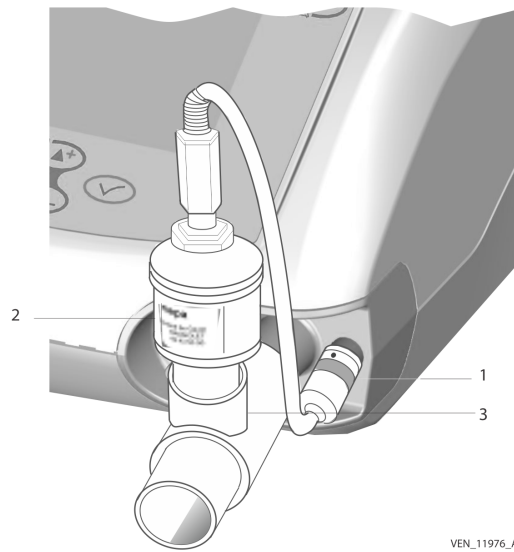
When using a new sensor, allow its temperature to become stable for about 20 minutes in ambient air before installing it, calibrating it, and starting ventilation.



Note:

A clinician or medical professional should be present when calibrating the FiO₂ sensor.

Figure 4-20. Connecting the FiO₂ Sensor



- 1 FiO₂ sensor connector 3 T-connector
- 2 FiO₂ sensor

To install the FiO₂ sensor:

1. Remove the sensor from the airtight packaging.
2. Connect the FiO₂ sensor connector to the FiO₂ receptacle on the ventilator.
3. Connect the FiO₂ sensor to a Ø15mm T-connector. Make sure the FiO₂ sensor is securely installed on the T-connector.



4. Connect the T-connector to the TO PATIENT outlet port on the ventilator. Make sure the T-connector is securely installed on the ventilator.

5. Fit the patient circuit and any accessories after the T-connector. If a bacteria filter is present in the circuit, it should be placed just after the sensor, so that the sensor is directly between the ventilator and the bacteria filter.

**Note:**

For information on calibrating the sensor once it is installed, see section **8.4, *Calibrating the FiO2 Sensor***.

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5 Operating Procedures

5.1 Turning on the Ventilator



WARNING:

Before operating the ventilator, read, understand, and strictly follow the information contained in Chapter 1, [Safety Information](#).



WARNING:

If the ventilator has been transported or stored at a temperature that differs more than $\pm 20^{\circ}\text{C}$ ($\pm 36^{\circ}\text{F}$) from the temperature in which it will be operating, the ventilator should be allowed to stabilize in its operating environment for at least 2 hours prior to use.



WARNING:

To reduce the risk of a fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (such as flammable anesthetics and/or heaters) away from the ventilator and oxygen hoses.



WARNING:

While the ventilator is in use, an alternative means of ventilation should always be available in the event of a ventilator problem. This is particularly true for ventilator-dependent patients. Supplementary observation, appropriate for the patient's condition, is also recommended.



WARNING:

To ensure that ventilation continues uninterrupted, ensure alternative power sources are available (AC power source, extra batteries, or an auxiliary DC adapter). Be prepared for the possibility of power failure by having an alternative means of ventilation ready for use—particularly for ventilator-dependent patients.



WARNING:

Do not start ventilation until you ensure that the device is suitably assembled, that the air inlet filter is properly installed and is not obstructed, and that there is proper clearance all around the Unit. Also ensure that the patient circuit is suitably connected to both the ventilator and the patient and that the patient circuit, including all hoses, is not damaged or obstructed.



WARNING:

The time required to reach essential performance and start ventilation from power on is approximately 15 seconds.

WARNING:
Users must always possess an additional breathing circuit and exhalation valve while using the V4C-560™ ventilator.

WARNING:
Verify the functionality of the alarms before connecting the patient to the ventilator.

WARNING:
Before starting ventilation, always verify that all settings are properly set in accordance with the required prescription.

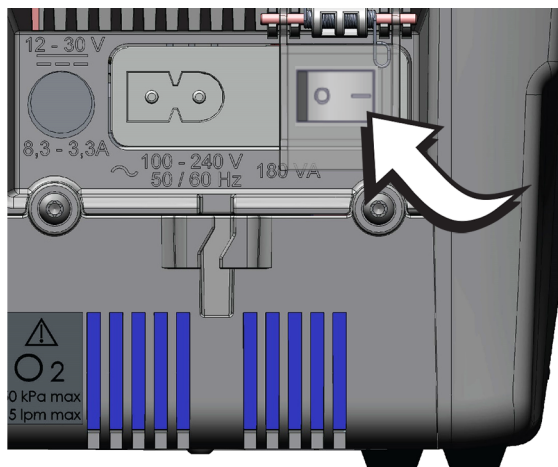
WARNING:
The ventilator offers a variety of breath delivery options. Throughout the patient’s treatment, the clinician should carefully select the ventilation mode and settings to use for that patient, based on clinical judgment, the condition and needs of the patient, and the benefits, limitations, and characteristics of the breath delivery options. As the patient’s condition changes over time, periodically assess the chosen modes and settings to determine whether those are best for the patient’s current needs.

WARNING:
If the ventilator fails the alarm tests or if you cannot complete the tests, refer to section 3.9, [Troubleshooting](#) or call your Equipment supplier or Baylis Medical.

WARNING:
Due to the internal battery’s limited reserve capacity, the ventilator should only be operated on the internal battery when no other power source is available. Ensure that the internal battery never becomes fully discharged.

To turn the ventilator on, set the I/O (power) switch (a covered, rocker-type switch located at the rear of the ventilator) to the I position, as shown in [Figure 5-1](#).

Figure 5-1. Turning on the Ventilator



VEN_10043_B

The following events occur:


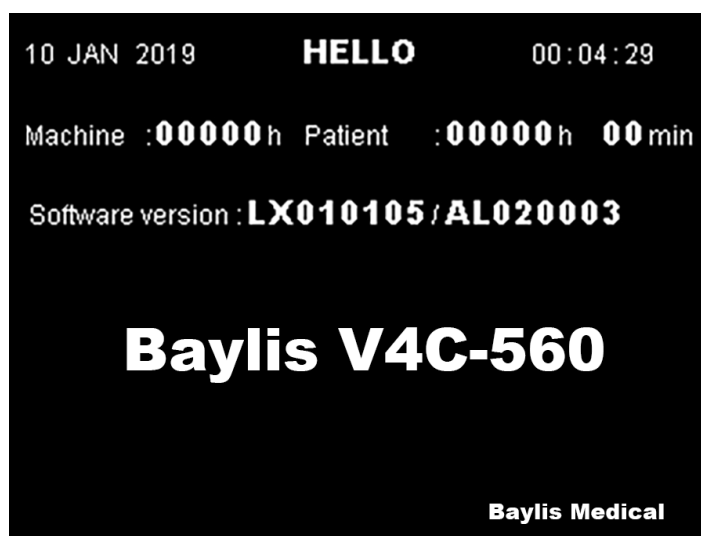
- The ventilator is turned on.
 - A Power On Self Test (POST) is carried out (when plugged in to an AC power source).
 - The front panel indicators flash (except for the indicator showing the type of power supply in use, which remains lit).
 - The audible alarms briefly sound.
 - The display's backlight turns on.
 - The Baylis Medical logo is shown momentarily.
-  • The blue ventilator standby indicator (Figure 5-2, item 2) to the right of the VENTILATION ON/OFF button (Figure 5-2, item 1) illuminates, indicating the device is in standby mode.

Figure 5-2. VENTILATION ON/OFF Button and Standby Indicator



- A Welcome menu screen is shown for about 5 seconds, which includes the machine counter and the patient counter, as shown in Figure 5-3.

Figure 5-3. Welcome Menu Screen



VEN_12628_A



Note:

If the ventilator had been previously stopped by use of the I/O (power) switch while ventilation was in progress, the ventilator starts directly in ventilation mode and does not show the Welcome menu screen.



Note:

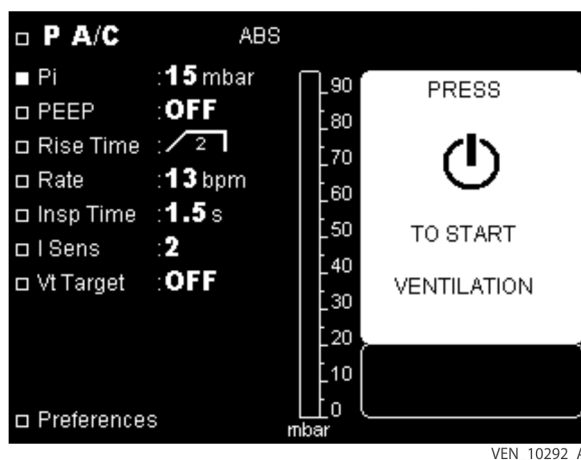
The alarm, technical fault, and event logs are stored in nonvolatile memory on the main CPU PCB, ensuring that the information is retained when the ventilator is powered off and during power loss conditions.



To skip the Welcome menu, press VENTILATION ON/OFF to start ventilation immediately.

The Ventilation menu screen is then shown.

Figure 5-4. Ventilation Menu Parameters



By default, the starting ventilation mode is the last one used, the settings being those that were active when the machine was last stopped.

If the ventilator’s memory of the settings is faulty, a CHECK SETTINGS alarm is activated. If this occurs, the desired parameters should be reset and saved; otherwise the machine will operate on default parameter values.

5.2 USB Menu Parameters



The USB menu is accessible even if the Locking key has been enabled.

The USB menu is automatically shown when the USB memory device is connected to the ventilator, when ventilation is either on or off.

Only one USB memory device may be connected at any time; otherwise, an error message will be shown.

To access patient data via a PC, the Puritan Bennett™ Respiratory Insight software package is available for clinicians. Contact Baylis Medical Technologies or your Product representative for further information.

5.2.1 USB Memory Device Specifications

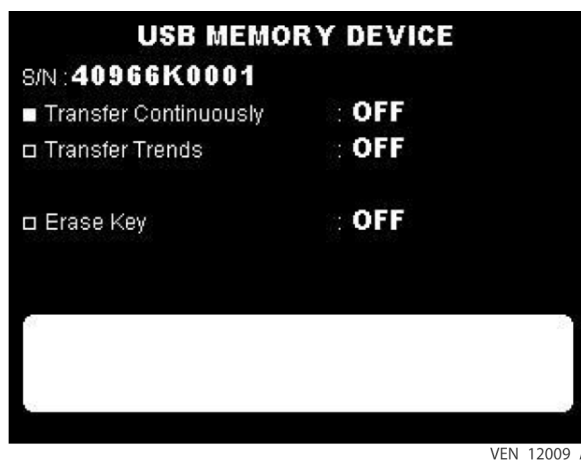
Table 5-1. USB Memory Device Specifications

Characteristics	Supported formats
USB compatibility	USB flash memory USB 2.0 or USB 1.1, 32 bit format
Number of files	Maximum 999 (sector size: 512-2048 bytes)
USB size	128 MB to 4GB (to guarantee accuracy of transfer time, at least 10% of the USB memory device capacity must be free)

5.2.2 USB Memory Device Menu

-  To access the USB Memory Device menu when a USB memory device is connected, press the MENU key several times, until the menu appears.

Figure 5-5. Selecting the USB Menu



-  In case of high priority alarm activation the ventilator will automatically show the alarm page. To return to the USB Memory Device menu, press the MENU key.

The adjustable parameters in this menu include the following:

- Transfer Continuously
- Transfer Trends
- Erase Key

Transfer Continuously

Up to 48 hours worth of data can be transferred from a ventilator to a USB memory device.

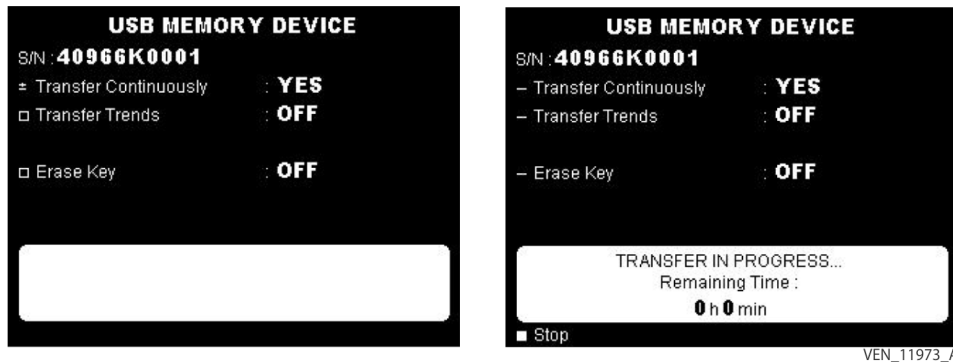
To record continuously, the USB memory device must be permanently connected to the ventilator while ventilation is active.

The following data will be recorded to the USB memory device:

- Monitoring: Pressure, inspired flow, exhaled flow and leak waveforms
- Trends: Leaks, VTI, VTE, Rate, I:E, M. Vol, PIP, and PEEP measurements

The data can be accessed by a doctor or service provider using the Puritan Bennett™ Respiratory Insight software package. Contact your Product representative for further information.

Figure 5-6. Selecting Transfer Continuously



To transfer continuous data from a ventilator to a USB memory device:



1. Use the UP or DOWN arrow keys to place the cursor at the Transfer Continuously position.



2. Press ENTER.



- The cursor changes to the plus/minus symbol.
- The parameter selected to be modified flashes.



3. Press UP or DOWN to change the selected parameter's value.



4. Press ENTER to confirm the new parameter setting.

- The new parameter setting is shown continuously.
- The cursor is placed at the STOP position.



5. To manually stop continuous transfer, press ENTER.



If a parameter change is not confirmed by pressing ENTER before 7 seconds elapse, the ventilator resets the parameter to its previous value.



Note:
All ventilator menus remain accessible during transfer time.



Note:
The message "TRANSFER IN PROGRESS... REMAINING TIME" is shown during the transfer time.

**Note:**

Other functions of the USB memory device are not available during continuous recording.

**Note:**

If the memory capacity on the USB memory device is insufficient the message “TRANSFER NOT ALLOWED - USB CAPACITY INSUFFICIENT” is shown and data transfer is not allowed. Delete the data on the USB memory device before restarting data transfer.

**Note:**

In case of USB memory device disconnection or transfer error, the message “TRANSFER ERROR - USB DISCONNECTION” or “TRANSFER ERROR - TECHNICAL PROBLEM” is shown. In this case, restart the transfer process. If the problem persists, contact your technical service representative.

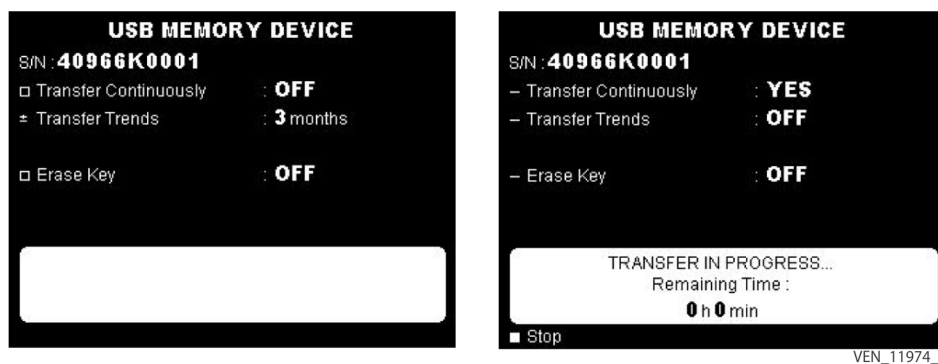
Transfer Trends

Up to 1 year’s worth of trend data can be transferred from a ventilator to a USB memory device.

Ventilation trends such as leaks, VTI, VTE, Rate, I:E, M. Vol, PIP, and PEEP measurements can be transferred from the ventilator to a USB memory device.

The data can be accessed by a doctor or service provider using the Puritan Bennett™ Respiratory Insight software package. Contact your Product representative for further information.

Figure 5-7. Selecting Transfer Trends



To transfer trend data from a ventilator to a USB memory device:



1. Use the UP or DOWN arrow keys to place the cursor at the Transfer Trends position.



2. Press ENTER.



- The cursor changes to the plus/minus symbol.
- The parameter selected to be modified flashes.



3. Press UP or DOWN to change the selected parameter’s value.




-  4. Press ENTER to confirm the new parameter setting.
 - The new parameter setting is shown continuously.
 - The cursor is placed at the STOP position.
-  5. To manually stop trend transfer, press ENTER.
-  If a parameter change is not confirmed by pressing ENTER before 7 seconds elapse, the ventilator resets the parameter to its previous value.

Table 5-2. Ventilator to USB Device Data Transfer Times

Amount of trends data (in months)	Transfer time from ventilator to USB memory device
3 months	Approximately 2 minutes
6 months	Approximately 4 minutes
9 months	Approximately 6 minutes
12 months	Approximately 8 minutes



Note:

The message “TRANSFER IN PROGRESS... REMAINING TIME” is shown during the transfer time.



Note:

Other USB memory device functions are available during transfer of trends.



Note:

If the memory capacity on the USB memory device is insufficient the message “TRANSFER NOT ALLOWED - USB CAPACITY INSUFFICIENT” is shown and data transfer is not allowed. Delete the data on the USB memory device before restarting data transfer.



Note:

In case of USB memory device disconnection or transfer error, the message “TRANSFER ERROR - USB DISCONNECTION” or “TRANSFER ERROR - TECHNICAL PROBLEM” is shown. In this case, restart the transfer process. If the problem persists, contact your technical service representative.

5.3 Starting Ventilation

Before starting ventilation, see Appendix [C, Operational Verification Checklist](#), and set the parameter values in the Preferences menu.



WARNING:

Verify the functionality of the alarms before connecting the patient to the ventilator.




WARNING:

Before starting ventilation, ensure that the device is properly assembled and that the air inlet filter, cooling vents, alarm sound diffusion holes, and side exhaust port are not obstructed. Ensure also that the patient circuit is of the proper configuration (double or single limb), properly connected to the ventilator, and that the circuit hoses are neither damaged nor compressed and contain no obstructions or foreign bodies.



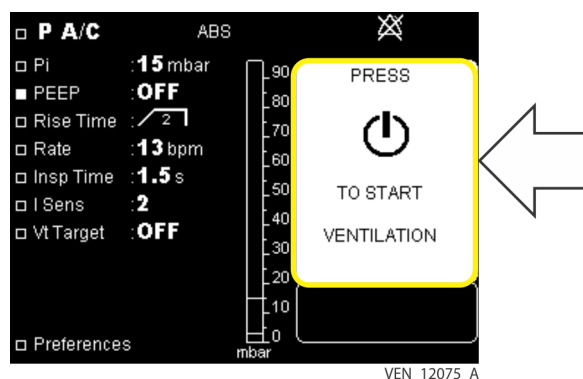
Note:

Many ventilator functions are not accessible when the Locking key  is enabled. For additional assistance, contact your clinician or Equipment representative.



When the ventilator is in standby (the ventilator is on, but ventilation has not started), a message that prompts the ventilator operator to press VENTILATION ON/OFF to start ventilation is shown in the right-hand window of the Ventilation and Alarm menus (Figure 5-8).

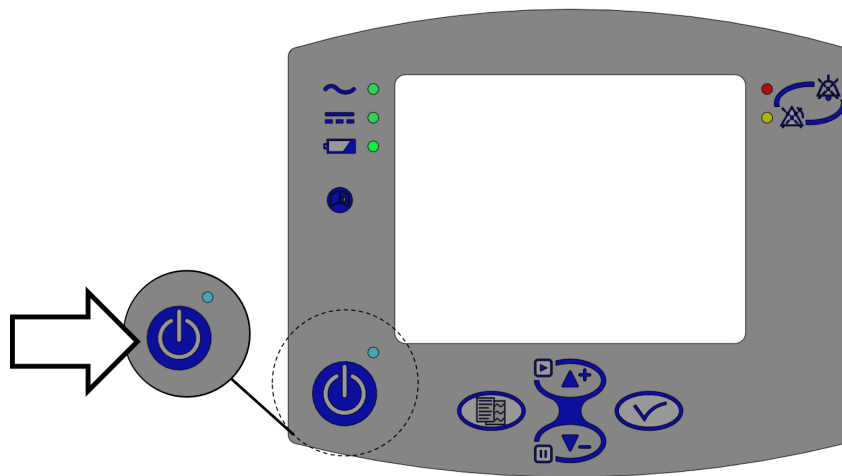
Figure 5-8. Prompt to Start Ventilation



To start ventilation, press and release VENTILATION ON/OFF (Figure 5-9, item 1).

- The blue light indicator, at the upper right of the VENTILATION ON/OFF button (Figure 5-9, item 2), turns off.
- A beep sounds.
- Ventilation starts.
- The values of the monitored parameters are shown in the right-hand window.

Figure 5-9. Starting Ventilation



5.4 Stopping Ventilation



WARNING:

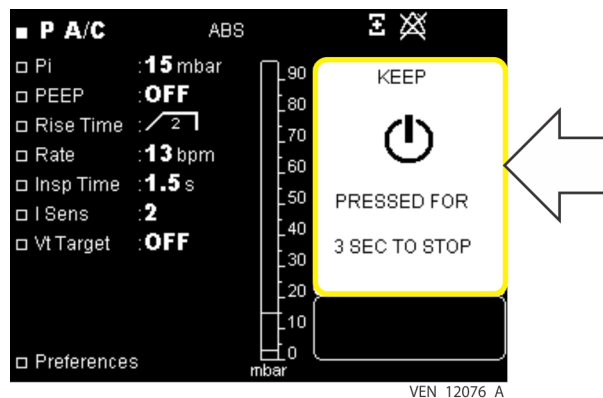
Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of expiratory gas, primarily carbon dioxide, may be inhaled by the patient. In some circumstances, inhaling carbon dioxide may lead to under-ventilation, suffocation, and serious injury or death.

To stop the ventilator:



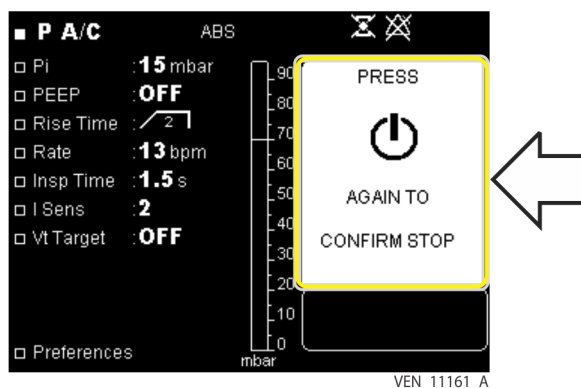
1. Press and hold the VENTILATION ON/OFF button (Figure 5-9, item 1) for 3 seconds. The following occurs:
 - A message prompting the user to keep the button pressed appears on the monitoring window, as shown in Figure 5-10.


Figure 5-10. Stopping Ventilation (1)



- After 3 seconds, a new message appears that directs the user to press the button again to confirm ventilation stop, as shown in Figure 5-11.

Figure 5-11. Stopping Ventilation (2)




- A double beep sounds.
- 2. Release the VENTILATION ON/OFF button.
- 3.  Press the VENTILATION ON/OFF button again within 5 seconds to confirm stop, otherwise ventilation will continue.
 - Ventilation stops.
 - The blue LED located to the upper right of the VENTILATION ON/OFF button (Figure 5-9, item 2) illuminates to indicate ventilation is on standby.
 - A prompt for a new start of ventilation is shown (see Figure 5-8 on page 5-9).

5.5 Turning Off the Ventilator



WARNING:

When the ventilator is switched back on after it was switched off while ventilation was in progress, it will immediately begin ventilating—without the user first having to press the VENTILATION ON/OFF  button.



WARNING:

Handle the ventilator with care after use, particularly when ambient temperatures are high. Some ventilator surfaces may be very hot, even if safety specifications are not exceeded.

Set the I/O (power) switch to the O position to turn off the ventilator.

- The blue LED to the right of the VENTILATION ON/OFF button turns off.
- The ventilator screen switches off.



Note:

When the ventilator is completely stopped, but is still connected to the AC power source (the green AC POWER indicator is illuminated), the internal battery continues charging.



Note:

A continuous alarm condition will be activated if the ventilator power switch is turned off while ventilation is in progress. When the power switch is turned back on again, the ventilation will resume without having to press the VENTILATION ON/OFF button.

6 Internal Battery



WARNING:

Even though the V4C-560™ ventilator meets current safety standards, the internal Lithium-ion battery of the device exceeds the 100Wh threshold and is therefore considered to be Dangerous Goods (DG) Class 9 – Miscellaneous, when transported in commerce. As such, the V4C-560™ ventilator and/or the associated Lithium-ion battery are subject to strict transport conditions under the Dangerous Goods Regulation for air transport (IATA: International Air Transport Association), International Maritime Dangerous Goods code for sea and the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) for Europe. Private individuals who transport the device are excluded from these regulations although for air transport some requirements apply. For air transport; the V4C-560™ ventilator is permitted as checked-in or carry-on baggage. Two spare batteries per person may be taken on board as carry-on luggage only, with the prior approval of the airline. This classification and regulatory requirements may vary depending upon the country and mode of transport. Therefore it is recommended that users verify with the carrier / airline as to which measures to take before the voyage.



WARNING:

Ensure that the ventilator's internal battery is fully charged before connecting the ventilator to an external DC power source. Powering the ventilator using an external 12–30 VDC power source (via the DC power cable) does not enable charging of its internal battery.



WARNING:

The maximum recommended shelf life of the internal battery is 2 years. Do not use a battery that has been stored for 2 years prior to its first use.



WARNING:

Periodic recharging is important to help maximize useful life of the battery. Do not store the internal battery for extended periods, without recharging, as this may reduce the maximum life.



WARNING:

Do not attempt to replace the battery yourself. Replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a fire hazard. Replacement must be completed by qualified service personnel only.

6.1 Battery Capacity

The reserve capacity offered by the internal battery depends on the level of ventilation parameters, the environmental conditions (primarily in terms of temperature) and the physiological characteristics of the patient.

With a fully charged battery at a normal room temperature of 25°C (±5°C), the ventilator can be expected to operate on internal battery power for the average durations shown in [Table 6-1](#).

Checking the battery charge level requires that the ventilator be running on battery power at the time of the battery check. To check the battery charge level, temporarily disconnect the ventilator from AC power (while in standby mode or while providing ventilation) and read the percent charge level shown adjacent to the battery icon at the top of the ventilator's display screen.

Table 6-1. Internal Battery Reserve Capacity

Displayed values	Average operating time on internal battery power ¹
Vt = 200 ml (±5 ml) PIP = 10 mbar (±2 mbar) Rate = 20 bpm	11 hours (-10%)
Vt = 300 ml (±5 ml) PIP = 20 mbar (±2 mbar) Rate = 15 bpm	9 hours (-10%)
Vt = 500 ml (±5 ml) PIP = 30 mbar (±2 mbar) Rate = 15 bpm	6.5 hours (-10%)
Vt = 750 ml (±5 ml) PIP = 45 mbar (±2 mbar) Rate = 20 bpm (maximum ventilation parameters)	4.5 hours (-10%)

1. Average durations shown are with a fully charged battery having less than 50 charge/recharge cycles.

The operational time of the ventilator when powered from a fully charged power source¹ is 6.5 hours (-10%) under the following conditions:

- Delivered Volume = 800 ml (±5 ml)
- Rate = 20 bpm
- I:E = 1:2
- Backlight = OFF
- Resistance = 5 hPa/lps
- Compliance = 50 ml/hPa

6.2 Battery Operation

**WARNING:**

Before using the ventilator's internal battery, ensure that the battery is fully charged and that the charge holds. Back up ventilators should be connected to an AC power source to protect the integrity of the battery.

**Note:**

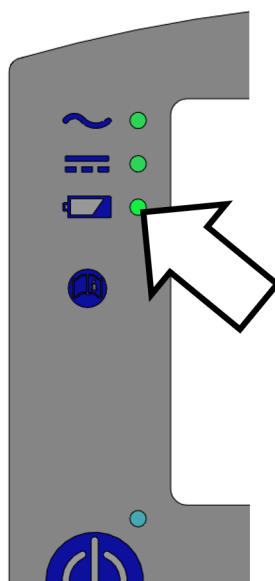
Buzzer and battery alarms may occur when the Unit is first powered on after the internal battery has been completely drained. Connect to an AC power source and recycle power.

**Note:**

In the event of AC power interruption or disconnection of the external AC or DC power supply, the ventilator automatically switches to its internal battery and the following events occur:

- The internal battery indicator at the top left of the ventilator's front panel is continuously lit. See Figure 6-1.

Figure 6-1. Internal Battery Indicator



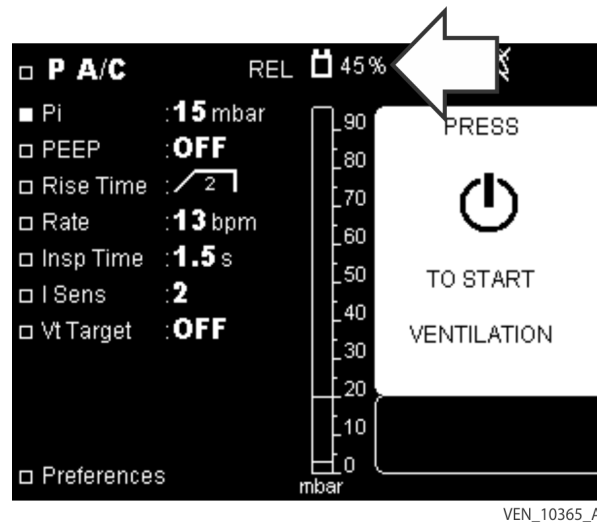
- A loss of external supply alarm is activated.



- The Battery symbol is shown at the top of the screen, on the general information line.
- Internal battery reserve capacity is shown to the right of the Battery symbol.

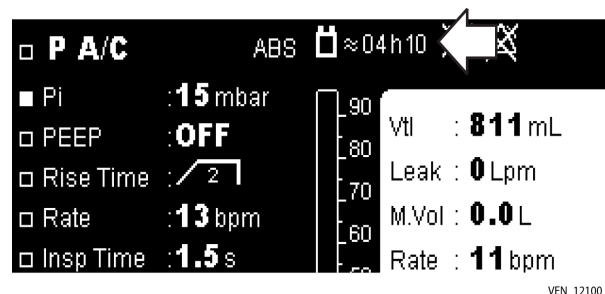
If ventilation is stopped, the internal battery reserve capacity is shown as a percentage of battery charge. See [Figure 6-2](#).

Figure 6-2. Battery Reserve Capacity as a Percentage



If the ventilator is running, the internal battery reserve is momentarily shown as a percentage. Then, after the ventilator calculates the battery time remaining (which takes about 2 minutes, depending on the power consumption of the ventilator), the internal battery reserve is then shown in hours and minutes (rounded to the nearest 10 minutes). See [Figure 6-3](#).

Figure 6-3. Battery Reserve Capacity in Hours and Minutes



The Low Battery and Empty Battery alarms (see [Chapter 3, Alarms and Troubleshooting](#)) are triggered when the internal battery reserve is reduced.



WARNING:

Due to the internal battery's limited reserve capacity, the ventilator should only be operated on the internal battery when no other power source is available. Ensure that the internal battery never becomes fully discharged.



WARNING:

When the Low Battery alarm is triggered, immediately connect the ventilator to an AC power supply to maintain ventilation and recharge the internal battery.

From the time that an Empty Battery alarm is activated, if no external supply is connected to the ventilator, other alarms may be triggered due to insufficient supply voltage.

In the final discharge phase, the Empty Battery alarm will become continuous, and ventilation may be interrupted at any time during this phase.

**Note:**

The Empty Battery alarm symbol may disappear shortly before the ventilator completely stops, but it always triggers a final, continuous alarm.

6.3 Testing the Battery

The ventilator continuously and automatically checks the state of the internal battery, even when the battery is not used as the main source of energy. The Battery Fault 1 alarm is activated whenever a problem is detected in the battery or the charger.

However, on a monthly basis you should disconnect the ventilator from the external power supply to check the integrity of the connections linking the internal battery to other ventilator components.

6.4 Recharging the Battery

In the event that the battery charge level is considered insufficient, as per the reserve capacity display, recharge of the internal battery is necessary. In general, it is recommended that the ventilator be allowed to charge when the battery drops below 80%, and that the ventilator be recharged systematically after storage and before using it again.

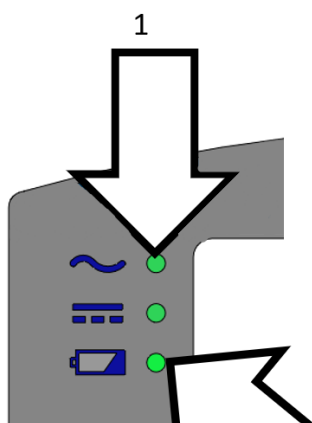
**Note:**

To avoid cycling and extend battery life while connected to an AC power source, the battery will not begin charging until it has dropped below an 85%-90% charge.

To charge the internal battery, connect the ventilator to the AC power source.

- The AC power indicator illuminates (Figure 6-4, item 1).
- The internal battery indicator flashes (Figure 6-4, item 2).

Figure 6-4. Power Indicators when Charging the Battery



When the battery charge is complete, the internal battery indicator turns off.

**WARNING:**

Even if the internal battery indicator is off, charge of the battery may sometimes be incomplete regardless of charge time when the ambient temperature is above 40°C (104°F). This is due to the characteristics of the battery's internal heat safety device.

Although it is not necessary to start the ventilator to charge the battery, charging the battery during operation will increase the time required to fully charge the internal battery.

When recharging a depleted internal battery, it may be necessary to leave the ventilator on charge for up to 6 hours if the ventilator is on standby and about 13 hours if ventilation is operating.

**WARNING:**

Ensure that the ventilator's internal battery is fully charged before connecting the ventilator to an external DC power source. Powering the ventilator using an external 12–30 VDC power source (via the DC power cable) does not enable charging of its internal battery.

6.5 Storage

If the ventilator is to be stored for an extended period of time, it is not necessary to remove the battery. However, the ventilator should be stored in cool, dry, well-ventilated environment, as follows:

- Temperature: approximately 21°C (70°F)
- Humidity: less than 80% RH

**Note:**

When the device is in storage it should be recharged monthly to maximize battery life.

**Note:**

If the battery is stored for more than 1 month at a temperature greater than 21°C (70°F), or for more than 1 or 2 weeks at a temperature greater than 45°C (113°F), the reserve capacity of the battery may be affected. It will then be necessary to recharge the battery before using it again.

**Note:**

If the ventilator has been in storage for longer than 30 days connect it to an AC power source, turn on the Unit by the I/O (power) switch at the rear of the ventilator, and let it charge for 15 minutes prior to starting ventilation.

**Note:**

Fully charge the internal battery prior to disconnecting from AC power source ("mains").

**Note:**

The battery should not be stored for more than 2 years, whatever the conditions.

7 Cleaning



WARNING:

A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated Equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet (TO PATIENT) port—or both ports if a double-limb circuit is used—is highly recommended.



WARNING:

To reduce the risk of infection, wash your hands thoroughly before and after handling the ventilator or its accessories.

7.1 Cleaning the Ventilator

Clean all external panels and surfaces before and after each patient use and as often as necessary to keep the ventilator clean. You should clean the ventilator weekly, whenever it is soiled or dirty, before any maintenance operation, and before storing the ventilator.



WARNING:

Use all cleaning solutions and products with caution. Read and follow the instructions associated with the cleaning solutions you use to clean your ventilator. Use only those solutions listed in [Table 7-1](#).



WARNING:

The ventilator should never be immersed in any liquid, and any liquid on the surface of the device should be wiped away immediately.



WARNING:

To avoid damage to the ventilator, in particular the batteries or electrical components, fluids must not be allowed to enter the device, particularly through the air inlet filter, cooling vents, or side exhaust port located in the side, rear, and bottom panels of the ventilator.

To clean the surface of the ventilator:

1. Dip a clean, soft cloth into a mixture of mild soap and water, or other approved cleaning solution. For a list of approved cleaning solutions, see [Table 7-1](#).

Table 7-1. Approved Cleaning Solutions for Exterior Ventilator Surfaces

Description
Mild dishwashing detergent
70% isopropyl alcohol (rubbing alcohol)
10% chlorine bleach (90% tap water)
Glutaraldehyde
Hospital disinfectant cleaners
Hydrogen peroxide
15% ammonia (85% tap water)
Ammonia-based household cleaners
Household cleaners

2. Squeeze the cloth thoroughly to remove excess liquid.
3. Lightly wipe the external casing of the ventilator, taking care not to allow excess moisture to enter any of the openings on the ventilator’s surface. See the warnings in this section.
4. Dry the ventilator surface with a clean, soft, lint-free cloth.

7.2 Cleaning the Accessories

Follow the accessory manufacturer’s instructions for cleaning the ventilator’s accessories and components, including the patient circuit.



WARNING:

After assembling, cleaning, or reassembling the patient circuit, and on a daily basis, inspect the hoses and other components to ensure that there are no cracks or leaks and that all connections are secure.




WARNING:

Never use a liquid cleaner inside the patient circuit, or on any component of a gas pathway. Clean the patient circuit only as specified by the manufacturer's instructions.

7.3 Cleaning the Exhalation Block



WARNING:

The exhalation block is intended for single use by a single patient . It may periodically be cleaned, but it cannot be disinfected or sterilized. To maintain good measurement quality when used continuously, clean the exhalation block periodically. The exhalation block should be changed every 4 months and cannot be reused with any other patient.



WARNING:

Ensure that the exhalation block is completely dried after cleaning and prior to use.

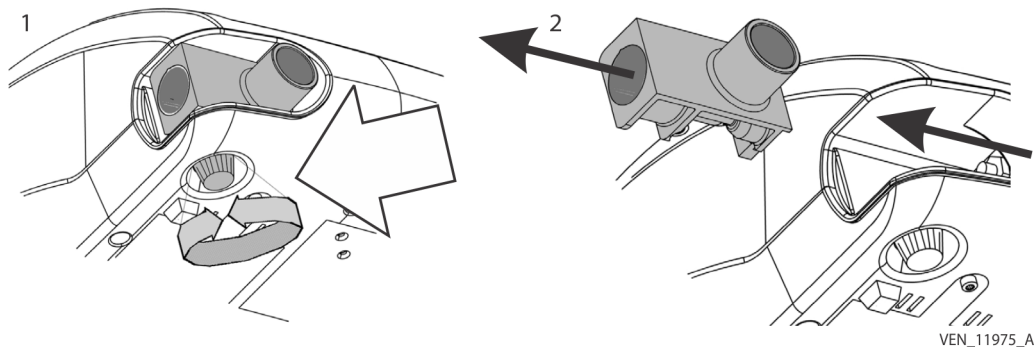


WARNING:

When an exhalation block is set up, each time it is removed, or after installing a new exhalation block on the machine, it is essential that the exhalation flow sensor be recalibrated before the exhalation block is used.

The exhalation block can be easily removed for inspection, cleaning, or replacement. No special tools are required. It is held in place by a single captive screw located on the bottom of the device.

Figure 7-1. Removing the Exhalation Block



1 Exhalation block installed (captive screw shown)

2 Exhalation block removed

To remove the exhalation block (see Figure 7-1):

1. Ensure the ventilator is turned off.
2. Loosen the captive screw located on the bottom of the ventilator that secures the exhalation block (view 1).
3. Grasp the exhalation port and slide the exhalation block toward the left side of the ventilator to remove it from its slot (view 2).

To reinstall a cleaned exhalation block or install a new exhalation block (see Figure 7-1):

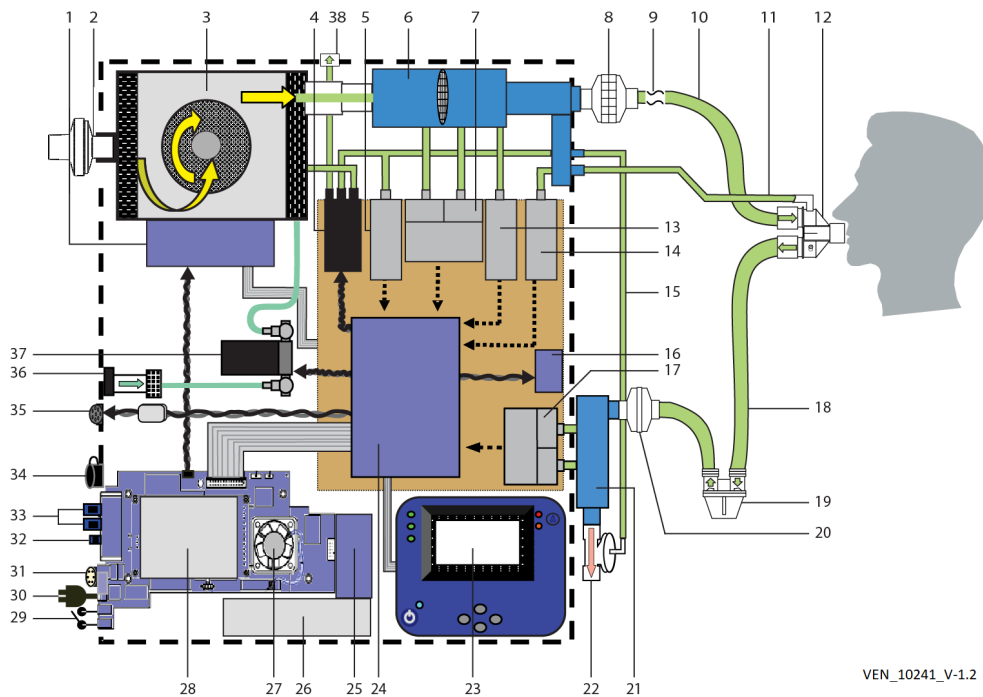
1. Slide the exhalation block into its slot.
2. Tighten the captive screw (view 1) to secure the exhalation block in place.

7.4 Pneumatic System

This section describes the components of the pneumatic system.

Figure 7-2 shows a pneumatic block diagram of the V4C-560™ Ventilator, including the patient circuit. The main pneumatic components that can potentially get contaminated during use are the air inlet filter (2); low pressure oxygen inlet /valve (36); oxygen solenoid valve (37); inlet and outlet silencers (not shown); turbine assembly (3); exhalation solenoid valve (4); inspiratory block (6); inspiratory flow sensor (7); proximal pressure sensor (14); inspiratory pressure sensor (13); exhalation valve (internal valve) (22); exhalation block (21); exhalation flow sensor (17); barometric pressure sensor (not shown); patient circuit (9, 10, 11, 12, 18, and 19); and inspiratory and expiratory bacteria filters (8 and 20).

Figure 7-2. V4C-560™ Ventilator Pneumatic Diagram



VEN_10241_V-1.2

- | | | | |
|---|----------------------------------|----|----------------------------|
| 1 | Turbine control PCBA | 20 | Exhalation bacteria filter |
| 2 | Air inlet filter | 21 | Exhalation block |
| 3 | Turbine | 22 | Exhalation valve |
| 4 | Exhalation solenoid valve | 23 | Display |
| 5 | Exhalation valve pressure sensor | 24 | CPU PCBA |
| 6 | Inspiratory block | 25 | Battery connection PCBA |
| 7 | Inspiratory flow sensor | 26 | Internal battery |
| 8 | Inspiratory bacteria filter | 27 | Cooling fan |

9	Humidifier, nebulizer, or additional water traps (not shown)	28	Power supply (located above power management PCBA)
10	Inspiratory tubing	29	Power switch
11	Proximal pressure tube	30	AC input
12	Patient wye	31	DC input
13	Inspiratory pressure sensor	32	PC port
14	Proximal pressure sensor	33	Type A USB ports (2)
15	Exhalation valve pilot tube	34	SpO ₂ port (not used)
16	Buzzer PCBA	35	Nurse call port
17	Exhalation bacteria filter	36	Low pressure O ₂ inlet
18	Exhalation tubing	37	O ₂ solenoid valve
19	Water trap	38	O ₂ exhaust port

The inspiratory filter protects the ventilator from contamination by the patient (primarily, rebreathed gas). To prevent any risk of cross contamination the use of Medtronic DAR™ filter (Ref: 351/5856 or equivalent) is recommended to protect the patient outlet port and the exhalation block port.

If the inspiratory or expiratory bacteria filters have not been changed frequently (according to institutional protocol and/or manufacturer recommendation) and have not been installed properly on the inlet and exhaust ports of the ventilator to prevent cross contamination, the entire inspiratory block requires cleaning and disinfection, the expiratory block requires replacement, circuits and filters require replacement, and flow sensor calibration should be considered before new patient use.

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8 Routine Maintenance

8.1 Overview

This chapter lists routine maintenance procedures for the V4C-560™ ventilator.



WARNING:

On a **DAILY** basis, inspect the patient circuit to ensure that it shows no signs of damage, is properly connected, and is operating correctly without leakage.



WARNING:

Do not attempt to open, repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only personnel authorized and qualified by Baylis Medical Technologies should repair, open or service the ventilator.



WARNING:

Ensure that the ventilator is powered off and not in use before performing routine maintenance.



WARNING:

Do not perform any maintenance activities while the ventilator is in use on a patient.



WARNING:

Contact local authorities to determine the proper method to dispose of potentially hazardous parts and accessories.

8.2 Calibrating the Exhalation Flow Sensor

Each time the exhalation block or circuit is removed and reinstalled or after installing a new exhalation block, the exhalation flow sensor must be recalibrated before using the ventilator. This process is automatic and does not require the use of a measurement device.



Note:

Perform calibration with either an adult or pediatric circuit. Use the appropriate Pediatric setting (Yes or No) in the Preferences menu.

To calibrate the exhalation flow sensor:

1. Ensure the ventilator is on and in standby mode.

2. Ensure the Locking key is disabled.
3. Obstruct the patient circuit's open connector. See [Figure 8-1](#).

Figure 8-1. Blocking the Patient Circuit (single-limb circuit at left; double-limb circuit at right)



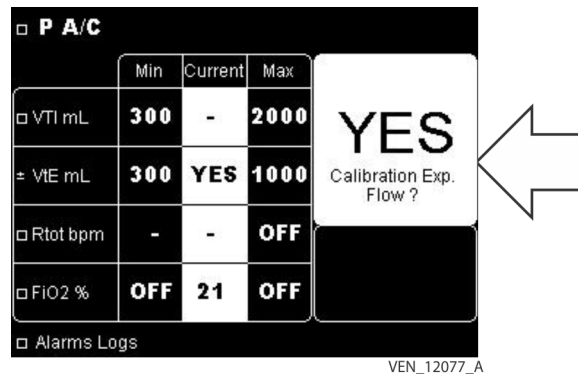
4. Press the MENU key to access the alarm settings menu—if this is not the menu currently shown.
5. Press the UP or DOWN key to place the cursor on the VTE setup line.
6. Press the ENTER key twice to access the Patient column (central column) of the VTE setup line.
 - “OFF” flashes in the central column.
 - “OFF” flashes in the window on the right.
 - The message “Calibration Exp. Flow?” also appears in the window on the right.

Figure 8-2. Calibrating the Exhalation Flow Sensor (1)

P A/C				OFF Calibration Exp. Flow ?
	Min	Current	Max	
VTI mL	300	-	2000	←
VE mL	300	OFF	1000	
Rtot bpm	-	-	OFF	
FiO2 %	OFF	21	OFF	
Alarms Logs				

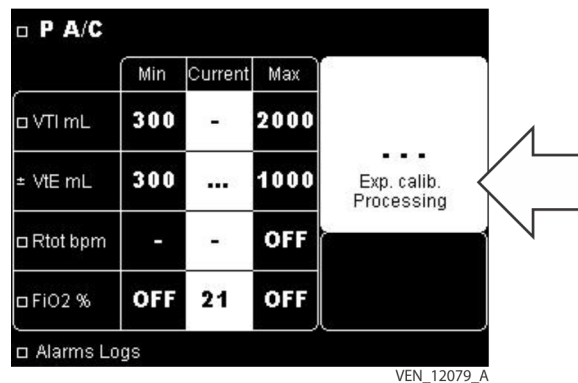
7. Press the UP or DOWN key. “YES” is shown instead of “OFF”.

Figure 8-3. Calibrating the Exhalation Flow Sensor (2)



8. Press the ENTER key to start calibration.
- The message "...Exp. calib. Processing..." is shown in the window on the right while calibration is in progress.

Figure 8-4. Calibrating the Exhalation Flow Sensor (3)



- The ventilator adjusts the speed of the blower to reach the initial calibration point.
- A short beep sounds to confirm the first adjustment.
- The ventilator automatically increases and adjusts the speed of the blower to reach the next calibration point.
- A short beep sounds to confirm the second adjustment.
- This process continues until adjustments are complete for all eight calibration points.

**Note:**

The exhalation flow sensor calibration procedure, once initiated, must run to its conclusion.

**Note:**

No message is shown when the ventilator passes calibration; a message is only shown if the calibration has failed.

In the event of calibration errors, the following events occur:

- The ventilator sounds a long beep at each point that fails calibration.
- An alarm is activated, and the message “CALIBRATION FAIL” is shown.
- The ventilator takes the previously saved value as the default and automatically switches to the next calibration point.


If a Calibration Fail alarm occurs:

1. Ensure the exhalation block is properly seated.
2. Ensure an approved circuit is in use (see circuit documentation).
3. Check the integrity of the circuit and all connections.
4. Ensure the correct circuit type is selected in the ventilator preferences.
5. Repeat the calibration procedure keeping a tight seal over the end of the circuit during calibration.


8.3 Calibrating the FiO₂ Sensor

Each time a measurement cell is removed and reinstalled, and on a weekly basis, the FiO₂ sensor must be recalibrated before using the ventilator. This process does not require the use of a measurement device.

To calibrate the FiO₂ sensor:

1. Ensure the ventilator is on and in standby mode.
-  2. Ensure the Locking key is disabled.
3. Connect the FiO₂ sensor cable to the ventilator. See section [4.8.3, Connecting the FiO₂ Sensor](#). Disconnect the sensor from the T-connector and expose it to room air. Wait 15-30s. Perform the rest of the calibration with the sensor exposed to room air.

-  4. Press the MENU key to access the alarm settings menu—if this is not the menu currently shown.

-  5. Press the UP or DOWN key to place the cursor on the FiO₂ setup line.


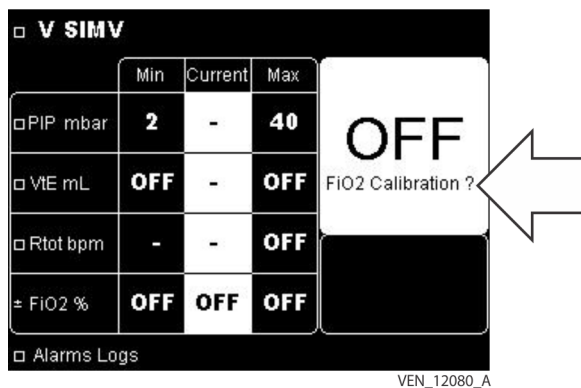
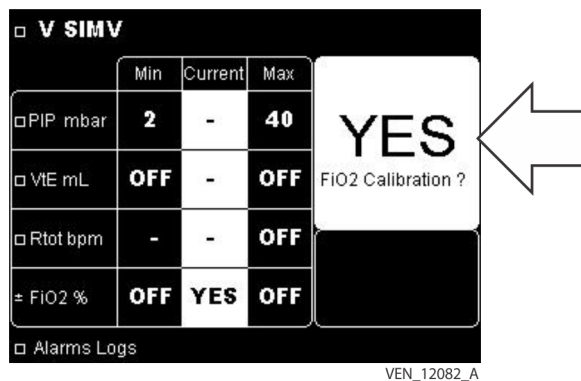
-  6. Press the ENTER key twice to access the Patient column (central column) of the FiO₂ setup line.
 - “OFF” flashes in the central column.
 - “OFF” flashes in the window on the right.
 - The message “FiO₂ Calibration?” also appears in the window on the right.

Figure 8-5. Calibrating the FiO₂ Sensor (1)



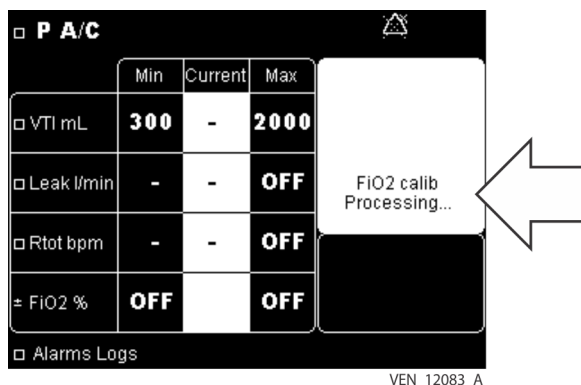
- Press the UP or DOWN key. "YES" is shown instead of "OFF".

Figure 8-6. Calibrating the FiO₂ Sensor (2)



- Press the ENTER key to start calibration.
 - The message "FiO₂ calib. Processing..." is shown in the window on the right while calibration is in progress.

Figure 8-7. Calibrating the FiO₂ Sensor (3)



- A short beep sounds to confirm that the FiO₂ sensor has been calibrated.



- Press the ENTER key to exit the FiO₂ setup line.



Note:

The FiO₂ sensor calibration procedure, once initiated, must run to its conclusion.

In the event of calibration errors, the following events occur:

- An alarm is activated and the message “FiO₂ CALIBRATION FAIL” is shown.
- The ventilator takes the previously saved value as the default.

8.4 Replacing the Air Inlet Filter



WARNING:

Do not use an air inlet filter with resistance higher than indicated in Table A-16.



WARNING:

Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. If necessary, replace the filter before the recommended replacement period is over.



WARNING:

Failing to replace a dirty air inlet filter, or operating the ventilator without a filter, may cause serious damage to the ventilator.

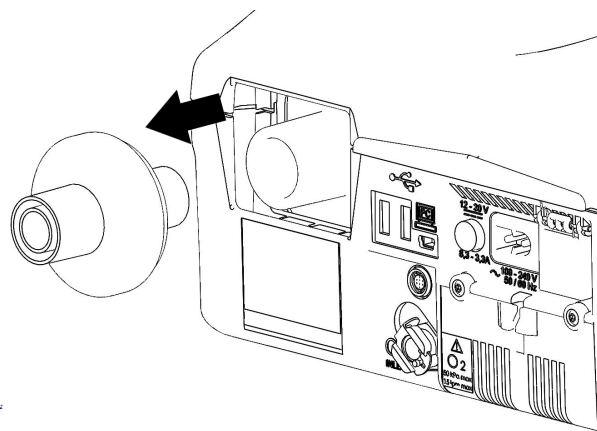


WARNING:

The air inlet filter is not reusable; do not attempt to wash, clean, or reuse it.

If the ventilator is used indoors, the condition of the air inlet filter should be checked every two weeks. If the ventilator is used outdoors or in a dusty environment, the air inlet filter should be checked every one week and replaced as necessary.

Figure 8-8. Replacing the Air Inlet Filter



To replace the air inlet filter (see Figure 8-8):

1. Pull the inlet filter to disconnect it from the inlet port at the back of the ventilator. Discard the used filter as instructed by the responsible organization.

**WARNING:**

Contact local authorities to determine the proper method to dispose of potentially hazardous parts and accessories.

- a. Connect the new inlet filter securely to the inlet port at the back of the ventilator. Proper installation of the filter prevents particles from entering the device.

8.5 Recommended Schedule of Maintenance

8.5.1 Preventive Maintenance Intervals

Table 8-1 lists the periodic maintenance activities required for the V4C-560™ Ventilator. Total machine hours appear on the welcome screen that appears when turning on the ventilator with the power switch, in the Preferences menu during normal operation, and also when entering maintenance mode.



Note:

Only qualified service personnel should open, repair, or service the ventilator.

Table 8-1. Preventive Maintenance Schedule

Frequency	Part	Maintenance
As needed	Ventilator external surface	Clean and disinfect. See section 7.1, Cleaning the Ventilator .
According to institutional protocol or manufacturer recommendation	Inspiratory bacteria filter	Replace.
	Exhalation bacteria filter	
	Patient circuit	
	O ₂ sensor	The oxygen sensor cannot be immersed in a cleaning or disinfecting solution, nor can it be sterilized. If it becomes contaminated, replace.
With each new patient (also see manufacturer’s recommendation)	Inspiratory bacteria filter	Replace.
	Exhalation bacteria filter	Replace. Recalibrate exhalation flow sensor after replacing filter.
	Patient circuit	Replace.
Check or replace every two weeks or more often.	Air inlet filter	Replace. Note: In particularly dusty environments, replace the air inlet filter more frequently to prevent clogging even if the preventive maintenance period has not elapsed. See section 8.4, Replacing the Air Inlet Filter for air inlet filter replacement instructions.
Every 4 months or with each new patient	Exhalation block ¹	Replace exhalation block and calibrate exhalation flow sensor after reinstallation of exhalation block. Refer to section 8.2, Calibrating the Exhalation Flow Sensor for calibration instructions.
Every 15 000 hours of use	Oxygen solenoid valve	Replace.
	Turbine	Replace.
	Exhalation solenoid valve	Replace.
	Cooling fan	Replace.

Table 8-1. Preventive Maintenance Schedule (Continued)

Frequency	Part	Maintenance
Every 12 months of storage or every 8 months of operation (or more often if persistent calibration failures occur)	FiO ₂ sensor	Replace.
Every 2 years	Inspiratory block	Clean and disinfect the inspiratory block using one of the disinfectants listed in Table 7-1 . ²
	Measurements check and calibration	These tasks should be performed by a qualified technician.
	Battery, lithium-ion 4.8 Ah memory	Replace.
	Battery, lithium, 3V	Replace.
	Buzzer PCBA	Replace.

¹ The exhalation block replacement frequency may be 3 months for patients ventilated by tracheotomy more than 12 hours per day. The replacement frequency may be extended to 6 months for patients ventilated less than 12 hours per day, depending on the frequency of technician visits.

² To prevent cross contamination, both cleaning and disinfection of the inspiratory block and flow sensor calibration should be considered before new patient use in the event that filters were not used at the inspiratory port or proximal Y piece.

The V4C-560 should have an expected service life of 10 years, provided that the preventative maintenance schedule in this manual is followed.

**WARNING:**

Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. Replace it when necessary—even before the recommended replacement period has elapsed.

**WARNING:**

The exhalation block is intended for single use by a single patient (Ⓜ). It may periodically be cleaned, but it cannot be disinfected or sterilized. To maintain good measurement quality when used continuously, clean the exhalation block periodically (refer to section 7.3, [Cleaning the Exhalation Block](#)). The exhalation block should be changed every 4 months and cannot be reused with any other patient.

**Note:**

For a list of parts and accessories, see Appendix [F](#), or contact your customer service representative.

**Note:**

For all additional accessories not necessarily considered as consumables consult the manufacturer's recommendations.

**Note:**

To prevent any risk of cross contamination, Baylis Medical Technologies recommends the use of Medtronic DAR™ filters (Ref: 351/5856 or equivalent) to protect the patient outlet port and the exhalation block port.

Failure to observe these recommendations may result in a loss of performance, excessive overheating, a loss of certain functions and, in the long term, compromise the longevity of the ventilator.

8.5.2 Maintenance of the Internal Battery

The internal battery does not need to be removed to verify its correct operation.

8.5.3 Periodic Test of the Internal Battery

The ventilator continuously and automatically checks the state of the internal battery, even when the internal battery is not used as the main power source.

However, the battery charge status should be checked MONTHLY by disconnecting the ventilator from external power supplies (see section 6.2, [Battery Operation](#)). Such a test is imperative after opening the ventilator or after a prolonged period of non-use (1 month or more), in order to ensure the correct operation of internal connections linking the battery to other components.

**WARNING:**

The maximum recommended shelf life of the internal battery is 2 years. Do not use a battery that has been stored for 2 years prior to its first use.

**WARNING:**

Periodic recharging is important to help maximize useful life of the battery. Do not store the internal battery for extended periods, without recharging, as this may reduce the maximum life.

8.5.4 Replacement of the Internal Battery

**WARNING:**

Do not attempt to replace the battery yourself. Replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a fire hazard. Replacement must be completed by qualified service personnel only.

The internal battery should be replaced every 2 years. Keep in mind that, for environmental protection, the ventilator and its components—including its internal battery—cannot be disposed of with household waste. Submit the ventilator and its components for suitable selective collection and possible recycling and observe all applicable regulations.

8.6 Service Assistance

**WARNING:**

If a problem with the ventilator is suspected, **FIRST CHECK THAT THE PATIENT IS NOT IN DANGER**. If necessary, remove the patient from the ventilator and provide an alternative means of ventilation.

**WARNING:**

Do not attempt to open, repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only qualified service personnel should open, repair or service the ventilator.

In the event of a problem with the ventilator, see Chapter 3, [Alarms and Troubleshooting](#). If you cannot determine the cause of the problem, contact your Equipment supplier or Baylis Medical Technologies.

For more information and local Baylis Medical Technologies Technical Service contact details, see [Man-ufacturer](#) in the Preface.

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A Specifications

A.1 Physical

Table A-1. Physical Description (excluding accessories)

Ventilator weight	9.9 lb. (4.5 kg)
Ventilator dimensions	9.25 in wide x 12.40 in deep x 6.0 in high (235 mm wide x 315 mm deep x 154 mm high)
Connectors	Inspiratory limb connector: ISO 22 mm (OD) conical Exhalation limb connector (on exhalation block): ISO 22 mm (ID) conical Oxygen inlet: female connector with valve
Device airway volume	2000 ml
Breathing circuit volume	
• Adult, dual limb	1150 ml
• Pediatric, dual limb	670 ml
• Adult, single limb	550 ml
• Pediatric, single limb	300 ml
Air inlet filter	Dimensions: 67 mm long x 59 mm wide Composition: Polypropylene electrostatic-based filter media Bacterial Efficiency: >99.999% Viral Efficiency: > 99.998%
Inspiratory bacteria filter requirement	Maximum allowable flow resistance: 4mbar at 60 lpm

A.2 Electrical

Table A-2. Electrical Supply

Voltage (nominal voltage range)	Frequency	Consumption
100 VAC to 240 VAC	50 Hz / 60 Hz	180 VA max
90–264 VAC (rated voltage range)	50 Hz / 60 Hz	180 VA max
12 VDC	N/A	8.3 A
30 VDC	N/A	3.3 A

Table A-3. Internal Lithium Ion Battery

Voltage	25.2 VDC
Full-load capacity	4.8 Ah
Ampere-hour rating	On standby: 1.5 Ah
	During ventilation: 0.5 Ah
Watt hour rating	120 Wh to 126 Wh
Charging current	Standby mode: 1.5 A/hr. (duration: <6 hr.)
	Ventilation mode: 0.5 A/hr. (duration: <13 hr.)
Average operating time at 25°C (±5°C) with a fully charged battery (having less than 50 charge/discharge cycles) at the following displayed values:	
Vt = 200 ml (±5 ml), PIP = 10 mbar (±2 mbar), Rate = 20 bpm	11 hr. (-10%)
Vt = 300 ml (±5 ml), PIP = 20 mbar (±2 mbar), Rate = 15 bpm	9 hr. (-10%)
Vt = 500 ml (±5 ml), PIP = 30 mbar (±2 mbar), Rate = 15 bpm	6.5 hr. (-10%)
Vt = 750 ml (±5 ml), PIP = 45 mbar (±2 mbar), Rate = 20 bpm (maximum settings)	4.5 hr. (-10%)

A.3 Indicators and Alarms

Table A-4. Power Indicators

Ventilation ON/OFF	AC power	DC power	Internal battery
<ul style="list-style-type: none"> • Blue in standby mode • Not lit if ventilation is in progress. 	Green	Green	<ul style="list-style-type: none"> • Flashing if the battery charge is in progress. • Continuously lit if the ventilator is powered by the internal battery.

Table A-5. Alarm Indicators

High priority	Medium priority	Low priority
Red flashing LED	Yellow flashing LED	Yellow continuously lit LED

Table A-6. Audio Alarms

Audio paused	Alarm volume	Power down alarm volume
60 s ±1 s	50 dBA to 80 dBA (Alarm volume setting MIN to alarm volume setting MAX) Measurement uncertainty: ±3 dBA	Minimum 65 dBA

A.4 Performance



Note:

Performance specifications listed are applicable when dry gases are used in the patient system.

Table A-7. Performance Parameter Specifications and Tolerances¹

Settings	Range	Tolerances
Volume	50 to 2000 ml	±(10 ml +15%)
Pressure	5 to 55 mbar	±(1 mbar +10%)
Time	0.3 to 6.0 s	±10%
Rate	1 to 60 bpm	±1 bpm
Inspiratory Sensitivity	0P to 5	N/A
Exhalation Sensitivity	5 to 95%	±(4 lpm +10% of target exhalation flow) based on E Sens within 50ms
Vt Sigh	Vt×1 to Vt×2	±(20ml +20%)
I:E Ratio	1:4 to 1:1	Insp. time ±50 ms and Exh. time ±50 ms or I:E ratio ±10%, whichever is greater
I/T Ratio	20% to 50%	Insp. time ±50 ms and Exh. time ±50 ms or I/T ratio ±10%, whichever is greater

1. The ventilator parameters' displayed values could vary based on patient settings.

A.5 Monitored Parameters

Table A-8. Monitored Parameter Tolerances

Ventilator parameter	Tolerances
Peak Inspiratory Pressure (PIP)	±(2 mbar +4%)
Positive End Expiratory Pressure (PEEP) ¹	±(2 mbar +4%)
Inspiratory Tidal Volume (VTI)	±(10 ml +15%) and ±(20 mL +20%) in CPAP mode above 200 mL or in NIV configuration
Exhalation Tidal Volume (VTE)	±(10 ml +15%)
Total Breath Rate (Rtot)	±1 bpm
I:E Ratio (I:E)	Insp. time ±50 ms and Exh. time ±50 ms or I:E ratio ±10%, whichever is greater
I/T Ratio (I/T)	Insp. time ±50 ms and Exh. time ±50 ms or I/T ratio ±10%, whichever is greater
Inspiratory Time (I Time)	±100 ms
Exhalation Time (E Time)	±100 ms

Table A-8. Monitored Parameter Tolerances (Continued)

Ventilator parameter	Tolerances
Inspiratory Minute Volume (M Vol)	$\pm(10 \text{ mL} + 15\% \text{ VTI}) \times \text{Rate}$ (with exhalation valve) and $\pm(20 \text{ mL} + 20\% \text{ VTI}) \times \text{Rate}$ in NIV configuration (without exhalation valve)
Vt Sigh	$\pm(20\text{ml} + 20\%)$
FiO ₂	$\pm(2.5\% + 2.5\% \text{ FiO}_2)$
Leak	$\pm(3 \text{ lpm} + 20\%)$
Apnea Index (AI)	$\pm 1 \text{ ev/h}$
Apnea Time	$\pm 1 \text{ s}$
% Spontaneous (Spont)	$\pm 1\%$
Peak Airway Pressure (Paw)	$\pm(2 \text{ mbar} + 4\%)$

1. The V4C-560™ ventilator does not have the capability to reduce pressure below the PEEP pressure during the exhalation phase.

A.6 Range, Resolution, and Accuracy

Table A-9 lists the ranges, resolutions, and accuracies for ventilator settings, alarm settings, and patient data.

Table A-9. Ventilator Range, Resolution, and Accuracy

Ventilator settings	Range, resolution, and accuracy
Mode	Range: V A/C, P A/C, V SIMV, P SIMV, PSV, CPAP Resolution: N/A Accuracy: N/A Default value: P A/C
Tidal volume (Vt)	Range: 50 mL to 2000 mL Resolution: 10 mL Accuracy: $\pm(10 \text{ ml} + 15\%)$ of setting Default value: 500 mL Depends on: Insp time, R-Rate in V SIMV and P SIMV Depends on: Rate and I:E (I/T) in V A/C
Vt Target	Range: 50 mL to 2000 mL Resolution: 10 mL Accuracy: Vt target < VTI < Vt target +20% if Max P is high enough to reach Vt target Default value: OFF (100 mL)
Inspiratory Pressure (Pi)	Range: 5 mbar to 55 mbar in valve configuration Range: 6 mbar to 30 mbar in leak configuration Resolution: 1 mbar Accuracy: $\pm(1 \text{ mbar} + 10\%)$ of Pi + PEEP setting Default value: 15 mbar Depends on: PEEP when Relative Pressure is set to YES

Table A-9. Ventilator Range, Resolution, and Accuracy (Continued)

Ventilator settings	Range, resolution, and accuracy
Pressure support (P Support)	Range: OFF or 5 mbar to 55 mbar in valve configuration Range: 6 mbar to 30 mbar in leak configuration Resolution: 1 mbar Accuracy: $\pm(1 \text{ mbar} + 10\%)$ of P Support + PEEP setting Default value: 15 mbar Depends on: PEEP when Relative Pressure is set to YES
I:E Ratio (I:E)	Range: 1:1 to 1:4 Resolution: 1/0.1 Accuracy: Insp. time ± 50 ms and Exh. time ± 50 ms or I:E ratio $\pm 10\%$, whichever is greater Default value: 1:2
I/T Ratio (I/T)	Range: 20% to 50% Resolution: 1% Accuracy: Insp. time ± 50 ms and Exh. time ± 50 ms or I/T ratio $\pm 10\%$, whichever is greater Default value: 33%
Inspiratory time (Insp Time)	Range: 0.3 s to 6.0 s in P A/C and V A/C modes; 0.3 s to 2.4 s in P SIMV and V SIMV modes Resolution: 0.1 s Accuracy: $\pm 10\%$ Default value: 1.5 s Depends on: R-Rate, Vt in V SIMV mode Depends on: R-Rate in P SIMV mode
Respiratory rate (R-Rate)	Range: 1 bpm to 60 bpm in V A/C and P A/C modes 1 bpm to 40 bpm in P SIMV and V SIMV modes Resolution: 1 bpm Accuracy: ± 1 bpm Default value: 13 Depends on: Insp Time and Vt in V SIMV mode Depends on: Insp Time in P SIMV modes Depends on: Vt in V A/C mode
Inspiratory sensitivity (I Sens)	Range: 0P to 5 Resolution: 1 Accuracy: N/A Default value: 2 In CPAP, I Sens is set to 2 and is not adjustable
Exhalation sensitivity (E Sens)	Range: 5% to 95% of peak flow Resolution: 5% Accuracy: $\pm(4 \text{ lpm} + 10\%$ of target exhalation flow) based on E Sens within 50ms Default value: 25% In CPAP, E Sens is fixed at 25% and is not adjustable

Table A-9. Ventilator Range, Resolution, and Accuracy (Continued)

Ventilator settings	Range, resolution, and accuracy
Ramp (Flow Pattern)	Range: Square (SQ), descending ramp (D), sinusoidal (S) Resolution: N/A Default value: Descending ramp (D) In V SIMV, flow pattern is set to square and is not adjustable
PEEP	Range: OFF (0.5 mbar) to 20 mbar Resolution: 1 mbar Accuracy: $\pm(1 \text{ mbar} + 10\%) \text{ mbar}$ Default value: OFF Depends on: Pi in P A/C and PSV modes when Relative Pressure is set to YES Depends on: P Support and Pi in P SIMV mode when Relative Pressure is set to YES Depends on: P Support in V SIMV mode when Relative Pressure is set to YES
Rise time	Range: 1 to 4 Resolution: 1 Default value: 2 Depends on: Insp time
Backup rate	Range: OFF or 4 to 40 bpm Resolution: 1 bpm Default value: 13 Depends on: Min I time In P SIMV and V SIMV, Backup rate = Max (8, R-Rate)
Apnea time	Range: AUTO or 1 to 60 s Resolution: 1 s Default value: AUTO Depends on: Backup R In PSV, Apnea time: AUTO = 60/Backup R In V SIMV or P SIMV, Apnea Time: AUTO = 12 In CPAP, Apnea Time: AUTO = 30
Minimum Inspired Tidal Volume (Min VTI)	Range: 30 mL to 2000 mL Resolution: 10 mL Default value: 300 Depends on: Max VTI
Maximum Inspired Tidal Volume (Max VTI)	Range: 80 mL to 3000 mL Resolution: 10 mL Default value: 2000 mL Depends on: Min VTI
Minimum Exhaled Tidal Volume (Min VTE)	Range: 30 mL to 1990 mL Resolution: 10 mL Default value: 300 Depends on: Max VTE

Table A-9. Ventilator Range, Resolution, and Accuracy (Continued)

Ventilator settings	Range, resolution, and accuracy
Maximum Exhaled Tidal Volume (Max VTE)	Range: 80 mL to 3000 mL Resolution: 10 mL Default value: 1000 Depends on: Min VTE
Maximum Respiratory Rate (Max Rtot)	Range: 10 bpm to 70 bpm in CPAP, P A/C, and V A/C modes and 17 bpm to 70 bpm in P SIMV and V SIMV modes Resolution: 1 bpm Default value: OFF Depends on: R-Rate
Minimum Peak Inspiratory Pressure (Min PIP)	Range: PIP-20% (not adjustable in pressure breath) Range: 2 to 52 (V SIMV); 2 to 82 (V A/C) Resolution: 1 Default value: 2 Depends on: PEEP, Max PIP
Maximum Peak Inspiratory Pressure (Max PIP)	Range: PIP+20% (not adjustable in pressure breath) Range: 12 to 90 in volume breath Resolution: 1 Default value: 40 Depends on: PEEP, Min PIP
Minimum inspiratory time (Min I time)	Range: 0.1 to 2.8 s Resolution: 0.1 s Default value: AUTO (Rise time + 300 ms) Depends on: Max I Time, Backup R, Rise time
Maximum inspiratory time (Max I time)	Range: 0.8 to 3 s Resolution: 0.1 s Default value: AUTO (minimum of 3 s or 30/monitored rate) Depends on: Min I Time, R-Rate
Minimum Fraction of Inspired Oxygen (Min FiO ₂)	Range: 18 to 90% Resolution: 1% Default value: OFF Depends on: Max FiO ₂
Maximum Fraction of Inspired Oxygen (Max FiO ₂)	Range: 30 to 100% Resolution: 1% Default value: OFF Depends on: Min FiO ₂

A.7 Environmental

The following environmental conditions shall be observed:

Table A-10. Environmental Conditions for Storage or Transport

Temperature	Humidity	Atmospheric pressure	Altitude
0°C to +50°C (+32°F to 122°F)	10% to 95% RH	500 hPa to 1060 hPa (7.2 psi to 15.4 psi)	-152 m to 3964 m (500 ft to 13 000 ft)

Table A-11. Environmental Conditions for Operation

Temperature	Humidity	Atmospheric pressure	Altitude
+5°C to 40°C (+41°F to 104°F)	10% to 95% RH	600 hPa to 1100 hPa (8.7 psi to 16.0 psi)	-152 m to 3964 m (500 ft to 13 000 ft)

Under extreme conditions of use, within the limits of a supply voltage of –20% and temperatures ranging from normal to 45°C (113°F) with ≤75% RH, the ventilator should not malfunction nor endanger the user. However, operating the device for prolonged periods or repeatedly under such extreme conditions could result in premature aging of components and more frequent maintenance.

A.8 USB

Table A-12. USB Memory Device Specifications

Characteristics	Supported formats
USB compatibility	USB flash memory USB 2.0 or USB 1.1
Memory file format	USB 32 bit format (sector size: 512 - 2048 bytes)
Number of files	Maximum 999
USB size	128 MB to 4 GB

Table A-13. Data Transfer Characteristics

Ventilator data description	Capacity
Trends capacity	86 MB
Events capacity	512 KB or 5500 events
Monitoring capacity	42 MB /48 hours

A.9 Pneumatic

Table A-14. Airway Resistances

Inspiratory	Exhalation
1.0 mbar at 30 lpm flow ± 0.1 mbar	0.5 mbar at 30 lpm ± 0.1 mbar
3.7 mbar at 60 lpm flow ± 0.1 mbar	1.1 mbar at 60 lpm ± 0.1 mbar

Table A-15. Patient Circuit Resistances¹

Adult double limb	Pediatric double limb
≤ 2 mbar at 60 lpm flow ²	≤ 2 mbar at 30 lpm flow

1. Includes exhalation valve.

2. Values obtained from the manufacturer's directions for use.

Table A-16. Air Inlet Resistance (Filter)

1.1 cmH₂O (1.079 mbar) at 30 lpm flow ± 0.1 cmH₂O

Table A-17. Oxygen Inlet Specifications

Maximum pressure	Maximum flow
50 kPa (7 psi)	15 lpm

Table A-18. Performance Specifications

Working pressure	5 mbar–55 mbar
Sound pressure level	30 dBA (per NF EN ISO 17510-1 test conditions) Does not exceed 55 dBA per EN ISO 80601-2-72 test conditions
Sound power level	Does not exceed 63 dBA per EN ISO 80601-2-72 test conditions
Maximum pressure limit	90 mbar
Internal compliance (ventilator)	0.0001 l/mbar
Inspiratory triggering response time (T_{tr})	100 ms
Average total system response time to change FiO₂ from 21% to 90% O₂	<30 s
Drift of measurement accuracy	FiO ₂ monitor will meet the accuracy requirements for at least 6 hours after the O ₂ sensor has been calibrated, and when used in accordance with the instructions for use.

A.10 Manufacturer's Declaration

Tables A-19 through A-22 contain the manufacturer's declarations for the ventilator's electromagnetic emissions and electromagnetic immunity, as well as a list of compliant cables.



WARNING:

Portable and mobile RF communications equipment can affect the performance of the V4C-560™ Ventilator. Install and use this device according to the information contained in this manual.

Interference may occur in the vicinity of equipment marked with the following symbol:



WARNING:

The ventilator should not be used adjacent to or stacked with other equipment, except as specified in this manual. If adjacent or stacked use is necessary, the ventilator should be observed to verify normal operation in the configurations in which it will be used.



WARNING:

This Equipment has been tested and found to comply with the EMC limits for IEC 60601-1-2 (EN 60601-1-2), the EMC Collateral Standard. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The Equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity or may cause degradation of the performance of this Equipment. However, there is no guarantee that interference will not occur in a particular installation.

If this Equipment does cause harmful interference with other devices, which can be determined by turning the Equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the Equipment.
- Connect the Equipment to an outlet on a circuit different from that to which the other device or devices are connected.
- Consult the manufacturer or field service technician for assistance.

Table A-19. Electromagnetic Emissions

The ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should ensure that it is used in such an environment.		
Phenomenon and standard	Compliance	Electromagnetic environment – guidance
Conducted and radiated RF emissions CISPR 11/EN 55011	Group 1 Class B	The ventilator uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The ventilator is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations and flicker IEC 61000-3-3	Complies	

Table A-20. Electromagnetic Immunity

Phenomenon	Basic EMC standard or test method	Immunity test levels for Home Healthcare environment
Electrostatic discharge	IEC/EN 61000-4-2	± 8kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transients/bursts	IEC/EN 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency
Surge	IEC/EN 61000-4-5	± 0,5 kV, ± 1 kV line-to-line ± 0,5 kV, ± 1 kV, ± 2 kV line-to-ground
Voltage dips	IEC/EN 61000-4-11	0% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC/EN 61000-4-11	0% UT; 250/300 cycle
Rated power frequency magnetic field	IEC/EN 61000-4-8	30 A/m (50/60 Hz)
NOTE: UT is the AC mains voltage prior to application of the test level.		

Table A-21. Electromagnetic Immunity—Conducted and Radiated RF

Phenomenon	Basic EMC standard or test method	Immunity test levels for Home Healthcare environment
Conducted disturbances induced by RF fields	IEC/EN 61000-4-6	3 V 0,15 MHz–80 MHz 6 V in ISM and amateur radio bands ¹ between 0,15 MHz and 80 MHz 80% AM at 1 kHz
Radiated RF EM fields	IEC/EN 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC/EN 61000-4-3	27 V/m, 18 Hz PM ² , 385 MHz 28 V/m, 18 Hz PM, 450 MHz 9 V/m, 217 Hz PM, 710 MHz 9 V/m, 217 Hz PM, 745 MHz 9 V/m, 217 Hz PM, 780 MHz 28V/m, 18 Hz PM, 810 MHz 28 V/m, 18 Hz PM, 870 MHz 28 V/m, 18 Hz PM, 930 MHz 28V/m, 217 Hz PM, 1720 MHz 28 V/m, 217 Hz PM, 1845 MHz 28 V/m, 217 Hz PM, 1970 MHz 27 V/m, 217 Hz PM, 2450 MHz 9V/m, 217 Hz PM, 5240 MHz 9 V/m, 217 Hz PM, 5500 MHz 9 V/m, 217 Hz PM, 5785 MHz

1. The ISM (industrial, scientific, and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz; 3,5 MHz to 4,0 MHz; 5,3 MHz to 5,4 MHz; 7 to 7,3 MHz; 10,1 MHz to 10,15 MHz; 14 MHz to 14,2 MHz; 18,07 MHz to 18,17 MHz; 21,0 MHz to 21,4 MHz; 24,89 MHz to 24,99 MHz; 28,0 MHz to 29,7 MHz; and 50,0 MHz to 54,0 MHz.
2. PM is the Pulse Modulation.

Table A-22. Compliant Cables and Accessories

Cable or accessory	Maximum length
Canada AC power cable assembly	1.8 m (5.9 ft)
Nurse call cable	5 m (16.4 ft)
12V DC car adapter cable	5 m (16.4 ft)
Oxygen connector	n/a

A.11 Standards Compliance and IEC Classification

A.11.1 General Standards

- Medical Electrical Equipment: General Requirements for Safety IEC 60601-1
- The ventilator will be constructed to comply with the following Product classifications as detailed in Clause 5 of 60601-1:
 - Class II Equipment
 - Internally Powered Equipment
 - Type BF Applied Parts
 - IP32 with respect to access to hazardous parts and ingress of moisture
 - Not suitable for use in the presence of flammable anesthetic mixtures
 - Not suitable for sterilization
 - Suitable for continuous operation
 - Detachable power supply cable
- CAN/CSA-C22.2 No. 60601-1, Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

A.11.2 Collateral Standards

- Medical Electrical Equipment - Part 1: General Requirements for Safety -2- Collateral standard Electro-Magnetic Compatibility requirements and tests IEC 60601-1-2 and EN 60601-1-2.
- Medical Electrical Equipment - Part 1: General Requirements for Safety -2- Collateral standard: Usability IEC 60601-1-6 and EN 60601-1-6.
- General Requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-8 and EN 60601-1-8.

A.11.3 Particular Standards

- Particular requirement for basic safety and Essential performance of home healthcare environmental ventilators for ventilator-dependent patients - EN ISO 80601-2-72.
- Anesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets EN ISO 5356-1.

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B Modes of Ventilation

B.1 Overview

This chapter is a general description of the various modes of ventilation and breath types available with the V4C-560™ ventilator.



Note:

The default ventilation mode setting is P A/C; for more information, see below.

B.2 Assist/Control (A/C) Modes

When set to an Assist/Control mode, machine-initiated breaths are delivered at a clinician-set volume or pressure, inspiratory time, and rate. If the patient triggers a spontaneous breath between machine breaths, the ventilator will deliver a breath based on the volume or pressure settings and inspiratory time.

Whether initiated by the patient or the ventilator, all breaths are delivered at the same preset volume or pressure and inspiratory time.

The names of the Assist/Control modes are:

- V A/C, if the breaths are based on a volume setting
- P A/C, if the breaths are based on a pressure setting

B.3 SIMV Modes

When set to a SIMV (Synchronized Intermittent Mandatory Ventilation) Mode, machine-initiated breaths are delivered at a clinician-set volume or pressure, inspiratory time, and rate. These mandatory breaths are synchronized with patient effort. If the patient triggers a spontaneous breath between machine breaths, the ventilator will deliver a spontaneous breath, which is pressure-supported.

CPAP spontaneous breaths are not available in SIMV modes.

The names of the SIMV modes are:

- V SIMV, if mandatory breaths are based on a volume setting
- P SIMV, if mandatory breaths are based on a pressure setting

B.4 CPAP Mode

In CPAP, the ventilator maintains a constant level of pressure in the patient's airway.

B.5 PSV Mode

PSV mode maintains a constant level of pressure in the patient's airway during exhalation. In addition, the ventilator applies a clinician-set pressure (Pressure Support) to each of the patient's breaths. This has the same benefits as CPAP, with the additional benefit of assisting the patient in moving gas into his or her lungs.

C Operational Verification Checklist

The operational verification and safety checks listed in Table C-1 below should be performed to ensure the ventilator is operating properly in the following circumstances:

- Prior to using the ventilator with a patient
- Monthly while the ventilator is in use
- Following maintenance or changes in ventilator settings

If the ventilator fails any of the safety checks below, or if you cannot complete these checks, see section 3.9, [Troubleshooting](#) or call the Equipment supplier or Baylis Medical (see section 8.6, [Service Assistance](#)).



WARNING:

Provide the patient with an alternate means of ventilation before conducting these tests.



WARNING:

To reduce the risk of infection, wash your hands thoroughly before and after handling the ventilator or its accessories.

Table C-1. Operational Verification Checklist


1	Verify the proper appearance and cleanliness of the ventilator.	<input type="checkbox"/> Pass
2	Verify all of the labels and markings on the ventilator are clear and legible.	<input type="checkbox"/> Pass
3	Confirm the air inlet filter is clean and correctly installed.	<input type="checkbox"/> Pass
4	Ensure the AC power cable does not exhibit any signs of damage, such as kinks, breaks, or damaged insulation.	<input type="checkbox"/> Pass
5	Connect the AC power cable. Ensure that all power supply indicators on the front panel flash, except for the AC power supply (mains) indicator, which should remain lit.	<input type="checkbox"/> Pass
6	Push the I/O (power) switch to the I position to activate the ventilator test: Check that the two alarm indicators and the standby indicator (located close to the VENTILATOR ON/OFF  button) flash. Ensure also that the two alarm buzzers sound.	<input type="checkbox"/> Pass
7	Perform the functioning alarms tests. See Appendix E, Alarms Tests .	<input type="checkbox"/> Pass
8	Verify the alarm volume is adapted to the patient environment.	<input type="checkbox"/> Pass

Table C-1. Operational Verification Checklist

9	Verify that the preventive maintenance schedule for the ventilator is followed. See Chapter 8, Routine Maintenance .	<input type="checkbox"/> Pass
10	Ensure the patient breathing circuit is correctly attached to the ventilator, with all the necessary components, and is free from any signs of damage and leaks. If exhaled volume monitoring is required, use the double-limb circuit for exhaled tidal volume monitoring.	<input type="checkbox"/> Pass

D Unpacking and Preparation

The V4C-560™ ventilator is delivered with the items listed in Table D-1.

Table D-1. Items Included with Ventilator

Item	Quantity	Baylis Catalogue Number	Medtronic/Covidien Catalogue Number
User Manual and Clinician's manual on CD/USB	1	N/A	N/A
Air inlet filters	10	B-10028771	N/A
Exhalation blocks (one pre-installed in the ventilator)	10	B-10046803	10046803
Oxygen connector	1	B-2962799	2962799
AC power cable	1	B-2977099	2977099
FiO ₂ measurement kit	1	B-3814199	3814199
Internal Battery	1	B-V4C-560-BATT	N/A
T10 Torx Key	1	N/A	N/A



WARNING:

Users must always possess an additional circuit and valve while using the V4C-560™ ventilator.

To unpack and prepare the ventilator:

1. From the plastic bag, remove the following:
 - The ventilator and its components and accessories
2. Remove the AC ("mains") power cable and the set of fine-particle air inlet filters.
3. Inspect the ventilator and ensure that:
 - The ventilator's outer casing and the I/O (power) switch's protective cover do not have any dents or scratches, which may indicate possible damage
 - The ventilator's labels and markings are clear and legible
 - The AC power cable does not exhibit any signs of damage, such as kinks, breaks, or cuts
 - If the battery is packaged outside the ventilator, contact an authorized service representative for battery installation



WARNING:

Never use a ventilator or any components or accessories that appear to be damaged. If any signs of damage are evident, contact your Equipment supplier or Baylis Medical Technologies.

4. Clean the ventilator with a mild soap solution, if necessary (see Chapter 7, [Cleaning](#)).
5. Ensure that the air inlet filter is installed.

To set up a patient circuit, see section 4.4, [Patient Circuit](#).

E Alarms Tests

Before connecting the ventilator to the patient, perform the following tests to ensure the ventilator's alarms are working properly.



WARNING:

Do not perform ventilator alarm tests while the patient is connected to the ventilator. Provide the patient with an alternate means of ventilation before conducting these tests.



WARNING:

If the ventilator fails any alarm test or if you cannot complete these tests, see the Troubleshooting section (refer to Chapter 3, [Alarms and Troubleshooting](#)) of this manual or call your Equipment supplier or Baylis Medical Technologies (refer to section 8.6, [Service Assistance](#)).



WARNING:

The Min PIP alarm setting must be adjusted for the patient, but must also be set high enough to allow the Patient Disconnection alarm to trigger properly. Perform the low pressure test (see section E.1, [Low Pressure Test](#)) to ensure that the alarm is properly set.




WARNING:

The Max Leak alarm setting must be adjusted for the patient, but must also be set low enough to allow the High Leakage alarm to trigger properly. Perform the max leak test (see section E.2, [Max Leak Test \(Only NIV\)](#)) to ensure that the alarm is functioning properly. This alarm only applies to leak configuration (NIV).



Note:

Many ventilator functions are not accessible when the Locking key  is enabled. For additional assistance contact your clinician or Equipment representative.



Note:

Most of these tests require that an approved patient circuit be connected to the ventilator. Ensure that your patient circuit is properly connected prior to performing these tests.



Note:

These tests require that a calibrated FiO₂ sensor be connected to the ventilator. Ensure that an FiO₂ sensor is securely installed and calibrated before performing these tests.

E.1 Low Pressure Test



WARNING:

The Min PIP alarm setting must be adjusted for the patient, but must also be set high enough to allow the Patient Disconnection alarm to trigger properly. Perform the following test to ensure that the Low PIP alarm is properly set.



Note:

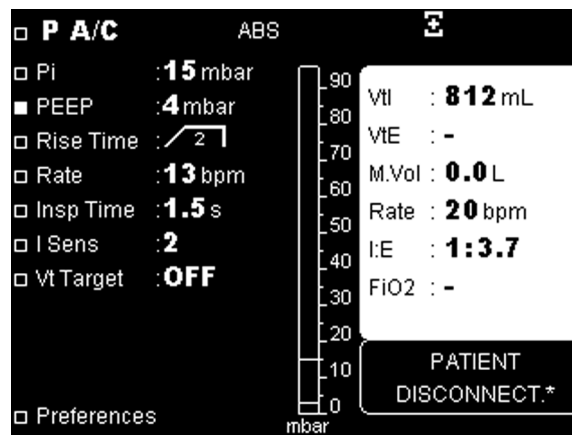
Before a low pressure test, the patient's clinician should have set ventilation and alarm parameters appropriately, and specified the circuit setup (single or dual).

To perform a low pressure test, do the following:



1. Press the VENTILATION ON/OFF key to start ventilation.
2. Keep the patient's end of the breathing circuit open and allow ventilation to continue.
3. Wait for the Apnea time setting plus 2 seconds (Apnea time is not always 5 seconds), then ensure that:
 - The high priority indicator (flashing red LED) illuminates
 - The audible alarm sounds
 - The Patient Disconnection alarm is shown

Figure E-1. Ventilator Screen (Patient Disconnection alarm shown)



VEN_12634_A



4. Press the ALARM CONTROL key once to pause the audible alarm.



5. Press and hold the VENTILATION ON/OFF key for 3 seconds, then release it. Press the VENTILATION ON/OFF key again to confirm stop.
 - The ventilator will switch to standby mode
 - Alarms are canceled

E.2 Max Leak Test (Only NIV)



WARNING:

The Max Leak alarm setting must be adjusted for the patient, but must also be set low enough to allow the High Leakage alarm to trigger properly. Perform the following test to ensure that the alarm is functioning properly. This alarm only applies to leak configuration (NIV).



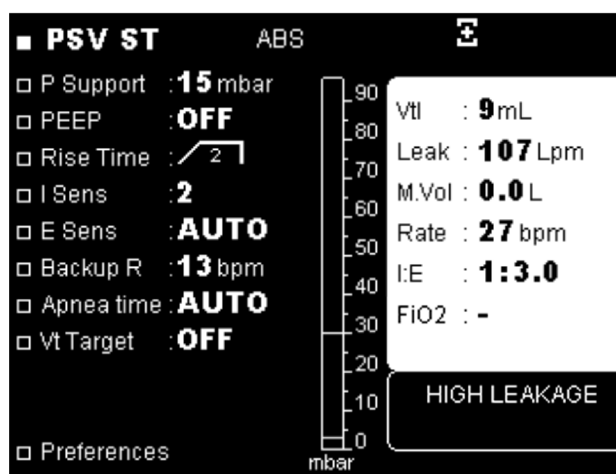
Note:

Before performing the max leak test, a clinician should set ventilation and alarm parameters appropriately.

To perform the max leak test:

1. Verify that the pressure tube of the patient circuit is properly connected to the appropriate fitting on both the ventilator and the proximal pressure port (see page 4-14).
2. Verify that the exhalation valve assembly is completely disconnected from the ventilator.
3. Press the VENTILATION ON/OFF key to start ventilation.
4. Decrease the upper Leak alarm limit to a value less than the stabilized Leak as shown on the ventilator screen.
5. Keep the patient's end of the breathing circuit open and allow ventilation to continue.
6. Allow the ventilator to deliver three consecutive breaths. At the beginning of the fourth breath, ensure that:
 - The high priority indicator (flashing red LED) illuminates
 - The audible alarm sounds
 - The High Leakage alarm is shown

Figure E-2. Ventilator Screen (High Leakage alarm shown)



**Note:**

If the ventilator detects a Patient Disconnect alarm, the ventilator will not declare a High Leakage alarm.



7. Press the ALARM CONTROL key once to pause the audible alarm.



8. Press and hold the VENTILATION ON/OFF key for 3 seconds, then release it.



9. Press the VENTILATION ON/OFF key again to confirm stop.

- Ventilation stops

E.3 Circuit Check

Perform a circuit check whenever replacing or altering a patient circuit.

Ensure the patient is fully disconnected from the ventilator prior to starting this test.

E.3.1 Accessing the Circuit Check Screen

**Note:**

Before performing a circuit check, stop ventilation using the VENTILATION ON/OFF key, **not** the I/O (power) switch. If the I/O (power) switch was used to stop ventilation, the circuit check function cannot be used unless first stopping ventilation using the VENTILATION ON/OFF key.

**Note:**

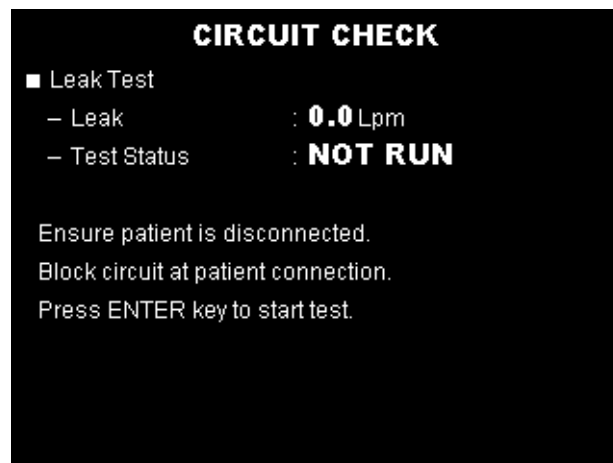
The circuit check screen cannot be accessed if the ventilator has been turned off without first being placed into standby. If unable to access the screen using this procedure, follow the normal procedure for turning the ventilator on, wait for it to enter standby mode, then follow the normal procedure for turning it off.

To access the circuit check screen:

1. Ensure that the ventilator's I/O (power) switch is set to O (off).



2. Press and hold the MENU key, while turning the I/O (power) switch to I (on). Continue to hold down the MENU key until the circuit check screen appears (approximately 3 seconds).

Figure E-3. Circuit Check Screen (before starting)

E.3.2 Performing the Circuit Check

To perform a circuit check:

1. Verify that the proximal pressure tube of the patient circuit is properly connected to the proximal pressure port (see section 4.4, [Patient Circuit](#)).
2. Verify that the exhalation valve tube is connected to the exhalation valve port.
3. Block the patient connection port or patient wye of the patient circuit (see [Figure E-4](#)).

Figure E-4. Blocking the Patient Circuit (single-limb circuit at left; double-limb circuit at right)


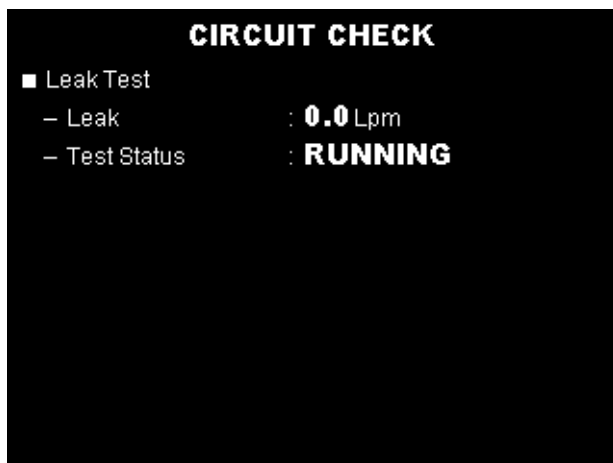
4.  Activate the circuit check by pressing the ENTER key.
5. During the circuit check (which typically takes about 10 seconds to complete), the ventilator will do the following:
 - a. Sound a short beep
 - b. Close the exhalation valve
 - c. Show Test Status as RUNNING (see [Figure E-5](#))

Figure E-5. Circuit Check (running)



- d. Increase pressure to 30 mbar ($\pm 10\%$ with no leak)
- e. Show flow sensor measurement as Leak in Lpm (updated every 2 seconds)
- f. Sound a short beep every time the flow measurement is updated
- g. Sound a long audible beep once the check is complete
- h. Show PASS (see Figure E-6) or FAIL (see Figure E-7) in the Test Status field

Figure E-6. Circuit Check (complete, passed)

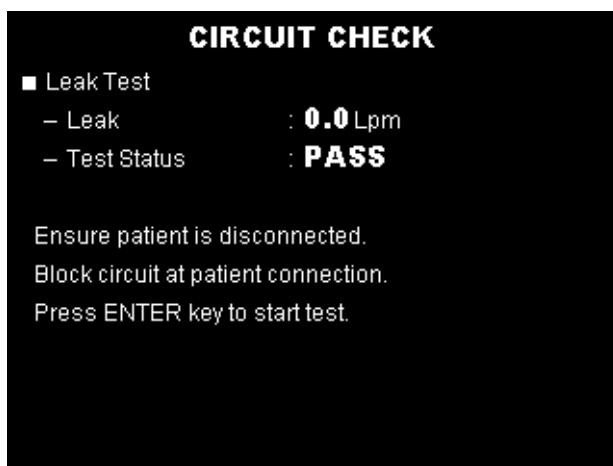
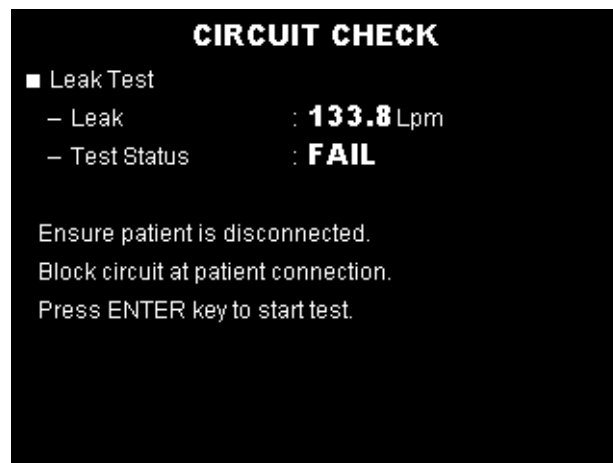


Figure E-7. Circuit Check (complete, failed)

6. Review the results. A FAIL result indicates leak(s) of greater than 1 L/min exist.

✓ To rerun the circuit check, press the ENTER key again.

To cancel the circuit check while it is running, press the UP, DOWN, ENTER, VENTILATION ON/OFF, or MENU key.

E.3.3 Troubleshooting a Failed Check

If the circuit check fails, do the following:

1. Ensure an approved circuit is in use. See [Table F-2](#).
2. Check patient circuit connections to the ventilator, examining each for leakage and tightness.
3. Replace the patient circuit if necessary.
4. Rerun the circuit check.
5. If the failure persists, have the ventilator evaluated by a qualified technician.

E.3.4 Returning to Ventilation Mode

Once the circuit check is complete, cycle ventilator power to exit the test.

To exit the circuit check screen and return to ventilation mode:

1. Set the ventilator's I/O (power) switch to O (off).
2. Wait for 30 seconds.
3. Set the ventilator's I/O (power) switch to I (on).

The ventilator will proceed through its power-on routine, as described in section [5.1, Turning on the Ventilator](#), and then will be in standby mode.

E.4 Power Failure Test



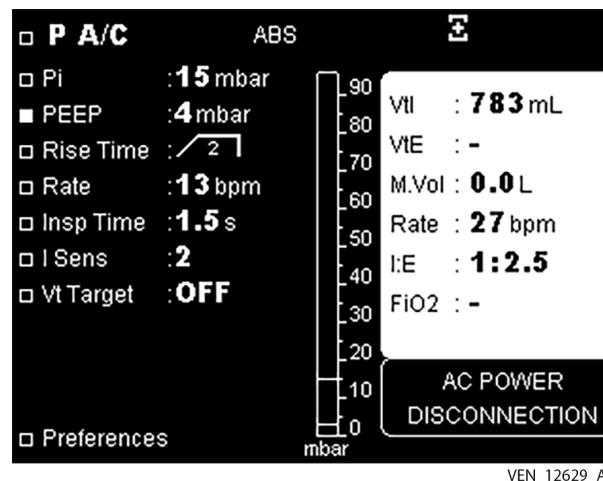
Note:

If the ventilator is operating on either the external power supply or the internal battery, you must plug it in to an AC power source before beginning this test.

To perform a power failure test:

1. Disconnect the ventilator from its AC power supply. Ensure that the following events occur:
 - The low priority indicator (continuous yellow LED) illuminates
 - An audible alarm sounds
 - The DC power indicator illuminates if the DC power source is connected; otherwise, the internal battery indicator illuminates
 - The AC Power Disconnection alarm is shown

Figure E-8. Ventilator Screen (AC Power Disconnection alarm shown)



2. Press the ALARM CONTROL key twice to reset the alarm.
3. Reconnect the ventilator to its AC power supply.

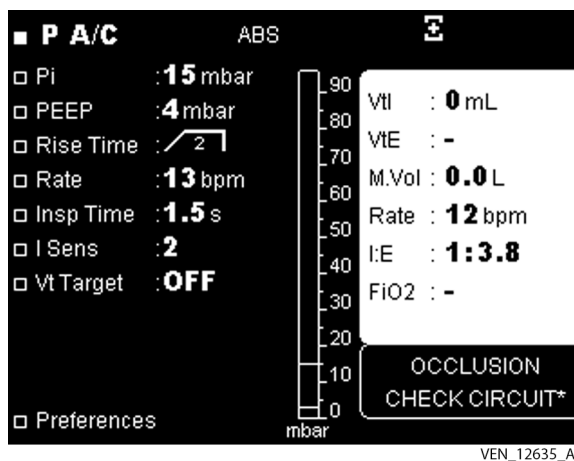
E.5 Occlusion Test

To perform an occlusion test:


1. Verify that the pressure tube of the patient circuit is properly connected to the appropriate fitting on both the ventilator and the proximal pressure port (see section 4.4, [Patient Circuit](#)).
2. Verify that the FiO2 sensor is properly connected to the proximal pressure tube (see section [Connecting the FiO2 Sensor](#), page 4-24).
3. Block the patient end or patient wye of the patient circuit. See [Figure E-9](#).

Figure E-9. Blocking the Patient Circuit (single-limb circuit at left; double-limb circuit at right)

4. Press the VENTILATION ON/OFF key to start ventilation.
5. After two breaths or after 5 seconds, whichever takes longer, ensure that the following events occur:
 - The high priority indicator (flashing red LED) illuminates
 - An audible alarm sounds
 - The Occlusion alarm is shown; the Low VTI alarm may also activate

Figure E-10. Ventilator Screen (Occlusion alarm shown)

6. Press the ALARM CONTROL key once to pause the alarm.
7. Unblock the patient end of the patient circuit, and connect the circuit to a test lung, if available. (Connect the circuit quickly to avoid unnecessary triggering of the Patient Disconnect alarm.)
 - The Occlusion alarm is canceled
 - The Patient Disconnect alarm will trigger if no test lung is available

8.  Press and hold the VENTILATION ON/OFF key for 3 seconds, then release it. Press the VENTILATION ON/OFF key again to confirm stop.
 - Ventilation stops

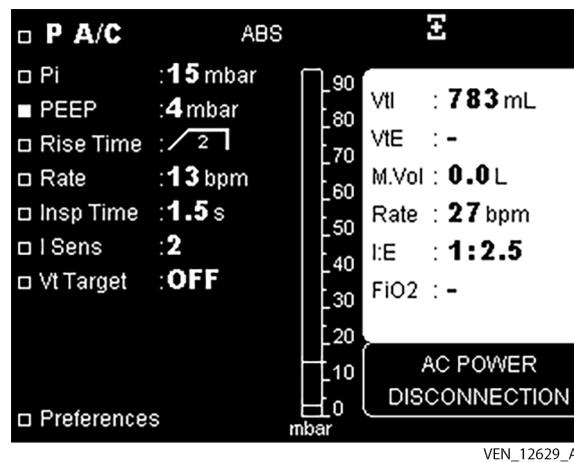
E.6 Battery Test



The ventilator is capable of testing the power of the battery (see Chapter 6, [Internal Battery](#)). You can determine which power source the ventilator is using by checking the power indicator, located on the top panel. The indicator light will be lit to indicate which power source is currently available.

To perform a battery test:

1. Disconnect the AC power supply cable (or the DC power cable, if it is connected) from the rear panel of the ventilator.
 - An AC Power Disconnection alarm will be shown

Figure E-11. Ventilator Screen (AC Power Disconnection alarm shown)



2.  Press the ALARM CONTROL key twice to reset the alarm. Ensure that the following events occur:
 - The internal battery indicator to the upper-left of the display illuminates
 - The battery symbol is shown at the top of the screen (along with its reserve capacity)
3.  Connect the AC (mains) power supply. Ensure that the following events occur:
 - The AC power indicator to the upper-left of the display illuminates
 - The internal battery indicator to the upper left of the display is flashing, which indicates that the battery is charging (this only occurs if the ventilator has run on battery power long enough to lose enough charge that the charger will turn on)
 - The battery symbol is no longer shown at the top of the screen

E.7 Involuntary Stop Test

To verify proper functioning of the very high priority audible alarm, perform the following.



1. Press the VENTILATION ON/OFF key to start ventilation.
2. Set the I/O (power) switch to the O (off) position to turn off the ventilator during ventilation. Ensure that the following events occur:
 - An audible alarm sounds continuously
 - The ventilator turns off; there should be no alarm indicators illuminated and no alarm messages shown



3. Press the ALARM CONTROL key once to cancel the audible alarm.

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F Parts and Accessories

Table F-1 provides a list of accessories that are available for the V4C-560™ ventilator. To order parts or accessories, contact your equipment supplier or Baylis Medical representative.

For a list of items delivered with the ventilator, see Appendix D, [Unpacking and Preparation](#).

Table F-1. List of Consumables and Accessories

Description	Baylis Catalogue Number	Medtronic/Covidien Catalogue Number
Oxygen connectors (pack of 10)	B-2962710	N/A
AC (mains) power cable	B-2977099	2977099
DC power cable (for connection to an external DC power source, such as a car 12 volt DC outlet)	N/A	3824600
Nurse call cable (5 meters)	N/A	3829800
Exhalation block, single-patient use (blue)	B-10046803	10046803
Air inlet filter (pack of 10)	B-10028771	N/A
Internal battery	B-V4C-560-BATT	N/A
FiO ₂ measurement kit	B-3814199	3814199
FiO ₂ sensor	B-10097559	10097559
2-way and 3-way Medtronic DAR™ valves	N/A	111P1160, 111P1161
Medtronic DAR™ inspiratory bacteria filters		
Electrostatic filter, large (formerly Barrierbac)	N/A	351U5979, 351U5878, 351U5410, 350U5865, 350U5879, 350U19006, 351U5856, or other
Electrostatic filter, small (formerly Barrierbac S)		
Electrostatic filter; small, angled port (formerly Barrierbac S Angled)		
Adult-pediatric electrostatic filter HME, large (formerly Hygrobac)		
Adult-pediatric electrostatic filter HME, small (formerly Hygrobac S)		
Adult-pediatric electrostatic filter HME, small, angled port (formerly Hygrobac S Angled)		
Infant-pediatric electrostatic filter HME, small (formerly Hygroboy)		
Adult-pediatric mechanical filter HME, large (formerly Hygroster)		
Mechanical filter, large (formerly Sterivent)		
Mechanical filter, compact (formerly Sterivent S)		
Mechanical filter, small (formerly Sterivent Mini)		

Table F-2 provides a list of consumable parts available for the ventilator.



WARNING:

To ensure proper performance of the ventilator, use a patient circuit recommended by Baylis Medical in this manual; see Chapter 4, [Installation and Assembly](#) and Appendix F, [Parts and Accessories](#). The total specified length of the patient circuit tubing as measured from the ventilator outlet to the ventilator inlet is 1.1 meters (3.6 ft) to 2.0 meters (6.6 feet). The tubing must conform to all applicable standards and must be fitted with Ø 22 mm terminals that also conform to all applicable standards. Ensure that both the length and the internal volume of the patient circuit are appropriate for the tidal volume: a corrugated tube of Ø 22 mm for adult patients, and a corrugated tube of Ø 15 mm for pediatric patients with a tidal volume lower than 200 ml.

Table F-2. List of Circuits

Description	Medtronic/Covidien Part number
Medtronic DAR™ double-limb patient circuit with exhalation valve, 180 cm, PVC, adult	5094000
Medtronic DAR™ double-limb patient circuit with exhalation valve, 180 cm, PVC, pediatric	5093900
Medtronic DAR™ single-limb patient circuit with exhalation valve, 180 cm, PVC, adult	5093600
Medtronic DAR™ single-limb patient circuit with exhalation valve, 180 cm, PVC, pediatric	5093500
Medtronic DAR™ single-limb patient circuit without exhalation valve, 180 cm, PVC, adult	5093300
Medtronic DAR™ single-limb patient circuit without exhalation valve, 180 cm, PVC, pediatric	5093100



Note:

The responsible organization is accountable for the compatibility of the ventilator and all of the parts and accessories used to connect to the patient before use.

For more information regarding parts and accessories for the V4C-560™ ventilator, contact Baylis Medical Technologies.

G Glossary

AC Power

Alternating current.



Alarm Pause

The audible and visual alarms cease and the alarm paused symbol appears. The symbol will remain until the cause of the alarm is addressed. For example, when the ventilator is running on internal battery, the AC Disconnection alarm may be paused, and the alarm paused symbol will appear until the device is plugged into AC. The paused alarm will be captured in the alarm log screen and can be reactivated.

Alarm Reset

Used only for the High Pressure alarm, this function resets the visual alarm message.

Apnea

The absence of breathing or a breathing pattern capable of supporting an individual's respiratory needs.

Apnea Index (AI)

The apnea index is the average number of apnea events per hour of ventilation. It is based on the Apnea alarm.

Apnea Time

Time allowed between breath starts before Apnea alarm occurs when no patient effort is detected.

Assist/Control

In Assist/Control mode, the ventilator delivers an assisted breath of a set volume or set pressure when the patient's breathing effort creates a flow or pressure drop that is greater than the sensitivity setting. In absence of patient breathing effort, the ventilator will deliver a controlled breath of the set volume or pressure. (Does not apply in PSV/CPAP mode).

Assisted Breath

A volume or pressure breath triggered by the patient but then controlled and terminated by the ventilator.



Audio Pause

Pauses the audible alarm for 60 seconds at a time and shows the audio paused symbol.

Back Up Rate

Rate of control cycles in PSV or SIMV modes during apnea phase.

Battery Level

Display of the remaining battery capacity; located adjacent to the battery symbol.

Bias Flow

Turbine flow during exhalation phase through the patient circuit to avoid rebreathing.

bpm

An abbreviation for “breaths per minute,” which is the unit of measure for breath rate (see below).

Breath Rate

The total number of breaths, both machine and spontaneous, delivered by a ventilator in one minute.

Caregiver

An individual who assists a patient with the tasks of daily living. This may be a family member, a live-in assistant, or the nursing staff of a health care facility.

cmH₂O

An abbreviation for “centimeters of water,” which is a unit of measure for pressure.

CPAP (Continuous Positive Airway Pressure)

Continuous airway pressure maintained throughout a spontaneous breath cycle.

Controlled Breath

A volume or pressure breath triggered, controlled and terminated by the ventilator.

DC Power

Direct current.

Double-Limb Patient Circuit

Patient circuit with a tube between the ventilator gas outlet and the patient for inspiratory gas and another tube between the patient and the exhalation block for exhalation gas.

Exhalation Block

Part of the ventilator that allows the connection of the exhalation limb of the patient circuit. The exhalation block is for single-patient use only.

Exhalation Phase

Phase of the breath cycle during which the patient exhales.

Exhalation Sensitivity

The exhalation sensitivity (E Sens) level is a percentage of peak flow at which a pressure-supported breath will be terminated.

Exhalation Tidal Volume (VTE)

Volume exhaled by the patient at each exhalation phase.

Exhaled Tidal Volume (VTE)

Exhaled volume measured for all breath types through the exhalation block. Monitored value available only with double-limb patient circuit. Exhaled volume is computed using a five-breath average.

Fraction of Inspired Oxygen (FiO₂)

Amount of oxygen delivered to the patient.

FiO₂ Sensor

The sensor that measures the amount of oxygen being delivered to the patient.

Flow

Volume of gas delivered by the ventilator compared to time, expressed in liters per minute (lpm).

Flow Pattern (Ramp Setting)

This is the flow distribution shape during the inspiration phase. There are three flow patterns available: Square waveform or constant flow, Decelerated (sawtooth waveform) or decreasing flow and Sinusoidal flow.

Freeze

Interruption of the waveform plot tracing on the ventilator's display.

hPa

An abbreviation for "hectopascal", which is a unit of measure for atmospheric pressure.

I:E Ratio

Inspiratory time versus exhalation time ratio.

Inspiratory Phase

Phase of the breath cycle during which the patient inspires.

Inspiratory Pressure (Pi)

The operator-set inspiratory pressure during a pressure control (PC) mandatory breath.

Inspiratory Sensitivity (I Sens)

Level of inspiratory effort the patient has to provide during the initiation of a machine breath. The sensitivity levels (from 0P to 5) correspond to differences in flow compared to the bias flow. Level 0P is the most sensitive (for a pediatric use) and requires the least effort to trigger a breath. Level 5 requires the most amount of effort to trigger a breath.

Inspiratory Tidal Volume (VTI)

Volume delivered to the patient at each inspiratory phase.

I Time (Inspiratory Time)

Inspiratory time measure.

Intentional Vent Stop Alarm

Ventilation has been switched off by the user/caregiver and the ventilator is in standby.

I/T Ratio

Inspiratory time versus total breath time ratio.

L

Liters (a unit of volume).

Leak

When ventilating with a double-limb circuit in leak configuration, it is the average unexpected leak during each cycle and over the past 24-hour period. When ventilating with a single-limb circuit there is no average leak.

LED

Light emitting diode; used as indicator lights on the ventilator's front panel.

lpm

Liters per minute (a unit of volume flow rate).

Machine Hours

Counter for the total ventilation time since manufacture or the last CPU board change.

Mains

AC power supply.

Max Leak

The maximum alarm setting of a high leakage threshold. An alarm will be triggered in the event the calculated leakage flow exceeds this limit.

Max Rtot (Total Breath Rate)

The maximum alarm setting to prevent hyperventilation or ventilator autotriggering. The High Rate alarm will be triggered if the total breath rate exceeds the maximum limit set.

Max P (Maximum Inspiration Pressure)

Max P allows the ventilator to adjust the inspiratory pressure up to a maximum limit in order to reach the target tidal volume (Vt Target).

mbar

An abbreviation for "millibar", which is a unit of measure for atmospheric pressure.

Mean Airway Pressure

Average patient pressure during each breath.

Minimum Exhalation Time

Minimum exhalation time before allowing the patient inspiratory trigger.

Minimum Inspiratory Time

Minimum inspiratory time before allowing the patient to exhale.

M Vol (Minute Volume)

Flow delivered at each breath to the patient is measured by the inspiratory flow sensor and that measurement is used to calculate minute volume ($V_t \times R_{tot}$).

Non-Invasive Ventilation (NIV)

Patient ventilation without the use of an endotracheal tube; instead using interfaces such as masks, nasal prongs, or uncuffed endotracheal tubes. NIV is also known as leak configuration.

P A/C (Pressure Assist/Control)

A ventilator mode which provides machine-initiated breaths delivered at a clinician-set pressure, inspiratory time, and rate.

Patient Breath

Breathing cycle initiated by the patient.

Patient Circuit

Tubing between the ventilator and the patient.

Patient Counter

Counter of ventilation time for the patient.

Patient Effort

Inspiratory effort initiated by the patient.

Pause

Waveforms freezing function.

Paw (Peak Airway Pressure)

The Peak Airway Pressure is the average peak pressure during the inspiratory phase, measured by each cycle and over the previous 24-hour period.

Peak Inspiratory Pressure (PIP)

The highest pressure measured in the patient circuit during the inspiration phase.

Positive End Expiratory Pressure (PEEP)

Pressure in the patient circuit at the end of expiration.

Pressure Control (P Control)

Augmentation of the patient's ventilation synchronously with inspiratory effort until a preset pressure is met. Pressure is maintained throughout patient inspiratory flow, and is cycled to expiration by time (controlled by the selected Inspiratory Time setting). Used in Assist/Control mode.

Pressure Support (P Support)

Augmentation of the patient's ventilation synchronously with inspiratory effort until a preset pressure is met. Pressure is maintained until inspiratory flow is reduced to a percentage of peak flow that depends on the exhalation sensitivity setting for the inspiration, when the ventilator cycles into exhalation. Available in SIMV mode.

PSI

Pounds per square inch.

PSV (Pressure Support Ventilation)

Pressure support ventilation.

Rebreathing

The patient breathes his/her exhaled gas.

Respiratory Rate

The number of breath cycles (inspiration + expiration) completed within one minute. Normal resting adult respiratory rates are from 12–20 breaths per minute (bpm).

Rise Time

This determines how the target pressure will be reached, and indirectly defines the minimum inspiration time.

Rtot

Parameter measured by the ventilator equal to the total number of breaths per minute (bpm).

Sigh

A sigh is an increased volume of gas delivered to the patient at a set rate (for example, every 50 breaths).

Spont Cyc (Spontaneous Cycling)

This is the percentage of ventilation cycles initiated by the patient over the previous 24-hour period.

Standby

The operational mode of the ventilator where it is powered (I/O (power) switch set to the I position), but is not ventilating the patient.

SIMV (Synchronized Intermittent Mandatory Ventilation)

A ventilator mode which provides a mechanism for synchronizing the ventilator-delivered breaths with a patient's inspiration, as detected by the ventilator.

Tidal Volume (Vt)

Volume of gas delivered to the patient in a breath.

Unfreeze

Resumption of the waveform plot tracing on the ventilator's display.

V A/C (Volume Assist/Control)

A ventilator mode which provides machine-initiated breaths are delivered at a clinician-set volume inspiratory time, and rate.

Vent Time (Ventilation Time)

The ventilation duration data is based on the patient counter and shows the total ventilation time in hours and minutes over the previous 24-hour period.

Volume Breath

Inspiration of the selected volume, delivered over the selected inspiratory time.

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