

Baylis Medical

V4C-O2E™ Oxygen Mixer



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Preface



WARNING:

This manual tells you how to respond to and troubleshoot issues with the V4C-O2E Oxygen Mixer, but it does NOT tell you how to respond to the patient. Always examine the patient first before examining the ventilator and Oxygen Mixer.

Purpose of This Manual

This manual contains important information regarding the safe operation of your V4C-O2E™ Oxygen Mixer. Your Oxygen Mixer is an electrical device that can provide years of useful service with the proper care, as described in this manual.

It is essential to read, understand and follow these instructions before using the V4C-O2E Oxygen Mixer. In order to use the V4C-O2E Oxygen Mixer 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.

It is essential to read, understand and follow the instructions of the compatible ventilator before using the V4C-O2E Oxygen Mixer.

Qualification of Personnel



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




Baylis Medical Technologies

2645 Matheson Blvd. East
Mississauga, Ontario
Canada
L4W 5S4
[T] +1 (905) 948-5800

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-O2E Oxygen Mixer.

In order to use the Oxygen Mixer 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.

1.2 Warnings

1.2.1 General Warnings Regarding Use of Equipment



WARNING:

Read and take account of the intended use of the V4C-O2E Oxygen Mixer before use.



WARNING:

Always read and follow all instructions and labelling of the compatible ventilator when using the V4C-O2E Oxygen Mixer. Ensure all warnings included in the manual of the compatible ventilator are read and understood prior to use with the V4C-O2E Oxygen Mixer.



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:

Never obstruct the air intake port or vents for any reason.



WARNING:

Only use the V4C-O2E Oxygen Mixer with compatible ventilators listed in Section 2.4, [Compatible Ventilators](#) and marked with an O2E port. Do not attempt to use the Oxygen Mixer with other ventilators.



WARNING:

This V4C-O2E Oxygen Mixer must be used only under the responsibility and on the prescription of a doctor.



WARNING:

Ventilator-dependent patients should always be monitored by trained and competent medical personnel. Patients should be regularly checked to ensure that the oxygen concentration settings match with the patient condition.



WARNING:

This manual tells you how to respond to and troubleshoot issues with the V4C-O2E Oxygen Mixer, but it does NOT tell you how to respond to the patient. Always examine the patient first before examining the ventilator and Oxygen Mixer.



WARNING:

Improper use of the V4C-O2E Oxygen Mixer, failure of the device, or failure to deliver oxygen can result in patient injury or death. Always follow instructions in this manual and that of the compatible ventilator, and always monitor the patient.











WARNING:

If at any time it is observed that excessive and consistent gas is exiting through the vents at the back of the Oxygen Mixer, call for maintenance.



WARNING:

If at any time a leak is suspected from or inside the V4C-O2E Oxygen Mixer, terminate use and call for maintenance. Excessive oxygen consumption may be indicative of a leak.

-  **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:**
When a ventilator 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 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.
-  **WARNING:**
Using the ventilator in battery mode while the V4C-O2E Oxygen Mixer is electrically connected, but not connected to an oxygen source can decrease the battery level of the ventilator. If the ventilator-V4C-O2E Oxygen Mixer system is being used without additional oxygen, follow instructions in Section 5.4, [Using the Compatible Ventilator Without the V4C-O2E Oxygen Mixer](#).
-  **WARNING:**
Battery capacity of the V4C-560 Ventilator may be affected by use with the V4C-O2E Oxygen Mixer and therefore values may differ from those in the manual of the compatible ventilator. Refer to the values in Section 2.9, [Battery Capacity](#) to understand battery life when using V4C-O2E Oxygen Mixer with a compatible ventilator.
-  **WARNING:**
The inspiration trigger threshold should be carefully modified in order to avoid the risk of false triggering or "autotriggering" of the ventilator. The least sensitive setting may result in autotriggering. In these scenarios, auto-triggering may be reduced by decreasing the FiO₂ level or using an inspiratory bacterial filter with a higher flow resistance. Always set an appropriate "Max Rtot" alarm limit when using inspiration triggering with the V4C-O2E Oxygen Mixer.
-  **WARNING:**
The delivered FiO₂ may be affected by a change in breath settings. When settings are adjusted or changed due to patient status, check the FiO₂ being delivered and adjust the oxygen knob as needed. See Section 5.2, [Changing FiO₂ During Ventilation Using a Compatible Ventilator](#) for instructions on how to adjust the FiO₂.
-  **WARNING:**
The V4C-O2E Oxygen Mixer must not be used with flammable anesthetic substances.



WARNING:

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



WARNING:

While the V4C-O2E Oxygen Mixer-Ventilator system is in use, an alternative means of ventilation should always be available in the event of a problem with the Oxygen Mixer. This is particularly true for ventilator-dependent patients. Supplementary observation, appropriate for the patient's condition, is also recommended.

1.2.2 Warnings Regarding Installation and Accessories



WARNING:

Always perform recommended tests of the compatible ventilator per its manual and the recommended V4C-O2E Oxygen Mixer tests in Section 9.2, [Functional Tests](#) prior to connecting a patient.



WARNING:

Never perform tests that could disrupt ventilation while the patient is being ventilated. Always provide an alternate means of ventilation where applicable.



WARNING:

Before starting ventilation, ensure that the device is properly assembled and confirm that the Oxygen Mixer's air intake port and vents are not obstructed.



WARNING:

Do not use unauthorized accessories with the V4C-O2E Oxygen Mixer system. Use of incorrect accessories can lead to malfunction or damage to the device.











WARNING:

Do not use V4C-O2E Oxygen Mixer with ventilators that are missing rubber feet. If a ventilator is missing any of its rubber feet, see instructions in Section 4.1, [Installation and Assembly](#) on how to install replacement feet which are supplied with the V4C-O2E Oxygen Mixer. Similarly, do not use V4C-O2E Oxygen Mixer if its rubber feet are missing.



WARNING:

Do not place anything in the space between the bottom of the ventilator and the top of the V4C-O2E Oxygen Mixer. Cooling vents located in this space may become compromised.

-  **WARNING:**
Do not use the V4C-O2E Oxygen Mixer if it is not appropriately affixed to the ventilator. See Section 4.1, [Installation and Assembly](#) for instructions on how to securely attach the V4C-O2E Oxygen Mixer to the ventilator.
-  **WARNING:**
Ensure that the patient is not positioned in a way that could lead to accidental disconnection.
-  **WARNING:**
Check that the tube connection between the V4C-O2E Oxygen Mixer and ventilator is well connected and not pinched before beginning ventilation. Take care when connecting the gas connection tubing, not to pinch or compromise its patency.
-  **WARNING:**
If any of the assembly steps in Section 4.1, [Installation and Assembly](#) cannot be completed do not use the V4C-O2E Oxygen Mixer. Contact your customer service representative.
-  **WARNING:**
Never use the V4C-O2E Oxygen Mixer or components that appear to be damaged or faulty. Contact [Baylis Medical Technologies](#) if the cause of a problem cannot be determined.
-  **WARNING:**
Verify the functionality of the alarms on the compatible ventilator before connecting the patient to the ventilator. See the manual of the compatible ventilator and the instructions in Section 9.2, [Functional Tests](#).
-  **WARNING:**
Before starting ventilation, ensure that the V4C-O2E Oxygen Mixer and compatible ventilator are properly assembled and that the system's air intake filter and cooling vents are not obstructed. Refer to Section 2.6, [Device Features](#) for the locations of these features. Also ensure 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:**
When disconnecting the oxygen supply hose, or at any other time, do not disconnect the oxygen mixer's Oxygen Inlet Module (See Section 2.7, [Specifications](#)) or the fittings that accompany it. These are critical components which assure the safe use of the oxygen mixer and must remain on the device at all times, including storage. For safe disassembly see instructions in Section 4.2, [Disassembly](#).

1.2.3 FiO₂ Readings and Calibration

**WARNING:**

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:**

If using the V4C-560 FiO₂ kit, changes in the ventilator's settings or mode may affect the calibration of the sensor. For the most accurate FiO₂ readings, recalibrate the sensor after any significant changes to the ventilator settings. If recalibrating follow the directions in Section 5.1, [FiO₂ Sensor Calibration](#).

**WARNING:**

If using the V4C-560 FiO₂ kit, the FiO₂ sensor may drift out of calibration as the ventilator initially warms; therefore, a two-step calibration is recommended whereby the sensor is first calibrated cold and then re-calibrated once it has warmed. See Sections 5.1, [FiO₂ Sensor Calibration](#) and 5.2, [Changing FiO₂ During Ventilation Using a Compatible Ventilator](#) for further instructions.

**WARNING:**

When setting FIO₂ do not overturn the oxygen knob. Stop once resistance is felt. See Figure 2-1 for location of knob.

1.2.4 Warnings Regarding Environmental Conditions

**WARNING:**

Read and take account of the environmental condition ranges for proper operation before using the V4C-O2E Oxygen Mixer.


**WARNING:**


Do not use the V4C-O2E Oxygen Mixer at an atmospheric pressure or temperature outside of the range stated in Section 2.7, [Specifications](#). Using the Oxygen Mixer outside of the specified temperature or atmospheric pressure range can affect the Oxygen Mixer performance and can result in patient injury or death.

**WARNING:**


Do not cover the V4C-O2E Oxygen Mixer or place it in a position that affects proper operation, including close to a heat source, on an uneven surface, or on a bed.


 **WARNING:**
Do not expose the V4C-O2E Oxygen Mixer to direct sunlight for prolonged periods of time.


 **WARNING:**
Avoid using the V4C-O2E Oxygen Mixer, if possible, in dusty environments. Dusty environments may require more vigilant monitoring, cleaning, and/or replacement of air intake filter and other filters.


 **WARNING:**
Wait for the device temperature to stabilize before using it after a transport or storage period.

1.2.5 Warnings Regarding Oxygen Supply

 **WARNING:**
The hose connecting the V4C-O2E Oxygen Mixer to the oxygen source is 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 gas connection is medical-grade oxygen. Never use a gas other than oxygen with the V4C-O2E Oxygen Mixer.

 **WARNING:**
Ensure the oxygen supply delivers a pressure and flow rate within the ranges stated in Section 2.7, [Specifications](#). Providing oxygen outside of the specified range may affect the breath delivered to the patient. Never exceed the maximum pressure specified.

 **WARNING:**
To avoid injury to the patient and/or possible damage to the V4C-O2E Oxygen Mixer: before using the V4C-O2E Oxygen Mixer, use appropriate equipment to regulate the oxygen supply to specifications before connecting the V4C-O2E Oxygen Mixer to the oxygen supply.

 **WARNING:**
Ensure sufficient supply of oxygen is available for the duration of ventilation.

 **WARNING:**
If the oxygen supplied to the V4C-O2E Oxygen Mixer is less than 100% O₂ the maximum FiO₂ delivery will be decreased.

 **WARNING:**
Turn off or disconnect oxygen supply when the V4C-O2E Oxygen Mixer is not in use.



WARNING:

Turn off oxygen supply if abnormal behavior of the device is observed and provide the patient with an alternative means of ventilation.



WARNING:

Oxygen flow to the ventilation system will begin automatically when an active breathing mode is selected. The V4C-O2E Oxygen Mixer will terminate oxygen flow when the ventilator is not in an active breathing mode.



WARNING:

In the event of power loss to the ventilator, oxygen delivery to the Oxygen Mixer will cease immediately. Safety valves on the V4C-O2E Oxygen Mixer ensure that room air is always available to the ventilator in all fault conditions, including in an oxygen loss scenario.



WARNING:

Never use the V4C-O2E Oxygen Mixer and the low pressure oxygen port of the compatible ventilator simultaneously. Only one source of oxygen can be delivered to the ventilator during use.



WARNING:

Do not connect high pressure oxygen directly to the ventilator. Always follow the instructions on the compatible ventilator when using its low flow oxygen port to deliver oxygen.



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 electrical connecting cable between the V4C-O2E Oxygen Mixer and the compatible ventilator delivers power to the Oxygen Mixer. It will automatically begin oxygen delivery when the ventilator enters an active ventilation state. Disconnecting this cable will cease power and oxygen delivery to the V4C-O2E Oxygen Mixer.

1.2.6 Warnings Regarding Alarms and Troubleshooting







WARNING:

Never use the V4C-O2E Oxygen Mixer without an appropriate FiO₂ monitor. Always ensure that the sensor has been properly calibrated before use. See Section 5.1, [FiO₂ Sensor Calibration](#) for calibration instructions.

-  **WARNING:**
Never use the V4C-O2E Oxygen Mixer without appropriately setting both high and low FiO₂ alarms on the compatible ventilator or FiO₂ monitor.
-  **WARNING:**
Never use the V4C-O2E Oxygen Mixer without appropriately setting both high and low pressure/ volume alarms on the compatible ventilator.
-  **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 ability for monitoring the patient and alerting the clinician to situations that may require intervention.
-  **WARNING:**
Do not attempt to open, repair or otherwise service the V4C-O2E Oxygen Mixer 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 V4C-O2E Oxygen Mixer.

1.2.7 Warnings on Storage and Maintenance

-  **WARNING:**
It is recommended to store the V4C-O2E Oxygen Mixer attached to the compatible ventilator and with the air connection tubing attached (this is to prevent dust from entering the gas pathway). If the V4C-O2E Oxygen Mixer is stored without the ventilator, it is recommended that it be stored in a bag or a box (preferably its original packaging) to ensure no dust or debris enter and contaminate the mixer.
-  **WARNING:**
To ensure proper performance of the Oxygen Mixer, the preventative maintenance schedule should be followed, per Section 7, [Routine Maintenance](#). For further information contact Baylis Medical Technologies. Failure to do so can result in malfunctioning or the device, which may result in patient injury.
-  **WARNING:**
Never use cleaners inside of the gas pathways. Always follow cleaning instructions indicated in Section 6, [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 V4C-O2E Oxygen Mixer 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 is required when using the Oxygen Mixer. To reduce the risk of infection, wash your hands thoroughly before and after handling the Oxygen Mixer.



WARNING:

Use all cleaning solutions and products with caution. Read and follow the instructions associated with the cleaning solutions you use to clean your Oxygen Mixer. Use only those solutions listed in Table 6-1.



WARNING:

The Oxygen Mixer should never be immersed in any liquid, and any liquid on the surface of the device should be wiped away immediately. To avoid damage to the Oxygen Mixer, in particular the electrical components, fluids must not be allowed to enter the device, particularly through the Oxygen Mixer's air intake filter or the cooling/venting apertures located on the rear and bottom panels of the Oxygen Mixer.

1.2.8 Warnings Regarding Filters



WARNING:

Do not use the V4C-O2E Oxygen Mixer without an inspiratory bacterial filter between the ventilator's outlet and the patient. Doing so can cause cross-contamination of the V4C-O2E Oxygen Mixer or delivery of contaminants to the patient.



WARNING:

Check the condition of the V4C-O2E Oxygen Mixer's air intake filter once a month when used indoors. If the V4C-O2E Oxygen Mixer is used outdoors or in a dusty environment, the Oxygen Mixer's air intake filter should be checked weekly and replaced as necessary. Do not wash or wet the filter as this may compromise its filtration or resistance.



WARNING:

If the Oxygen Mixer's air intake filter appears visibly soiled, replace it even if the recommended maintenance period has not yet elapsed.



WARNING:

Never use the device without an air intake filter installed. Always use the approved filters. Use of an incorrect filter may impact breath delivery. See Section 2.7, [Specifications](#) for filter specifications and Section 4.1, [Installation and Assembly](#) for installation instructions.



WARNING:

Do not use the V4C-O2E Oxygen Mixer with filters whose flow resistance is greater than allowable. Doing so may increase circuit resistance and compromise spontaneous breathing. For information on allowable filter resistances see Section 2.7, [Specifications](#).



WARNING:

Always ensure that any filters are removed from the back of the ventilator before connecting the gas connection tube of the Oxygen Mixer. Using the V4C-O2E Oxygen Mixer with the ventilator's air intake filter in place at the back of the ventilator could impact flow resistance of the system.

1.3 Symbols and Labels

Various labels or specific markings are affixed to the V4C-O2E Oxygen Mixer that describe precautions to be taken for the correct use and to contribute to the traceability of the Product. See Table 1-1 for illustrations of these labels and markings and Table 1-2 for their locations on the V4C-O2E Oxygen Mixer. Use the item numbers in Table 1-2 to locate the labels in Figure 1-1, Figure 1-2, and Figure 1-3.

Table 1-1. V4C-O2E Oxygen Mixer symbols

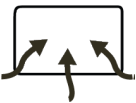






Symbol	Description
	Air intake; do not obstruct. This label appears on the Oxygen Mixer's air intake.
	Air exhaust, do not obstruct.
	It is essential to read, understand, and follow these instructions before using the V4C-O2E Oxygen Mixer (ISO 7000-0434A). This symbol appears on the V4C-O2E Oxygen Mixer's back panel.
	It is mandatory to read, understand, and follow these instructions before using the V4C-O2E Oxygen Mixer. This symbol appears on the Oxygen Mixer's back panel.
	Manufacturer.
	Date of manufacture.
	Serial number.

Table 1-1. V4C-O2E Oxygen Mixer symbols (Continued)



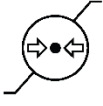









Symbol	Description
	Humidity range. See Section 2.7, Specifications for specifications.
	Temperature limitations. See Section 2.7, Specifications for specifications.
	Atmospheric pressure limitations. See section 2.7, Specifications for specifications.
	Catalogue number.
	Index of Protection rating for the V4C-O2E Oxygen Mixer's enclosure, defined in IEC 60529. This symbol appears on the V4C-O2E Oxygen Mixer's back panel.
	O2E port. This symbol appears on the V4C-O2E Oxygen Mixer's back panel.
	O ₂ inlet. This symbol appears on the V4C-O2E Oxygen Mixer's back panel.
	Keep dry.
	Fragile.
	This side up.
	Stacking limitation. 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. For the V4C-O2E Oxygen Mixer, n=2.
	TÜV SÜD certification marking. This symbol appears on the V4C-O2E Oxygen Mixer's side panel.

Table 1-2. V4C-O2E Oxygen Mixer labels and markings


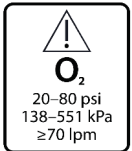
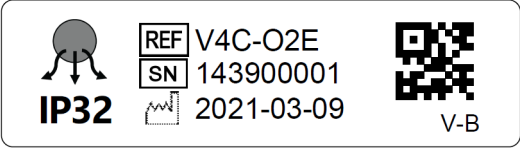



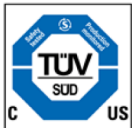
Label or Marking	Description
	<p>1. Do not obstruct label.</p>
	<p>2. O₂ pressure info label.</p>
	<p>3. General info label.</p>
	<p>4. O₂E port marking.</p>
	<p>5. O₂ inlet marking.</p>
	<p>6. Baylis address label.</p>
	<p>7. TÜV SÜD certification marking label.</p>

Figure 1-1. Location of labels — rear view

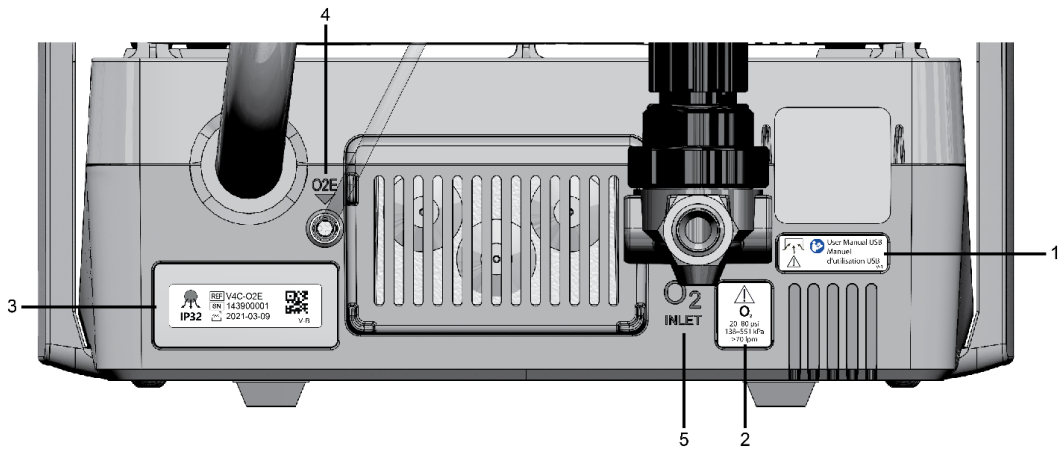


Figure 1-2. Location of labels — bottom view

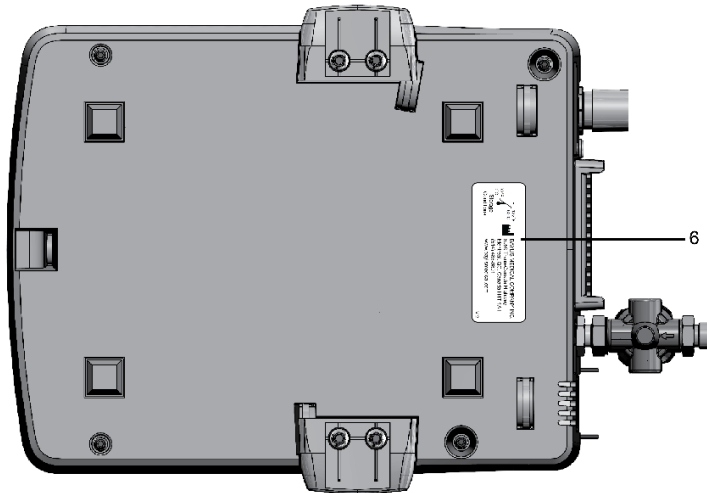


Figure 1-3. Location of labels — side view



2 Overview



WARNING:

Always read and follow all instructions and labelling of the compatible ventilator when using the V4C-O2E Oxygen Mixer. Ensure all warnings included in the manual of the compatible ventilator are read and understood prior to use with the V4C-O2E Oxygen Mixer.



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:

Only use the V4C-O2E Oxygen Mixer with compatible ventilators listed in Section 2.4, [Compatible Ventilators](#) and marked with an O2E port. Do not attempt to use the Oxygen Mixer with other ventilators.



WARNING:

This V4C-O2E Oxygen Mixer must be used only under the responsibility and on the prescription of a doctor.



WARNING:

Ventilator-dependent patients should always be monitored by trained and competent medical personnel. Patients should be regularly checked to ensure that the oxygen concentration settings match with the patient condition.



WARNING:

This manual tells you how to respond to and troubleshoot issues with the V4C-O2E Oxygen Mixer, but it does NOT tell you how to respond to the patient. Always examine the patient first before examining the ventilator and Oxygen Mixer.



WARNING:

Improper use of the V4C-O2E Oxygen Mixer, failure of the device, or failure to deliver oxygen can result in patient injury or death. Always follow instructions in this manual and that of the compatible ventilator, and always monitor the patient.



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



WARNING:

Do not expose the V4C-O2E Oxygen Mixer to direct sunlight for prolonged periods of time.



WARNING:

Avoid using the V4C-O2E Oxygen Mixer, if possible, in dusty environments. Dusty environments may require more vigilant monitoring, cleaning, and/or replacement of air intake filter and other filters.

2.1 Indications for Use



WARNING:

Read and take account of the intended use of the V4C-O2E Oxygen Mixer before use.

The V4C-O2E Oxygen Mixer is indicated for use with compatible ventilators to increase the oxygen concentration of gas delivered during continuous or intermittent mechanical ventilatory support of patients who require mechanical ventilation.

The V4C-O2E Oxygen Mixer is 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-O2E Oxygen Mixer.

2.1.1 Target Patients

The V4C-O2E Oxygen Mixer supports all breathing modes stated in the V4C-560 Ventilator Clinician's Manual. This Oxygen Mixer is intended for use in all patient groups stated in the manual of the compatible ventilator, including adult and pediatric.

2.1.2 Target Environments



WARNING:

Wait for the device temperature to stabilize before using it after a transport or storage period.

**WARNING:**

It is recommended to store the V4C-O2E Oxygen Mixer attached to the compatible ventilator and with the air connection tubing attached (this is to prevent dust from entering the gas pathway). If the V4C-O2E Oxygen Mixer is stored without the ventilator, it is recommended that it be stored in a bag or a box (preferably its original packaging) to ensure no dust or debris enter and contaminate the Oxygen Mixer.

The V4C-O2E Oxygen Mixer is suitable for use in institutional and home settings, where applicable to the compatible ventilator. It is not intended for use in emergency transport ventilation.

2.1.3 Target Operators

The ventilator may be operated by:

- Respiratory therapists
- Doctors
- Nurses
- Homecare providers
- Patient and patient's families

2.2 Contraindications

The V4C-O2E Oxygen Mixer is not for use with anesthetic gases, and is not intended for use during emergency transport.

2.3 Operational Use

The V4C-O2E Oxygen Mixer can be used with compatible ventilators to expand the range of oxygen concentrations which can be delivered to the patient up to 100%.

The mixer accepts oxygen from a standard gas pipeline system or oxygen tank and mixes it with room air to the concentration set by the user.

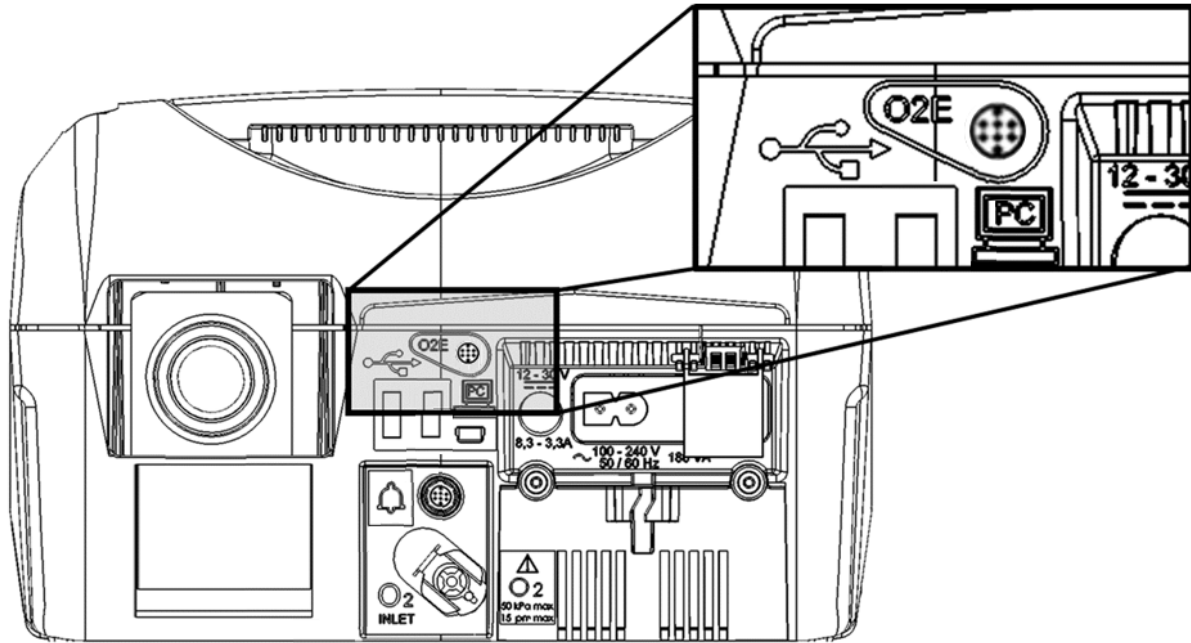
The V4C-O2E Oxygen Mixer requires an external FiO₂ monitor or one integrated into the compatible ventilator.

2.4 Compatible Ventilators

The V4C-O2E Oxygen Mixer is compatible with the following ventilator models:

- **Baylis Medical V4C-560™ Ventilator** with an O2E port as shown in Figure 4-1.

Figure 2-1. O2E port on the V4C-560 Ventilator



2.5 Operating Parameters

When used with the V4C-560 Ventilator, the compatible ventilator can deliver 21-100% FiO₂ air-oxygen mixtures.

Table 2-1. FiO₂ specifications

FiO ₂ range*	21-100%
Response time to change in FiO ₂ setting from 21% to 90% O ₂ (measured at the patient wye).	<30 s

* Patient lung pathology and the ventilator settings selected affect the maximum achievable FiO₂. Some use cases will result in a maximum achievable FiO₂ <100%. If the desired FiO₂ cannot be reached, switching to a volume control mode, using a double limb circuit, reducing the driving pressure, or decreasing the breathing rate may increase the FiO₂ delivered. If a patient requires no less than 100% FiO₂ in these use cases, consider alternate means of ventilation.

2.6 Device Features

Figure 2-2. V4C-O2E Oxygen Mixer features on the front and back panels

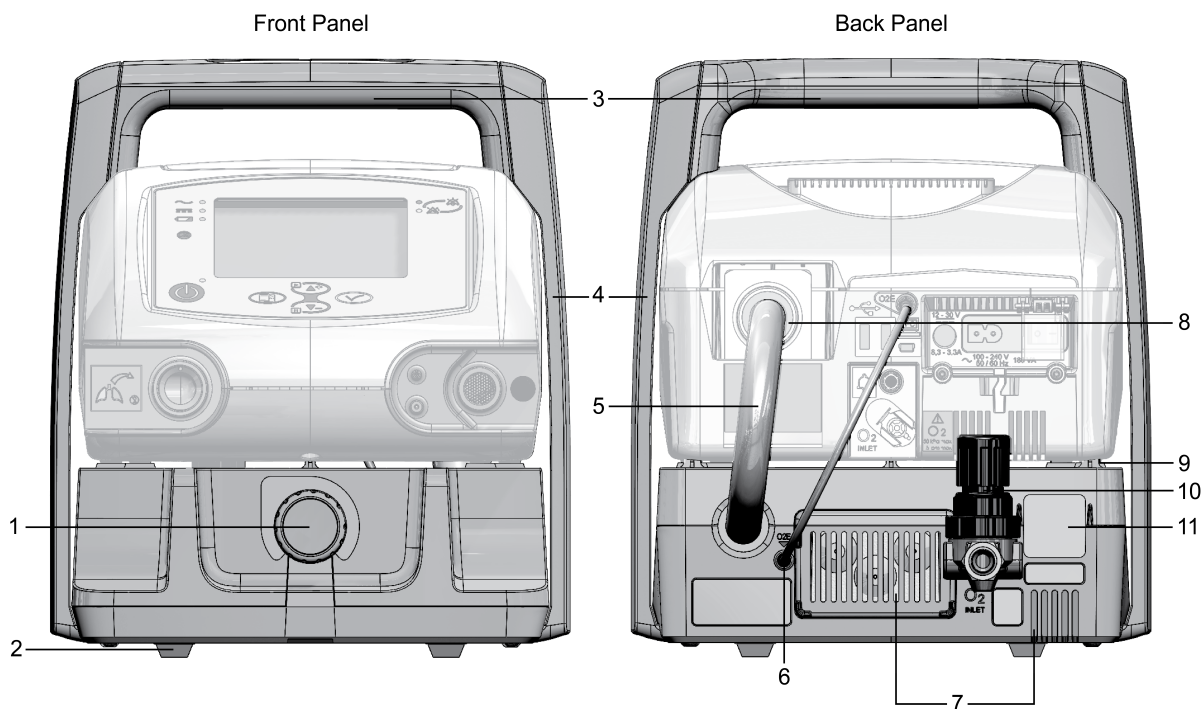


Table 2-2. Figure 2-2 legend

Call-out Number	Feature	Description
1	FiO ₂ adjustment knob	Used in conjunction with an external FiO ₂ monitor to adjust the delivered oxygen concentration.
2	V4C-O2E Oxygen Mixer adhesive feet	Features which ensure the Oxygen Mixer is elevated from the surface it's on and prevents blocking of the vents on the underside of the device.
3	Handle	Used for carrying the Oxygen Mixer - Ventilator system.
4	Side arms	Secures the ventilator to the Oxygen Mixer.
5	Gas connection tubing	Delivers gas from the Oxygen Mixer to the compatible ventilator.
6	Electrical connecting cable port	Used to connect the Oxygen Mixer to the ventilator, providing power and relevant signals.
7	Vents	Allow air and cooling to move in and out of the enclosure.
8	Gas connection tube adapter	Male-male conical adapter allows the Oxygen Mixer tubing to connect to the ventilator's air intake.
9	V4C-560 Ventilator adhesive feet	Features which ensure the ventilator is elevated from the surface it is on (including the Oxygen Mixer) and prevents blocking of the vents on the underside of the ventilator.

Table 2-2. Figure 2-2 legend

Call-out Number	Feature	Description
10	Oxygen inlet module	Connection point to oxygen hose.
11	Air intake and air intake filter	Location where air is drawn into the system. Filters air as it enters the Oxygen Mixer.

2.7 Specifications

Table 2-3. V4C-O2E Oxygen Mixer specifications

Parameter	Value
V4C-O2E Oxygen Mixer weight	2.75 kg (6 lbs)
V4C-O2E Oxygen Mixer dimensions	383 x 264 x 309 mm
Connectors	Gas connection tubing: male 22 mm (OD) conical Oxygen inlet connection: Male CGA DISS-type body, No. 1240 connector
Inspiratory bacteria filter requirements	See the list of acceptable inspiratory filters in the manual of the compatible ventilator. Maximum allowable flow resistance when using the Oxygen Mixer: Adult: 2.9 cmH2O at 60 lpm Pediatric: 3.0 cmH2O at 30 lpm
V4C-O2E Oxygen Mixer air intake filter	See Baylis Medical V4C-O2E Air Intake Filter (HW01XXXXFMINT) in Section 11, Unpacking and Accessories .
Compatible ventilators	Baylis Medical V4C-560 Ventilator bearing the O2E connector on the back panel. See Section 2.4, Compatible Ventilators for more information.
Oxygen source requirement	20-80 psi (138-551 kPa) Minimum flow rate 70 lpm

2.8 Environmental and Storage Conditions



WARNING:

Read and take account of the environmental condition ranges for proper operation before using the V4C-O2E Oxygen Mixer.

**WARNING:**

Do not use the V4C-O2E Oxygen Mixer at an atmospheric pressure or temperature outside of the range stated in Section 2.7, [Specifications](#). Using the Oxygen Mixer outside of the specified temperature or atmospheric pressure range can affect the Oxygen Mixer performance and can result in patient injury or death.

The following environmental conditions shall be observed:

Table 2-4. Environmental conditions for operation

Temperature	Humidity	Atmospheric Pressure
+5°C to +25°C (+41°F to +104°F)	10 % to 90 %, non-condensing	600 hPa to 1100 hPa (8psi to 16psi)

Table 2-5. Environmental conditions for storage and shipping

Temperature	Humidity	Atmospheric Pressure
0°C to +50°C (32°F to +122°F)	10 % to 95 %, non-condensing	500 hPa to 1060 hPa (7.2psi to 15.4psi)

2.9 Battery Capacity

**WARNING:**

Using the ventilator in battery mode while the V4C-O2E Oxygen Mixer is electrically connected, but not connected to an oxygen source can decrease the battery level of the ventilator. If the ventilator-Oxygen Mixer system is being used without additional oxygen, follow instructions in Section 5.4, [Using the Compatible Ventilator Without the V4C-O2E Oxygen Mixer](#).

**WARNING:**

Battery capacity of the V4C-560 Ventilator may be affected by use with the V4C-O2E Oxygen Mixer and therefore values may differ from those in the manual of the compatible ventilator. Refer to the values in Section 2.9, [Battery Capacity](#) to understand battery life when using V4C-O2E Oxygen Mixer with a compatible V4C-560™ Ventilator.

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. Use of the V4C-O2E Oxygen Mixer may alter the reserve capacity of the compatible ventilator from those in the manual of the compatible ventilator.

With a fully charged battery at a normal room temperature of 25°C (±5°C), the V4C-560 Ventilator and V4C-O2E Oxygen Mixer system can be expected to operate on internal battery power for the average durations shown in Table 2-6.

Table 2-6. Internal battery reserve capacity

Displayed Values	Average Operating Time on Internal Battery Power*
Vt = 200 ml (±5 ml) PIP = 10 mbar (±2 mbar) Rate = 20 bpm	10 hours (-10%)
Vt = 300 ml (±5 ml) PIP = 20 mbar (±2 mbar) Rate = 15 bpm	8 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 ventilator parameters)	4.5 hours (-10%)
Vt = 800 ml (±5 ml) Rate = 20 bpm I:E = 1:2 Backlight = OFF Resistance = 5 hPa/lps Compliance = 50 ml/hPa	6.5 hours (-10%)

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

2.10 If Failure Occurs

If a problem with the Oxygen Mixer 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. Refer to Section 3, [Alarms and Troubleshooting](#). If you cannot determine the cause of a problem, contact your equipment supplier or Baylis Medical Technologies.

3 Alarms and Troubleshooting



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:

This manual tells you how to respond to and troubleshoot issues with the V4C-O2E Oxygen Mixer, but it does NOT tell you how to respond to the patient. Always examine the patient first before examining the ventilator and Oxygen Mixer.



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.



WARNING:

The inspiration trigger threshold should be carefully modified in order to avoid the risk of false triggering or “autotriggering” of the ventilator. The least sensitive setting may result in autotriggering. In these scenarios, auto-triggering may be reduced by decreasing the FiO₂ level or using an inspiratory bacterial filter with a higher flow resistance. Always set an appropriate “Max Rtot” alarm limit when using inspiration triggering with the V4C-O2E Oxygen Mixer.



WARNING:

In the event of power loss to the ventilator, oxygen delivery to the Oxygen Mixer will cease immediately. Safety valves on the V4C-O2E Oxygen Mixer ensure that room air is always available to the ventilator in all fault conditions, including in an oxygen loss scenario.



WARNING:

Never use the V4C-O2E Oxygen Mixer and the low pressure oxygen port of the compatible ventilator simultaneously. Only one source of oxygen can be delivered to the ventilator during use.



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:

Do not attempt to open, repair or otherwise service the V4C-O2E Oxygen Mixer yourself. Doing so might endanger the patient, damage the Oxygen Mixer, and/or void your warranty. Only personnel authorized and qualified by Baylis Medical Technologies should repair, open or service the V4C-O2E Oxygen Mixer.

3.1 Troubleshooting Overview

In the event of an alarm, follow troubleshooting steps of the compatible ventilator first, before attempting troubleshooting of the V4C-O2E Oxygen Mixer.

Table 3-1. V4C-O2E Oxygen Mixer troubleshooting

Alarm Message or Symptom	Possible Reason for the Event	Corrective Action
<p>Target FiO₂ cannot be reached (too low) OR Low FiO₂ alarm OR Loss of oxygen</p>	<p>Low oxygen delivery to the patient. Incorrect calibration of oxygen sensor. Accuracy of FiO₂ sensor. Air ingress in gas pathway. Incorrect gas connection(s) between Oxygen Mixer and ventilator. Incorrect electrical connection(s) between Oxygen Mixer and ventilator. Fault in oxygen supply. Ventilator fault, stall, loss of power, or overheat.</p>	<p>Wait 10 breaths for the FiO₂ to stabilize. Check the status of the ventilator. Ensure it is powered on, ventilating, and there are no active alarms. Turn the FiO₂ adjustment knob to the right and note if the FiO₂ changes. Do not attempt to turn the knob past the point where resistance is felt. If the knob is unresponsive see troubleshooting for "FiO₂ Knob unresponsive". Recalibrate the FiO₂ sensor. See calibration steps in Section 5.1, FiO₂ Sensor Calibration. Ensure the oxygen cell has not expired. Ensure the appropriate electrical connecting cable is connected. Ensure the gas connection tube and oxygen input is connected and there are no leaks. Confirm that oxygen supply is delivering 100% oxygen. Confirm the oxygen supply is delivering uninterrupted flow to the Oxygen Mixer at the appropriate pressure and flow rate (see Section 2.7, Specifications). Some combinations of breath settings and patient characteristics may result in decreased maximum achievable FiO₂. See section 2.5, Operating Parameters for further information. If fault does not clear, discontinue use of the V4C-O2E Oxygen Mixer. Contact your customer service representative for assistance.</p>

Table 3-1. V4C-O2E Oxygen Mixer troubleshooting

Alarm Message or Symptom	Possible Reason for the Event	Corrective Action
<p>Target FiO₂ cannot be reached (too high) OR High FiO₂ alarm OR FiO₂ reads >100%</p>	<p>High oxygen delivery to patient. Incorrect calibration of oxygen sensor. Accuracy of FiO₂ sensor. Incorrect connection(s) between Oxygen Mixer and ventilator (electrical or gas). Leak in gas pathway.</p>	<p>Wait 10 breaths for the FiO₂ stabilize. Turn FiO₂ adjustment knob to the left and note if the FiO₂ changes. Do not attempt to turn the knob past the point where resistance is felt. If the knob is unresponsive see troubleshooting for "FiO₂ Knob unresponsive". Recalibrate the FiO₂ sensor. See calibration steps in Section 5.1, FiO₂ Sensor Calibration. Ensure the oxygen cell has not expired. Ensure nothing is blocking the air intake port of the Oxygen Mixer. Confirm that no oxygen is being delivered to the low pressure oxygen inlet of the compatible ventilator. Delivering oxygen directly to the ventilator while using the V4C-O2E Oxygen Mixer will impact FiO₂ percentage delivered to the patient. If fault doesn't clear, discontinue use of the V4C-O2E Oxygen Mixer. Contact your customer service representative for assistance.</p>
<p>High PEEP / High Pressure</p>	<p>Internal technical fault.</p>	<p>Follow all troubleshooting steps on the compatible ventilator. Discontinue use of the V4C-O2E Oxygen Mixer and contact your customer service representative for assistance.</p>

Table 3-1. V4C-O2E Oxygen Mixer troubleshooting

Alarm Message or Symptom	Possible Reason for the Event	Corrective Action
<p>FiO₂ Knob unresponsive</p>	<p>Loose connection. Internal technical fault.</p>	<p>Inspect the V4C-O2E Oxygen Mixer for signs of damage. Discontinue use if any damage is identified and contact your customer service representative for assistance.</p> <p>Ensure the appropriate electrical connecting cable is connected to the Oxygen Mixer and the compatible ventilator.</p> <p>Ensure the gas connection tube and oxygen input is connected and there are no leaks.</p> <p>Confirm that oxygen supply is delivering 100% oxygen.</p> <p>Confirm the oxygen supply is delivering uninterrupted flow to the Oxygen Mixer at the appropriate pressure and flow rate.</p> <p>Discontinue use of the V4C-O2E Oxygen Mixer and contact your customer service representative for assistance.</p>

4 Installation and Assembly



WARNING:

Only use the V4C-O2E Oxygen Mixer with compatible ventilators listed in Section 2.4, [Compatible Ventilators](#) and marked with an "O2E" port. Do not attempt to use the Oxygen Mixer with other ventilators.



WARNING:

Do not use unauthorized accessories with the V4C-O2E Oxygen Mixer system. Use of incorrect accessories can lead to malfunction or damage to the device.



WARNING:

Do not place anything in the space between the bottom of the ventilator and the top of the V4C-O2E Oxygen Mixer. Cooling vents located in this space may become compromised.



WARNING:

Do not use the V4C-O2E Oxygen Mixer if it is not appropriately affixed to the ventilator. See Section 4.1, [Installation and Assembly](#) for instructions on how to securely attach the V4C-O2E Oxygen Mixer to the ventilator.



WARNING:

If any of the assembly steps in Section 4.1, [Installation and Assembly](#) cannot be completed do not use the V4C-O2E Oxygen Mixer. Contact your customer service representative.



WARNING:

Never use the V4C-O2E Oxygen Mixer or components that appear to be damaged or faulty. Contact Baylis Medical Technologies if the cause of a problem cannot be determined.



WARNING:

Do not connect high pressure oxygen directly to the ventilator. Always follow the instructions on the compatible ventilator when using its low flow oxygen port to deliver oxygen.

4.1 Installation and Assembly



WARNING:

The V4C-O2E Oxygen Mixer must not be used with flammable anesthetic substances.



WARNING:

Do not use V4C-O2E Oxygen Mixer with ventilators that are missing rubber feet. If a ventilator is missing any of its rubber feet, see instructions in Section 4.1, [Installation and Assembly](#) on how to install replacement feet which are supplied with the V4C-O2E Oxygen Mixer. Similarly, do not use V4C-O2E Oxygen Mixer if its rubber feet are missing.



WARNING:

Wait for the device temperature to stabilize before using it after a transport or storage period.



WARNING:

The hose connecting the V4C-O2E Oxygen Mixer to the oxygen source is 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 gas connection is medical-grade oxygen. Never use a gas other than oxygen with the V4C-O2E Oxygen Mixer.



WARNING:

Ensure the oxygen supply delivers a pressure and flow rate within the ranges stated in Section 2.7, [Specifications](#). Providing oxygen outside of the specified range may affect the breath delivered to the patient. Never exceed the maximum pressure specified.



WARNING:

To avoid injury to the patient and/or possible damage to the V4C-O2E Oxygen Mixer: before using the V4C-O2E Oxygen Mixer, use appropriate equipment to regulate the oxygen supply to specifications before connecting the V4C-O2E Oxygen Mixer to the oxygen supply.



WARNING:

Never use the V4C-O2E Oxygen Mixer and the low pressure oxygen port of the compatible ventilator simultaneously. Only one source of oxygen can be delivered to the ventilator during use.



WARNING:

Do not use the V4C-O2E Oxygen Mixer without an inspiratory bacterial filter between the ventilator's outlet and the patient. Doing so can cause cross-contamination of the V4C-O2E Oxygen Mixer or delivery of contaminants to the patient.

**WARNING:**

Never use the device without an air intake filter installed. Always use the approved filters. Use of an incorrect filter may impact breath delivery. See Section 2.7, [Specifications](#) for filter specifications and Section 4.1, [Installation and Assembly](#) for installation instructions.

**WARNING:**

Check the condition of the V4C-O2E Oxygen Mixer's air intake filter once a month when used indoors. If the V4C-O2E Oxygen Mixer is used outdoors or in a dusty environment, the Oxygen Mixer's air intake filter should be checked weekly and replaced as necessary. Do not wash or wet the filter as this may compromise its filtration or resistance.

**WARNING:**

If the Oxygen Mixer's air intake filter appears visibly soiled, replace it even if the recommended maintenance period has not yet elapsed.

**WARNING:**

Do not use the V4C-O2E Oxygen Mixer with filters whose flow resistance is greater than allowable. Doing so may increase circuit resistance and compromise spontaneous breathing. For information on allowable filter resistances see Section 2.7, [Specifications](#).

**WARNING:**

Always ensure that any filters are removed from the back of the ventilator before connecting the gas connection tube of the Oxygen Mixer. Using the V4C-O2E Oxygen Mixer with the ventilator's air intake filter in place at the back of the ventilator could impact flow resistance of the system.

To assemble the ventilator and Oxygen Mixer:

1. Refer to Figure 4-1 and Figure 4-2. Use the installation tool to attach the side arms to the V4C-O2E Oxygen Mixer enclosure with four M6 screws and four M6 washers, until fully secured.

**Note:**

Refer to Figure 4-1 and Figure 4-2. It is recommended to lay the Oxygen Mixer on its side and attach one side arm, then rotate it onto its opposite side and attach the second side arm.

Figure 4-1. Attaching the first side arm

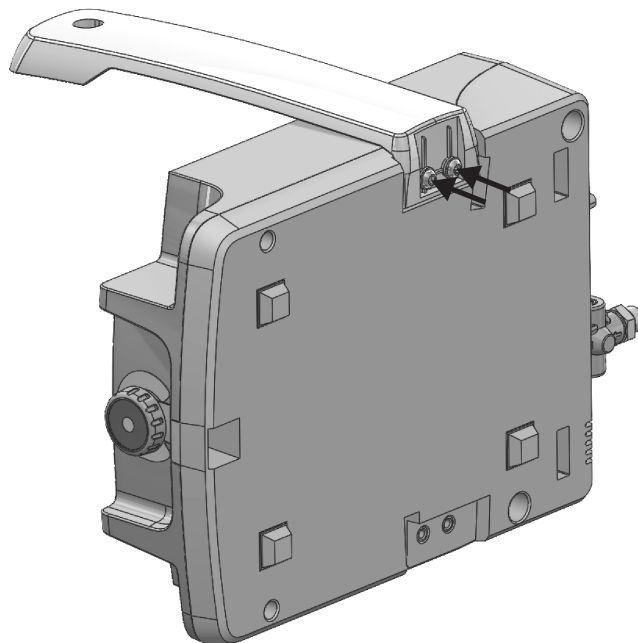
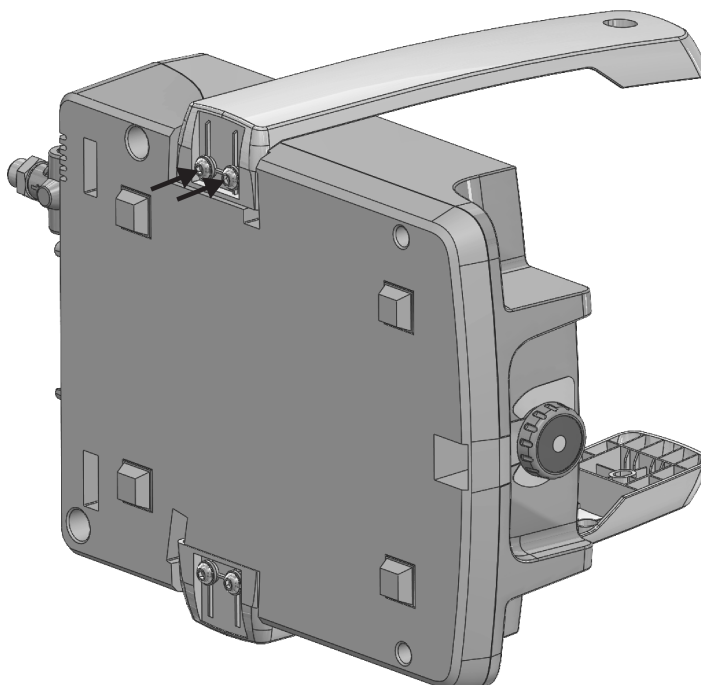


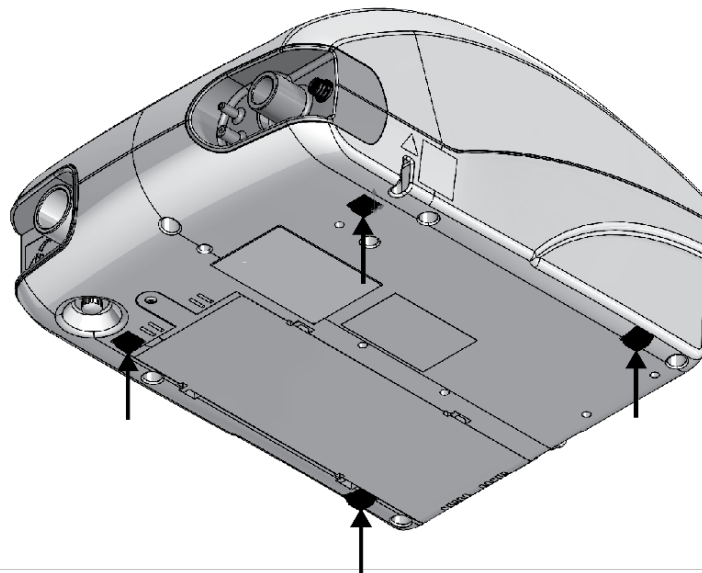
Figure 4-2. Attaching the second side arm



Caution: Never rest the Oxygen Mixer on its back face or on the oxygen inlet module. Take care when maneuvering the device not to knock the oxygen inlet module on the table or another object.

2. Refer to Figure 4-3. Confirm that the four adhesive feet on the compatible ventilator are not missing or damaged.

Figure 4-3. Compatible ventilator feet location



3. If any adhesive feet on the compatible ventilator are missing or damaged, install new adhesive feet:
 - a. If necessary, remove damaged adhesive feet.
 - b. Clean the foot recesses with alcohol wipes and allow to dry.
 - c. Remove adhesive backing and install the feet in the compatible ventilator foot recesses. Press firmly.



Caution:
Using the Oxygen Mixer with a ventilator that is missing its rubber feet could lead to damage or malfunction of the device.

4. Refer to Figure 4-4 and Figure 4-5. Bend the side arms out and lower the compatible ventilator onto the V4C-O2E Oxygen Mixer. Make sure that the posts on the V4C-O2E Oxygen Mixer are aligned with the compatible ventilator and that the ventilator's feet are positioned inside of the corresponding recesses on the Oxygen Mixer's top surface.

Figure 4-4. Location of V4C-O2E Oxygen Mixer recesses (1) and posts (2).

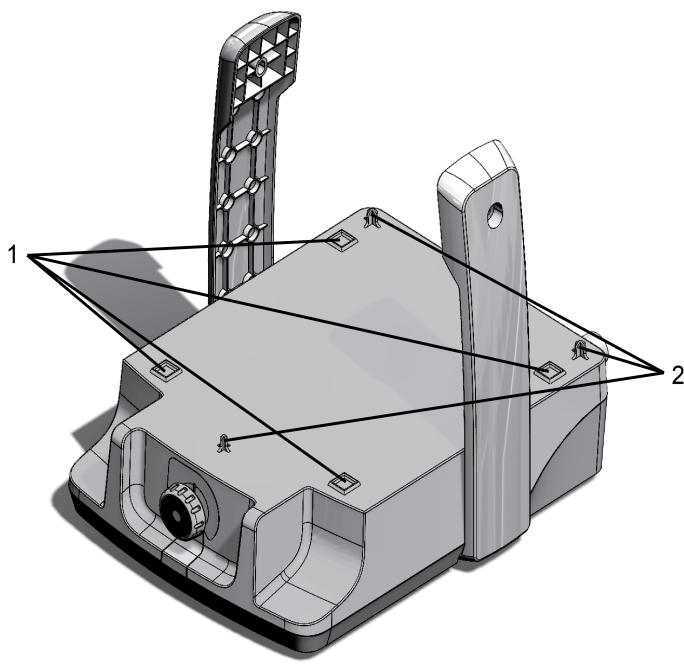
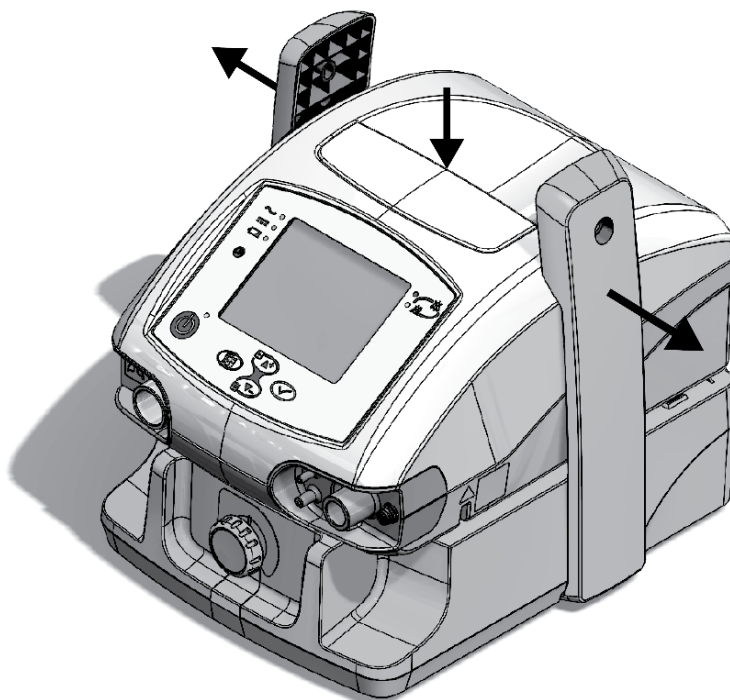
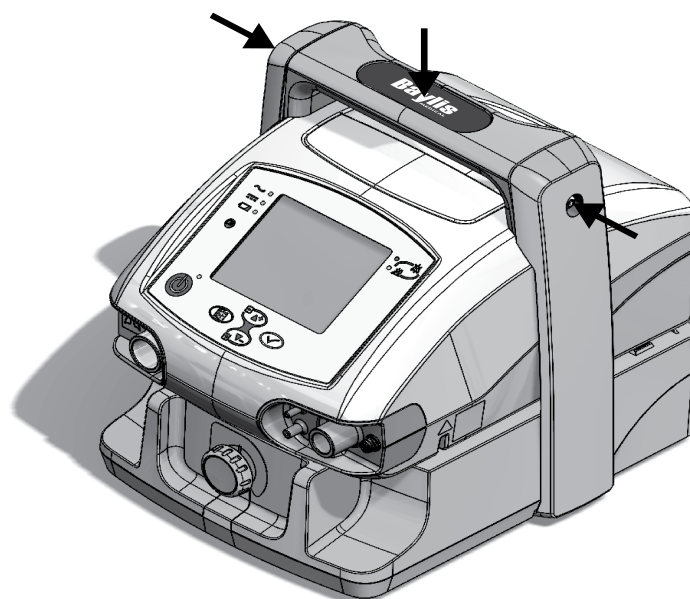


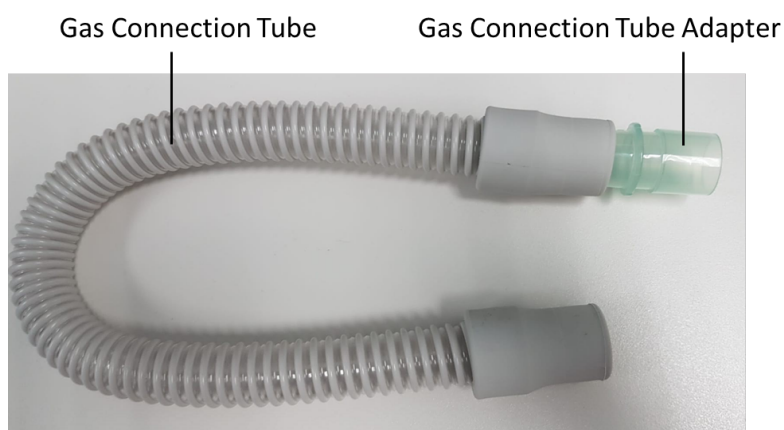
Figure 4-5. Lowering the compatible ventilator onto the V4C-O2E Oxygen Mixer



5. Refer to Figure 4-6. Lower the handle on to the side arms with the Baylis Medical logo facing the front (the straight face of the handle is facing forward). Press down firmly to secure the handle. Install 2 M6 screws and 2 M6 washers as shown. Use the installation tool to tighten both screws approximately halfway, then complete the tightening until the ventilator is secure in the Oxygen Mixer. The ventilator should not move in the side arms when carried by the handle. Do not over-tighten screws.

Figure 4-6. Installing the handle

6. Attach the gas connection tube adapter to the gas connection tube. See Figure 4-7.

Figure 4-7. Gas connection tube adapter installed on the gas connection tube

7. Refer to Figure 4-8 and Figure 4-9. Install the gas connection tube (1) to the V4C-O2E Oxygen Mixer air outlet and the gas connection tube adapter to the compatible ventilator's air inlet. Ensure it is not pinched or kinked along its length.

**Note:**

Refer to Figure 4-10. Confirm that any filter on the conical connector which protrudes from the back of the ventilator is removed.

Figure 4-8. Installing V4C-O2E Oxygen Mixer connections and air intake filter

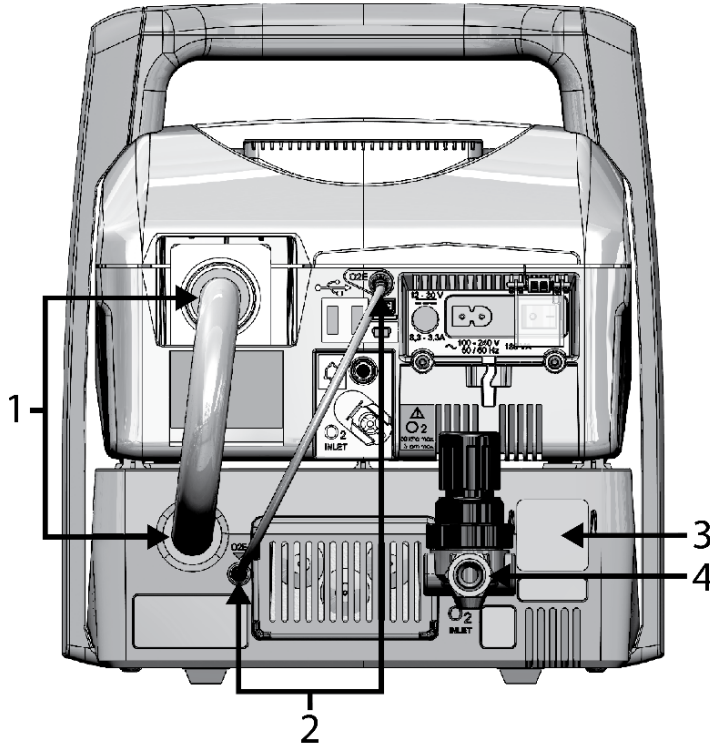


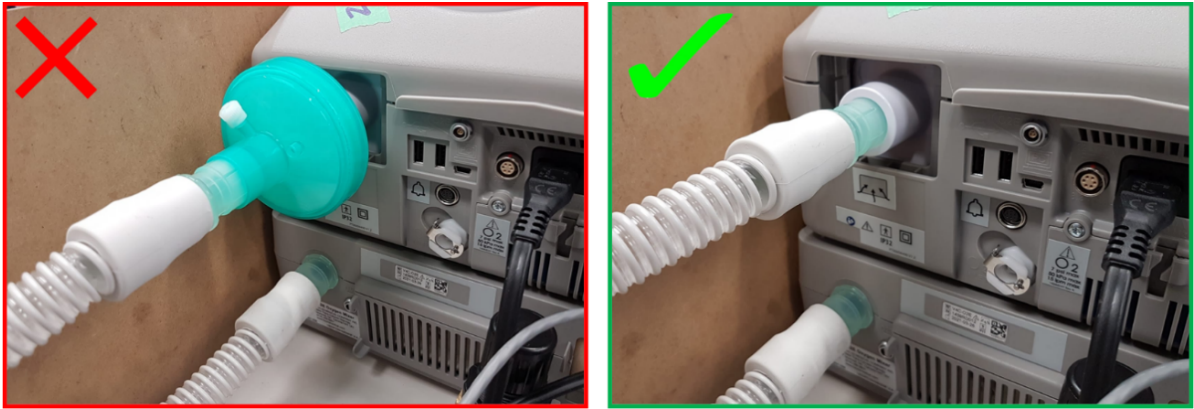
Table 4-1. Figure 4-8 legend

Call-out Number	Description
1	Gas connection tube
2	O2E electrical connecting cable
3	Air intake filter
4	Oxygen hose connection

Figure 4-9. Gas connection tube and adapter connected to the ventilator



Figure 4-10. Confirming no filter is installed on the back of the V4C-560 Ventilator



8. Refer to Figure 4-8. Install the O2E electrical connecting cable (2) from the compatible ventilator O2E port to the V4C-O2E Oxygen Mixer. Refer to Figure 4-11. When connecting the cable, line up the red marking on the cable's connector with the red marked notch on the O2E port to ensure the correct orientation.

Figure 4-11. Red markings on the electrical cable and O2E port



Caution:
Connection of the cable between the Oxygen Mixer and the ventilator begins power delivery to the V4C-O2E Oxygen Mixer automatically when the ventilator enters an active ventilation state.



Caution:
When attaching the cable to its ports, failure to line up the red markings before applying force, could lead to damage of the cable pins.



Note:
Both ends of the cable are identical and the cable can be attached in either orientation.

9. Refer to Figure 4-8. Confirm that the air intake filter (3) is installed in the V4C-O2E Oxygen Mixer.



Note:
If the air intake filter is missing, incorrectly installed, soiled, or damaged refer to Section 7, [Routine Maintenance](#) for instructions on replacing it.

10. Confirm that the low pressure oxygen port of the compatible ventilator does not have an oxygen source attached. Using the V4C-O2E Oxygen Mixer and the low-pressure oxygen port of the ventilator simultaneously could impact the ventilator's function.
11. Refer to Figure 4-8. Connect the hex nut side of the oxygen hose to the oxygen inlet, located on the oxygen inlet module (4). Connect the opposite end of the hose to the oxygen supply.

**Caution:**

The V4C-O2E Oxygen Mixer is rated for 20-80 psi (138-551 kPa) oxygen sources. Using higher or lower pressure oxygen sources can interfere with the operation of the V4C-O2E Oxygen Mixer.

**Note:**

Oxygen delivery to the V4C-O2E Oxygen Mixer is initiated automatically when the ventilator enters an active ventilation mode. Oxygen flow is terminated when the ventilator is not actively ventilating or is powered off.

**Note:**

Ensure that the oxygen hose used has the correct connector type for the oxygen supply being used. DISS connection types are common in Canada. British Standard are common in South Asia.

4.2 Disassembly

**WARNING:**

When disconnecting the oxygen supply hose, or at any other time, do not disconnect the Oxygen Mixer's oxygen inlet module (See Section 2.7, [Specifications](#)) or the fittings that accompany it. These are critical components which assure the safe use of the Oxygen Mixer and must remain on the device at all times, including storage. For safe disassembly see instructions in Section 4.2, [Disassembly](#).

**WARNING:**

It is recommended to store the V4C-O2E Oxygen Mixer attached to the compatible ventilator and with the air connection tubing attached (this is to prevent dust from entering the gas pathway). If the V4C-O2E Oxygen Mixer is stored without the ventilator, it is recommended that it be stored in a bag or a box (preferably its original packaging) to ensure no dust or debris enter and contaminate the mixer.

1. Ensure the ventilator is OFF and disconnected from the patient prior to disassembly.
2. Disconnect the oxygen hose from the oxygen supply, ensuring standard practice for the oxygen source are followed.

**Caution:**

Do not remove the oxygen inlet module or its fitting from the back of the V4C-O2E Oxygen Mixer. The oxygen inlet module must remain on the Oxygen Mixer at all times, including in storage. It should not be removed under any circumstances.

3. Disconnect the electrical connecting cable from the ventilator.



Note:

Disconnecting this cable ceases power delivery to the V4C-O2E Oxygen Mixer.

4. Disconnect the gas connection tubing and the gas tube adapter from the ventilator.



Caution:

Ensure the appropriate filter is re-installed on the back of the ventilator's air intake before initiating use of the ventilator without the V4C-O2E Oxygen Mixer. For more information on filter type and assembly consult the manual of the compatible ventilator.



Caution:

Ensure the gas tube adapter is not left on the ventilator when the Oxygen Mixer is not being used.



Note:

The compatible ventilator can be used without removing it from the Oxygen Mixer's handles. To use it in this state see Section 5.4, [Using the Compatible Ventilator Without the V4C-O2E Oxygen Mixer](#).

5. Using the installation tool, unscrew the two M6X25 bolts from the handle (bolt locations are shown in Figure 4-6). Remove the handle from the sidearms.
6. Slide the compatible ventilator up and out of the Oxygen Mixer's side-arms.

5 Operating Procedures



WARNING:

While the V4C-O2E Oxygen Mixer-Ventilator system is in use, an alternative means of ventilation should always be available in the event of a problem with the Oxygen Mixer. This is particularly true for ventilator-dependent patients. Supplementary observation, appropriate for the patient's condition, is also recommended.



WARNING:

Never obstruct the air intake port or vents for any reason.



WARNING:

Only use the V4C-O2E Oxygen Mixer with compatible ventilators listed in Section 2.4, [Compatible Ventilators](#) and marked with an "O2E" port. Do not attempt to use the Oxygen Mixer with other ventilators.



WARNING:

Ventilator-dependent patients should always be monitored by trained and competent medical personnel. Patients should be regularly checked to ensure that the oxygen concentration settings match with the patient condition.



WARNING:

If at any time it is observed that excessive and consistent gas is exiting through the vents at the back of the Oxygen Mixer, call for maintenance.




WARNING:


If at any time a leak is suspected from or inside the V4C-O2E Oxygen Mixer, terminate use and call for maintenance. Excessive oxygen consumption may be indicative of a leak.





WARNING:


The inspiration trigger threshold should be carefully modified in order to avoid the risk of false triggering or "autotriggering" of the ventilator. The least sensitive setting may result in autotriggering. In these scenarios, auto-triggering may be reduced by decreasing the FiO₂ level or using an inspiratory bacterial filter with a higher flow resistance. Always set an appropriate "Max Rtot" alarm limit when using inspiration triggering with the V4C-O2E Oxygen Mixer.


 **WARNING:**
The delivered FiO_2 may be affected by a change in breath settings. When settings are adjusted or changed due to patient status, check the FiO_2 being delivered and adjust the oxygen knob as needed. See Section 5.2, [Changing \$\text{FiO}_2\$ During Ventilation Using a Compatible Ventilator](#) for instructions on how to adjust the FiO_2 .

 **WARNING:**
To reduce the risk of infection, wash your hands thoroughly before and after handling the Oxygen Mixer or its accessories.


 **WARNING:**
Always perform recommended tests of the compatible ventilator per its manual and the recommended V4C-O2E Oxygen Mixer tests in Section 9.2, [Functional Tests](#) prior to connecting a patient.


 **WARNING:**
Before starting ventilation, ensure that the device is properly assembled and confirm that the Oxygen Mixer's air intake port and vents are not obstructed.

 **WARNING:**
Do not use unauthorized accessories with the V4C-O2E Oxygen Mixer system. Use of incorrect accessories can lead to malfunction or damage to the device.

 **WARNING:**
Do not place anything in the space between the bottom of the ventilator and the top of the V4C-O2E Oxygen Mixer. Cooling vents located in this space may become compromised.

 **WARNING:**
Ensure that the patient is not positioned in a way that could lead to accidental disconnection.

 **WARNING:**
Check that the tube connection between the V4C-O2E Oxygen Mixer and ventilator is well connected and not pinched before beginning ventilation. Take care when connecting the gas connection tubing, not to pinch or compromise its patency.

 **WARNING:**
Verify the functionality of the alarms on the compatible ventilator before connecting the patient to the ventilator. See the manual of the compatible ventilator and the instructions in Section 9.2, [Functional Tests](#).



WARNING:

Before starting ventilation, ensure that the V4C-O2E Oxygen Mixer and compatible ventilator are properly assembled and that the system's air intake filter and cooling vents are not obstructed. Refer to Section 2.6, [Device Features](#) for the locations of these features. Also ensure 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 electrical connecting cable between the V4C-O2E Oxygen Mixer and the compatible ventilator delivers power to the oxygen mixer. It will automatically begin oxygen delivery when the ventilator enters an active ventilation state. Disconnecting this cable will cease power and oxygen delivery to the V4C-O2E Oxygen Mixer.



WARNING:

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:

If using the V4C-560 FiO₂ kit, the FiO₂ sensor may drift out of calibration as the ventilator initially warms; therefore, a two-step calibration is recommended whereby the sensor is first calibrated cold and then re-calibrated once it has warmed. See Sections 5.1, [FiO₂ Sensor Calibration](#) and 5.2, [Changing FiO₂ During Ventilation Using a Compatible Ventilator](#) for further instructions.



WARNING:

When setting FIO₂ do not overturn the oxygen knob. Stop once resistance is felt. See Figure 2-2 for location of knob.



WARNING:

Do not use the V4C-O2E Oxygen Mixer at an atmospheric pressure or temperature outside of the range stated in Section 2.7, [Specifications](#). Using the Oxygen Mixer outside of the specified temperature or atmospheric pressure range can affect the Oxygen Mixer performance and can result in patient injury or death.



WARNING:

Do not cover the V4C-O2E Oxygen Mixer or place it in a position that affects proper operation, including close to a heat source, on an uneven surface, or on a bed.



WARNING:

Do not expose the V4C-O2E Oxygen Mixer to direct sunlight for prolonged periods of time.



WARNING:

To avoid injury to the patient and/or possible damage to the V4C-O2E Oxygen Mixer: before using the V4C-O2E Oxygen Mixer, use appropriate equipment to regulate the oxygen supply to specifications before connecting the V4C-O2E Oxygen Mixer to the oxygen supply.



WARNING:

Ensure sufficient supply of oxygen is available for the duration of ventilation.



WARNING:

If the oxygen supplied to the V4C-O2E Oxygen Mixer is less than 100% O₂ the maximum FiO₂ delivery will be decreased.



WARNING:

Turn off oxygen supply if abnormal behavior of the device is observed and provide the patient with an alternative means of ventilation.



WARNING:

Oxygen flow to the ventilation system will begin automatically when an active breathing mode is selected. The V4C-O2E Oxygen Mixer will terminate oxygen flow when the ventilator is not in an active breathing mode.



WARNING:

In the event of power loss to the ventilator, oxygen delivery to the Oxygen Mixer will cease immediately. Safety valves on the V4C-O2E Oxygen Mixer ensure that room air is always available to the ventilator in all fault conditions, including in an oxygen loss scenario.



WARNING:

Never use the V4C-O2E Oxygen Mixer and the low pressure oxygen port of the compatible ventilator simultaneously. Only one source of oxygen can be delivered to the ventilator during use.



WARNING:

Never use the V4C-O2E Oxygen Mixer without an appropriate FiO₂ monitor. Always ensure that the sensor has been properly calibrated before use. See Section 5.1, [FiO₂ Sensor Calibration](#) for calibration instructions.



WARNING:

Never use the V4C-O2E Oxygen Mixer without appropriately setting both high and low FiO₂ alarms on the compatible ventilator or FiO₂ monitor.

**WARNING:**

Never use the V4C-O2E Oxygen Mixer without appropriately setting both high and low pressure/volume alarms on the compatible ventilator.

**WARNING:**

Do not use the V4C-O2E Oxygen Mixer without an inspiratory bacterial filter between the ventilator's outlet and the patient. Doing so can cause cross-contamination of the V4C-O2E Oxygen Mixer or delivery of contaminants to the patient.

**WARNING:**

If the Oxygen Mixer's air intake filter appears visibly soiled, replace it even if the recommended maintenance period has not yet elapsed.

5.1 FiO₂ Sensor Calibration

If using the V4C-560 Ventilator FiO₂ kit, each time a measurement cell is removed and reinstalled, and on a weekly basis, the FiO₂ sensor must be recalibrated before using the ventilator.

Follow steps in Section 5.1.1, [Calibrating the V4C-560 FiO₂ Kit for Use with the V4C-O2E Oxygen Mixer](#) to ensure the most accurate calibration procedure. This process does not require the use of a measurement device.

If using an alternative FiO₂ sensor, follow all instructions and warnings of that sensor to ensure proper calibration.

5.1.1 Calibrating the V4C-560 FiO₂ Kit for Use with the V4C-O2E Oxygen Mixer

As the ventilator initially warms, the FiO₂ sensor's warming may cause it to drift out of calibration, therefore a two-step calibration is recommended whereby the sensor is first calibrated cold and then re-calibrated once it has warmed.

1. Confirm that the V4C-O2E Oxygen Mixer is correctly installed as per Section 4.1, [Installation and Assembly](#).
2. Set-up the ventilator according to its labeling and manual, including running any functional tests.
3. Complete the Operational Verification Checklist per Section 9.1, [Operations Verification Checklist](#), including the Functional Tests (Section 9.2, [Functional Tests](#)).
4. Calibrate the FiO₂ sensor. If using the V4C-560 Ventilator FiO₂ kit, calibrate per the instructions in the V4C-560 Ventilator Clinician's Manual. This includes disconnecting the sensor from the T-connector and exposing it to room air, waiting 15-30s, and calibrating the sensor.
5. Start ventilating with desired settings.

6. Set the desired FiO_2 using the adjustment knob.
7. After a minimum of **1 hour** of ventilation, recalibrate the sensor as described below.



Caution:
During the warm up period the FiO_2 readings may drift and the reading may no longer be accurate. Always monitor the patient.

- a. While ventilation continues, remove the FiO_2 sensor from the T-connector and expose it to ambient air.
- b. Using a gloved hand or tubing cap, ensure the T-connector opening is plugged during this time to ensure uninterrupted breath delivery to the patient.
- c. Shake the sensor in ambient air for 45 seconds.
- d. Immediately use the V4C-560 Ventilator screen to calibrate the sensor per instructions in the V4C-560 Ventilator Clinician's Manual Section 10.3 Calibrating the FiO_2 Sensor.



Note:
Always continue normal ventilation during recalibration.



Caution:
The duration of shaking of the sensor affects the accuracy of calibration, therefore following the directions in this manual will ensure the most accurate readings of the sensor. If the sensor is shaken less than the suggested amount residual oxygen on the sensor may affect calibration. If the sensor is shaken for longer than recommended, the sensor will cool and this may impact the calibration.

8. Return the sensor to T-connector.
9. If necessary, adjust the delivered FiO_2 with the adjustment knob.



Caution:
If at any point during ventilation the mode or settings are significantly changed, recalibrating the sensor at the new settings will provide the most accurate reading. Wait at minimum 15 minutes from the time the settings were changed to recalibrate the sensor. Follow the directions in Step 7 for the best calibration results.

5.2 Changing FiO₂ During Ventilation Using a Compatible Ventilator

**WARNING:**

If using the V4C-560 FiO₂ kit, changes in the ventilator's settings or mode may affect the calibration of the sensor. For the most accurate FiO₂ readings, recalibrate the sensor after any significant changes to the ventilator settings. If recalibrating follow the directions in Section 5.1, [FiO₂ Sensor Calibration](#).

1. During ventilation, gradually turn the O₂ knob clockwise to increase the FiO₂ or counterclockwise to decrease the FiO₂.

**Caution:**

Turning the knob with excess force past the usable limit may damage the V4C-O2E Oxygen Mixer. Stop turning when resistance is felt.

**Note:**

The two extremes of the knob position may yield little to no FiO₂ changes, while the centre of the knob will have the highest sensitivity to change. This is normal behaviour. For further information see Section 8, [Theory of Operation](#).

**Note:**

In normal operation, there may be resistance when adjusting the oxygen knob from its maximum or minimum position and an audible sound or clicking may occur. For more information on the functioning of the knob see Section 8, [Theory of Operation](#).

2. Monitor the FiO₂ on the compatible ventilator. Stop at the desired FiO₂.

**Note:**

It may take a few breaths after FiO₂ adjustment for the FiO₂ reading to settle. Wait for a few breaths before adjusting further.

3. Adjust the High and Low FiO₂ alarms to reflect the new FiO₂ percentage. It is recommended to set the alarms within 5% of the required FiO₂. Consult the instructions of the compatible ventilator or the FiO₂ sensor to set and adjust these alarms.

**Caution:**

The FiO₂ delivered is dependent on the breath settings. When the settings are changed (either manually or due to a change in patient status), the FiO₂ may change. For this reason,

appropriate setting of the High and Low FiO₂ alarms is required to ensure that the user is alerted should such a change occur.

5.3 Stopping Ventilation While Using the V4C-O2E Oxygen Mixer



WARNING:

Turn off or disconnect oxygen supply when the V4C-O2E Oxygen Mixer is not in use.

1. Confirm that a patient is not connected to the compatible ventilator.
2. Stop ventilation as per the compatible ventilator's manual.

5.4 Using the Compatible Ventilator Without the V4C-O2E Oxygen Mixer

The compatible ventilator can be used without removing it from the Oxygen Mixer's handles. To do so follow the steps below.

1. Disconnect the oxygen hose from the oxygen source.
2. Disconnect the gas connection tube and adapter from the compatible ventilator. Optionally, disconnect the gas connection tube and adapter from the Oxygen Mixer and store, ensuring the tube is properly protected from dust or contaminant ingress in storage.
3. Install an air intake filter on the back of the ventilator per its manual.
4. Disconnect the Oxygen Mixer's electrical connecting cable from the compatible ventilator.
5. Optionally remove the electrical connecting cable from the Oxygen Mixer and store.
6. Follow the compatible ventilator's manual to start ventilation, including running all start-up checks and tests, as well as any needed calibrations.



Caution:

Leaving the Oxygen Mixer electrically connected to a ventilator in battery mode, while not connected to an oxygen source may impact the ventilator's battery level.

6 Cleaning



WARNING:

Never use cleaners inside of the gas pathways. Always follow cleaning instructions indicated in Section 6, [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 V4C-O2E Oxygen Mixer 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 is required when using the Oxygen Mixer. To reduce the risk of infection, wash your hands thoroughly before and after handling the Oxygen Mixer.



WARNING:

Use all cleaning solutions and products with caution. Read and follow the instructions associated with the cleaning solutions you use to clean your Oxygen Mixer. Use only those solutions listed in Table 6-1.



WARNING:

The Oxygen Mixer should never be immersed in any liquid, and any liquid on the surface of the device should be wiped away immediately. To avoid damage to the Oxygen Mixer, in particular the electrical components, fluids must not be allowed to enter the device, particularly through the Oxygen Mixer's air intake filter or the cooling/venting apertures located on the rear and bottom panels of the Oxygen Mixer.

Clean all external panels and surfaces before and after each patient use and as often as necessary to keep the V4C-O2E Oxygen Mixer clean. You should clean the ventilator and Oxygen Mixer periodically, whenever it is soiled or dirty, before any maintenance operation, and before storing the device.

To clean the surface of the V4C-O2E Oxygen Mixer:

1. Dip a clean, soft cloth into a mixture of mild soap and water, or other approved cleaning solution. Refer to Table 6-1 for a list of approved cleaning solutions.
2. Squeeze the cloth thoroughly to remove excess liquid.
3. Lightly wipe the external casing of the V4C-O2E Oxygen Mixer, taking care not to allow excess moisture to enter any of the openings on the V4C-O2E Oxygen Mixer's surface or the Oxygen Mixer air intake filter.

4. Lightly wipe the electrical connecting cable and the outside of the gas connection tube. Take care not to allow cleaning solutions to enter the tubing.
5. Dry the V4C-O2E Oxygen Mixer surface and its accessories with a clean, soft, lint-free cloth.

Table 6-1. Approved cleaning solutions for exterior Oxygen Mixer surfaces

Value
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

7 Routine Maintenance



WARNING:

Avoid using the V4C-O2E Oxygen Mixer, if possible, in dusty environments. Dusty environments may require more vigilant monitoring, cleaning, and/or replacement of air intake filter and other filters.



WARNING:

Do not attempt to open, repair or otherwise service the V4C-O2E Oxygen Mixer 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 V4C-O2E Oxygen Mixer.



WARNING:

To ensure proper performance of the Oxygen Mixer, the preventative maintenance schedule should be followed, per Section 7, [Routine Maintenance](#). For further information contact Baylis Medical Technologies. Failure to do so can result in malfunctioning or the device, which may result in patient injury.



WARNING:

Never use cleaners inside of the gas pathways. Always follow cleaning instructions indicated in Section 6, [Cleaning](#).



WARNING:

Check the condition of the V4C-O2E Oxygen Mixer's air intake filter once a month when used indoors. If the V4C-O2E Oxygen Mixer is used outdoors or in a dusty environment, the Oxygen Mixer's air intake filter should be checked weekly and replaced as necessary. Do not wash or wet the filter as this may compromise its filtration or resistance.



WARNING:

If the Oxygen Mixer's air intake filter appears visibly soiled, replace it even if the recommended maintenance period has not yet elapsed.



WARNING:

Never use the device without an air intake filter installed. Always use the approved filters. Use of an incorrect filter may impact breath delivery. See Section 2.7, [Specifications](#) for filter specifications and Section 4.1, [Installation and Assembly](#) for installation instructions.

1. Replacement of the Oxygen Mixer's air intake filter.
 - Once per month or when visibly soiled, whichever comes first.
 - If the V4C-O2E Oxygen Mixer is used outdoors or in a dusty environment, the Oxygen Mixer's air intake filter should be checked weekly and replaced as necessary.

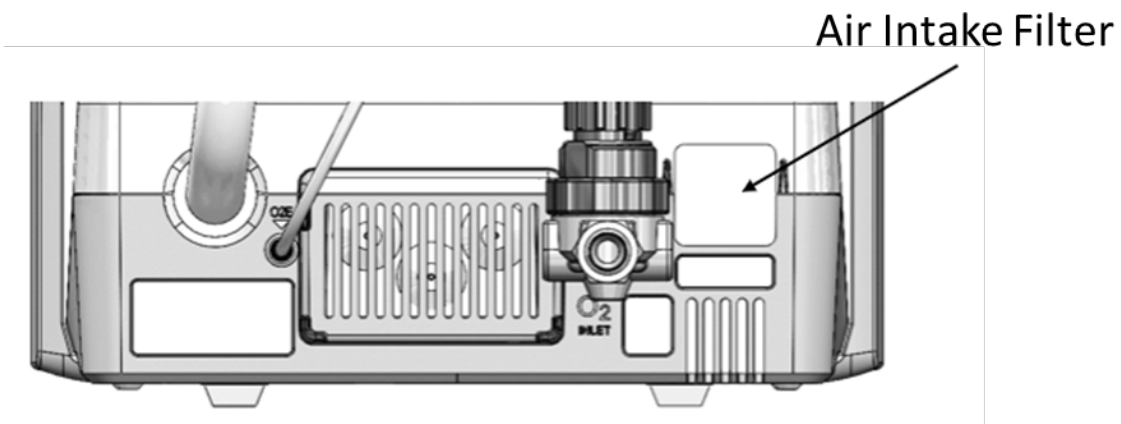


Caution:
Always check the expiration date on the filter's package before use to ensure it has not passed its "use-by" date.

To replace the filter:

- a. Using two fingers, pinch and grip the air intake filter located on rear of V4C-O2E Oxygen Mixer (Figure 7-1).

Figure 7-1. V4C-O2E air intake filter location



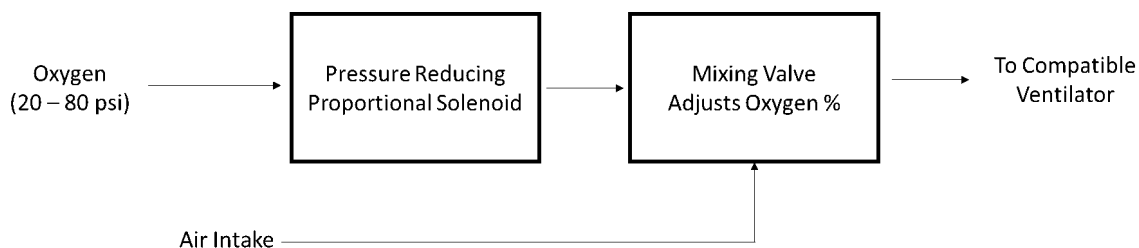
- b. Remove the old air intake filter and discard.
 - c. Replace by pressing the new air intake filter into the empty cavity.
 - d. Ensure that the filter is flush with the surface of the enclosure.
2. Clean the ventilator per Chapter 6. Clean all external panels and surfaces before and after each patient use and as often as necessary to keep the V4C-O2E Oxygen Mixer clean. You should clean the ventilator and Oxygen Mixer periodically, whenever it is soiled or dirty, before any maintenance operation, and before storing the device.
 3. Send the V4C-O2E Oxygen Mixer for preventative maintenance every 2 years for servicing. The first maintenance must be completed after 2 years of use, or 3 years from the date of manufacture, whichever comes first. Subsequent maintenance must be performed every 2 years from the date of the last service. Please contact your Baylis Medical Technologies representative to arrange service of the device.

The V4C-O2E Oxygen Mixer should have an expected service life of 10 years, provided that the preventative maintenance schedule in this manual is followed.

8 Theory of Operation

The V4C-O2E Oxygen Mixer is primarily composed of a pressure controlled proportional solenoid, which actively controls the pressure of the incoming oxygen over the course of a delivered breath, and a mixing valve which can be used to adjust the proportion of air and oxygen delivered to the ventilator.

Figure 8-1. V4C-O2E Oxygen Mixer theory of operation



The pressure controlled solenoid actively adjusts the oxygen flow to maintain the appropriate pressure and flow of oxygen through the Oxygen Mixer for the given FiO_2 settings and breath parameters.

The Oxygen Mixer is equipped with emergency pressure relief valves which will ensure that excess pressure does not reach the patient in a fault situation. The Oxygen Mixer is additionally equipped with vacuum breaking valves, which allow for air ingress into the Oxygen Mixer should the oxygen supply ever become compromised.

The mixing valve works by moving a gasket back and forth between the air and oxygen gas lines in order to create the desired oxygen percentage. This motion is controlled by the knob on the front of the Oxygen Mixer. In a pure oxygen or pure air delivery position the gasket completely seals one of the gas lines and allows free flow of the other (see Figure 8-1). A clicking sound is sometimes heard when the gasket releases from one side of the gas pathway, unsealing that side. This is normal.

Figure 8-2. Internal function of the mixing valve

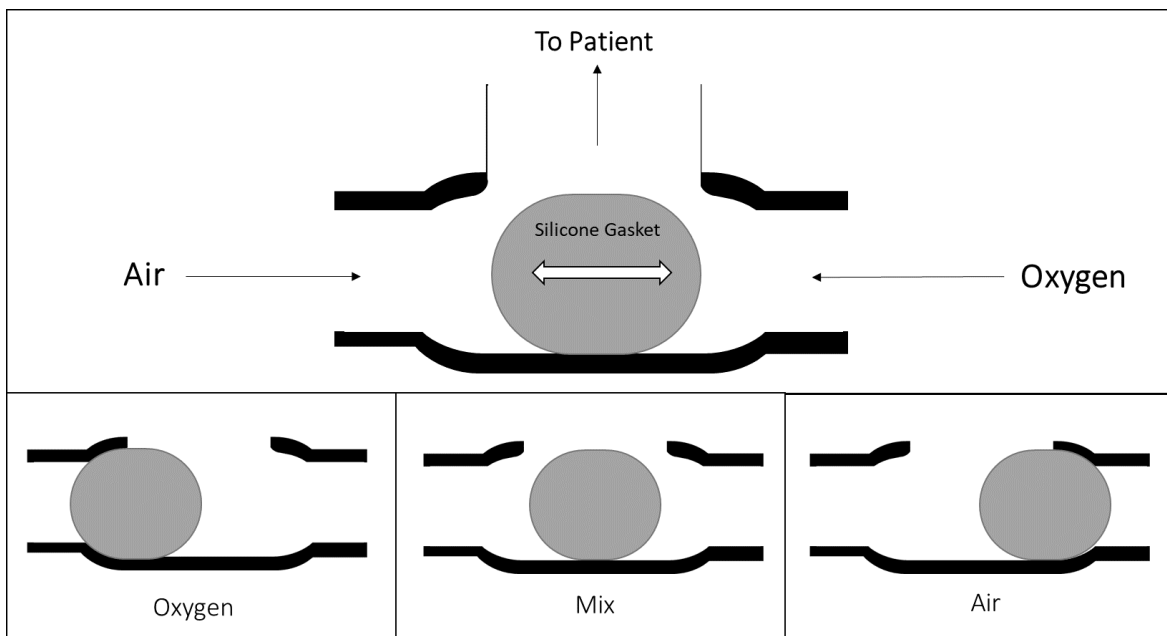
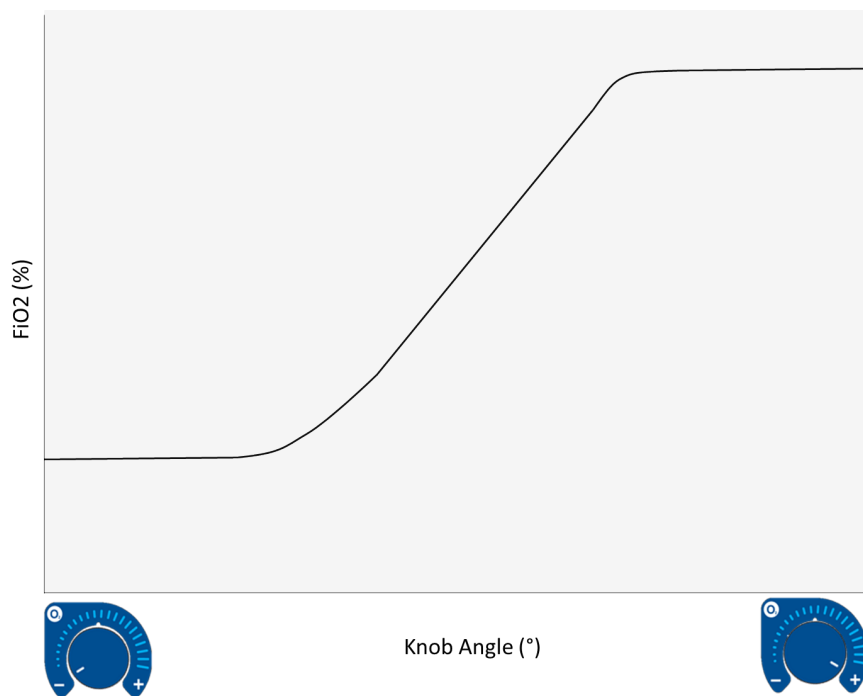


Figure 8-3 shows the shape of the curve of the FiO_2 percentage as a function of knob position.

Figure 8-3. The $\text{FiO}_2\%$ output as a function of the knob's position



9 Operational Verification Checklist and Functional Testing



WARNING:

Always perform recommended tests of the compatible ventilator per its manual and the recommended V4C-O2E Oxygen Mixer tests in Section 9.2, [Functional Tests](#) prior to connecting a patient.



WARNING:

Do not use the V4C-O2E Oxygen Mixer if it is not appropriately affixed to the ventilator. See Section 4.1, [Installation and Assembly](#) for instructions on how to securely attach the V4C-O2E Oxygen Mixer to the ventilator.



WARNING:

Never use the V4C-O2E Oxygen Mixer or components that appear to be damaged or faulty. Contact Baylis Medical Technologies if the cause of a problem cannot be determined.



WARNING:

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:

Read and take account of the environmental condition ranges for proper operation before using the V4C-O2E Oxygen Mixer.

9.1 Operations Verification Checklist



WARNING:

Ensure sufficient supply of oxygen is available for the duration of ventilation.



WARNING:

Never use the V4C-O2E Oxygen Mixer without an appropriate FiO₂ monitor. Always ensure that the sensor has been properly calibrated before use. See Section 5.1, [FiO₂ Sensor Calibration](#) for calibration instructions.



WARNING:

Never use the V4C-O2E Oxygen Mixer without appropriately setting both high and low FiO₂ alarms on the compatible ventilator or FiO₂ monitor.



WARNING:

Never use the V4C-O2E Oxygen Mixer without appropriately setting both high and low pressure/ volume alarms on the compatible ventilator.



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 ability for monitoring the patient and alerting the clinician to situations that may require intervention.



WARNING:

Do not use the V4C-O2E Oxygen Mixer without an inspiratory bacterial filter between the ventilator's outlet and the patient. Doing so can cause cross-contamination of the V4C-O2E Oxygen Mixer or delivery of contaminants to the patient.



WARNING:

Before starting ventilation, ensure that the V4C-O2E Oxygen Mixer and compatible ventilator are properly assembled and that the system's air intake filter and cooling vents are not obstructed. Refer to Section 2.6, [Device Features](#) for the locations of these features. Also ensure 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.

The operational verification and safety checks listed in Table 9-1 below should be performed to ensure the Oxygen Mixer is operating properly in the following circumstances:

- Prior to using the V4C-O2E Oxygen Mixer with a patient
- Monthly
- Following maintenance

If the Oxygen Mixer fails any of the safety checks below, or if you cannot complete these checks, refer to Section 3.1, [Troubleshooting Overview](#).

Table 9-1. Operational verification checklist

1	Verify the proper appearance and cleanliness of the Oxygen Mixer.	<input type="checkbox"/> Pass
2	Verify all of the labels and markings on the Oxygen Mixer are clear and legible.	<input type="checkbox"/> Pass
3	Confirm the Oxygen Mixer's air intake filter is clean and correctly installed.	<input type="checkbox"/> Pass
4	Ensure the electrical connecting cable does not exhibit any signs of damage, such as kinks, breaks, or damaged insulation, and is appropriately and securely attached to both the ventilator and Oxygen Mixer.	<input type="checkbox"/> Pass
5	Ensure the gas connection tubing does not exhibit any signs of damage, such as kinks or breaks, and that it is securely attached to the gas intake of the ventilator.	<input type="checkbox"/> Pass
6	Ensure oxygen supply line is securely attached and that the oxygen pressure delivered is within range specified in Section 2.7.	<input type="checkbox"/> Pass
7	Ensure the Oxygen Mixer, and particularly the side arms and handle, are securely attached to the ventilator. Ensure screws are fully secured.	<input type="checkbox"/> Pass
8	Ensure the low pressure oxygen port of the ventilator does not have an oxygen source connected.	<input type="checkbox"/> Pass
9	Perform the Functional Tests. Refer to Section 9.2.	<input type="checkbox"/> Pass
10	Ensure the High and Low FiO ₂ alarms are set on the compatible ventilator. It is recommended that these alarms be set within $\pm 5\%$ of the required FiO ₂ .	<input type="checkbox"/> Pass
11	Ensure the high and low VTE/VTI, the high pressure, the Max Rtot, bpm and any other applicable alarms are set on the compatible ventilator based on the settings and mode being used.	<input type="checkbox"/> Pass

9.2 Functional Tests



WARNING:

Never perform tests that could disrupt ventilation while the patient is being ventilated. Always provide an alternate means of ventilation where applicable.



WARNING:

If at any time it is observed that excessive and consistent gas is exiting through the vents at the back of the Oxygen Mixer, call for maintenance.



WARNING:

If at any time a leak is suspected from or inside the V4C-O2E Oxygen Mixer, terminate use and call for maintenance. Excessive oxygen consumption may be indicative of a leak.



WARNING:

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

**WARNING:**

Ensure that the patient is not positioned in a way that could lead to accidental disconnection.

Complete Functional Tests in the following situations:

- Prior to using the V4C-O2E Oxygen Mixer with a patient
- Monthly
- Following maintenance

9.2.1 Test 1 — Compatible Ventilator Alarms Test

Complete all tests in the compatible ventilator's manual with the V4C-O2E Oxygen Mixer connected. For the V4C-560 Ventilator, follow Clinician's Manual Section F - Alarms Tests. Confirm all alarms tests pass.

9.2.2 Test 2 — High FiO₂ Test

To perform a High FiO₂ test, do the following:

1. Ensure V4C-O2E Oxygen Mixer is installed per Section 4.1, [Installation and Assembly](#). Ensure the ventilator is set-up per the V4C-560 Ventilator Clinician's Manual.
2. Run this test with an ADULT patient limb. Connect the patient end of the patient circuit to a test lung.
3. Calibrate the FiO₂ sensor per the manual of the compatible ventilator or FiO₂ sensor. A single step calibration can be used for this test.
4. Press the VENTILATION ON/OFF key to start ventilation.
5. Set the ventilator to the following settings based on what circuit type is being used to perform the test:

Table 9-2. Ventilator settings for high FiO₂ test

Double Limb Circuit	Single Limb Circuit
<ul style="list-style-type: none"> • P A/C mode • Breath rate: 35 • IP: 25 • PEEP: 15 • Rise time: 1 • Insp time: 0.6 	<ul style="list-style-type: none"> • P A/C mode • Breath rate: 15 • IP: 14 • PEEP: 9 • Rise time: 1 • Insp time: 0.8

6. Allow ventilation to continue for 10 breaths.
7. Using the adjustment knob turn the knob all the way to the right.
8. Confirm that the oxygen percentage delivered is $\geq 94\%$.

**Note:**

If FiO_2 cannot be reached recalibrate the FiO_2 sensor and repeat the test.

9.2.3 Test 3 — Low FiO_2 Test

To perform a Low FiO_2 test, do the following:

1. Ensure V4C-O2E Oxygen Mixer is installed per Section 4.1, [Installation and Assembly](#). Ensure the ventilator is set-up per its instruction manual.
2. Run this test with an ADULT patient limb. Connect the patient end of the patient circuit to a test lung.
3. Calibrate the FiO_2 sensor per the manual of the compatible ventilator or FiO_2 sensor. A single step calibration can be used for this test.
4. Press the VENTILATION ON/OFF key to start ventilation.
5. Set the ventilator to the following settings:
 - P A/C mode
 - Breath rate: 15
 - IP: 14
 - PEEP: 9
 - Rise time: 1
 - Insp time: 0.8
6. Using the adjustment knob turn the knob all the way to the left.
7. Confirm that the oxygen percentage delivered is $< 26\%$.

**Note:**

If FiO_2 cannot be reached or if the Check FiO_2 Sensor alarm sounds, recalibrate the FiO_2 sensor and repeat the test.

9.2.4 Test 4 — FiO₂ Alarms Test

To perform an FiO₂ Alarms Test, do the following:

1. Ensure V4C-O2E Oxygen Mixer is installed per Section 4.1, [Installation and Assembly](#). Ensure the ventilator is set-up per its instruction manual.
2. Connect the patient end of the patient circuit to a test lung.
3. Calibrate the FiO₂ sensor per the manual of the compatible ventilator or FiO₂ sensor. A single step calibration can be used for this test.
4. Set the ventilator to the following settings:
 - P A/C mode
 - Breath rate: 15
 - IP: 14
 - PEEP: 9
 - Rise time: 1
 - Insp time: 0.8
5. Set the High FiO₂ alarm to 80% and the Low FiO₂ alarm to 40%.
6. Press the VENTILATION ON/OFF key to start ventilation.
7. Using the adjustment knob turn the knob all the way to the right.
8. Wait for FiO₂ to surpass alarm threshold.
9. Wait 45 seconds.
10. Confirm the High FiO₂ alarm triggers.
11. Turn the adjustment knob all the way to the left.
12. Wait for FiO₂ to dip below alarm threshold.
13. Wait 45 seconds.
14. Confirm the Low FiO₂ alarm triggers.



Note:

If during this test the Check FiO₂ Sensor alarm sounds, recalibrate the sensor and repeat the test.

10 Part Numbers



WARNING:

Do not use unauthorized accessories with the V4C-O2E Oxygen Mixer system. Use of incorrect accessories can lead to malfunction or damage to the device.



WARNING:

Never use the V4C-O2E Oxygen Mixer or components that appear to be damaged or faulty. Contact Baylis Medical Technologies if the cause of a problem cannot be determined.



WARNING:

Do not use the V4C-O2E Oxygen Mixer with filters whose flow resistance is greater than allowable. Doing so may increase circuit resistance and compromise spontaneous breathing. For information on allowable filter resistances see Section 2.7, [Specifications](#).

Table 10-1 provides a list of accessories that are required for use of the V4C-O2E Oxygen Mixer. To order parts or accessories, contact your equipment supplier or Baylis Medical Technologies representative. For a list of items delivered with the ventilator, see Section 11, [Unpacking and Accessories](#).

Table 10-1. Part numbers

Parameter	Value
Installation Kit: 4 x V4C-560 Ventilator Adhesive Feet 6 x M6 Washers 6 x M6 Screws 1 x Allen Key	INSTKIT24O2E
1 x Electrical Connecting Cable	CW03PVGYO2ECBL
4 x V4C-O2E Air intake filter	HW01XXXXFMINT
1 x Gas connection tubing	TUB0018
1 x Gas connection tubing adapter	1969000
1 x Oxygen Hose (DISS - commonly used in Canada)	HS-10IO-DHDFC4

11 Unpacking and Accessories



WARNING:

Do not use unauthorized accessories with the V4C-O2E Oxygen Mixer system. Use of incorrect accessories can lead to malfunction or damage to the device.



WARNING:

Never use the V4C-O2E Oxygen Mixer or components that appear to be damaged or faulty. Contact Baylis Medical Technologies if the cause of a problem cannot be determined.

To unpack and prepare the V4C-O2E Oxygen Mixer:

1. Open the carton to remove the V4C-O2E Oxygen Mixer, the oxygen hose, and accessories from the inner cardboard box.
2. Inspect the V4C-O2E Oxygen Mixer and ensure that:
 - The outer casing and accessories do not have any dents or scratches, which may indicate possible damage.
 - The V4C-O2E Oxygen Mixer's labels and markings are clear and legible.
 - The electrical connecting cable does not exhibit any signs of damage, such as kinks, breaks, or cuts.
 - The gas connection tube does not exhibit any signs of damage, such as kinks, breaks, or cuts.
 - Oxygen hose is present in the box.
 - The oxygen hose does not exhibit any signs of damage, such as kinks, breaks, or cuts.
 - Ensure all necessary accessories are included per Table 11-1.
 - Ensure the air intake filters have not passed their "use-by" date.

Table 11-1. Parts and accessories provided with the V4C-O2E Oxygen Mixer

Item	Description	Catalogue Number
1 x V4C-O2E Oxygen Mixer	Enhances FiO ₂ range of compatible ventilators.	V4C-O2E
2 x Side arms	Used to secure the ventilator to the Oxygen Mixer.	
1 x Handle	Used to secure the ventilator to the Oxygen Mixer and to allow the system to be carried.	
6 x M6 washers	Used to secure the ventilator to the Oxygen Mixer.	INSTKIT24O2E
6 x M6 screws		
1 x M6 allen key		
4 x Ventilator adhesive feet	Provided in the event that the compatible ventilator is missing its rubber feet. See Section 4.1, Installation and Assembly for installation instructions.	
1 x Alcohol swab	Provided to clean surface before installing ventilator rubber feet. See section 4.1, Installation and Assembly for installation instructions.	N/A
1 x Electrical connecting cable	Electrical connection between the Oxygen Mixer and the compatible ventilator	CW03PVGYO2ECBL
1 x Air intake filter (pre-installed)	Filters gas entering through the Oxygen Mixer's air intake.	HW01XXXXFMINT
8 x Replacement air intake filters	Replacement filters for the Oxygen Mixer's air intake.	
1 x Gas connection tubing	Delivers gas from the Oxygen Mixer to the compatible ventilator.	TUB0018
1 x Gas connection tubing adapter	Male-to-male conical adapter used to connect the gas transfer tubing to compatible ventilators.	1969000
1 x Instructions for Use (English/French)	USB Key containing the User's Manual.	QMSDMR01436-USB
1 x Quick start guide (English/French)	A hardcopy of operation instructions of the V4C-O2E Oxygen Mixer.	QMSDMR01436-HC
1 x Oxygen hose (DISS - commonly used in Canada)	Used to connect the oxygen source to the V4C-O2E Oxygen Mixer. This hose is made for use with medical oxygen. The connection is a DISS CGA 1240 connector for use in Canada.	HS-10IO-DHDFC4

12 Electromagnetic Emissions and Immunity

Table 12-1. Electromagnetic emissions

The ventilator and Oxygen Mixer are intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.		
Phenomenon and standard	Compliance	Electromagnetic Environment - Guidance
Power Line Conducted Emissions CISPR 11	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.
Radiated RF Emissions CISPR 11		
Harmonic Emissions IEC 60601-1-2 / 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 Emissions IEC 60601-1-2 / IEC 61000-3-3	Complies	

Table 12-2. Electromagnetic immunity

Phenomenon	Basic EMC Standard / Test Method	Immunity Test Levels for Home Healthcare Environment
Electrostatic Discharge	IEC 60601-1-2 / IEC 61000-4-2	± 8kV Contact; ±15 kV Air
Electrical Fast Transients/Bursts*	IEC 60601-1-2 / IEC 61000-4-4	±2 kV for power supply lines (mains) ±1 kV for input/output lines 100 kHz pulse repetition frequency
Surge Immunity*	IEC 60601-1-2 / IEC 61000-4-5	± 1 kV line-to-line
Rated Power Frequency Magnetic Field	IEC 60601-1-2 / IEC 61000-4-8	30 A/m (60Hz)
Voltage Dips	IEC 60601-1-2 / IEC 61000-4-11	0% during 0.5 cycle 0% during 1 cycle 70% during 30 cycles
Voltage Interruptions		0% during 300 cycles
NOTE: UT is the AC mains voltage prior to application of the test level		

* The system is a Class II electrical device, therefore the tests were performed between Line and Neutral only.

Table 12-3. Electromagnetic immunity — conducted and radiated RF

Phenomenon	Basic EMC Standard / Test Method	Immunity Test Levels for Home Healthcare Environment
Radiated Field Immunity	IEC 60601-1-2 / IEC 61000-4-3	10 V/m (80% AM at 1KHz sine) 80 MHz – 2.7 GHz
Proximity Fields from RF Wireless Communications Equipment		Proximity Fields provided in Table 9 of the basic EMC standard
Conducted Disturbances Induced by RF Fields (Conducted RF Immunity)	IEC 60601-1-2 / IEC 61000-4-6	3 Vrms 150 KHz - 80 MHz 6 Vrms in ISM/amateur radio bands between 150 KHz and 80 MHz

13 Glossary

Battery Level

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

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.

cmH₂O

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

Driving Pressure

Plateau airway pressure minus PEEP.

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).

hPa

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

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 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.

lpm

Liters per minute (a unit of volume flow rate).

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.

mbar

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

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 Effort

Inspiratory effort initiated by the patient.

Peak Inspiratory Pressure (PIP)

The highest pressure measured in the patient circuit during the inspiration phase.

Peak End Expiratory Pressure (PEEP)

Pressure in the patient circuit at the end of expiration.

PSI

Pounds per square inch.

Rtot

Parameter measured by the ventilator equal to the total number of breaths per minute (bpm).

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.

VTE (Exhalation Tidal Volume)

Volume exhaled by the patient at each exhalation phase.

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 Baylis Medical Technologies Inc
2645 Matheson Blvd. East, Mississauga, Ontario L4W 5S4 Canada
www.baylismedtech.com

[T] +1 (905) 948-5800

Baylis
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