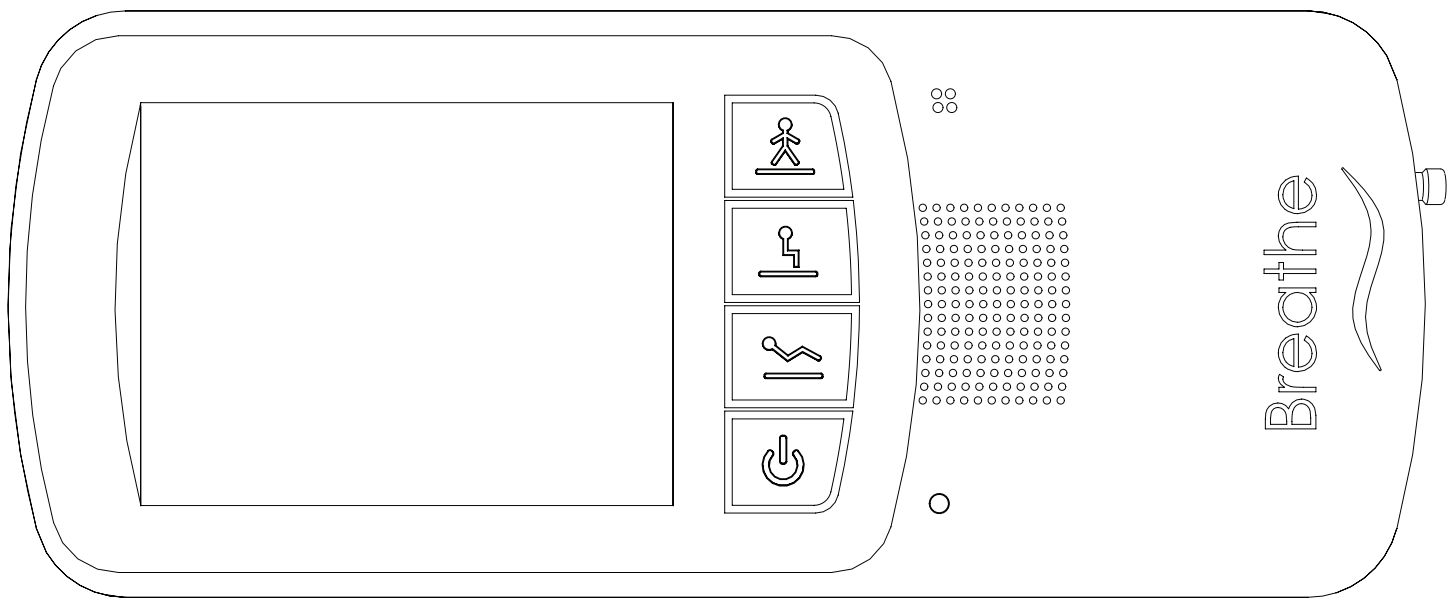




Hillrom™



LIFE2000® VENTILATOR

Clinician Instructions for Use

NOTICE OF EMERGENCY USE OF VENTILATORS DURING THE COVID-19 PANDEMIC

The FDA issued a guidance document on March 24, 2020, Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. During this emergency and while the policy is in effect, FDA does not intend to object to limited modifications to the FDA-cleared indications without prior submission of a 510(k) where the modifications do not create undue risks. Hillrom[™] does not yet have FDA 510(k) clearance on the use of The Life2000[®] Ventilator Software version 06.08.00.00. Hillrom[™] intends to adhere to FDA's recommendations to market The Life2000[®] Ventilator with appropriate testing and labeling while the policy is in effect but does not have specific 510(k) clearance at this time.

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CHAPTER 1: LIFE2000® VENTILATOR INTRODUCTION

INDICATIONS FOR USE

The Life2000® Ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation.

The ventilator is intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult patients who require the following types of ventilatory support:

- Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask).
- Assist/Control mode of ventilation.





The ventilator is suitable for use in institutional settings.

WARNING:

Use the Life2000® Ventilator only for patients who meet the Indications for Use. If the ventilator is used for patients that do not meet the Indications for Use, patients may not receive appropriate respiratory therapy.

SYMBOLS AND CONVENTIONS

The following symbols and conventions are used throughout this manual:

THIS	MEANS THIS
 WARNING:	Indicates hazards that, if not avoided, may cause severe injury or death.
 CAUTION:	Indicates hazards that, if not avoided, may result in minor or moderate injury, or damage to or impaired performance of equipment.
 TIP: and  TIPS:	Indicates tips that may be helpful when using the ventilator.
NOTE: and NOTES:	Indicates additional information about a behavior or feature.
BOLD TEXT	Buttons, icons, menu items, and screen names displayed on the touch screen are indicated with bold text. For example, the Menu screen has several buttons, including Home Screen , Settings , and Information .

1 LIFE2000® VENTILATOR INTRODUCTION

SAFETY INFORMATION

Please read the following safety warnings and cautions in their entirety before using the Life2000® Ventilator. Warnings and cautions can also be found throughout this *Instructions for Use*.



WARNING:

- The Life2000® Ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician.
- Use the Life2000® Ventilator only for patients who meet the Indications for Use. If the ventilator is used for patients that do not meet the Indications for Use, patients may not receive appropriate respiratory therapy.
- If the Life2000® Ventilator is not functioning properly, respiratory therapy may be compromised and may result in patient harm or death. Always have an alternate means of ventilation or oxygen therapy available.
- The operator of the ventilator is responsible for reading and understanding this manual before use.
- Failure to read this *Instructions for Use* may result in product misuse, which may cause equipment damage or patient mistreatment.
- The prescription and other device settings should only be changed on the order of the supervising physician.
- 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.
- 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 or open flame because flammable materials burn more readily in the presence of oxygen.
- Do not submerge the ventilator in liquids or pour liquids on it. Liquids may cause components in the ventilator to malfunction.
- Do not use the Life2000® Ventilator in magnetic resonance imaging (MRI) environments. MRI equipment may cause electronic components in the ventilator to malfunction.
- Do not use the ventilator in the presence of flammable anesthetics.
- Do not use the ventilator with oxygen in the presence of flammable anesthetics such as fluroxene, cyclopropane, divinyl ether, ethyl chloride, ethyl ether, and ethylene, as they may form flammable or explosive mixtures with oxygen.
- Do not use the ventilator with helium or helium mixtures.
- Do not use the ventilator with nitric oxide.
- Do not use the ventilator in a hyperbaric chamber.
- 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 while using the ventilator may also increase the risk of choking.
- Do not insert foreign objects into any part of the ventilator.
- The backside of the ventilator enclosure may reach 49°C in a 40°C environment.
- Unauthorized modifications can result in equipment damage, or patient injury or death.

⚠ WARNING:

- For any accessories, read the label and accompanying document(s) before use.
- Use only approved accessories and replacement parts with the ventilator. If unauthorized accessories or replacement parts are used with the ventilator, the ventilator may be damaged and performance may be degraded.
- Do not connect the ventilator components or accessories to any other equipment that is not described in this *Instructions for Use*.
- Adding attachments or other components and/or sub-assemblies to the ventilator breathing system can cause an increase in expiratory resistance at the patient connection
- Adding humidification or nebulization can increase the resistance of the breathing circuit. The operator of the ventilator needs to monitor the breathing system for increased resistance and blockage.
- Ventilator accuracy can be affected by the gas added by use of a nebulizer.
- Adding attachments or other components or sub-assemblies to the ventilator can change the pressure gradient across the ventilator system and can affect ventilator performance.
- To ensure accuracy of oxygen administration and to monitor for the presence of contamination (incorrect gas connected), use an external oxygen monitor to verify the oxygen concentration in the delivered gas.
- To monitor minute volume, use an external exhaled volume monitor.
- Before beginning ventilation therapy, verify that there is an adequate supply of source gas for the intended duration of the therapy. Otherwise, the patient may not receive appropriate therapy.
- Use only an approved oxygen or air hose with the ventilator. If an unauthorized oxygen or air hose is used with the ventilator, the ventilator may be damaged.
- Use the ventilator only with approved medical compressed gas (oxygen or dry air). Use with non-approved sources of gas may cause the ventilator to malfunction and the patient may not receive appropriate respiratory therapy.
- If the ventilator is not used with a regulator capable of 41 PSI to 87 PSI (nominal 50 PSI) with greater than 40 LPM capability, patients may not receive appropriate respiratory therapy.
- To prevent risk of cross-contamination, clean and disinfect the ventilator before using it on a new patient, and use a new Breathe Pillows Entrainment Interface.
- The Breathe Pillows Entrainment Interface is designed for single-patient use. To prevent risk of cross-contamination, use a new Breathe Pillows Entrainment Interface.
- Do not subject Breathe Pillows Entrainment Interface to heat sterilization, hot water pasteurization, autoclaving, radiation sterilization, ethylene oxide gas sterilization, or attempt to clean them in a dishwasher or microwave oven. Doing any of these may damage the interface and impair gas delivery.
- Properly secure the Breathe Pillows Entrainment Interface to the face and route tubing around the ears to avoid strangulation.
- Do not cover the ventilator, touch screen, speaker, or backup alarm buzzer with tape or any other object. Covering the ventilator or any of its parts might cause difficulty in hearing alarms and might affect ventilator performance.
- Reducing the alarm loudness level to lower than the ambient sound level will impede alarm condition recognition.
- If upgrading software from version 05.11.00 to 05.12.00 re-evaluate the ventilator settings if PEEP is applied
- If upgrading a patient ventilator from ventilator REF MS-01-0001 to ventilator REF MS-01-0118 re-evaluate ventilator settings if PEEP is applied.

1 LIFE2000® VENTILATOR INTRODUCTION

CAUTION:

- No user serviceable components are inside the device.
- 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.
- Use only the 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.
- 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 fall and be damaged.
- Secure the ventilator to prevent it from falling or becoming damaged.
- A 90-day replacement schedule for the Breathe Pillows Entrainment Interface is recommended.
- Do not use a Breathe Pillows Entrainment Interface that is cracked, odorous, broken, or kinked. If a damaged interface is used, the patient may not receive adequate respiratory therapy.
- 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.
- Keep in a clean environment to protect the equipment from ingress of dust, lint, and pests.
- Do not leave exposed to the sun or other sources of radiant heat, it may overheat.
- Do not allow children or pets to access the ventilator; it may become damaged.

FEATURES

The Life2000® Ventilator is a critical care, volume control mechanical ventilator designed for a broad range of applications in care settings. The ventilator is compatible with any 50-PSI (nominal) medical-grade oxygen or air source, and:

- Offers three different volume control modes of operation:
 - Control Ventilation
 - Assist/Control Ventilation
 - Assist Ventilation.
- Enables clinicians to define three Prescription Settings based on patient needs.
- Allows for an adjustable PEEP setting for each Prescription Setting.
- Allows for an adjustable trigger sensitivity for each Prescription Setting.
- Includes the ability to set various critical alarms for each Prescription Setting.
- Has up to four hours of battery-powered operation.
- Displays patient breath rate, Peak Inspiratory Pressure (PIP), average flow, and current volume level.

LIFE2000® VENTILATOR VERSIONS

There are two released ventilator versions of the Life2000® Ventilator. You will be able to identify the version of the ventilator based on the REF number.

The functionality of the ventilator's Communication Port, Battery Charge Icon, and System Alarms differ for each version of the ventilator. Please make sure to identify the REF number of the ventilator to ensure proper use of your system.

IDENTIFYING THE REF NUMBER

The REF number is located on the label on the back of the ventilator, see examples below.



1 LIFE2000® VENTILATOR INTRODUCTION

PACKAGING CONTENTS

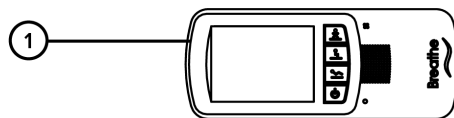
⚠ WARNING: For any accessories, read the label and accompanying document(s) before use.

i TIP:

The ventilator is shipped in specially designed, protective boxes. Do not throw away the boxes; keep them for future transportation needs.

1 Life2000® Ventilator (ventilator)

The ventilator can be used with medical grade 50-PSI (nominal) pressure sources.



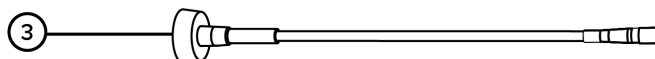
2 Battery charger and AC power cord

The battery charger and AC power cord connect the ventilator to an AC power source.



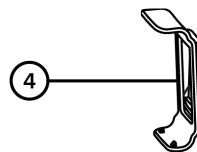
3 Oxygen hose (6 ft.)

This high-pressure hose can be used to connect the ventilator to an oxygen cylinder.



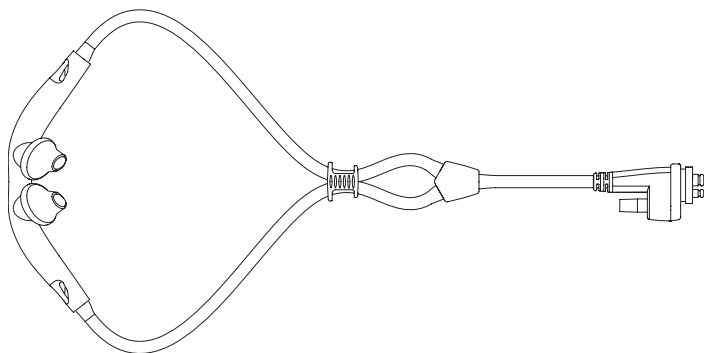
4 Belt clip

The belt clip is used to secure the ventilator.



NOTE: Packaging contents may vary depending on the part number ordered.

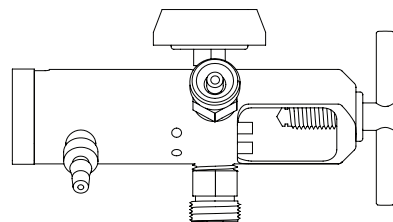
ESSENTIAL ACCESSORIES



Breathe Pillows Entrainment Interface

The Life2000® Ventilator requires the use the Breathe Pillows Entrainment Interface.

The non-invasive Breathe Pillows Entrainment Interface connects directly to the ventilator and is available in four sizes: extra small, small, medium, and large.

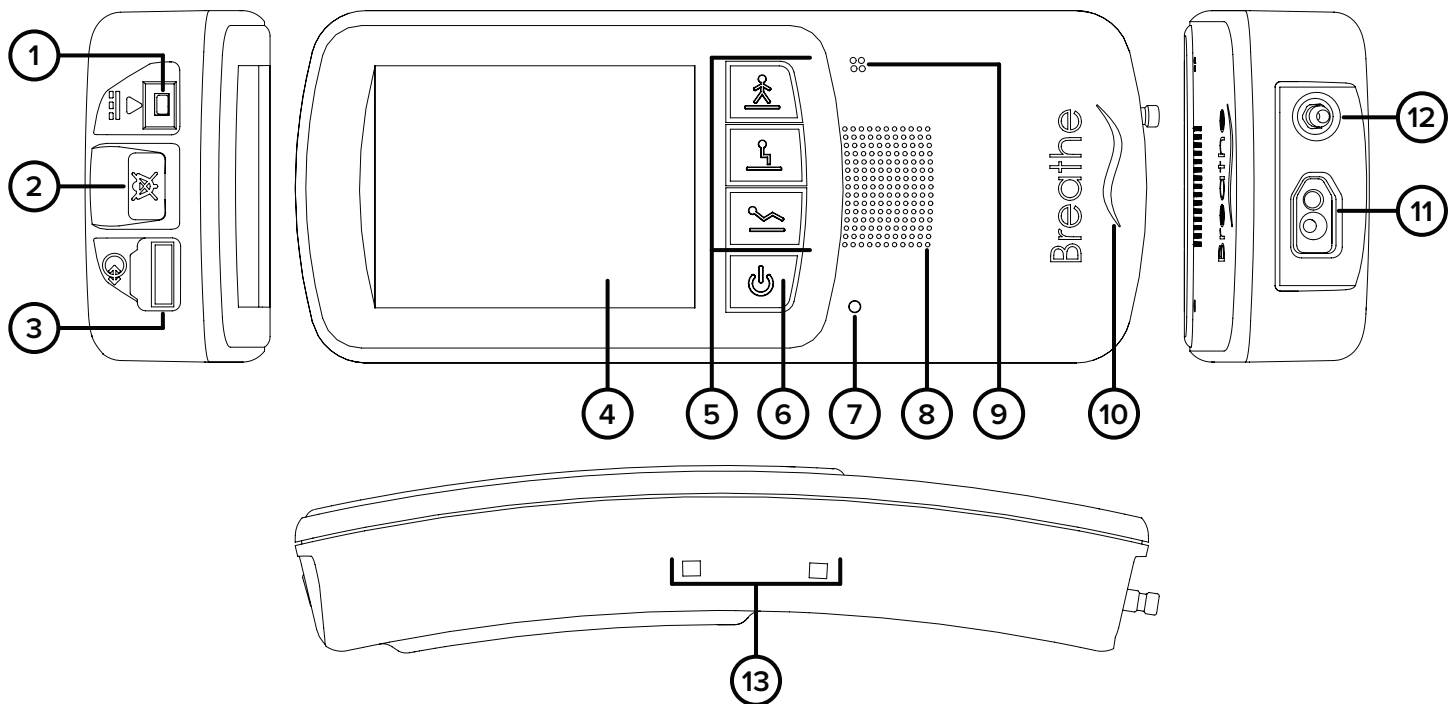


Oxygen or air regulator

A regulator is required and must be obtained separately to connect the ventilator to an oxygen or air cylinder. For regulator requirements see "Connecting to a Source Gas Cylinder" on page 14.

NOTE: A regulator is not required when using a wall pressure source.




COMPONENTS



TOP

- 1** Battery charger connection
- 2** Silence Alarm button
- 3** Communication Port

FRONT

- 4** Touch screen
- 5** Prescription Settings buttons
 -  High Activity button
 -  Medium Activity button
 -  Low Activity button
- 6** Power button
- 7** Power indicator light
- 8** Alarm speaker
- 9** Backup alarm speaker
- 10** Breath indicator light

BOTTOM

- 11** Interface connection
- 12** Gas inlet connection

SIDES

- 13** Belt clip sockets

CHAPTER 2: VENTILATOR SETUP

VENTILATOR SETUP

This chapter provides information about powering on and securing the ventilator, and instructions for connecting the Life2000® Ventilator to a pressure source by using an oxygen hose or optional air hose.

A regulator is required to connect the ventilator to an oxygen or air cylinder.

An adapter may be required to connect to a wall source.

NOTES:

- If not connected to AC power, make sure the ventilator battery has sufficient charge for your length of use.
- Instructions provided here are not intended to supersede your facility's procedures; always follow your facility's procedures.
- The responsible organization is responsible for ensuring compatibility of the ventilator and the parts used to connect to the patient before use.

TESTING THE VENTILATOR

In a multi-patient setting, the ventilator must be tested before it is assigned to a new patient. For instructions on testing the ventilator, see "Testing Ventilator Alarms" on page 76.

CONNECTING TO A PRESSURE SOURCE

Connect the ventilator to a 50-PSI (nominal) medical grade oxygen or air pressure source, such as a wall source or cylinder, by using the Life2000® oxygen or air hose.

Choose the appropriate hose for the source gas cylinder you will use. A 6 ft. oxygen hose is included with the ventilator and is compatible with medical oxygen pressure sources. Connection to an air pressure source requires an optional air hose. For information about ordering accessories and replacement parts, see "Accessories and Replacement Parts" on page 89.

A regulator is required to connect the ventilator to an oxygen or air cylinder.

An adapter may be required to connect to a wall source.

WARNING:

- Use the ventilator only with approved medical compressed gas (oxygen or dry air). Use with non-approved sources of gas may cause the ventilator to malfunction and the patient may not receive appropriate respiratory therapy.
- Use only an approved Life2000® oxygen or air hose with the ventilator. If an unauthorized oxygen or air hose is used with the ventilator, the ventilator may be damaged.
- Do not use the Life2000® Ventilator with oxygen in the presence of flammable anesthetics such as fluroxene, cyclopropane, divinyl ether, ethyl chloride, ethyl ether, and ethylene, as they may form flammable or explosive mixtures with oxygen.
- 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 or open flame because flammable materials burn more readily in the presence of oxygen.
- Do not use the ventilator in the presence of flammable anesthetics.

TIP:

The oxygen or air 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 delivering therapy, a Low Gas Pressure alarm will occur. For more information see "Low Gas Pressure" on page 62.

2 VENTILATOR SETUP

CONNECTING TO A SOURCE GAS CYLINDER

A regulator is required to connect the ventilator to an oxygen or air cylinder. Ensure that the gas regulator meets the requirements below and is appropriate for the cylinder being used.

REGULATOR REQUIREMENTS	
Pressure output	41-87 PSI (50 PSI nominal)
Pressure flow	≥ 40 LPM at ≥ 41 PSI
Pressure fitting	DISS 1240 for use with an oxygen hose and cylinder
	DISS 1160-A for use with an air hose and cylinder
Flow fitting*	¼" Barb connector
Minimum required selectable flow*	0, 4 (L/min)

* Required for purging only. For more information, see "Purging the Breathe Pillows Entrainment Interface" on page 72.



WARNING:

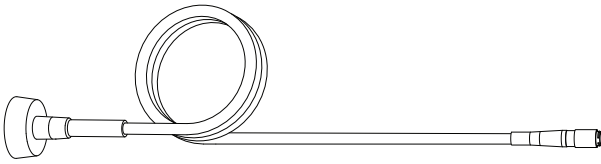
- If the ventilator is not used with a regulator capable of 41 PSI to 87 PSI (nominal 50 PSI) with greater than 40 LPM capability, patients may not receive appropriate respiratory therapy.
- Before beginning ventilation therapy, verify that there is an adequate supply of source gas for the intended duration of the therapy. Otherwise, the patient may not receive appropriate therapy.



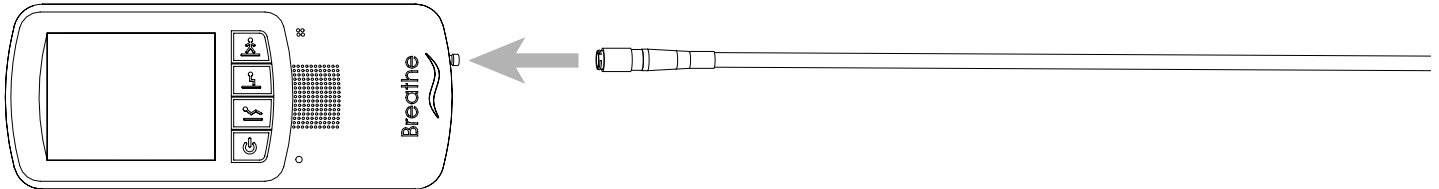
TIPS:

- If using a cylinder, make sure your gas supply is sufficient for your length of use. For more information about estimating gas usage, see "Cylinder Duration Information" on page 16.
- The Life2000® Ventilator can work using most common medical grade gas cylinders when using the appropriately-rated regulator. Ensure the appropriate regulator for the cylinder is being used before connecting to the ventilator. Information about the gas cylinder and its specific regulator requirements may be found by contacting the gas cylinder supplier.

- 1 Choose the appropriate hose for the source gas cylinder.



- 2 Visually inspect the oxygen or air hose for damage before using it.
- 3 Ensure the ventilator is powered off.



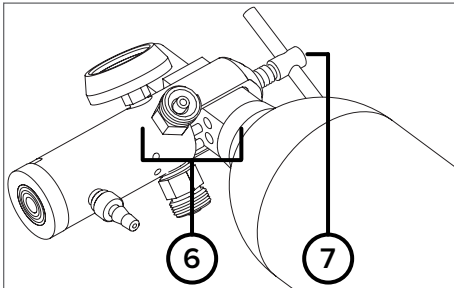
- 4 Connect the oxygen or air hose to the ventilator by pushing the small quick connect end of the hose onto the gas inlet connection on the ventilator; when connected, the quick connect end will click into place.

NOTE: To disconnect the gas hose from the ventilator, pull back on the quick connect end of the hose.

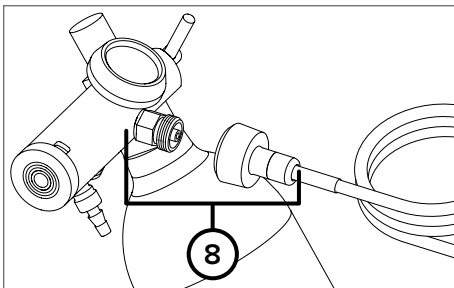
Refer to the regulator and source gas supply manufacturers' instructions for more information about how to connect the cylinder and regulator; the instructions below are provided as an example.

NOTE: If using a cylinder with a built-in regulator, skip to step 8.

- 5 Ensure that the regulator is preset to 50 PSI [or adjust the regulator pressure to 41 PSI to 87 PSI (50 PSI nominal)].



- 6 Slide the regulator over the neck of the cylinder, and line up the pins on the regulator with the holes in the cylinder neck.
- 7 Tighten the tee screw on the regulator by turning the handle clockwise.



- 8 Connect the oxygen or air hose to the DISS connector end of the regulator by turning it clockwise.
NOTE: If present, the barbed outlet flow regulator should be set to 0 or OFF during use to conserve your gas supply.
- 9 Turn on the gas supply according to the regulator and gas cylinder manufacturers' instructions.
NOTE: When not in use, turn off the gas supply according to the regulator and gas supply manufacturers' instructions.

2 VENTILATOR SETUP

CYLINDER DURATION INFORMATION

The duration of compressed medical oxygen and air cylinders depends on the volume of the cylinder and the breathing pattern of each patient, which can change throughout the day. Observe daily air and/or oxygen consumption a few times before estimating typical use. The following tables can be used to obtain approximate values only.

NOTE: These tables assume a PEEP value of 0 cmH₂O.

CYLINDER SIZE B: 164 LITERS (M6)

	BREATHS PER MINUTE (BPM)								
	12	14	16	18	20	22	24	26	28
Volume (ml)	Duration in hours								
50	4.6	3.9	3.4	3.0	2.7	2.5	2.3	2.1	2.0
100	2.3	2.0	1.7	1.5	1.4	1.2	1.1	1.1	1.0
150	1.5	1.3	1.1	1.0	0.9	0.8	0.8	0.7	0.7
200	1.1	1.0	0.9	0.8	0.7	0.6	0.6	0.5	0.5
250	0.9	0.8	0.7	0.6	0.5	0.5	0.5	0.4	0.4
500	0.5	0.4	0.3	0.3	0.3	0.2	0.2	0.2	0.2
750	0.3	0.3	0.2	0.2	0.2	0.2	0.2	0.1	0.1

CYLINDER SIZE D: 425 LITERS (M15)

	BREATHS PER MINUTE (BPM)								
	12	14	16	18	20	22	24	26	28
Volume (ml)	Duration in hours								
50	11.8	10.1	8.9	7.9	7.1	6.4	5.9	5.4	5.1
100	5.9	5.1	4.4	3.9	3.5	3.2	3.0	2.7	2.5
150	3.9	3.4	3.0	2.6	2.4	2.1	2.0	1.8	1.7
200	3.0	2.5	2.2	2.0	1.8	1.6	1.5	1.4	1.3
250	2.4	2.0	1.8	1.6	1.4	1.3	1.2	1.1	1.0
500	1.2	1.0	0.9	0.8	0.7	0.6	0.6	0.5	0.5
750	0.8	0.7	0.6	0.5	0.5	0.4	0.4	0.4	0.3

CYLINDER SIZE E: 660 LITERS (M24)

	BREATHS PER MINUTE (BPM)								
	12	14	16	18	20	22	24	26	28
Volume (ml)	Duration in hours								
50	18.3	15.7	13.8	12.2	11.0	10.0	9.2	8.5	7.9
100	9.2	7.9	6.9	6.1	5.5	5.0	4.6	4.2	3.9
150	6.1	5.2	4.6	4.1	3.7	3.3	3.1	2.8	2.6
200	4.6	3.9	3.4	3.1	2.8	2.5	2.3	2.1	2.0
250	3.7	3.1	2.8	2.4	2.2	2.0	1.8	1.7	1.6
500	1.8	1.6	1.4	1.2	1.1	1.0	0.9	0.8	0.8
750	1.2	1.0	0.9	0.8	0.7	0.7	0.6	0.6	0.5

For other cylinder sizes or partially-filled cylinders, the following chart and equation can be used to estimate cylinder duration.

GAS USAGE (LPM) CHART

	BREATHS PER MINUTE (BPM)								
	12	14	16	18	20	22	24	26	28
Volume (ml)	Gas Usage (LPM)								
50	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4
100	1.2	1.4	1.6	1.8	2.0	2.2	2.4	2.6	2.8
150	1.8	2.1	2.4	2.7	3.0	3.3	3.6	3.9	4.2
200	2.4	2.8	3.2	3.6	4.0	4.4	4.8	5.2	5.6
250	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0
500	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0
750	9.0	10.5	12.0	13.5	15.0	16.5	18.0	19.5	21.0

NOTE: This table uses a PEEP value of 0 cmH₂O.

$$\text{cylinder duration (minutes)} = \frac{\left(\frac{P_T V_T}{14.7} \right)}{\text{gas usage (LPM)}}$$

Where:

P_T = cylinder pressure (per the regulator gauge, typically 2200 PSI for full cylinder),

V_T = empty cylinder volume or water volume (4.5L for an E cylinder), and

Gas usage (LPM) = determined by values displayed on the ventilator **Home Screen**, or by the Gas Usage Chart above.

REPLACING THE SOURCE GAS CYLINDER

When the source gas cylinder needs to be replaced:

- 1 Place the patient on an alternate means of ventilation, if necessary.
- 2 Power off the ventilator.
NOTE: Alarms might be encountered and/or the Prescription Setting might be inadvertently changed if the ventilator is not powered off before replacing the cylinder.
- 3 Turn off gas supply according to the regulator and gas supply manufacturers' instructions.
- 4 Remove the regulator and attached gas hose from the old cylinder by turning the handle counterclockwise.
- 5 Slide the regulator over the neck of the new cylinder, and line up the pins on the regulator with the holes in the cylinder neck. Tighten the tee screw on the regulator by turning the handle clockwise. (The gas supply hose should still be connected to the regulator.)
- 6 Turn on gas supply according to the regulator and gas supply manufacturers' instructions.
- 7 Power on the ventilator.

NOTE: Ventilation will not begin until a Prescription Setting button is selected. For more information see "Choosing a Prescription Setting Button" on page 46.

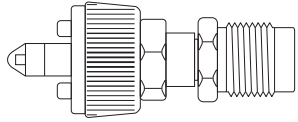
2 VENTILATOR SETUP

CONNECTING TO A WALL PRESSURE SOURCE

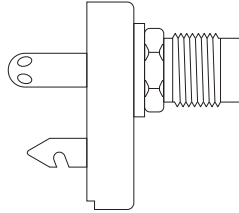
To connect to your facility's medical gas wall sources, the Life2000® Ventilator oxygen hose requires a DISS 1240 fitting. An adapter may be required; examples of common adapters are provided below.

ADAPTERS FOR OXYGEN WALL CONNECTIONS

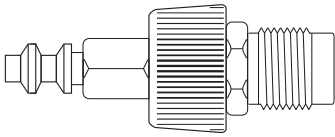
OHMEDA



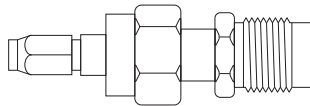
CHEMETRON



PURITAN-BENNETT

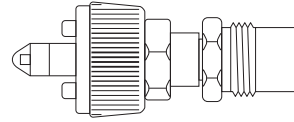


SCHRADER

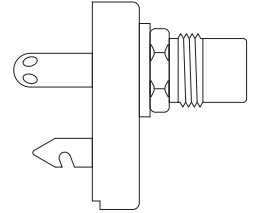


ADAPTERS FOR AIR WALL CONNECTIONS

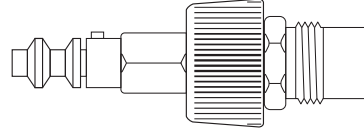
OHMEDA



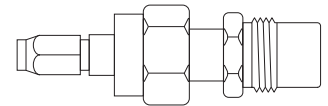
CHEMETRON



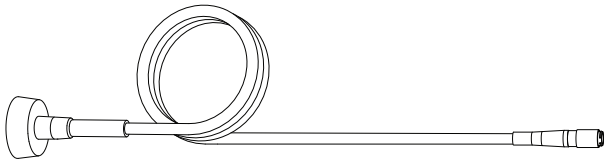
PURITAN-BENNETT



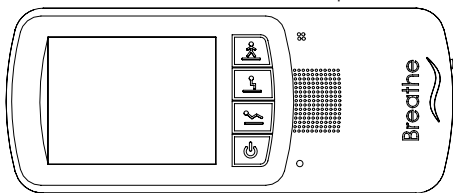
SCHRADER



- 1 Choose the appropriate hose for the source gas.

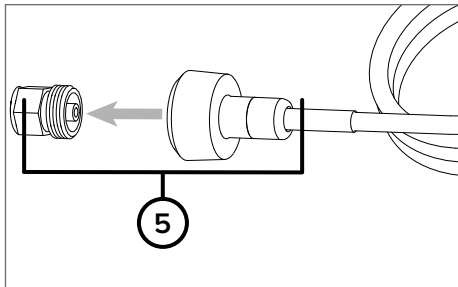


- 2 Visually inspect the oxygen or air hose for damage before using it.
- 3 Ensure the ventilator is powered off.



- 4 Connect the oxygen or air hose to the ventilator by pushing the small quick connect end of the hose onto the gas inlet connection on the ventilator; when connected, the quick connect end will click into place.

NOTE: To disconnect the gas hose from the ventilator, pull back on the quick connect end of the hose.



- 5 Connect the oxygen or air hose to the DISS connector end of the wall pressure source or adapter by turning it clockwise.

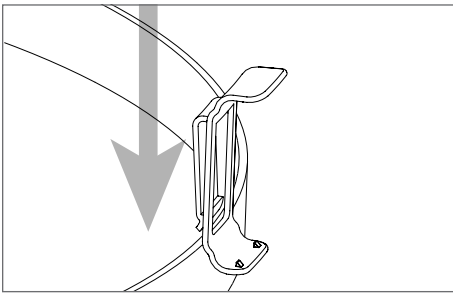
SECURING THE VENTILATOR

BELT CLIP

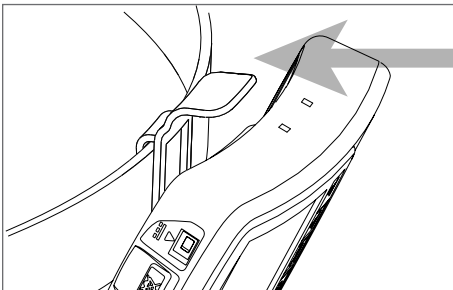
You can attach the ventilator to a belt or waistband using the included belt clip. The ventilator can be worn on either the right or left side.

CAUTION:

- Make sure the clip is securely fastened to the belt and the ventilator. If the clip is not securely fastened to the belt and the ventilator, the ventilator may fall and be damaged.
- Always secure the ventilator to prevent it from falling or becoming damaged.
- Use only the approved belt clip with the ventilator.



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



- 2 Line up the belt clip with the belt clip sockets on the ventilator. Push in the ventilator towards the belt clip until the ventilator clicks into place on both the top and bottom.

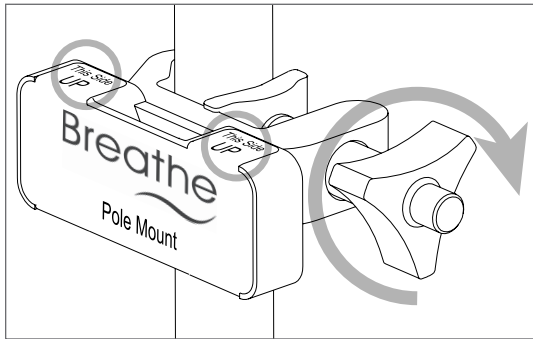
2 VENTILATOR SETUP

POLE MOUNT

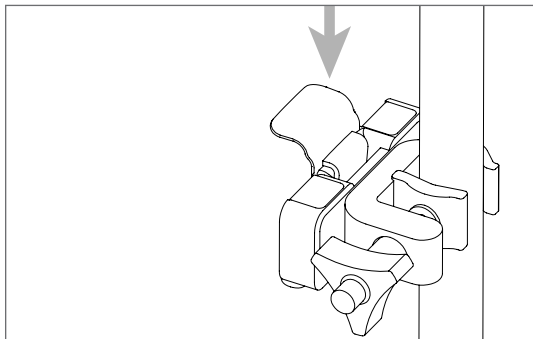
You can attach the ventilator to a pole or railing using an optional pole mount. For information about ordering accessories and replacement parts, see "Accessories and Replacement Parts" on page 89.

CAUTION:

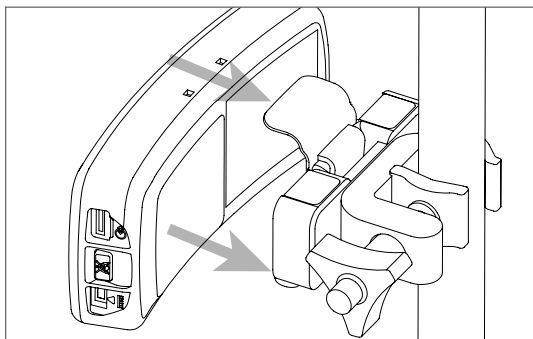
- Make sure the pole mount is securely attached to the pole, and the ventilator and clip are securely fastened to the pole mount and the ventilator. If the clip is not securely attached to the pole mount and the ventilator, the ventilator may fall and be damaged.
- Always secure the ventilator to prevent it from falling or becoming damaged.
- Use only the approved belt clip and pole mount with the ventilator.



- 1 Position the pole mount around the pole in the correct orientation.
- 2 Turn the knob on the pole mount until the pole mount is securely attached to the pole.

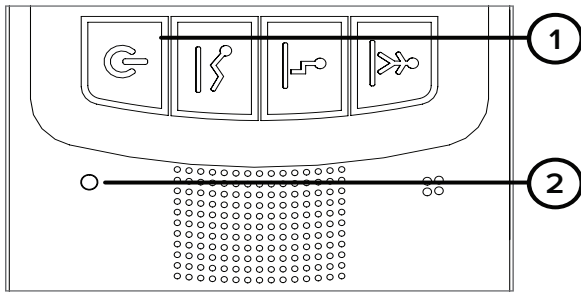


- 3 Slide the belt clip for the ventilator into the opening on the top of the pole mount and push down until it clicks into place.

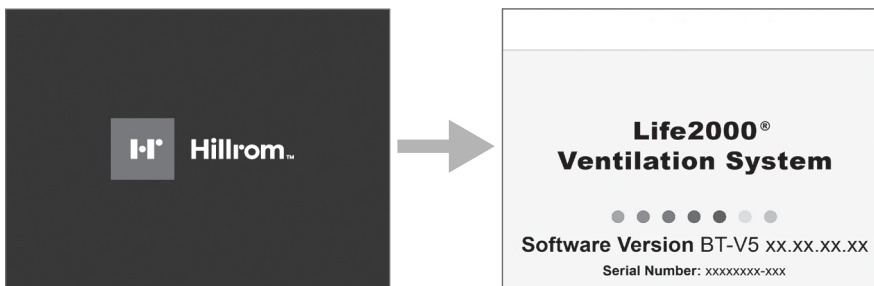


- 4 Attach the ventilator to the belt clip on the pole mount by lining up the belt clip with the belt clip sockets on the ventilator. Push the ventilator in towards the vent clip and pole mount until the ventilator clicks into place on both the top and bottom.

POWERING ON SEQUENCE

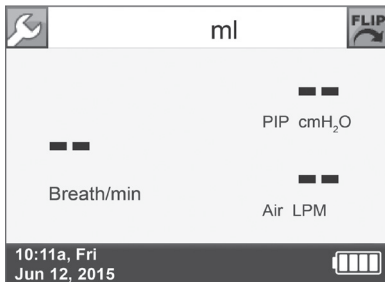


- 1 Power on the ventilator by pressing the power button.
- 2 Ensure that the green power indicator light is on.



- 3 When the startup screen is displayed, listen for audible tones to test the alarm speaker.

During the start up sequence, the ventilator will perform 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 tones when you turn on the ventilator, contact your service representative.



- 4 When the **Home Screen** is displayed, the touch screen is ready to use.

NOTE: Ventilation will not begin until a Prescription Setting button is selected. For more information see "Choosing a Prescription Setting Button" on page 46.

TIP:

The ventilator is shipped with factory-set default values. Be sure to adjust the **Prescription Settings** based on a physician's order before use. For more information see "Chapter 4: Ventilation Settings" on page 30.

2 VENTILATOR SETUP

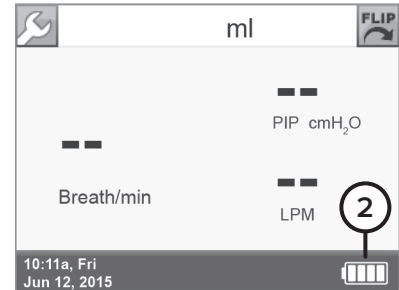
CHECKING THE BATTERY CHARGE

BATTERY CHARGE ICONS AND APPROXIMATE TIME REMAINING

- 1 Ensure that the ventilator is powered on.
- 2 Check the Ventilator Battery Charge icon on the touch screen to see the current battery charge level for the ventilator. Refer to the chart below to determine the approximate amount of ventilator battery charge.

When the ventilator is connected to AC, the ventilator battery charge icon should display either the charging icon or the icon for 100% charged.

NOTE: There may be a delay of up to 20 seconds before the Ventilator Battery Charge icon appears on the touch screen.



BATTERY CHARGE ICON							
APPROX. CHARGE AMOUNT	Charging*	< 5%	< 15%	15–35%	36–56%	57–79% 57-84%»	80–100% 85-100%»
APPROX. TIME REMAINING	N/A	Critically low. Recharge immediately.	Less than 0.5 hour. [†] ** Recharge immediately.	0.5–1.5 hours ^{†**}	1.5-2.5 hours**	2.5-3 hours**	4-5 hours **
			Less than 0.75 hour. [†] Recharge immediately.	0.75–2 hours [‡]	2-3.25 hours [‡]	3.25-5 hours [‡]	5-6 hours [‡]

Approx. Time Remaining based on the following ventilator settings: BR 12, Volume 350, PEEP 0, I-Time 1.0

**Applicable to Ventilator REF MS-01-0100

› Applicable to Ventilator REF MS-01-0118

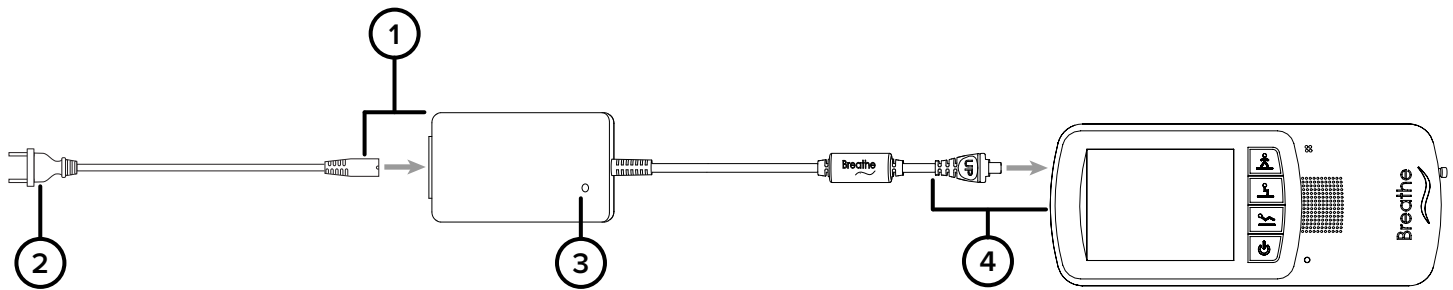
»Applicable to Software version 5.12.00 or 06.06.00 or greater

* The charging icon may still appear when the ventilator is 100% charged.

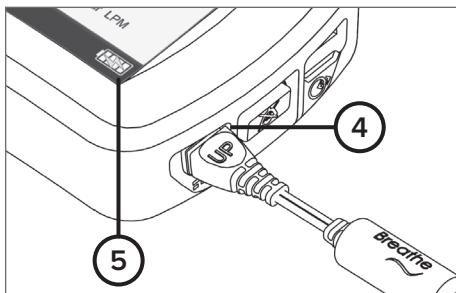
[†] Very low battery alarm will sound with less than 15% charge.

[‡] Low battery alarm will sound with less than 25% charge.

CHARGING THE VENTILATOR



- 1 Plug the AC power cord into the battery charger.
- 2 Connect the AC plug into an AC power source.
- 3 The battery charger indicator light will turn green or red when connected to AC power.



- 4 Connect the battery charger cord to the battery charger connection port. The word "UP" on the battery charger cord will be on top.
- 5 If powered on, check the **Battery Charge Icon** on the touch screen to see the ventilator's current battery charge status.

NOTES:

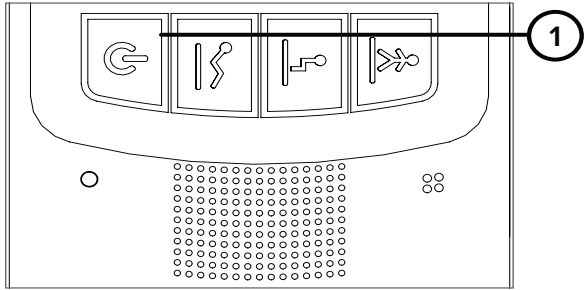
- When charging the battery, there may be a 5-10 second delay before the **Battery Charge Icon** appears on the touch screen.
- The ventilator can be used while the battery is charging.
- The ventilator performance is the same regardless of power source (internal battery or AC).
- A fully charged battery in good condition is designed to operate for four hours of typical use, but exact operating time depends on patient breath rate.
- The ventilator sounds an alarm and displays an alarm message when the battery has less than 25% of its charge and then again when it has less than 15%.

⚠ CAUTION:

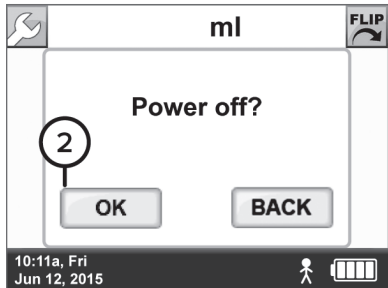
- Do not place the battery charger on wet surfaces or use in wet environments. Wet environments may damage the battery charger and may cause electric shock.
- Use only the approved battery charger and cord set with the ventilator. If an unauthorized battery charger or cord set is used with the ventilator, the ventilator may be damaged.

2 VENTILATOR SETUP

POWERING OFF SEQUENCE FOR THE VENTILATOR



- 1 To power off the ventilator, press the Power button for three seconds until a confirmation screen appears.



- 2 To continue to power off the ventilator, choose **OK**.

NOTE: If a selection is not made within 20 seconds or if the **BACK** button is selected, the previous screen will be displayed and the ventilation status will not be affected.

CHAPTER 3: CONNECTING THE INTERFACE

THE INTERFACES

The Life2000® Ventilator requires the use of the Breathe Pillows Entrainment Interface or the Universal Circuit® Connector. These interfaces are only compatible with Hillrom_® ventilators.

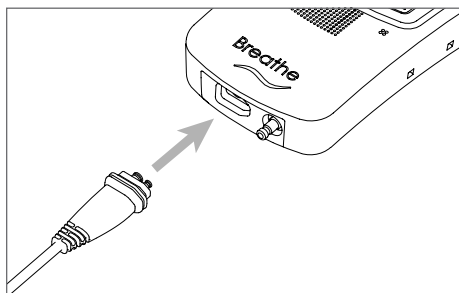
The non-invasive Breathe Pillows Entrainment Interface connects directly to the ventilator and is available in four sizes: extra small, small, medium, and large.

The Universal Circuit® Connector is used to connect any commercially available non-invasive mask (full face, nasal, or pillows) or tracheostomy tube to a Life2000® ventilator.

NOTES:

- For information about ordering accessories and replacement parts, see "Accessories and Replacement Parts" on page 89.
- Before using an interface, visually inspect it for damage.
- If the patient experiences adverse side effects, discontinue use of the interface and contact a physician.

CONNECTING THE INTERFACE TO THE VENTILATOR

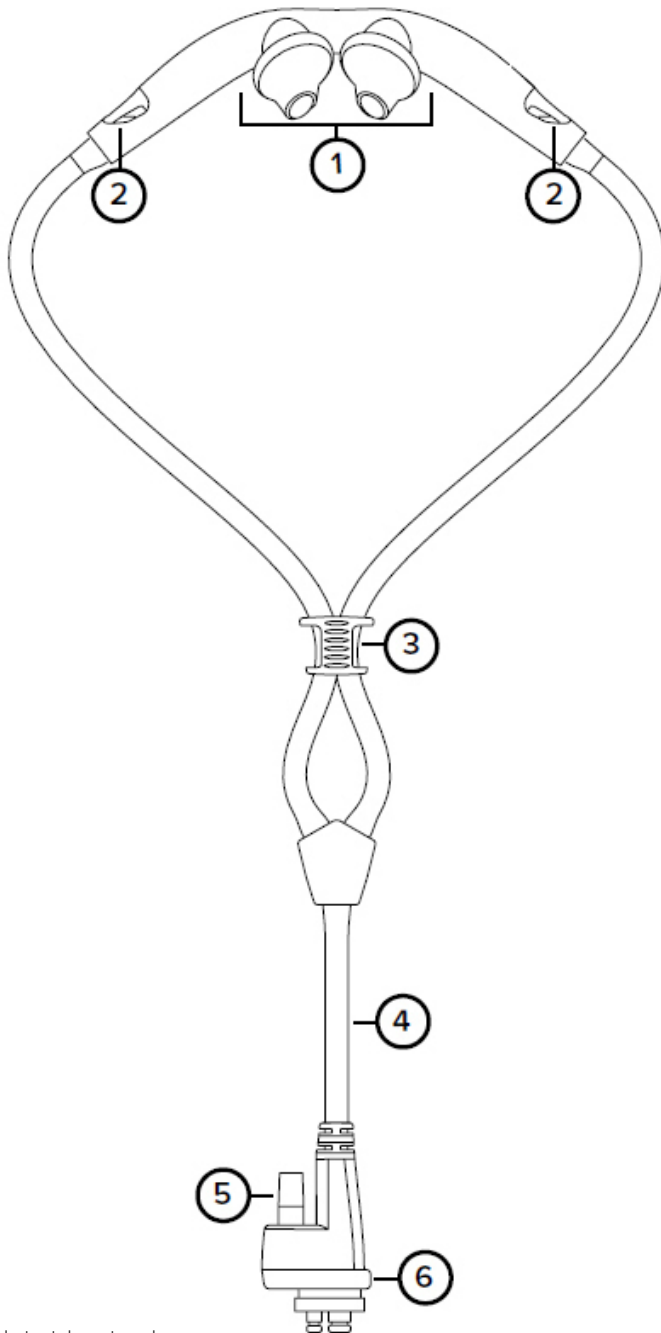


Plug the interface into the interface connection on the bottom of the ventilator until it clicks.

3 CONNECTING THE INTERFACE

THE BREATHE PILLOWS ENTRAINMENT INTERFACE

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



Product not shown to scale.

Breathe Pillows Entrainment Interface

- ① Nasal pillows (patient side)
- ② Entrainment ports
- ③ Tube fit adjuster (cinch)
- ④ Interface tubing
- ⑤ Oxygen tubing connection (*)
- ⑥ Ventilator connector

Required, but not included: (*)

CombO₂® hose or third-party oxygen tubing (e.g., Salter Labs® Oxygen Tubing).

⚠ CAUTION:

- Do not use a Breathe Pillows Entrainment Interface that is cracked, odorous, broken, or kinked. If a damaged interface is used, the patient may not receive adequate respiratory therapy.
- Recommended 90-day replacement schedule for the Breathe Pillows Entrainment Interface.

⚠ WARNING:

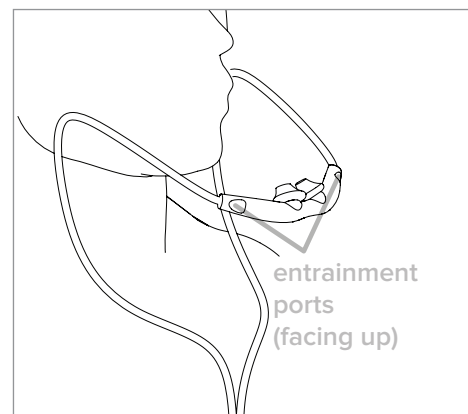
- Properly secure the Breathe Pillows Entrainment Interface to the face and route tubing around the ears to avoid strangulation.
- The Breathe Pillows Entrainment Interface is designed for single-patient use. To prevent risk of cross-contamination use a new Breathe Pillows Entrainment Interface for each new patient.

NOTES:

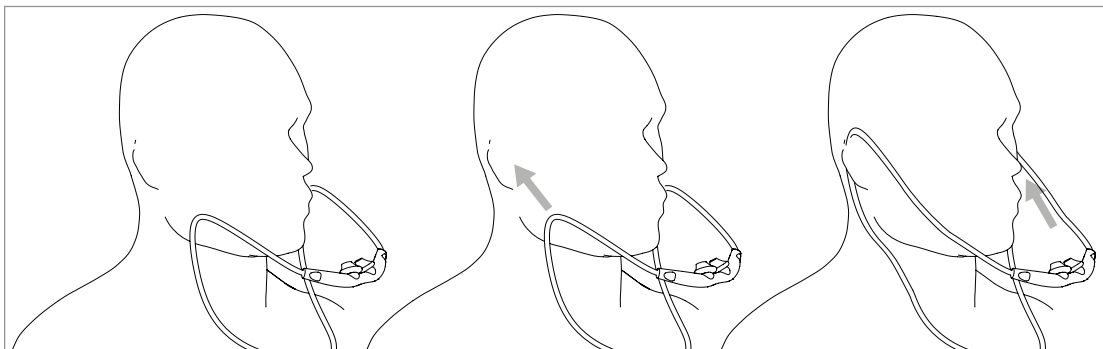
- Do not use the Breathe Pillows Entrainment Interface if the package seal is broken.
- The Breathe Pillows Entrainment Interface assembly is packaged clean but not sterile.
- The Breathe Pillows Entrainment Interface does not need to be cleaned or sterilized prior to first use.

WEARING THE BREATHE PILLOWS ENTRAINMENT INTERFACE

- 1 Place the interface in front of the patient with the curve of the Interface towards the patient's face and the entrainment ports facing up.



- 2 Loop the interface tubing over the ears and position the nasal pillows snugly inside the nostrils (see below).

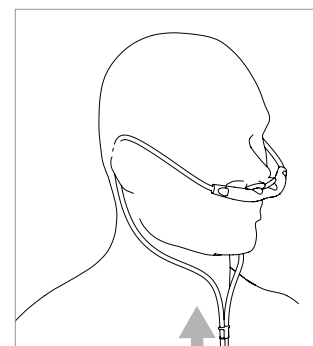


- 3 Using the tube fit adjuster (cinch), adjust the tubing length under the chin so that the interface is secured snugly and comfortably.



WARNING:

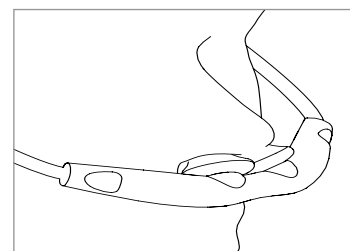
Properly secure the interface to the face and route tubing around the ears to avoid strangulation.



CHECKING THE BREATHE PILLOWS ENTRAINMENT INTERFACE POSITIONING

The interface is placed correctly when:

- 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.
- Entrainment ports are not obstructed.



If any one of these conditions is not met, reposition the interface. If problems persist, try a different interface size.



TIP: When the Interface is in use, periodically check that it is positioned correctly and make adjustments as required. If the patient's skin becomes irritated, replace or discontinue using the interface.

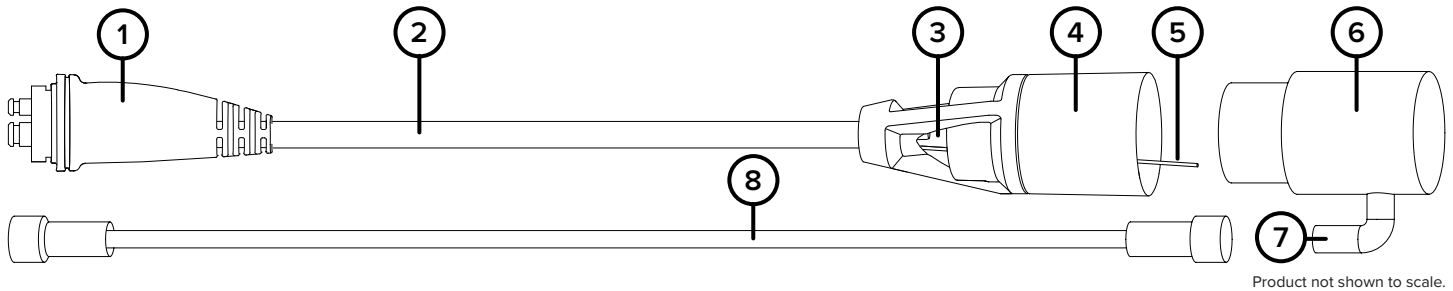
3 CONNECTING THE INTERFACE

THE UNIVERSAL CIRCUIT® CONNECTOR

The Universal Circuit® Connector is used to connect any commercially available non-invasive mask (full face, nasal, or pillows) or tracheostomy tube to a Life2000® ventilator or compressor.

The Universal Circuit® Connector is only compatible with Life2000® ventilators and compressors.

NOTE: The interface assembly is packaged clean but not sterile. The Universal Circuit® Connector does not need to be cleaned or sterilized prior to first use.



Universal Circuit® Connector
(available separately)

- ① Compressor or ventilator connector
- ② Interface tubing
- ③ Entrainment ports
- ④ Universal Circuit® Connector (patient side)
- ⑤ Sense tube

Oxygen adapter

- ⑥ Oxygen adapter
- ⑦ Barb connection
- ⑧ Oxygen tubing

⚠ WARNING:

- The Universal Circuit® Connector is designed for single-patient use. To prevent risk of cross-contamination use a new Universal Circuit® Connector for each new patient. For the third-party mask or tube, refer to the user guide provided by the manufacturer.
- The interface, source gas supply hose, and power cords should be positioned to avoid restricting movement, causing a tripping hazard, or posing a strangulation risk

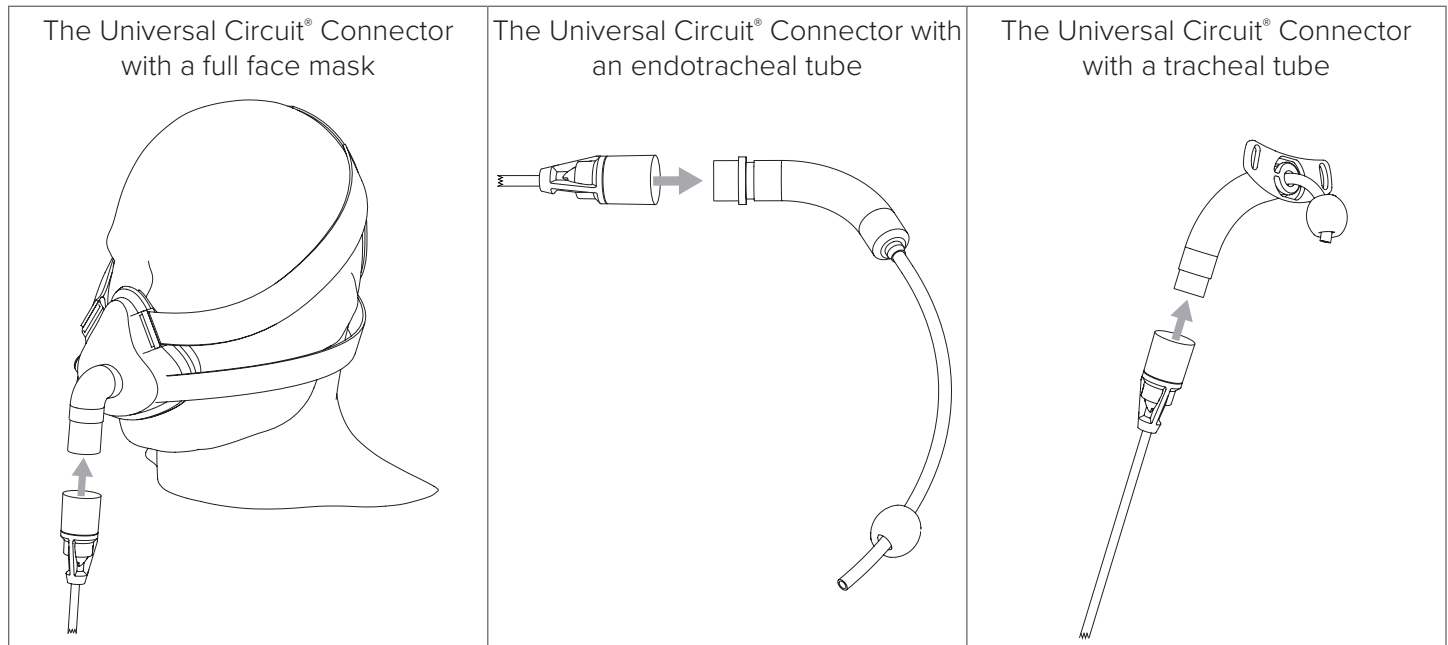
⚠ CAUTION:

- A 90-day replacement schedule for the Universal Circuit® Connector and interface accessories is recommended.
- Do not use a Universal Circuit® Connector, oxygen adapter, or oxygen tubing that is cracked, odorous, broken, or kinked. If a damaged interface is used, the patient may not receive adequate respiratory therapy.

NOTE:

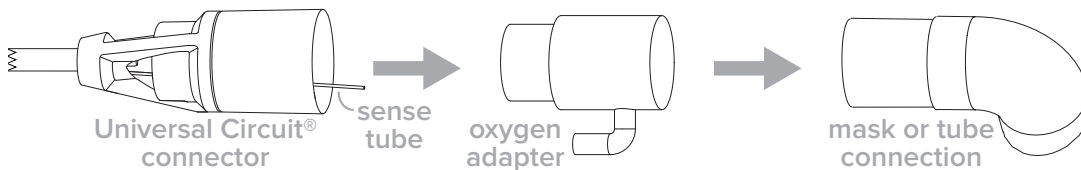
The Life2000® has been validated for use with a Bacterial Filter or a Heat and Moisture Exchanger (HME) with resistance up to 1.8 cmH₂O at 60 LPM. Always monitor performance of ventilator and alarms when introducing new components into the system.

EXAMPLES OF PATIENT MASK AND TUBE CONNECTIONS

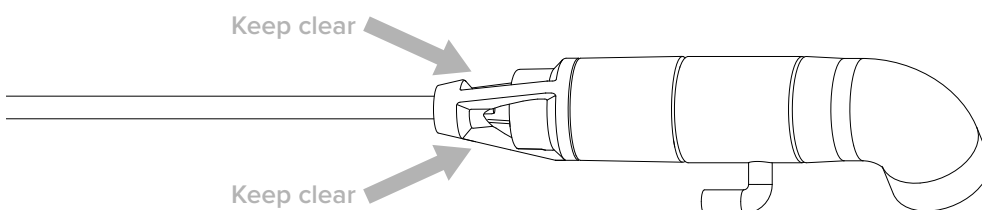


CONNECTING THE UNIVERSAL CIRCUIT® CONNECTOR TO THE OXYGEN ADAPTER AND PATIENT MASK OR TUBE

- 1 Place the oxygen adapter between the Universal Circuit® Connector and the third-party patient mask or tube connection. Your mask or tube connection may differ (a full face mask connection is shown as an example).
NOTE: Before using the interface and oxygen adapter, visually inspect them for damage.



- 2 Connect the Universal Circuit® Connector to the oxygen adapter, ensuring that the sense tube does not become kinked or pinched.
- 3 Connect the oxygen adapter to the third-party patient mask or tube connection.
- 4 Ensure that the entrainment ports are clear of any obstruction and are not covered by any clothing or bedding.



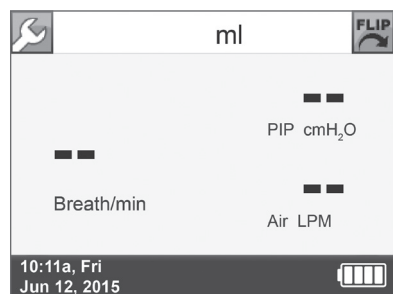
CHAPTER 4: VENTILATION SETTINGS

INTRODUCTION TO VENTILATION SETTINGS

All of the clinical and utility menus can be accessed, viewed, and edited by the touch screen on the ventilator.

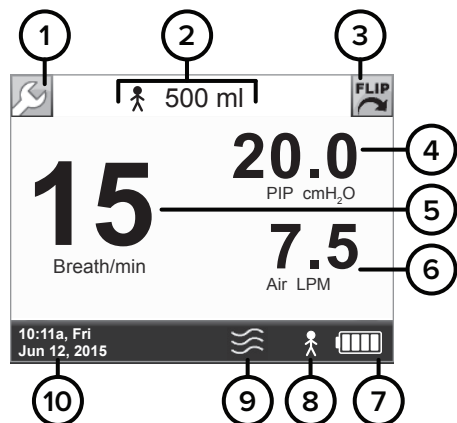
To use the touch screen, simply touch a button or an area of the screen you want to make active. An audible “click” indicates the feature you touch is activated.

HOME SCREEN



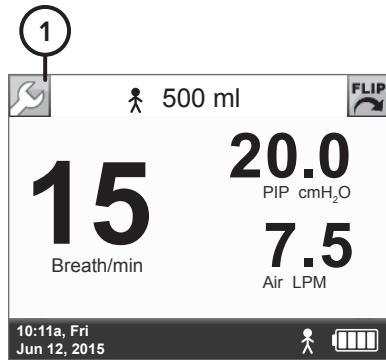
When the ventilator is powered on, it completes a self test and then displays the **Home Screen**. This screen indicates that the ventilator is ready for use.

When a Prescription Setting button is selected, the **Home Screen** will display the breath rate (**Breath/min** or **BPM**), Peak Inspiratory Pressure (**PIP cmH₂O**), and gas flow rate (**Air LPM** or **O₂ LPM**).

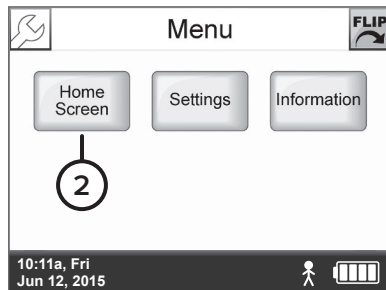


- 1 The **Wrench Button** is used to go to the **Menu** screen
- 2 The current **Prescription Setting Icon** and **Output Volume** (displayed on the **Home Screen** during ventilation)
- 3 The **Flip Button** flips the screen 180°.
- 4 Peak Inspiratory Pressure (**PIP cmH₂O**) indicator (displayed on the **Home Screen** during ventilation)
- 5 Current breath rate (**Breath/min** or **BPM**) (displayed on the **Home Screen** during ventilation)
- 6 Average gas flow in liters per minute (**Air LPM** or **O₂ LPM**) based on Prescription Setting and patient's current breath rate (displayed on the **Home Screen** during ventilation)
NOTE: The **Home Screen** will display **Air LPM** or **O₂ LPM** based on the option prescribed.
- 7 **Battery Charge Icon**
- 8 Current **Prescription Setting Icon** (displayed during ventilation)
- 9 The **Vibration Icon** indicates that the ventilator is set for vibration.
- 10 Time and date

MOVING BETWEEN THE HOME SCREEN AND MENU SCREEN



- 1 Touch the **Wrench Button** to go to the **Menu Screen**.

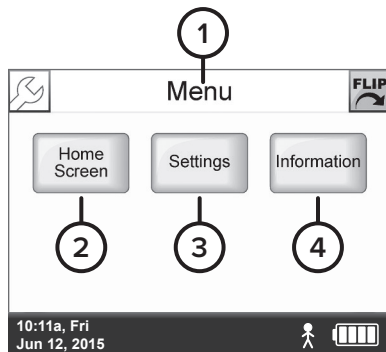


- 2 Touch the **Home Screen** button to go to the **Home Screen**.

MENU SCREEN

Use the **Menu** screen to go to the **Settings** menu, get information about the ventilator's software version and total operating time, or go back to the **Home Screen**.

To get to the **Menu** screen, touch the **Wrench Button** from any screen.

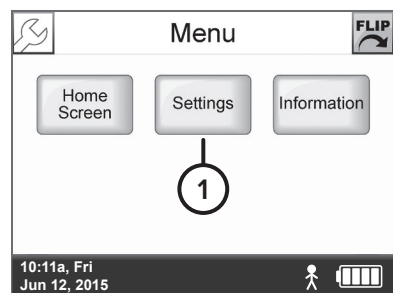


- 1 Screen name
- 2 Touch to go to the **Home Screen**.
- 3 Touch to go to **Settings** for **Trigger Sensitivity**, **Utilities**, and **Clinician's Settings**.
- 4 Touch to go to **Information** for details about the software version, ventilator serial number, and total operating time.

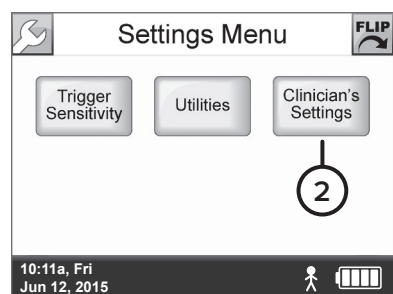
4 VENTILATION SETTINGS

DEFINING CLINICAL SETTINGS

NOTE: For facilities where trained healthcare professionals are the intended users, the password to access clinical settings may be enabled or disabled. For more information, contact customer service.

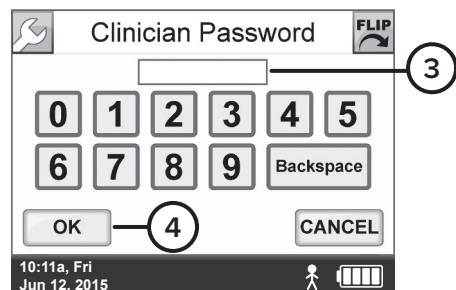


- 1 On the **Menu** screen, touch **Settings**.



- 2 On the **Settings Menu** screen, touch **Clinician's Settings**.

NOTE: Access to the **Clinician's Settings** menu is restricted to trained clinical personnel.



- 3 On the **Clinician Password** screen, enter the password.

NOTE: To obtain the Clinician Password contact customer service.

- 4 Touch **OK** to access the **Clinician's Settings**.

DISABLING ACCESS TO THE CLINICIAN'S SETTINGS MENU

There are two ways to disable access to the **Clinician's Settings** menu to prevent unintended changes to the programmed clinical settings.

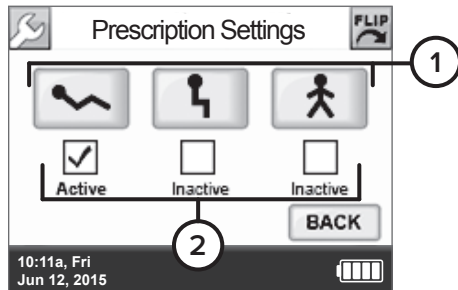
AUTOMATIC TIMEOUT: An Automatic Timeout disables access to the **Clinician's Settings** menu after five minutes of inactivity in the **Clinician's Settings** menu. The password must be re-entered to regain access to the **Clinician's Settings** menu.

NOTE: Automatic Timeout begins after the Touch Screen Energy-Save Mode. For more information, see "Touch Screen Energy-Save Mode" on page 54.

POWERING OFF: Powering off the ventilator will also disable access to the **Clinician's Settings** menu; when the ventilator is powered on again, the password must be re-entered to access the **Clinician's Settings** menu.

VIEWING AND EDITING PRESCRIPTION SETTINGS

The buttons on the **Prescription Settings** screen correspond to the Low Activity, Medium Activity, and High Activity Prescription Settings buttons on the ventilator. Patients will then be able to press an Activity button to select their therapy.



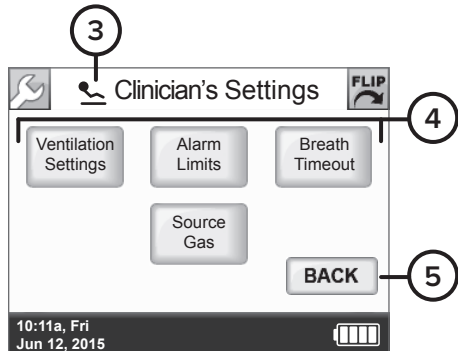
- 1 Press the **Prescription Setting Button** representing the Prescription Setting (for Low Activity, Medium Activity, or High Activity) that you want to view or edit.
- 2 Check the box below a **Prescription Setting Button** to make the button active (checked) or inactive (unchecked). Only active **Prescription Setting Buttons** are available to the patient as therapy options.

NOTES:

- The **BACK** button on the **Prescriptions Setting** screen is used to return to the **Settings Menu** screen.
- At least one **Prescription Setting Button** must always be active.

TIP:

The ventilator is shipped with factory-set default values. Be sure to adjust the **Prescription Settings** based on a physician's order.



- 3 The **Prescription Setting Icon** that is being viewed or edited appears at the top of the screen.
- 4 For each of the three **Prescription Settings** that can be made available to the patient, set up **Ventilation Settings**, **Alarm Limits**, **Breath Timeout**, and **Source Gas** parameters according to a physician's order.
- 5 If setting up more than one **Prescription Setting**, after setting up all the parameters for one **Prescription Setting**, use the **BACK** button to return to the **Prescription Settings** screen to set up additional **Prescription Settings**.




NOTES:

- Viewing or editing a **Prescription Setting** or making a **Prescription Setting Button** active does not begin ventilation therapy. For more information, see "Choosing a Prescription Setting Button" on page 46.
- The **Ventilation Settings** must be adjusted to meet the patient's ventilatory needs.

4 VENTILATION SETTINGS

FACTORY DEFAULT PRESCRIPTION SETTINGS

The following table lists the Life2000® factory default **Prescription Settings** that may be edited. For a full list of factory defaults, see the "Summary of Factory Default Settings" on page 56.

DESCRIPTION	DEFAULT VALUE		
	 LOW ACTIVITY	 MEDIUM ACTIVITY	 HIGH ACTIVITY
Ventilation Settings			
Volume	150 ml	180 ml	200 ml
I-Time (Inspiratory Time)	.75 sec		
PEEP (Positive End Expiratory Pressure)	0 cmH ₂ O		
Sensitivity (Trigger Sensitivity)	4*		
BR (Breath Rate)	12 BPM*		
*Ventilation mode: Assist/Control ventilation mode			
Alarm Limits			
High BR (Breath Rate) alarm limit	50 BPM		
Low BR (Breath Rate) alarm limit	5 BPM		
High PIP (Peak Inspiratory Pressure) alarm limit	30 cmH ₂ O		
Low PIP (Peak Inspiratory Pressure) alarm limit	1 cmH ₂ O		
Breath Timeout			
Breath Timeout Action	12 BPM		
Breath Timeout Period	60 seconds		
Source Gas			
Source Gas	O ₂ (Oxygen)		

NOTE: Each **Prescription Setting** is independent of other **Prescription Settings**.

The following factory default cannot be edited:

DESCRIPTION	DEFAULT VALUE
High PEEP (Positive End Expiratory Pressure) Pressure alarm limit	+7 cmH ₂ O (above PEEP setting)

BREATH TYPES

There are two breath types that apply to the Volume Control ventilation provided by the ventilator:

- Mandatory
- Assisted

MANDATORY BREATH

A mandatory breath (or machine breath) is completely controlled by the ventilator. The ventilator controls both the beginning (triggering) and end (cycling) of the inspiratory phase.

ASSISTED BREATH

An assisted breath is controlled by both the patient and the ventilator. Breaths are initiated by the patient's effort and volume delivery is controlled by the prescribed volume setting and inspiratory time.

VENTILATION MODES AND SETTINGS

The ventilator delivers an inspired tidal volume to the patient according to the clinical settings: volume, breath rate, trigger sensitivity, PEEP, and inspiratory time. Three different volume control modes are available:

- Control
- Assist/Control
- Assist

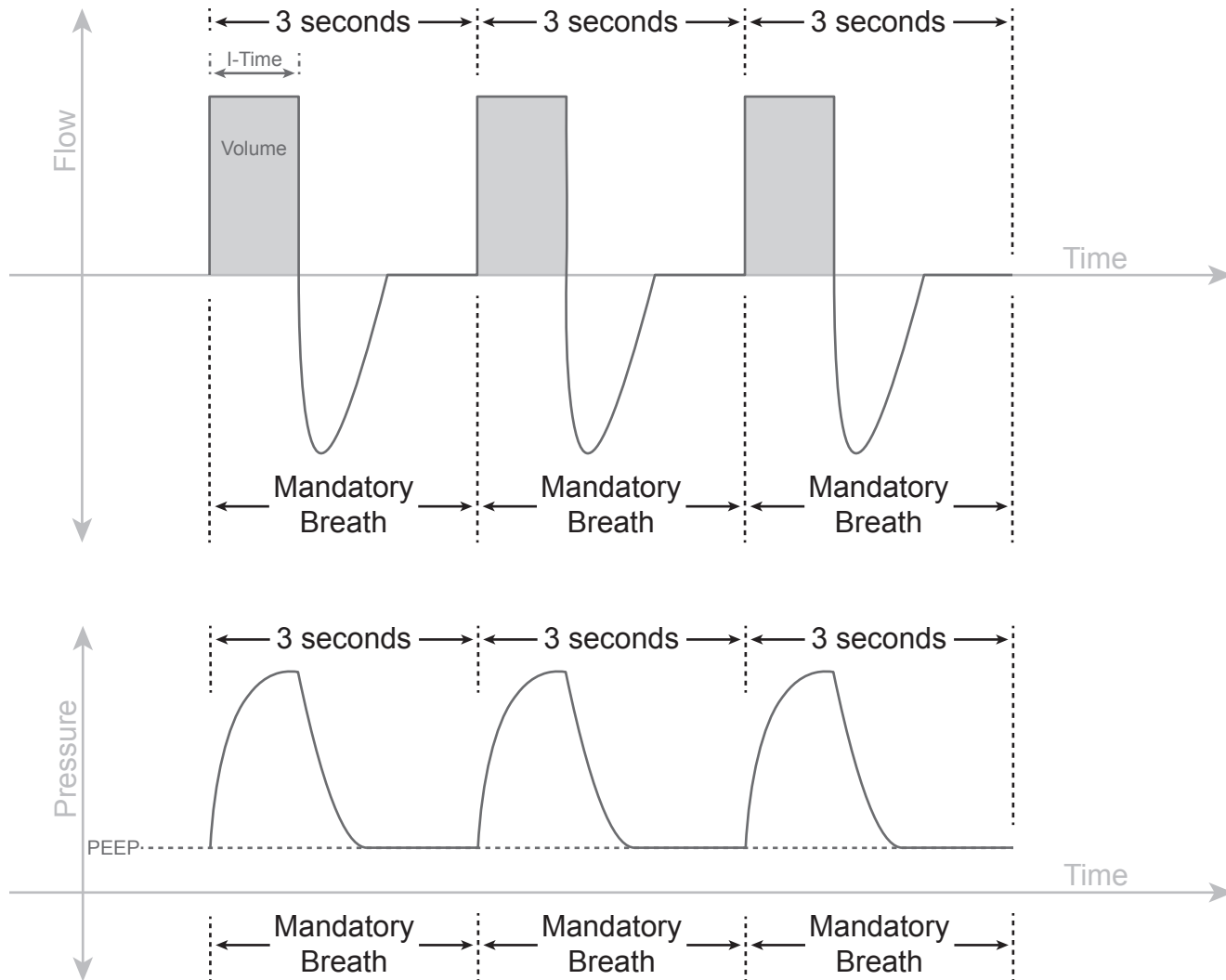
The **Ventilation Settings** screen provides options to set the different ventilation modes. Consult the following table to adjust parameters accordingly:

VENTILATION MODES*	SET TRIGGER SENSITIVITY TO:	SET BREATH RATE TO:
Control	OFF	≥ 1
Assist/Control	0 to 9	≥ 1
Assist	0 to 9	0
*SETTINGS BASED ON PRESCRIPTION		

4 VENTILATION SETTINGS

SETTING VENTILATION PARAMETERS IN CONTROL VENTILATION MODE

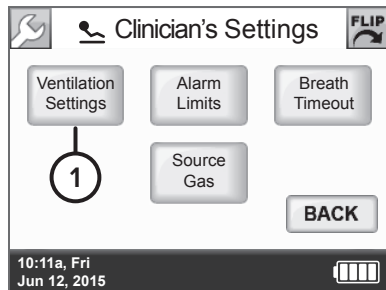
In this mode, the ventilator delivers volume control therapy only for mandatory breaths. A mandatory breath is delivered according to the breath rate setting (**BR**). This also means that a breath will not be triggered based on patient's inspiratory effort.



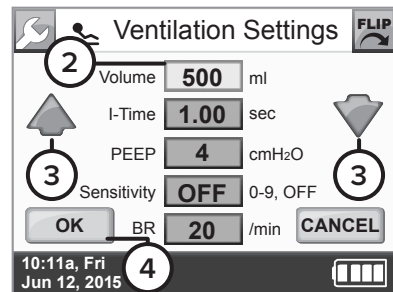
To set a **Prescription Setting** for Control Ventilation Mode, the following parameters need to be set according to the table below:

VENTILATION MODE*	SET TRIGGER SENSITIVITY TO:	SET BREATH RATE TO:
Control	OFF	≥ 1
*SETTINGS BASED ON PRESCRIPTION		

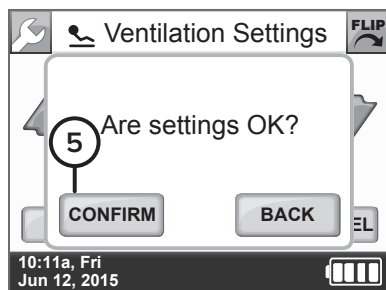
To set the **Prescription Setting**:



- 1 On the **Clinician's Settings** screen, touch **Ventilation Settings**.



- 2 On the **Ventilation Settings** screen, touch the box beside the setting 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 setting you want to change, and then press **OK**.



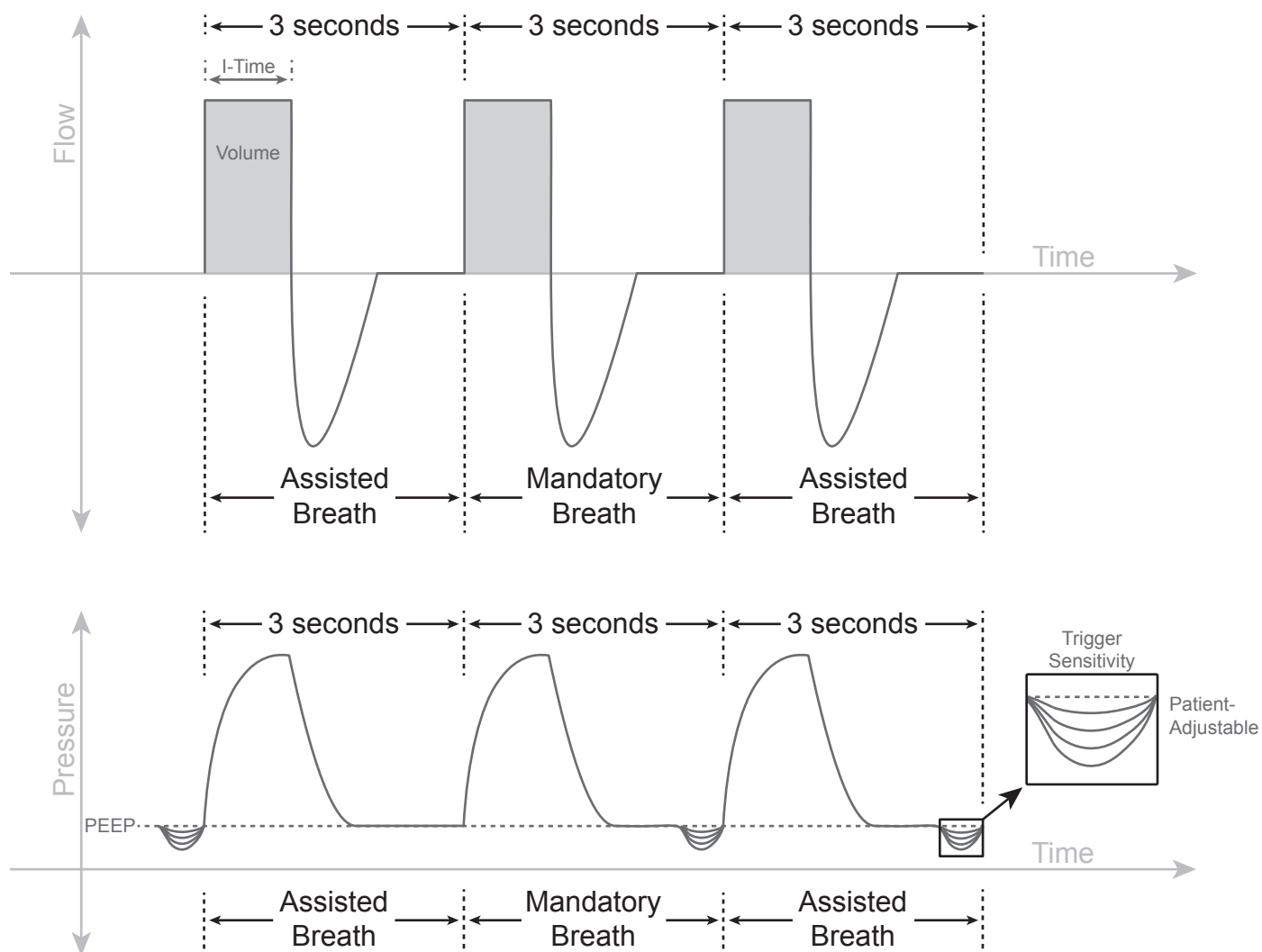
- 5 In the message asking if the settings are **OK**, touch **CONFIRM**.
NOTE: Changes to settings only take effect when you touch **CONFIRM**.

NOTE: An "Incompatible Settings" message appears when the PEEP or Volume setting is incompatible to maintain clinical settings. Touch **OK** and then re-evaluate and readjust the Volume, PEEP, or I-Time setting in the **Ventilation Settings** screen. For more information, see "Incompatible Settings" Message" on page 47.

4 VENTILATION SETTINGS

SETTING VENTILATION PARAMETERS IN ASSIST/CONTROL VENTILATION MODE

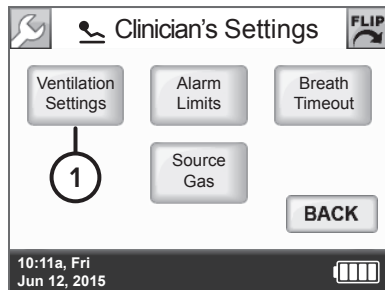
In this mode, the ventilator provides tidal volume during inhalation for assisted and mandatory breaths. An assisted breath is started when there is patient effort, but it is ended when the inspiratory time (**I-Time**) setting has been met. A mandatory breath is delivered if the patient does not breathe within the prescribed breath rate (**BR**) setting. This ensures that the patient receives a minimum number of breaths per minute.



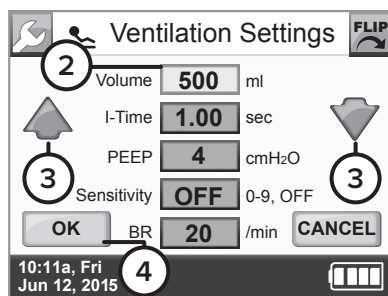
To set a **Prescription Setting** for Assist/Control ventilation mode, the following parameters need to be set according to the table below:

VENTILATION MODE*	SET TRIGGER SENSITIVITY TO:	SET BREATH RATE TO:
Assist/Control	0 to 9	≥ 1
*SETTINGS BASED ON PRESCRIPTION		

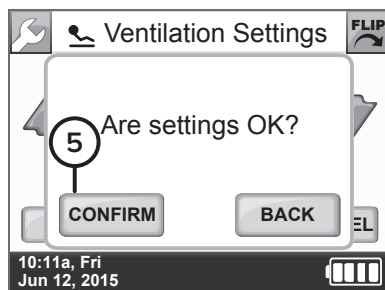
To set the **Prescription Setting**:



- 1 On the **Clinician's Settings** screen, touch **Ventilation Settings**.



- 2 On the **Ventilation Settings** screen, touch the box beside the setting 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 setting you want to change, and then press **OK**.



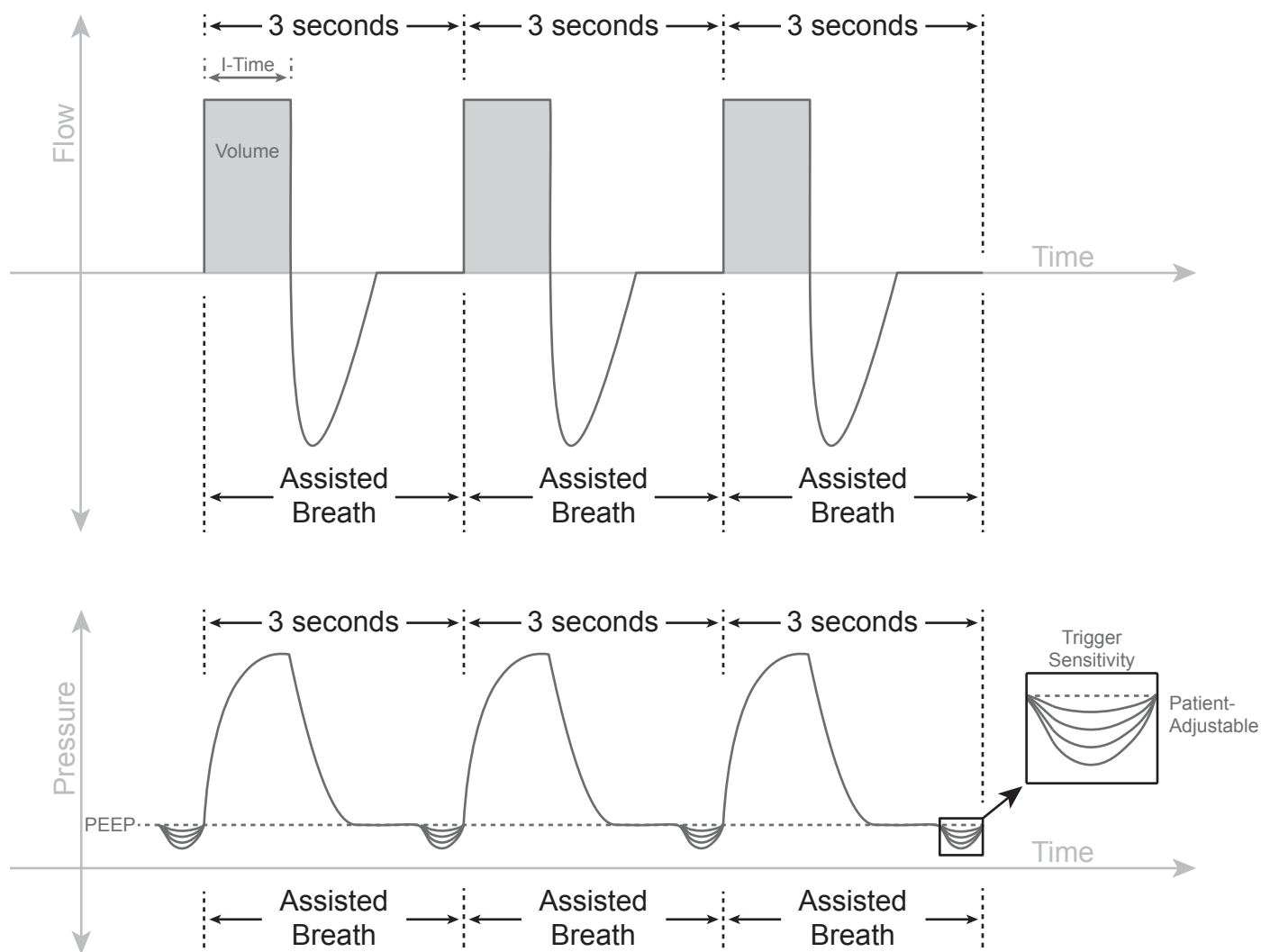
- 5 In the message asking if the settings are **OK**, touch **CONFIRM**.
NOTE: Changes to settings only take effect when you touch **CONFIRM**.

NOTE: An "Incompatible Settings" message appears when the PEEP or Volume setting is incompatible to maintain clinical settings. Touch **OK** and then re-evaluate and readjust the Volume, PEEP, or I-Time setting in the **Ventilation Settings** screen. For more information, see "Incompatible Settings" Message" on page 47.

4 VENTILATION SETTINGS

SETTING VENTILATION PARAMETERS IN ASSIST VENTILATION MODE

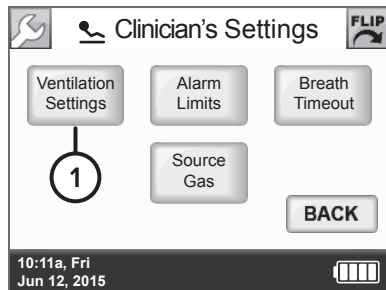
In this mode, the ventilator provides tidal volume during inhalation for assisted breaths. An assisted breath is started when there is patient effort and is ended when the inspiratory time (**I-Time**) setting has been met. If the ventilator does not detect breaths during the allotted time as defined by the breath **Timeout Period**, the ventilator will deliver breaths or a continuous flow of gas based on the **Timeout Action** setting.



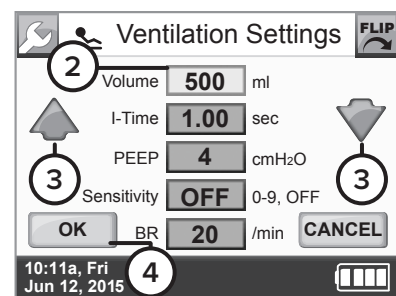
To set a **Prescription Setting** for Assist ventilation mode, the following parameters need to be set according to the table below:

VENTILATION MODE*	SET TRIGGER SENSITIVITY TO:	SET BREATH RATE TO:
Assist	0 to 9	0
*SETTINGS BASED ON PRESCRIPTION		

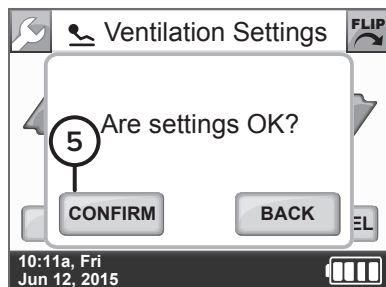
To set the **Prescription Setting**:



- 1 On the **Clinician's Settings** screen, touch **Ventilation Settings**.



- 2 On the **Ventilation Settings** screen, touch the box beside the setting 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 setting you want to change, and then press **OK**.



- 5 In the message asking if the settings are **OK**, touch **CONFIRM**.
NOTE: Changes to settings only take effect when you touch **CONFIRM**.

NOTE: An "Incompatible Settings" message appears when the PEEP or Volume setting is incompatible to maintain clinical settings. Touch **OK** and then re-evaluate and readjust the Volume, PEEP, or I-Time setting in the **Ventilation Settings** screen. For more information, see "'Incompatible Settings' Message" on page 47.

4 VENTILATION SETTINGS

VENTILATION SETTINGS SUMMARY

PARAMETER	MINIMUM	MAXIMUM	INCREMENT
Volume (ml)	50	750	10
I-Time (sec))	.15	3.00	50
PEEP (cmH ₂ O)	0	10 or 20*	1
Sensitivity	Control ventilation mode: OFF	Control ventilation mode: OFF	1
	Assist or Assist/Control ventilation mode: 9	Assist or Assist/Control ventilation mode: 0	
BR (/min)	0	40	1

*for software revisions before 06.08.00.00, PEEP Range is 0 to 10 cmH₂O

TIPS:

- **Volume:** You can set an output volume between 50 ml and 750 ml, in increments of 10 ml.
NOTE: Volume levels are not adjusted for altitude. For more information see the "Altitude Volume Adjustment Table" on page 90.
- **I-Time (Inspiratory Time):** The time over which the selected target volume is delivered.
NOTE: The actual I-Time may be longer or shorter than set if additional time is required to deliver the set volume. The actual delivery time may also be longer or shorter than set to maintain a minimum delivered peak gas flow rate of 8–40 LPM range.
- **PEEP (Positive End Expiratory Pressure):** PEEP can be adjusted as per the prescription. PEEP values can be set from 0–10 cm H₂O (for software versions before 06.08.00.00) or 0–20 cm H₂O (for software versions 06.08.00.00 or newer).
- **Sensitivity (Trigger Sensitivity):** Specifies the minimum negative pressure threshold necessary to trigger a delivery. The sensitivity setting, adjustable in increments of 1, ranges from 0–9 or OFF, with 0 being the most sensitive and 9 being the least sensitive.
NOTE: Trigger sensitivity can be adjusted by the patient unless it is set to **OFF** in the **Ventilation Settings** screen. For more information, see "Adjusting the Trigger Sensitivity" on page 48.

Trigger sensitivity settings vary in a non-linear fashion, with relatively finer resolution at lower settings and relatively coarser resolution at higher settings.

Trigger sensitivity can be adjusted by both the clinician and the patient. Breaths can be triggered by the patient or by the ventilator based on the **Ventilation Settings**.

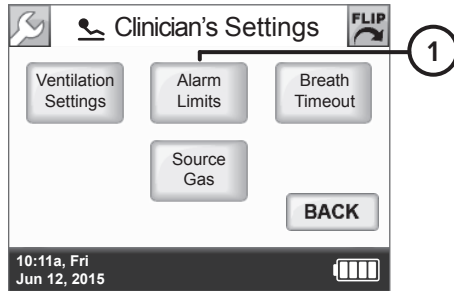
- **BR (Breath Rate):** The breath rate per minute determines the minimum quantity of machine breaths delivered.

WARNING:

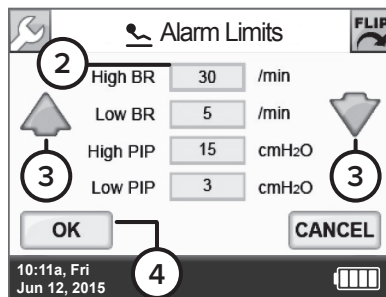
- If upgrading software from version 05.11.00 to 05.12.00 re-evaluate the ventilator settings if PEEP is applied.
- If upgrading a patient ventilator from ventilator REF MS-01-0001 to ventilator REF MS-01-0118 re-evaluate ventilator settings if PEEP is applied.

SETTING ALARM LIMITS FOR BREATH RATE AND PIP

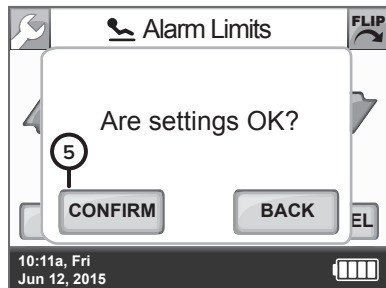
To view or edit critical alarms, access the **Alarm Limits** screen from the **Clinician's Settings** screen.



- 1 On the **Clinician's Settings** screen, touch **Alarm Limits**.



- 2 On the **Set Alarm Limits** screen, touch the box corresponding to the alarm limit you want to change.
- 3 Touch the **Up Arrow** or the **Down Arrow** to change the value in the box. If you press and hold an arrow, the value automatically increases or decreases.
- 4 Repeat steps 2 and 3 for each setting you want to change, and then press **OK**.



- 5 In the message asking if the settings are **OK**, touch **CONFIRM**.
NOTE: Changes to settings only take effect when you touch **CONFIRM**.

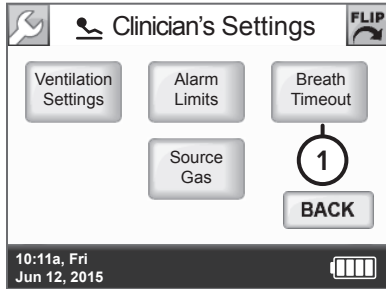
ALARM LIMITS SETTINGS SUMMARY

ALARM	DEFAULT	MINIMUM	MAXIMUM	INCREMENT
High Breath Rate Alarm Limit (BPM)	50	5	120	1
Low Breath Rate Alarm Limit (BPM)	5	0	119	1
High PIP Alarm Limit (cmH ₂ O)	30	5	40	1
Low PIP Alarm Limit (cmH ₂ O)	1	1	15	1

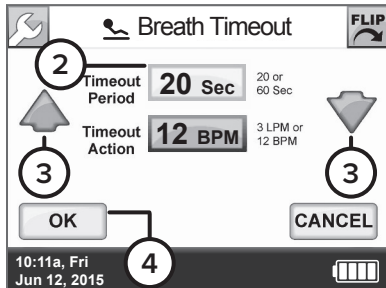
i TIP: The breath rate monitor value is based on a four-breath average.

4 VENTILATION SETTINGS

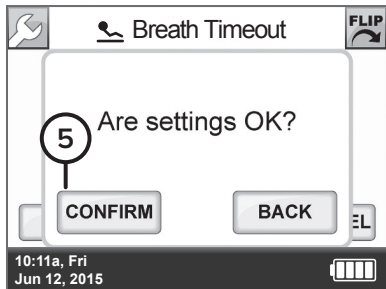
SETTING BREATH TIMEOUT (APNEA BACKUP VENTILATION MODE)



- 1 On the **Clinician's Settings** screen, touch **Breath Timeout**.



- 2 On the **Breath Timeout** screen, touch the **Timeout Period** or **Timeout Action** box you want to change.
- 3 Touch the **Up Arrow** or the **Down Arrow** to change the value in the box. If you press and hold an arrow, the value automatically sequences through the values.
- 4 Repeat steps 2 and 3 for each setting you want to change, and then press **OK**.



- 5 In the message asking if the settings are **OK**, touch **CONFIRM**.
NOTE: Changes to settings only take effect when you touch **CONFIRM**.



TIP:

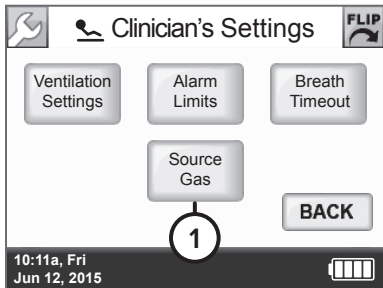
The **Breath Timeout** screen has two options for setting the **Breath Timeout** alarm. You can set the time to trigger the alarm at **20** or **60** seconds and the backup ventilation mode to **3 LPM** continuous flow or **12 BPM** at the current volume setting.

BREATH TIMEOUT SETTINGS SUMMARY

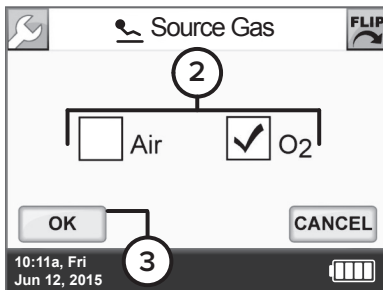
PARAMETER	DEFAULT	ALTERNATE
Timeout Period	60 seconds	20 seconds
Timeout Action	12 BPM	3 LPM

SELECTING THE SOURCE GAS

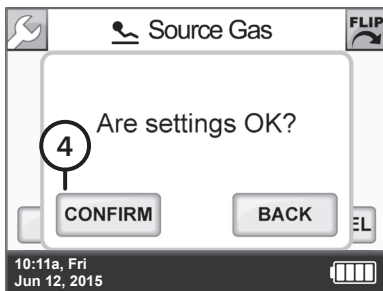
The Life2000® Ventilator uses **O₂** (oxygen) as the factory set default source gas. If using air, select **Air** as the **Source Gas**.



- 1 On the **Clinician's Settings** screen, touch **Source Gas**.



- 2 On the **Source Gas** screen, touch the appropriate check box for the source gas prescribed by the physician.
- 3 Touch **OK** to confirm your selection.



- 4 In the message asking if the settings are **OK**, touch **CONFIRM**.
NOTE: Changes to settings only take effect when you touch **CONFIRM**.

SOURCE GAS SETTINGS SUMMARY

DEFAULT	ALTERNATE
O ₂ (Oxygen)	Air

4 VENTILATION SETTINGS

CHOOSING A PRESCRIPTION SETTING BUTTON

When the ventilator is first powered on, you must select an Prescription Setting button to begin therapy. The three Prescription Setting buttons on the ventilator are programmed to correspond to up to three different prescriptions as directed by a physician.



Low Activity button



Medium Activity button

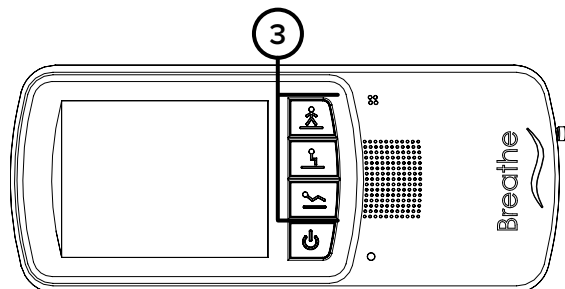


High Activity button

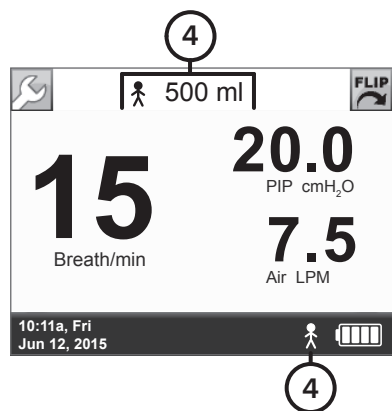
Choose a Prescription Setting button appropriate for the patient's needs. The Prescription Setting button selection can be changed by the patient at any time, if set and activated by a clinician.

NOTE: One, two, or three prescriptions may be active, as directed by a physician. For more information, see "Viewing and Editing Prescription Settings" on page 33.

- 1 Ensure that the ventilator is powered on.
- 2 Ensure a pressure source is connected to the ventilator and turned on.



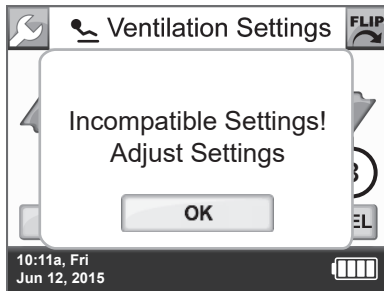
- 3 Press and hold a Prescription Setting button until you hear a tone that indicates it is active.



- 4 The touch screen will display the **Home Screen**. Confirm the selected **Prescription Setting Icon** is displayed at the bottom of the touch screen and the **Prescription Setting Icon** and **Output Volume** are displayed at the top of the screen. (The **High Activity Prescription Setting Icon** is shown for illustrative purposes here.) The ventilator will begin ventilating using the chosen Prescription Setting parameters after one breath.

NOTE: The currently-ventilating **Prescription Setting Icon** and **Output Volume** are displayed at the top of all screens unless you are in the **Clinician's Settings**.

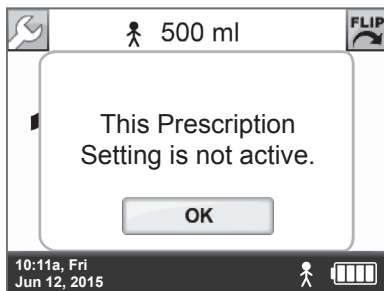
“INCOMPATIBLE SETTINGS” MESSAGE



An "Incompatible Settings" message appears when the PEEP or Volume setting is incompatible to maintain clinical settings.

Touch OK and then re-evaluate and readjust the Volume, PEEP, or I-Time setting in the Ventilation Settings screen.

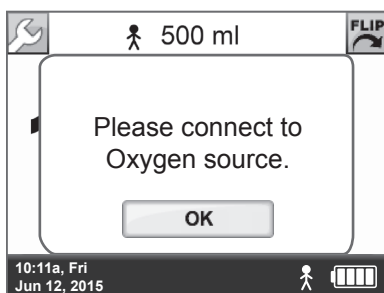
“THIS PRESCRIPTION SETTING IS NOT ACTIVE” MESSAGE



If the Prescription Setting button selected on the ventilator is not active, this message will appear on the touch screen. If therapy already began with a different Prescription Setting, the ventilator will continue delivering therapy using the previous Prescription Setting.

Touch **OK** and choose another active Prescription Setting button to change the currently-ventilating prescription.

“CONNECT OXYGEN SOURCE” OR “DISCONNECT OXYGEN SOURCE” MESSAGE



After powering on, or during therapy when selecting a Prescription Setting with a different source gas, a message will appear as a reminder to connect or disconnect oxygen as appropriate for the chosen Prescription Setting. Verify that the correct source gas is connected.

After connecting or disconnecting oxygen per the chosen Prescription Setting, touch **OK** to begin ventilating with the new Prescription Setting.

For more information, see "Selecting the Source Gas" on page 45.

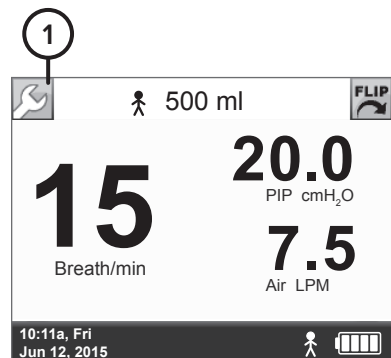
4 VENTILATION SETTINGS

ADJUSTING THE TRIGGER SENSITIVITY

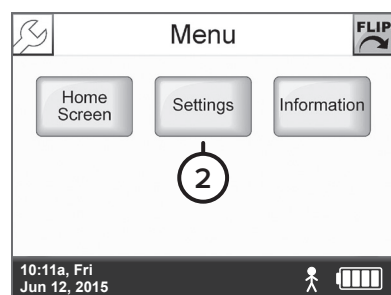
Trigger sensitivity determines how easily a patient's inspiratory effort triggers the breath delivery. For shallow breathing, set the trigger sensitivity to a low number. You can choose a setting between 0 and 9. Zero is the most sensitive and 9 is the least sensitive setting.

A Prescription Setting button must already be selected (the ventilator must be currently ventilating) to allow changes to the **Trigger Sensitivity** settings through the patient-accessible **Settings** menu.

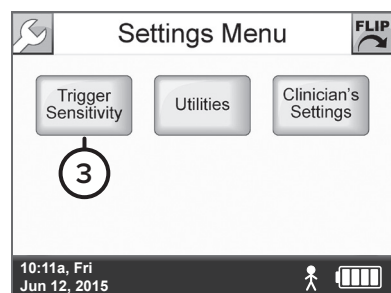
ACCESSING THE TRIGGER SENSITIVITY SCREEN



- 1 On any screen, touch the **Wrench Button**.



- 2 On the **Menu** screen, touch **Settings**.

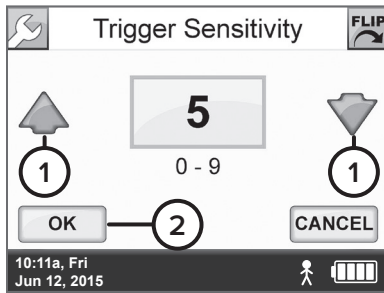


- 3 On the **Settings Menu** screen, touch **Trigger Sensitivity**.

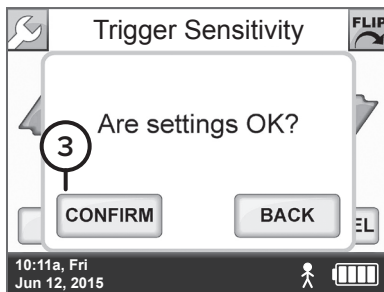
NOTE: A grayed-out **Trigger Sensitivity** button indicates that this feature is not available for one of the following reasons:

- A Prescription Setting button has not been chosen (the ventilator is not currently ventilating). For more information, see "Choosing a Prescription Setting Button" on page 46.
- The currently ventilating Prescription Setting is in Control Mode. For more information, see "Setting Ventilation Parameters in Control Ventilation Mode" on page 36.

CHANGING TRIGGER SENSITIVITY



- 1 While ventilating, 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**.



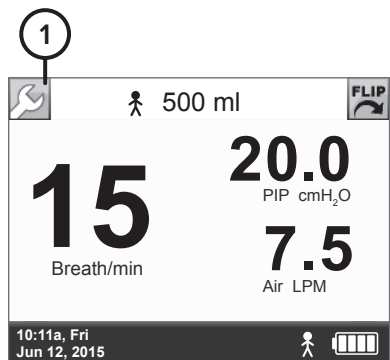
- 3 In the message asking if the settings are **OK**, touch **CONFIRM**.
NOTE: Changes to settings only take effect when you touch **CONFIRM**.

This **Trigger Sensitivity** setting will be saved as part of the currently-ventilating Prescription Setting parameters.

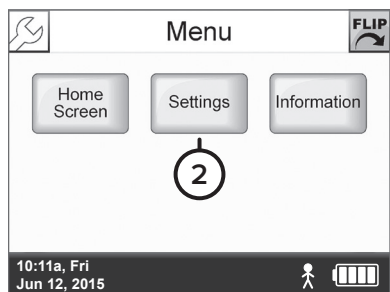
4 VENTILATION SETTINGS

ACCESSING THE UTILITIES MENU

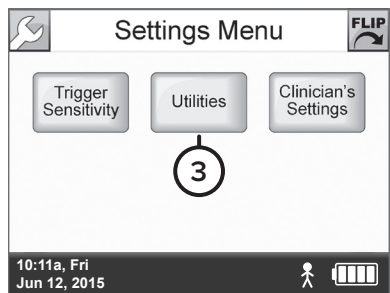
With the Utilities menu, you can change the time and date, brightness of the touch screen, volume of audible alarms, and set alarm notifications for vibration.



1 On any screen, touch the **Wrench Button**.



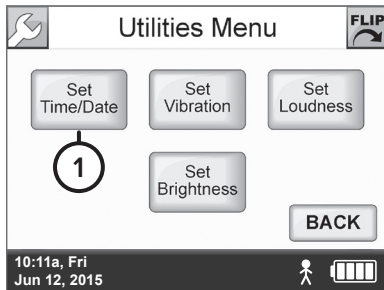
2 On the **Menu** screen, touch **Settings**.



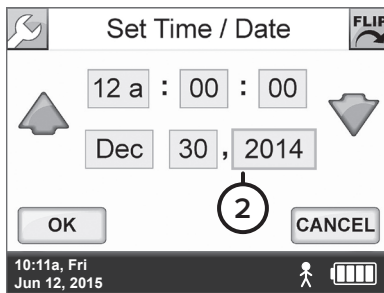
3 On the **Settings Menu** screen, touch **Utilities**.

SETTING TIME AND DATE

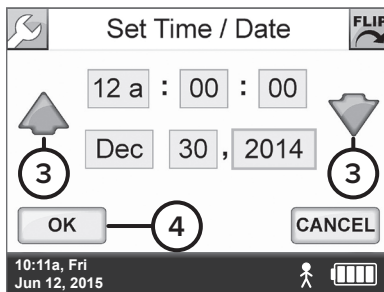
Customize the time and date that appear on the ventilator.



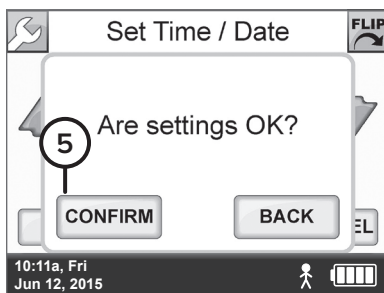
- 1 On the **Utilities Menu** screen, touch **Set Time/Date**.



- 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**.

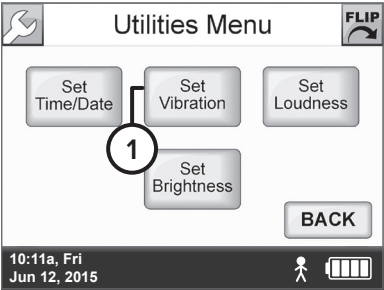


- 5 In the message asking if the settings are **OK**, touch **CONFIRM**.
NOTE: Changes to settings only take effect when you touch **CONFIRM**.

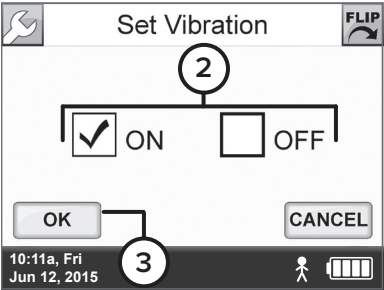
4 VENTILATION SETTINGS

SETTING VIBRATION

The **Set Vibration** screen lets you change alarm notifications 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.

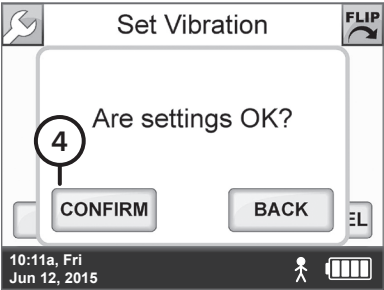


1 On the **Utilities Menu** screen, touch **Set Vibration**.



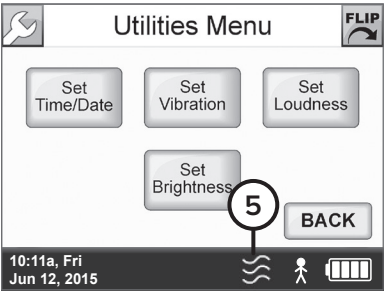
2 On the **Set Vibration** screen, touch **ON** or **OFF**.


3 When you are finished, touch **OK**.



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

NOTE: Changes to settings only take effect when you touch **CONFIRM**.



5 Check that the **Vibration Icon**  appears, indicating the ventilator is set for vibration.

VIBRATION SETTINGS SUMMARY

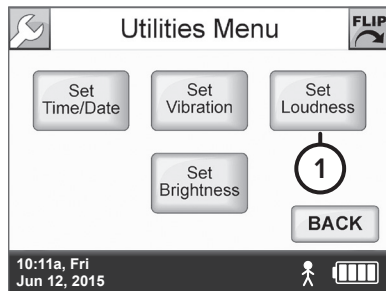
DEFAULT	ALTERNATE
OFF	ON

SETTING LOUDNESS

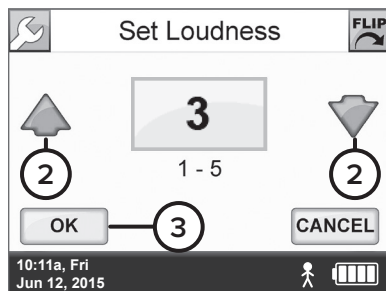
Loudness settings represent the audio volume of the ventilator's alarm notifications. Set the alarm volume settings to a value that can be heard by the user in the environment that it is being used.

WARNING:

Reducing the alarm loudness level to lower than the ambient sound level will impede alarm condition recognition.



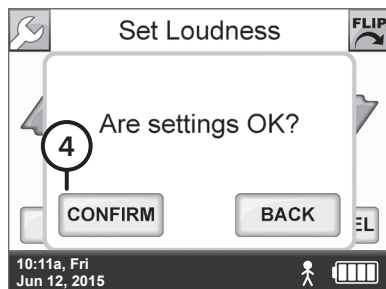
- 1 On the **Utilities Menu** screen, touch **Set Loudness**.



- 2 Touch the **Up Arrow** to increase the audio loudness 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**.

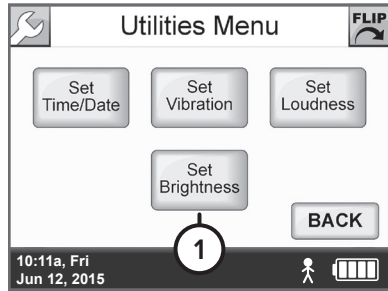
LOUDNESS SETTINGS SUMMARY

DEFAULT	MINIMUM	MAXIMUM	INCREMENT
5	1	5	1

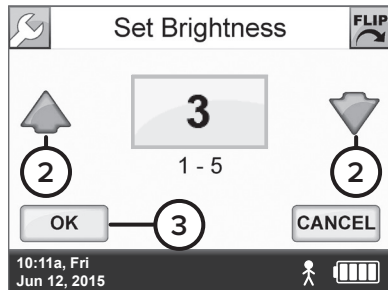
4 VENTILATION SETTINGS

ADJUSTING SCREEN BRIGHTNESS

Set the screen brightness to improve readability or adjust for changing viewing conditions.



- 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**.

BRIGHTNESS SETTINGS SUMMARY

DEFAULT	MINIMUM	MAXIMUM	INCREMENT
3	1	5	1

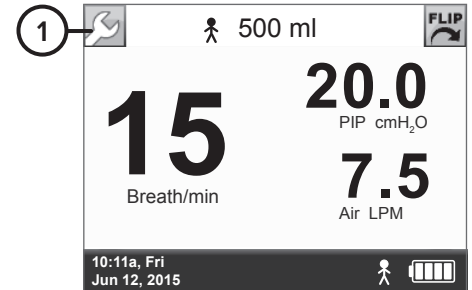
TOUCH SCREEN ENERGY-SAVE MODE

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**.

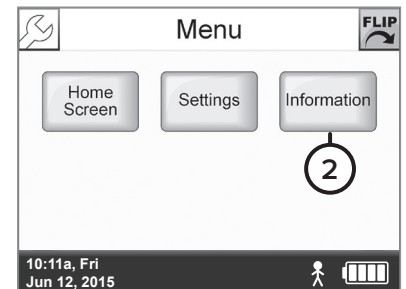
VIEWING SOFTWARE VERSION INFORMATION

The Information screen displays information about the ventilator and its operation.

- 1 On any screen, touch the **Wrench** button.

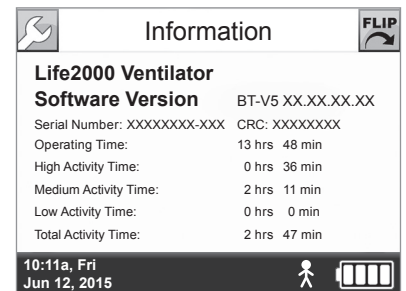


- 2 On the **Menu** screen, touch **Information**.



- 3 The screen displays information about the ventilator and its operation.
 - Software Version is the version of software currently running on the ventilator.
 - Serial Number is the ventilator's serial number.
 - Operating Time is the total time the ventilator has been powered on.
 - High Activity Time is the time the ventilator has delivered therapy using the High Activity prescription.
 - Medium Activity Time is the time the ventilator has delivered therapy using the Medium Activity prescription.
 - Low Activity Time is the time the ventilator has delivered therapy using the Low Activity prescription.
 - Total Activity Time is the total time the ventilator has delivered therapy using any of the three prescriptions (Total Activity Time = High Activity Time + Medium Activity Time + Low Activity Time).




These screen values are accurate to within two minutes.



4 VENTILATION SETTINGS

SUMMARY OF FACTORY DEFAULT SETTINGS

The following table lists the factory default settings for the ventilator.

CLINICIAN'S MENU SETTINGS	DEFAULT VALUE		
	 LOW ACTIVITY	 MEDIUM ACTIVITY	 HIGH ACTIVITY
Ventilation Settings			
Volume	150 ml	180 ml	200 ml
I-Time (Inspiratory Time)	.75 sec		
PEEP (Positive End Expiratory Pressure)	0 cmH ₂ O		
Sensitivity (Trigger Sensitivity)	4*		
BR (Breath Rate)	12 BPM*		
* Ventilation mode: Assist/Control ventilation mode			
Alarm Limits			
High BR (Breath Rate) alarm limit	50 BPM		
Low BR (Breath Rate) alarm limit	5 BPM		
High PIP (Peak Inspiratory Pressure) alarm limit	20 cmH ₂ O		
Low PIP (Peak Inspiratory Pressure) alarm limit	1 cmH ₂ O		
High PEEP (Positive End Expiratory Pressure) Pressure alarm limit	+7 cmH ₂ O (above PEEP setting) [†]		
† High PEEP Pressure alarm limit is automatically set and cannot be adjusted.			
Breath Timeout			
Breath Timeout Action	12 BPM		
Breath Timeout Period	60 seconds		
Source Gas			
Source Gas	O ₂		
UTILITIES MENU SETTINGS	DEFAULT VALUE		
Vibration	OFF		
Audio Loudness	5		
Screen Brightness	3		

NOTE: Default values may be reset by entering the above values into the ventilator.

INTRODUCTION TO ALARMS AND TROUBLESHOOTING

WARNING:

- If the Life2000® Ventilator is not functioning properly, respiratory therapy may be compromised and may result in patient harm or death. Always have an alternate means of ventilation or oxygen therapy available.
- Reducing the alarm loudness level to lower than the ambient sound level will impede alarm condition recognition.
- Do not cover the ventilator, touch screen, speaker, or backup alarm buzzer with tape or any other object. Covering the ventilator or any of its parts might cause difficulty in hearing alarms and might affect ventilator performance.

ALARMS

Ventilator alarms are visual notifications that appear on the touch screen and are accompanied by distinct sounds or vibration (when set for vibration).

TROUBLESHOOTING

For more information about resolving situations that may occur during normal use of the ventilator that are not associated with an alarm, see "Troubleshooting" on page 64.

5 ALARMS AND TROUBLESHOOTING

ALARM SOUNDS AND MESSAGE DISPLAY

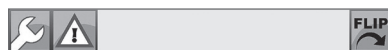
When an alarm notification occurs there is a distinct sound and a display message corresponding to the priority level of the alarm. The priority level of an alarm is indicated by the color and the rate at which the message flashes.



High-Priority Alarm

A red, rapidly flashing alarm message is an alarm that indicates a situation that requires immediate attention.

Sound: Sequence of two sets of five tones



Medium-Priority Alarm

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

Sound: Sequence of three tones



Low-Priority Alarm

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

Sound: Single tone

ACTIVE ALARMS WINDOW

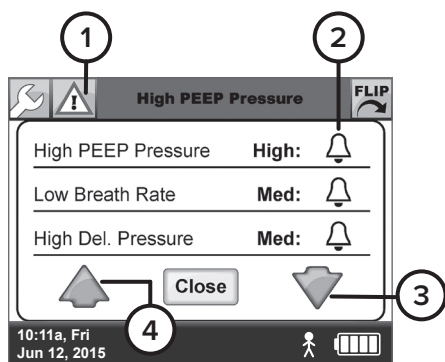
Multiple alarms may occur at the same time. Touch the **Active Alarms Button** at the top of the touch screen to display a list of active alarms.

NOTE: The **Active Alarms Button** is only visible during alarm notifications.

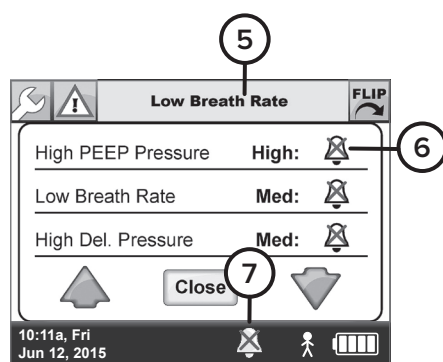


TIP:

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 **Up Arrow** and **Down Arrow** to scroll through the list.



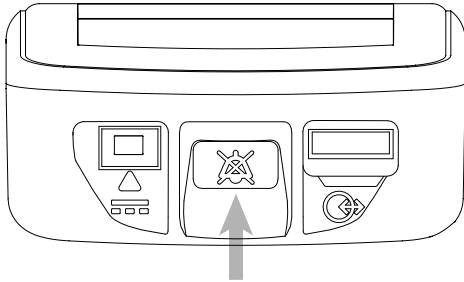
- 1 Touch the **Active Alarms Button** to display the alarm list.
- 2 **Alarm Icon**
- 3 Use the **Down Arrow** to view additional active alarms.
- 4 Use the **Up Arrow** to scroll to the beginning of the list of active alarms.



- 5 The alarm message at the top of the screen alternates between each occurring alarm.
- 6 **Alarm Silenced Icon**
- 7 The **Alarm Silenced Icon** is displayed at the bottom of the touch screen when all alarms are silenced.

SILENCING AND CLEARING ALARMS

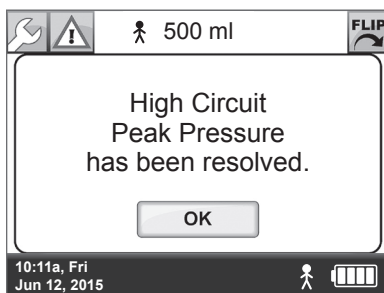
Silencing and clearing alarms is a multi-step process that depends on alarm priority and the number of active alarms.



- 1 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. If more than one alarm occurs, press the Silence Alarm button once for each alarm. The Silence Alarm button also temporarily stops vibration if the ventilator is set for vibration; for more information see "Setting Vibration" on page 52.

If the alarm is a medium- or high-priority alarm and is not silenced after 60 seconds, the alarm will continue with an additional buzzer and the breath light indicator will illuminate red until the condition is resolved.

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



- 3 After resolving a High Temperature, High Circuit Pressure, or High PEEP Pressure high-priority alarm, touch **OK** in the message that indicates the alarm has been resolved.

5 ALARMS AND TROUBLESHOOTING

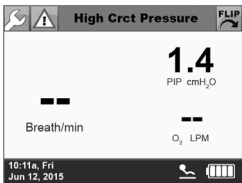
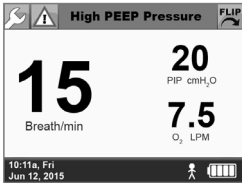
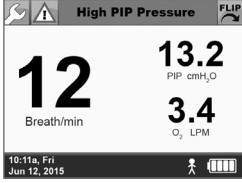
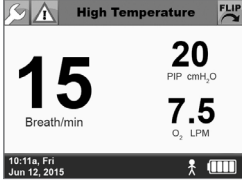
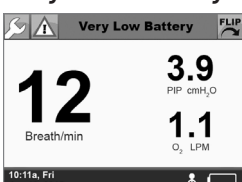
ALARMS

The following tables list high-, medium-, and low-priority alarms. For each alarm, the tables list the notification, the possible causes for the alarm, and possible options for resolving it. The sample screens are for illustrative purposes only.

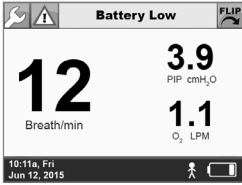
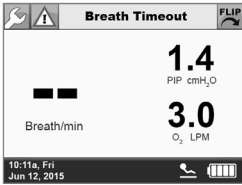

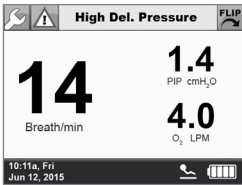
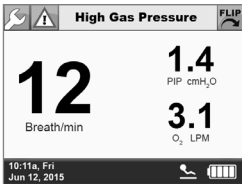
NOTES:

- When attempting to resolve alarm conditions, ensure that the patient receives adequate ventilation therapy; place the patient on an alternate means of ventilation if necessary.
- If an alarm persists, place the patient on an alternate means of ventilation and contact your service representative.

HIGH-PRIORITY ALARMS

NOTIFICATION	CAUSE	CHECKS AND POSSIBLE RESOLUTION
High Crct Pressure (High Circuit Pressure) 	Interface may be pinched or kinked	Check the interface tubing: replace it if it is pinched or kinked.
High PEEP Pressure 	Interface may be blocked	Check the interface tubing for any obstruction; inspect and clean the interface per the instructions for cleaning the interface.
High PIP Pressure 	Peak Inspiratory Pressure (PIP) exceeds the set limit	Check the interface or tubing for any obstruction. Check all connectors for possible damage. Re-adjust volume setting for the active prescription.
High Temperature 	Ventilator CPU or battery temperature is above the allowable limit	Check to make sure the ventilator is: <ul style="list-style-type: none"> Not near a heat source. In a well-ventilated area. Not covered or enclosed. Operating within the given operating environmental specifications (see page 67).
Very Low Battery 	Battery capacity drops below 15%	Connect the ventilator to the battery charger and an AC power source to recharge the battery.

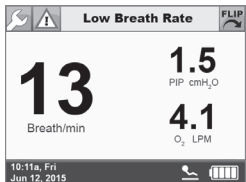
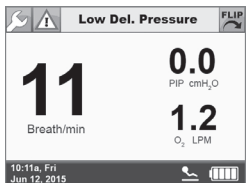
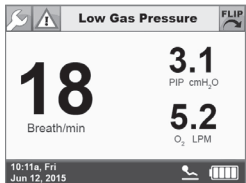
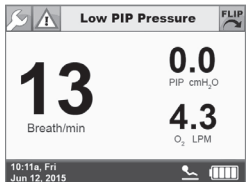

MEDIUM-PRIORITY ALARMS

NOTIFICATION	CAUSE	CHECKS AND POSSIBLE RESOLUTION
Battery Low 	Ventilator battery capacity drops below 25%.	Connect the ventilator to the battery charger and an AC power source to recharge the battery.
Breath Timeout 	No breath is detected for 20 or 60 seconds, depending on the setting	<p>Patient is not breathing.</p> <p>Patient is breathing through the mouth while using the Breathe Pillows Entrainment Interface.</p> <p>Breaths are too shallow to trigger ventilation; change the trigger sensitivity to a lower setting (higher sensitivity).</p> <p>Ensure patient interface is not leaking at patient side.</p> <p>Inspect and clean the interface per the instructions for cleaning the interface.</p>
High Breath Rate 	Respiratory rate exceeds the set limit.	<p>Patient is breathing faster than the rate set by the clinician.</p> <p>Inspect and clean the interface per the instructions for cleaning the interface.</p> <p>The ventilator may be false triggering because the trigger sensitivity setting is too low (in Assist or Assist/Control ventilation mode). Verify the ventilator is syncing with patient effort and adjust trigger sensitivity to a higher setting (lower sensitivity).</p>
High Del. Pressure (High Delivery Pressure) 	Interface pressure during delivery exceeds the maximum expected.	<p>Check the interface; ensure the interface tubing is not pinched, crushed, bent, or kinked.</p> <p>Replace the interface if the tubing is damaged.</p>
High Gas Pressure 	Gas pressure exceeds the allowable limit.	<p>Place the patient on an alternate means of ventilation.</p> <p>Ensure that you are using a 50-PSI (nominal) regulator when using a cylinder.</p> <p>If the alarm is not resolved, power off the ventilator and disconnect it from the pressure source. Contact your service representative.</p>

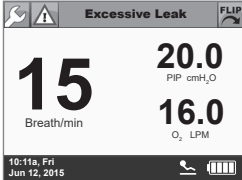
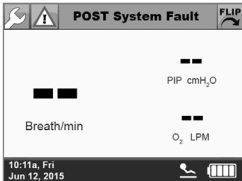
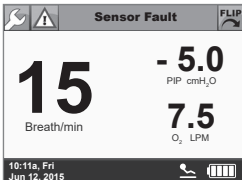
- When attempting to resolve alarm conditions, ensure that the patient receives adequate ventilation therapy; place the patient on an alternate means of ventilation if necessary.
- If an alarm persists, place the patient on an alternate means of ventilation and contact your service representative.

5 ALARMS AND TROUBLESHOOTING

MEDIUM-PRIORITY ALARMS (CONTINUED)

NOTIFICATION	CAUSE	CHECKS AND POSSIBLE RESOLUTION
Low Breath Rate 	Respiratory rate falls below set limit.	<p>Patient is breathing through the mouth while using the Breathe Pillows Entrainment Interface.</p> <p>Breaths are too shallow to trigger ventilation; change the trigger sensitivity to a lower setting (higher sensitivity).</p> <p>Ensure patient interface is not leaking at patient side.</p> <p>Inspect and clean the interface per the instructions for cleaning the interface.</p>
Low Del. Pressure (Low Delivery Pressure) 	Interface pressure during delivery fails to exceed the minimum expected.	<p>Check the interface connections.</p> <p>Check the interface; replace it if it is leaking or has any damage.</p>
Low Gas Pressure 	Gas pressure drops below the allowable limit	<p>Check all connections for possible leak.</p> <p>Ensure that the gas supply hose is not kinked or pinched.</p> <p>If using a cylinder as the pressure source:</p> <ul style="list-style-type: none"> • Ensure you are using a 50-PSI (nominal) regulator with a minimum outlet flow of ≥ 40 LPM at ≥ 41 PSI. • Ensure the gas source (e.g. cylinder) has a sufficient supply of gas (e.g. check that the cylinder is not empty.) • Ensure the cylinder valve is on or fully open. <p>If using a wall pressure source, ensure that the wall pressure source is on and operational.</p> <p>Connect the ventilator to another gas source.</p>
Low PIP Pressure 	Peak Inspiratory Pressure (PIP) below set limit	<p>Ensure patient interface is not leaking at patient side.</p> <p>Consider switching to another active Prescription Setting.</p> <p>If the alarm persists, contact your physician.</p>
System Fault 	Internal fault detected during operation	<p>If a system fault occurs, in the message on the touch screen to reboot, touch OK; the ventilator will turn itself off and then on again. Restart ventilation by pressing an Activity Button on the ventilator.</p> <p>If the system fault persists, place the patient on an alternate means of ventilation (if necessary) and contact your service representative.</p>

LOW-PRIORITY ALARMS

NOTIFICATION	CAUSE	CHECKS AND POSSIBLE RESOLUTION
Excessive Leak 	An excessive leak is present	Ensure patient interface or mask is positioned to ensure a proper seal.
POST System Fault 	System fault is detected during ventilator power on.	Power off the ventilator, and power it on again. If the system fault persists, place the patient on an alternate means of ventilation (if necessary) and contact your service representative.
Sensor Fault 	Sensor Fault detected during use of ventilator.	If unable to clear the alarm and the system fault persists, place the patient on an alternate means of ventilation (if necessary) and contact your service representative.

- When attempting to resolve alarm conditions, ensure that the patient receives adequate ventilation therapy; place the patient on an alternate means of ventilation if necessary.
- If an alarm persists, place the patient on an alternate means of ventilation and contact your service representative.

5 ALARMS AND TROUBLESHOOTING

TROUBLESHOOTING

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

NOTES:

- When attempting to troubleshoot, ensure that the patient receives adequate ventilation therapy; place the patient on an alternate means of ventilation if necessary.
- If the situation cannot be resolved by following the instructions here, place the patient on an alternate means of ventilation and contact your service representative.

NOTIFICATION	CAUSE	CHECKS AND POSSIBLE RESOLUTION
Breath indicator light is not syncing with patient breathing or is missing patient breaths	<p>A ventilator Prescription Setting button has not been pressed.</p> <p>Patient interface is not connected or is leaking.</p> <p>Patient's breath is too shallow to trigger breath.</p> <p>Patient is mouth breathing.</p> <p>Secretions may have built up on the interface, blocking the sense port.</p> <p>Patient is breathing faster than 40 BPM.</p>	<p>Press a Prescription Setting button.</p> <p>Verify that the interface is properly connected to the ventilator and is not leaking at patient side.</p> <p>Change the trigger sensitivity setting to a lower setting (higher sensitivity).</p> <p>Instruct patient to breathe in through their nose (pursed-lipped breathing is acceptable).</p> <p>Inspect and clean the interface per the instructions for cleaning the interface.</p> <p>It is normal for the ventilator to limit breath rate to 40 BPM.</p>
No volume output	<p>Ventilator is not on.</p> <p>A Prescription Setting button has not been pressed to start therapy.</p> <p>Patient interface is not connected or is leaking.</p> <p>Battery is depleted, if running on battery.</p> <p>Ventilator is inoperative.</p> <p>Oxygen or air hose is disconnected.</p> <p>Oxygen or air cylinder is empty, if using cylinder.</p> <p>Incorrect source gas supply hose is being used.</p> <p>Wall pressure source isn't operational.</p>	<p>Turn the ventilator on.</p> <p>Press a Prescription Setting button.</p> <p>Verify that the interface is properly connected to the ventilator and is not leaking at patient side.</p> <p>Connect the ventilator to the battery charger and an AC power source to recharge the battery.</p> <p>If there still is no volume output, contact your service representative.</p> <p>Check the gas supply hose connections.</p> <p>Replace the cylinder, or connect to a wall pressure source.</p> <p>Ensure that the correct gas supply hose (oxygen or air) is connected.</p> <p>Try another wall pressure source.</p>

TROUBLESHOOTING (CONTINUED)

NOTIFICATION	CAUSE	CHECKS AND POSSIBLE RESOLUTION
Breath indicator light is not flashing and there is no volume output	Ventilator is not on. A ventilator Prescription Setting button has not been pressed.	Ensure ventilator is on. Press a Prescription Setting button.
Ventilator is triggering during exhalation.	Secretions have built up on the interface.	Inspect and clean the interface per the instructions for cleaning the interface.
Ventilator is delivering therapy without being triggered by patient effort.	Ventilator is in Control or Assist/Control ventilation mode. The trigger sensitivity is too sensitive. Secretions have built up on the interface. Patient interface or connector is damaged.	It is normal for the ventilator to deliver therapy based on breath rate and breath timeout settings; adjust settings as required. Adjust trigger sensitivity to a higher setting (lower sensitivity). Inspect and clean the interface per the instructions for cleaning the interface. Check the patient interface and connector for damage and replace if necessary.
Ventilator sometimes misses breaths.	Patient is breathing faster than 40 BPM. Secretions have built up on the interface. Patient interface is not properly connected or is leaking.	It is normal for the ventilator to limit breath rate to 40 BPM. Inspect and clean the interface per the instructions for cleaning the interface. Verify that the interface is properly connected to the ventilator and is not leaking at patient side.
Therapy delivery is causing coughing or irritation in airway.	Interface is not positioned correctly. Patient is breathing against ventilator-triggered breaths.	Reposition the interface per the instructions in "Chapter 3: Connecting the Interface". Switch to another active Prescription Setting. If symptoms persist, contact your physician.
Ventilator battery does not last as long as expected after a charge.	Ventilator battery is not charged completely. Ventilator battery life is nearing its end.	Connect the ventilator to the battery charger and an AC power source to recharge the battery. Contact your service representative.
An alarm flashes on the screen intermittently	Low gas pressure	The cylinder is nearly empty; connect the ventilator to a full cylinder, or connect to a wall pressure source.
Ventilator buzzer sounds constantly for two to five minutes and screen goes black	The ventilator battery is damaged.	Contact your service representative.
Ventilator does not turn on	Ventilator battery is completely discharged.	Connect the ventilator to the battery charger and an AC power source to recharge the battery.

- When attempting to troubleshoot, ensure that the patient receives adequate ventilation therapy; place the patient on an alternate means of ventilation if necessary.
- If the situation cannot be resolved by following the instructions here, place the patient on an alternate means of ventilation and contact your service representative.

5 ALARMS AND TROUBLESHOOTING

TROUBLESHOOTING (CONTINUED)

NOTIFICATION	CAUSE	CHECKS AND POSSIBLE RESOLUTION
The oxygen or air hose does not connect to the gas source.	An incorrect source gas supply hose is being used. An incompatible regulator is being used, if using a cylinder. An incorrect adapter is being used, if using a wall pressure source.	Ensure you are using the correct approved gas supply hose (oxygen or air). Ensure the gas regulator is 42-87 PSI with a standard DISS fitting. Ensure that the adapter has a DISS 1240 fitting for oxygen or a DISS 1160-A fitting for air.
Cylinder does not last as long as expected, if using a cylinder.	Patient breath rate is higher than expected. Selected Prescription Setting requires higher volumes of gas. Cylinder was not full at the beginning of ventilation. The gas regulator is not properly connected to the gas cylinder. Flow regulator is on. The gas regulator may have a leak.	Refer to "Cylinder Duration Information" on page 16. Obtain a new or larger cylinder. Obtain a new cylinder. Reconnect the gas regulator to the gas cylinder and verify there are no leaks. Ensure the flow valve on the regulator is off or set to 0. The regulator sealing washer that connects to the gas cylinder may be worn or damaged. Contact your service representative.
Negative PIP value is displayed	Low PIP	When using the Life2000® Ventilator interfaced with the UCC in conjunction with a full-face mask; when the system is disconnected, the Low PIP alarm will be initiated and a negative value PIP may be displayed.
"Incompatible Settings" message is displayed	The PEEP or Volume setting is incompatible to maintain clinical settings.	Touch OK and then re-evaluate and readjust the Volume, PEEP, or I-Time setting in the Ventilation Settings screen.
"This Prescription Setting is not active" message is displayed	The selected Prescription Setting button is not active.	Touch OK and choose another active Prescription Setting button to change the currently-ventilating prescription.
"Connect Oxygen Source" or "Disconnect Oxygen Source" message is displayed	A reminder to verify that the correct source gas is connected	Verify that the correct source gas is connected, then press OK to begin ventilating.

- When attempting to troubleshoot, ensure that the patient receives adequate ventilation therapy; place the patient on an alternate means of ventilation if necessary.
- If the situation cannot be resolved by following the instructions here, place the patient on an alternate means of ventilation and contact your service representative.

CHAPTER 6: MAINTENANCE

CLEANING BEFORE FIRST USE

It is not necessary to clean or sterilize the Life2000® Ventilator before the first use.

DAILY CHECKS

Look at the ventilator components daily. If any of the following conditions are discovered, discontinue use of the ventilator:

- Check for cracks in the casing.
- Check for loose or damaged buttons, connectors, or other control and alarm components.
- Check the interface and the oxygen or air hose (if applicable) for leaks and loose or damaged cabling or connectors.

Essential Performance:

- Absence of system fault alarms
- Unintended change of settings and modes
- Absence of false alarms
- No interruption of operation without alarms.

Do not use, or discontinue use of the ventilator, if damage is discovered. For instructions on servicing or replacing damaged ventilator components, contact your Hillrom_® service representative.

ENVIRONMENTAL SPECIFICATIONS

Do not use the ventilator if the ambient temperature is greater than 40°C (104°F) or less than 5°C (41°F).

Store the ventilator in ambient temperatures less than 60°C (140°F) and greater than -20°C (-4°F).

WARNING:

The backside of the ventilator enclosure may reach 49°C in a 40°C environment.

6 MAINTENANCE

ALARM CHECKS

Confirm that when the ventilator is powered on, it makes audible tones. If tones are not heard, the ventilator should be returned to your service representative

CLEANING AND DISINFECTING THE VENTILATOR

Using a clean cloth, clean and disinfect the external surfaces of the ventilation system with:

- Clorox Disposable Wipes
- PDI Super Sani-Cloth® Germicidal Disposable Wipes
- 70% isopropyl alcohol
- Virex II

- **NOTE:** Always follow the cleaning manufacturer's suggested wait time before you wipe off the residue.
- Wipe the surface of the ventilation system with clean dry cloth to remove any residual cleaner.
- Do not clean the ventilation system with petrochemical or oil-based materials.
- Clean the touch screen with a soft microfiber cloth and disinfect with PDI Super Sani-Cloth® Germicidal Disposable Wipes as necessary. After allowing for the manufacturer's suggested wait time, wipe the screen with clean cloth to remove any residual cleaner.



CAUTION:

- 70% isopropyl alcohol or Virex II may damage the touch screen. When cleaning external surfaces of the ventilation system with 70% isopropyl alcohol or Virex II, avoid contact with the touch screen.
- Keep in a clean environment to protect the ventilation system from ingress of dust, lint, and pests.
- Do not leave exposed to the sun or other sources of radiant heat, it may overheat.
- Do not allow children or pets to access the ventilation system; it may become damaged.

CLEANING FOR SINGLE PATIENT USE

VENTILATOR

Once a week, or more often if necessary, follow the instructions found in the “Cleaning and Disinfecting the Ventilator” section of this chapter.

BREATHE PILLOWS ENTRAINMENT INTERFACE

Once a week, or more often if necessary, follow the instructions found in the “Cleaning the Breathe Pillows Entrainment Interface” section of this chapter.

6 MAINTENANCE

CLEANING FOR MULTI-PATIENT USE

WARNING:

To prevent risk of cross-contamination, clean and disinfect the ventilator before using it on a new patient, and use a new Breathe Pillows Entrainment Interface.

In addition to the cleaning and maintenance instructions for single-patient use, you must perform the following before the ventilator is provided to a new patient.

VENTILATOR

Follow the instructions in "Cleaning and Disinfecting the Ventilator" on page 68.

BREATHE PILLOWS ENTRAINMENT INTERFACE

Replace between patients.

CLEANING AND DISINFECTING THE OXYGEN HOSES

OXYGEN HOSES

To disinfect the hoses, use a clean cloth, clean and disinfect the external surfaces of the hoses with the cleaners listed below:

- Clorox Disposable Wipes
- PDI Super Sani-Cloth® Germicidal Disposable Wipes
- 70% isopropyl alcohol
- Virex II

NOTE:

- Always follow the cleaning manufacturer's suggested wait time before you wipe off the residue.
- Wipe the surface of the ventilation system with clean dry cloth to remove any residual cleaner.

WARNING:

Do not subject source gas supply hoses to heat sterilization, hot water pasteurization, autoclaving, radiation sterilization, ethylene oxide gas sterilization, or attempt to clean them in a dishwasher or microwave oven. Doing any of these may damage the hoses and impair gas delivery.

THIRD-PARTY PATIENT MASK OR TUBE

Follow the manufacturer's instructions.

CLEANING THE BREATHE PILLOWS ENTRAINMENT INTERFACE

⚠ WARNING:

Do not subject the Breathe Pillows Entrainment 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 gas delivery.

If mucous accumulates on the patient 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 such as dishwashing soap to remove it.

CLEANING INSTRUCTIONS FOR THE BREATHE PILLOWS ENTRAINMENT INTERFACE

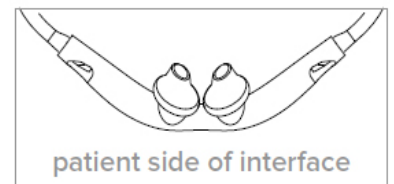
NOTE: These cleaning instructions require the interface to be disconnected from the ventilator. Ensure that the patient receives adequate ventilation therapy; place the patient on an alternate means of ventilation if necessary.

BEFORE CLEANING:

- ① Place the patient on an alternate means of ventilation, if necessary.
- ② Turn off the low-flow oxygen source according to the manufacturer's instructions.
- ③ Power off the ventilator.
- ④ Disconnect the Interface from the ventilator.
- ⑤ Disconnect the oxygen tubing from the interface.

CLEAN THE INTERFACE:

- ⑥ Submerge the patient side of the Interface in a clean container of mixed warm water suitable for drinking and a mild detergent (e.g., dishwashing soap) and agitate the patient side of the Interface to clean it. Rinse the patient side of the Interface thoroughly with warm water.



PURGE THE INTERFACE:

- ⑦ Perform a purge immediately after the rinse to completely dry the Interface and to clear any excess water that may impede air flow. For purging instructions, see the section "Purging the Breathe Pillows Entrainment Interface" on the next page.

DRY THE INTERFACE:

- ⑧ Hang the Interface to completely dry in a location away from direct sunlight.

PURGE THE INTERFACE AGAIN:

- ⑨ Before reusing the Interface, perform a second purge to clear any excess water that may impede air flow. For purging instructions, see the section "Purging the Breathe Pillows Entrainment Interface."

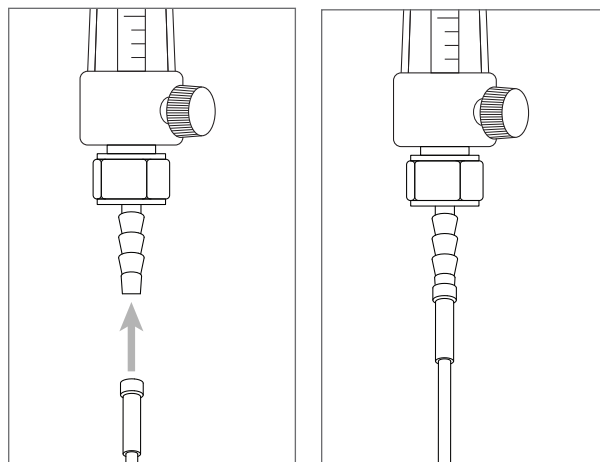
6 MAINTENANCE

PURGING THE BREATHE PILLOWS ENTRAINMENT INTERFACE

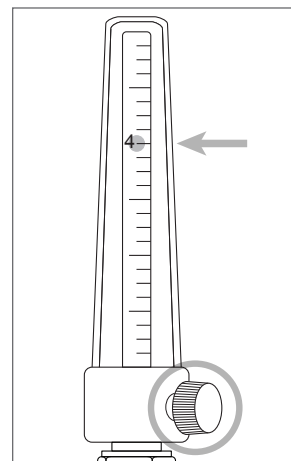
After cleaning and completely drying the interface or when you suspect dust or debris has entered the airflow passage, purge the interface with the purge tube and either a wall pressure source (with a flow meter) or a cylinder. **NOTE:** The ventilator is not required for the purging process.

PURGING USING A WALL PRESSURE SOURCE

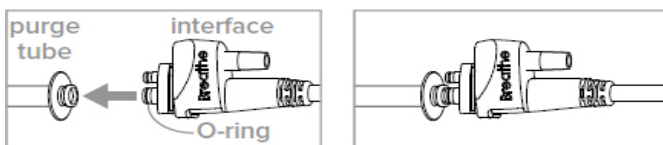
- 1 Using a wall pressure source with a flow meter, place the green end of the purge tube over the barbed outlet on the flow meter until it is securely attached.



- 2 Rotate the knob on the flow meter to adjust the flow to 4 LPM

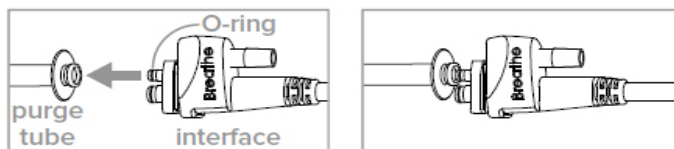


- 3 Firmly press and hold the smaller end of the purge tube over one of the interface ports that connect the interface to the compressor.
NOTE: Take care not to slide the tube over the O-ring of the port.

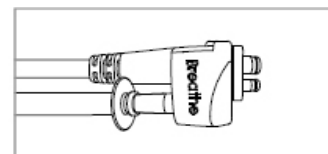
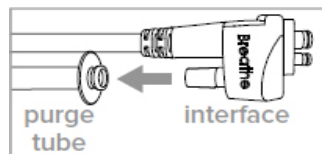


Hold the purge tube over the interface port until all the water and/or dust or debris is purged from the tube.

- 4 Repeat step 3 for the other interface port.



- 5 Firmly press the smaller end of the purge tube over the oxygen tubing connection on the interface.



- 6 Rotate the knob on the flow meter to the zero or OFF position.

- 7 Remove the purge tube from the barbed outlet.

- 8 Store the purge tube in a clean place for future use.

PURGING USING A CYLINDER

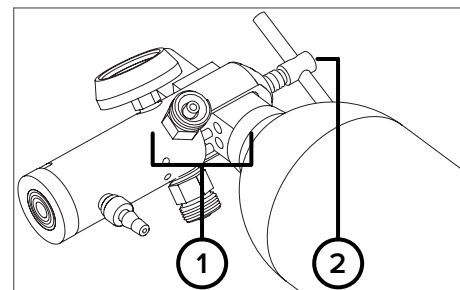
Purging with a cylinder requires a flow regulated barbed output. The instructions below are provided as an example of purging using a regulator with an integrated flow regulated barbed output.

Refer to the regulator and source gas supply manufacturer's instructions for more information about how to connect the cylinder and regulator.

NOTE: If using a cylinder with a built-in regulator, skip to step 3.

- 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.

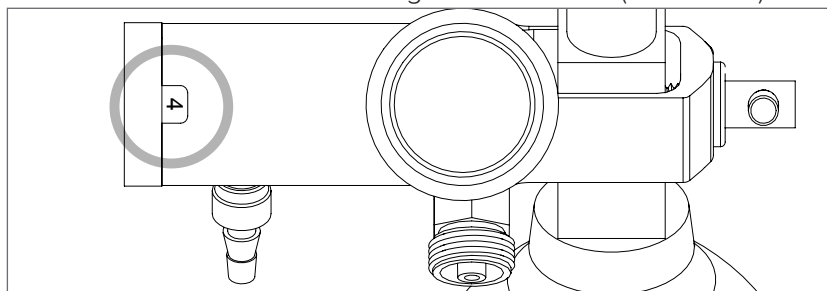
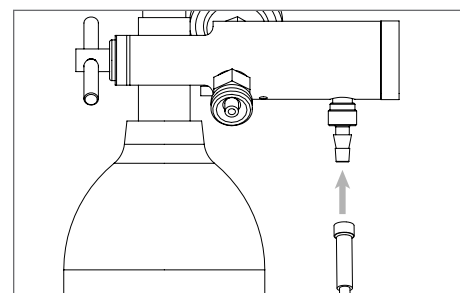
- 2 Tighten the tee screw on the regulator by turning the handle clockwise.



- 3 Place the green end of the purge tube over the barbed outlet until it is securely attached.

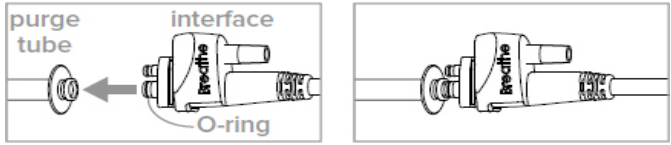
- 4 Turn on the gas supply according to the regulator and source gas supply manufacturer's instructions.

- 5 Rotate the barbed outlet flow regulator to 4 LPM (see below).



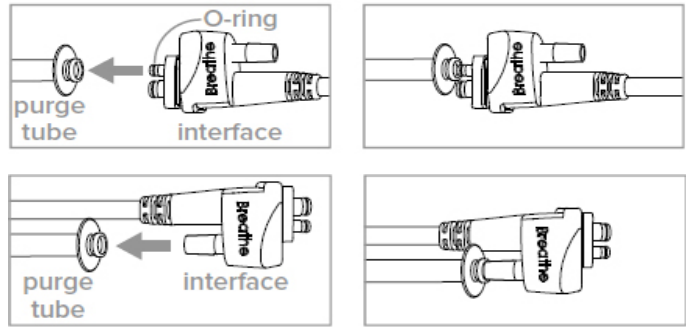
6 MAINTENANCE

- ⑥ Firmly press and hold the smaller end of the purge tube over one of the interface ports that connect the interface to the compressor.
NOTE: 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 Firmly press the smaller end of the purge tube over the oxygen tubing connection on the interface.



- ⑨ Rotate the barbed outlet flow regulator to the zero or OFF position.
- ⑩ Turn off the gas supply according to the regulator and gas supply manufacturer's instructions.
- ⑪ Remove the purge tube from the barbed outlet.
- ⑫ Store the purge tube in a clean place for future use.

PREVENTIVE MAINTENANCE

 **WARNING:** Unauthorized modifications can result in equipment damage, or patient injury or death.

 **CAUTION:** No user serviceable components are inside the device.

Contact your service representative to make arrangements for preventive maintenance, service, and component replacement 2.5 years from the date of shipment.

The ventilator can only be serviced or repaired by an authorized service center. Trained personnel and authorized service centers are provided with the proper documentation to maintain the ventilator.

When shipping the ventilator, use proper packaging for protection.

 **TIP:**

The ventilator is shipped in specially designed, protective boxes. Do not throw away the boxes; keep them for future transportation needs.

BATTERY REPLACEMENT

Contact your service representative to make arrangements for replacing the battery if battery runtime degrades to an unacceptable level. The battery can only be serviced or repaired by an authorized service center.

6 MAINTENANCE

TESTING VENTILATOR ALARMS

This section gives instructions for testing ventilator alarms. Procedures described in this section are only to be performed by trained personnel.

Connect the ventilator to an AC power source or ensure the battery has sufficient charge before beginning testing.

If any test fails, contact your service representative.

VERIFYING POWER-ON SELF-TEST ALARMS

- ① Press the Power button to turn on the ventilator.
- ② Verify that there are audible tones while powering on the ventilator.

VERIFYING BACKUP ALARM BUZZER

- ① With the ventilator powered on and source gas connected and set to 50 psig, press an available Activity Button on the ventilator. The top of the touch screen should display a Low Gas Pressure Alarm and you should hear a sequence of three tones.
- ② Allow the ventilator to continue to alarm. After 70 seconds, the alarm should sound with an additional buzzer and the breath light indicator will illuminate red to indicate the alarm has not been silenced.
- ③ Power off the ventilator.

CHECKING ALARM CONDITIONS

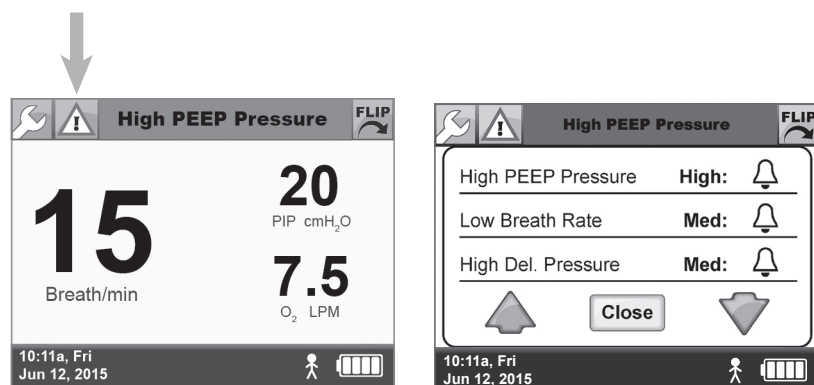
Do not test while the ventilator is being used on a patient.

These testing procedures require clinical settings to be changed. If necessary, record clinical settings before beginning.

For each test verify both corresponding alarm notifications occur and are correct:

- 1 The visual alarm appears on the touch screen, and
- 2 The audio alarm is audible, or the ventilator vibrates if set for vibration.

NOTE: Other alarms and/or multiple alarms may occur during the testing procedure. If a different alarm occurs from the one you're testing for, use the **Active Alarms** button on the touch screen to display the alarm list. The alarm you are testing for may be listed in the list of additional alarms. For more information, see "Chapter 5: Alarms and Troubleshooting" on page 57.



As long as the alarm you are testing for is listed, the test may be considered complete.

If the alarm is not listed, turn off the ventilator, and turn it back on. Check that the test settings are correct and repeat the test.

EQUIPMENT REQUIRED FOR TESTING

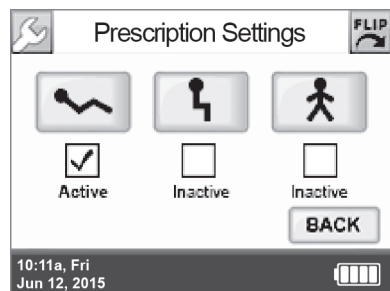
- 1 Life2000® Ventilator
- 2 An adjustable gas source connected to an adjustable regulator (to test the High Gas Pressure alarm, both must be able to reach 95 PSI). Either oxygen or air may be used for testing.
- 3 A Breathe Pillows Entrainment Interface

NOTE: The interface will be handled during testing. Thoroughly clean the testing interface before using it on a patient or purchase the Performance Verification Testing Kit for Life2000® Ventilators. For information about ordering accessories and replacement parts, see "Accessories and Replacement Parts" on page 89.

6 MAINTENANCE

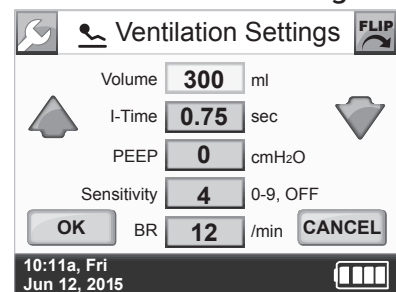
TESTING SETUP

- 1 Power on the ventilator. If necessary, record clinical settings before changing settings.



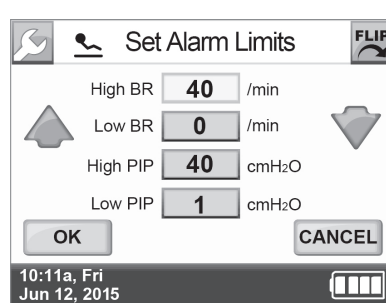
- 2 Using the Clinician's Menu, activate only the **Low Activity Prescription Setting**.

Set the **Ventilation Settings** to:



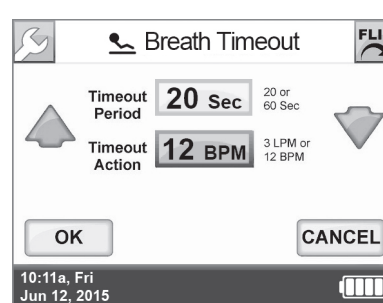
Touch **OK** and then **CONFIRM**.

Set the **Alarm Limits** to:



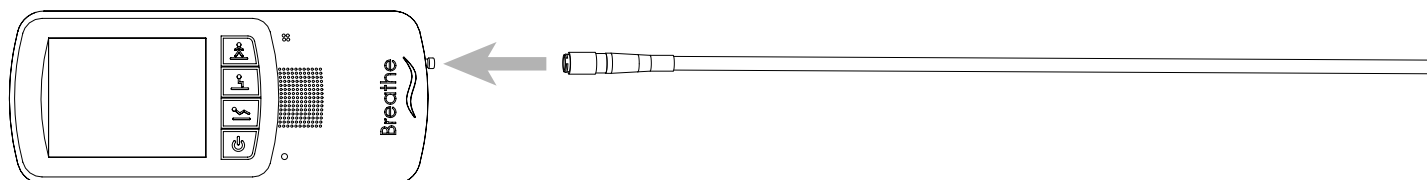
Touch **OK** and then **CONFIRM**.

Set the **Breath Timeout** to:

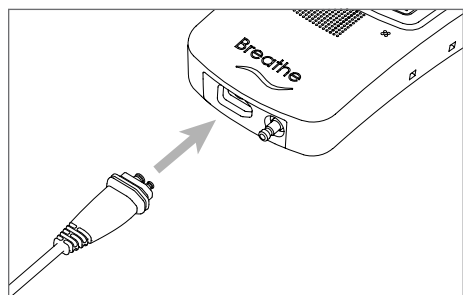


Touch **OK** and then **CONFIRM**.

Set the **Source Gas** to whatever source gas is being used for testing.



- 3 Connect the adjustable source gas to the ventilator using an adjustable regulator set to 50 PSI. Turn on the source gas to 50 PSI nominal.



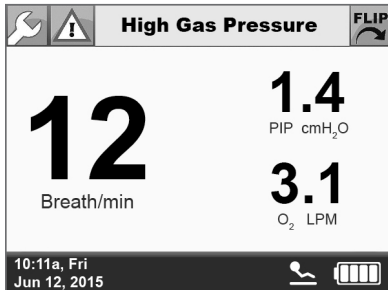
- 4 Connect the interface. For more information, see "Chapter 3: Connecting the Interface" on page 25.

NOTE: The interface does not need to be worn during testing.

Place the ventilator on a flat surface where the interface connection will not be jostled. Set the interface aside, with nasal pillows and tubing free of anything that might impede air flow.

1. TESTING THE HIGH GAS PRESSURE ALARM (MEDIUM PRIORITY)

- 1 Begin by ventilating using the Low Activity Prescription Setting. Allow the ventilator to ventilate for a few breaths.
- 2 With the source gas supply on and connected to the ventilator and an adjustable regulator, set the regulator to 95 PSI.



- 3 The top of the touch screen should display the High Gas Pressure alarm and you should hear a sequence of three tones indicating a medium-priority alarm or vibrate.

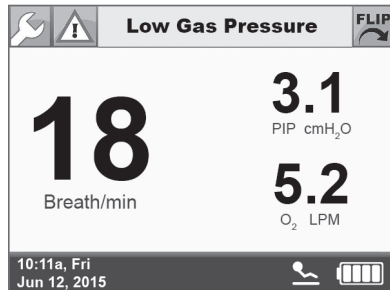
NOTES:

- If the Low PIP Pressure alarm is displayed before the High Gas Pressure alarm, increase the volume in the **Ventilation Settings** until the Low PIP Pressure alarm clears. Changes to the **Ventilation Settings** take effect only after selecting the **OK** and **CONFIRM** buttons.
 - If a low- or medium-priority alarm occurs while the ventilator is set for vibration, and the alarm is not resolved within 60 seconds, an audible alarm occurs.
- 4 After verifying the correct alarm notifications, adjust the regulator to 50 PSI.
The High Gas Pressure alarm will resolve itself once the regulator has been adjusted to 50 PSI.

6 MAINTENANCE

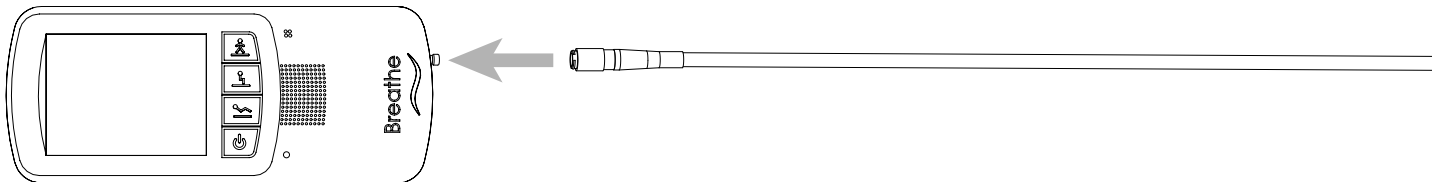
2. TESTING THE LOW GAS PRESSURE ALARM (MEDIUM PRIORITY)

- 1 Begin by ventilating using the Low Activity setting. Allow the ventilator to ventilate for a few breaths.
- 2 Disconnect the source gas supply hose from the ventilator connection by pulling back on the knurled ring until the hose detaches.



- 3 The top of the touch screen should display the Low Gas Pressure alarm, and you should hear a sequence of three tones indicating a medium-priority alarm or vibrate. Allow the ventilator to continue to alarm.

NOTE: If a low- or medium-priority alarm occurs while the ventilator is in vibration mode, and the alarm is not resolved within 60 seconds, an audible alarm occurs.



- 4 After verifying the correct alarm notifications, reattach the source gas supply hose to the ventilator. The Low Gas Pressure alarm will resolve itself once the gas supply is correctly reattached.

3. TESTING THE HIGH DELIVERY PRESSURE ALARM (MEDIUM PRIORITY)

- 1 Begin by ventilating using the Low Activity setting. Allow the ventilator to ventilate for a few breaths.
- 2 As soon as the breath indicator light shows a breath being delivered by the ventilator, quickly pinch the interface tubing near the ventilator connection.



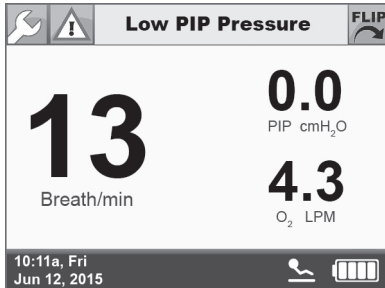
- 3 The top of the touch screen should display the High Delivery Pressure (High Del. Pressure) alarm, and you should hear a sequence of three tones indicating a medium-priority alarm or vibrate.

NOTE: If a low- or medium-priority alarm occurs while the ventilator is in vibration mode, and the alarm is not resolved within 60 seconds, an audible alarm occurs.

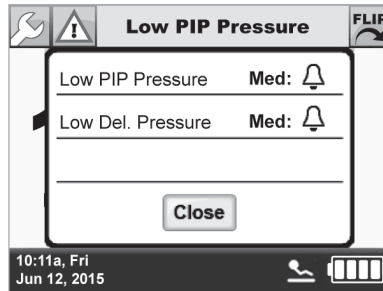
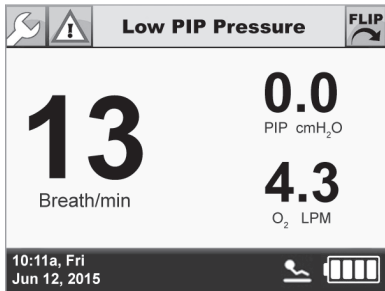
- 4 After verifying the correct alarm notifications, release the interface tubing. The High Delivery Pressure alarm will resolve itself once the interface has been released.

4. TESTING THE LOW PIP PRESSURE ALARM (MEDIUM PRIORITY) AND LOW DELIVERY PRESSURE ALARM (MEDIUM PRIORITY)

- 1 Begin by ventilating using the Low Activity setting. Continue to use the current **Ventilation Settings**. Allow the ventilator to ventilate for a few breaths.
- 2 Disconnect the interface from the ventilator.

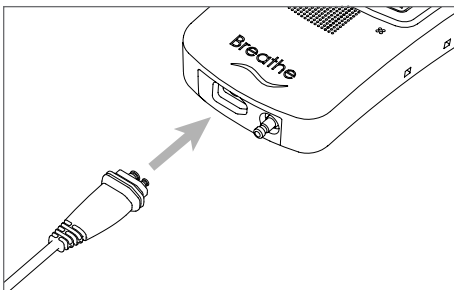


- 3 The top of the touch screen should display the Low PIP Pressure alarm, and you should hear a sequence of three tones indicating a medium-priority alarm or vibrate.

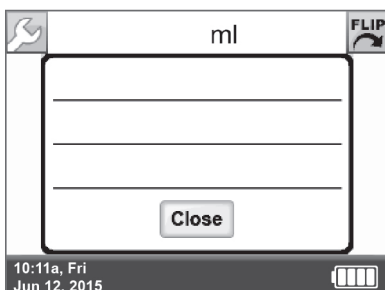


- 4 Use the active alarms button at the top of the touch screen to display the active alarms window; the Low Del. Pressure alarm should be listed in the list of alarms.

NOTE: If a low- or medium-priority alarm occurs while the ventilator is in vibration mode, and the alarm is not resolved within 60 seconds, an audible alarm occurs.



- 5 After verifying the correct alarm notifications, reconnect the interface to the ventilator. The alarms should resolve themselves once the interface is correctly reattached.

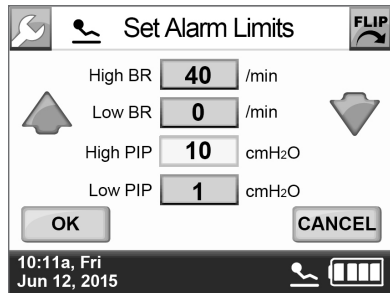


- 6 Close the active alarm list by touching the **Close** button.

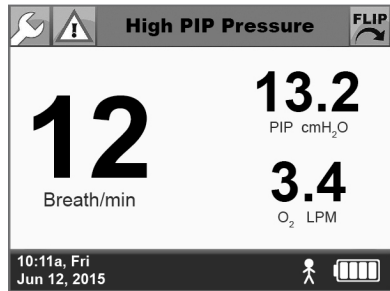
6 MAINTENANCE

5. TESTING THE HIGH PIP PRESSURE ALARM (HIGH PRIORITY)

- 1 Begin by ventilating using the Low Activity setting. Continue to use the current **Ventilation Settings**. Allow the ventilator to ventilate for a few breaths.



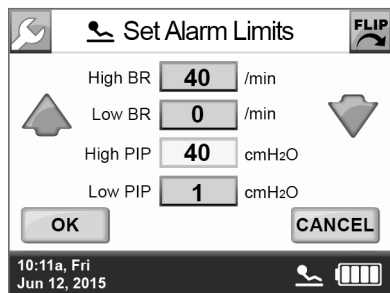
- 2 Using the **Clinician's Settings** Menu, navigate to **Alarm Limits** and change the **High PIP** alarm limit to 10 cmH₂O. Select **OK** and **CONFIRM**.
- 3 Use your thumbs to completely plug the nasal pillows on the Breathe Pillows Entrainment Interface until the ventilator alarms.



- 3 The top of the touch screen should display the High PIP Pressure alarm, and you should hear a sequence of two sets of five tones indicating a high priority alarm.

NOTE: For a high-priority alarm, an audible tone immediately occurs with a vibration alarm with no delay.

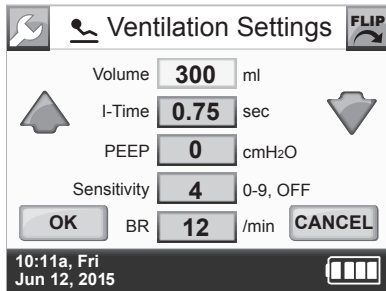
- 4 After verifying the correct alarm notifications for the High PIP Pressure alarm, release the interface and allow the alarm to resolve itself.



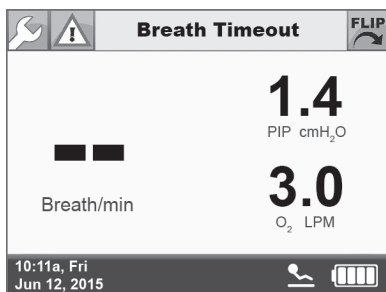
- 5 Using the **Clinician's Settings** Menu, navigate to **Alarm Limits** and return the **High PIP** alarm limit to 40 cmH₂O. Select **OK** and **CONFIRM**.

6. TESTING THE BREATH TIMEOUT ALARM (MEDIUM PRIORITY) AND HIGH CIRCUIT PRESSURE ALARM (HIGH PRIORITY)

- 1 Begin by ventilating using the Low Activity setting. Allow the ventilator to ventilate for a few breaths.



- 2 Using the **Clinician's Settings** Menu, navigate to Alarm Limits and change the **BR** setting to 0/min.

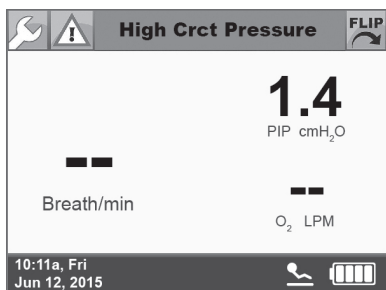


- 3 Wait up to 20 seconds to allow the Breath Timeout to trigger. The top of the touch screen should display the Breath Timeout alarm, and you should hear a sequence of three tones indicating a medium-priority alarm or vibrate.

NOTES:

- The High Del. Pressure alarm may appear before the Breath Timeout alarm.
- If a low- or medium-priority alarm occurs while the ventilator is set for vibration, and the alarm is not resolved within 60 seconds, an audible alarm occurs.

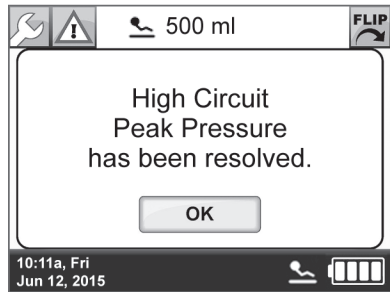
- 4 After verifying the correct alarm notifications for the Breath Timeout alarm, kink (try to impede air flow) the interface tubing near the connection to the ventilator.



- 5 Within a few seconds the top of the touch screen should display the High Circuit Pressure (High Crct Pressure), and you should hear a sequence of two sets of five tones indicating a high priority alarm.

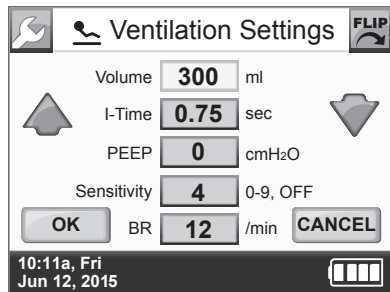
NOTE: For a high-priority alarm, an audible tone immediately occurs with a vibration alarm with no delay.

6 MAINTENANCE



- 6 After verifying the correct alarm notifications for the High Circuit Pressure alarm, release the interface tubing and allow the High Circuit Pressure alarm to resolve itself.

Touch **OK** in the message that indicates the alarm has been resolved.

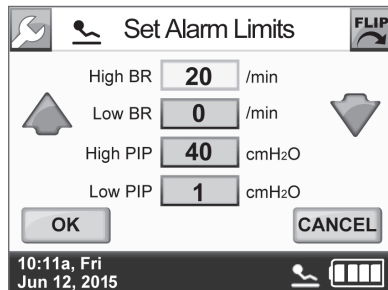


- 7 Using the **Clinician's Settings** Menu, navigate to **Ventilation Settings** and return the **BR** setting to 12/min. Select **OK** and **CONFIRM**.

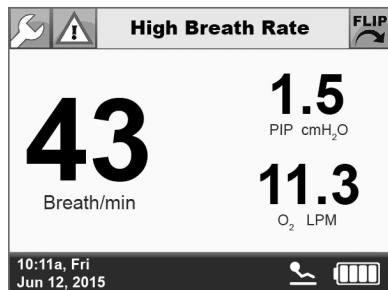
The **Breath Timeout** alarm will resolve itself once the setting is changed.

7. TESTING THE HIGH BREATH RATE ALARM (MEDIUM PRIORITY)

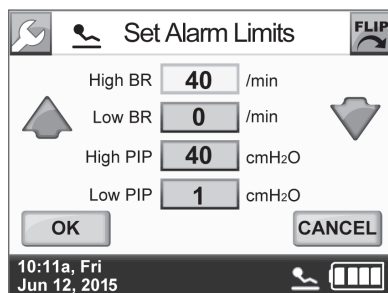
- 1 Begin by ventilating using the Low Activity setting. Continue to use the current **Ventilation Settings**. Allow the ventilator to ventilate for a few breaths.



- 2 Using the **Clinician's Settings** Menu, navigate to **Alarm Limits** and change the **High BR** alarm limit to 20/min. Select **OK** and **CONFIRM**.
- 3 Repeatedly pinch the interface tubing near the ventilator to impede, but not completely stop, airflow. Pinch more than once every three seconds to alarm.



- 4 The top of the touch screen should display the High Breath Rate alarm, and you should hear a sequence of three tones indicating a medium-priority alarm or vibrate.
NOTE: If a low- or medium-priority alarm occurs while the ventilator is in vibration mode, and the alarm is not resolved within 60 seconds, an audible alarm occurs.
- 5 After verifying the correct alarm notifications, release the interface tubing. The High Breath Rate alarm will resolve itself within a few breaths.

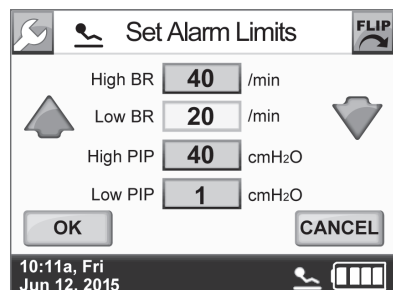


- 6 Using the **Clinician's Settings** Menu, navigate to **Alarm Limits** and return the **High BR** alarm limit to 40/min. Select **OK** and **CONFIRM**.

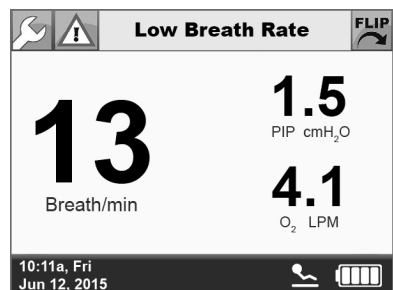
6 MAINTENANCE

8. TESTING THE LOW BREATH RATE ALARM (MEDIUM PRIORITY)

- 1 Begin by ventilating using the Low Activity setting. Continue to use the current **Ventilation Settings**. Allow the ventilator to ventilate for a few breaths.

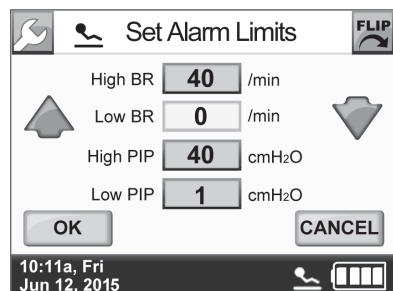


- 2 Using the **Clinician's Settings** Menu, navigate to **Alarm Limits** and change the **Low BR** alarm limit to 20/min. Select **OK** and **CONFIRM**.



- 3 The top of the touch screen should display the Low Breath Rate alarm, and you should hear a sequence of three tones indicating a medium-priority alarm or vibrate.
NOTE: If a low- or medium-priority alarm occurs while the ventilator is in vibration mode, and the alarm is not resolved within 60 seconds, an audible alarm occurs.

- 4 After verifying the correct alarm notifications, release the interface tubing.

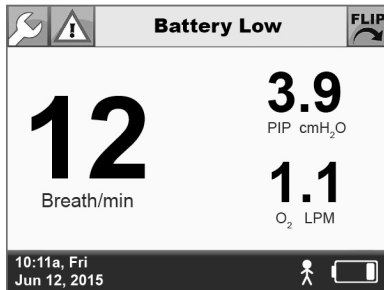


- 5 Using the **Clinician's Settings** Menu, navigate to **Alarm Limits** and return the **Low BR** alarm limit to 0/min. Select **OK** and **CONFIRM**.

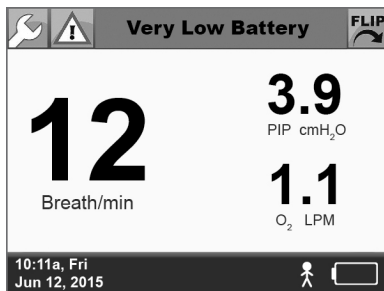
The **Low BR** alarm will resolve itself when the **Low BR** alarm limit is returned to 0/min.

9. TESTING THE BATTERY LOW ALARM (MEDIUM-PRIORITY) AND VERY LOW BATTERY ALARM (HIGH-PRIORITY)

- 1 If the ventilator is connected to an AC power source, disconnect the ventilator from the power source so it is running on its internal battery.
- 2 Ventilate by using the High Activity Setting.
- 3 Allow the ventilator to ventilate until the Battery Low Alarm occurs (25% battery charge).



- 4 The top of the touch screen should display the Battery Low alarm and you should hear a sequence of three tones indicating a medium-priority alarm or vibrate.
NOTE: If a low- or medium-priority alarm occurs while the ventilator is in vibration mode, and the alarm is not resolved within 60 seconds, an audible alarm occurs.
- 5 After verifying the correct alarm notifications for the Battery Low alarm, allow the ventilator to continue ventilating at the High Activity setting. The ventilator will continue to alarm for the Battery Low alarm until the Very Low Battery alarm occurs (15% battery charge).



- 6 When the Very Low Battery alarm occurs, the screen should display the Very Low Battery alarm, and you should hear a sequence of two sets of five tones indicating a high priority alarm.
NOTE: For a high-priority alarm, an audible tone immediately occurs with a vibration alarm with no delay.
- 7 After verifying the correct alarm notifications for the Very Low Battery alarm, connect the ventilator to an AC power source and allow the internal battery to recharge.

AFTER CHECKING ALARM CONDITIONS

After testing has been completed successfully, program clinical settings for patient use and make sure that the ventilator has sufficient charge before using it on a patient.

OXYGEN MONITOR

WARNING:

To ensure accuracy of oxygen administration and to monitor for the presence of contamination (incorrect gas connected), use an external oxygen monitor to verify the oxygen concentration in the delivered gas.

If the patient requires oxygen monitoring, use the appropriate equipment. Sampling should be taken from the connection to the patient interface.


EXHALATION VOLUME MONITOR

WARNING:

To monitor minute volume, use an external exhaled volume monitor.

If the patient requires exhalation volume monitoring, use the appropriate equipment. Sampling should be taken from the connection to the patient interface.

ACCESSORIES AND REPLACEMENT PARTS

 **WARNING:** For any accessories, read the label and accompanying document(s) before use.

PART NUMBER	PRODUCT DESCRIPTION
Interfaces (for single patient use only)	
BT-60-0013	Breathe Entrainment Pillows Interface®, Extra Small
BT-60-0014	Breathe Entrainment Pillows Interface, Small
BT-60-0015	Breathe Entrainment Pillows Interface, Medium
BT-60-0016	Breathe Entrainment Pillows Interface, Large
BT-60-0010	Universal Circuit Connector®
Source Gas Supply Hoses	
BT-55-0005	Oxygen Hose, 20 ft.
Power Supply and Charger	
MS-02-0178	Battery Charger Replacement
MS-03-0019	Charger AC Cord Replacement
Other	
MS-03-0772	Belt Clip Replacement
BT-00-0017	Ventilator Pole Mount (includes belt clip)
BT-55-0031	Ventilator Carry Case and 7.5 ft. Belt

CHAPTER 8: ALTITUDE VOLUME ADJUSTMENT TABLE

ALTITUDE VOLUME ADJUSTMENT TABLE

The volume output by the ventilator is not automatically adjusted for altitude. The following table shows the actual volume output for several volume settings at different altitudes. Check the performance of the ventilator for adequate therapy delivery in the environment(s) in which it will be used and adjust the volume to compensate for altitude when necessary.

			VOLUME SETTING ON LIFE2000® VENTILATOR					
Atmospheric Pressure	Approximate Altitude		90	150	250	350	500	750
HPA	FEET	METERS	ML VOLUME OUTPUT					
1100	-2290	-700	84	140	234	327	468	702
1075	-1640	-500	86	143	238	334	477	715
1050	-990	-300	87	146	243	340	486	729
1025	-320	-100	89	149	248	347	495	743
1000	370	110	91	152	253	354	505	758
975	1060	320	93	155	258	361	516	773
950	1770	540	95	158	263	369	527	790
925	2500	760	97	161	269	377	538	807
900	3240	990	99	165	275	385	550	826
875	4000	1220	101	169	282	394	563	845
850	4780	1460	104	173	288	404	577	865
825	5580	1700	106	177	295	413	591	886
800	6400	1950	109	182	303	424	606	908
775	7230	2200	112	186	310	435	621	931
750	8090	2470	115	191	319	447	638	957
725	8980	2740	118	197	328	459	656	984
700	9880	3010	121	202	337	472	675	1012
675	10820	3300	125	209	348	487	695	1043
650	11780	3590	129	215	358	501	716	1075
625	12780	3890	133	222	370	517	739	1109
600	13800	4210	138	229	382	535	765	1147

CHAPTER 9: PRINCIPLES OF OPERATION

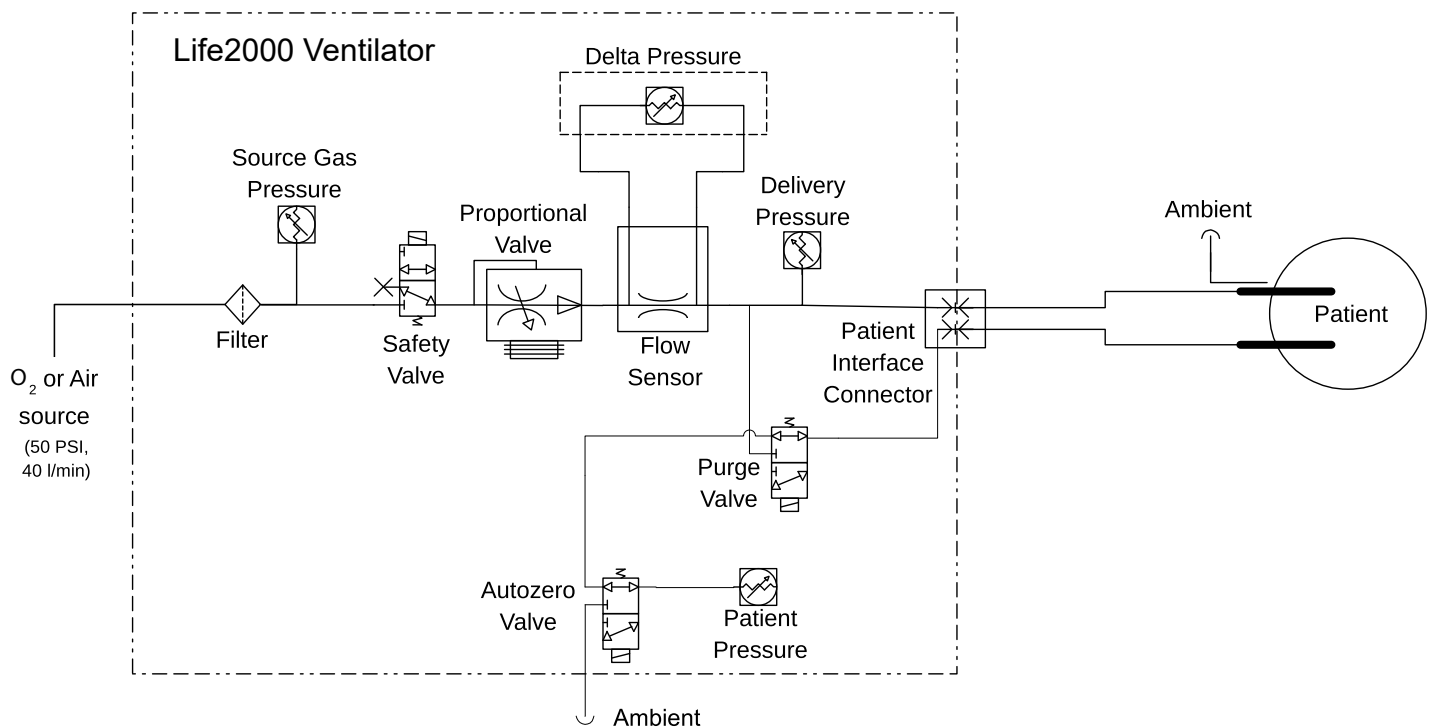
GENERAL OVERVIEW

The Life2000® Ventilator utilizes an electromechanical pneumatic system under the control of a microprocessor to deliver patient ventilation. The following description and diagram illustrate the major components of the ventilator.

OPERATION SUMMARY

The ventilator uses pressurized air or pressurized oxygen (see diagram below). Air or oxygen enters through an inlet filter. The air or oxygen is then delivered to the safety valve and then to the flow valve, which controls all inspiratory gas flow to the patient. A flow sensor is also provided to measure delivered flow to the patient, and the closed-loop control system ensures the delivery of the required flow to the patient. A pressure sensor is used to measure the pressure at the patient connection to ensure patient safety. The electromechanical pneumatic system also controls PEEP during exhalation.

PNEUMATIC DIAGRAM OF THE LIFE2000® VENTILATOR



CHAPTER 10: PERFORMANCE SPECIFICATIONS

The Life2000® Ventilator is classified per IEC 60601-1 as portable, Class II, Type BF, continuous operation. The ventilator is not IP rated for ingress of liquids; keep dry.

PERFORMANCE SPECIFICATIONS

PARAMETER	DESCRIPTION
General Information	
Available ventilation modes	Volume ventilation with Control, Assist/Control, and Assist ventilation modes
Connection to patient	Breathe Pillows Entrainment Interface
Features And Description	
Frequency	Ventilator can cycle at ≤ 40 BPM Accuracy: $\pm 10\%$ or 1 BPM, whichever is greater
Tidal Volume	Up to 2,000 ml
Volume output range	Range: 50 ml to 750 ml Resolution: 10 ml Accuracy: $\pm 15\%$ and ± 15 ml of set value, measured at ATP (ambient temperature and pressure)
Volume output settings	3 programmable Prescription Settings can provide different volume outputs as prescribed by the physician Each setting is clinician definable between 50 ml to 750 ml
Volume output adjustment	Volume output may be adjusted by patient as prescribed by physician using the available programmable prescription settings.
Inspiratory Time (I-Time)	Range: 0.15 sec to 3.00 sec Resolution: 0.05 sec Accuracy: ± 0.05 sec
Delivered peak gas flow rate from ventilator	8 LPM minimum 40 LPM maximum
Volume control	Closed loop proportional valve system
PEEP	Range: 0 to 10 cm H ₂ O (for software versions before 06.08.00.00) or 0–20 cm H ₂ O (for software versions 06.08.00.00 or newer). Resolution: 1 cmH ₂ O Accuracy: ± 2 cmH ₂ O
PIP Monitor ($P_{LIM\ max}$)	1 to 40 cmH ₂ O
Means of triggering	The breath delivery is triggered depending on the breath type—mandatory or assisted—and ventilation mode. The sensitivity setting, adjustable in increments of 1, ranges from 0 to 9, with 0 being the most sensitive and 9 being the least sensitive.
Inspiratory trigger delay time	Volume delivery is initiated based on the breath type and ventilation mode.
Available waveforms	Square waveform

PARAMETER	DESCRIPTION												
Means of initiating and terminating inspiratory phases	<p>Control ventilation mode: The inspiratory phase is started and terminated by the ventilator based on set respiratory rate and inspiratory time.</p> <p>Assist/Control ventilation mode: The inspiratory phase is started based on the patient’s breath triggering or by the ventilator based on set respiratory rate and terminated by the set inspiratory time.</p> <p>Assist ventilation mode: The inspiratory phase is started based on the patient’s breath triggering and terminated by the set inspiratory time.</p>												
Backup ventilation parameters	If a Breath Timeout alarm is triggered, the ventilator delivers the set volume at a continuous flow rate of 3 LPM or 12 BPM, preset by a clinician. When a patient’s breath is detected again, the ventilator delivers the set volume based on Ventilation Settings parameters.												
Other Operating Requirements And Features													
Inspiratory pressure relief	Pressure is relieved through the patient’s mouth or through the patient interface.												
Expiratory resistance at patient connection	<p>Breathe Pillows Entrainment Interface:</p> <table><tr><td>Extra Small:</td><td>1.9 cmH₂O at 30 LPM</td><td>4.6 cmH₂O at 50 LPM</td></tr><tr><td>Small:</td><td>1.1 cmH₂O at 30 LPM</td><td>3.5 cmH₂O at 50 LPM</td></tr><tr><td>Medium:</td><td>1.0 cmH₂O at 30 LPM</td><td>3.3 cmH₂O at 50 LPM</td></tr><tr><td>Large:</td><td>0.96 cmH₂O at 30 LPM</td><td>2.5 cmH₂O at 50 LPM</td></tr></table>	Extra Small:	1.9 cmH ₂ O at 30 LPM	4.6 cmH ₂ O at 50 LPM	Small:	1.1 cmH ₂ O at 30 LPM	3.5 cmH ₂ O at 50 LPM	Medium:	1.0 cmH ₂ O at 30 LPM	3.3 cmH ₂ O at 50 LPM	Large:	0.96 cmH ₂ O at 30 LPM	2.5 cmH ₂ O at 50 LPM
Extra Small:	1.9 cmH ₂ O at 30 LPM	4.6 cmH ₂ O at 50 LPM											
Small:	1.1 cmH ₂ O at 30 LPM	3.5 cmH ₂ O at 50 LPM											
Medium:	1.0 cmH ₂ O at 30 LPM	3.3 cmH ₂ O at 50 LPM											
Large:	0.96 cmH ₂ O at 30 LPM	2.5 cmH ₂ O at 50 LPM											
Inspiratory resistance at patient connection	<p>Breathe Pillows Entrainment Interface:</p> <table><tr><td>Extra Small:</td><td>2.4 cmH₂O at 30 LPM</td></tr><tr><td>Small:</td><td>1.3 cmH₂O at 30 LPM</td></tr><tr><td>Medium:</td><td>1.0 cmH₂O at 30 LPM</td></tr><tr><td>Large:</td><td>0.75 cmH₂O at 30 LPM</td></tr></table>	Extra Small:	2.4 cmH ₂ O at 30 LPM	Small:	1.3 cmH ₂ O at 30 LPM	Medium:	1.0 cmH ₂ O at 30 LPM	Large:	0.75 cmH ₂ O at 30 LPM				
Extra Small:	2.4 cmH ₂ O at 30 LPM												
Small:	1.3 cmH ₂ O at 30 LPM												
Medium:	1.0 cmH ₂ O at 30 LPM												
Large:	0.75 cmH ₂ O at 30 LPM												
Breath sensing line purge flow	A flow of gas is delivered through the sensing lumen to keep the sensing line patent.												
Fail safe mechanisms	Safety valve prevents overpressure condition in lung, mitigating breath stacking												
Flow/pressure generator type	Ventilation uses gas pressure from an external pressurized source gas. The ventilator has no internal gas or pressure generation.												
Input pressure source requirements	<p>41 PSI to 87 PSI and ≥ 40 LPM flow continuous output @ 41 PSI</p> <p>Compatible sources:</p> <ul style="list-style-type: none">Regulated medical grade oxygen or air gas cylindersMedical grade oxygen or air wall sourcesAny other medical grade oxygen or air sources meeting the above criteria												

10 PERFORMANCE SPECIFICATIONS

PARAMETER	DESCRIPTION
Range, resolution, and accuracy of respiratory rate monitor	Range: 1 BPM to 120 BPM Resolution: 1 BPM Accuracy: $\pm 10\%$ or 1 BPM, whichever is greater, up to 50 BPM
Range, resolution, and accuracy of oxygen or air minute volume display	Range: 0 LPM to 28 LPM. Resolution: 0.1 LPM. Accuracy: $\pm 10\%$ or $\pm(10 \text{ ml} \times \text{average breath rate})$, whichever is greater. NOTE: The displayed oxygen or air minute volume is the product of the average breath rate times the average measured oxygen or air volume settings. During continuous delivery, the ventilator displays an oxygen or air minute volume of 3.0 LPM.
Oxygen or air source time (portable oxygen or air systems)	The duration of the source gas depends on the flow (LPM as displayed on the ventilator Home Screen) and the cylinder size.
Oxygen or air source time (stationary oxygen or air systems)	Indefinite
Usage types	Stationary use: place on table or flat surface. Portable use: secure on cart, IV pole, railing, or wheelchair. Wearable use: secure with belt clip.
Battery Specifications	
Type	Lithium ion, rechargeable, not user replaceable.
Ampere/hour rating	1800 mAh
Maximum current	450 mA
Operating Voltage	7.4 V internal
Duration	Approximately 5-6 hours*
* Approx. Time Remaining based on the following ventilator settings: BR 12, Volume 350, PEEP 0, I-Time 1.0	
If the battery performance degrades to unacceptable levels before the scheduled 2.5 year replacement, contact your Hillrom _® service representative.	
Ventilator AC Battery Charger Specifications	
Input AC voltage	100-240 VAC
Input AC frequency	50-60 Hz
Input AC current	0.3 A max.
Output DC voltage	8.4 VDC
Output DC current	1.3 A
Insulation class	Class II
Electrical safety approvals	UL 60601-1, EN 60950, EN 60601-1, EN 60335-2-29
Dimensions	3.55" x 1.77" x 1.26" (90 x 45 x 32 mm)
Weight	0.25 lb. (115 g)
Power Cord	6 ft. IEC 320-E7 compliant cord

PARAMETER	DESCRIPTION
Special Features	
Alarm vibrate	Instead of an audio alarm, the user can enable the alarm to vibrate for medium- and low-level alarms.
Touch screen flip	User can flip the screen orientation 180°.
Ventilator Alarm Notifications	
High Priority Alarm	At maximum loudness setting: 73 db(A) At minimum loudness setting: 60 db(A)
Medium Priority Alarm	At maximum loudness setting: 72 db(A) At minimum loudness setting: 59 db(A)
Ventilator Alarms	
High Circuit Pressure	Interface may be pinched or kinked
High PEEP Pressure	Interface may be blocked
High PIP Pressure	Peak Inspiratory Pressure (PIP) exceeds the set limit
High Temperature	Ventilator CPU or battery temperature is above the allowable limit
Very Low Battery	Ventilator battery capacity drops below 15%
Battery Low	Ventilator battery capacity drops below 25%
Breath Timeout	No breath is detected for 20 seconds or 60 seconds, depending on the setting
High Breath Rate	Respiratory rate exceeds the set limit
High Delivery Pressure	Interface pressure during delivery exceeds the maximum expected
High Gas Pressure	Source gas pressure exceeds the allowable limit (95 PSI)
Low Breath Rate	Respiratory rate falls below the set limit
Low Delivery Pressure	Interface pressure during delivery fails to exceed the minimum expected
Low Gas Pressure	Source gas pressure drops below the allowable limit (35 PSI)
Low PIP Pressure	PIP below set limit
System Fault	Internal fault detected during operation
Excessive Leak	An excessive leak is present
POST System Fault	System fault detected during ventilator power on
Sensor Fault	Sensor Fault detected during use of ventilator.
Monitors and Indicators	
Ventilator user interface	Touch screen LCD for settings, monitors, and alarms Mechanical buttons for on/off, alarm silence, and prescription settings
Pressure monitoring	Ventilator output pressure and airway pressure are monitored continuously. Airway pressure is monitored using a lumen in the gas delivery circuit wall, which terminates in a sensing port on the distal end of the circuit.
Volume Setting displays	Delivered volume setting is displayed
Breath indicator	LED visual indicator indicating an inspiration
Battery indicator	Indicates percentage of battery charge remaining. Always displayed on touch screen. Alarm occurs when capacity is below 25% and again at 15%.

10 PERFORMANCE SPECIFICATIONS

PARAMETER	DESCRIPTION
Physical Features	
Ventilator weight	Approximately 1 lb. (excluding source gas and accessories)
Ventilator size	3 1/8" x 1 1/4" x 7 1/2"
Latex	The ventilator does not contain natural rubber latex.
Storage and Transport Environment	
Storage & Transport Temperature	-20°C to 60°C (-4°F to 140°F)
Storage & Transport Humidity	10% to 95% non-condensing
Operating Environment	
Operating Temperature	5°C to 40°C (41°F to 104°F)
Operating Humidity	15% to 90% non-condensing
Operating Altitude	1100 hPa to 625 hPa or approximately -2300 ft. to 12,800 ft. (-700 m to 3900 m)
Expected Service Life	
Expected Service Life	<p>The Life2000® Ventilator has a five year design life when operated in accordance with the <i>Instructions For Use</i> provided.</p> <p>Do not use the ventilator past its expected service date.</p>
Service Intervals	
Service Intervals	2.5 years from the date of shipment

CHAPTER 11: COMPLIANCE AND IEC CLASSIFICATION

IEC COMPLIANCE: EN/IEC 60601-1-2:2001 (Medical electrical equipment Part 1-2: General requirements for safety-Collateral standard: Electromagnetic compatibility-Requirements and tests) defines the RF emissions limits and minimum RF immunity requirements for different types of medical electrical equipment. The following tables include the RF emissions limits and RF immunity requirements for, and results of tests upon, the Life2000® Ventilator.

The Life2000® Ventilator needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual.

The use of accessories, transducers and cables other than those specified by Hillrom™ may result in increased emissions or decreased immunity of the Life2000® Ventilator.

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC EMISSIONS

The Life2000® Ventilator is intended for use in the electromagnetic environment specified below. The customer or user of the ventilator should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Life2000® Ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B*	
Harmonic emissions IEC 61000-3-2	Complies†	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies†	

* The ventilator complies with Class B requirements.

† The ventilator does not produce a minimum of 75 watts and does not produce flicker.

11 COMPLIANCE AND IEC CLASSIFICATION

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY


The Life2000® Ventilator is intended for use in the electromagnetic environment specified below. The customer or user of the ventilator should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (95% dip in U_T for 0.5 cycle)	<11.5 V (>95% dip in 230 V) and <6 V (>95% dip in 120 V) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment.
	40% U_T (60% dip in U_T for 5 cycles)	92 V (60% dip in 230 V) and 48 V (60% dip in 120 V) for 5 cycles	
	70% U_T (30% dip in U_T for 25 cycles)	161 V (30% dip in 230 V) and 84 V (30% dip in 120 V) for 25 cycles	
	<5% U_T (> 95% dip in U_T for 5 seconds)	<11.5 V (>95% dip in 230 V) and <6 V (>95% dip in 120 V) for 5 seconds	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY

The Life2000® Ventilator is intended for use in the electromagnetic environment specified below. The customer or user of the ventilator should ensure that it is used in such an environment.

LIFE2000® VENTILATOR

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Life2000® Ventilator, including cables, than the recommended separations distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1.17 \sqrt{P} \text{ 150 kHz to 80MHz}$ $d = 0.35 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 0.70 \sqrt{P} \text{ 800 MHz to 2.5GHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	<p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey* should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>

NOTE 1: U_T is the AC mains voltage prior to application of the test level.

NOTE 2: At 80 MHz, the higher frequency range applies.

NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TB broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ventilator is used exceeds the applicable RF compliance level above, the ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ventilator.

11 COMPLIANCE AND IEC CLASSIFICATION

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION EQUIPMENT AND THE LIFE2000® VENTILATOR

The Life2000® Ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The clinician can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ventilator as recommended in this table, according to the maximum output power of the communications equipment.

LIFE2000® VENTILATOR














Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.17	0.035	0.070
0.1	0.37	0.11	0.22
1	1.17	0.35	0.70
10	3.69	1.1	2.2
100	11.70	3.5	7.0

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.













NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.












For transmitters rated at a maximum output power not listed above, the recommended separations distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.










CHAPTER 12: ICONS

ICON	WHERE USED	MEANING
	Ventilator	Indicates communication port. This port is only used by the manufacturer.
	Ventilator	Indicates power-in port.
	Ventilator and compressor	Indicates direct current.
	Ventilator, ventilator label, and compressor label	The Silence Alarm button silences a vibration or audible alarm for 60 seconds.
	Ventilator touch screen	Displayed in the Active Alarms window of the touch screen if an active alarm has not been silenced.
	Ventilator touch screen	Displayed in the Active Alarms window of the touch screen if an active alarm has been silenced. Displayed on the bottom of touch screen if all active alarms have been silenced.
	Ventilator touch screen	Displayed on touch screen. Touching the Wrench button displays the Menu screen.
	Ventilator touch screen	Displayed on touch screen. Touching the Flip button rotates the touch screen 180°.
	Ventilator touch screen	Displayed on touch screen if ventilator is in vibrate mode.
	Ventilator label and compressor label	Indicates catalog number and denotes the location of the part number
	Ventilator label and compressor label	Indicates serial number and denotes the location of the serial number
	Ventilator label	Alternative to the prescription device labeling statement "Caution: Federal law restricts this device to sale by or on the order of a physician."
	Purge tube connector label, purge tube label, pole mount label, source gas supply hose label, and interface labels	Indicates that the product is not sterile.

12 ICONS

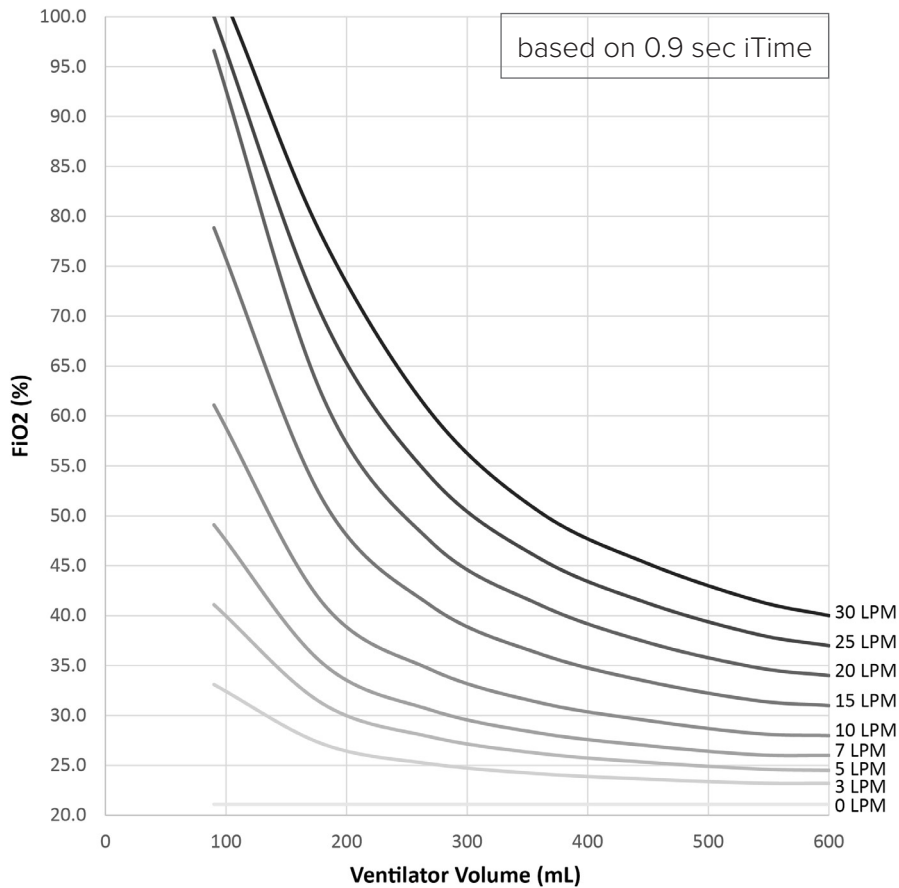
ICON	WHERE USED	MEANING
	Ventilator touch screen	Displayed on touch screen if ventilator battery status is unknown or charge is critically low (< 5%).
	Ventilator touch screen	Displayed on touch screen if ventilator battery has approximately 5-14% of its charge remaining.
	Ventilator touch screen	Displayed on touch screen if ventilator battery has approximately 15–35% of its charge remaining.
	Ventilator touch screen	Displayed on touch screen if ventilator battery has approximately 36–56% of its charge remaining.
	Ventilator touch screen	Displayed on touch screen if ventilator battery has approximately 57–84% of its charge remaining.
	Ventilator touch screen	Displayed on touch screen if ventilator battery charge has approximately 85–100% of its charge remaining.
	Ventilator touch screen	Displayed on touch screen if battery is charging.
	Ventilator label and compressor label	Indicates BF type equipment. Device isolates the patient from any live voltage in the equipment.
	Ventilator label, compressor label, ventilator battery charger label, and compressor external power supply	Indicates a Class II device. Device is double insulated and does not require a safety connection to electrical earth (US: ground).
	Ventilator label and compressor label	Consult <i>Instructions for Use</i> .
	Ventilator label and compressor label	Indicates that the device poses unacceptable risks within the magnetic resonance (MR) environment.
	Ventilator label and compressor label	Keep dry. Indicates that the device needs to be protected from moisture.

ICON	WHERE USED	MEANING
	Ventilator label, compressor label, compressor external power supply	Indicates disposal of device must conform to WEEE Directive (Waste in Electrical and Electronic Equipment) 2011/65/EU.
	Ventilator battery charger label	This symbol is used to support the Battery Directive 2006/66/EC.
	Ventilator battery charger label and compressor external power supply	Indicates the battery charger meets European Economic Area standards for use.
	Ventilator label and compressor label	Indicates manufacturer and denotes manufacturer name and address.
	Ventilator battery charger label and compressor external power supply	Indicates product meets US standards for use with medical electrical equipment.
	Ventilator battery charger label	Consult <i>Instructions for Use</i> .
	Ventilator label, compressor label, and documentation	Documentation includes important information that must be read before using device.
	Ventilator battery charger label	Indicates indoor use only and denotes that it should only be used indoors
	Ventilator battery charger label	Indicates battery charge. The black shaded area represents the amount of charge within the battery.
	Compressor external power supply	Certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission
	Compressor external power supply	Indicates compliance with the latest DOE Efficiency Level VI requirements for average efficiency and standby power

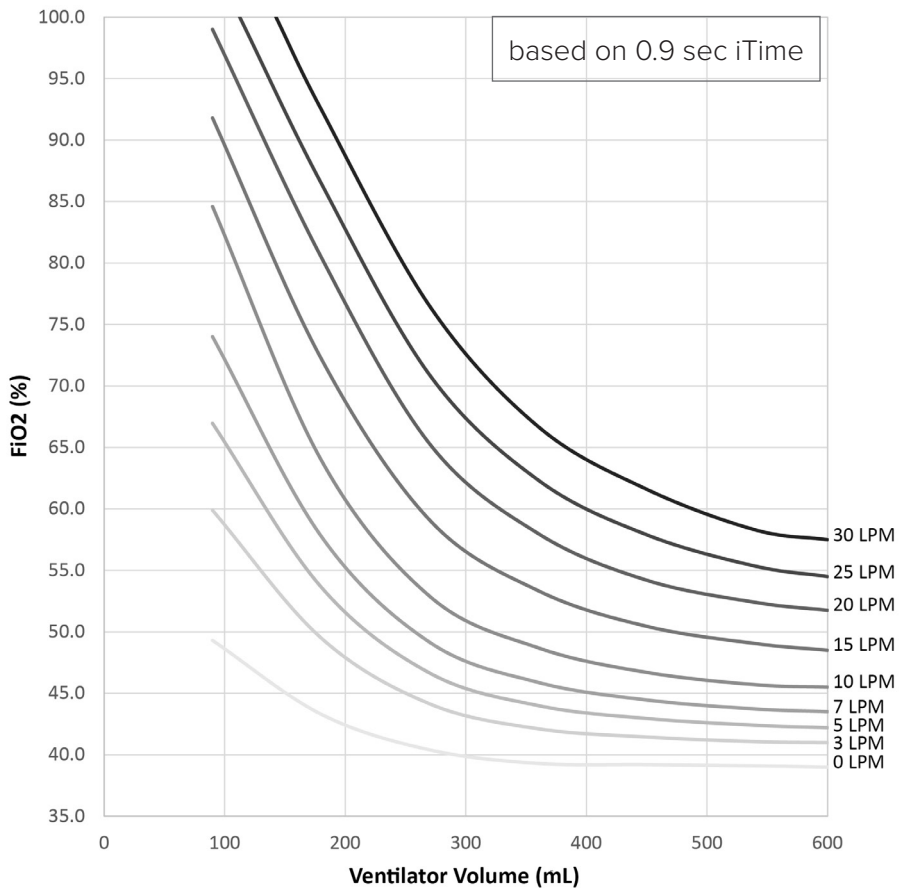
ICON	WHERE USED	MEANING
	Compressor external power supply	Indicates compliance with RoHS.
	Compressor	Indicates the unlocking knob is in the unlocked position.
	Compressor	When lit, indicates the locking knob is in the locked position.
	Compressor	Battery Charge Status button
	Compressor	Power on/off button
	Ventilator	Power on/off button
	Ventilator and ventilator touch screen	<p>On the ventilator, the Low Activity Button delivers prescription parameters set by a clinician in the Clinician's Settings menu.</p> <p>Displayed on the Prescription Settings screen as a label for the Low Activity Prescription Setting parameters set by a clinician.</p> <p>Displayed on the touch screen if the ventilator is set to the Low Activity Prescription Setting.</p>
	Ventilator and ventilator touch screen	<p>On the ventilator, the Medium Activity Button delivers prescription parameters set by a clinician in the Clinician's Settings menu.</p> <p>Displayed on the Prescription Settings screen as a label for the Medium Activity Prescription Setting parameters set by a clinician.</p> <p>Displayed on the touch screen if the ventilator is set to the Medium Activity Prescription Setting.</p>
	Ventilator and ventilator touch screen	<p>On the ventilator, the High Activity Button delivers prescription parameters set by a clinician in the Clinician's Settings menu.</p> <p>Displayed on the Prescription Settings screen as a label for the High Activity Prescription Setting parameters set by a clinician.</p> <p>Displayed on the touch screen if the ventilator is set to the High Activity Prescription Setting.</p>

APPENDIX: FiO₂ GRAPHS

UNIVERSAL CIRCUIT® CONNECTOR USING AIR AS THE PRESSURE SOURCE*



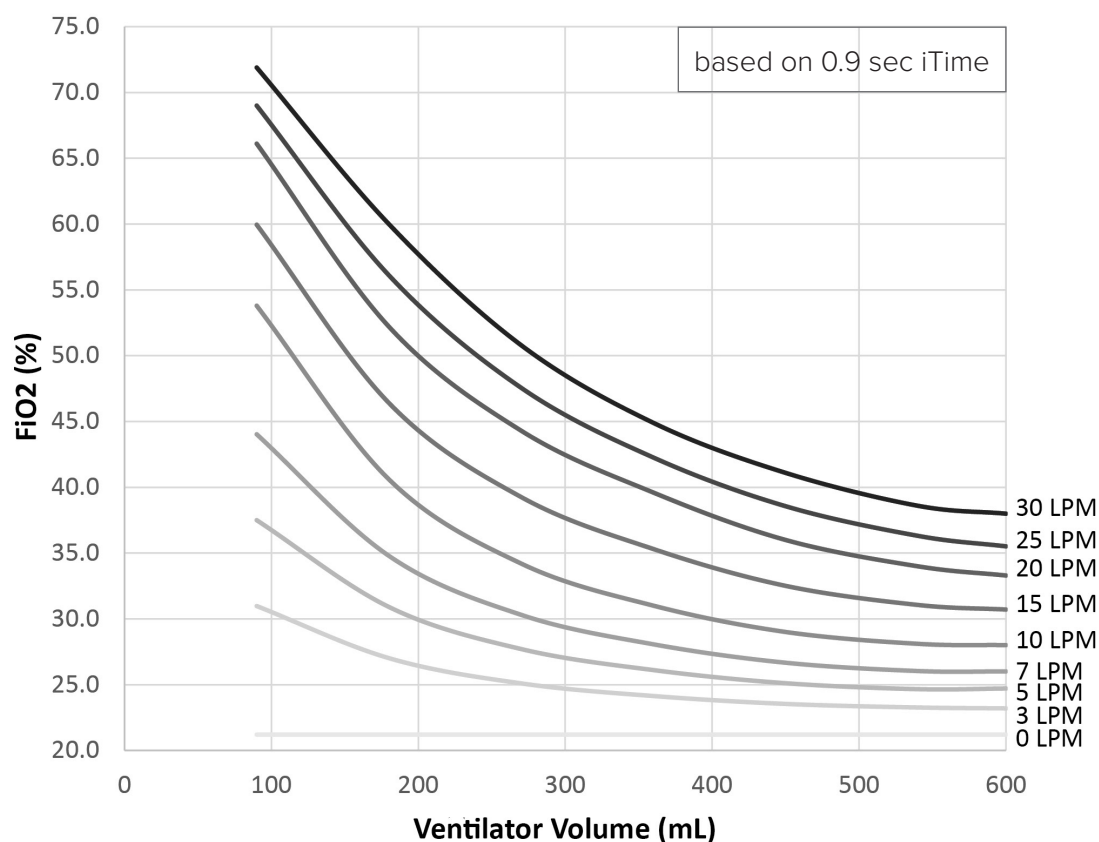
UNIVERSAL CIRCUIT® CONNECTOR USING OXYGEN AS THE PRESSURE SOURCE*



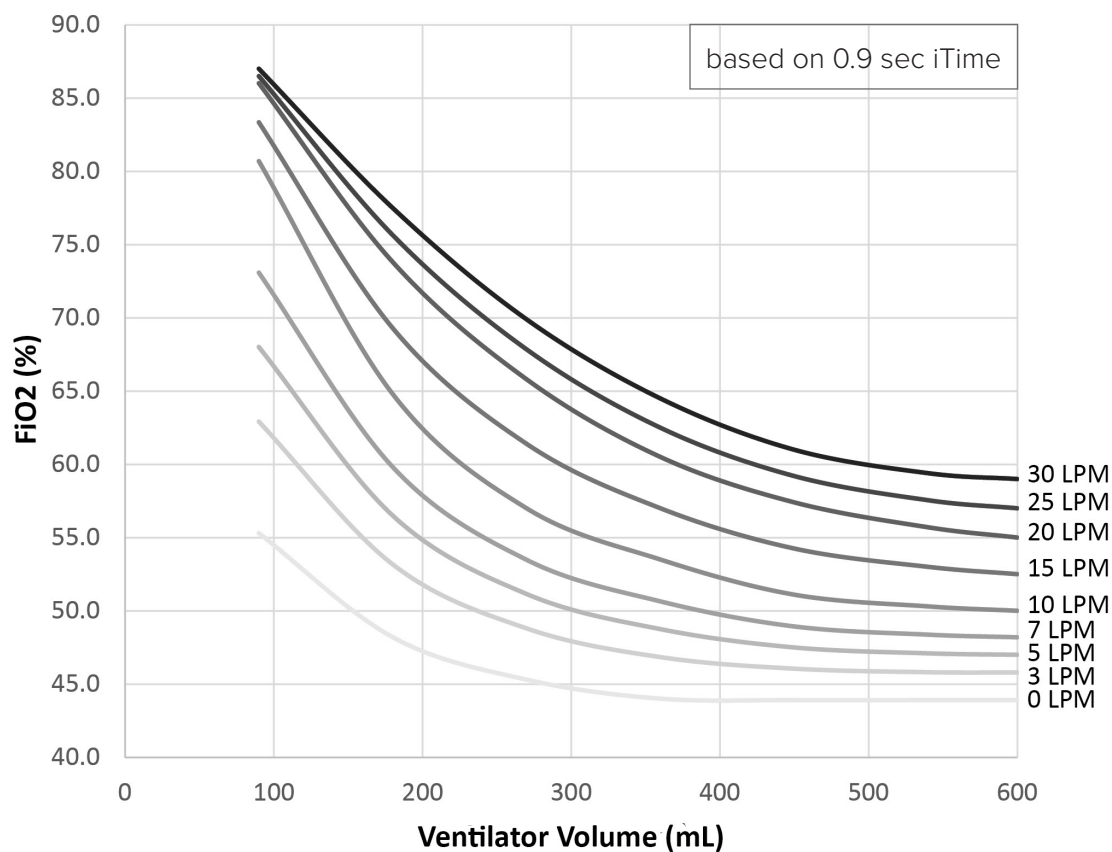
* entrained with supplemental oxygen in the volumes (LPM) shown

APPENDIX: FiO₂ GRAPHS

BREATHE PILLOWS ENTRAINMENT INTERFACE USING AIR AS THE PRESSURE SOURCE*



BREATHE PILLOWS ENTRAINMENT INTERFACE USING OXYGEN AS THE PRESSURE SOURCE*



* entrained with supplemental oxygen in the volumes (LPM) shown

LIMITED WARRANTY

LIMITED WARRANTY

Breathe Technologies, Inc., a Hillrom[®], warrants that the Life2000[®] ventilators will be free from defects in material and workmanship for a period of one (1) year from the date of shipment. Products that are repaired or replaced under this Limited Warranty will be covered by this Limited Warranty for the greater of the remaining balance of the original warranty or ninety (90) days.

Patient interfaces and accessories manufactured by Breathe Technologies are warranted for thirty (30) days from date of shipment.

Accessories and replacement parts manufactured by third parties and used with Breathe Technologies ventilators, including, but not limited to regulators, are not covered under this warranty.

This limited warranty shall only extend to the original end user of the product purchased. This limited warranty may not be assigned or transferred.

WARRANTY SERVICE

Breathe Technologies, Inc. will, at its discretion, either repair, replace, or issue credit for products that prove to be defective during the applicable warranty period.

For warranty service or repair, the product must be returned to Breathe Technologies, Inc. or a service facility designated by Breathe Technologies, Inc. with shipping prepaid by the end user.

LIMITATIONS OF WARRANTY; EXCLUSIVE REMEDY

Ordinary maintenance, as specified in this Instructions for Use and the Service Manual, is not covered under this Limited Warranty.

The Limited Warranty does not apply to damages or defects resulting from:

1. Improper or inadequate maintenance of the unit.
2. Failure to follow instructions, improper use or misuse of the unit.
3. Unauthorized modifications or repairs to the unit.
4. Use of the unit with unauthorized accessories, e.g., external battery or AC adapter.
5. Operation of the unit outside the specified environment.
6. Fire, flood, earthquake, acts of war or terrorism, or acts of God.

The foregoing limited warranty is in lieu of and specifically excludes and replaces, to the maximum extent permitted by applicable law, all other express or implied warranties, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

No person (including any agent, dealer, or representative of Breathe Technologies, Inc.) is authorized to make any representation or warranty concerning the product or its associated accessories, except to refer to this limited warranty.

The exclusive remedy with respect to any losses or damages resulting from any cause whatsoever shall be as specified above. Breathe Technologies, Inc. shall not be liable for any consequential or incidental damages of any kind, including, but not limited to, exemplary damages, special, punitive, commercial loss from any cause, business interruption of any nature, loss of profits or personal injury, even if Breathe Technologies, Inc. has been advised of the possibilities of such damages, however occasioned, whether by negligence or otherwise.

The maximum liability of Breathe Technologies, Inc. under this limited warranty shall in no event exceed the purchase price of the product.

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations and exclusions may not apply to you. Some states do not allow limitations on how long an implied warranty lasts, so these limitations may not apply to you.

This limited warranty gives you specific legal rights, and you may also have other rights, which may vary from state to state.

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The Life2000® Ventilator contains electrical components that must be disposed of according to the guidelines of the WEEE Directive (Waste in Electrical and Electronic Equipment) 2011/65/EU. Follow local regulations when disposing of the ventilator and accessories when disposal is required and at the end of the expected service life.



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