

X-VENT

Operations Manual



X-VENT Emergency Ventilator



Before You Begin

Contact the Manufacturer.

This manual corresponds with the **X-VENT Model 1**. Enexor Health Systems, LLC ("Enexor Health") can be contacted at the following:

Enexor Health Systems, LLC
1 Enterprise Court
Franklin, TN 37067

Phone: (615) 224-8466
Email: info@enexorhealth.com

FDA Status.

The X-VENT Emergency Ventilator has not been FDA cleared or approved.

Enexor Health Systems was granted EUA authorization for this ventilator by the FDA in accordance with the Ventilator EUA dated March 24, 2020. This ventilator is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of ventilators under section 564(b)(1) of the Action 21 U.S.C 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The X-VENT is a continuous use, emergency ventilator intended to provide invasive and non-invasive ventilatory support for adult patients > 35 kg of weight with respiratory insufficiency or failure. The X-VENT is to be used under prescription only and is intended to be used in hospitals, hospital-type facilities, or other institutional health care environments. X-VENT provides patients with emergency ventilatory support when no alternative standard ventilators are available.

The X-VENT is intended for use by qualified physicians and respiratory therapists who have undergone training on the use of the X-VENT ventilator. It provides three (3) modes of ventilation: pressure control, volume control, and assist (CPAP).

General Warnings.

The following general safety requirements and specifications must be observed during all phases of operation of the X-VENT. Failure to comply with these precautions or with specific warnings elsewhere in this manual violates safety standards of design, manufacturing, and intended use.

Before You Start.

Before using the X-VENT Ventilator, please review the FDA Fact Sheet for Health Care Providers and Fact Sheet for Recipients. They can be found at these links:

Fact Sheet for Health Care Providers: <https://www.fda.gov/media/137468/download>
Fact Sheet for Recipients: <https://www.fda.gov/media/137469/download>



Warning! This device is not FDA cleared or approved.



Warning! This device has been granted an Emergency Use Authorization by the FDA for use during the COVID-19 pandemic. This device is a last resort and should only be used when legally market ventilators are not available.



Warning! The X-VENT Emergency Ventilator is not intended to be a comprehensive monitoring device and does not raise alarms for all types of conditions that may arise while connected to a patient.



Warning! Any operation of the X-VENT without adequate training and understanding of its attributes and functions is unsafe and could cause serious harm to patients. All potential operators of the X-VENT should read through this manual in its entirety prior to operating this piston-driven emergency ventilator.



Warning! Only qualified medical personnel are authorized to prescribe settings for the X-VENT Emergency Ventilator.

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Warning! This manual only describes how to operate and respond to the X-VENT. It does not describe or imply how to treat patients.



Warning! At all times during use of the X-VENT, an alternative means of ventilation should be nearby and available in the event of an unexpected malfunction. Failure to have an alternative means of ventilation such as a self-inflating, manually-powered resuscitator with mask can result in patient death if the ventilator fails.



Warning! Ventilation should not be started until the X-VENT is properly assembled, all tubes, hoses, valves and filters are properly installed and unobstructed, and the patient circuit is properly connected to both the X-VENT and the patient.



Warning! If O₂ is being used, connect the optional O₂ system before operation of the X-VENT.



Warning! Operators of the X-VENT should wash hands thoroughly per CDC Guidelines before and after handling the X-VENT and/or its accessories.



Warning! Keep all fire hazards - such as matches, lit cigarettes, flammable anesthetics, heaters, unsealed lead acid batteries, etc. away from the X-VENT and nearby oxygen hoses.



Warning! Modifications to the X-VENT are not allowed. Doing so could result in equipment failure and could seriously injure or harm the patient.



Warning! The X-VENT is not rated to operate at altitudes outside of the following limits, -1,261 to 12,971 feet.



Warning! While in operation mode do not cover the ventilator or place it in a position that has the potential to affect proper operation and ventilation.



Warning! Do not clean the X-VENT in an autoclave. Do not submerge to clean. The X-VENT is not air proof or watertight.



Warning! An incorrect tidal volume setting may cause serious harm to the patient.



Warning! Failure to properly follow the set-up and connection instructions - as well as failure to properly set up and attach parts not included with the X-VENT (e.g. tubing, valves, face mask, etc.) - could result in severely compromised functioning of the X-VENT and could also result in equally severe and serious harm to patients.



Warning! Accessories used with the X-VENT such as tubing, additional filters, masks, patient circuits, etc. should be disposed of between patients and as needed.



Warning! It is recommended that the patient circuit be replaced as often as necessary for infection control.

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Warning! Always ensure that you do not restrict any gas intake ports when setting up the patient circuit.



Warning! Damaged or obstructed patient circuit components - including all hoses and tubes - should not be used with the X-VENT. This can result in seriously injury or harm to the patient.



Warning! Always make sure that the ventilator's immediate surroundings allow for proper operating of the device without the possibility of folding, pinching, or otherwise damaging any of the required cables, tubes, or hoses being used.



Warning! Ensure that the X-VENT's emergency stop button (labeled, "STOP") is always accessible.



Warning! There are internal AC and DC over current protection breakers that require tools for access. These breakers are not meant to be serviceable by the user. If the user suspects that these breakers are tripped, contact service support.



Warning! This ventilator has not been tested for Electromagnetic Compatibility ("EMC"). It may produce electromagnetic disturbances that will affect the performance of other equipment. It may fail to perform as expected in the presence of electromagnetic disturbances from other equipment.



Warning! The software for this ventilator was not developed using a controlled life cycle development process.



Warning! This ventilator relies on the integrity of the protective earth ground to reduce the risk of electrical shock. Check the integrity and verify the function of the protective earth ground of the supply mains receptacle prior to use.



Warning! Ventilator breathing systems, their parts and accessories are validated for use with specific ventilators. Incompatible parts can result in degraded performance and the responsible organization is accountable for the compatibility of the ventilator and all of the parts and accessories used to connect to the patient before use.



Warning! Due to the rapid development cycle for this emergency use device, all efforts were made to verify the software, but defects may still exist. The consequences of these defects are unknown.



Warning! This ventilator is classified as a portable EUV. It is intended to be carried (but not operating) from one location to another.



Warning! Due to internal piston trapping zone inside the center of the metal enclosure, always shutdown the unit before performing any kind of maintenance.



Warning! Do not place body parts underneath the unit creating a trapping hazard with the bottom sheet metal.



Warning! Small fan housings are guarded by the metal enclosure overhang and the factory enclosure. Caution should be taken for hair or other objects smaller than a finger that could come in contact.

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Warning! This ventilator can *operate* in temperatures ranging from -0°C to 40°C and 6%-90% non-condensing humidity.



Warning! This ventilator can be *stored* in temperatures ranging from -25°C to 70°C and 0%-93% non-condensing humidity.



Warning! This ventilator has been developed using a risk management process outlined in ISO14971.



Warning! This ventilator is not suitable for use in an oxygen enriched environment (> 25% O₂). Designed for use in a well-ventilated space.



Warning! Using attachments or accessories with the ventilator that contravene the instructions for use of the X-VENT can lead to the risk of patient death or serious deterioration of health.



Warning! Circuit leakage may prevent PIP from reaching set pressures when the X-VENT is operated in Pressure Control mode or the intended tidal volume from reaching the patient if operating in Volume Control mode.



Warning! The X-Vent has only been tested at 500 ft elevation and between 15°C to 30°C ambient temperatures.



Warning! Operators of this equipment are restricted to physicians, anesthesiologists, pulmonologists, respiratory therapists, and others who are otherwise qualified to understand and safely operate ventilators.



Warning! Do not attempt to service or perform maintenance on the X-VENT while it is actively in use.

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Chapter 1

General Information

Product Description.

The X-VENT Emergency Ventilator is an extremely durable, piston-driven emergency ventilator designed to operate in hospitals or severe, under-resourced environments. It is intended for use in hospitals (or other institutional health care settings), or field hospital settings. The X-VENT is a Class I internally powered device.

Indications for Use.

The X-VENT is a continuous use, emergency ventilator intended to provide invasive and non-invasive ventilatory support for adult patients > 35 kg of weight with respiratory insufficiency or failure. The X-VENT is to be used under prescription only and is intended to be used in hospitals, hospital-type facilities, or other institutional health care environments. X-VENT provides patients with emergency ventilatory support when no alternative standard ventilators are available.

The X-VENT is intended for use by qualified physicians and respiratory therapists who have undergone training on the use of the X-VENT ventilator.

Battery Warnings.

Note that the X-VENT will operate off of an internal battery under the following conditions:

- The IEC POWER CABLE is disconnected;
- The POWER ROCKER on the back of the unit is turned off;
- There is a power outage or disruption.



Note: This ventilator is equipped with 2x 12VDC sealed lead acid non-spillable internal batteries.



Warning! In a high oxygen environment, only sealed lead acid or lithium ion batteries may be used.

Cleaning Instructions.

The X-VENT is constructed primarily of aluminum and steel which should be sterilized between patients and disinfected periodically while in storage. To clean and disinfect the X-VENT, wipe down the controls and the entire outside of the equipment with a compatible disinfectant. The X-VENT is to be disinfected as often as is required by hospital infection control protocols. See **Chapter 10 - Cleaning** for more information.

FDA Tracking Requirements.

U.S. Federal Law (21 CFR 821) requires the tracking of ventilators. Under this law, owners of this ventilator must notify Enexor Health Systems if this product is:

- Received;
- Lost, stolen, or destroyed;
- Donated, resold, or otherwise distributed to a different organization.

If any such event occurs, contact Enexor Health Systems in writing with the following information:

- Originators organization – Company name, address, contact name, contact phone number, email;
- Serial number of the ventilator;
- Disposition of the ventilator (for example, received, lost, stolen, destroyed, distributed to another organization), new location and/or organization (if known and different from originator's organization) – company name, address, contact name, and contact phone number;
- Date when change took effect.

Please address the information to:

Enexor Health Systems, LLC
1 Enterprise Court
Franklin, TN 37067

Phone: (615) 224-8466

Email: info@enexorhealth.com

For more information on battery alarms, see **Chapter 6 - Alarms.**

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Notification of Adverse Events.

As a health care provider, you may have responsibilities under the Safe Medical Devices Act (SMDA) for reporting to Enexor Health Systems, and possibly to the FDA, the occurrence of certain events. These events, described in 21 CFR Part 803, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, Enexor Health Systems requests to be notified of device failures or malfunctions. This information is required to ensure that Enexor Health Systems provides only the highest quality products.

Warranty.

Enexor Health Systems warrants that the X-VENT Emergency Ventilator is free from defects in material and workmanship for a period of one (1) year from the date of shipment, with the following limitations:

Enexor Health Systems will, at its option, either repair, replace, or issue credit for products that prove to be defective during the warranty period.

For warranty service or repair, the product must be returned to Enexor Health Systems or a service facility designated by Enexor Health Systems, shipping prepaid by the Buyer.

Limitation of Warranty

Ordinary maintenance, as specified in the X-VENT Emergency Ventilator Operator's Manual, is not covered under the foregoing warranty. The foregoing warranty does not apply to defects or damage to the unit resulting from:

- Improper use or misuse;
- Improper or inadequate maintenance;
- Unauthorized modifications or repairs;
- Use of the unit with unauthorized accessories, e.g. external battery or AC adapter;
- Use or storage outside the specified environment.

No Implied Warranties

This warranty is exclusive. There are no other warranties expressed or implied.

Limitation of Liability

Enexor Health Systems shall not be liable for loss of profits, loss of use, consequential damages, or any other claim based on breach of warranty. Enexor Health Systems' liability for damages of any kind shall be limited to the purchase price of the defective unit.

Technical Support.

If the X-VENT Emergency Ventilator requires service or additional parts, please contact the Enexor Health Systems **24-Hour Technical Support Department**:

Phone: (615) 224-8466

Email: service@enexorhealth.com

When requesting support, please have the following information on hand:

- Ventilator Serial Number;
- Description of the problem and part name (if known);
- Department using the equipment and name of person to contact;
- Purchase order to allow for tracking of equipment;
- Purchase order for device with an expired warranty.

Returning a Ventilator for Service

Before sending a ventilator to Enexor Health Systems Technical Support, please obtain a service request (SR) number from the service representative.

Pack the X-VENT Emergency Ventilator into its original or equivalent packaging. Please ensure that the SR number is visible on the packaging.

Return the device to:

Enexor Health Systems, LLC
ATTN: Service Department
1 Enterprise Ct.
Franklin, TN 37067

X-VENT Parts Included.

- One (1) 10 foot Power Cord;
- One (1) X-VENT Filter;
- One (1) 24V 5Ah Battery System.

X-VENT Parts Not Included.

- PEEP Valve;
- Patient Dual Circuit;
- In-line Bacterial Filter(s).

Chapter 2

Setting up the X-VENT Emergency Ventilator

Install X-VENT Room Air Filter.

Locate the ROOM AIR FILTER ACCESS PANEL on the RIGHT SIDE of the X-VENT. REMOVE the access panel by loosening six (6) THUMB SCREWS. INSERT the ROOM AIR FILTER. VERIFY that the filter is installed all the way. REPLACE the access panel and tighten the six (6) access panel THUMB SCREWS.

Note: The ROOM AIR FILTER on the X-VENT should be replaced every 3-6 months. You *do not* need to replace this filter between patients.

Figure 2.1 - Installing the X-VENT Inspiratory Filter.

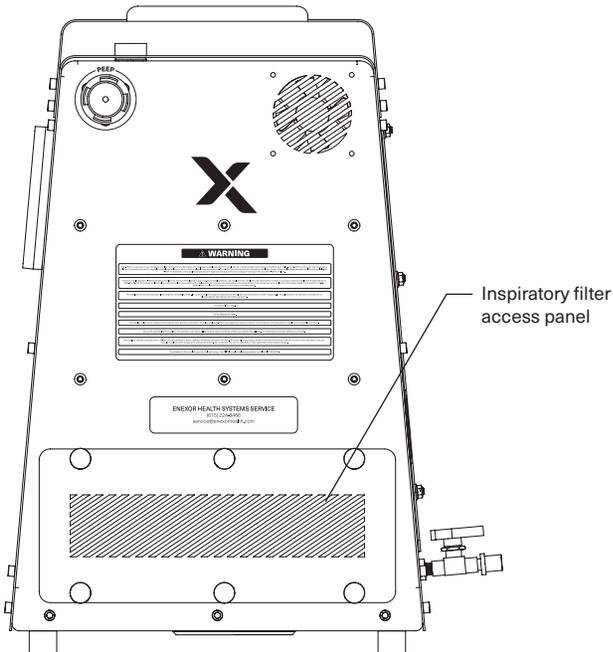
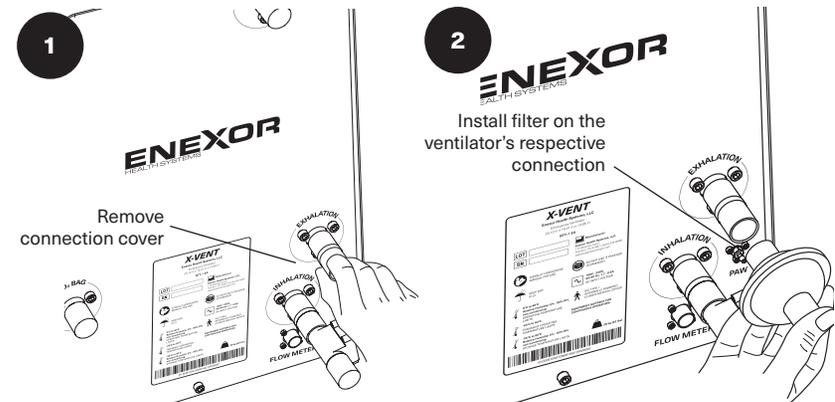


Figure 2.2 - Installing the X-VENT Expiratory Filter.



Install Expiratory Bacterial/Viral Filter.

Locate the EXPIRATORY CONNECTION on the LEFT SIDE of the X-VENT. If the protective cover is on the connection, remove the cover before proceeding. INSTALL a single IN-LINE BACTERIAL VIRAL FILTER on the ventilator's EXPIRATORY CONNECTION. For some in-line filters, a 22 mm to 15 mm adapter may be required. VERIFY that the filter is secured tightly to prevent leaks. REPLACE the filter after each patient.

Note: Only **one (1)** IN-LINE BACTERIAL VIRAL FILTER is **required** for safe and effective use of the X-VENT, however it is **recommended** that all patient connections (**INHALATION, EXHALATION** and **PRESSURE RELIEF**) are fitted with an IN-LINE BACTERIAL VIRAL FILTER between each patient.

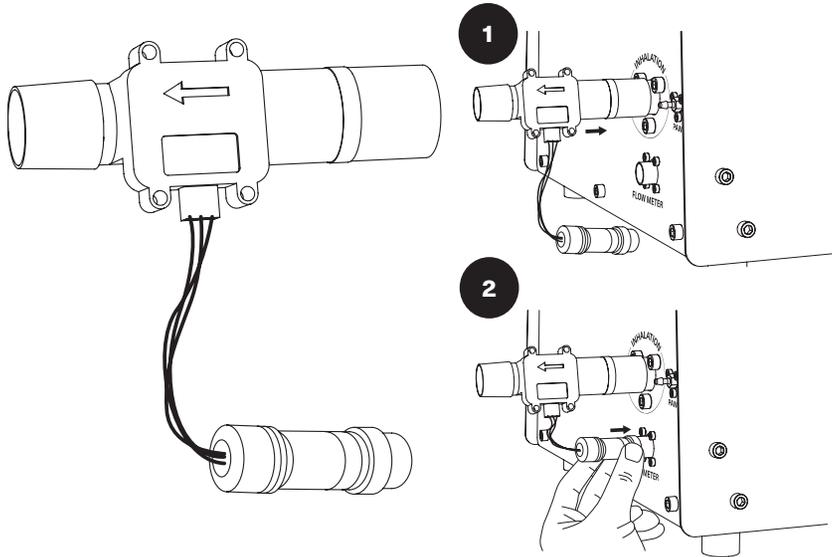
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Install Inspiratory Flow Meter.

Attach the INSPIRATORY FLOW METER included with the X-VENT to the INHALATION CONNECTION located on the LEFT side of the X-VENT. VERIFY that the flow meter is installed *before* the INSPIRATORY BACTERIA FILTER. VERIFY that the connections are secured tightly. VERIFY that the arrow on the flow meter is pointing AWAY from the X-VENT. SECURE the FLOW METER ELECTRICAL CABLE to the X-VENT FLOW METER CONNECTION and VERIFY the cable is securely connected to both the INSPIRATORY FLOW METER and the FLOW METER CONNECTION.

Figure 2.3 - Installing the Inspiratory Flow Meter.



Warning! The X-VENT will not operate without the INSPIRATORY FLOW METER properly connected to the X-VENT.

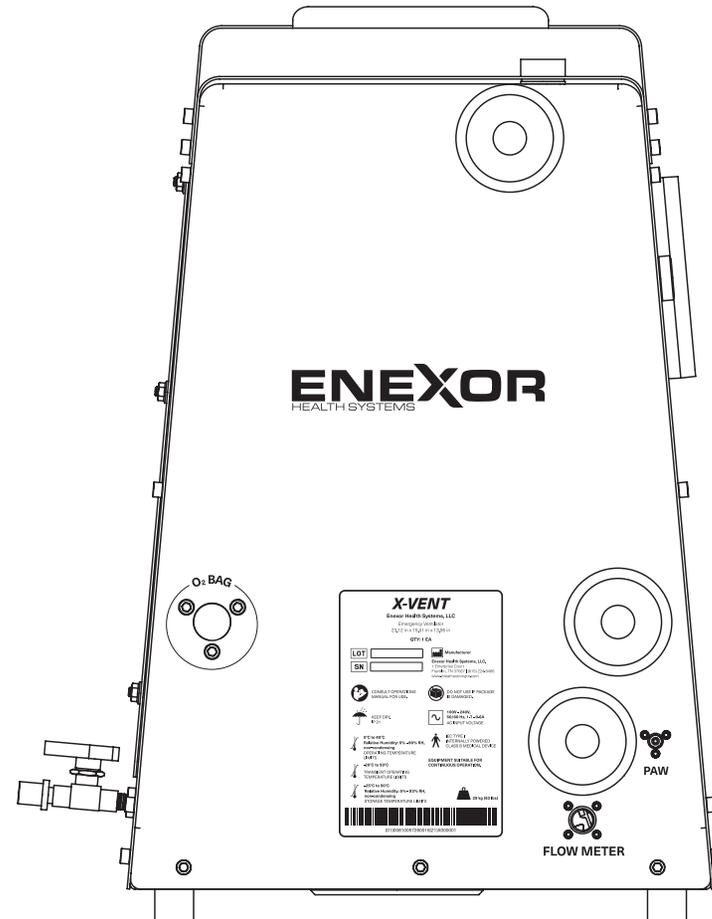


Note: You can verify that the INSPIRATORY FLOW METER is properly connected and communicating with the X-VENT by running a system TEST.

Install Additional Bacterial/Viral Filters.

Repeat the same steps outlined in Figure 2.2 for the INSPIRATORY and PRESSURE RELIEF CONNECTIONS. It is recommended that all patient connections are equipped with an IN-LINE BACTERIAL VIRAL FILTER.

Figure 2.4 - X-VENT complete patient connections view.



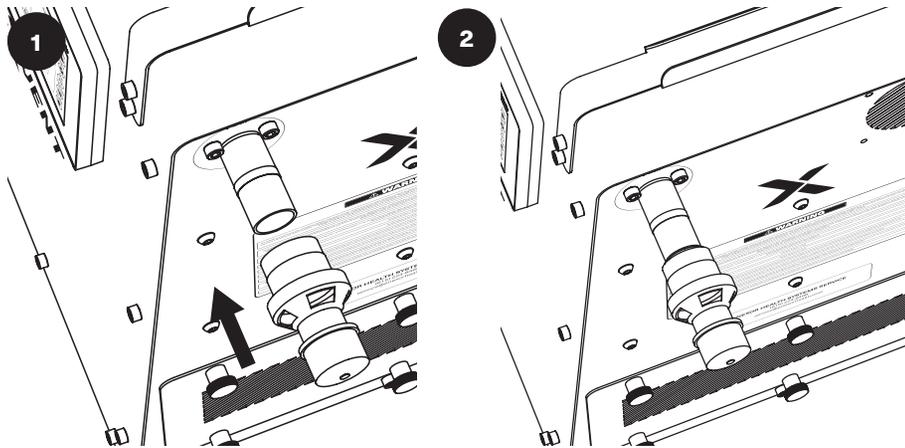
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Install PEEP.

Locate the PEEP connection on the RIGHT side of the X-VENT near the top. Install the PEEP on the X-VENT PEEP CONNECTION. The X-VENT is set-up to **accept 22mm and 30mm PEEP connections.**

If a 30mm PEEP connection is used, utilize the 30mm to 22mm ADAPTER included with the X-VENT. **VERIFY** that the PEEP is secured in place tightly. Failure to securely fasten the PEEP on the X-VENT PEEP CONNECTION can lead to improper ventilation and will likely trigger an alarm.

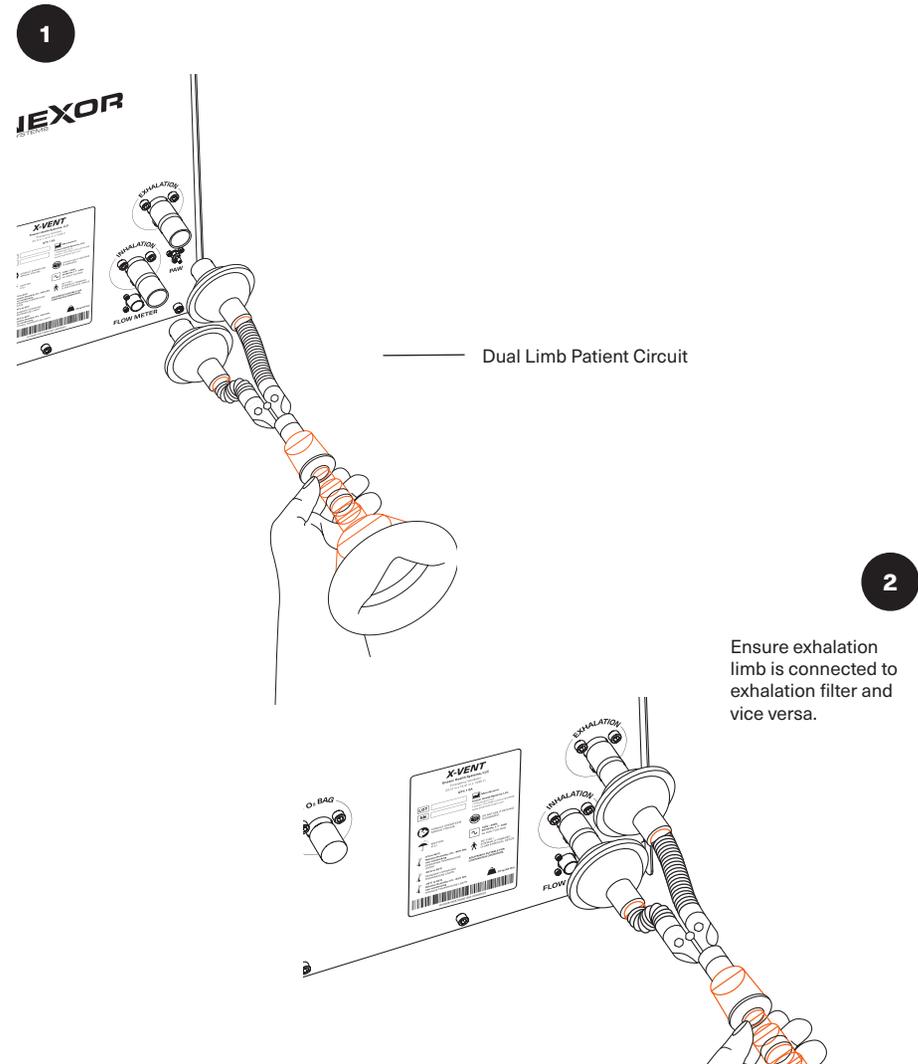
Figure 2.5 - Installing the PEEP on the X-VENT PEEP Connection



Install Patient Circuit.

Locate the INHALATION and EXHALATION CONNECTION(S) on the LEFT side of the X-VENT. **VERIFY** that the inspiratory and expiratory filters are installed. Install a DUAL LIMB PATIENT CIRCUIT to the X-VENT connection points. **VERIFY** that the DUAL LIMB PATIENT CIRCUIT is connected to the INSPIRATORY and EXPIRATORY FILTERS. **VERIFY** that both the inhalation and exhalation connections are tightly secured.

Figure 2.6 - Installing the Patient Circuit



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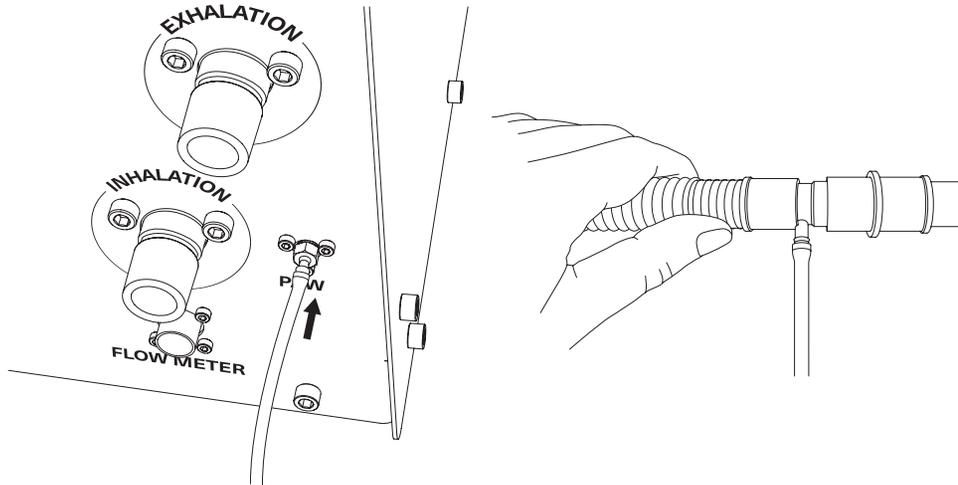


Warning! If O₂ is being used, connect the optional O₂ system before operation of the X-VENT (see Chapter 5).

Install Patient Airway Pressure Sensor.

ATTACH the PATIENT AIRWAY PRESSURE LINE to the PATIENT AIRWAY (PAW) PRESSURE PORT on the LEFT SIDE of the X-VENT. Once connected, pull on the line to ensure it is on securely. VERIFY that the line is connected to the GAS SAMPLING PORT on the PATIENT BREATHING CIRCUIT. You can verify the PATIENT AIRWAY PRESSURE SENSOR is functioning properly by running a system TEST.

Figure 2.7 - Connecting the Patient Airway Pressure Tube



Warning! Failure to properly connect the PATIENT AIRWAY PRESSURE LINE to the PATIENT AIRWAY (PAW) PRESSURE PORT will trigger an alarm and/or prevent operation of the X-VENT.

About the Patient Circuit

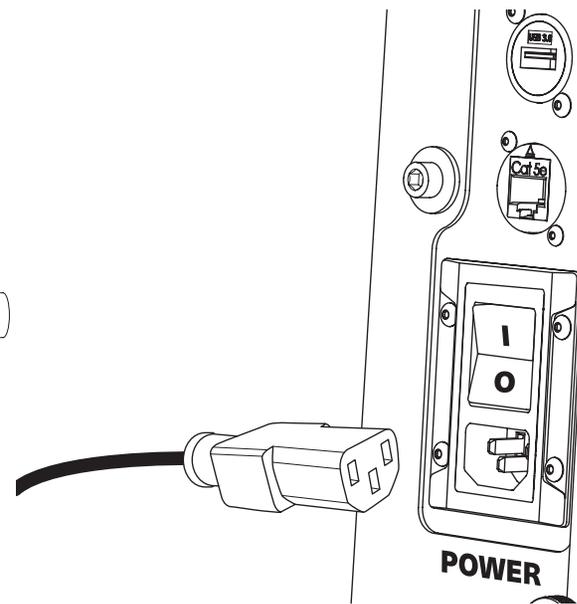
The X-VENT requires the use of a non-heated, dual limb patient circuit used in conjunction with a heat and moisture exchange (HME).

Connect to Power.

Using AC Power

Locate the AC POWER CONNECTION on the BACK SIDE of the X-VENT. CONNECT the grounded power cord to the BACK SIDE of the X-VENT. The connection is a locking C13 plug, which is often used for computer monitors and other electronic devices. The X-VENT is designed to connect to 110-240VAC 50/60Hz 1.7-0.8A. VERIFY that the connection is secure to prevent accidental disconnection.

Figure 2.8 - Connecting to AC Power



Using DC Power

The X-VENT has the ability to "cold-start" from its internal DC batteries. Before powering on the X-VENT from battery power it is recommended that the unit have at least 2 (two) hours connected to an A/C power source to ensure the batteries are fully recharged. The X-VENT does not provide detailed battery information, only an alarm when the battery is critically low. To start the unit from DC power, TOGGLE the POWER SWITCH on the BACK SIDE of the unit from OFF (I/O) to ON (I/O).

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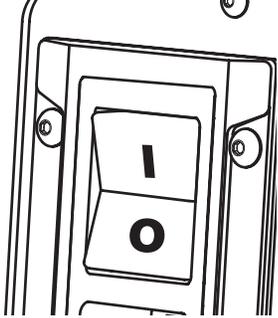


Warning! There are internal AC and DC over current protection breakers that require tools for access. These breakers are not meant to be serviceable by the user. If the user suspects that these breakers are tripped, contact service support.

Powering on the X-VENT.

If you have followed all of the steps outlined above in Chapter 2, you are likely ready to power on the X-VENT and prep for patient use. To power on the X-VENT, TOGGLE the POWER ROCKER SWITCH on the BACK SIDE of the unit from OFF (I/O) to ON (I/O).

Figure 2.9 - Powering on the X-VENT.



Power on checklist.

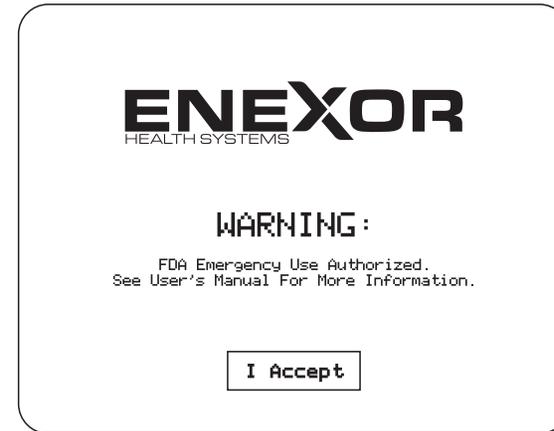
After powering on the X-VENT, it is recommended that you assess the unit. Complete the checklist below to ensure the X-VENT has completed a successful startup.

- The X-VENT made an audible click moments after toggling the power rocker to ON.
- The X-VENT's Human Machine Interface (HMI) Screen turned on and is displaying a loading bar.
- The X-VENT made an audible sound for self calibration.
- The X-VENT successfully loaded its software and the STARTUP SCREEN displayed in Figure 2.10 is presented.



Note: Self calibration times vary based on a variety of factors and are often very quick (<1 second).

Figure 2.10 - X-VENT "STARTUP SCREEN".



Powering off the X-VENT.

To power off the X-VENT, TOGGLE the POWER ROCKER SWITCH from ON (I/O) to OFF (I/O). A prompt will appear on the HMI notifying the operator of a loss in power. If no action is taken within sixty (60) seconds, the X-VENT will remain on and return to the previous screen. Pressing YES will bring up a conformation window. Pressing YES again will immediately turn off the X-VENT and cease all ventilation operations.



Note: The X-VENT will take a minimum of one (1) minute to startup/restart after a complete power down. Do not power off the unit while a patient is connected to the X-VENT.

If the X-VENT HMI touchscreen is not accessible, you may also press and hold the STOP button for at least fifteen (15) seconds after TOGGING the POWER ROCKER SWITCH from ON (I/O) to OFF (I/O). This will instantly power off the X-VENT. This method should only be used if the HMI touchscreen is unresponsive or inaccessible.

Chapter 3

Digital Touch Screen Readouts

X-VENT HMI Interface.

The X-VENT Emergency Ventilator is controlled by the HMI touchscreen which communicates with the X-VENT's on-board controller for semi-autonomous operation. The touch interface allows the operator to view current system readouts and set operating setpoints. Additionally, the operator can switch between system modes of operation as well as run system functions such as TEST and MAINTENANCE modes. This section will cover the X-VENT's HMI interface, how to use it, and basic error troubleshooting.

Note: If the X-VENT controls become difficult to select, use the Calibrate Touchscreen control to recalibrate the touchscreen sensor. See *"Available Device Settings"* included in the X-VENT supplemental information package for more information.

Locking the HMI.

To lock the X-VENT touchscreen and protect against accidental button presses, press and hold the LOCK ICON located on the BOTTOM LEFT CORNER of the X-VENT's HMI screen for three (3) seconds. Once locked, the system will beep and the LOCK ICON's color will turn red. To unlock the touchscreen, press and hold the LOCK ICON in BOTTOM LEFT CORNER of the X-VENT's HMI for three (3) seconds again. See **Figure 3.3** for the lock button location.

Navigating the HMI.

The MENU SCREEN is accessible from almost any screen by simply tapping the navigation arrow located in the middle left edge of each screen (see **Figure 3.1-2**). This button will always direct the Operator to the MENU SCREEN, regardless of the system run state, operating mode, or screen selection. The MENU SCREEN consists of five (5) user interface buttons which include HOME, DASHBOARD, MODE, TRENDS, and ALARMS. When running in battery mode, the MENU SCREEN will display a POWER icon which can be used to turn off the X-VENT.

Figure 3.1 - Menu Screen (1), Dashboard Screen (2)

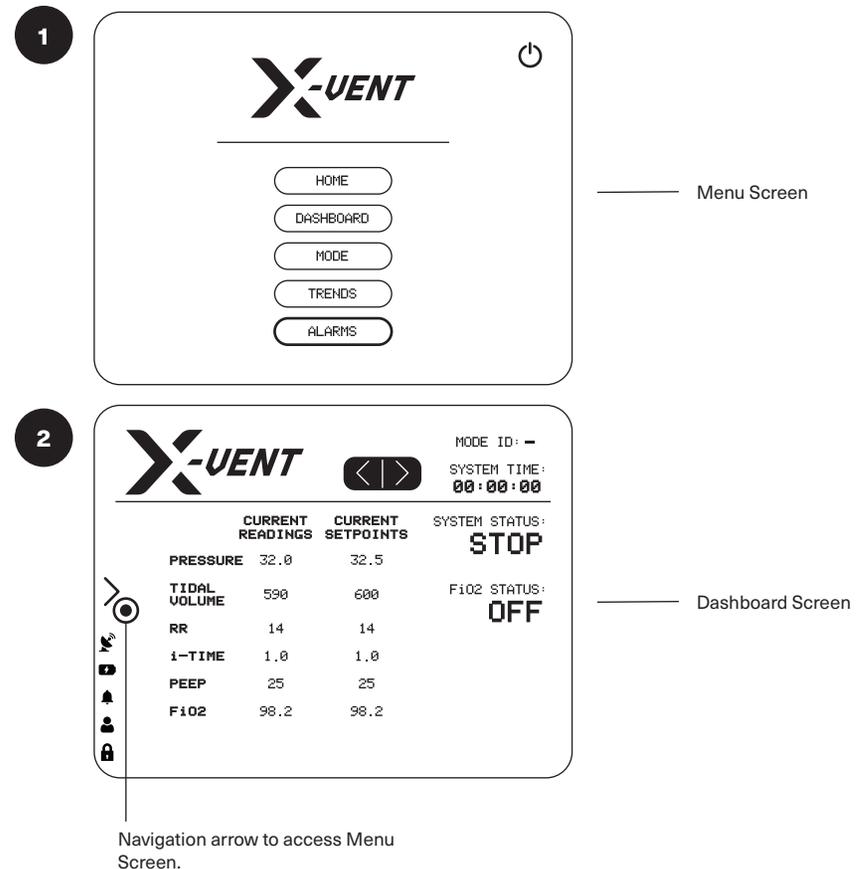
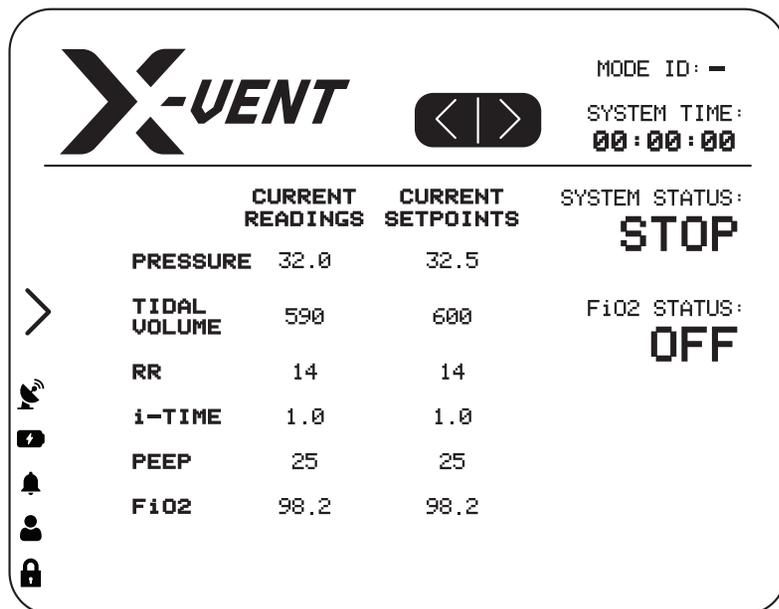


Figure 3.2 - Dashboard Screen (Page 1)



X-VENT Dashboard Screen.

The X-VENT monitors multiple parameters. View monitored X-VENT Ventilation therapy data by pressing the DASHBOARD button located on the MENU SCREEN. The DASHBOARD SCREEN provides a detailed overview of a variety of patient and system details. The DASHBOARD SCREEN is comprised of five (5) pages which the operator can navigate between by using the navigation arrows located at the top of any of the dashboard pages (see **Figure 3.3**).

Note: Displayed data is dependent on the set Mode and the number of breaths delivered. Monitors will display "--" if they are not available for the set Mode.

Dashboard Page 1 | Setpoints & Readouts

This page displays the current setpoints and their associated live readouts for the X-VENT's therapy settings. It also displays the current system time, run status and FiO₂ status. This page was designed to give a quick at-a-glance view of all ventilation therapy settings.

Dashboard Page 2 | Patient Dashboard

The PATIENT DASHBOARD page allows the clinician to view and edit patient data. Patient data is used to calculate Ideal Body Weight (IBW) which the X-VENT uses to recommend ETT depth and Tidal Volume setpoints on a mL/kg basis. You can also use the NEW PATIENT button to clear out existing data and prepare the X-VENT for a new patient. See *"Patient Data Input" on page 22* for more information.

Dashboard Page 3 | X-VENT Calculations

The calculations page shows useful values that are calculated by the on-board controller using multiple data points. These values can help the clinician/therapist in determining the best therapy adjustments to provide the best care to the patient.

Dashboard Page 4 | Sensor Readouts

The sensor readout page displays current solenoid valve status as sensor readings. This can help in troubleshooting a component failure on the X-VENT and provide the clinician with verification that therapy is being delivered accurately.

Dashboard Page 5 | System Counters

The system counters page provides a detailed count of various component cycles as well as hourly counters for things such as hours in operation and time since last maintenance. This page is helpful to ensure the X-VENT is being properly maintained, and can assist maintenance staff in identifying parts for replacement before they hit their mean time between failures (MTBF). A similar display of this page is also available in the maintenance menu, under system information. See *"Maintenance Screen" on page 49* for more information.

X-VENT EMERGENCY VENTILATOR

X-VENT HMI: Navigation and Displays.

The Menu Screen

The X-VENT's MENU SCREEN is the primary or "default" screen for the X-VENT. Using the global navigation button located on the middle left hand side of most screens will navigate the operator back to the MENU SCREEN. The menu screen enables navigation to almost all of the X-VENT's modes and features. See **Figure 3.3** for reference and **Figure 3.4** for a detailed list of the Menu Items and their description.

Global System Buttons/Alerts

The X-VENT has a series of global notifications and a few global actions that exist across nearly all of its displays. They are outlined below:

- **Alarm Active** - Displayed only when an alarm is active. (Sometimes visible)
- **Battery Power** - Displayed only when the system is operating on internal battery power. (Sometimes visible)
- **Lock touchscreen toggle** - Press and hold the lock button for three (3) seconds to toggle touchscreen lockout. (Always visible)
- **Login** - Tap to login to a user account/view user settings. (Always visible)
- **Remote Device Connected** - Tap to view number of connected devices and toggle connections. (Sometimes visible)

Figure 3.3 - The X-VENT Menu Screen & Global Actions/Alerts

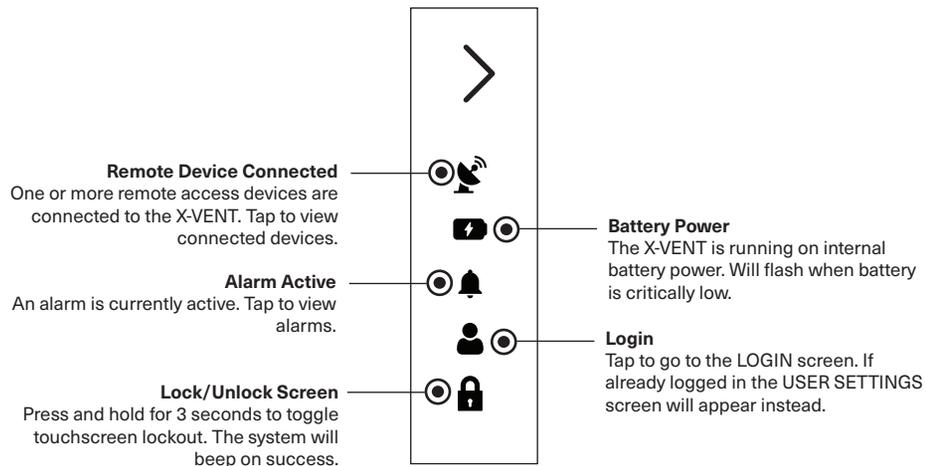


Figure 3.4 - Menu Screen Menu Items

Menu Item	Description
Mode	Displays mode selection for main system operating modes. <ul style="list-style-type: none"> • PRESSURE CONTROL MODE [MODE ID: PC] • VOLUME CONTROL MODE [MODE ID: VC] • ASSIST MODE [MODE ID: AM] • TEST MODE
Dashboard	Displays multiple system readouts, setpoints and warnings along with the system run status and patient information.
Home (Run)	A custom RUN SCREEN exists for each mode and is color coded based on the specific mode color. Each RUN SCREEN controls different variables most applicable to the associated mode.
Trend	Displays a selection of various trend graphs for viewing by the clinician or therapist to assist in treatment.
Alarms	Displays a log of current and past alarms triggered during operation. The alarm screen also allows for setting alarm setpoints.

X-VENT HMI: Confirming Changes.

The X-VENT will always prompt the Operator to CONFIRM before any changes are made to modes, setpoints, or alarms. This is intentional and designed to avoid accidentally entering incorrect setpoints. An example of this is shown below in **Figure 3.5**.

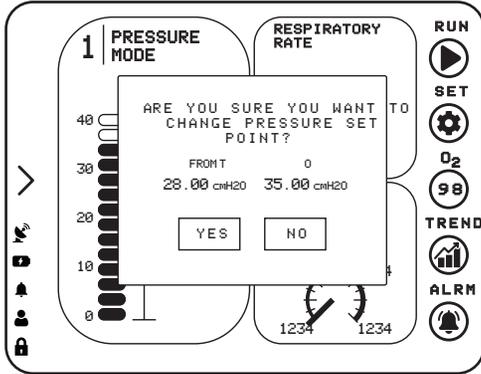
Settings will not be changed until the Operator CONFIRMS the input. To CONFIRM the input, simply tap the YES button. Tapping NO will result in no change to system settings.



Warning! To ensure patient safety, VERIFY that all system settings and presets are appropriate before providing therapy, and on a routine basis during therapy.

X-VENT EMERGENCY VENTILATOR

Figure 3.5 - Confirm Changes



X-VENT HMI: Operating Modes.

The X-VENT can operate in three (3) primary modes: (i) PRESSURE CONTROL MODE, (ii) VOLUME CONTROL MODE and (iii) ASSIST CONTROL MODE. Each mode controls a different primary variable (i.e., pressure, volume) and has controls for auxiliary variables such as RESPIRATORY RATE (BPM) and i-TIME. Each mode has a RUN screen that displays an overview for the mode and has controls for editing setpoints, viewing mode specific trends and setting alarms. To switch between modes, tap the MODE button from the MENU screen, as shown in **Figure 3.6** and **Figure 3.7**.

When selecting a system mode, the operator will be prompted to input the desired setpoints for that mode. Changing setpoints for a new mode while currently operating in a different mode *will not* alter the therapy settings in the current mode of operation. It is not until the operator confirms the setpoints for the new mode of ventilation that therapy setpoints are changed.

When selecting a mode different from the current mode, the system will direct the operator to the SET-UP screen for that mode, as shown in **Figure 3.8**.

For more information on the modes of ventilation available on the X-VENT and how they operate see "[Modes of Ventilation](#)" on page 23.

For more information on starting therapy on the X-VENT see "[Starting Ventilation Therapy](#)" on page 30.

Figure 3.6 - Switching Between Modes

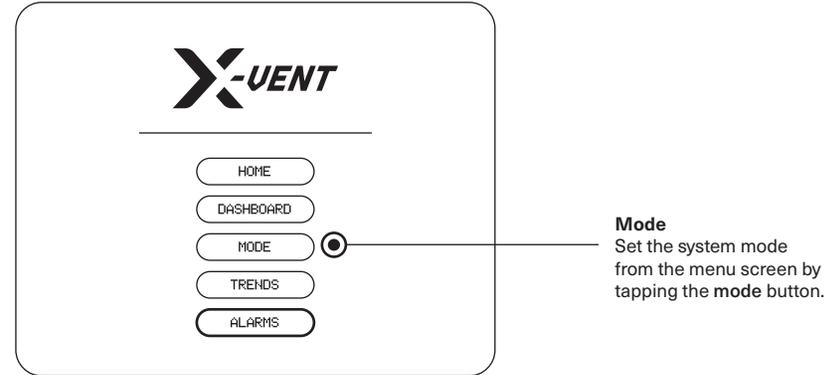
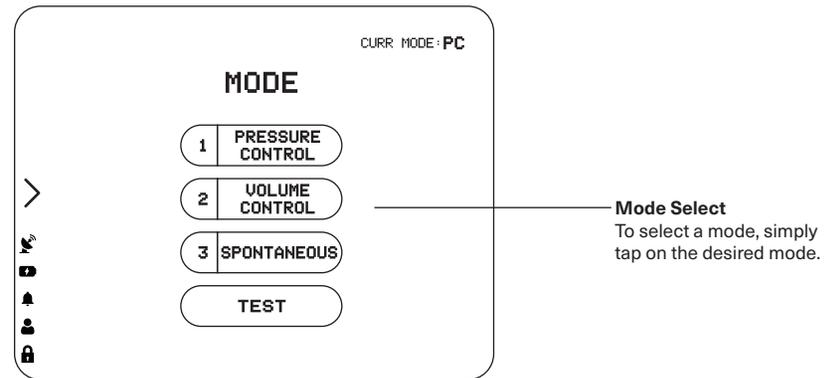


Figure 3.7 - Mode Selection



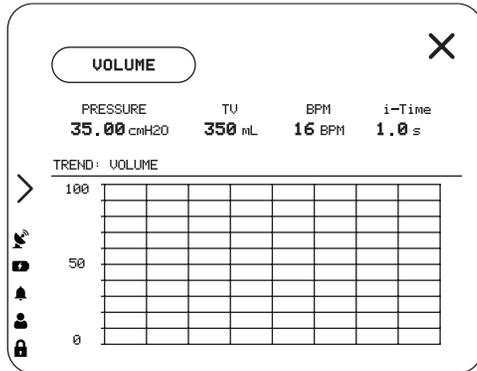
X-VENT HMI: Trends.

The X-VENT Emergency Ventilator is designed to display standard charts for key variables. Each operating mode will have a TREND button on the respective RUN screen that will take the operator to the TREND SELECT screen.

Alternately, the operator can access the TREND SELECT screen from the MENU screen by pressing the TREND button.

X-VENT EMERGENCY VENTILATOR

Figure 3.8 - Volume Trend Screen



Each graphic trend is based off of data gathered from sensors and calculations sourced from the X-VENT's on-board controller. Due to limitations within the hardware of the HMI, trend functionality is somewhat limited and there is no ability to zoom in on a trend at this time. Additionally some trends may only show data on a per breath cycle basis instead of in a continuous trend line. The purpose of the trend data is to provide the operator with graphical feedback of how therapy is being received by the patient. If more detailed data is required, the clinician or therapist should view data displayed on the DASHBOARD screens.

X-VENT HMI: Changing Setpoints.

How to Change Setpoints

There are multiple ways to change setpoints on the X-VENT. All of these methods are achieved through the HMI. The key ways to change the X-VENT's operating mode are outlined later in **Chapter 4**.

1. Tap the SET button on the selected mode RUN screen to bring up the set screen and change multiple variables at once. **Figure 3.9-1**
2. Tap the DISPLAY VALUE for the desired setpoint requiring a change. **Figure 3.9-2**
3. Tap the respective button for the desired setpoint on the mode specific SETUP screen. **Figure 3.10**

Figure 3.9-1 - Set 1

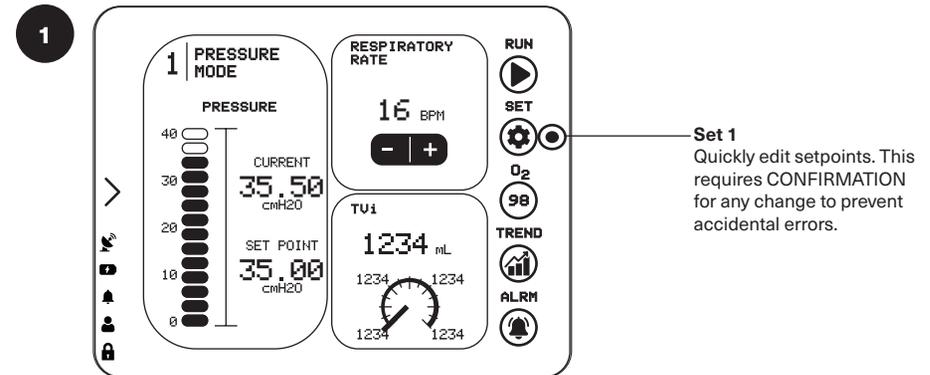
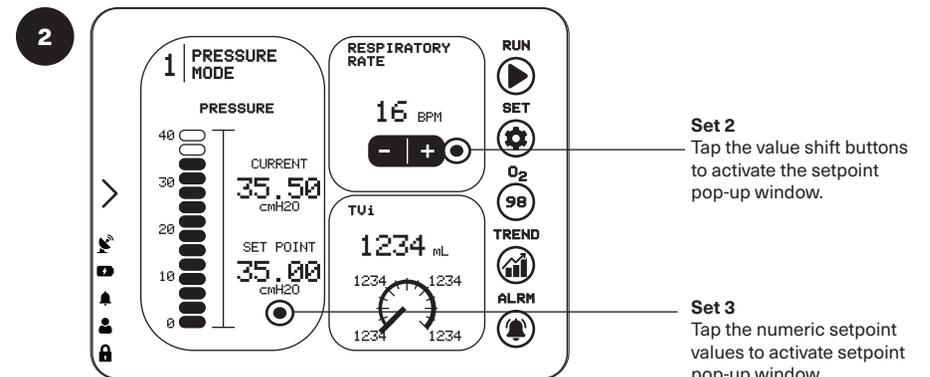


Figure 3.9-2 - Set 2 and Set 3



X-VENT EMERGENCY VENTILATOR

Figure 3.10 - Set-Up Page

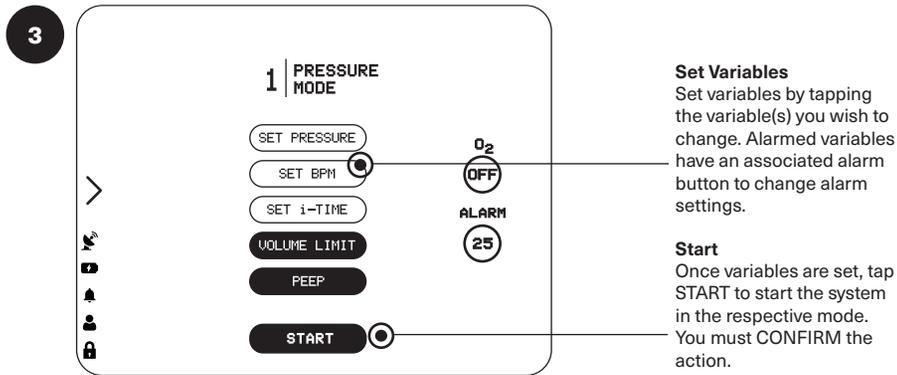
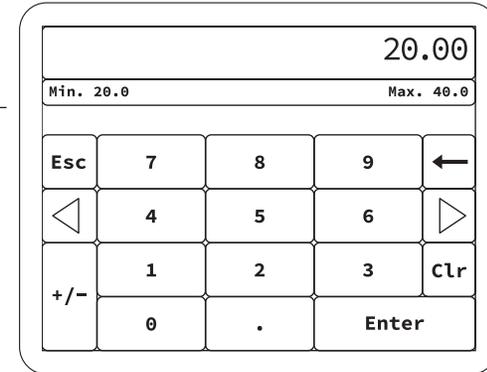


Figure 3.12 - Precision Value Input Window

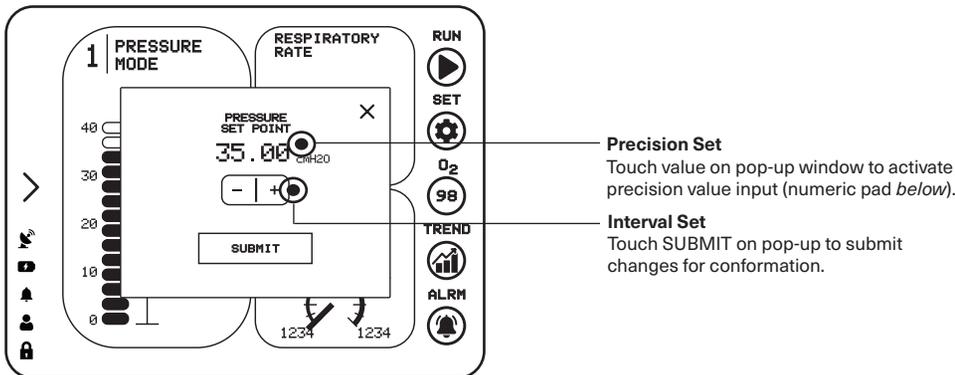
Precision Value Input Window



Precision Changes vs. Interval Changes

There are two ways to alter setpoints once you are on a CHANGE SETPOINT popup. First, you can use the incremental (-|+) buttons which will decrease/increase the selected setpoint in preset increments. Each variable has a preset increment in which it is programmed to increase or decrease. For more fine-tuned adjustments, the operator can tap the SETPOINT DISPLAY on the CHANGE SETPOINT popup to bring up the PRECISION VALUE INPUT window. This will allow the operator to enter in an exact value for the setpoint out to the smallest increment that setpoint allows.

Figure 3.11 - Precision and Interval Set | Change Setpoint Popup



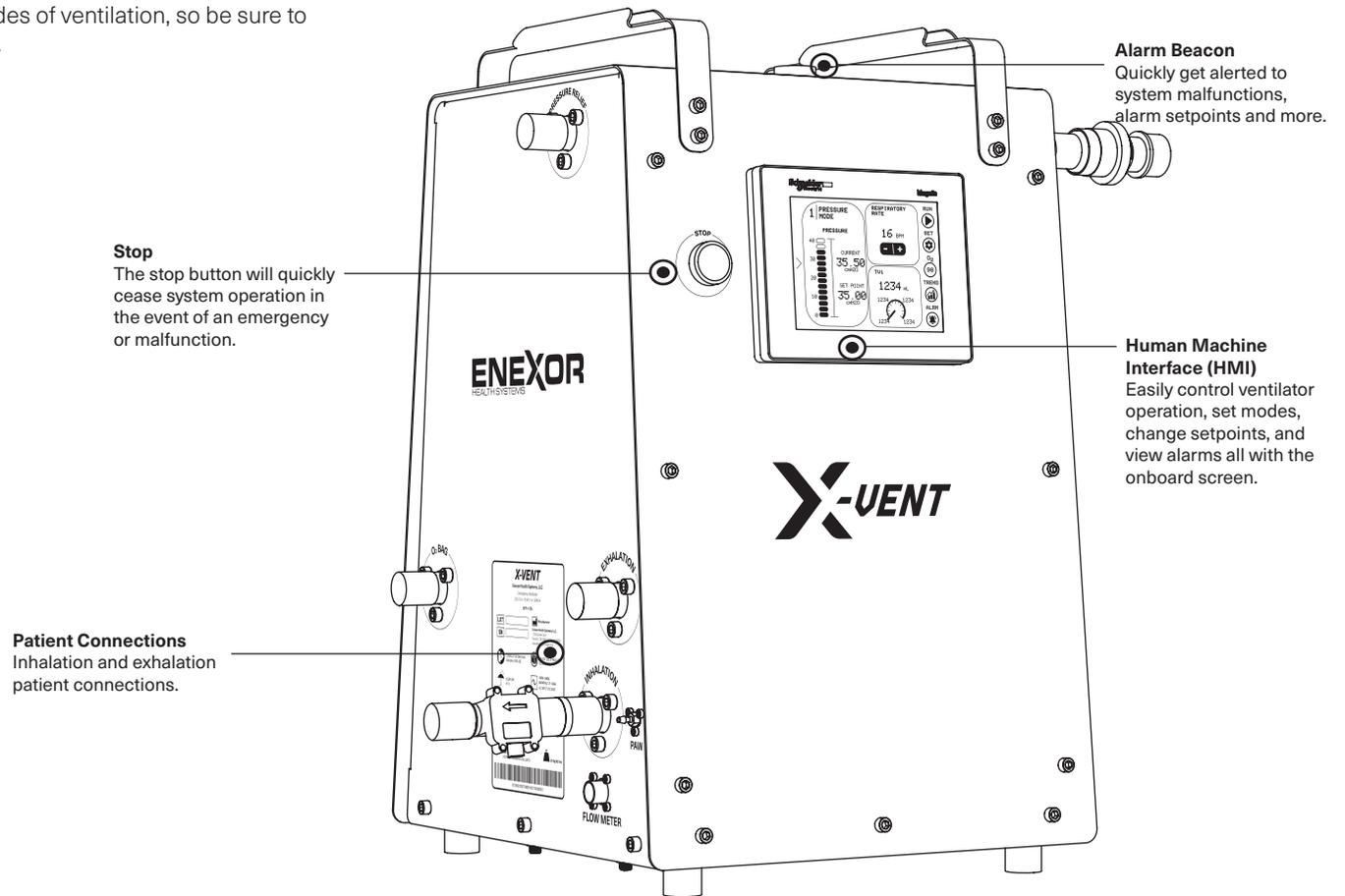
Chapter 4

Operating the X-VENT Emergency Ventilator

Getting Started.

The X-VENT was designed to be simple and easy-to-use. There are three (3) modes of ventilation offered on the X-VENT, each of which is outlined in this chapter. Many ventilators use different terminology to describe modes of ventilation, so be sure to review each mode in detail before using the X-VENT.

Figure 4.0 - X-VENT Exterior Overview



X-VENT EMERGENCY VENTILATOR

Setting up a New Patient.

The first screen you will be presented with after turning on the X-VENT and acknowledging the initial EUA warning is the NEW SITE screen. The X-VENT requires HUMIDITY, TEMPERATURE, and ALTITUDE data to accurately compute FiO2 and other values. Additionally the X-VENT uses the Patient's HEIGHT, WEIGHT, GENDER and AGE to calculate the patient's Ideal Body Weight and recommends a starting TIDAL VOLUME in relation to the aforementioned variables. Setting up the SITE and PATIENT data is a key first step in starting the X-VENT.

Site Data Input

SITE data refers to data relevant to the location of the X-VENT. This data is retained between patients for convenience and in a stable environment will rarely be changed. Unlike PATIENT data, once SITE data has been set for a particular patient, it can't be changed. Only when creating a new patient can SITE data be altered.

Figure 4.1 - New Site Screen

1 SITE INFORMATION	
SITE NAME AaBbCcDdEeFf	TEMPERATURE (C) 123 C
RELATIVE HUMIDITY (%) 123 %	ALTITUDE (m) 12345 m
X-VENT	

The following variables are required for SITE data:

- 1 SITE NAME
- 2 ALTITUDE (m)
- 3 TEMPERATURE (C)
- 4 HUMIDITY (%)

Patient Data Input

PATIENT data refers to data relevant to the patient intended to receive therapy from the X-VENT. This data is cleared after each power cycle and can be cleared from the DASHBOARD screen by pressing the NEW PATIENT button. Failure to provide accurate patient data will skew the RECOMMENDED PATIENT TARGETS, however it will not alter ventilation therapy behavior.

Figure 4.2 - New Patient Screen

2 PATIENT INFORMATION	
PATIENT NAME AaBbCcDdEeFf	AGE 123
GENDER <input type="radio"/> MALE <input type="radio"/> FEMALE	WEIGHT (kg) 12345 kg
HEIGHT (cm) 123 cm	
X-VENT	

The following variables are required for PATIENT data:

- 1 PATIENT NAME
- 2 WEIGHT (kg)
- 3 GENDER
- 4 HEIGHT (cm)
- 5 AGE

Completing a System Test

After completing the SITE and PATIENT data inputs, the operator will be prompted to complete a system test. Although not required, it is highly recommended that the operator complete a full test before beginning therapy on the X-VENT. See ["Test Mode" on page 26](#) for more information. Press RUN to run the TEST. Press SKIP to skip.

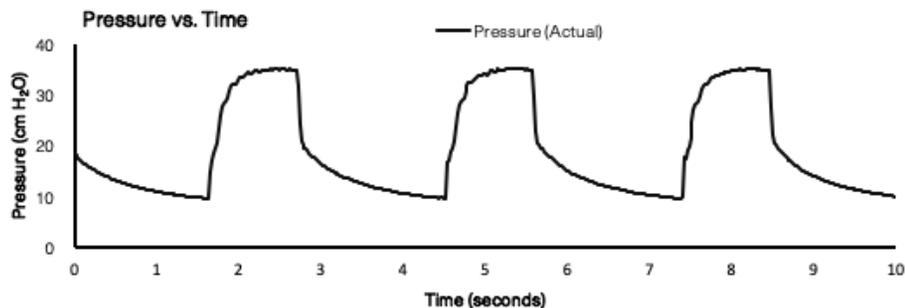
X-VENT EMERGENCY VENTILATOR

Modes of Ventilation.

Pressure Control Mode

PRESSURE CONTROL mode on the X-VENT Emergency Ventilator allows the clinician to control the pressure, in cmH₂O, delivered to the patient each breath cycle for a set RESPIRATORY RATE (BPM) and INHALATION TIME. If settings are changed during operation, they will be updated during the next breath cycle. PRESSURE CONTROL on the X-VENT uses MANDATORY breaths. Mandatory breaths are initiated by the X-VENT based on the set Breath Rate and delivered as pressure breath. Breaths cycle at the end of the set INSPIRATORY TIME. See **Figure 4.3** for a sample pressure waveform.

Figure 4.3 - Pressure Control Example Waveform



The first four (4) breath cycles in PRESSURE CONTROL mode are used for calibration and may sound different from the subsequent breaths. Please allow the X-VENT time to complete this calibration to ensure that PRESSURE CONTROL mode runs accurately.

Note: The maximum VOLUME delivered in PRESSURE CONTROL MODE is limited to the VOLUME LIMIT setpoint. In some cases, the VOLUME LIMIT may prevent the X-VENT from delivering the entirety of the set PRESSURE to the patient.

Figure 4.4-1 - Pressure Control Set Screen

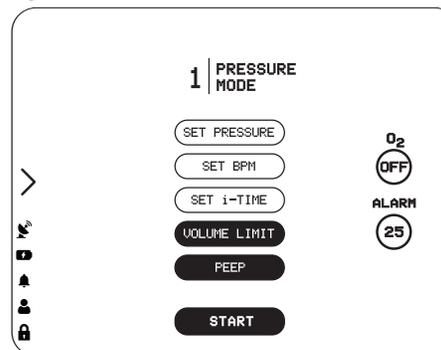
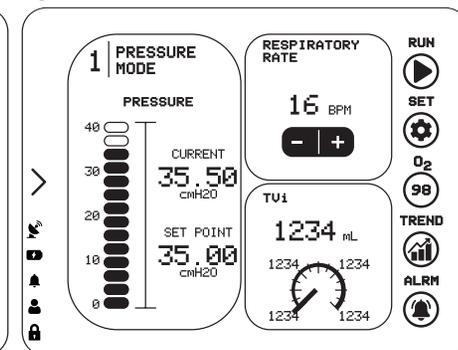


Figure 4.4-2 - Pressure Control Mode Run Screen



How to operate:

1. From the MENU screen, press MODE and then select PRESSURE CONTROL.
2. Depending on the current state of the machine, the Operator will either be sent to the PRESSURE START screen, or the PRESSURE RUN screen. The run screen will only appear when PRESSURE CONTROL mode is already in use.
3. Use the PRESSURE START screen to set variable and alarm setpoints. See ["X-VENT HMI: Changing Setpoints" on page 19](#) for more information.
4. Tap START. A confirmation screen will appear asking the Operator to CONFIRM the values set. Upon confirmation, the system will begin running with the specified settings.
5. To STOP, simply tap the button labeled RUN on the PRESSURE RUN screen. A CONFIRM prompt will appear for confirmation.

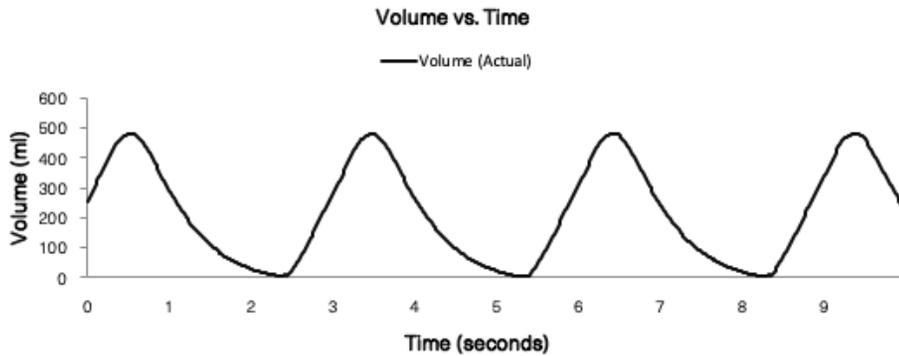
Note: A PEEP valve is required for the X-VENT to deliver therapy properly. The PEEP value entered by the Operator does not correlate to an internal PEEP. An external PEEP valve is required. Anytime the external PEEP value is updated, the clinician should update the PEEP setpoint on the X-VENT.

X-VENT EMERGENCY VENTILATOR

Volume Control Mode

The VOLUME CONTROL mode on the X-VENT Emergency Ventilator allows the clinician to control the tidal volume, in mL, delivered to the patient each breath cycle for a set RESPIRATORY RATE (BPM) and INHALATION TIME. If settings are changed during operation, they will be updated during the next breath cycle. VOLUME CONTROL on the X-VENT uses MANDATORY breaths. Mandatory breaths are initiated by the X-VENT based on the set Breath Rate and delivered as volume breath. Breaths cycle at the end of the set INSPIRATORY TIME. See **Figure 4.5** for a sample volume waveform.

Figure 4.5 - Volume Control Example Waveform



The VOLUME CONTROL mode on the X-VENT Emergency Ventilator allows the clinician to control the tidal volume, in mL

Note: The maximum PRESSURE delivered in VOLUME CONTROL MODE is limited to the PRESSURE LIMIT setpoint. In some cases, the PRESSURE LIMIT may prevent the X-VENT from delivering the entirety of the set TIDAL VOLUME to the patient.

Figure 4.6-1 - Volume Control Set Screen

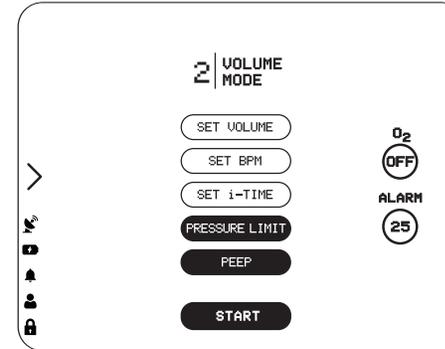
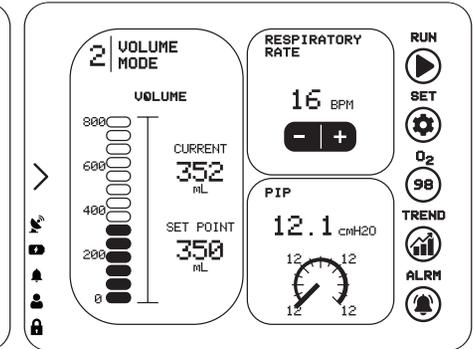


Figure 4.6-2 - Volume Control Mode Run Screen



How to operate:

1. From the MENU screen, press MODE and select VOLUME CONTROL.
2. Depending on the current state of the machine, the Operator will either be sent to the VOLUME START screen, or the VOLUME RUN screen. The run screen will only appear when VOLUME CONTROL mode is already in use.
3. Use the VOLUME START screen to set variable and alarm setpoints. See ["X-VENT HMI: Changing Setpoints" on page 19](#) for more information.
4. Tap START. A confirmation screen will appear asking the Operator to CONFIRM the values set. Upon confirmation, the system will begin running with the specified settings.
5. To STOP, simply tap the button labeled RUN on the VOLUME RUN screen. A CONFIRM prompt will appear for confirmation.

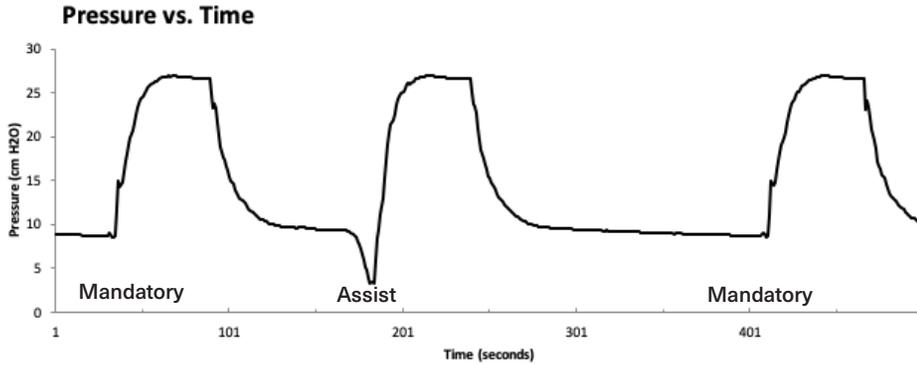
Note: A PEEP valve is required for the X-VENT to deliver therapy properly. The PEEP value entered by the Operator does not correlate to an internal PEEP. An external PEEP valve is required. Anytime the external PEEP value is updated, the clinician should update the PEEP setpoint on the X-VENT.

X-VENT EMERGENCY VENTILATOR

Assist Mode

ASSIST mode provides mandatory and assist pressure breaths, depending on the timing of detected patient effort. Patient effort will trigger an assist pressure breath. If no patient effort is detected within a breath period, X-VENT will provide a mandatory pressure breath. Both mandatory and assist breaths are delivered at the set Pressure Control (above PEEP) over the set Inspiratory Time. When a breath cycles, the pressure of the PATIENT CIRCUIT drops to the set PEEP. See **Figure 4.7** for a sample assist waveform.

Figure 4.7 - Volume Control Example Waveform



ASSIST mode has the ability to replicate other modes of ventilation. For more information reference the "Comparable Ventilation Modes" chart included in the X-VENT supplemental information package.



Note: A PEEP valve is required for the X-VENT to deliver therapy properly. The PEEP value entered by the Operator does not correlate to an internal PEEP. An external PEEP valve is required. Anytime the external PEEP value is updated, the clinician should update the PEEP setpoint on the X-VENT.

Figure 4.8-1 - Assist Mode Set Screen

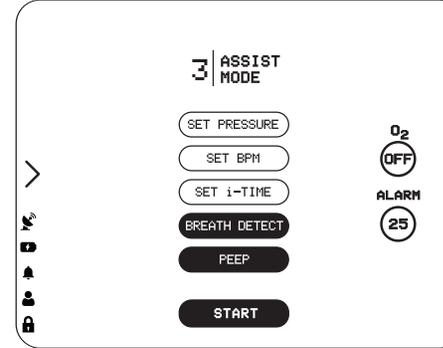
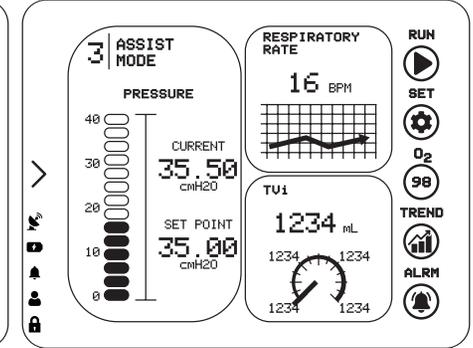


Figure 4.8-2 - Assist Mode Run Screen



How to operate:

1. From the MENU screen, tap MODE and select ASSIST.
2. Depending on the current state of the machine, you will either be sent to the ASSIST START screen, or the ASSIST RUN screen. The run screen will only appear when ASSIST mode is already in use.
3. Use the ASSIST START screen to set variable and alarm setpoints. See ["X-VENT HMI: Changing Setpoints" on page 19](#) for more information.
4. Tap START. A confirmation screen will appear asking the Operator to CONFIRM the set values. Upon confirmation, the system will begin running with the specified settings.
5. To STOP, simply tap the button labeled RUN on the ASSIST RUN screen. A CONFIRM prompt will appear for confirmation.

X-VENT EMERGENCY VENTILATOR

Test Mode.

Entering Test Mode

TEST MODE on the X-VENT Emergency Ventilator can be executed to verify that the mechanical components of the system are operating properly. During test mode, the system will move automatically. It's important that no body parts are near the mechanical components during this time. Following the test, the Operator will be notified if the test is successful or has failed. If the test failed, replace the mechanical components as required. See **Chapter 1** for Enxor Health Systems' X-VENT Technical Support information.

Figure 4.9 - Test Mode Screen



TEST MODE calculates the resistance and leak of the PATIENT CIRCUIT. Based on these calculations, the X-VENT verifies the integrity of the PATIENT CIRCUIT, and improves the accuracy of therapy delivered during ventilation. If used, the test will also verify the connection status of the INHALATION FLOW METER as well as the PATIENT AIRWAY (PAW) PRESSURE SENSOR.

TEST MODE on the X-VENT will complete three (3) different tests.

- 1) SENSOR TEST
- 2) LEAK TEST
- 3) PRESSURE TEST

At the end of each test, the X-VENT will display a TEST SUMMARY SCREEN showing the results of the test, which components passed/failed and a prompt to continue to the next test. If the X-VENT fails a test, a button will appear to RETRY the test. After three (3) failed

attempts of a test, an option will appear to SKIP the test and proceed to the next test. A final TEST OVERVIEW will be displayed once all three (3) tests are complete.

To ensure therapy is delivered accurately, you must perform a system TEST whenever prompted, the patient circuit is changed, or the device is powered on.



Warning! Ventilation therapy is paused while TEST MODE is operational. If Ventilation therapy is critical to patient care, provide backup ventilation for the duration of the test.

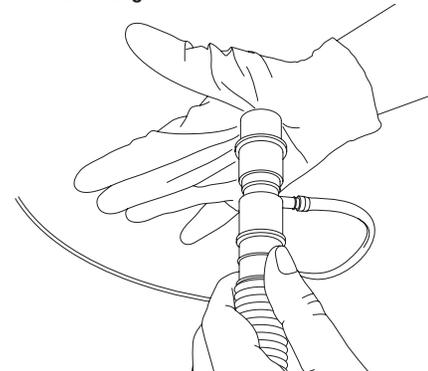


Note: Though accuracy may be reduced, X-VENT may still be used to provide ventilation therapy when a TEST fails. If time constraints make running the test inadvisable, press the SKIP button to immediately initiate Ventilation therapy.

Some control changes cause the X-VENT to prompt you to run TEST MODE. You may also press the TEST button on the MODE SCREEN to begin a TEST at any time. To run a TEST, carefully follow the on-screen instructions. When instructed, use a clean, gloved hand (or a plug) to obstruct the circuit completely, as follows:

- If you are using an DUAL LIMB PATIENT CIRCUIT, disconnect the patient interface and block the circuit at its end.
- If you are using a MOUTHPIECE PATIENT CIRCUIT, leave the mouthpiece connected, and block the open end.

Figure 4.10 - Blocking the Patient Circuit



X-VENT EMERGENCY VENTILATOR

If the test completes successfully, reconnect the PATIENT CIRCUIT to the patient and resume Ventilation therapy. If the test fails, inspect the PATIENT CIRCUIT configuration for leaks or improper setup. Resolve any issues with the PATIENT CIRCUIT, and then press **RESTART** to run the Test again.

Figure 4.11-1 - Test 1 Step

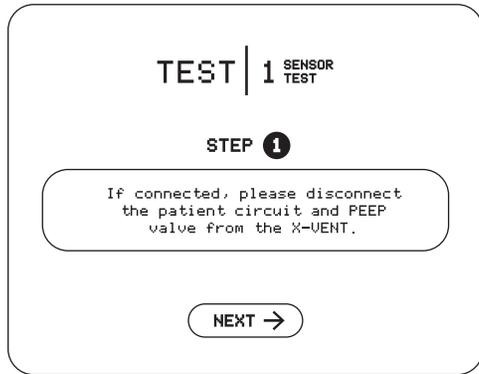


Figure 4.11-2 - Test 1 Start

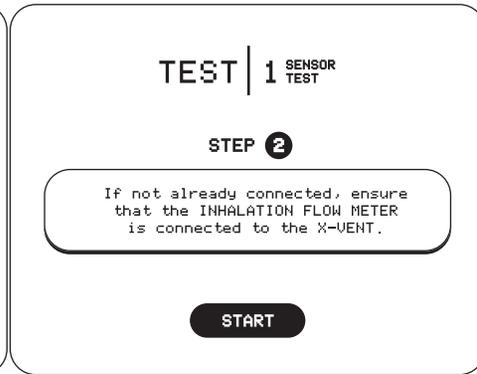


Figure 4.11-3 - Test In Progress

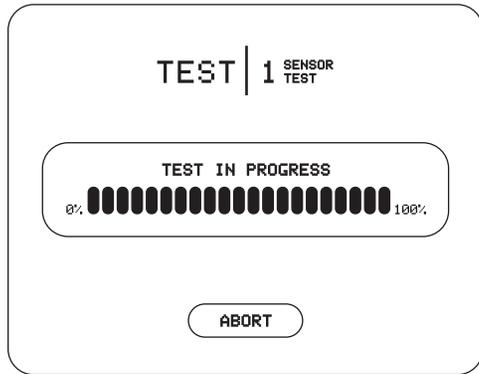
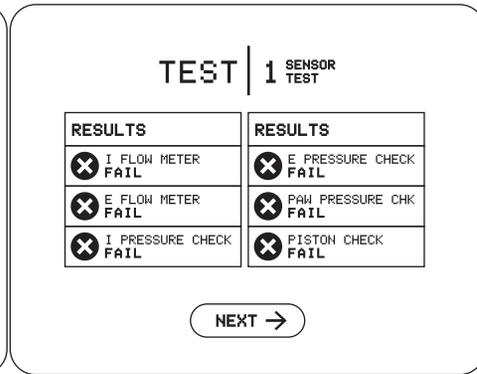


Figure 4.11-4 - Test Summary



Entering Maintenance Mode

MAINTENANCE MODE on the X-VENT is used to move the mechanical components during troubleshooting or maintenance activities and should only be used by a trained and qualified individual. For more information on MAINTENANCE MODE see ["Maintenance Mode" on page 45](#).



Warning! MAINTENANCE MODE should only be used by a trained and qualified individual.

Troubleshooting.

If the Operator is experiencing trouble with the X-VENT, the best course of action is to contact Enexor Health Systems' X-VENT Support Line (**Chapter 1**) for assistance from one of Enexor Health Systems' team members. Common problems are listed in **Figure 4.12**:

Figure 4.12 - Troubleshooting the X-VENT System

Problem	Solution
Blank Screen	<ul style="list-style-type: none"> Is the unit plugged in and powered on? Is the HMI securely attached the unit?
Touch Screen Not Working Properly	<ul style="list-style-type: none"> Is the screen calibrated? Contact support.
ERROR: COM port unable to connect	This error typically means that the HMI is unable to communicate with the controller. Contact support.
ERROR: System values not displayed	Communication error between the HMI and PLC. Contact support.

Chapter 5

Oxygen Integration, Setup and Operation

X-VENT Oxygen System.

The X-VENT Emergency Ventilator is equipped with the ability to integrate with both low and high pressure oxygen systems. This section will outline the best way to safely connect an oxygen system to the X-VENT as well as how to monitor and control oxygen therapy to the patient from the HMI.



Warning! The X-VENT has been tested at 500 ft elevation between 15°C to 30°C ambient temperatures.

Setting up the FiO₂ circuit.

To add oxygen to the patient circuit you will need to ensure you have the necessary attachments. Prior to enabling FiO₂ on the X-VENT the following items need to be connected:

1. O₂ Bag
2. Oxygen connection from 0-15 LPM O₂ flow meter

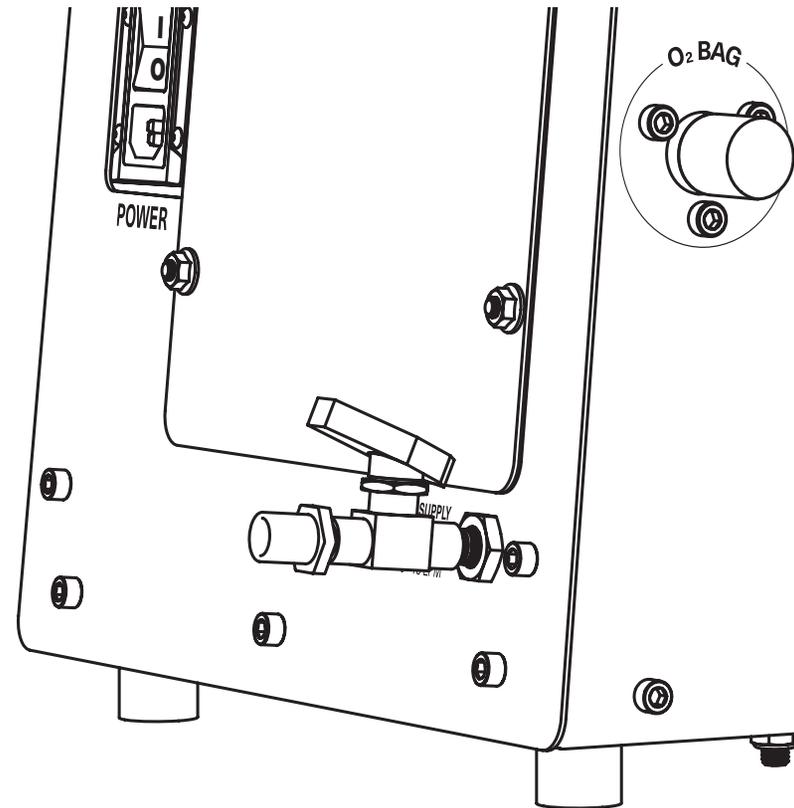


Warning! Before connecting O₂ to the X-VENT, ensure that the O₂ MANUAL ISOLATION VALVE is closed.

Connection from 0-15LPM flow meter to X-VENT

Connect tubing from LOW FLOW O₂ FLOW METER (0-15 LPM) to LOW FLOW O₂ port on the back of the X-VENT.

Figure 5.1 - Connecting the 0-15 LMP Flow Meter to Hospital O₂ Supply

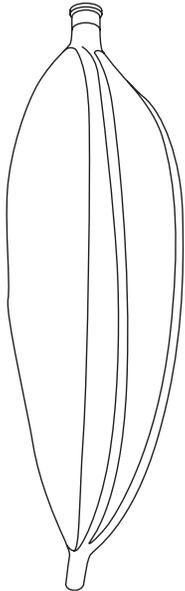


X-VENT EMERGENCY VENTILATOR

Connect an O₂ Bag

Connect a one (1) to three (3) Liter O₂ reserve bag to the O₂ BAG CONNECTION on the LEFT SIDE of the X-VENT. CHECK to ensure that the O₂ BAG is securely fastened to the O₂ BAG CONNECTION on the X-VENT in order to prevent leaks.

Figure 5.2 - Connecting the O₂ Bag to the X-VENT



Starting Ventilation With O₂.

Start X-VENT and enable O₂

To begin patient ventilation with O₂, turn on the X-VENT and choose a desired mode. After choosing the mode, set the mode setpoints. Once you have configured the mode with your desired setpoints, you can either start ventilation and set/enable FiO₂ within the MODE RUN SCREEN or you can set/enable FiO₂ before starting ventilation at the MODE START SCREEN.

To start FiO₂ prior to starting ventilation, follow these steps:

1. Press the O₂ button on the MODE START SCREEN
2. Press ENABLE button on FiO₂ MENU SCREEN
3. Press ENABLE on the ENABLE FiO₂ SCREEN
4. Confirm

Figure 5.3 - Start FiO₂ prior to starting ventilation



To start FiO₂ while ventilating, follow these steps:

1. Press the O₂ button on the current MODE RUN SCREEN
2. Press ENABLE button on FiO₂ MENU SCREEN
3. Press ENABLE on the ENABLE FiO₂ SCREEN
4. Confirm

Figure 5.4 - Start FiO₂ after starting ventilation



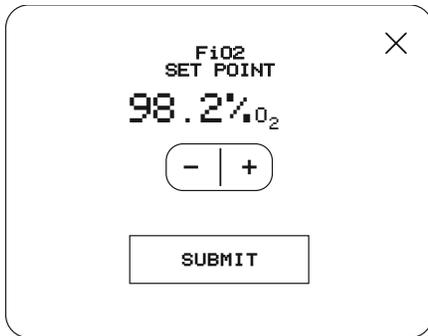
Set desired O₂ setpoint

There are many ways to set the FiO₂ setpoint on the X-VENT. If you have just enabled FiO₂, you can click the O₂ icon again to bring up the setpoint screen if it did not already launch after enabling. If you already have FiO₂ enabled and the system is currently running, you can use the SET or O₂ buttons on the current MODE RUN SCREEN to bring up the FiO₂ setpoint prompt. Simply use the dedicated (-/+) buttons to decrease

X-VENT EMERGENCY VENTILATOR

or tap the numeric setpoint display at the top to bring up the PRECISION VALUE INPUT window.

Figure 5.5 - Setting the FiO2 setpoint



Start ventilation

To start ventilation in O₂ mode, use the same steps outlined in **Chapter 4 - Operating the X-VENT**.



Warning! Wait five (5) breath cycles before setting the O₂ Flow Meter to the recommended O₂ flow rate.

Open manual O₂ valve

Open the O₂ MANUAL ISOLATION VALVE located on the back of the X-VENT. The O₂ BAG will begin to inflate and oxygen is now flowing to the patient.

Verify recommended O₂ flow rate

After enabling FiO₂, setting the FiO₂ setpoint, and starting ventilation you can now go back to the FiO₂ MENU screen and press the O₂ FLOW METER button to obtain the O₂ FLOW RATE. Use the displayed value for O₂ FLOW RATE to set the EXTERNAL FLOW METER.

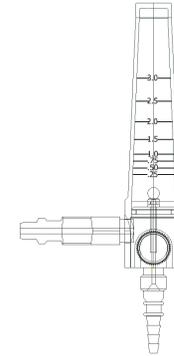
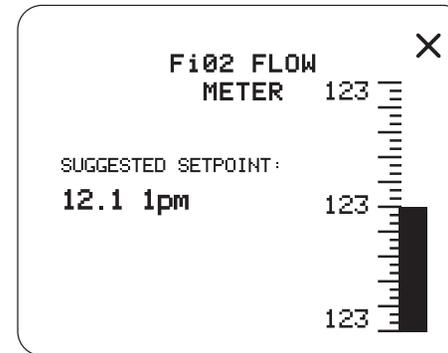


Note: The displayed value for O₂ flow rate will change and should be re-verified after starting ventilation.

Set the O₂ flow meter

Lastly, set the LOW FLOW O₂ FLOW METER to the value displayed on the O₂ FLOW METER screen.

Figure 5.6 - Setting the External O₂ Flow Meter



Verify

Verify that the patient is being ventilated as intended.

Disabling O₂ Mode.

Disable O₂ mode on the X-VENT

1. Manually set LOW FLOW O₂ FLOW METER to zero (0).
2. Close the isolation valve.
3. Press O₂ button on current MODE RUN or MODE SET SCREEN.
4. Press DISABLE button on FiO₂ MENU SCREEN.
5. Press DISABLE.
6. Confirm.

Chapter 6

Alarms

An X-VENT alarm will activate whenever the device detects a condition that requires clinician or caregiver attention. Alarms will generate an audible tone, a flashing beacon, and/or a flashing red box on the outer edges of the HMI screen.

The X-VENT's alarm system has five (5) primary Alarm Categories:

1. **Pressure Alarms**
2. **Volume Alarms**
3. **Assist Alarms**
4. **Power/Battery Alarms**
5. **Mechanical Alarms**

Figure 6.0 shows the five types of X-VENT alarms, their behaviors, and how to manage them.

 **Warning!** In environments containing multiple X-VENT devices, or similar devices set with different alarm limits (such as an intensive care unit), alarm conditions may be confused with other alarm sources. Failure to respond to an alarm condition quickly may result in patient harm.

Figure 6.0 - Alarm Conditions

Alert	Condition Detected	Response
Ventilator Disconnected	Pressure <0.5 cmH2O while ventilator is in operation.	Ventilator disconnected. Check patient circuit for blockages and or loose connections.
Low Pressure Alarm	Patient disconnected or pressure lower than setpoint.	Machine maintains settings, Alarm for clinician.
High Pressure Alarm	Pressure reached high pressure setpoint.	Machine maintains operation. Clinician corrects situation; alarm will clear.

Alert	Condition Detected	Response
High High Pressure Alarm*	Pressure above 50 cmH2O.	Pressure relief active.
TV Limit reached during PC	Tidal volume reached high setpoint.	Machine maintains settings. Alarm for clinician.
Pressure Limit reached during VC	Pressure reached high setpoint.	Machine maintains settings. Alarm for clinician.
Spontaneous breath did not occur	The patient fails to trigger inhalation, the alarm sounds for one (1) second.	Clinician adjusts respiratory parameters per clinical guidance.
Low Minute Volume	Minute Volume lower than setpoint.	Alarm for clinician.
High Minute Volume	Minute Volume higher than setpoint.	Alarm for clinician.
AC Power Disconnected	AC power disconnected.	Machine maintains settings and continues operation using internal batteries.
Battery Critically Low	Battery critically low.	Charge battery by connecting unit to AC power.
I Pressure Sensor Failure*	Inspiratory Pressure Sensor failure detected.	Alarm for clinician.
E Pressure Sensor Failure*	Expiratory Pressure Sensor failure detected.	Alarm for clinician.
Airway Pressure Sensor Failure*	Expiratory Pressure Sensor failure detected.	Alarm for clinician.
Pressure Sensor Disagreement*	Pressure sensor readings differ.	Alarm for clinician.
Low O₂ Pressure	O ₂ pressure below setpoint.	O ₂ delivery stops until alarm is resolved.
High O₂ Pressure	O ₂ pressure above setpoint.	O ₂ delivery stops until alarm is resolved.
Leak Detected	TVi-TVe above setpoint.	Machine maintains settings. Alarm for clinician.

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Alert	Condition Detected	Response
PEEP Error	PEEP setpoint does not equal detected PEEP.	Machine maintains settings. Alarm for clinician.
Mechanical Failure: Fault Code #	Mechanical failure detected. System will cease operation.	Contact support.
PLC/HMI Communication Failure	PLC/HMI heartbeat lost. Unit will continue operating. Use STOP button to cease ventilation.	Contact support.
PLC Failure	PLC failure detected. Unit will cease operation.	Contact support.
Calibration failed	Calibration did not pass requirements.	Address specific failed condition.

* Indicates the alarm is latched – the alarm will not clear on its own. User acknowledgment required.

Silence Alarms.

The X-VENT will emit an audible series of tones whenever an alarm activates. Press the MUTE ALARMS button on the ALARM SCREEN of the X-VENT to silence the active alarm tones for 120 seconds. If a new alarm condition is triggered after silencing the alarms, the audible tones will resume and the operator will have to press the MUTE ALARMS button to re-silence the alarm. Failure to resolve the alarm condition within 120 seconds from muting the alarm will result in re-activation of the audible tones.



Note: The visual alarms, including the HMI visual flash and the ALARM BEACON will remain on until the alarm condition is CLEARED.

Setting Alarm Setpoints.

Using the HMI to set alarms

You can use the X-VENT's interface to view, mute, and set alarms. All of this can be done through the ALARM SCREEN which you can access from the MENU SCREEN and/or the MODE RUN SCREEN on the HMI.



Warning! The clinician is responsible for setting alarm limits appropriately for each patient condition. Do not set alarm limits to values that render the alarm system useless. Failure to set alarm limit values appropriately for the Patient condition may result in patient harm.

Figure 6.1 - Alarm Screen

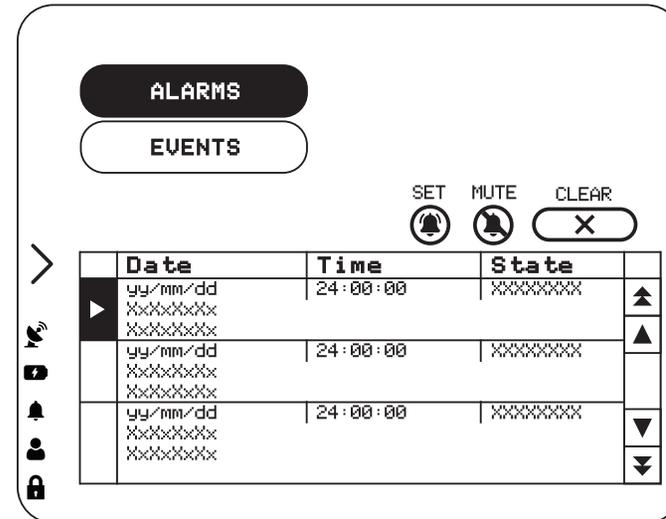
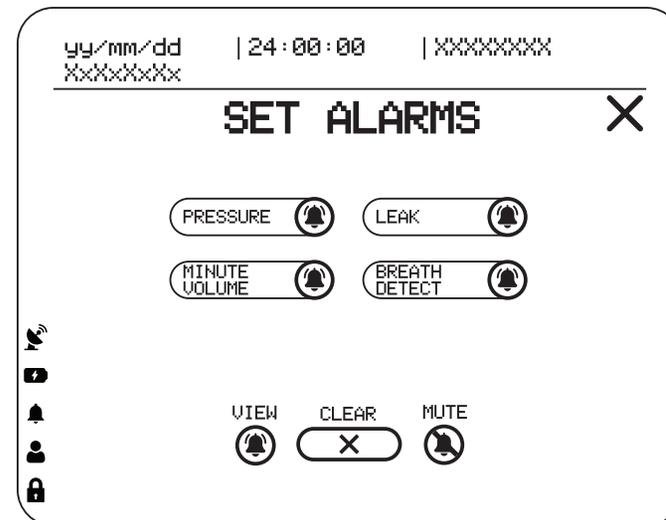


Figure 6.2 - Set Alarms Screen



The Alarm Log.

The X-VENT's Alarm Log lists all active alarms, and all other alarms activated since the last time the log was cleared.

To view the X-VENT's Alarm Log at any time, press the ALARMS BUTTON from the MENU SCREEN, or press the ALRM button on any MODE RUN SCREEN.

To clear the list of all but the active alarm conditions, press the CLEAR ALARMS button from the ALARM SCREEN or the SET ALARMS SCREEN. Information about the alarm will also be stored in the X-VENT's Internal Event Log storage.

The Event Log.

The Event Log stores the date and time of unit power on and off, alarm activation, the alarm name, and information about operator interactions with the X-VENT alarm system and controls. The most recent 20,000 events, including alarms and changes to control settings will be accessible through the Event Log. As the X-VENT's Event Log reaches capacity, the oldest Event Log records will be overwritten one at a time as new logs are created. Events in the Event Log cannot be deleted.

 **Note:** The Event Log, including information about activated alarms, is retained through shut down. The Event Log will be stored for at least one (1) year after a total loss of device power.

 **Note:** Timestamps on events in the Event Log (and Alarm Log) are based on the configured X-VENT Date and Time setting at the time the event occurred. If the X-VENT Date and Time settings are incorrect, the timestamps shown in the log will also be incorrect, and cannot be corrected.

Clearing an Alarm.

Visual indicators of an alarm condition remain in a list in the Alarm Log until the alarm condition is resolved and the list is cleared. To clear an activated alarm:

1. Press the MUTE ALARMS button on the ALARM SCREEN to silence the alarm tones, if desired.
2. Resolve the alarm condition by taking the appropriate action. When an alarm

condition is resolved, the alarm will clear. A log of the alarm activation will be recorded in the Alarm Log and the Event Log.

3. Access the Alarm Log through the MENU SCREEN, or by pressing the ALRM button on any MODE RUN SCREEN, then select CLEAR ALARMS to remove all but active alarms from the Alarm Log.



Note: At this time the X-VENT *can not* connect to a remote alarm and/or nurse call system. Do not attempt to connect one of these systems to any ports on the back of the X-VENT. The ETHERNET port on the back of the X-VENT is designed solely for the remote monitoring feature.

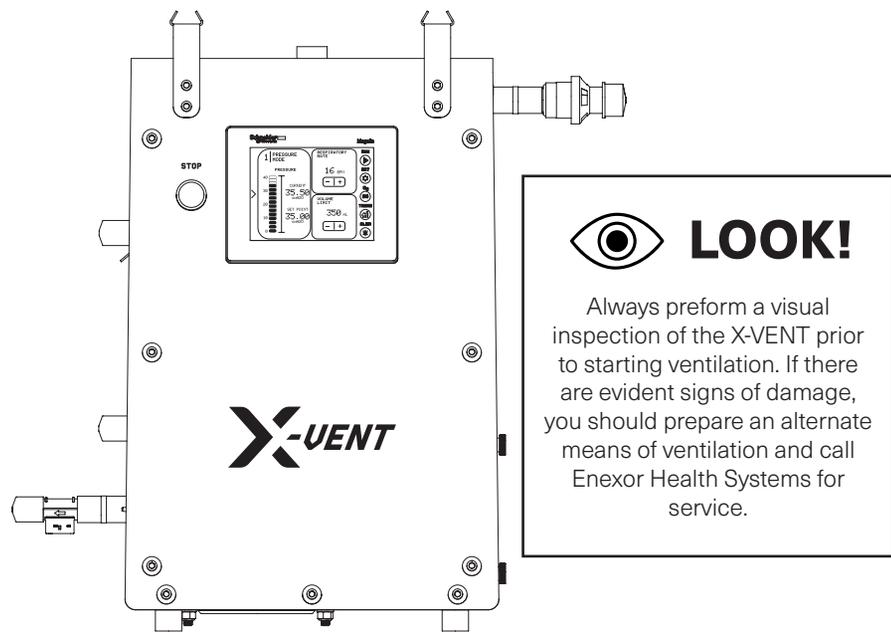
Chapter 7

Starting Ventilation Therapy

Starting Ventilation Therapy on the X-VENT.

Before starting ventilation therapy on the X-VENT it is recommended that the operator complete all of the steps outlined in **Chapter 2** of this manual. If using Oxygen therapy, it is also advised that the operator review **Chapter 5**. This chapter is intended as a quick start for ventilation and does not contain the detailed information that is outlined in previous chapters. The operator should review the manual in its entirety before beginning ventilation.

 **Warning!** If critical to patient care, always have an alternative means of ventilation available. In case of unexpected X-VENT operation, failure to have alternative means of therapy available may result in patient harm or death.



To begin ventilation therapy:

- 1** Connect the PATIENT CIRCUIT and any required filter, accessories or other components. See ["Setting up the X-VENT" on page 10](#) for instructions.
- 2** TOGGLE the POWER ROCKER SWITCH on the back of the X-VENT to the ON position.
- 3** Input relevant SITE and PATIENT data on the NEW SITE and NEW PATIENT screens. See ["Setting Up A New Patient" on page 22](#) for instructions.
- 4** Run the TEST.

 **Note:** If the TEST screen does not appear automatically, run a user-initiated TEST by pressing the MENU button, and then the TEST button.

- 5** Either tap on one of the RECOMMENDED PATIENT TARGETS to enter VOLUME CONTROL MODE or tap the check mark on the RECOMMENDED PATIENT TARGETS screen and select the desired mode of ventilation from the MODE screen.

 **Note:** Starting Therapy from the RECOMMENDED PATIENT TARGETS screen will start VOLUME CONTROL MODE with a RESP RATE of 15 BPM and an INSPIRATION TIME of 1.0 Seconds.

- 6** Ventilation therapy will begin. For information about monitored Ventilation therapy parameters, see ["X-VENT Dashboard Screen" on page 16](#).

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Changing Between Modes of Ventilation.

Before starting ventilation therapy on the X-VENT it is recommended that the operator complete all of the steps outlined in **Chapter 4** of this manual.

- 1 Navigate to the MENU screen, and then press the MODE button.
- 2 Select the desired mode and set applicable setpoints and alarms.
- 3 Press START on the bottom of the screen to begin Ventilation therapy using the defined setpoint and alarm settings.

Starting Oxygen Therapy.

Before starting ventilation therapy on the X-VENT it is recommended that the operator complete all of the steps outlined in **Chapter 5** of this manual. The X-VENT configuration can be configured to provide Oxygen therapy from its external O₂ connection using a low or high flow oxygen source. See *"Oxygen Therapy Setup" on page 28* for details.



Warning! Do not smoke near elevated oxygen levels. Smoking near elevated oxygen levels greatly increases the risk of fire, and may result in facial burns or death. Do not smoke in the same room as, or produce open flames within 2 meters of, a running oxygen concentrator or other oxygen sources or accessories that are in use. Leave the room containing the oxygen source if smoking. If the patient is smoking, remove the patient circuit or mask. If the patient or caregiver intends to smoke but cannot leave the room, turn off the oxygen source and wait ten minutes before smoking.

- 1 Verify an external source of oxygen is connected to the X-VENT. See *"Connecting Oxygen" on page 28* for setup instructions.
- 2 Ensure that the external O₂ bag is connected to the O₂ BAG CONNECTION of the LEFT SIDE of the X-VENT.
- 3 Enable oxygen mode on the X-VENT by pressing the O₂ button on the MODE RUN, SET or SETUP screen.

4

Set the external O₂ FLOW METER control to the suggested setpoint on the O₂ FLOW METER popup window to provide the prescribed Oxygen therapy to the patient.



Note: See *"Changing Oxygen Settings" on page 28* for detailed instructions.

5

Use the FiO₂ MENU popup window to Enable/Disable FiO₂, Change the O₂ setpoint and view the O₂ Flow Meter suggested flow rate.

Responding to Alarms.

The X-VENT operator must be capable of responding to alarm conditions and promptly performing the necessary corrective actions. See *"Alarms" on page 31* for information on each alarm condition. In case of an X-VENT malfunction, the operator must be able to promptly provide an alternative means of ventilation.

Using the STOP Button.

The only physical button on the X-VENT (aside from the power switch) is the STOP button. The STOP button can be used to cease ventilation in the event of an emergency or mechanical failure. To cease ventilation using the STOP button, the operator must PRESS and HOLD the STOP button for three (3) seconds while the system is running in one of the modes of ventilation. Once pressed, a popup will appear on the HMI with a countdown, starting at three (3) and decreasing by one (1) each second until the unit has ceased ventilation. An alarm will trigger to notify the operator that the unit has paused ventilation. To resume ventilation, the operator can tap the RUN button on the MODE RUN SCREEN and set the system to RUN via the popup window.



Note: The STOP button is always active, even when the HMI touchscreen is in a locked state.

Powering off the X-VENT.

To power off the X-VENT, TOGGLE the POWER ROCKER SWITCH from ON (I/O) to OFF (I/O). A prompt will appear on the HMI notifying the operator of a loss in power. If no action is taken within 60 seconds, the X-VENT will remain on and return to the previous screen. Pressing YES will bring up a conformation window. Pressing YES again will immediately turn off the X-VENT and cease all ventilation operations. For more information see *"Powering off the X-VENT" on page 14*.

X-VENT EMERGENCY VENTILATOR

Operations Manual | Chapter 7: Starting Ventilation Therapy

Checkout Worksheet

The checkout procedures listed in the following worksheet should be performed before using the X-VENT on a patient, and periodically during use. Print and complete a copy of this worksheet to verify the X-VENT checkout procedures were completed.

Function	Settings	Requirement	Pass / Fail / NA
Visual Inspection	N/A	No part of the device or connected components appear damaged	
Calibration	N/A	Audible sound of motor and piston moving at X-VENT power on	
Power	N/A	X-VENT functions on external and internal battery power	
Ventilation and Oxygen	Circuit Type: Dual Limb Ventilation Mode: Volume Control Tidal Volume: 500 mL PEEP: 10 cmH ₂ O Breath Rate: 12 BPM Inspiratory Time: 1.7 seconds FiO ₂ : 30% (using external highpressure oxygen), or 3 L/min O ₂ Flow Equivalent	The Vte monitor reads between 374 and 642 mL	
		The Leak monitor reads between 0 and 1 L/min	
		The PEEP monitor reads between 8 and 12 cmH ₂ O	
		The delivered Breath Rate is 12 BPM	
		After 5 minutes, the FiO ₂ monitor reads between 24% and 36% (if used)	
Alarms	Maintain settings configured as part of Ventilation checkout procedure.	There are no active alarms	
		Decannulation causes Patient Circuit Disconnect and/or Low Minute Volume alarm to activate as expected	
		Disconnecting the Patient Circuit causes Patient Circuit Disconnect and/or Low Minute Volume alarm to activate as expected	

X-VENT Serial Number: _____

Tester Name: _____ Date: _____

Signature: _____



Chapter 8

User Login, Management and Settings



Warning! Failure to utilize strong passwords may lead to unauthorized access to equipment. Always use best practice password and security policies to prevent unauthorized access to this equipment.



Warning! Never use generic or 'default' passwords that can be easily compromised. Operators should change 'default' passwords IMMEDIATELY upon receipt of this product.

User management overview.

The X-VENT has a built-in permissions based user management system. This system serves a few key functions: SECURITY, EVENT LOGGING, TRACEABILITY, and REMOTE MONITORING/CONTROL. Some functionality on the X-VENT, such as MAINTENANCE mode, cannot be accessed without authenticating to a user account. Other functions, such as user based event logging, will not function without authenticating to a user account.

Enexor Health Systems recommends utilizing the user management capabilities of the X-VENT as a best practice, however user management is not required and the X-VENT will operate with or without an authenticated user operating the system.

Logging into the X-VENT.

To log into the X-VENT, tap the USER ICON located in the GLOBAL MENU on the left-hand side of the X-VENT's touchscreen. If you have already authenticated to a user account, the X-VENT will display the USER SETTINGS screen shown in **Figure 8.3**. If no user is currently authenticated, the X-VENT will direct the operator to the LOGIN screen shown in **Figure 8.2**.

The X-VENT will display a system notification bar at the bottom of the touchscreen if there is an error authenticating or if a password has expired. If you need assistance, you should contact Enexor Health Systems for support.

USER ICON located in the GLOBAL MENU on the X-VENT's touchscreen.



The chart in **Figure 8.1** shows the different user groups and their respective user-name(s) and password(s). You can create additional users for each user group as long as you are authenticated as a user with a greater security level. For example, 'user' in the 'admin' user group can create additional 'clinician' users but cannot create additional 'admin' users.

Figure 8.1 - Default User Accounts

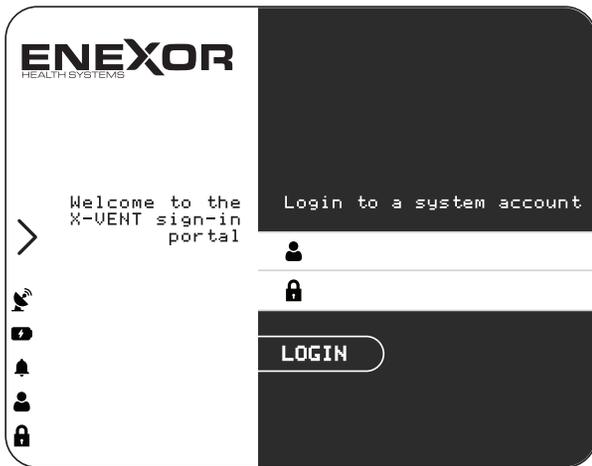
Username	Security Level	Group	Default Password	Permissions
user	1	CLINICIAN	user	<ul style="list-style-type: none"> Create new users in the CLINICIAN user group. Assigns user to all logged system events and alarms. Allows remote control/monitoring (if equipped).
maintenance	2	MAINTENANCE	maintenance	<ul style="list-style-type: none"> Access maintenance mode. System updates. Access maintenance mode.
admin	3	ADMIN	admin	<ul style="list-style-type: none"> Download on-board log files. Allows remote control/monitoring (if equipped)
----	4	SUPERADMIN	----	<ul style="list-style-type: none"> For Enexor Health Systems Technicians only.



Note: Usernames and passwords are case sensitive. The system keyboard defaults to CAPS LOCK after each system restart.

- 1 Use the USER ICON in the GLOBAL MENU to access the LOGIN screen.
- 2 Input both the USERNAME and PASSWORD in their respective fields on the LOGIN screen.
- 3 Tap LOGIN to authenticate the user.

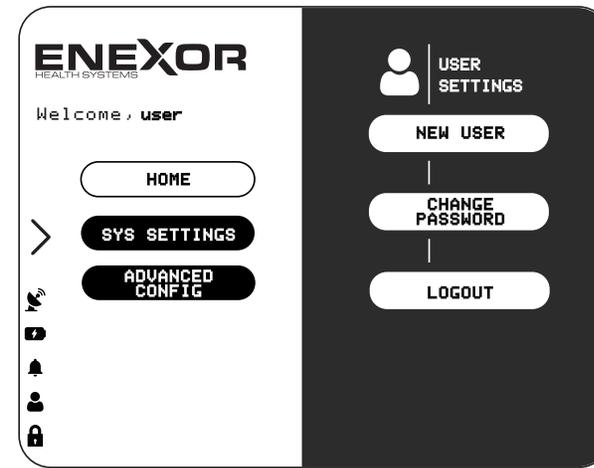
Figure 8.2 - X-VENT Login Screen



User settings.

Once logged in, the operator will be directed to the USER SETTINGS screen shown in **Figure 8.3**. Options in the left-hand menu will vary based on the user's security level. Options in the right-hand menu are available for all users regardless of security level. The SYS SETTINGS button will direct the operator to the X-VENT's SYSTEM SETTINGS screen where additional settings such as date/time, remote access control, and maintenance mode are located. See "[System Settings](#)" on [page 40](#) for more information.

Figure 8.3 - X-VENT User Settings Screen



User management.

Creating a new user

The NEW USER button located on the USER SETTINGS screen will direct the operator to the USER MANAGEMENT screen where they can add, remove, and change user(s) and their password(s).

To add a new user:

1. Select the USER GROUP you want to add the new user to by pressing the DROPDOWN MENU labeled 'Group'.
2. Press the username located in the 'User' DROPDOWN MENU to enter a new username. (Note: you must press on the text, not the dropdown arrow. If a keyboard window fails to appear, check to ensure you are authenticated as a user with a higher security group clearance than the user group you are trying to add to.)
3. Enter in a password for the user in the 'Pwd' field.
4. Confirm the password for the user in the 'Confirm Pwd' field.
5. Press the ADD USER button (icon with a green "+" in the top right).

Removing a user

In some cases the operator may want to remove a user from a user group. To remove a user from a group, follow the steps outlined below.



Note: Deleting a user is a permanent action that can't be undone. Proceed with caution when deleting users.



Note: The admin user has the ability to delete the maintenance user. If the maintenance user is accidentally deleted, follow the steps for creating a new user to add the maintenance user back.

To remove a user:

1. Navigate to the USER MANAGEMENT screen (press the NEW USER button on the USER SETTINGS screen).
2. Select the user group of the user to be removed using the DORPDOWN MENU labeled 'Group'.
3. Select the user to be removed using the DROPDOWN MENU labeled 'User'.
4. Press the DELETE USER button (icon with a red 'X' in the top right)
5. Confirm the action displayed on the popup window.

Updating passwords

The CHANGE PASSWORD button will direct the operator to the CHANGE PASSWORD screen. This will change the password for the user account that is *currently* authenticated. The NEW USER button will direct the operator to the USER MANAGEMENT screen. This can be used to change the password for user accounts that are not currently authenticated provided that the current authenticated user has the appropriate security level access.

To change the current users password:

1. Press the CHANGE PASSWORD button on the USER SETTINGS screen.
2. Enter a new password.
3. Confirm the new password.
4. Press the 'CHANGE' button.

To change a specific user's password:

1. Select the USER GROUP of the user whose password is to be changed by pressing the DROPDOWN MENU labeled 'Group'.
2. Select the USERNAME of the user located in the 'User' DROPDOWN MENU.
3. Enter a new password for the user in the 'Pwd' field.
4. Confirm the password for the user in the 'Confirm Pwd' field.

5. Press the UPDATE USER button (icon with a blue arrow in the top right).

Using user event logging.

The X-VENT has built in user logging functionality. To utilize this feature, ensure that operators are authenticated to a user account. User data will be tied to all alarms and events once authenticated. See "[The Event Log](#)" on page 33 for more information.

Chapter 9

System Settings

Accessing the X-VENT's system settings.

To access the X-VENT's internal settings, press and hold the X-VENT logo on the MENU screen for five (5) seconds until the SYSTEM SETTINGS screen appears.

Note: You cannot access the SYSTEM SETTINGS screen while the X-VENT is operating. Stop ventilation ebefore trying to access the SYSTEM SETTINGS.

Figure 9.1 - X-VENT System Settings Screen

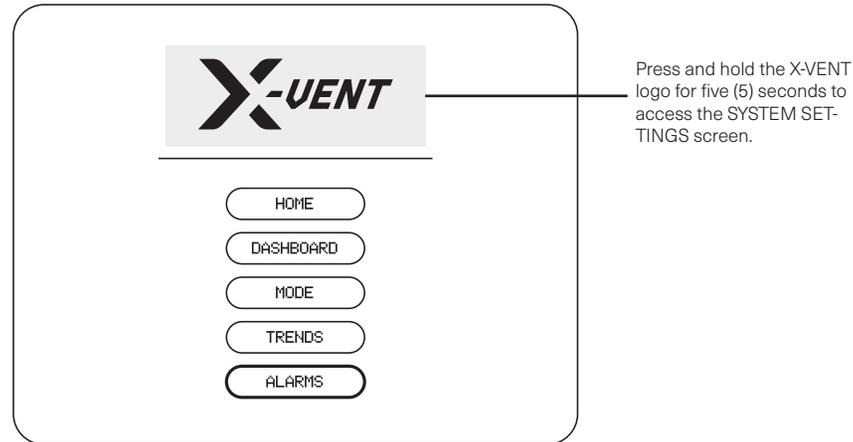
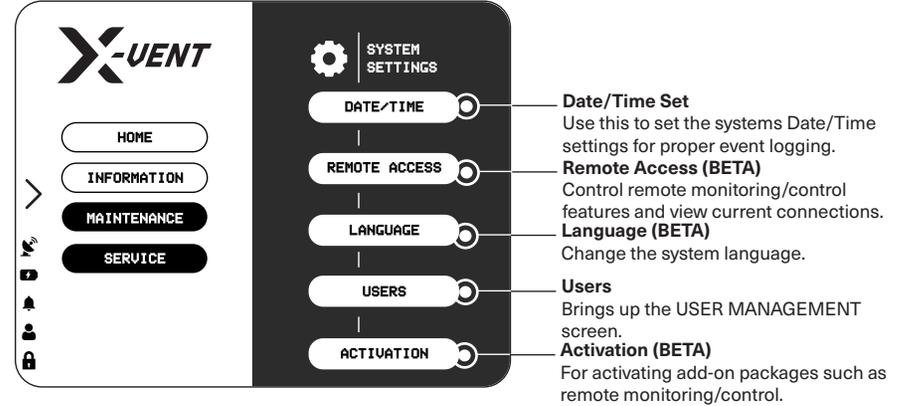


Figure 9.2 - System Settings Screen



To exit the SYSTEM SETTINGS screen, press the HOME button in the GLOBAL MENU or hit the HOME button in the left-hand menu.

The SYSTEM SETTINGS screen is shown in **Figure 9.2**. Some settings are still in BETA testing and are not available on all units. These settings include REMOTE ACCESS, LANGUAGE, and ACTIVATION.

Chapter 10

Cleaning and Disinfecting the X-VENT

The X-VENT Emergency Ventilator requires routine cleaning after each use. Enexor Health Systems recognizes that sanitation practices vary widely among health care institutions. It is not possible for Enexor Health Systems to either specify or require specific practices that will meet all needs. Enexor Health Systems is not responsible for the effectiveness of procedures used to clean, disinfect, and sterilize parts, or other practices carried out in the patient care environment. This manual can only provide general guidelines to clean, sterilize, and disinfect parts. It is the operator's responsibility to ensure the validity and effectiveness of the methods used.

The organization responsible for the use and maintenance of the X-VENT should perform all adjustments, cleaning, and disinfection of the ventilator. Follow all instructions provided in this manual to prevent damage to the X-VENT during cleaning and maintenance procedures.

 **Note:** All single-patient use components are not intended for cleaning, sterilization, or re-use. Replace the X-VENT's single-patient use components and patient circuits regularly, following your healthcare institution's protocol.

Warnings and Advisories.



Warning: All ventilator external surfaces should be cleaned prior to initial use, before and after each patient use, and as may be required.



Warning: To avoid patient exposure to sterilizing agents, be sure to sterilize parts in accordance with the techniques described in the table below. Exposure to sterilizing agents may reduce the life of some parts.



Warning: Handle filters with care to minimize the risk of bacterial contamination or physical damage.



Warning: Make sure unit is completely powered off before cleaning it.



Warning: Do not use paint thinner, organic solvents, or a strong acid compound to clean the touch screen.



Warning: Do not immerse the ventilator in liquids.

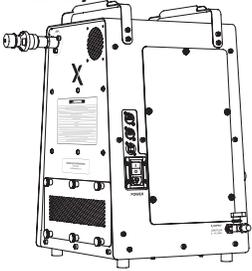
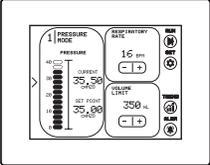
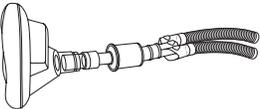
X-VENT EMERGENCY VENTILATOR

Prepare for Cleaning.

Power down the X-VENT

Make sure the unit is completely powered down and remove any peripherals including the power cord. Visually inspect the unit for any damage and notify a certified technician of any damage.

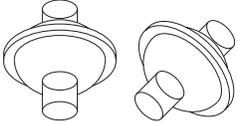
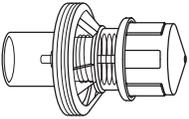
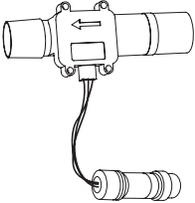
Figure 10.1 - Cleaning Procedures

Part	Procedure	Comments
Ventilator Exterior (Excluding the touch screen and labels) 	<p>Wipe clean with a damp cloth and mild soap solution or with one of the chemicals listed below or its equivalent. Use a damp cloth and water to rinse off chemical residue as necessary.</p> <ul style="list-style-type: none">• Mild dish-washing detergent• Isopropyl alcohol (70% solution)• Bleach (10% solution)• Window cleaning solution (with isopropyl alcohol and ammonia)• Ammonia (15% solution)• Hydrogen peroxide (3% solution)• Formula 409® cleaner (Clorox Company)• Amphyl® disinfectant (National Laboratories, Reckitt & Colman Inc.)• Cavicide® surface disinfectant (Metrex Research Corporation)• Control III® germicide (Meril Products, Inc.)• Glutaraldehyde (3.4% solution)	<ul style="list-style-type: none">• Do not allow liquid or sprays to penetrate the ventilator or cable connections.• Do not attempt to sterilize the ventilator by exposure to ethylene oxide (ETO) gas.• Do not use pressurized air to clean or dry the ventilator, including the air filter.
Ventilator Touch Screen 	<p>Wipe clean with a damp cloth and mild soap solution or with one of the chemicals listed below only. Use a damp cloth and water to rinse off chemical residue as necessary.</p> <ul style="list-style-type: none">• Mild dishwashing detergent• Methanol (10% solution)	<ul style="list-style-type: none">• Do not use paint thinner, organic solvents, or a strong acid compound to clean the touch screen.• Do not use hard or pointed objects to operate the touch panel, since it can damage the panel surface.
Patient Circuit Tubing (external only) 	<p>Disassemble and clean, then autoclave, pasteurize, or chemically disinfect. Discard single-patient use patient circuits.</p>	<ul style="list-style-type: none">• If you submerge the patient circuit in liquid, use pressurized air to blow the moisture from inside the tubing before use.• Inspect for nicks and cuts, and replace if damaged.• Run leak check test when a new circuit is installed.

X-VENT EMERGENCY VENTILATOR

Operations Manual | Chapter 10: Cleaning and Disinfecting

Figure 10.1 - Cleaning Procedures (continued)

Part	Procedure	Comments
Expiratory and Inspiratory Bacteria Filters (external only) 	Reusable filters: autoclave. Single-patient use: discard. Before discarding, disinfect or sterilize according to your institution's protocol.	<ul style="list-style-type: none">• Do not chemically disinfect or expose to ETO gas.• Check filter resistance before reuse.• Follow manufacturer's recommendations for re-usability.
PEEP Valve (external only) 	Reusable PEEP: autoclave. Single-patient use: discard. Before discarding, disinfect or sterilize according to your institution's protocol.	<ul style="list-style-type: none">• Do not attempt to disassemble the PEEP valve, as this may damage the spring action.
Inspiratory Flow Meter (external only) 	Detach from unit and surface clean with Isopropyl alcohol (70% solution).	<ul style="list-style-type: none">• Do not allow liquid or sprays to penetrate the flow meter or cable connections.• The Flow Meter can be used with any X-VENT and is not specific to a single unit.

Step-by-Step Cleaning Guide.

X-VENT cleaning procedures

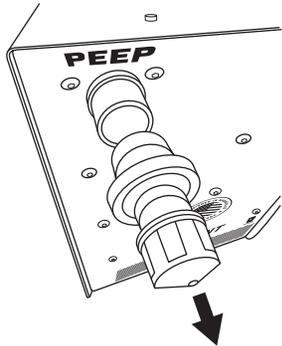
This method covers cleaning any parts that may come in contact with patient expiratory gases. O₂ and HEPA filter entrances are not to be cleaned in this process and can damage parts if cleaned in this manner.

Step 1

Remove PEEP valve

Remove the PEEP valve and adapters from the unit. Autoclave the PEEP valve (if releasable) or discard single use PEEP valves and associated adapters.

1 Figure 10.2-1 - Removing the PEEP Valve

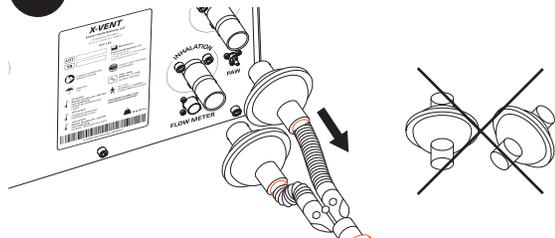


Step 2

Disconnect patient circuit

Disconnect the patient circuit from the X-VENT's inhalation and exhalation ports. Discard the particle filter(s). Discard single use patient circuit or clean to manufacturer/facility standard.

2 Figure 10.2-2 - Disconnecting the Patient Circuit

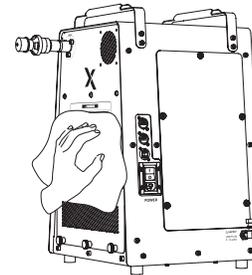


Step 3

Clean external surface

Wipe down the external enclosure with a damp cloth and mild cleaning solution (see Figure 8.1 for reference). Be sure to clean all areas thoroughly.

3 Figure 10.2-3 - Cleaning the External Surface

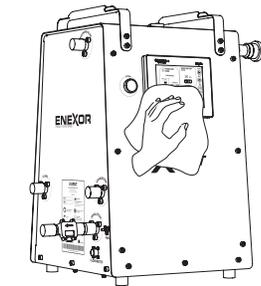


Step 4

Clean HMI touchscreen

Only clean the touchscreen with a damp cloth and mild dishwashing detergent and/or 10% methanol. Do not use harsh chemicals or solvents on the screen as it might result in permanent damage.

4 Figure 10.2-3 - Cleaning the HMI Touchscreen



Note: Pay close attention to the LCD screen while cleaning, to ensure buttons on the HMI touchscreen are not unintentionally pressed. Enexor recommends locking the touchscreen using the lock screen "hot corner", and then gently wiping over the top of and across the touchscreen to clean it. This technique helps prevent inadvertent button presses.

X-VENT EMERGENCY VENTILATOR

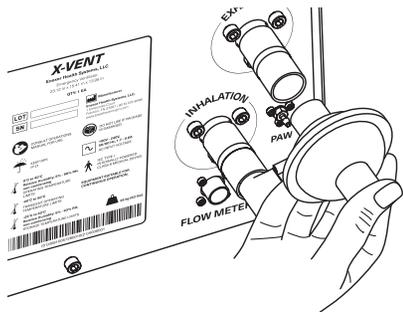
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Replacing patient consumables.

Replacing the External Bacterial Filter(s)

The external bacterial filter(s) are intended for single-patient use. Replace the external bacterial filter(s) between patient uses, whenever they become soiled or damaged, or every 30 days (at a minimum). Follow your healthcare institution's protocol for replacement criteria.

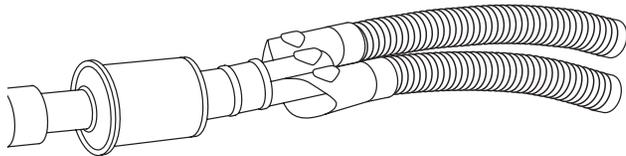
Figure 10.3 - Replacing the External Bacterial Filter(s)



Replacing the Dual Limb Patient Circuit

If you are using a single-use patient circuit, you will need to disconnect and dispose of the circuit after each patient. Do not attempt to reuse a single use patient circuit.

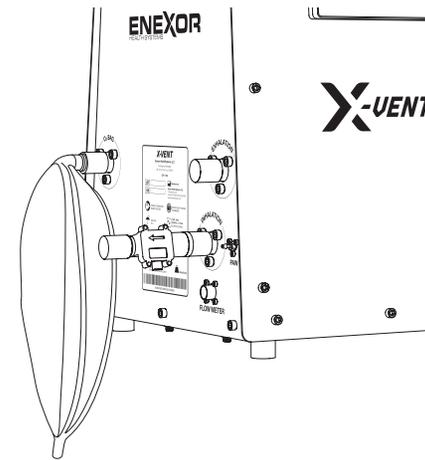
Figure 10.4 - Replacing the Patient Circuit



Replacing the O₂ Bag

The O₂ BAG does *not* need to be replaced after each use as the patient gases never mix with O₂ gas pathway. Enexor Health Systems recommend that the O₂ BAG be replaced on an as-needed basis, once every six (6) months, or according to your institution's protocols. To replace, remove the old O₂ bag and attach a new one to the O₂ BAG CONNECTION on the X-VENT.

Figure 10.5 - Replacing the O₂ Bag



Chapter 11

Maintenance and Service Program (MAS)

Enexor Health Systems' X-VENT Emergency Ventilator MAS program provides comprehensive service and maintenance support coverage for the X-VENT purchased by the customer; it includes the below.

Customer Required Maintenance.

Customers are required to inspect the X-VENT air filter regularly and replace the filter when dirty. Depending on the terms of sale, Enexor Health Systems may provide one filter every six (6) months to the Customer's designated site. The X-VENT controller will prompt customers to check the air filter every six (6) months. The Customer will need to follow controller prompts to confirm filter replacement.

The Customer must provide routine visual inspections and notify Enexor Health Systems of any visible damage.

On-Site Planned Maintenance.

X-VENT equipment should be inspected, evaluated, safety tested, and performance tested. Maintenance of the X-VENT shall be done to bring/keep the unit within performance specifications. Worn out components will be replaced, including other parts per the designated maintenance schedule. See **Figure 9.1 - "Recommended Preventative Maintenance Schedule" on Page 47** for more information.

Repair Parts.

If Enexor Health Systems finds any component needing a minor repair during planned maintenance, Enexor Health Systems will provide the necessary labor and parts required for repairs needed to ensure the unit meets all specifications.

Warranty on Parts and Labor.

X-VENT parts are quality tested and backed by a one (1) year parts warranty. All X-VENT parts are quality tested to ensure superior performance with the system.

Exclusions.

The repair and replacement of parts covered by this MAS program are limited to failures or adjustments needed due to the regular use of the equipment. This agreement does not cover repairs or parts in the case of equipment damage, improper or misuse of the equipment, maintenance, or storage. Defective equipment due to improper or

inadequate maintenance, repairs done by a third party not authorized by Enexor Health Systems, unauthorized modification, operation outside of product specifications, misuse, abuse, negligence, accident, improper operation are not covered under this MAS. Repair under these circumstances will be quoted in advance and work done under a hospital purchase order.

Travel Charges & Unscheduled Labor.

One, unscheduled service and one, annual planned maintenance visit is covered in the annual MAS program. Additional travel or unnecessary travel to attend forced service calls, including service performed and parts replaced, shall be invoiced.

Customer Support Services.

Support by phone or email will be provided. 24-hour emergency technical support will be available to assist Customers with any technical issues.

Phone: (615) 224-8466

Email: service@enexorhealth.com

Customer satisfaction is Enexor Health Systems' primary goal. To ensure this is consistently accomplished, customer feedback in the form of audits or surveys will be conducted, which will assist Enexor Health Systems in evaluating the future direction the company must take to achieve its customer satisfaction goals.

X-VENT EMERGENCY VENTILATOR

Figure 11.1 - Recommended Preventative Maintenance Schedule

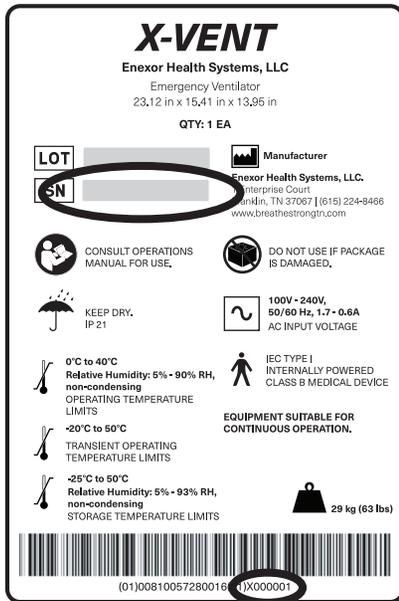
Periodicity	Maintenance	Performed by:
Before storage	<ul style="list-style-type: none"> Fully charge internal batteries. 	Caregiver or Clinician
Every 12 months (in Storage), or every 30 days (active batteries)	<ul style="list-style-type: none"> Fully charge internal batteries. 	Caregiver or Clinician
Before each patient use	<ul style="list-style-type: none"> Run a system TEST. Perform Checkout Procedures. See “Checkout Procedure” on page 36 for instructions. Clean the exterior of X-VENT, See “Cleaning X-VENT Exterior” on page 42 for instructions. 	Caregiver or Clinician
Every day during use	<ul style="list-style-type: none"> Inspect the X-VENT exterior, including all connection ports and connected components, for signs of damage. 	Caregiver or Clinician
Every month during use	<ul style="list-style-type: none"> Test the X-VENT alarm system. See “Sensor Check” on page 49 for instructions. Test the X-VENT batteries and power cord. See “Sensor Check” on page 49 for instructions. 	Caregiver or Clinician
Every six months during use	<ul style="list-style-type: none"> Replace the Room Air Filter. See “Install X-VENT Room Air Filter” on page 10 for instructions. 	Caregiver, Clinician, or Maintenance Technician.
“Maintenance Required” alarm	<ul style="list-style-type: none"> Maintenance check. See “Performing a Maintenance Check” on page 45 for instructions. (Required) Grease linear actuator motor (Required) SOV inspection/replacement (As-needed) Battery check/replacement (As-needed) <p>Call Enexor Health Systems for walk-through.</p>	Facility maintenance technician or certified X-VENT technician.
Every two years, or every 10,000 hours	<ul style="list-style-type: none"> Replace the X-VENT’s internal batteries. <p>Call Enexor Health Systems for walk-through.</p>	Facility maintenance technician or certified X-VENT technician.

X-VENT EMERGENCY VENTILATOR

Locating the serial number.

On occasion, the serial number of the X-VENT may be required. The serial number is located on the X-VENT's UDI device label located on the LEFT-HAND SIDE of the unit. **Figure 11.2** depicts the UDI label and the location of the serial number.

Figure 11.2 - X-VENT UDI Label



Maintenance Mode.

Maintenance mode on the X-VENT provides the operator, as well as maintenance technicians, the flexibility to run detailed tests and view detailed system information about the device. The X-VENT prevents operation of a device while in maintenance mode. Maintenance mode is only intended for advanced troubleshooting and performing routine maintenance on the unit such as ROOM AIR FILTER replacement and required preventative maintenance outlined in ["Recommended Preventative Maintenance Schedule" on page 47](#).

Accessing Maintenance Mode

Maintenance mode is restricted to the 'maintenance' and 'admin' user groups to prevent unauthorized access. See **Figure 8.1 "Default User Accounts" on page 37** for the default username and password required to access maintenance mode.

System Settings Screen

The SYSTEM SETTINGS screen houses the MAINTENANCE and INFORMATION buttons in the left-hand menu. The SYSTEM INFORMATION screen displays a page system similar to the DASHBOARD screens, displaying system information and counters that can help support staff troubleshoot device malfunctions. The MAINTENANCE screen displays a variety of interactive buttons that can be used for testing and troubleshooting.

Figure 11.3-1 - Login Screen

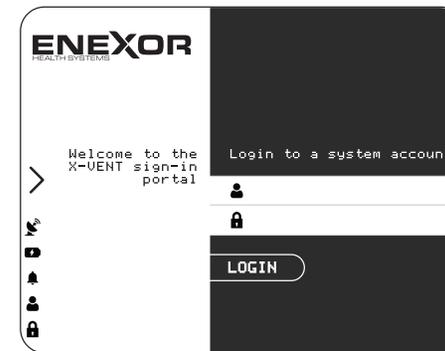
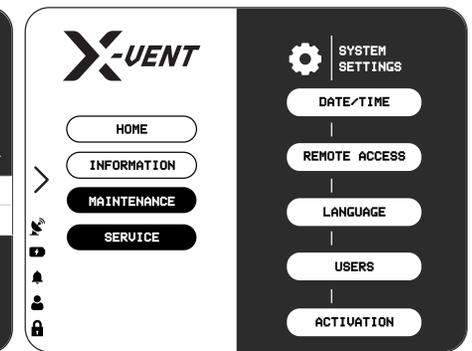


Figure 11.3-2 - System Settings Screen



For more information on system settings and their functions see ["Accessing the X-VENT's System Settings" on page 40](#).

X-VENT EMERGENCY VENTILATOR

Maintenance Screen.

Piston Control

The PISTON CONTROL feature allows for the operator to move the piston UP and DOWN using the respective buttons. It also displays the current ENCODER POSITION and MOTOR POSITION.

SOV Check

The SOV buttons allow for the operator to check the function of the X-VENT's three (3) solenoid valves. These valves are essential for effective operation of the X-VENT. The operator can tap these buttons to TOGGLE a valve OPEN and CLOSED. If there is no audible click of the valve, it is likely faulty and needs to be replaced. If this is the case, call Enexor Health Systems for service and decommission the unit until it has been serviced.

Sensor Check

The SENSOR readings allow the operator to see real time sensor data being fed into the X-VENT's onboard controller.

Reset

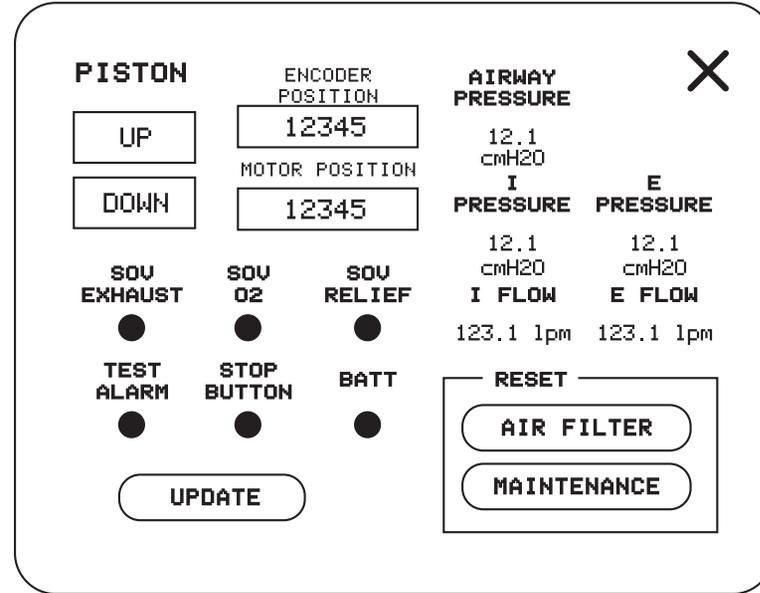
The RESET section consists of two buttons: Maintenance and Air Filter. These buttons reset the counters respective to each. Do not use these if you have not preformed maintenance on the unit or replaced the ROOM AIR FILTER. To reset a counter, press the desired button and follow the on-screen prompts.

Update

Currently, this feature is limited to internal use for Enexor Health Systems. In future versions of the X-VENT, software updates can be completed after connecting the X-VENT to the Internet.

If a software update is available, the purchaser will receive an E-Mail from Enexor Health Systems with detailed instructions for updating the X-VENT via the USB PORT located on the back of the unit.

Figure 11.4 - Maintenance Screen



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X-VENT Emergency Ventilator

