This manual provides detailed information about the Breathe Non-Invasive Open Ventilation (NIOV™) System and step-by-step instructions for using its features.

Chapter 1: Introduction includes critical information that must be read before using the system:

- **Indications for Use** outlines who can typically benefit from using the ventilation system.
- **Safety Information** lists precautions that must be taken to ensure safe operation of the ventilation system.

Chapter 2: System Overview gives an overview of the ventilation system’s features.

Chapter 3: Using the Ventilation System describes the six basic tasks that you will perform when using the system:

- Check the battery charge.
- Connect and turn on an oxygen supply.
- Connect and wear the Breathe NIOV Pillows Interface.
- Attach the ventilator.
- Turn on the ventilator and choose an activity setting.
- Adjust the trigger sensitivity.

Chapter 4: Alarms and Troubleshooting describes how alarms are displayed and gives information on what triggers them and how to clear them.

Chapter 5: Setup and Care describes procedures for defining ventilator system settings and for caring for the system.

Chapter 6: Icons provides a reference chart for the symbols used.

Symbols and Conventions

To make it easier to find information you need and alert you to potential hazards, the following symbols and conventions are used throughout this manual:

<table>
<thead>
<tr>
<th>This</th>
<th>Means this</th>
</tr>
</thead>
<tbody>
<tr>
<td>![WARNING]</td>
<td>Indicates hazards that, if not avoided, may cause severe injury or death.</td>
</tr>
<tr>
<td>![CAUTION]</td>
<td>Indicates hazards that, if not avoided, may result in minor or moderate injury, or damage to or impaired performance of equipment.</td>
</tr>
<tr>
<td>![TIP]</td>
<td>Indicates tips or additional information that may be helpful when using the ventilation system.</td>
</tr>
</tbody>
</table>

The names of menu items and buttons displayed on the ventilator touch screen are indicated with bold text. For example, the **Menu** screen has several buttons, including **Home Screen**, **Settings**, and **Information**.
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INTRODUCTION
This section includes the critical information that must be read before using the system.

Indications for Use
Clinical Considerations for Use
Patient Participation
Safety Information

INDICATIONS FOR USE
The NIOV Ventilator, with accessories, is a volume assist ventilator intended to aid adult patients with respiratory insufficiency. It is designed for patients that are capable of spontaneously breathing a minimum tidal volume of 3.5 ml/kg of predicted body weight. The device is designed for continuous applications such as patient ambulation, physical therapy, occupational therapy, respiratory therapy, and other rehabilitation efforts in an institutional or home care environment. The device is intended for operation by trained personnel, patients or their caregivers under the direction of a physician.

PATIENT PARTICIPATION
The use of the NIOV Ventilation System requires moderate patient participation, and therefore the patient must be able to understand and comply with instructions.

WARNING: Use the NIOV Ventilation System only for patients who meet the indications for use. If the ventilation system is used for patients that do not meet the ventilation system indications for use, patients may not receive appropriate respiratory therapy.
SYSTEM OVERVIEW

This section describes the basic parts and functions of the NIOV Ventilation System.

Ventilation System Components
Breathe Pillows Interface
Ventilator Features
Turning the Ventilator On and Off
Touch Screen Features
Touch Screen Energy-Save Mode

SAFETY INFORMATION

Before using the NIOV Ventilation System, you must be appropriately trained and must fully understand potential safety hazards. Read the following safety warnings and cautions in their entirety before using the ventilation system. Additional warnings and cautions can be found throughout this manual.

WARNING: The NIOV Ventilation System is not designed for patients who cannot spontaneously breathe or who are fully dependent on mechanical ventilation.

Failure to read the manual may result in product misuse, which may cause equipment damage or patient mistreatment.

If the NIOV Ventilation System is not functioning correctly, you may not receive appropriate respiratory therapy. Always have an alternate means of oxygen therapy available.

Do not allow smoking near oxygen sources or near the ventilator and do not place oxygen sources or the ventilator near any source of direct heat because flammable materials burn more readily in the presence of oxygen.

If the NIOV Ventilation System is not functioning correctly, use your standard oxygen therapy and contact your health care provider.

CAUTION: Do not use the NIOV Ventilation System in magnetic resonance imaging (MRI) environments. MRI equipment may cause electronic components in the ventilator to malfunction.

Do not submerge the ventilator in liquids or pour liquids on it. Liquids may cause components in the ventilator to malfunction.

Do not eat, drink, or chew gum while using the ventilator. Food or liquids that make contact with the ventilator may cause components in the ventilator to malfunction. Eating, drinking, or chewing gum may also increase the risk of choking.

When the ventilator is in use, keep it in a well-ventilated area to prevent it from overheating. The ventilator may overheat and be permanently damaged if it is used in an area that is not well ventilated.
VENTILATION SYSTEM COMPONENTS

The NIOV Ventilation System is an ultra-lightweight, wearable, system designed to improve breathing by providing increased ventilation to adult respiratory patients when they need it. Because of the system’s portability, patients have greater mobility and can move about freely and easily.

The NIOV Ventilation System consists of the ventilator, Breathe Pillows Interface, oxygen hose, battery charger, purge tube, and belt clip. The ventilation system is intended for use by patients in the home or institutional setting.

Note: The ventilation system does not include an oxygen cylinder. Shipping configurations may vary based on order.

TIP: The ventilator is shipped in a specially designed, protective box. Do not throw away the box. Keep it for future transportation needs.

BREATHE PILLOWS INTERFACE

The Breathe Pillows Interface for use with the ventilator is not included with the ventilation system components and is shipped separately. For instructions on how to fit, adjust, and connect the interface, see the section Using the NIOV Ventilation System in this manual and refer to the Breathe Pillows Interface Quick Start guide included with each interface.

WARNING: Use the NIOV Ventilation System only with the Pillows Interface. If the ventilation system is used with another manufacturer’s interface, the ventilator may not function correctly and you may not receive appropriate respiratory therapy.

CAUTION: Use a Pillows Interface for a maximum of 30 days. If an interface is used for more than 30 days, its performance may degrade and you may not receive adequate respiratory therapy.

Do not use a Pillows Interface that is cracked, odorous, broken, or kinked. If a damaged interface is used, you may not receive adequate respiratory therapy.

VENTILATOR FEATURES

The following illustrations identify the ventilator buttons and connections.
**System Overview**

**TURNING THE VENTILATOR ON AND OFF**

- To turn the ventilator on, press the **Power** button.
- To turn the ventilator off, press the **Power** button for approximately three seconds.

**Turn On Sequence**

When you turn on the ventilator, the green power light is illuminated. The ventilator performs a self test. During the test, all indicator lights should briefly flash and an audible alarm should briefly sound. This self test can take up to 15 seconds to complete. If you do not hear an audible alarm when you turn on the ventilator, contact your health care provider.

**WARNING:** Do not cover the ventilator speaker or backup alarm buzzer with tape or any other object. Covering the ventilator speaker or buzzer may make it difficult for a patient to hear alarms, which may result in inadequate respiratory therapy.

---

**Activity and Power Buttons**

<table>
<thead>
<tr>
<th>Button Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Activity</td>
<td></td>
</tr>
<tr>
<td>Medium Activity</td>
<td></td>
</tr>
<tr>
<td>High Activity</td>
<td></td>
</tr>
<tr>
<td>Power</td>
<td></td>
</tr>
</tbody>
</table>

---

**Top End of Ventilator**

1. Battery charger connection
2. Alarm Silence button
3. Not used

**Bottom End of Ventilator**

1. Interface port
2. Oxygen supply connection

---

**Breathe Technologies Ventilator**

- **Software Version:** BT-V2 xx.xx.xx.xx
- **Serial Number:** xxxxxxxxxx

1. Green power light is on.
2. Test screen is displayed. (The software version in this screen is for illustration purposes only.)
3. Home screen is displayed without data.
4. When the Home screen is displayed, the touch screen is ready to use.
TOUCH SCREEN FEATURES

The NIOV Ventilation System uses a touch screen for setting up the ventilator, monitoring patient data, and displaying alarm information. To use the touch screen, simply touch a screen button or an area of the screen you want to make active. An audible "click" indicates the feature you touch is activated.

There are two main ventilator screens: the Home screen and the Menu screen.

Home Screen

When you turn on the ventilator, after it completes a self test, the touch screen displays the Home screen. After the oxygen supply is connected and the patient is wearing the Pillows Interface, when you press a ventilator Activity button, the Home screen displays patient oxygen flow rate and breath rate.

The following illustration shows the buttons, icons, and information displayed on the Home screen.

1 Touch the Wrench button to go to the Menu screen.
2 Current Activity icon and augmentation volume.
3 Touch the Flip button to flip the screen 180°.
4 Current breaths per minute (BPM).
5 Average oxygen flow in liters per minute, based on activity setting and patient’s current breath rate.
6 Battery Charge icon.
7 Current Activity icon. Use the ventilator Activity buttons to change an activity setting.
8 Vibration icon indicating ventilator is in vibration mode.
9 Time and date display.

Menu Screen

Use the Menu screen to go to the Settings menu, get information about the software version of the ventilator and ventilator use, or go back to the Home screen.

To get to the Menu screen, on any ventilator screen, touch the Wrench button.

Moving Between the Home Screen and Menu Screen

1 Touch the Wrench button to go to the Menu screen.
2 Touch to go to the Home screen.
3 Touch to go to the Settings screen for Trigger Sensitivity, and Utilities.
4 Touch to go to the Software Version screen for software version and total use time.

TOUCH SCREEN ENERGY-SAVE MODE

After two minutes with no user interaction, the touch screen automatically enters energy-save mode and dims the screen. Touching the screen again will reactivate it and display the Home screen.
Using the Ventilation System

This section describes the six basic steps you need to perform to set up and use the NIOV Ventilation System.

Step 1. Check the Battery Charge
Step 2. Connect and Turn on an Oxygen Supply
Step 3. Connect and Wear the Pillows Interface
Step 4. Attach the Ventilator
Step 5. Turn On the Ventilator and Choose an Activity Setting
Step 6. Adjust the Trigger Sensitivity

Step 1: Check the Battery Charge

Before you use the ventilator, check that the battery is fully charged.

1. Press the Power button to turn on the ventilator.

2. Check that the fully charged Battery Charge icon is displayed before using the ventilation system.

It takes approximately three hours to fully recharge the battery when the ventilator’s power is turned off. A fully charged battery should last approximately four hours.

Assemble the Battery Charger and Charge the Battery

If the ventilator is off, the battery charger light turns green when the battery is fully charged. The ventilator can be on and in use while the battery is charging, but the battery charger light will remain red. Although the ventilator can be charged while in use, it is recommended that the ventilator is charged with the power off to ensure a full charge. Check the Battery Charge icon on the touch screen to see the current battery charge level.
3 USING THE VENTILATION SYSTEM

STEP 2: CONNECT AND TURN ON AN OXYGEN SUPPLY

This section gives instructions on connecting the oxygen regulator and ventilator to an oxygen cylinder, turning the oxygen supply on and off, and replacing an oxygen cylinder.

1 Connect the battery charger cord to the ventilator charger port. The word UP on the battery charger cord will be facing the front of the ventilator.
2 Plug the power cord of the battery charger assembly into the battery charger.
3 Plug in the wall plug.

Note: the ventilator can be used while the battery is charging.

CAUTION: Do not place the battery charger on wet surfaces or use in wet environments. Wet environments may damage the battery charger and may cause electric shock.

CAUTION: Use only the Breathe Technologies approved battery charger and cord set with the ventilator. If an unauthorized battery charger or cord set is used with the ventilator, the ventilator may be damaged.

WARNING: If the NIOV Ventilation System is not used with a regulator capable of 41–87 psig (nominal 50 psig) with greater than 28 LPM capability, you may not receive appropriate respiratory therapy.

CAUTION: Use only a Breathe Technologies approved O2 supply hose with the ventilator. If an unauthorized O2 supply hose is used with the ventilator, the ventilator may be damaged.

TIP: Use a regulator to regulate the pressure to 41–87 psig (50 psig nominal) before attaching oxygen to the ventilator. Refer to the regulator and oxygen supply manufacturers’ instructions.

TIP: The oxygen supply hose should remain connected to the ventilator at all times, except when required to be disconnected for maintenance, testing, or replacement. If it is disconnected while the ventilator is on and a therapy level active, an alarm occurs. If this happens, turn the ventilator off, and reconnect the hose.

Connecting the Regulator to an Oxygen Cylinder

1 Slide the regulator over the neck of the cylinder, and line up the pins on the regulator with the holes in the cylinder neck.
2 Ensure the barbed outlet airflow gauge is set to 0.

Connecting the Ventilator to an Oxygen Cylinder

1 Turn the ventilator off by firmly pressing the Power button for about three seconds.
2 Tighten the tee screw on the regulator by turning the handle clockwise.
3 Using the Ventilation System

2 Push the small oxygen supply hose connector onto the oxygen supply connection until it snaps into place.

3 Connect the green oxygen supply hose connector to the oxygen regulator by turning it clockwise.

4 With the ventilator power off and the oxygen supply hose connected to the ventilator and oxygen supply, follow the regulator and oxygen supply manufacturers’ instructions for turning on the oxygen supply.

Replacing an Oxygen Cylinder

When an oxygen cylinder needs to be replaced:

1 Turn the ventilator off by firmly pressing the Power button for at least three seconds.

2 Follow the oxygen and regulator manufacturers’ instructions for shutting off the oxygen supply.

3 Disconnect the ventilator oxygen supply hose from the oxygen supply.

4 Connect the ventilator oxygen supply hose to a new oxygen cylinder.

5 Follow the oxygen and regulator manufacturers’ instructions for turning on the oxygen cylinder.

Replacing an Oxygen Cylinder

When an oxygen cylinder needs to be replaced:

1 Turn the ventilator off by firmly pressing the Power button for at least three seconds.

2 Follow the oxygen and regulator manufacturers’ instructions for shutting off the oxygen supply.

3 Disconnect the ventilator oxygen supply hose from the oxygen supply.

4 Connect the ventilator oxygen supply hose to a new oxygen cylinder.

5 Follow the oxygen and regulator manufacturers’ instructions for turning on the oxygen cylinder.

Connecting the Interface to the Ventilator

1 Turn off the ventilator.

2 Plug the interface into the ventilator port.

Connecting the Interface to the Ventilator

1 Turn off the ventilator.

2 Plug the interface into the ventilator port.

STEP 3: CONNECT AND WEAR THE PILLOWS INTERFACE

Before using the Pillows Interface, visually inspect it for damage.

The interface comes in four sizes: extra small, small, medium, and large. Your health care provider determines what size is best for you. The interface assembly is packaged clean but not sterile.

Connecting the Interface to the Ventilator

1 Turn off the ventilator.

2 Plug the interface into the ventilator port.

Connecting the Interface to the Ventilator

1 Turn off the ventilator.

2 Plug the interface into the ventilator port.
Wearing the Interface

1 Place the interface in front of you with the arrows underneath pointing up and the curve of the interface towards you.

2 Loop the interface tubing over the ears so the pillows of the interface are positioned snugly inside the nostrils. For proper positioning of the interface, see the next section in this Step: Checking the Interface Positioning.

3 Adjust the tubing length under the chin so that the interface is comfortably secured.

Checking the Interface Positioning

The interface is placed correctly if the following conditions are met:

- The interface pillows rest snugly inside the nostrils, as shown.
- The fit is comfortable.
- The interface does not make breathing difficult.
- Air does not flow to the eyes, cheeks, or lips.

If any one of these conditions is not met, reposition the interface. If problems persist, contact your health care provider.

TIP: When the interface is in use, periodically check that it is positioned correctly and make adjustments as required. If skin becomes irritated, stop using the device, and contact your health care provider.
3 USING THE VENTILATION SYSTEM

STEP 4: ATTACH THE VENTILATOR

You can attach the ventilator to a belt or waistband. Instructions here describe how to use the belt clip to attach the ventilator to a belt or waist band. The ventilator can be worn on either the right or left side.

1 Position the clip over the belt, and push down until it is secure.

2 Line up the belt clip with the ventilator sockets, and push down until the clip audibly snaps into place.

CAUTION: Make sure the clip is securely fastened to the belt and the ventilator. If the clip is not securely fastened to the belt or the ventilator, the ventilator may drop and be damaged.

STEP 5: TURN ON THE VENTILATOR AND CHOOS AN ACTIVITY SETTING

When you first turn on the ventilator, no activity setting is active. The three Activity buttons on the ventilator (Low Activity, Medium Activity, High Activity) correspond to three different augmentation volumes prescribed by a physician. Choose an Activity button appropriate for your level of activity. You can change the level at any time.

1 Turn on the ventilator.

2 Press an Activity button for about one second until you hear a tone that indicates it is active.

3 Confirm the selected Activity icon is displayed on the touch screen (High Activity shown).

STEP 6: ADJUST THE TRIGGER SENSITIVITY

Trigger sensitivity determines how easily your breath triggers the ventilator to deliver oxygen. For shallow breathing, set the trigger sensitivity to a low number. You can choose a setting between 0 and 9. Zero is the most sensitive and 9 is the least sensitive setting.

Getting to the Trigger Sensitivity Screen

1 On any ventilator screen, touch the Wrench button.
Chapter 4
ALARMS AND TROUBLESHOOTING

This section describes the alarm functions and possible troubleshooting solutions.

Audio Alarm Sounds
Alarm Message Display
Active Alarms Window
Silencing and Clearing Alarms Summary
NIOV Ventilation System Alarms
Additional Troubleshooting Situations

2 On the Menu screen, touch Settings.

1 On the Trigger Sensitivity screen, touch the Up arrow to increase the value or the Down arrow to decrease it. If you press and hold an arrow, the number automatically increases or decreases.

Note: The lower the number, the more sensitive the setting.

2 When you are finished, touch OK.

3 In the message asking if the settings are OK, touch Confirm.

Note: Changes to settings only take effect when you touch Confirm.
4 ALARMS AND TROUBLESHOOTING

An alarm indicates a condition that needs to be identified and resolved. There are three alarm priority levels: high, medium, and low. This section describes alarm priority levels, the alarm messages displayed at the top of the touch screen, and the Active Alarms window. The section also includes tables that list the possible causes of an alarm and the options for resolving it.

ALARM MESSAGE DISPLAY

When an audible alarm occurs, an alarm message flashes at the top of the touch screen. The priority level of an alarm is indicated by the color and the rate at which the message flashes.

A red, rapidly flashing alarm message is a high-priority alarm and indicates a situation that requires immediate attention.

A yellow, steadily flashing alarm message is a medium-priority alarm and indicates a potentially hazardous situation that must be resolved in a timely manner.

A blue, non-flashing alarm message is a low-priority alarm and indicates a problem that is not hazardous but should be resolved.

ACTIVE ALARMS WINDOW

Multiple alarms may occur at the same time. Touch the Active Alarms button at the top of the touch screen to display a list of active alarms.

1 Touch the Active Alarms button to display the alarm list.
2 Alarm icon.
3 Scroll Down arrow.
4 Scroll Up arrow.

TIPS: The Active Alarms window displays up to three alarms, from highest to lowest priority (red, yellow, blue). If there are more than three alarms, you can use the Scroll Up and Scroll Down arrows to scroll through the list.

AUDIO ALARM SOUNDS

Each alarm priority level has a distinct sound, described as follows:

Alarm Priority Levels and Corresponding Sounds

- **High-priority alarm**
  - Sound: Sequence of two sets of five tones
- **Medium-priority alarm**
  - Sound: Sequence of three tones
- **Low-priority alarm**
  - Sound: Single tone

- **Alarm message**
  - Alternates between each occurring alarm.

- **Alarm Silenced icon**
  - Displayed when all alarms are silenced.

- **Active Alarms window**
  - Displays up to three alarms, from highest to lowest priority (red, yellow, blue). If there are more than three alarms, you can use the Scroll Up and Scroll Down arrows to scroll through the list.
Silencing and clearing alarms is a multi-step process that depends on alarm priority and how many alarms are active.

1 **Silence Alarm** button.

Press the **Silence Alarm** button to temporarily silence the alarm for 60 seconds. Pressing the **Silence Alarm** button silences only one alarm at a time—in audible or vibrating alarm mode. If more than one alarm occurs, press the **Silence Alarm** button once for each alarm. If the alarm is a medium- or high-priority alarm and is not silenced after 60 seconds, the alarm will resume with an additional buzzer.

2 Resolve the condition that triggered the alarm. For help resolving alarms, see the alarm and troubleshooting tables that follow for possible causes of an alarm and options to resolve it. If an alarm silence button is pressed but not resolved, the alarm will sound again after 60 seconds.

3 After resolving a high-priority alarm, touch **OK** in the message that indicates the alarm has been resolved.

The following tables list high-, medium-, and low-priority alarms. For each alarm, the tables list the screen message, the possible causes for the alarm, and the checks and options for resolving it.

### High-Priority Alarms

<table>
<thead>
<tr>
<th>Screen Alert</th>
<th>Cause</th>
<th>Checks and Possible Resolution</th>
</tr>
</thead>
</table>
| **High Temperature**       | CPU or battery temperature is above the allowable limit. | Check to make sure the ventilator is:  
• Not near a heat source.  
• In a well ventilated area.  
• Not covered or enclosed. |
| **High Circuit Pressure**  | Interface may be pinched or kinked.        | Check the interface tube. Replace it if it is pinched or kinked. |
| **High PEEP Pressure**     | Interface may be blocked.                  | Inspect and clean the interface per the instruction for cleaning the interface. |

### Medium-Priority Alarms

<table>
<thead>
<tr>
<th>Screen Alert</th>
<th>Cause</th>
<th>Checks and Possible Resolution</th>
</tr>
</thead>
</table>
| **Breath Timeout** | No breath is detected for 20 or 60 seconds, depending on the setting. | • Patient is not breathing or breath is too shallow to trigger augmentation.  
  **Note:** The ventilator is not indicated for patients who are not spontaneously breathing with a minimum volume of 3.5 ml/kg.  
• Inspect and clean the interface per the instruction for cleaning the interface. |
### Medium-Priority Alarms

<table>
<thead>
<tr>
<th>Screen Alert</th>
<th>Cause</th>
<th>Checks and Possible Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Breath Rate</td>
<td>• Respiratory rate exceeds the set limit.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is breathing faster than the rate set by a clinician.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Inspect and clean the interface per the instruction for cleaning the interface.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Screen Alert</th>
<th>Cause</th>
<th>Checks and Possible Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Del. Pressure</td>
<td>Interface pressure during delivery exceeds the maximum expected.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Check the interface. Replace it if the tubing is torn, bent, or kinked.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Make sure the tubing is not pinched or crushed.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Screen Alert</th>
<th>Cause</th>
<th>Checks and Possible Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Gas Pressure</td>
<td>Source gas pressure exceeds the allowable limit.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Use a regulator to adjust the source gas pressure to within the acceptable range of 41–87 psig (50 psig nominal).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Screen Alert</th>
<th>Cause</th>
<th>Checks and Possible Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Breath Rate</td>
<td>Respiratory rate falls below the set limit.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient’s breathing is too shallow to consistently trigger augmentation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Inspect and clean the interface per the instruction for cleaning the interface.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient is breathing through the mouth.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Screen Alert</th>
<th>Cause</th>
<th>Checks and Possible Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Del. Pressure</td>
<td>Interface pressure during delivery falls to exceed the minimum expected.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Check the interface connection to the ventilator.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Check the interface. Replace it if it is leaking.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Check the oxygen input pressure. If it is &lt;41 psig, use a regulator to adjust it within the acceptable range of 41–87 psig (50 psig nominal).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Check the oxygen supply to ventilator connections.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Screen Alert</th>
<th>Cause</th>
<th>Checks and Possible Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Gas Pressure</td>
<td>Source gas pressure drops below the allowable limit.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Check the oxygen supply level.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Check the oxygen supply to ventilator connections.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Check the oxygen supply regulator.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Check that the oxygen cylinder valve is fully open.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Screen Alert</th>
<th>Cause</th>
<th>Checks and Possible Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Fault</td>
<td>Internal fault detected during operation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• If a system fault occurs, in the message to reboot the ventilator, touch OK. Turn off the ventilator, and turn it on again.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• If system fault persists, continue with your prescribed backup therapy and contact your health care provider.</td>
<td></td>
</tr>
</tbody>
</table>

### Low-Priority Alarms

<table>
<thead>
<tr>
<th>Screen Alert</th>
<th>Cause</th>
<th>Checks and Possible Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery Low</td>
<td>Battery capacity drops below 25%.</td>
<td>• Recharge the battery.</td>
</tr>
<tr>
<td></td>
<td>• If the battery does not recharge, contact your health care provider.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Screen Alert</th>
<th>Cause</th>
<th>Checks and Possible Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Fault</td>
<td>System fault detected during power on.</td>
<td>• If a system fault occurs, in the message to reboot the ventilator, touch OK. Turn off the ventilator, and turn it on again.</td>
</tr>
<tr>
<td></td>
<td>• If system fault persists, continue with your prescribed backup therapy and contact your health care provider.</td>
<td></td>
</tr>
</tbody>
</table>

### ADDITIONAL TROUBLESHOOTING SITUATIONS

The following table lists situations that may occur during normal use of the ventilation system that do not have an alarm associated with them. The possible causes and options for resolving these situations are also listed.

#### Additional Troubleshooting Situations

<table>
<thead>
<tr>
<th>Observation</th>
<th>Cause</th>
<th>Possible Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breath indicator light is not flashing with the patient’s breathing.</td>
<td>• Patient’s breath is too shallow to trigger augmentation.</td>
<td>• Change the trigger sensitivity setting to a lower setting.</td>
</tr>
<tr>
<td></td>
<td>• Secretions may have built up on the pillows of the interface, blocking delivery of air.</td>
<td>• Inspect and clean the interface per the instruction for cleaning the interface.</td>
</tr>
<tr>
<td></td>
<td>• Patient is mouth breathing.</td>
<td>• Instruct patient to breathe in through their nose (purse lipped breathing is acceptable).</td>
</tr>
</tbody>
</table>
### Observation Cause Possible Resolution

#### Breath indicator light is not flashing.
- A ventilator **Activity** button has not been pressed.
- Secretions may have built up on the pillows of the interface, blocking delivery of air.
- **Press an Activity button.**
- **Inspect and clean the interface per the instruction for cleaning the interface.**

#### Buzzer sounds continuously at a constant pitch for two minutes or more.
- The ventilator battery is internally disconnected.
- The backup buzzer will sound for two to five minutes before it is silenced.
- **Contact your health care provider.**

#### Gas delivery is causing coughing or irritation in airway.
- Interface is not positioned correctly.
- **If symptoms persist, stop treatment with the ventilator, and contact your physician.**

#### No volume output.
- Oxygen supply is disconnected.
- Oxygen supply is empty.
- Ventilator is not on.
- Battery is depleted.
- Ventilator is inoperative.
- **Reconnect the oxygen supply.**
- **Replace the oxygen supply.**
- **Turn the ventilator on.**
- **Recharge the battery.**
- **If there is no volume output, contact your health care provider.**

#### Oxygen supply does not last as long as expected.
- User breath rate is higher than expected.
- Oxygen supply is not full at the start of use.
- The gas regulator is not properly connected to the oxygen cylinder.
- **Obtain a new oxygen supply.**
- **Reconnect the gas regulator to the oxygen cylinder.**

### Observation Cause Possible Resolution

#### Ventilator battery does not last as long as expected after a recharge.
- Battery is not charged completely.
- Battery life is nearing its end.
- Battery has become untrained.
- **Recharge battery.**
- **Contact your health care provider.**
- **Retrain the battery, as shown in section 5.**

#### Ventilator is autocycling (delivering gas without being triggered by the patient’s breathing or delivering gas multiple times during one breath).
- Secretions have built up on the pillows of the interface.
- **Inspect and clean the interface per the instruction for cleaning the interface.**
- **Adjust trigger sensitivity to a higher number.**

#### Ventilator is triggering during exhalation.
- Secretions have built up on the pillows of the interface.
- **Inspect and clean the interface per the instruction for cleaning the interface.**

#### Ventilator sometimes misses breaths.
- User is breathing faster than 40 BPM.
- Secretions have built up on the pillows of the interface.
- **It is normal for the ventilator to limit augmentation to less than 40 BPM.**
- **Inspect and clean the interface per the instruction for cleaning the interface.**

#### Ventilator sounds like it is triggering, but no gas is being delivered.
- No oxygen supply is connected.
- **Reconnect oxygen supply.**
This section describes how to change settings using the Utilities menu and instructions on basic care of the system.

**Changing Ventilator Settings**

With the Utilities menu, you can change the time and date, brightness of the touch screen, volume of audible alarms, and set alarms to vibrate mode.

**Getting to the Utilities Menu**

1. On any ventilator screen, touch the Wrench button.

2. On the Menu screen, touch Settings.

3. On the Settings Menu screen, touch Utilities. (The Clinician’s Settings menu is for clinician use only.)
**SETTING TIME AND DATE**

1. On the Utilities Menu screen, touch Set Time/Date.

2. On the Set Time/Date screen, touch the box you want to change.

3. Touch the Up arrow to increase the value in the box or the Down arrow to decrease it. If you press and hold an arrow, the value automatically increases or decreases.

4. Repeat steps 2 and 3 for each box you want to change, and then touch OK.

6. In the message asking if the settings are OK, touch Confirm.

   **Note:** Changes to settings only take effect when you touch Confirm.

---

**SETTING VIBRATION MODE**

The Set Vibration screen lets you change alarms from audible tones to a vibration. However, if a low- or medium-priority vibrating alarm occurs and is not resolved in 60 seconds, an audible alarm occurs. For a high-priority alarm, an audible tone immediately occurs with a vibration alarm with no delay.

1. On the Utilities Menu screen, touch Set Vibration.

2. On the Set Vibration screen, touch On or Off.

3. When you are finished, touch OK.

4. In the message asking if the settings are OK, touch Confirm, and check that the Vibrate icon appears at the bottom of the touch screen, indicating the ventilator is in vibrate mode.

   **Note:** Changes to settings only take effect when you touch Confirm.
5 SETUP AND CARE

SETTING AUDIO LOUDNESS

1 On the Utilities Menu screen, touch Set Loudness.

2 Touch the Up arrow to increase the volume level or the Down arrow to decrease it. If you press and hold an arrow, the number automatically increases or decreases.
   
   You can choose a loudness level between 1 and 5, with 5 being the loudest and 1 the quietest.

3 When you are finished, touch OK.

4 In the message asking if the settings are OK, touch Confirm.

   Note: Changes to settings only take effect when you touch Confirm.

ADJUSTING SCREEN BRIGHTNESS

1 On the Utilities Menu screen, touch Set Brightness.

2 Touch the Up arrow to increase the brightness or the Down arrow to decrease it. If you press and hold an arrow, the number automatically increases or decreases.

   You can choose a brightness level between 1 and 5, with 5 being the brightest and 1 the dimmest.

3 When you are finished, touch OK.

4 In the message asking if the settings are OK, touch Confirm.

   Note: Changes to settings only take effect when you touch Confirm.
VIEWING SOFTWARE VERSION INFORMATION

The Software Version screen displays the software version number, its release date, and the ventilator's total operating time.

Getting to the Software Version Screen

1. On any ventilator screen, touch the Wrench button.
2. On the Menu screen, touch Information.

The screen displays software version, serial number, and total operating time.

CARING FOR THE NIOV VENTILATION SYSTEM

This section gives instructions on how to care for the NIOV Ventilation System, including daily visual checks and guidelines for cleaning and storage.

Daily Visual Checks

Look at the ventilation system components daily. If you uncover any of the following, do not use the ventilation system. Contact your health care provider for instructions on servicing or replacing damaged ventilation system components.

- Check for cracks in the ventilator casing.
- Check the ventilator for loose or damaged buttons, connectors, or other control and alarm components.
- Check the oxygen supply hose and the interface for leaks and loose or damaged cabling or connectors.

Alarm Checks

Confirm that when the ventilator is turned on, it makes audible tones. If tones are not heard, the ventilator should be returned to your health care provider for servicing.

Cleaning the Ventilator

- Wipe the external surfaces of the ventilator with 70% isopropyl alcohol as necessary and between uses.
- Clean the touch screen with a soft microfiber cloth.

CAUTION: 70% isopropyl alcohol may damage the touch screen. When cleaning external surfaces of the ventilator with 70% isopropyl alcohol, avoid contact with the touch screen.

Cleaning External Surfaces of the Pillows Interface

- If mucus accumulates on the pillows of the interface, use a clean cloth to remove it.
- If dirt is visible on the outside of the interface, use a clean cloth and mild detergent to remove it.

Periodic Cleaning and Purging of the Pillows Interface

Periodically clean the interface following these steps:

1. Disconnect the interface from the ventilator.
2. Submerge the interface end of the interface in a clean container of warm water suitable for drinking, and agitate the interface to clean it.
3. Remove the interface from the water, and hang it so excess water drains from the interface.
4. Before reusing the interface, perform a purge to clear any excess water that may impede air flow. For purging instructions, see the section Purging the Pillows Interface that immediately follows.

WARNING: Do not subject the Pillows Interface to heat sterilization, hot water pasteurization, autoclaving, radiation sterilization, ethylene oxide gas sterilization, or attempt to clean it in a dishwasher or microwave oven. Doing any of these may damage the interface and impair oxygen delivery.
Purging the Pillows Interface
After cleaning the interface or when you suspect dust or debris has entered the air-flow passage, purge the interface.

1. Slide the regulator over the neck of the cylinder, and line up the pins on the regulator with the holes in the cylinder neck.

2. Tighten the tee screw on the regulator by turning the handle clockwise.

3. Place the larger end of the purge tube over the barbed outlet.

4. Open the oxygen main valve according to the cylinder and regulator manufacturers’ instructions.

5. Rotate the barbed outlet flow regulator to 4 LPM.

6. Firmly press and hold the smaller end of the purge tube over one of the interface ports that connects the interface to the ventilator. Take care not to slide the tube over the O-ring of the port. Hold the purge tube over the interface port until all the water is purged from the tube.

7. Repeat step 6 for the other interface port.

8. Rotate the barbed outlet flow regulator to the zero or OFF position.

9. Shut off the oxygen main valve according to the cylinder and regulator manufacturers’ instructions.

10. Remove the purge tube from the barbed outlet.

Maintenance
The NIOV Ventilation System does not require calibration or routine maintenance. Preventive maintenance, including replacing the O2 supply hose, is required after 2½ years of use. Contact your healthcare provider to make arrangements for preventive maintenance.

Environment Specifications
Do not use the NIOV Ventilation System if the ambient temperature is greater than 104°F (40°C) or less than 5°C (41°F).
Battery Retraining

After a battery has been charged numerous times, the battery charge icon may not accurately display the battery charge. For example, after fully charging the battery, the battery charge icon may only display 3 bars instead of 4. In this case, the battery has more charge than the battery charge icon indicates. Or, the battery charge icon may display 2 bars when the charge is really only 1. In this case, the battery has less charge than the battery icon indicates. If you notice that the battery seems to last longer or shorter than the battery charge icon suggests, you may need to "retrain" the battery so the icon more accurately displays the battery charge.

Retraining the battery involves discharging it fully and then recharging it fully until the battery icon on the touch screen accurately reflects a full charge and no charge.

To retrain a battery follow these steps:

1. Turn on the ventilator, press an Activity button, and let the battery discharge fully until the ventilator shuts itself off.
2. Confirm the ventilator is off. Connect the wall battery charger to the ventilator. Confirm that the charger light is red.
3. Let the ventilator charge until the charger light turns green.
4. Turn the ventilator on. Check that the battery charge icon displays four white bars. If it does not, repeat steps 2 - 4.

Note: You will encounter a System Fault alarm after turning on the ventilator once the battery is fully discharged and recharged again. Press OK on the alarm display screen to allow the ventilator to reboot.

If after repeating steps 2 - 4 a second time, the ventilator still does not show four white bars, contact your health care provider.

Battery Replacement

The internal ventilator battery is not serviced in the field. It should be replaced every 2.5 years or when runtime degrades to an unacceptable level. Contact your Breathe Technologies service provider to make arrangements for replacing the battery.

Oxygen Supply Information

The NIOV ventilator is compatible with compressed medical oxygen cylinders and hospital wall oxygen. The duration of compressed medical oxygen cylinders depends on the volume of the cylinder and the breathing pattern of each patient, which can change throughout the day. Observe your daily oxygen consumption a few times before estimating typical use. The following tables can be used to obtain approximate values only.

<table>
<thead>
<tr>
<th>Cylinder size B: 164 liters (M-6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breaths per minute (BPM)</td>
</tr>
<tr>
<td>12  14  16  18  20  22  24  26  28</td>
</tr>
<tr>
<td>Tidal volume (ml)</td>
</tr>
<tr>
<td>50</td>
</tr>
<tr>
<td>100</td>
</tr>
<tr>
<td>150</td>
</tr>
<tr>
<td>200</td>
</tr>
<tr>
<td>250</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Cylinder size D: 425 liters (M-15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breaths per minute (BPM)</td>
</tr>
<tr>
<td>12  14  16  18  20  22  24  26  28</td>
</tr>
<tr>
<td>Tidal volume (ml)</td>
</tr>
<tr>
<td>50</td>
</tr>
<tr>
<td>100</td>
</tr>
<tr>
<td>150</td>
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<tr>
<td>200</td>
</tr>
<tr>
<td>250</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Cylinder size E: 660 liters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breaths per minute (BPM)</td>
</tr>
<tr>
<td>12  14  16  18  20  22  24  26  28</td>
</tr>
<tr>
<td>Tidal volume (ml)</td>
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<td>50</td>
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<tr>
<td>150</td>
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<tr>
<td>200</td>
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<tr>
<td>250</td>
</tr>
<tr>
<td>Icon</td>
</tr>
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<tr>
<td><img src="image" alt="Power Button" /></td>
</tr>
<tr>
<td><img src="image" alt="Orientation Marker" /></td>
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<tr>
<td><img src="image" alt="Battery Status" /></td>
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<tr>
<td><img src="image" alt="Alarm Silence" /></td>
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<tr>
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<tr>
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<tr>
<td><img src="image" alt="Active Alarms" /></td>
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<tr>
<td><img src="image" alt="Low Activity" /></td>
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<tr>
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<td><img src="image" alt="Battery Status" /></td>
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<td><img src="image" alt="Battery Status" /></td>
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<tr>
<td>Icon</td>
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<tr>
<td>------</td>
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<td><img src="image3" alt="Touch Screen" /></td>
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<tr>
<td><img src="image4" alt="Wrench" /></td>
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<tr>
<td><img src="image6" alt="Ventilator" /></td>
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<tr>
<td><img src="image7" alt="BF Type Equipment" /></td>
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<tr>
<td><img src="image8" alt="IPX1" /></td>
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<td><img src="image9" alt="Class II Device" /></td>
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<td><img src="image10" alt="Documentation" /></td>
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<td><img src="image14" alt="Manufacturer" /></td>
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<tr>
<td><img src="image20" alt="European Economic Area Standards" /></td>
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<tr>
<td><img src="image21" alt="Battery Charge" /></td>
</tr>
<tr>
<td><img src="image22" alt="Battery Charger European Standards" /></td>
</tr>
</tbody>
</table>
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