Ventis Medical VM-2000

Emergency and Transport Ventilator

Operator Manual — Instructions for Use

March 2024

Trademark Information

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If more than 1 year has elapsed since the date above, contact Ventis Medical to inquire about any updates to the product or this manual.

Notice to Operators

The detailed information and instructions within this Operator Manual are designed to ensure the safe and effective setup, use, and maintenance of the VM-2000. The VM-2000 must be setup, operated, maintained, and repaired in accordance with the instructions provided in this manual, together with the accompanying product labels and document supplements.

It is important to thoroughly read and understand this manual in its entirety before operating the ventilator. Operating or servicing this device without a complete understanding of its characteristics may cause harm to the patient or operator and may permanently damage the device. The ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and in accordance with applicable laws and regulations. This manual describes how to operate and respond to the ventilator but does NOT include instructions on how to respond to the patient.

While the information set forth is believed to be accurate, it is NOT a substitute for the exercise of professional judgement. Always reference the most current applicable version of this manual. If in doubt, contact Ventis Medical.

United States federal law restricts this device to sale by or on the order of a licensed medical practitioner. Outside the United States, check local laws for any restrictions that may apply.

For service information, contact: support@ventismed.com

FDA Tracking Requirements

U.S. Federal Law (21 CFR 821) requires the tracking of ventilators. Under this law, owners of this ventilator are required to register the device and to inform Ventis Medical if the device is sold, given to another organization, or destroyed. This allows Ventis Medical to notify the operator of safety updates, a recall or software updates. Please follow instructions on the registration card contained in the package, or send the following information to support@ventismed.com:

Call Ventis Medical Customer Service at:
Ventis Medical, Inc.
515 Executive Drive
Princeton, NJ, 08540
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Contents

1. Introduction

1.1. Safety Information

Operators must read and understand the following information about WARNING and CAUTION statements before operating the VM-2000. General WARNINGs and CAUTIONs are listed below. Specific WARNINGs appear throughout the manual.

WARNING

"WARNING" statements alert the reader to potentially hazardous situations, which, if not avoided, could result in death or serious injury.

CAUTION

"CAUTION" statements alert the reader to potentially hazardous situations, which, if not avoided, could result in equipment damage. These situations could indirectly cause death or serious injury if the equipment damage causes the ventilator to operate improperly.

1.2. General Warning Statements

WARNING

Alternative Ventilation: An alternative means of ventilating the patient should always be available.

Accessories: Do not add any attachments or accessories to the ventilator that are not intended for use in combination with the ventilator. Doing so may result in a ventilator malfunction and could put the patient at risk of injury.

CO_2 Monitoring: The VM-2000 should be used with $ETCO_2$ sensor to measure end tidal CO_2 at patient connection when operating.

Debris Inside Enclosure: Do not operate the VM-2000 if any debris, particulates, or other types of contamination have entered the ports.

Equipment Damage/Malfunction: Do not operate the VM-2000 or any components or accessories that appear to be damaged, fail inspection, or malfunction in any way. Immediately discontinue use, provide alternative ventilation as appropriate, and immediately contact an authorized service technician or Ventis Medical. If equipment is damaged or behaves in a way that is inconsistent with normal operation, stop use of the device immediately, unplug the device, power it off, and disconnect external Oxygen.

Preventative Maintenance: Failure to follow the Preventative Maintenance procedures described in this manual could result in device malfunction.

Battery: If damage to the battery is suspected, install a replacement battery immediately or take unit out of service immediately.

Accessories: Serious harm to the patient may result from the use of unauthorized parts or accessories. Only use accessories approved by Ventis Medical. Usage of unauthorized parts or accessories may also cause increased electromagnetic emissions or reduced immunity from other EMI sources. Refer to information in the **Device Disposables** and **Accessories** section below.

NOT MRI Compatible: Do not put the VM-2000, any components, or any accessories inside an MRI machine.

Cross Contamination Risk: Ventis Medical does not recommend reusing the Breathing Circuit, since it may result in cross contamination between patients. Reuse of single-use components increases the risk of cross contamination between patients. A patient treated by mechanical ventilation is highly vulnerable to infection. Dirty or contaminated equipment is a potential source of infection. To reduce the risks of infection, users must regularly clean the ventilator and its accessories — both before and after each use, as well as following any maintenance procedure.

Visual Alarm Indicators: Do not cover or obstruct visual alarm indicators in any way. Always have the user interface in view.

Airway Obstructions: Vomitus and foreign objects may obstruct the patient end of the Patient Breathing Circuit. Refer to instructions on clearing debris from the Patient Breathing Circuit.

Secure Device: During evacuation or transport, Ventis Medical strongly recommends that the VM-2000 be secured to the patient or litter. Failure to properly secure the VM-2000 could damage the device and could harm the patient by dislodging the Breathing Circuit or airway.

Hazards from Electrical Shock: The operator should not simultaneously touch the patient and the electrical connectors of the ventilator, battery, or other accessories.

Fire Hazard: If using supplemental Oxygen, avoid smoking or open flames. Leaks at oxygen connections can cause dangerous O_2 levels in the vicinity of the leak. To avoid the risk of ignition, visually inspect oxygen connections before and after connecting supplemental O_2 and take measures to properly ventilate the area. Do not use oil, grease, or combustible lubricants in contact with any part of the ventilator, regulator, or cylinder. Only use lubricants that are approved for oxygen use.

Personal Injury and Electrical Shock: To avoid electric shock hazard, do not open the enclosure casing and do not use batteries, AC adapters, cables, or external power supplies with visible signs of damage. Only use power supplies approved by Ventis Medical.

Hazards from Unauthorized Modifications: Unauthorized modifications of ventilatory equipment can result in death or serious injury. All servicing and repair of the VM-2000 must be performed by a qualified service technician in accordance with your local hospital procedures. Contact Ventis Medical at service@ventismed.com for details regarding qualification requirements.

Device Placement: Extensive exposure to direct sunlight may degrade the VM-2000 housing and its accessories. Concentrations of dust, lint, dander and pests can clog the VM-2000 filter over time. Avoid leaving the VM-2000 in direct sunlight or in environments with concentrations of lint, dander and pests.

EMI: Do not stack the VM-2000 with other electrical devices during operation. Do not use the VM-2000 within electromagnetic fields exceeding limits described in the EMC appendix. Sources of electromagnetic fields include security systems, wireless communications equipment, appliances, and medical imaging systems.

DO NOT USE in a Hyperbaric Chamber: Do not use the ventilator in a hyperbaric chamber.

AVOID Nitric or Nitrous Oxide: Do not use the ventilator in the presence of nitric or nitrous oxide.

AVOID Helium: Do not use the ventilator with helium or in the presence of mixtures in combination with helium.

NO Conductive Tubing: Do not use antistatic or conductive hoses or conductive patient tubing with the device.

AVOID Explosive Environments: Do not use the ventilator in explosive environments. Such use might cause an explosion.

NO Closed Suctioning: EMS ventilator is NOT intended for use with closed suctioning.

Single-use Accessories: Do not reuse single-use breathing circuit parts and other accessories, including Flow Sensors. They must be discarded after single use.

Use Duration: The device is not intended for >30 days of use, according to its toxicologic testing.

1.3. Caution Statements

CAUTION

Restricted Use: The VM-2000 is a restricted device that must be used according to its intended use by qualified trained personnel under the direction of a physician, within proper use and in accordance with applicable laws and regulations.

Use Outside Specified Normal Operating Conditions: The performance of the VM-2000 may be affected if it is used outside of the specified NORMAL OPERATING CONDITIONS. Refer to information in the Use Environment section below.

Ventilator Presets: Presets are intended to aid operators with the initial setup, but may not be appropriate in all situations, or when in use for an extended period. Operators should refer to appropriate guidelines or their medical director to determine the suitability of these presets for a given situation.

Service Personnel Qualifications: All servicing and repair of the VM-2000 must be performed by a qualified service technician in accordance with your local hospital procedures. Contact Ventis Medical at service@ventismed.com for details regarding qualification requirements.

Power Source / External Power: Only use the power source specified for use with the Ventis Medical VM-2000.

Wet Environments: If using the VM-2000 in a wet environment, protect the device by covering it with a protective barrier to avoid contact with moisture.

Storage Environment: Storage of the VM-2000 outside the specified storage environment may materially impact device performance and permanently damage and shorten the life of the device.

Battery Replacement & Disposal: The VM-2000 battery should only be replaced by a trained user. Batteries should be disposed of according to local environmental legislation.

Transport of Lithium-Ion Batteries: Regulations govern the transportation of lithium-ion batteries and devices that have lithium-ion batteries. Check the appropriate statutes to ensure compliance before transporting the device and/or the batteries.

Uncertain Power Sources: Before connecting the VM-2000 AC Power Supply to uncertain power input sources, verify the VM-2000 battery is in good condition and fully charged. Connecting to an improperly rated power source may damage the AC Power Supply, preventing the VM-2000 battery from charging.

Autoclave/Sterilization: Never place any part of the VM-2000 or its accessories in an autoclave. Unless otherwise indicated, the VM-2000 and its accessories are shipped clean, but not sterile.

Liquids: To avoid inadvertent damage, do not pour or spray liquids directly on the VM-2000 except for as specifically instructed by Ventis Medical for the purpose of cleaning & disinfecting. Additionally, do not place a vessel filled with liquid on the ventilator. If a liquid enters the product, fire and shock may occur.

Cybersecurity: This ventilator operates off stand-alone software and does not connect to any network, so the potential risk associated with digital cyberattacks is minimal.

FiO2 Monitoring: The VM-2000 includes an oxygen sensor. It is the responsibility of the user to monitor the titration of supplemental oxygen (if used).

No Overhead Alarm Integration: Patient monitoring is essential to address alarms when they occur. The VM-2000 device does not integrate with any overhead alarm systems or other conventional alarm systems that are standard in a clinical environment.

Patient Monitoring: Qualified personnel must constantly monitor patients. These personnel should be prepared to troubleshoot alarms, address equipment malfunctions, and address circumstances in which the equipment becomes inoperative.

Audible Indicators: Do not allow the ventilator Alarm Speaker Port to become covered or obstructed in any way by stickers, labels, clothing, or other equipment.

Noisy Environments: Alarms may be difficult to hear in noisy environments. Take extra precautions to closely monitor the patient and ventilator in these environments.

DO NOT use with an Oxygen Concentrator: The VM-2000 is not intended to be used with Oxygen concentrators.

Unintentional Changes: To prevent accidental changes to the settings or inadvertent device shut-off, verify the user interface is protected from unintentional contact.

Incorrect USB Usage: The USB connection is only for use with a flash drive device and should not have a voltage supply device attached to it.

Alarm Limits: Setting the alarm limits to extreme values can render the alarm system useless.

Nebulization or Humidification: The use of nebulization or humidification can increase the resistance of breathing system filters. The operator must monitor the breathing system filter frequently for increased resistance and blockage.

1.4. Capabilities and Limitations

CAPABILITY	DETAILS
Ventilation Modes	1) Assist Control (AC) – Volume Control 2) Synchronized Intermittent Ventilation (SIMV) – Volume Control 3) CPAP 4) NPPV
Manual Breath	Breath delivered by pressing the Manual Breath Key
Adjustable PEEP	Range 0-20 cmH_2O, increments of 1 cmH_2O, default is 5 cmH_2O
Adjustable Tidal Volume	Range 200 – 2000 mL, increments of 1 mL, default is 500 mL
T insp	Supports Inspiratory Time of .3 -5 seconds, increments of .1 seconds, default is 1 second
Adjustable Respiratory Rate	1) AC: Ranges 10 – 40 breaths per minute, increments of 1 breath per minute, default is 12 breaths per minute 2) SIMV: Ranges 0 – 40 breaths per minute, increments of 1 breath per minute, default is 12 breaths per minute 3) CPAP: 0 breaths per minute
Adjustable P insp Alarm	Range 15-90 cmH_2O, increments of 1 cmH_2O, default is 30 cmH_2O
Sensitivity	1) AC: 1 – 9 LPM or OFF, default is 3 2) SIMV / CPAP: 1 – 9 LPM, default is 3
Display Patient Parameters (Delivery)	Peak Inspiratory Pressure (PIP), Tidal Volume (TV), Respiratory Rate (RR), Positive End Expiratory Pressure (PEEP), FIO_2, $ETCO_2$ *(Note: Optional $ETCO_2$ monitor required for $ETCO_2$ reading)*
Display Ventilatory Settings	Tidal Volume (TV), Respiratory Rate (RR), Positive End Expiratory Pressure (PEEP), Inspiratory Time (T insp), Ventilation Mode, Peak Inspiratory Pressure (P insp), and Sensitivity
GUI with Touch Screen	Presentation of text, graphs, pictures, and videos. Graphical data improves patient management through visualization of pressure, volume, and flow and permits contextual help
Battery-powered	In addition to wall-power, device supports rechargeable batteries (up to 8 hours) and primary batteries (up to 6 hours)[1].

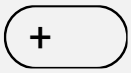
CAPABILITY	DETAILS
Alarms	Text, audio, and visual indicators, including alarms for: • Tidal Volume, Respiratory Rate, PEEP, or Inspiratory Pressure not achieved or exceeds threshold values • Tubing disconnections, misconnections, occlusion, and leak • FIO_2 above or below set limits • $ETCO_2$ above or below set limits (if optional sensor is present) • Low battery status • Technical alarms
Ventilation without supplemental O_2	Device is compatible with low pressure oxygen sources and blenders, but will function without supplemental O_2
Exhaust Filtration	Expiratory filter mitigates environmental contamination

[1] Under following conditions: TV 500, RR 10, PEEP 5, R5, C50

LIMITATION	DETAILS
NOT MRI Compatible	Do not put the VM-2000, any components, or accessories near or inside an MRI machine.

1.5. General Symbols List

Symbol	Title & Usage	Symbol	Title & Usage
	Caution		On/Off Power Button
	Consult Instructions for Use		Audio Pause
	Do Not Reuse		Class II Equipment
	Date of Manufacture		Alternating Current
	Manufacturer		Direct Current
	Waste Container		Not made with natural rubber latex
	Catalog Number		Battery Level
	Serial Number		AC Power Connected
	Batch Code		Fragile, Handle with Care
	Use-By Date		Temperature Limit
	Do Not Use if Package is Damaged	IP54	Enclosure Protection Rating
	Non-Sterile		Settings
	Start/Resume Ventilation		Help
	Stop Ventilation (Pause / End)		Keyboard Entry
	Graphical View		Leave Keyboard View

Symbol	Title & Usage	Symbol	Title & Usage
	Battery Not Installed		Decrease Increment
	Increase Increment		Manual Breath
	Delete		Power Source Connection
	BF Applied Part		MR Unsafe

2. Device Overview

2.1. Device Introduction

The VM-2000 is designed to provide continuous or intermittent ventilatory support for care of individuals who require mechanical ventilation. VM-2000 is intended for adult patients and can support both invasive and non-invasive ventilation.

The VM-2000 ventilator is intended for institutional environments and during transportation. It may be used in hospital and pre-hospital (transport) environments.

The VM-2000 ventilator is a restricted medical device intended to be used only by qualified trained personnel under the direction of a physician in all defined use environments.

FIGURE 1: VM-2000

VM-2000 uses a single-patient-use breathing circuit with a Pressure Monitoring Line, Control Line, and Flow Sensor to deliver air to patients using a motor-blower system. The device runs AC wall power, and / or batteries. To support use in environments where compressed oxygen is unavailable or ill-advised, the device does not require compressed oxygen.

The Ventis User Interface™ allows for rapid initiation of emergency ventilation based on default parameters. An operator can quickly begin ventilation by connecting the patient to the breathing circuit, and if necessary, adjusting ventilatory settings using the touch screen input before selecting START.

Once the therapy is initiated, breaths are delivered to the patient based on the configured settings. Operators can monitor patients closely through a graphical breath-by-breath display and audio/visual alarms to deliver high-quality care. Audio and visual alarm indicators help troubleshoot issues.

2.2. Indications for Use / Intended Use

The VM-2000 ventilator is intended to provide continuous or intermittent ventilatory support for the care of the individuals who require mechanical ventilation. The ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult patients, who require the following types of ventilatory support:

- Positive Pressure Ventilation, delivered invasively (via endotracheal tube or trach tube) or non-invasively (via mask).
- Assist/Control, SIMV, CPAP and NPPV modes of ventilation.

The ventilator is suitable for use in institutional or transport settings.

CAUTION

Federal law (U.S.A) restricts this device to sale by or on the order of a licensed medical practitioner. Outside the U.S.A., check local laws for any restrictions that may apply.

2.3. Contra-Indications

None known.

2.4. Training

Operators must be appropriately trained or licensed in their respective specialty in accordance with all hospital or institutional policies regarding training and certification for their respective field or job. Operators should familiarize themselves with all operations of the device through the Instructions for Use contained in this Operator Manual and Quick Start Setup Guide prior to use.

2.5. Use Environment

Normal Operating Environment

The VM-2000 is a portable device. The product should be used on adults only, in a hospital or pre-hospital setting by qualified trained professionals under the direction of a physician.

Use in emergency helicopters or road ambulances: The VM-2000 must always be appropriately secured during transport. For mounting options and details, see the VM-2000 Helicopter Transport Case and Mounting System, or the VM-2000 Ambulance Transport Case and Mounting System and confirm that the ventilator is adequately secured. See the respective accessory instructions for use.

Humidity and Temperature

Performance specifications are based on use in temperature range of -10 to 40 degrees C and controlled relative humidity noncondensing (15% - 90%). The device should only be operated within this temperature range and humidity range.

Oxygen Source

The VM-2000 is designed to be suitable for use with a low-pressure oxygen source; however, this device should not be used in an environment that has an ambient concentration of oxygen greater than 25%. The device will alarm and notify the operator if ambient oxygen concentration of greater than 25% is detected.

CAUTION

Use of the ventilator at altitudes [above 4,000 meters above sea level] or outside of specified environmental operating conditions can result in degradation of ventilator performance.

3. Device Description

3.1. System Overview

3.1.1. Introduction

The VM-2000 delivers patient ventilation using an electronically controlled motor/blower system. The device runs on AC power using a Class II external power supply. Additionally, it can be powered by a Primary or Rechargeable battery to protect against power failure or unstable power. Details of battery specifications are listed below: Electrical systems control air/gas delivery through a blower system, monitor alarms, and distribute power.

The user provides inputs to the VM-2000's control system through the Touch Screen, Manual Breath Button, and On/Off Power Button. User inputs become instructions to deliver a controlled volume or pressure of gas to the patient. The unit has a Type BF Applied Part, which is the breathing circuit. The VM-2000 receives data inputs from the proximal flow sensor, and other sensors within the ventilator. Based on this monitored data, the VM-2000 adjusts gas delivery to the patient, which is monitored continuously by an alarm system. Monitored data is displayed by the Ventis User Interface™.

The VM-2000 system has independent functions to control the delivery of ventilation and monitoring. The control and monitoring functions are then continuously cross-checked by an independent alarm function. Additionally, the VM-2000 provides a power management sub-system with watchdog function and audio alarm that is separate and independent of the Ventilation/Monitoring/Alarm system. This sub-system monitors the operational status of the Ventilation/Monitoring/Alarm system using a watchdog timer and detects fault conditions. If the watchdog function detects an error state in the ventilation-control/monitoring function, an independent audio alarm will alert the operator to a failure condition even if there is an unrecoverable single-fault software or hardware condition.

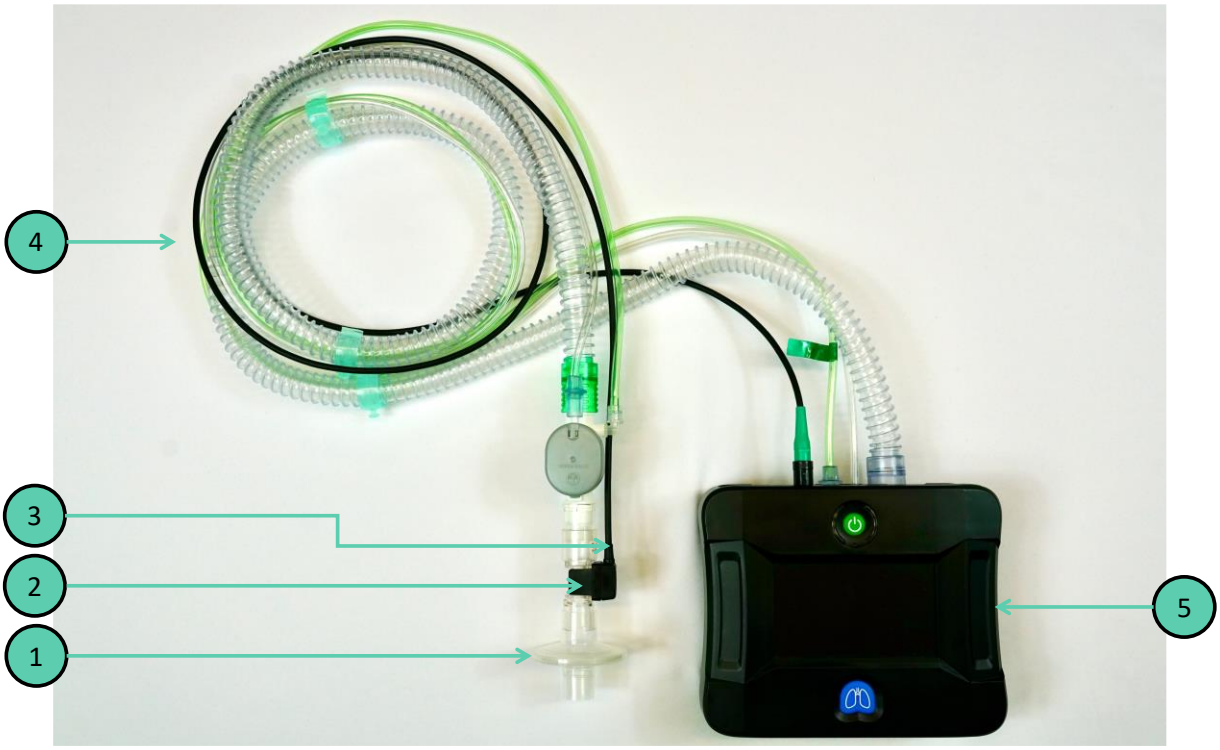


FIGURE 2: VM-2000 WITH ACCESSORIES

ITEM	DESCRIPTION
1	Breathing Filter
2	Flow Sensor
3	Flow Sensor Cable
4	Breathing Circuit
5	Ventilator Unit

3.1.2. Gas Supply and Delivery

The VM-2000 uses ambient air, either alone or mixed with low-pressure Oxygen. The use of medical oxygen is not mandatory for use. Based on user inputs, the Control System drives the air/gas blower system. The target volume is delivered by modulating the speed of the motor fan to deliver an intended volume of gas through an Air/Gas Reservoir to the patient. Patient Peak Inspiratory Pressure (PIP) is monitored in the Breathing Circuit to prevent the pressure from exceeding the PIP limit.

As depicted in **Figure 3**: **Pneumatic System Overview**, air enters through the reservoir on inspiration, and mixes at low-pressure with external Oxygen supply (if present). Before entering the internal device breathing pathway, gas travels from the ambient environment and through the Inlet Filter installed within the Inlet housing to prevent any external debris, particulate, or other sources of contamination from entering the unit. An O_2 sensor located in the ventilator housing measures the ambient concentration of

Oxygen and triggers an alarm for concentrations greater than 25%. The gas is then channeled through the internal breathing pathway enclosed in the ventilator unit, and through the breathing circuit connected at the device outlet. In the breathing circuit, flow is measured by a flow sensor. Measurements taken at the flow sensor and near the patient connection are used in the pressure, flow, and volume measurements. After the flow sensor, gas passes through the Breathing Filter before entering the patient airway.

The Exhalation Valve is driven by a Control Line using a Solenoid Valve housed inside the ventilator unit. On inspiration, the Control Line closes the Exhalation Valve, so all gas delivered is channeled to the patient. On exhalation, the Control Line opens the Exhalation Valve so that gas exhaled by the patient can be vented into the atmosphere. Patient exhalation will pass through the Breathing Filter so that internal components and atmosphere are protected from potential microbial contamination, dust, dirt and particulates.

This system protects the device from exceeding 90 cmH_2O under both normal and single fault conditions. In the passive state, the Exhale Valve is designed to be open, allowing the patient to breath freely. In a single fault condition where the motor fails, the Exhale Valve will be released. If for some reason the Exhale Valve fails in a single fault condition, the patient will be able to breathe through the main breathing pathway because there is no check valve between the airway and the gas inlet preventing backflow.

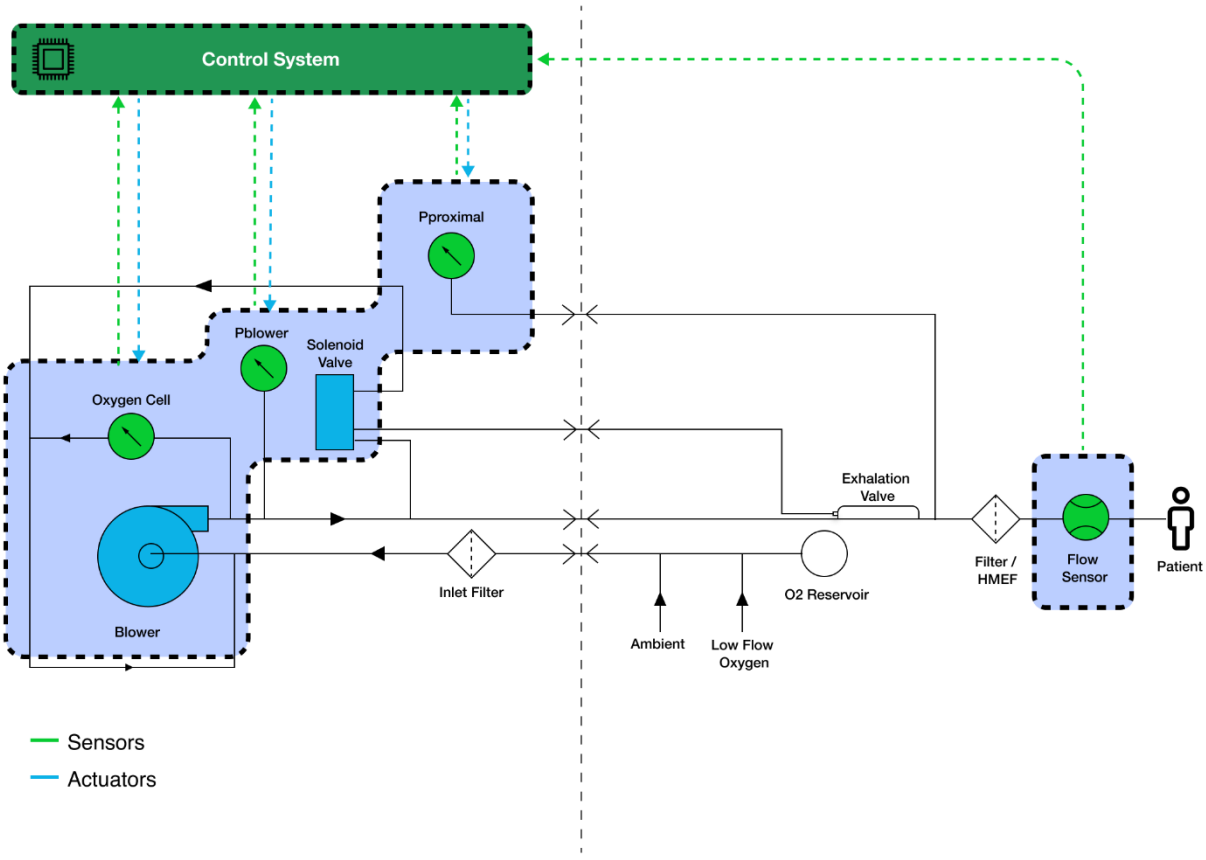


FIGURE 3: PNEUMATIC SYSTEM OVERVIEW

3.2. Ventilator Unit

FIGURE 4: VM-2000 FRONT VIEW

ITEM	DESCRIPTION
1	**On/Off Power Button:** Powers the ventilator on and off and indicates operation state. • Press to turn on. Green LED indicators communicate the unit is powered on. • Press and hold to turn off. Operator will be required to confirm selection if ventilator is in active ventilation mode.
2	**LED Patient/Device Alarm Indicator:** Indicates status and alerts user to alarm condition. Flashing Amber or Red LED indicators communicate alarm condition.
3	**LED Battery Status Indicator:** Indicates status of AC wall power. LED will be green when device plugged into external power.
4	**Touch Screen:** Graphical User Interface with touch screen access to device measurements and controls (**see Figure 7-A/7-B: General Touch Screen Layout**).
5	**Manual Breath Key:** Press to deliver single breath at the set Tidal Volume when device is powered on and set up properly for use. This will be allowed during the window when the patient is not in an active inspiration or expiration.

FIGURE 5: VM-2000 BACK VIEW

ITEM	DESCRIPTION
1	**Back Panel Label:** Provides basic device UDI information, and other relevant warnings/symbols.
2	**Battery Pack**: Battery pack is installed into the battery slot on the back of the device to provide alternative power.
3	**Battery Latch:** Secures battery.

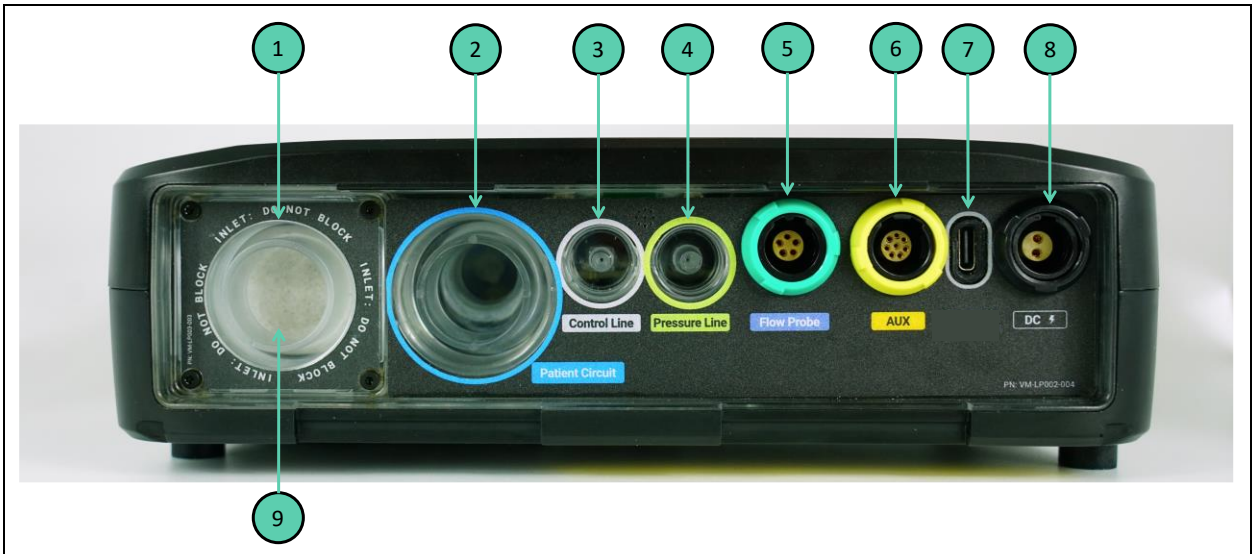


FIGURE 6: VM-2000 PORT PLATE

ITEM	DESCRIPTION
1	**Air/Gas Inlet:** Ambient Air intake, and Air/Gas Reservoir connection (Inlet Filter installed within Air/Gas inlet housing).
2	**Outlet**: Supplies gas to patient when connected to breathing circuit.
3	**Control Line Port:** Connection point between Control Line to control inhalation and Ventilator Unit.
4	**Patient Pressure Monitoring Port:** Connection point between Pressure Monitoring Line and Ventilator Unit.
5	**Flow Sensor Port:** Connection point between Air/Gas Flow Sensor Cable and Ventilator.
6	**Auxiliary Sensor Port:** Auxiliary accessory connection port for optional $ETCO_2$ Sensor or a compatible alarm system.
7	**USB:** Connection for downloading logs and for service.
8	**Power Jack:** AC Power Source connection.
9	**Inlet Filter:** Installed within housing. Prevents debris from entering air pathway in ventilator.

3.3. Device Disposables and Accessories

Only use accessories and disposables that meet the specifications set forth in **Section 3.3: Device Disposable and Accessories.** The VM-2000 meets all specifications listed in **Appendix A: Specifications** when used with disposables and accessories that meet the approved specifications. Examples of accessories that meet the specifications are listed in the table below.

WARNING

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

Ventis Supplied Accessories

ITEM	PART #	DESCRIPTION
Inlet Filter	VM-511	Filter to prevent debris from entering ventilator air pathway.
Flow Sensor Cable	VM-521	Line to connect air/gas flow sensor to ventilator unit.
Primary Battery Pack	VM-401	DC 21V, 2.8Ah Lithium/Manganese Dioxide (Li/MnO_2) battery pack. Battery pack meets IEC 60086-4 compliance. Power measurement and low battery warning provided by software fuel gauge and battery voltage measurement.
Rechargeable Battery Pack	VM-402	Battery pack meets IEC 62133 compliance. Power measurement and low battery warning provided by software fuel gauge and battery voltage measurement.
AC Power Supply	VM-420	Connection between device and battery to external AC power source. AC Power supply is a medical grade, IEC 60601-1 compliant, Class II (device, and has input requirements of 100-240VAC, 50-60Hz, 1.5A).
$ETCO_2$ Sensor	VM-701	$ETCO_2$ sensor to measure end tidal CO_2 at patient connection.
Flow Sensor	VM-522	Digital flow meter designed for use in a proximal/expiratory environment to measure gas/flow at patient connection that meets the following specifications: • Flow range: ± 250 slm, bidirectional • Small dead space < 10ml Update time <=.5ms

TABLE 1: VENTIS MEDICAL VM-2000 ACCESSORIES

Requirements for Compatible Accessories

The following items are intended for use with the VM-2000 and define requirements for off-the-shelf components intended for use with respiratory devices. Parts that meet defined requirements can be independently purchased as standard off-the shelf components and used with the VM-2000.

Legally Marketed User Supplied Accessories

ITEM	REQUIREMENTS	COMPATIBLE PARTS
Patient Breathing Circuit	Legally marketed breathing circuit to channel air to and from the patient's airway, that meets the following specifications: • Single limb breathing system with monitoring line and active exhalation valve, 22mm, 1.8m. long • Compliance < 1mL/cmH_2O • Resistance to flow at 30L/min <= 1.0cm H_2O	Intersurgical 5191000 Breathing Circuit
Breathing Filter	Legally marketed single-use patient breathing filter to protect internal components and atmosphere from potential microbial contamination, dust, dirt, and other particulate that meets the following specifications: • Resistance to flow at 30L/min <= 1.0cm H_2O • Dead Space: <70mL • Connectors: 22ID – 22OD/15ID • BE / BFE Efficiency > 99.99% • Conforms to 23328-1 and 23328-02	Intersurgical 1944030 Breathing Filter Sun Medical FH603003 Breathing Filter
Heat and Moisture Exchange Filter (HMEF)	Legally marketed HMEF to provide heat & moisture delivery/recovery to retain moisture within the breathing system that meets the following specifications: • Resistance to flow at 30L/min <= 1.0cm H_2O • Dead Space: <70mL • Connectors: 22ID – 22OD/15ID • BE / BFE Efficiency > 99.99% • Conforms to 23328-1 and 23328-02	Sun Medical FH603005 Heat and Moisture Exchange Filter (HMEF)
Oxygen Blender	Legally marketed oxygen blender capable of providing variable oxygen, that meets the following specifications: • Flow range: 10 – 30 LPM • Oxygen levels: 21% - 100%	Maxtec Maxblend2 Oxygen Blender R229P01-001
Air/Gas Reservoir	Reservoir to allow delivery of low flow Oxygen using a flow regulated Oxygen source, comprised of a legally marketed airway tube and elbow airway components that meet the following specifications: - **Reservoir tube:** 6ft ventilator tube, with 22mm cuffs	Reservoir tube: Sunset Healthcare Solutions TUB06 tubing (6ft ventilator tube with 22mm cuffs) Connection:

Legally Marketed User Supplied Accessories

ITEM	REQUIREMENTS	COMPATIBLE PARTS
	- **Connection:** 22mm male to female connector with 6mm OD stem and cap	Straight connector 22M - 6mm OD stem and cap - 22F
$ETCO_2$ Airway Adapter	Legally marketed disposable airway adapter for mainstream adult single use $ETCO_2$ monitoring airway adaptor.	Zoll 606300 Disposal Airway Adaptor

TABLE 2: REQUIREMENTS FOR COMPATIBLE ACCESSORIES

NOTE

In addition to the accessories listed above an airway is required for use. Further, an ETCO2 and an SpO2 sensor are recommended for use, when available.

- **Airway:** Operators must identify an airway appropriate for the situation and have it ready for use. The VM-2000 should always be used with an airway that is appropriate based on the training of the provider and needs of the patient. Consult your medical director. Only use accessories approved by Ventis Medical for use with the VM-2000. To verify if an airway is approved for use with the VM-2000, contact support@ventismed.com.

- **$ETCO_2$ Sensor:** It is recommended to monitor $ETCO_2$ inhaled/exhaled CO_2 using the optional ETCO2 sensor or a stand-alone ETCO2 sensor.

- **SpO_2 Sensor:** A pulse oximeter should be used to monitor SpO_2. The VM-2000 should always be used with a pulse oximeter that is appropriate based on the training of the provider and patient needs.

3.4. Filters

The VM-2000 operating setup incorporates two filters: the Inlet Filter and the Breathing Filter/HMEF.

Inlet Filter: The Inlet Filter is intended to protect the internal components of the VM-2000 system from dust, dirt, and other particles. The filter comes installed within the ventilator inlet housing (See Figure 6: **VM-2000 Port Plate**). An Inlet Filter must be properly installed inside the Air/Gas Inlet port at all times. Inspect the housing to ensure that the filter is properly installed. Ventis Medical recommends inspecting the Inlet Filter for signs of damage prior to use or dirt/dust saturation prior to use. In a typical intra-hospital setting, the Inlet Filter requires service after 240 hours of use, and should be inspected between patients; however, in particularly dirty or dusty environments replacement may be required at more frequent intervals. Inlet Filters should only be replaced by qualified service personnel.

WARNING

Immediately take the device out of service if debris, particulate, or other sources of contamination has entered the internal VM-2000 system. The delivered Tidal Volume may decrease significantly without alarming.

Never operate the unit without a filter in place. A clean Inlet Filter must be always in place.
Never use a wet, moist, or damaged Inlet Filter.

CAUTION

Ventis Medical recommends having the Inlet Filter replaced after use in particularly dirty or dusty environments. In a typical intra-hospital setting, the Inlet Filter may require replacement less often. Inspect the Inlet Filter for signs of damage prior to use. Inlet Filter should only be replaced by qualified service personnel.

Failure to properly maintain the Inlet Filter can impair performance as well as shorten the life expectancy of the unit due to increased workload on the pump motor.

Only use filters approved for the VM-2000. Using other filters may impact device performance.

Breathing Filter/HMEF: The VM-2000 should always be used with either a Breathing Filter that meets requirements outlined in **Table 2:** Requirements For Compatible Accessories (e.g., Intersurgical 1944030 Breathing Filter, or Sun Medical FH603003 Breathing Filter) or HMEF Breathing Filter (Sun Medical FH603005) while meeting performance specifications.

The disposable breathing filter offers a high degree of protection for the device's internal components, and protection from potential bacterial and viral contamination of the atmosphere from exhaled gas. Bacterial and Viral Filtration efficiency of the Breathing Filter is >99.99%. Additional technical characteristics are listed in **Table 2: Requirements for Compatible Accessories**.

3.5. Ventis User Interface (VUI™)

Once the device is powered on, all controls to deliver ventilation are accessible through the touch screen, and are organized based on task for rapid setup, clear monitoring, and troubleshooting. The Manual Breath Key is used to deliver a single breath at the set Tidal Volume and is located on the front panel of the device not on the touch screen. **See Figure 4: VM-2000 Front View** for details. For details about manual breath delivery, refer to the **Manual Trigger Breaths** section**.**

The device is controlled using the Ventis User Interface's touch input. Control changes that impact ventilatory settings accessed through the touch screen require confirmation to prevent inadvertent changes. To begin ventilation, the user must press and hold the On/Off Power Button to power the device on, and confirm by selecting START. Adjusting ventilator parameters requires operators to input the target value and press CONFIRM. If the target value is outside of the allowed range, the device will not accept the changes (either the user will not be able to input the value, or a pop-up message will display on screen indicating that the desired combination is not allowed). If the user navigates from a control window without confirming their change for any reason, the device will prompt user that their change

was not saved. In this situation, the device will not modify ventilatory delivery and the display will revert to the current device settings.

The color of the patient parameters displayed changes depending on whether values are within expected range. White numerical parameters in the Main Measured Parameters Pane communicate that the measured patient parameters are within expected range based on Alarm Thresholds (For more details about Alarms and Alarm Thresholds, refer to **Section 3.8.3: Quick Alarm Reference Guide** section). If measured patient parameters are outside of the expected range, they will display as red,. The Display Window located in the center of the touch screen interface either will display basic contextual information as needed, or breath-by-breath graphical data that can be interpreted by appropriately trained users. Graphical data will be displayed when Graphical View is selected. Selecting controls in the Ventilatory Settings Pane will open a screen onto the display window that allows users to view or change settings (**See Figure 7-A/7-B: General Touch Screen Layout**).

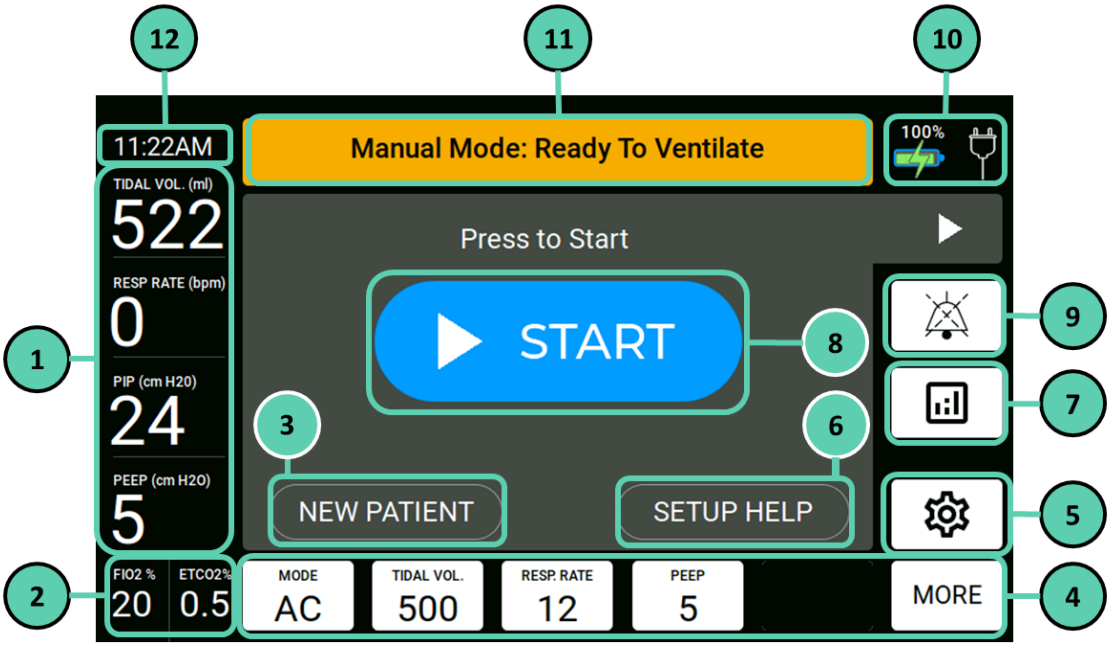


FIGURE 7-A: GENERAL TOUCH SCREEN LAYOUT

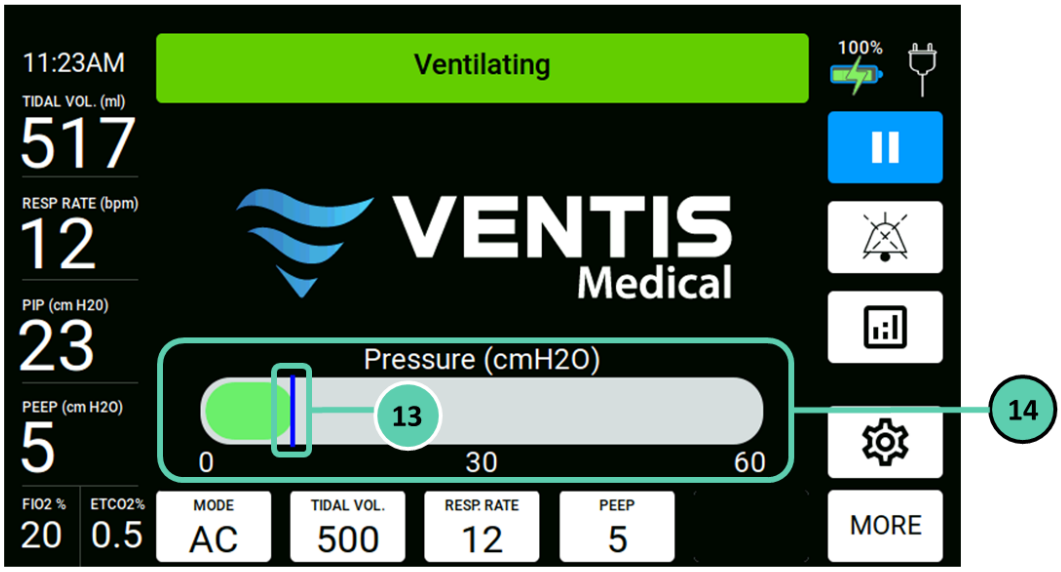


FIGURE 7-B: GENERAL TOUCH SCREEN LAYOUT

ITEM	DESCRIPTION
1	**Main Measured Patient Parameters:** Displays breath-by-breath measured Tidal Vol (mL), Resp. Rate (BPM), PIP (cmH_2O), and PEEP (cmH_2O). If the patient's condition becomes critical, the color of the numeric parameters change to red for a high priority alarm or to yellow for a medium priority alarm.
2	**Measured Patient FIO_2 and $ETCO_2$ Parameters:** Displays FIO_2 and $ETCO_2$ if optional $ETCO_2$ sensor is utilized.
3	**New Patient:** Restores default preset ventilation settings and alarm limits.
4	**Ventilatory Settings Pane:** View the most important ventilation controls. Touch the 'MORE' button to display additional controls for the selected Mode.
5	**System Settings and Configuration**
6	**Basic Setup Instructions:** View relevant information about parameter presets and guidance.
7	**Graphical View:** Select to view pressure, flow, volume, and $ETCO_2$ (if sensor present) wave forms to show the patient's breath cycles.
8	**Start:** Initiates continuous ventilation based on ventilation settings when user selects START.
9	**Audio Pause**. Touch this key to pause the generation of auditory alarm signals for 120 seconds.

10	**Battery/Power Source Status:** Displays battery status and charging state.
11	**Device Operational Status/Message Bar:** Displays operational status and color-coded alarm messages. The device will display one of the following operational status messages during normal (non-alarm) operating conditions: ▪ **"Manual Mode: Ready to Ventilate"**: Device is turned on and ready to deliver continuous ventilation. Operator can deliver individual breaths by pressing the Manual Breath Key on the front of the device. The device will not trigger mandatory or spontaneous breaths unless the user selects to start ventilation in a continuous ventilation Mode. ▪ **"Ventilating":** Continuous ventilation is being delivered (Modes: AC or SIMV). ▪ **"Paused: Press to Start":** Continuous ventilation is paused. Operator can deliver individual breaths by pressing the Manual Breath Key on the front of the device. The device will revert to the last active state automatically within 30 seconds. **Alarms:** If an alarm condition is activated, Device Operational Status/Message Bar turns yellow or red based on alarm priority and displays alarm name. The device will display an alarm message. For a full list of alarms, refer to **Section 3.8.3: Quick Alarm Reference Guide** section.
12	**Time:** Defaulted to eastern time, with option to configure via the device maintenance menu.
13	**PIP Indicator**: Vertical line indicates the peak pressure value of the breath.
14	**Patient Pressure Bar Graph:** Bar graph that displays the current patient pressure during ventilation. The bar color depends on whether the breath is patient initiated or machine initiated (patient = blue, machine = green).

3.6. Controls

Ventilator Settings can be modified primarily through a standard layout, by entering the keypad input screen, and keying in the desired value.

Alternatively, in certain screens indicated by a slider icon located on the top right of the keyboard, two additional methods are available on the Slider Input Screen:

1. Using a slider to adjust the value on the main control screen
2. Modifying the value through + / - increment keys on the main control screen

Each control has a defined maximum and minimum threshold, as well as increment keys that the user can use to manipulate the desired setting for convenience.

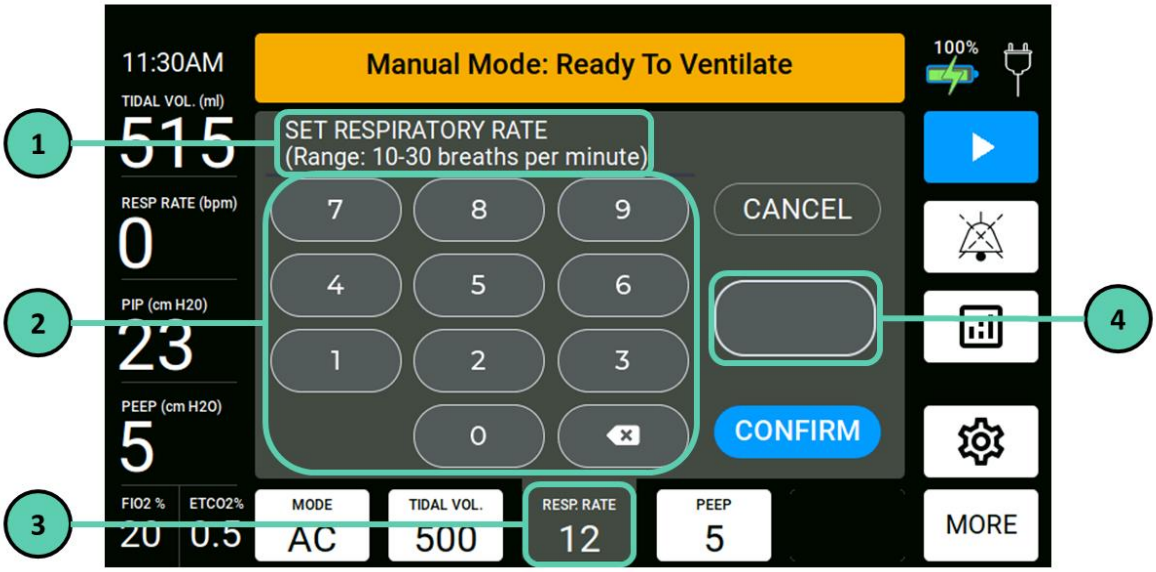


FIGURE 8: KEYPAD INPUT SCREEN

ITEM	DESCRIPTION
1	**Parameter name and allowed range:** The active parameter and range of allowed inputs will be displayed at the top of the keypad input screen
2	**Keypad**: To enter desired parameter value, input it on the keypad
3	**Setting Tab:** Select to access parameter settings. The setting tab will display whatever parameter value is currently set.
4	**Parameter display:** The selected value will be visible within the parameter display

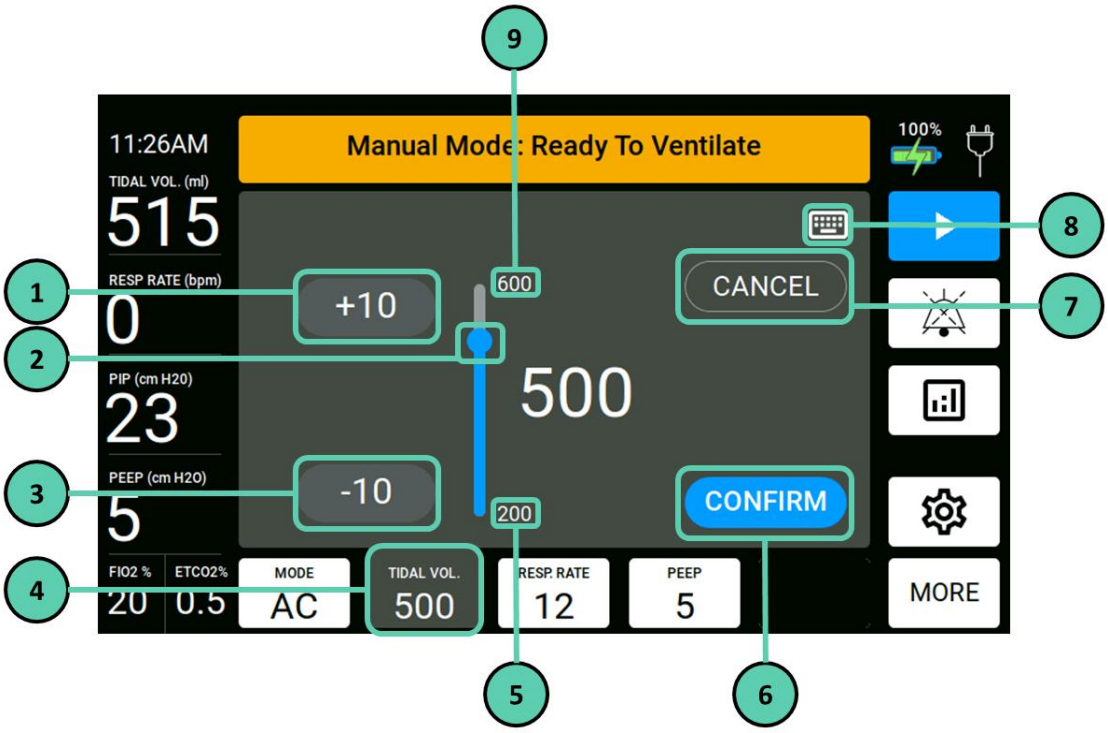


FIGURE 8-B: SLIDER INPUT SCREEN

ITEM	DESCRIPTION
1	**Increment Key – Increase:** Allows user to quickly increase setting by common increment value. User must select Confirm to apply change.
2	**Setting Slider:** For some settings, users can achieve increased levels of precision by keying in value or using slider. User must select Confirm to apply change.
3	**Increment Key – Decrease:** Allows user to quickly decrease setting by common increment value. User must select Confirm to apply change.
4	**Setting Tab:** Select to access parameter settings. The setting tab will display whatever parameter value is currently set.
5	**Min Threshold:** Indicates maximum setting value.
6	**Confirm:** Applies change and closes window.
7	**Cancel:** Does not apply change and closes window.
8	**Keypad Entry:** Allows user to access Keypad Entry Screen. User must select Confirm to apply change.
9	**Min Threshold:** Indicates minimum setting value.

3.7. Device Labels

The VM-2000 has one label on the inlet filter, one label on the port plate, and one label on the back panel. These labels are intended as a reference to users who have read this manual. The back panel device label includes information concerning device Serial Number and other unique identification information.

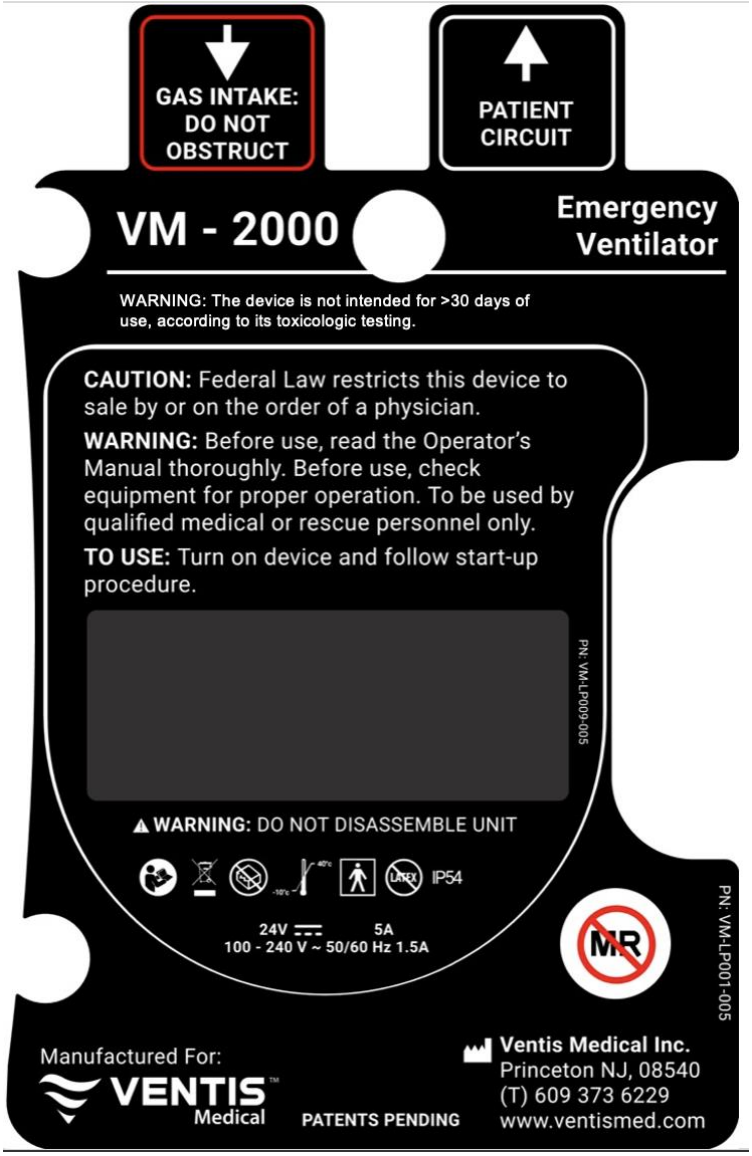


FIGURE 9: BACK PANEL LABEL

The port plate label provides a reference to identify the connection points on the device for users who have read the operator's manual. Additionally, the inlet label identifies the air/gas inlet, and clearly instructs users not to obstruct the air/gas inlet.

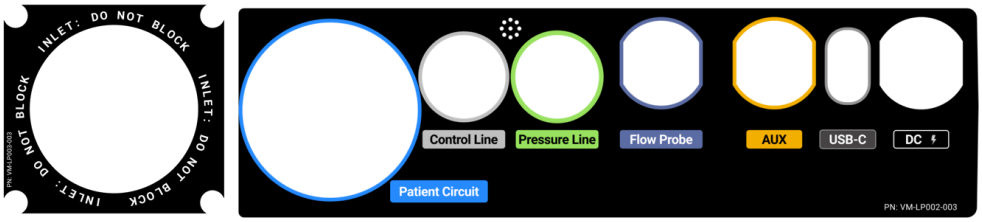


FIGURE 10: INLET LABEL (LEFT) AND PORT PLATE LABEL (RIGHT)

FIGURE 11: PRIMARY BATTERY LABEL (LEFT) AND SECONDARY (RECHARGEABLE) BATTERY LABEL (RIGHT)

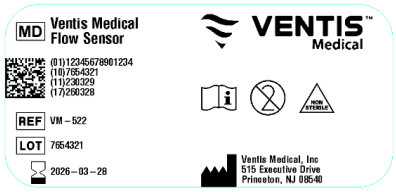


Figure 12: Flow Sensor Label

VM-2000 accessories are appropriately labeled with accessory serial number and reference information for use by users who have read the operator's manual.

3.8. Alarms

The VM-2000 has several alarms to alert the operator of potentially unsafe physiological conditions. These alarms are triggered by monitoring internal device parameters and patient airway pressures.

These alarms have been categorized as:

- High priority
- Medium priority
- Low priority

All alarms within a priority band will follow a standard pattern for display & audio response. **Table 3: Overview of Alarm Severity Categorizations** shows the audio and visual characteristics of these types of alarms and instructs the operator on how to respond. In addition, there are other alarm conditions associated with technical fault alarms, service information, and operator messages.

The device will continue delivering breaths during most alarms; however, when an alarm condition is serious enough to possibly compromise safe ventilation, the device defaults to a safety state, and will either adjust settings or attempt to give breaths depending on the fault and risk to the patient until the issue is resolved. Once the problem is resolved, the device will resume normal operation. In addition, the device has apnea alarms and controls, which will automatically trigger a breath. In SIMV mode, the apnea alarm will be triggered when the patient hasn't triggered a breath within the apnea interval and the ventilator will enter backup mode.

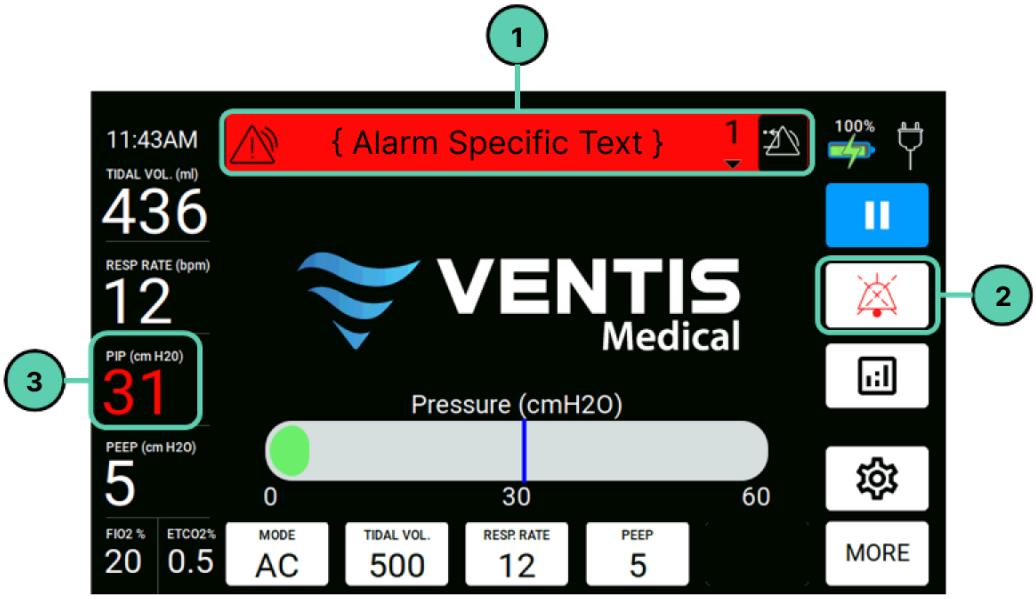
The device has standard audio and visual responses to alarm conditions based on alarm priority. All alarms are accompanied by a standard audible alarm signal determined by their priority. Alarm sounds occur at a level of 77 DBA, with a maximum sound power of 99 db. **Table 3: Overview of Alarm Severity Categorizations** shows the audio and visual characteristics of these types of alarms and instructs the operator on how to respond. **Figure 32-A/32-B: Alarm Response** shows the ventilator's visual alarm indications, including:

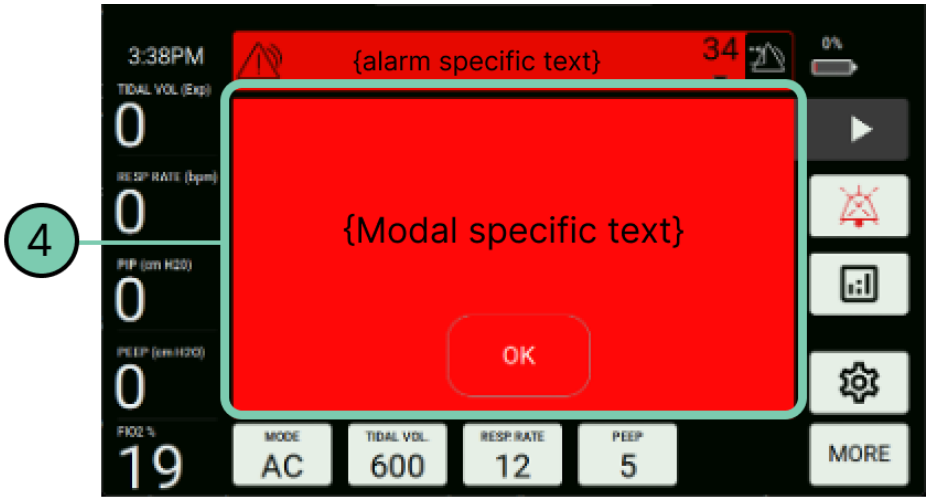
- Visual LED Indicator continuous or flashing, yellow or flashing red (dependent on alarm priority)
- Alarm displayed in Device Operational Status/Message Bar on Touch Screen
- Audio Pause key turns red, allows operator to pause generation of auditory alarm signals for 120 seconds

Additionally, the main monitoring parameters (MMP) change their colors from white to red when a corresponding alarm activates.

Alarm ventilation limits are pre-set by default and can be modified by the operator if clinically necessary. If desired, functional validation can be performed to verify proper operation of critical device alarms including high airway pressure, circuit disconnect, and hypoventilation.

General format for VM-2000 alarm interface





All alarms adhere to the following format when triggered:

1. Device operational status / message bar displays alarm name and changes color based on priority
2. Flashing alarm, audio pause signal
3. If relevant parameter triggers high priority alarm, that monitored parameter will turn red
4. If relevent, a modal with alarm specific text is initiated

All alarms are accompanied by an audible alarm signal determined by their priority

3.8.1. Pre-use Checks

3.8.1.1. Occlusion Alarm Pre-Use Check

To perform a functional test of the circuit occlusion alarm:

1. Connect Patient Breathing Circuit based on the configuration described in **STEP 1: Set Up** Breathing Circuit for Use and Verify Proper Operation.
2. Place cap on end of circuit.
3. Turn device on.
4. Start ventilation.
5. Validate that the unit reports Tubing Occlusion in device operational status bar and produces valid visual and audio alarm response.

3.8.1.2. Functional Test of Circuit Disconnect

To perform a functional test of the circuit disconnect alarm:

1. Connect Patient Breathing Circuit based on the configuration described in **STEP 1: Set Up** Breathing Circuit for Use and Verify Proper Operation.
2. Remove cap on end of circuit.
3. Turn device on.
4. Start ventilation.
5. Validate that the unit reports Tubing Disconnect in device operational status bar and produces valid visual and audio alarm response.

3.8.1.3. Apnea Check

To perform a functional test of the Apnea backup mode alarm prior to patient use:

1. Connect Patient Breathing Circuit based on the configuration described in **STEP 1: Set Up** Breathing Circuit for Use and Verify Proper Operation.
2. Attach a test lung to the patient end of the Breathing Circuit.
3. Set the ventilation in SIMV mode.
4. Set Respiratory Rate = 1.
5. Start ventilation.
6. Verify that an Apnea alarm sounds and that the device initiates backup ventilation after 10 seconds and produces audio and visual alarm response.

3.8.1.4. PIP Limit / High Pressure Alarm Check

To perform a functional test of PIP Limit / High pressure alarm:

1. Connect Patient Breathing Circuit based on the configuration described in **STEP 1: Set Up** Breathing Circuit for Use and Verify Proper Operation.
2. Attach a test lung to the patient end of the Breathing Circuit with resistance = 50, and compliance = 10.
3. Start ventilation in AC mode with: TV = 200, PEEP = 5, RR = 10, P. Insp. = 20, T insp = 1
4. Wait 30 seconds.
5. Adjust the Tidal Volume to 500.
6. Verify that the unit reports that the PIP limit has been reached and produces audio and visual alarm response. Note that other alarms such as Tidal Volume not reached may also occur.

A circuit check for resistance, compliance and leak can also be performed by accessing this test through the Setting Menu as described in that section.

WARNING

Failure to respond to alarms can result in serious harm or death. Alarms should always be monitored, and the operator should be prepared to ventilate with alternative method of ventilation.

The absence of an alarm does not indicate the patient is receiving adequate ventilation. If the VM-2000 is used for extended periods, it is recommended the operator monitor blood gases to ensure adequate gas exchange.

Failure to respond to alarms can result in serious harm or death. Alarms should always be monitored, and the operator should be prepared to ventilate with alternative method of ventilation.

The absence of an alarm does not indicate the patient is receiving adequate ventilation. If the VM-2000 is used for extended periods, it is recommended the operator monitor blood gases to ensure adequate gas exchange.

CAUTION

Patient monitoring is essential to ensure alarms are addressed as soon as they are triggered. Device will not integrate with any overhead alarm systems, or other alarm systems usually used to indicate issues in the standard clinical environment.

Transient high-pressure increases may occur. Clinical judgement is required in these situations.

3.8.2. Alarm Severity Categorizations

A list of Alarm Severity Categorizations as well as the audio and visual indicator are shown below.

ALARM TYPE	MESSAGE BAR	ALARM INDICATOR	AUDIO	ACTION REQUIRED	SOUND
High priority alarm	Red, with alarm message	Flashing Red	A sequence of 10 beeps, repeated until the alarm condition is cleared.	The patient's safety is compromised. The problem needs immediate attention.	77DBA - max sound power of 99db
Medium priority alarm	Yellow, with alarm message	Flashing Yellow	A sequence of 3 beeps, repeated periodically.	The patient needs prompt attention.	77DBA - max sound power of 99db
Low priority alarm	Grey, with alarm message	Steady Yellow	One beep, repeated only when a higher priority alarm is cleared	Operator awareness is required.	77DBA - max sound power of 99db
High priority alarm Technical Fault – Critical	Red, with message: "Ventilator Failure— Switch to Backup Ventilation Immediately"	Flashing Red	Same as for high priority alarm, if technically possible. If not, a buzzer sounds. The alarm cannot be silenced.	Provide alternative ventilation (The ventilator enters the Safety Mode, or, if it cannot safely ventilate, the ambient state). Turn off the ventilator. Have ventilator serviced.	77DBA - max sound power of 99db

TABLE 3: OVERVIEW OF ALARM SEVERITY CATEGORIZATION

3.8.3. Quick Alarm Reference Guide

3.8.3.1. General Device Alarms

ALARM	ALARM TYPE	PRIORITY	TRIGGER	PROBABLE CAUSE	WHAT TO DO
Patient Circuit Disconnect Detected	PHYSIOLOGICAL	**HIGH**	Inspiratory pressure falls below threshold (default: PEEP + 9cmH_2O) during inspiration; flow detected in system	Disconnected patient circuit, leaking airway, or leak in breathing circuit	• Check patient's status and airway • Check that circuit is connected to the patient and ventilator • Check circuit for a leak
Circuit Disconnect or Inlet Blocked	PHYSIOLOGICAL	**HIGH**	Low pressure, flow not detected in system	Disconnected patient circuit, blocked ventilator inlet	• Check breathing circuit for disconnection • Check ventilator inlet for blockage
Check for Circuit Leak	TECHNICAL	**HIGH**	Leak associated to 3 of 5 consecutive breaths exceeds calculated leak threshold	Leak in patient breathing circuit	• Check the breathing circuit and proximal lines for disconnection • If NIV, check mask position • Check for circuit leaks
Patient Circuit Occlusion Detected	PHYSIOLOGICAL	**HIGH**	PIP exceeds active P insp setting, and no flow detected	Breathing circuit blockage	• Check the patient's status and airway • Verify breathing circuit tubing is not kinked or obstructed • Verify correct placement of airway and that it is clear of obstructions

ALARM	ALARM TYPE	PRIORITY	TRIGGER	PROBABLE CAUSE	WHAT TO DO
AC Power Disconnected Modal: "Wall supply unplugged; connect to a wall supply if possible"	TECHNICAL	**LOW**	No external power detected	AC power loss or outage, AC power disconnected, damage at connection to external power, power source not plugged in	Confirm operation on internal battery is intended or restore external power: • Check unit connection to power source • If battery power intended, check the external battery charge level and charge /replace if depleted, only while connected to AC • Prepare to ventilate by alternative means if power supply is unavailable
Battery Low (<15%) – No AC Modal: "CONNECT AC IMMEDIATELY!; Battery Low; Do not change battery until AC connected"	TECHNICAL	**HIGH**	Battery at 15% charge, not connected to AC Power	Battery at 15% of capacity	• Connect device to external power source • If battery power intended, check the external battery charge level and charge /replace if depleted, only while connected to AC • Prepare to ventilate by alternative means if power supply is unavailable
Battery Very Low (<10%) – No AC Modal: "CONNECT AC IMMEDIATELY!; Battery Very Low; Do not change battery until AC connected"			Battery at 10% charge, not connected to AC Power	Battery at 10% of capacity	
Battery Almost Out (<5%) – No AC Modal: "CONNECT AC IMMEDIATELY!; Battery Almost Out; Do not change battery until AC connected"			Battery at 5% charge, not connected to AC Power	Battery at 5% of capacity	
Battery Critical (0%) – No AC Modal: "CONNECT AC IMMEDIATELY!; Battery Critical; Do not change battery until AC connected"			Battery at 0% charge, not connected to AC Power	Battery at 0% of capacity	

ALARM	ALARM TYPE	PRIORITY	TRIGGER	PROBABLE CAUSE	WHAT TO DO
Battery Status Unknown Modal: "Battery Status Unknown"	TECHNICAL	**LOW**	Battery status cannot be read by unit	Faulty battery	• Connect device to external power source • Replace battery • Prepare to ventilate by alternative means if power supply is unavailable
Check Pressure Line Connection	TECHNICAL	**HIGH**	Pressure line disconnected or misconnected	Pressure line disconnected	• Check pressure line is properly connected
Flow Sensor Disconnect Modal: "Flow sensor not functioning properly; check flow cable connections; Ventilator in Safety Mode"	TECHNICAL	**HIGH**	No flow sensor detected	Flow sensor disconnected	• Check flow sensor cable is properly connected
ETCO2 Sensor Disconnected Modal: "ETCO2 sensor disconnected"	TECHNICAL	**LOW**	No ETCO2 sensor detected	ETCO2 sensor disconnected	• Check ETCO2 sensor cable is properly connected
FIO2 Sensor Error: No FIO2 Reading Modal: "Patient FIO2 Sensor Error"	TECHNICAL	**HIGH**	Patient FIO2 sensor malfunction	FIO2 sensor problem	• Provide an alternate method of ventilation then contact customer service
Patient FIO2 Sensor Calibration Required Modal: "FIO2 Sensor Calibration Required."	TECHNICAL	**LOW**	Issue with patient FIO2 sensor calibration	Issue with patient FIO2 sensor calibration	• Calibrate sensor when possible • If problems calibrating, service unit
Flow Sensor Problem: Safety Mode Modal: "Flow sensor not functioning properly; check flow cable connections; ventilator in Safety Mode."	TECHNICAL	**HIGH**	No flow sensor detected	Flow sensor disconnected	• Check flow sensor is properly connected

ALARM	ALARM TYPE	PRIORITY	TRIGGER	PROBABLE CAUSE	WHAT TO DO
Check Control Line or Inlet Filter	TECHNICAL	**HIGH**	Control line disconnected or misconnected	Control line disconnected	• Check control line is properly connected • Check that inlet filter is not blocked

TABLE 4: GENERAL DEVICE ALARMS

3.8.3.2. Measured Patient Parameter Alarms

ALARM	ALARM TYPE	PRIORITY	TRIGGER	PROBABLE CAUSE	WHAT TO DO
Low Respiratory Rate	PHYSIOLOGICAL	**MEDIUM**	RR below the Minimum Respiratory Rate limit. (Default: 0)	Patient respiratory rate low	• Check the patient's status and airway • Evaluate and adjust the ventilation settings • Check the circuit connections
High Respiratory Rate	PHYSIOLOGICAL	**HIGH**	RR above the Minimum Respiratory Rate limit. (Default: 40)	Patient respiratory rate high	• Check the patient's status and airway • Evaluate and adjust the ventilation settings
Apnea Detected: In Backup Mode	PHYSIOLOGICAL	**HIGH**	Breath not detected within apnea interval (Defaults to 10 seconds)	Patient does not take breath within apnea interval	• Give manual breath or increase Resp. Rate to a higher value • Check the patient's status and airway • Evaluate and adjust the ventilation settings
Pause Expired	PHYSIOLOGICAL	**HIGH**	PAUSE countdown timer expires (30 seconds)	Device has been paused and no breath has been delivered	• Ventilation will resume automatically

ALARM	ALARM TYPE	PRIORITY	TRIGGER	PROBABLE CAUSE	WHAT TO DO
High Inspiratory Pressure	PHYSIOLOGICAL	**HIGH**	P insp exceeds active P insp alarm limit (Default*:* 30 cmH_2O)	Kinked breathing circuit, blocked airway, low patient lung compliance, high patient airway resistance, vomitus in airway, tension pneumothorax, patient is actively exhaling during the inspiratory phase of the device (may be accompanied by Breath Assist and/or HIGH PEEP alarm)	• Check the patient's status and airway • Check the breathing circuit • Evaluate and adjust the ventilation settings if necessary
Low Inspiratory Pressure	PHYSIOLOGICAL	**HIGH**	Measured patient pressure is below the Minimum P insp alarm limit for 3 breaths. (Default: 6 cmH20)	System or pulmonary leak	• Check the patient's status and airway • Check breathing circuit connection is not leaking • Evaluate and adjust the ventilation settings • Evaluate and adjust the alarm settings
High Tidal Volume	PHYSIOLOGICAL	**HIGH**	Tidal Volume exceeds Max Tidal Volume alarm limit (Default: 115% of the set Tidal Volume) for 3 consecutive breaths or for 3 of the 5 previous breaths	Large patient-initiated breath	• Evaluate the patient's status • Evaluate and adjust the ventilation settings • Evaluate and adjust the alarm settings

ALARM	ALARM TYPE	PRIORITY	TRIGGER	PROBABLE CAUSE	WHAT TO DO
PEEP Exceeds Maximum	PHYSIOLOGICAL	**HIGH**	PEEP exceeds threshold (Default: PEEP setting + 5cmH2O)	Kinked breathing circuit, blocked airway, increased patient Resp Rate, breath stacking	• Check the patient's status and airway • Evaluate and adjust the ventilation settings • Verify Breathing Circuit tubing is not kinked or obstructed
PEEP Below Minimum	PHYSIOLOGICAL	**HIGH**	PEEP falls below threshold (Default: PEEP setting – 3cmH2O)	Kinked or disconnected breathing circuit, system leak	• Check the patient's status • Evaluate and adjust the ventilation settings • Verify Breathing Circuit tubing is not kinked, obstructed, or leaking
Low Tidal Volume	PHYSIOLOGICAL	**HIGH**	Tidal Volume fails to meet Min Tidal Volume Alarm Limit (Default: 85% of the set Tidal Volume) for 3 consecutive breaths or for 3 of the 5 previous breaths	Patient-initiated breaths inadequate	• Check the patient's status and airway • Evaluate and adjust the ventilation settings • Evaluate and adjust the alarm setting • Check for disconnections in breathing circuit or pressure sensor tubing
FIO_2 Below Minimum	PHYSIOLOGICAL	**HIGH**	FIO_2 oxygen reading falls below minimum set threshold (Default: 21%)	Low oxygen	• Check supplemental oxygen supply • Evaluate and adjust the alarm settings
FIO_2 Exceeds Maximum	PHYSIOLOGICAL	**HIGH**	FIO_2 oxygen reading exceeds maximum set threshold (Default: 100%)	Oxygen too high	• Check supplemental oxygen supply • Evaluate and adjust the alarm settings

ALARM	ALARM TYPE	PRIORITY	TRIGGER	PROBABLE CAUSE	WHAT TO DO
$ETCO_2$ Below Minimum	PHYSIOLOGICAL	**HIGH**	$ETCO_2$ oxygen reading falls below minimum set threshold (Default:0 kPa)	Low CO_2	• Check the patient's status and airway • Evaluate and adjust the ventilator settings • Evaluate and adjust the alarm settings
$ETCO_2$ Exceeds Maximum	PHYSIOLOGICAL	**HIGH**	$ETCO_2$ oxygen reading exceeds maximum set threshold (Default: 6 kPa)	CO_2 too high	• Check the patient's status and airway • Evaluate and adjust the ventilator settings • Evaluate and adjust the alarm settings
Low Minute Ventilation	PHYSIOLOGICAL	**HIGH**	Measured minute volume falls below Maximum Minute Ventilation Alarm Limit (Default:0 lpm)	Shallow breaths	• Check the patient's status and airway • Evaluate and adjust the ventilator settings • Evaluate and adjust the alarm settings
High Minute Ventilation	PHYSIOLOGICAL	**MEDIUM**	Measured minute volume exceeds Maximum Minute Ventilation Alarm Limit (Default:30 lpm)	Patient hyperventilation	• Check the patient's status and airway • Evaluate and adjust the ventilator settings • Evaluate and adjust the alarm settings

TABLE 5: MEASURED PATIENT PARAMETER ALARMS

3.8.3.3. Additional Hazard Mitigations

ALARM	ALARM TYPE	PRIORITY	TRIGGER	PROBABLE CAUSE	WHAT TO DO
Technical Fault: Restart	TECHNICAL	**HIGH**	No data / bad data received from the main device CPU	Technical fault	• Restart unit and if Technical Fault persists, ventilate by alternative means and service unit
Technical Fault: Switch to Backup Message Bar: "Technical Fault: Switch to Backup"	TECHNICAL	**HIGH**	Malfunction detected	Technical fault	• If Technical Fault persists, ventilate by alternative means and service unit
High Temperature: Cool Unit Now	TECHNICAL	**HIGH**	Unit internal temperature exceeds threshold	Extreme temperature environment, or extreme operating conditions	• Remove unit from excessive temperature environment • Cool unit • If high temperature persists, ventilate by alternative means and service unit
Unexpected Power down Modal: "Unexpected Power down"	TECHNICAL	**LOW**	Loss of power, technical failure	Loss of power source or technical problem	• Restore power supply • If Technical Fault persists, ventilate by alternative means and service unit
Audio Failure: Switch to Backup Modal: "Audio System Error – Backup in use"	TECHNICAL	**LOW**	Audio system malfunction	Technical fault	• If Technical Fault persists, ventilate by alternative means and service unit
N/A (Screen is not functioning, 10 beep alarm audible)	TECHNICAL	**HIGH**	Touchscreen malfunction	Technical fault	• Ventilate by alternative means • Service unit immediately
High Internal O_2: Switch to Backup	TECHNICAL	**HIGH**	Ambient oxygen level is >25%	Oxygen enriched environment or internal leak	• Remove unit from enriched oxygen environment • Stop flow of O_2 • Ventilate by alternative means • Turn device off, service unit

TABLE 6: ADDITIONAL HAZARD MITIGATION

3.8.3.4. Responding to Alarms

ALARM	PROBABLE CAUSE	WHAT TO DO
AC Power Disconnected Modal: "Wall supply unplugged; connect to a wall supply if possible"	AC power loss or outage, AC power disconnected, damage at connection to external power, power source not plugged in	Confirm operation on internal battery is intended or restore external power: Check unit connection to power source If battery power intended, check the external battery charge level and charge /replace if depleted, only while connected to AC Prepare to ventilate by alternative means if power supply is unavailable
Apnea Detected: In Backup Mode	Patient does not take breath within apnea interval	Give manual breath or increase Resp. Rate to a higher value Check the patient's status and airway Evaluate and adjust the ventilation settings
Audio Failure: Switch to Backup Modal: "Audio System Error – Backup in use"	Technical fault	If Technical Fault persists, ventilate by alternative means and service unit
Battery Critical (0%) – No AC Modal: "CONNECT AC IMMEDIATELY!; Battery Critical; Do not change battery until AC connected"	Battery at 0% of capacity	Connect device to external power source If battery power intended, check the external battery charge level and charge /replace if depleted, only while connected to AC Prepare to ventilate by alternative means if power supply is unavailable
Battery Almost Out (<5%) – No AC Modal: "CONNECT AC IMMEDIATELY!; Battery Almost Out; Do not change battery until AC connected"	Battery at 5% of capacity	
Battery Very Low (<10%) – No AC Modal: "CONNECT AC IMMEDIATELY!; Battery Very Low; Do not change battery until AC connected"	Battery at 10% of capacity	
Battery Low (<15%) – No AC Modal: "CONNECT AC IMMEDIATELY!; Battery Low; Do not change battery until AC connected"	Battery at 15% of capacity	
Battery Status Unknown Modal: "Battery Status Unknown"	Faulty battery	Connect device to external power source If battery power intended, check the external battery charge level and charge /replace if depleted, only while connected to AC Prepare to ventilate by alternative means if power supply is unavailable
Check Control Line or Inlet Filter	Control line disconnected	Check control line is properly connected Check that inlet filter is not blocked
Check Circuit for Leak	Leak in patient breathing circuit	Check the breathing circuit and proximal lines for disconnection If NIV, check mask position Check for circuit leaks
Check Pressure Line Connection	Pressure line disconnected	Check pressure line is properly connected
Circuit Disconnect or Inlet Blocked	Disconnected patient circuit, blocked ventilator inlet	Check breathing circuit for disconnection Check ventilator inlet for blockage

Alarm	Probable Cause	What To Do
ETCO2 Below Minimum	Low CO_2	Check the patient's status and airway Evaluate and adjust the ventilator settings Evaluate and adjust the alarm settings
ETCO2 Exceeds Maximum	CO_2 too high	
ETCO2 Sensor Disconnect Modal: "ETCO2 sensor disconnected"	ETCO2 sensor disconnected	Check ETCO2 sensor cable is properly connected
FIO2 Below Minimum	Low oxygen	Check supplemental oxygen supply Evaluate and adjust the alarm settings
FIO2 Exceeds Maximum	Oxygen too high	
FIO2 Sensor Error: No FIO2 Reading Modal: "Patient FIO2 Sensor Error"	FIO2 sensor problem	Provide an alternate method of ventilation then contact customer service
Flow Sensor Disconnect Modal: "Flow sensor not functioning properly; check flow cable connections; Ventilator in Safety Mode"	Flow sensor disconnected	Check flow sensor cable is properly connected
Flow Sensor Problem: Safety Mode Modal: "Flow sensor not functioning properly; check flow cable connections; ventilator in Safety Mode."	Flow sensor disconnected	Check flow sensor is properly connected
High Minute Ventilation	Patient hyperventilation	Check the patient's status and airway Evaluate and adjust the ventilator settings Evaluate and adjust the alarm settings
PEEP Exceeds Maximum	Kinked breathing circuit, blocked airway, increased patient Resp Rate, breath stacking	Check the patient's status and airway Evaluate and adjust the ventilation settings Verify Breathing Circuit tubing is not kinked or obstructed
High Respiratory Rate	Patient respiratory rate high	Check the patient's status and airway Evaluate and adjust the ventilation settings
High Temperature: Cool Unit Now	Extreme temperature environment, or extreme operating conditions	Remove unit from excessive temperature environment Cool unit If high temperature persists, ventilate by alternative means and service unit
High Internal O_2: Switch to Backup	Oxygen enriched environment or internal leak	Remove unit from enriched oxygen environment Stop flow of O_2 Ventilate by alternative means Turn device off Service unit
Low Minute Ventilation	Shallow breaths	Check the patient's status and airway Evaluate and adjust the ventilator settings Evaluate and adjust the alarm settings
PEEP Below Minimum	Kinked or disconnected breathing circuit, system leak	Check the patient's status Evaluate and adjust the ventilation settings Verify Breathing Circuit tubing is not kinked, obstructed, or leaking
Low Respiratory Rate	Patient respiratory rate low	Check the patient's status and airway Evaluate and adjust the ventilation settings Check the circuit connections

Alarm	Probable Cause	What To Do
High Tidal Volume	Large patient-initiated breath	Evaluate the patient's status Evaluate and adjust the ventilation settings Evaluate and adjust the alarm settings
Low Inspiratory Pressure	System or pulmonary leak	Check the patient's status and airway Check breathing circuit connection is not leaking Evaluate and adjust the ventilation settings Evaluate and adjust the alarm settings
Low Tidal Volume	Patient-initiated breaths inadequate	Check the patient's status and airway Evaluate and adjust the ventilation settings Evaluate and adjust the alarm setting Check for disconnections in breathing circuit or pressure sensor tubing
N/A (Screen is not functioning, 10 beep alarm audible)	Technical fault	Ventilate by alternative means Service unit immediately
Patient Circuit Disconnect Detected	Disconnected patient circuit, leaking airway, or leak in breathing circuit	Check patient's status and airway Check that circuit is connected to the patient and ventilator Check circuit for a leak
Patient Circuit Occlusion Detected	Breathing circuit blockage	Check the patient's status and airway Verify breathing circuit tubing is not kinked or obstructed Verify correct placement of airway and that it is clear of obstructions
Patient FIO2 Sensor Calibration Required Modal: "FIO2 Sensor Calibration Required."	Issue with patient FIO2 sensor calibration	Calibrate sensor when possible If problems calibrating, service unit
Pause Expired	Device has been paused and no breath has been delivered	Ventilation will resume automatically
High Inspiratory Pressure	Kinked breathing circuit, blocked airway, low patient lung compliance, high patient airway resistance, vomitus in airway, tension pneumothorax, patient is actively exhaling during the inspiratory phase of the device (may be accompanied by Breath Assist and/or HIGH PEEP alarm)	Check the patient's status and airway Check the breathing circuit Evaluate and adjust the ventilation settings if necessary
Technical Fault: Restart	Technical fault	Restart unit and if Technical Fault persists, ventilate by alternative means and service unit
Technical Fault: Switch to Backup	Technical fault	If Technical Fault persists, ventilate by alternative means and service unit
Unexpected Power Down Modal: "Unexpected Power down"	Loss of power source or technical problem	Restore power supply If Technical Fault persists, ventilate by alternative means and service unit

TABLE: Responding to Alarms

4. Device Setup: Prepare for Use

4.1. Unboxing Instructions

Inspect the transport container for evidence of damage during transit. If damaged, notify the delivery service immediately. Carefully remove the ventilator and all accessories from the transport container. Confirm presence of all items listed on the packing slip. Notify an authorized sales representative or Ventis Medical of any discrepancies. Examine the ventilator and accessories for visible damage. Do not use ventilator or accessories if damaged. Unless otherwise indicated, the VM-2000 and its accessories are provided clean, not sterile. It is best to keep all accessories packaged until needed.

4.2. Pre-Work Prior to Use

WARNING

Serious harm to the patient may result from the use of unauthorized parts or accessories. To ensure proper performance of the ventilator, only use accessories approved by Ventis Medical.

4.2.1. Verify Contents

Verify the transport container contains the following contents:

QTY	ITEM	PART #
1 EA	Ventilator Unit	VM-2000
1 EA	Flow Sensor Cable	VM-521
1 EA	Flow Sensor	VM-522
1 EA	AC Power Supply	VM-420
1 EA	Inlet Filter (Installed in device)	VM-511

TABLE 7: VENTILATOR PACKAGE CONTENTS

Verify access to the necessary device accessories/disposables that meet specifications listed in **Section 3.3: Device Disposables and Accessories**.

QTY	ITEM
1 EA	Breathing Circuit
1 EA	Breathing Filter
1 EA	HMEF Filter
1 EA	Primary Battery (or Rechargeable)

QTY	ITEM
1 EA	Rechargeable Battery (or Primary)

TABLE 8: DEVICE ACCESSORIES / DISPOSABLES

NOTE

An airway is required for use but is not included with kit. Further, an accessory blender or connector and tubing for use will be required for use with Supplemental Oxygen. Finally, $EtCO_2$ sensor an SpO_2 are recommended for use, when available.

4.2.2. Set Up Power Supply

The VM-2000 is powered by AC wall current through a Class II external power supply, as well as internally through battery power. A battery should always be installed as a backup power supply, even when VM-2000 is connected to wall power. Then, if available, plug in power supply to reliable source, and connect to device. When the VM-2000 is connected to external power using the AC Power Supply (P/N: VM-420), it will operate using external power source. If this source is disconnected, the device will default to run from the battery power supply.

Locate approved primary battery pack (P/N: VM-401) or rechargeable battery pack (P/N VM-402) and insert into the battery slot on the back of the device. It is recommended to charge the rechargeable pack prior to initial use (3 hours) if possible.

When the device is plugged in and running on wall power with a fully charged rechargeable battery, the LED will be a solid green. If the device is running on battery power, the LED will be off. At full capacity, the operational time of the device running on the fully charged rechargeable battery power is approximately 8 hours. The operational time of the device running on a new, full primary battery pack is approximately 6 hours. Alarms are in place to detect and alert the operator of low-battery criteria.

FULLY CHARGED	DESCRIPTION
At 15% of capacity	A Low Priority Alarm will sound. At least 1 hour of power remain in the device.
At 10% of capacity	A Medium Priority Alarm will sound. At least 45 min of power remain in the device.
At 5% of capacity	A High Priority Alarm will sound. At least 20 minutes of power remain in the device.
At 0% of capacity	A High Priority Alarm will sound. At least 2 minutes of power remain.

CAUTION

Only use power accessories approved by Ventis Medical.

Use caution when connecting to unreliable power sources. When connecting power supply to an AC power source, follow power input specifications of 100-240VAC, 50-60Hz, 1.5A.

5. VM-2000: Instructions for Use

5.1. Set Up Breathing Circuit for Use and Verify Proper Operation

5.1.1. Set up Breathing Circuit

Prior to set-up and use, validate that all components are free of damage and safe to use. The initial set-up consists of four primary external components: (1) Patient Breathing Circuit, (2) Flow Sensor, (3) Flow Sensor Cable, and (4) Breathing Filter or a HMEF.

Locate unused Breathing Circuit, Flow Sensor, Flow Sensor Cable, and Breathing Filter/HMEF in their original packaging. If operating with Supplemental Oxygen, also locate an Air/Gas Reservoir per the specifications listed under **Device Disposables and Accessories**.

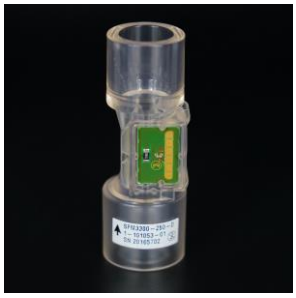
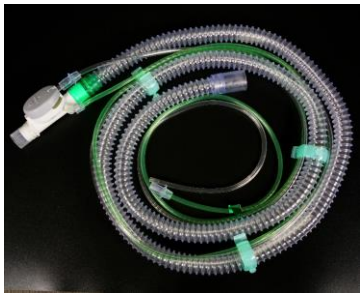
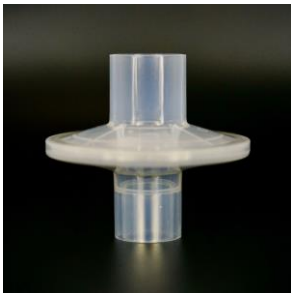


FIGURE 12-A: FLOW SENSOR (LEFT) AND FIGURE 12-B: FLOW SENSOR CABLE (RIGHT)





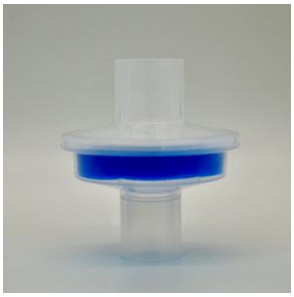
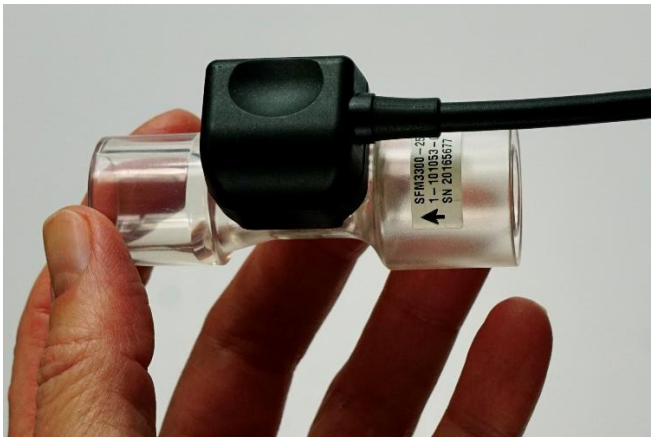
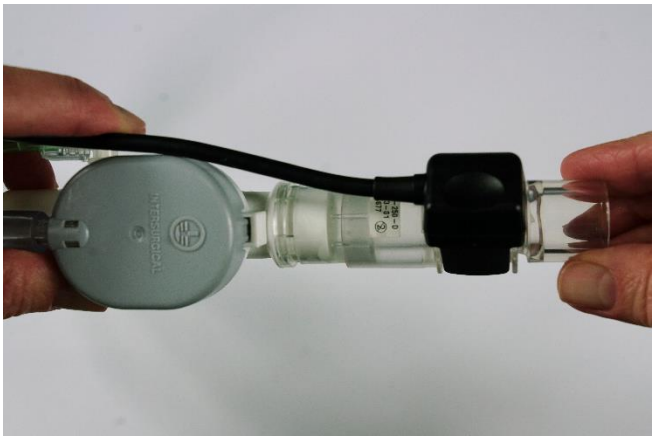


FIGURE 12-C: BREATHING CIRCUIT (LEFT) AND FIGURE 12-D: BREATHING FILTER (MIDDLE) AND FIGURE 12-E: HMEF

#	DESCRIPTION
1	Remove parts from packaging.
2	Connect Flow Sensor Cable to Flow Sensor by snapping connector into place, as shown below.  ***FIGURE 12-F: FLOW SENSOR CONNECTION TO FLOW SENSOR CABLE***
	WARNING Do not to touch the flow sensor pins and the patient at the same time to comply with patient safety requirements.
3	Connect Flow Sensor to the patient site of the Breathing Circuit as shown in **Figure 13: Flow Sensor Connection to Breathing Circuit**.  ***FIGURE 13: FLOW SENSOR CONNECTION TO BREATHING CIRCUIT***

#	DESCRIPTION
4	To prevent contamination between the patient and the environment, connect standard Breathing Filter or HMEF to Breathing Circuit by placing it on the patient side of the Flow Sensor.

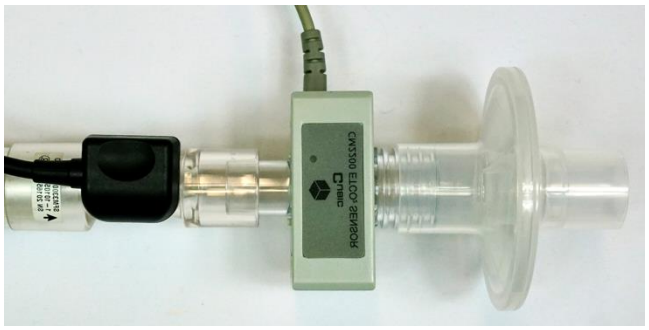


FIGURE 14: BREATHING FILTER CONNECTION TO BREATHING CIRCUIT

CAUTION

To minimize the risk of bacterial contamination or physical damage, handle breathing filter with care.

To prevent patient or ventilator contamination, always use a bacterial filter between the flow sensor and the patient airway.

5.1.2. Connect $ETCO_2$ Sensor to Breathing Circuit (Optional)

Optionally, connect the main-stream $ETCO_2$ sensor as shown below.

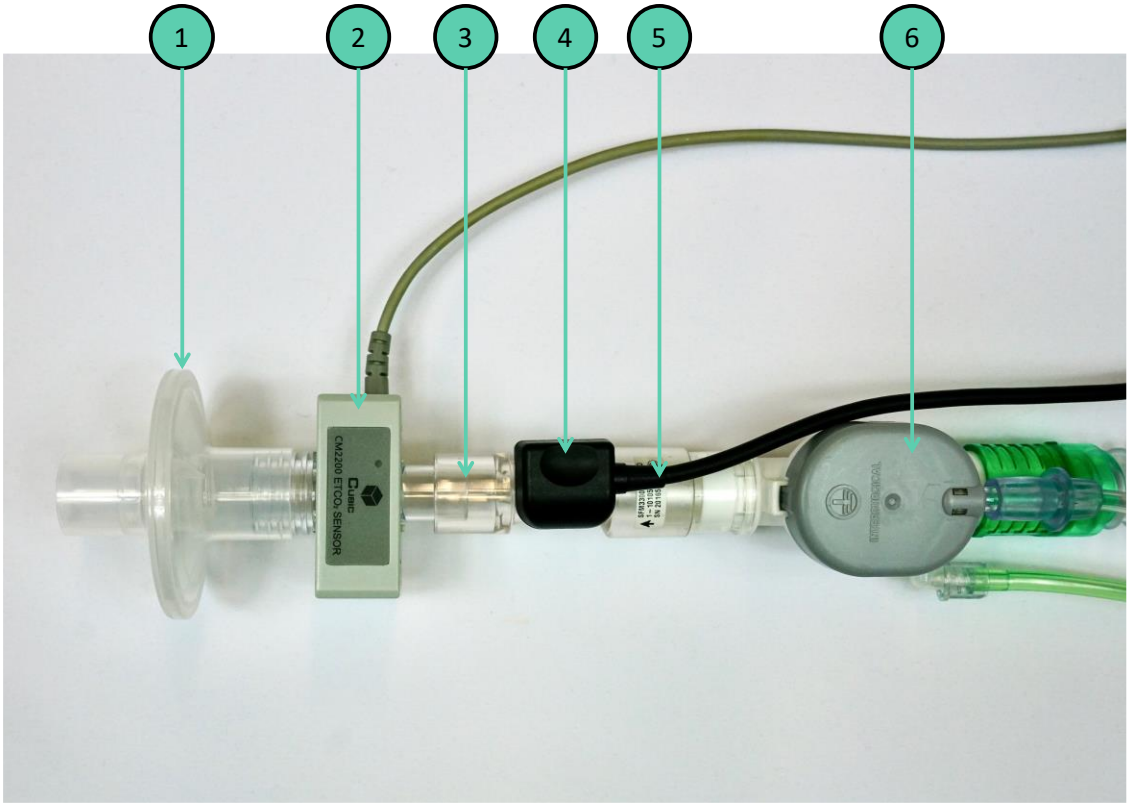
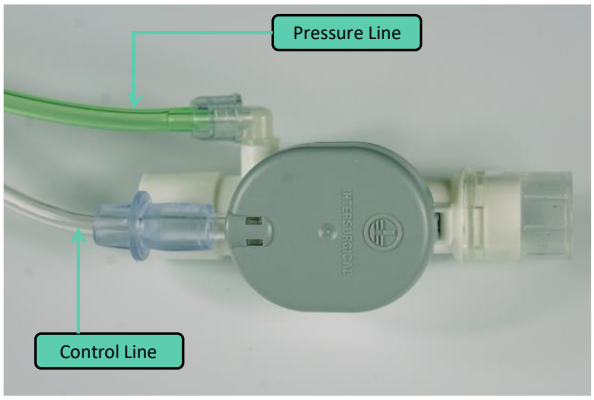
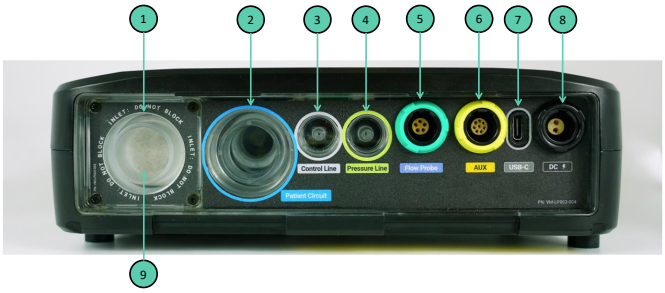


FIGURE 15: ASSEMBLED BREATHING CIRCUIT WITH ETCO2

ITEM	DESCRIPTION
1	**Patient Breathing Filter**
2	**$ETCO_2$ Sensor**
3	**$ETCO_2$ Airway Adaptor**
4	**Flow Sensor**
5	**Flow Sensor Cable**
6	**Breathing Circuit**

5.1.3. Connect Breathing Circuit to Ventilator

Prior to use, inspect the Breathing Circuit to verify it has been assembled correctly with no visible signs of damage (**See Figure 15: Assembled Breathing Circuit with $ETCO_2$**).

#	DESCRIPTION	
1	Identify the Control Line and the Pressure Monitoring Line on the Patient Circuit.	 ***FIGURE 16: CONTROL AND PRESSURE MONITORING LINE***
2	Connect the terminal ends of the four unique cables from the assembled Breathing Circuit to their respective port on the ventilator. A. Connect the termination of the Breathing Circuit to the port labeled **Patient Circuit**. B. Connect the termination of the Control Line to port labeled **Control Line.** C. Connect the termination of the Pressure Monitoring Line to port labeled **Pressure Line.** D. Connect the termination of the Flow Sensor Cable to the port labeled **Flow Probe**.	 ***FIGURE 17: PORT PLATE CONNECTIONS (NOTE THAT (6) $ETCO_2$ PROBE IS AN OPTIONAL ACCESSORY)***
3	After assembly, ensure that the Breathing Circuit is properly positioned by preventing cables from being pushed, pulled, or kinked during the patient's movement or other procedures.	

WARNING

Do not block the Air/Gas Inlet.

Failure to properly connect the Breathing Circuit and accessories may materially impact device performance.

Only use Breathing Circuits expressly approved by Ventis Medical for use with the VM-2000 Ventilator.

Do not use damaged or misassembled Breathing Circuits.

Always dispose of the circuit after each patient use following the institutional guidelines for biologically contaminated material. Reusing the circuit can result in cross contamination between patients.

To prevent possible patient injury, make sure the ventilator is set up for the appropriate patient type with the appropriate breathing circuit parts before delivering ventilation.

NOTE

If operating in an environment where water may drip on or near the ventilator unit, refer to instructions in Step 3 to attach Air/Gas Reservoir to Inlet port.

5.1.4. Power On

The ventilator can be powered on by pressing the On/Off Power Button located on the front of the device (**See Figure 18: Power On).** The device will proceed to perform an automated system pre-check of software to validate proper initialization of device software function (including controls, alarms, and ventilation). If the device successfully passes pre checks, the Operational Status bar will read: **Manual Mode: Ready to Ventilate**. If the screen does not display this message, the device has failed system prechecks. If the precheck fails, do not use device: provide alternative ventilation using backup source and have ventilator serviced.

CAUTION

To prevent possible patient injury, make sure the ventilator is set up for the appropriate patient type with the appropriate breathing circuit accessories.

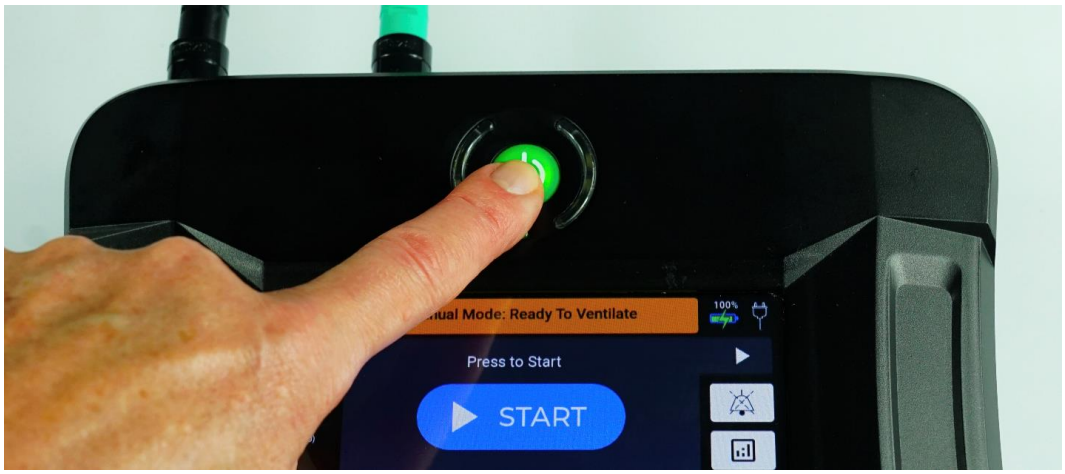


FIGURE 18: POWER ON

5.1.5. Turn Device On

1. Plug the device into the nearest uninterrupted power outlet.
2. Turn the ventilator on by pressing the On/Off Power Button as shown in **Figure 18: Power On**.
3. Allow device to Power On.
4. Once the device is ready to begin ventilation, the Operational Status Bar will display: **Manual Mode: Ready to Ventilate.** The ventilator is ready for patient-use.

5.1.6. Verify Basic Functionality

1. Prior to attaching patient airway, place a cap or a gloved hand over the end of the breathing circuit
2. Select **START** 

to initiate continuous ventilation using default ventilator presets.
3. Verify that the expected audio and visual alarm response for Breathing Circuit Obstruction is triggered per **Table 3: Overview of Alarm Severity Categorizations**.
4. Remove the cap and verify that the expected audio and visual alarm response for Patient Disconnect is triggered per **Table 3: Overview of Alarm Severity Categorizations**.
5. If either alarm response is not observed, provide alternative ventilation, turn off the VM-2000, and have ventilator serviced.
6. Refer to additional recommended steps to verify alarm response listed in **Section 3.8.1 Pre Use Checks**
7. If expected alarm response is observed from conditions produced in Step 3 - 6, proceed to 5.1.7 Attach Airway.

5.1.7. Attach Airway

An airway is necessary to channel air from the Patient Breathing Circuit to the patient. The Breathing Circuit can be connected to a variety of airways using the standard 22mm O.D. / 15mm I.D. patient connection port. The VM-2000 should always be used with an airway that is appropriate based on the training of the provider and needs of the patient. Read and follow separate airway Instructions for Use. To attach airway:

1. Attach/secure airway to patient by following Instructions for use of selected airway.
2. Attach Breathing Circuit to airway at patient connection port.
3. Once ventilation begins, evaluate the patient, and verify the rise and fall of the chest as well as the absence of Alarms. Monitor pulse oximeter if available.

WARNING

Rebreathing CO_2 should be minimized. Place the device as close to the patient as possible.

The ventilation supplied to the patient can be adversely affected by the gas added using a pneumatic nebulizer.

CAUTION

Refer to the Instruction for Use of the airway used for further instruction.

5.2. Initialize Ventilatory Settings and Start Ventilation

Presets are automatically defaulted as outlined in **Table 9: Ventilator Presets by Mode**. Before ventilation, users should validate that an appropriate Tidal Volume is selected. Select **START** 

once ventilatory settings have been initiated to begin ventilation.

WARNING

Do not cover the ventilator or place in a position that affects proper operation. Avoid positioning the ventilator in a place where cables may become pushed, pulled, or kinked during the patient's movement or other procedures.

PARAMETER	AC	SIMV
Tidal Vol. (mL)	500	500
Resp. Rate (BPM)	12	12
PEEP (cmH_2O)	5	5
P Support (cmH_2O)	N/A	10
T insp (sec)	1.0	1.0
P insp Alarm (cmH_2O)	30	30
Sensitivity (LPM)	3	3

TABLE 9: VENTILATOR PRESETS BY MODE

NOTE

Before proceeding, verify that the ventilator is set up as instructed in the instructions to **Setup Breathing Circuit for Use and Verify Proper Operation** (**See Figure 15: Assembled Breathing Circuit**). Additionally, refer to **Controls** section of this document to become familiar with touch screen controls (including to select, activate, and confirm parameters) prior to use.

5.2.1. Begin Ventilation

1. Review default settings on the Ventilatory Settings Pane. See **Table 11: Ventilatory Settings** for details on setting definitions, accuracy, and other information.
2. The pre-set default settings from **Table 9: Ventilator Presets by Mode** can be re-initialized by pressing the **New Patient** button on the home screen.
3. If unsure of target Tidal Volume, Refer to **Table 12-A: Quick Reference for Tidal Volume (Male)** or **Table 12-B: Quick Reference for Tidal Volume (Female)** for clinical guidance on recommended Tidal Volume based on patient height.
4. For instructions on how to adjust Tidal Volume setting, refer to 5.2.2**: Modify Settings.**
5. For instructions on how to adjust other settings, refer to 5.2.2: **Modify Settings**.
6. To deliver a manual trigger breath before beginning continuous ventilation, refer to **Section 5.8 Manual Trigger Breath**.
7. Once desired settings have been set and validated, select **START** 

to initiate ventilation.
   a. Monitor the patient and verify adequate chest rise.
   b. Refer to information in the **Alarm** section for information on how to respond to alarms.

5.2.2. Modify Settings

The ability to deliver a more targeted and consistent therapy by adjusting the settings if clinically indicated. If the situation allows, qualified operators can adjust desired Mode, Tidal Vol, Respiratory Rate, PEEP, PIP, T Insp, P insp and Sensitivity. This section defines how to adjust settings for ventilation on an

individual patient from the preset values. Settings can be adjusted prior to initiating or during active ventilation.

5.2.2.1. Setting details - Ventilation Modes

WARNING

To prevent possible patient injury, DO NOT use noninvasive ventilation on patients with no or irregular spontaneous breaths. Noninvasive ventilation is intended to provide supplemental ventilatory support to patients with regular spontaneous breaths.

VM-2000 can be operated in any of the following Modes, either in invasive or non-invasive mode:

MODE	VENTILATION TYPE	DESCRIPTION
Assist/Control (AC)	Assist Control – Volume Controlled	Ventilator delivers a fully supported mandatory breath whether ventilator (time) or patient triggered. A primary Mode of ventilation used in respiratory failure.
SIMV	Synchronized Intermittent Mandatory Ventilation – Volume Controlled	Both mandatory ventilator initiated breaths, and patient-initiated breaths may be delivered in the SIMV Mode. The ventilator delivers a mandatory, fully supported breath, when time triggered. However, when the breath is patient triggered, the ventilator provides pressure supported inspiration (Range: 0 to 60 cm H2O) when flow is detected above a minimum threshold. The volume of the patient-triggered breath depends on lung compliance and patient's effort.
CPAP	Continuous Positive Airway Pressure	CPAP is active when SIMV is selected, Respiratory Rate is set to 0, and Pressure Support is set to 0. In CPAP mode, when a patient trigger is detected, a patient breath is given. Breaths will be Pressure Support or Spontaneous breaths according to the Pressure Support setting.
NPPV	Non Invasive Positive Pressure Ventilation	NPPV is used when the patient interface is a mask, rather than an invasive conduit such as an endotracheal tube. In NPPV, the VM-2000 will compensate for leaks. NPPV is a secondary mode that can be delivered in any ventilatory mode.

TABLE 10: VM-2000 MODES

For each Mode, the following list of settings can be modified. All specifications include a tolerance of +/- 10% of nominal value unless stated otherwise. Delivered Tidal Volume may be materially affected by low lung compliance (<0.01 L / cm H_2O)

5.2.2.2. Settings details device parameters

VALUE	DESCRIPTION	INCR.	RANGE	ACCURACY
Tidal Vol. (mL)	The Tidal Vol. setting controls the volume of gas delivered to the patient in each breath. To maintain a desired Minute Volume (TV x RR), the Tidal Volume may be decreased (to avoid reaching the PIP Limit) and the RR may be increased.	± 1 mL	200 – 2000 mL	+/- 10%
Resp. Rate (BPM)	The Resp. Rate setting controls the target number of breaths delivered to the patient in a minute.	± 1 BPM	0 – 40 BPM	+/- 1
PEEP (cmH_2O)	The PEEP (Positive End Expiratory Pressure) setting controls the positive pressure that will remain in the airway at the end of a respiratory cycle. VM-2000 is designed to safely reach targeted PEEP value by slowly incrementing PEEP with each breath. VM-2000 may take up to a minute to reach targeted PEEP value. WARNING Specifications listed are for APPROVED breathing circuits only. If a breathing circuit is used that has not been approved for use with VM-2000, the range and accuracy of PEEP delivered may vary.	± 1 cmH_2O	0 – 20 cmH_2O	+/- (2+4% PEEP setting)
P Support (cmH_2O)	The P Support setting controls inspiratory Pressure Support delivered during patient triggered breaths in SIMV mode. The level of pressure support is the level above PEEP.	± 1 cmH_2O	0 – 60 cmH_2O	+/- (2+4% setting)
T insp (seconds)	The T insp controls the duration of time for the inspiration portion of the breath.	± 0.1s	.3 to 5.0s	+/- 10%

P insp. Alarm (cmH_2O)	The P insp. Alarm setting controls the PIP limit during the Inspiratory Phase. When the P insp. control is reached, the gas flow rate to the patient will be decreased to keep the Peak Inspiratory Pressure at or below the limit until the exhalation phase is triggered. If the inspiratory pressure exceeds the maximum threshold permissible by the device, the unit will enter the exhalation phase to prevent barotrauma. In this scenario, an audible and visual alarm indicator will be triggered. Transient high-pressure increases may occur – clinical judgement is required in these cases.	± 1 cmH_2O	15 – 90 cmH_2O	+/- (2+4% setting)
	WARNING If PIP alarm limit is reached, VM-2000 will limit the inspiratory phase and less Tidal Volume than set will be delivered to patient.			
Sensitivity	The sensitivity setting determines the minimum negative flow limit necessary to trigger a delivery.	--	1 – 9 LPM and OFF (OFF only in AC mode)	+/- 10%

TABLE 11: VENTILATORY SETTINGS

5.2.3. Determining Tidal Volume:

Tidal Volume should be set based upon Predicted Body Weight (PBW). Recommendations are provided per AHRQ Safety Program for Mechanically Ventilated Patients (KG = kilogram; mL = milliliter; PBW = predicted body weight)[1]

It has been shown that when Tidal Volume is based on clinician estimation of need or visual estimation of height, it is frequently overestimated. To calculate predicted body weight (PBW) mL/KG:

- PBW (male) = 50 + [[height (inches) – 60] X 2.3]
- PBW (female) = 45.5 + [[height (inches) – 60]X 2.3]

NOTE

For transgender or transsexual patients, use their gender assignment prior to their transition when referencing these tables, not their current gender.

See **Table 12-A Quick Reference for Tidal Volume (Male)** and Table 12-B: **Quick Reference for**

[1] Low Tidal Volume Ventilation Guide for Reducing Ventilator-Associated Events in Mechanically Ventilated Patients. 2017 Jan; AHRQ Pub. No. 16(17)-0018-5-EF

Tidal Volume (Female) for standard guidance.

5.2.4. Male: Tidal Volume Reference (Low Tidal Volume Ventilation)

HEIGHT (In.)	PBW (KG)	PBW (LB)	6 mL/KG (2.7 mL/LB)
4'7" (55")	38.5	84.9	230
4'8" (56")	40.8	89.9	250
4'9" (57")	43.1	95.0	260
4'10" (58")	45.4	100.1	270
4'11" (59")	47.7	105.2	290
5'0" (60")	50	110.2	300
5'1" (61")	52.3	115.3	320
5'2" (62")	54.6	120.4	330
5'3" (63")	56.9	125.4	340
5'4" (64")	59.2	130.5	360
5'5" (65")	61.5	135.6	370
5'6" (66")	63.8	140.7	390
5'7" (67")	66.1	145.7	400
5'8" (68")	68.4	150.8	410
5'9" (69")	70.7	155.9	430
5'10" (70")	73	160.9	440
5'11" (71")	75.3	166.0	450
6'0" (72")	77.6	171.1	470
6'1" (73")	79.9	176.1	480
6'2" (74")	82.2	181.2	500
6'3" (75")	84.5	186.3	510
6'4" (76")	86.8	191.4	520

TABLE 12-A: QUICK REFERENCE FOR TIDAL VOLUME (MALE)

5.2.5. Female: Tidal Volume Reference (Low Tidal Volume Ventilation)

HEIGHT	PBW (KG)	PBW (LB)	6 mL/KG (2.7 mL/LB)
4'7" (55")	34	75.0	210
4'8" (56")	36.3	80.0	220
4'9" (57")	38.6	85.1	230
4'10" (58")	40.9	90.2	250
4'11" (59")	43.2	95.2	260
5'0" (60")	45.5	100.3	280
5'1" (61")	47.8	105.4	290
5'2" (62")	50.1	110.5	300
5'3" (63")	52.4	115.5	320
5'4" (64")	54.7	120.6	330

HEIGHT	PBW (KG)	PBW (LB)	6 mL/KG (2.7 mL/LB)
5'5" (65")	57	125.7	340
5'6" (66")	59.3	130.7	360
5'7" (67")	61.6	135.8	370
5'8" (68")	63.9	140.9	390
5'9" (69")	66.2	145.9	400
5'10" (70")	68.5	151.0	410
5'11" (71")	70.8	156.1	430
6'0" (72")	73.1	161.2	440
6'1" (73")	75.4	166.2	450
6'2" (74")	77.7	171.3	470
6'3" (75")	80	176.4	480
6'4" (76")	82.3	181.4	500

TABLE -B: QUICK REFERENCE FOR TIDAL VOLUME (FEMALE)

5.2.6. Steps to Modify Settings

The Ventilatory Settings Panel, located on the bottom of the display, consists of the most important ventilation controls. Here, clinicians/physicians can access the primary Modes to use for ventilatory delivery, and associated settings.

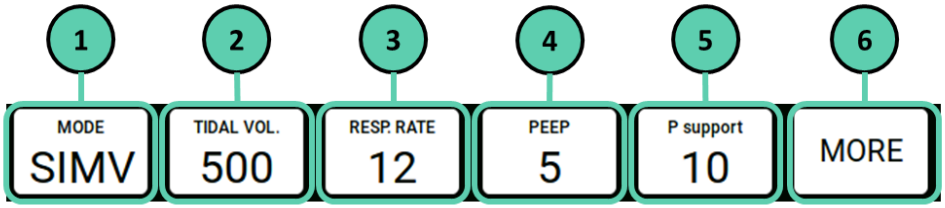


FIGURE 19: CHANGING SETTINGS – VENTILATORY SETTINGS PANE (PRIMARY)

1	Mode Control	**4**	PEEP Control
2	Tidal Volume Control	**5**	P Support Control
3	Respiratory Rate Control	**6**	More

The user can select More (**See Figure 19: Changing Ventilatory Settings – Ventilatory Settings Pane (Primary)**) from the home screen to access additional controls.

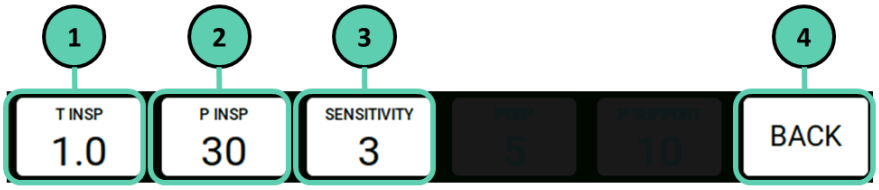


FIGURE 20: CHANGING SETTINGS – VENTILATORY SETTINGS PANE (MORE)

1	T insp Control	**3**	Sensitivity Control
2	P insp Control	**4**	Back - Return to Primary Controls

5.2.6.1. Modify Tidal Volume

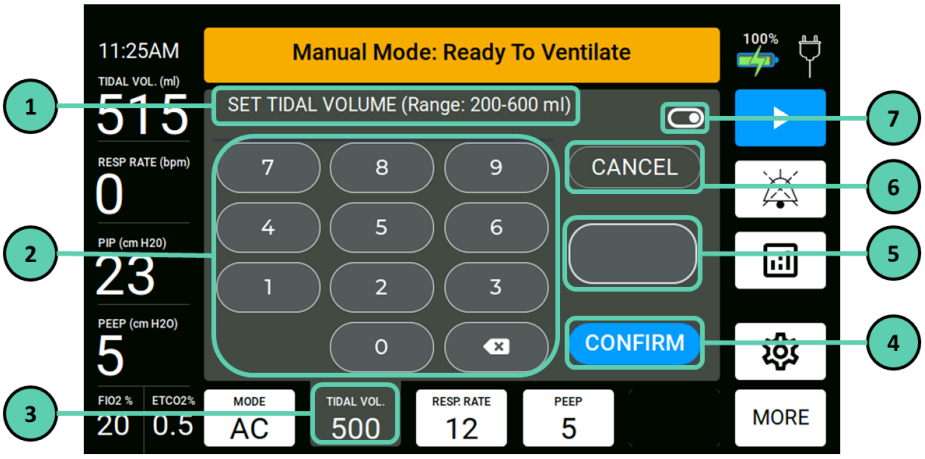


FIGURE 21: TIDAL VOLUME CONTROL WINDOW

1	Parameter and Range	**5**	Preview Parameter
2	Keypad for Parameter Entry	**6**	Cancel
3	Active Parameter Value	**7**	Slider Input Screen Toggle
4	Confirm Parameter		

1. To modify Tidal Volume, select the Tidal Volume Control on the Ventilatory Settings Pane to open the Tidal Volume Control Window.
2. Use keypad to enter target Tidal Volume.
3. Once target Tidal Volume value is set, select CONFIRM to apply change. If general action needs to be reverted, select CANCEL to exit screen.

5.2.6.2. Modify Respiratory Rate

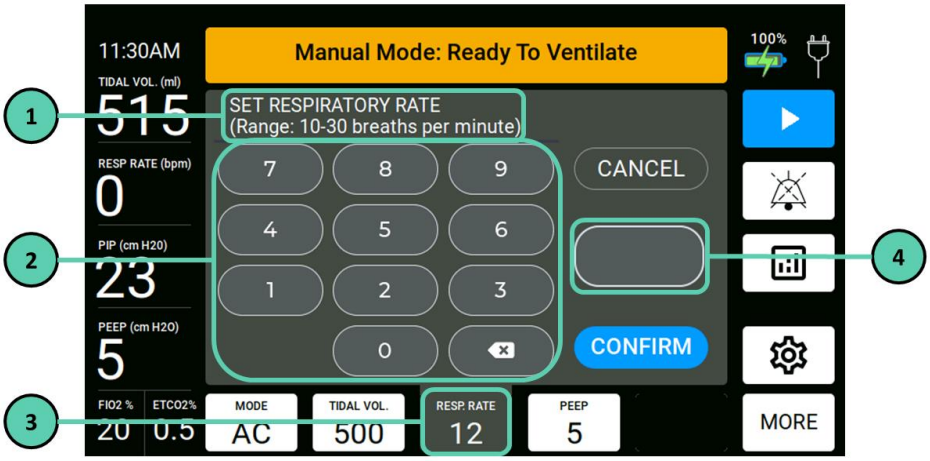


FIGURE 22: RESP. RATE CONTROL WINDOW

1	Parameter and Range	**3**	Active Parameter Value
2	Keypad for Parameter Entry	**4**	Preview Parameter

1. To modify Resp. Rate, select the Resp. Rate Control on the Ventilatory Settings Pane to open the Resp. Rate Control Window.
2. Use keypad to enter target Resp. Rate
3. Once target Resp. Rate value is set, select CONFIRM to apply change. If general action needs to be reverted, select CANCEL to exit screen.

5.2.6.3. *Modify PEEP*

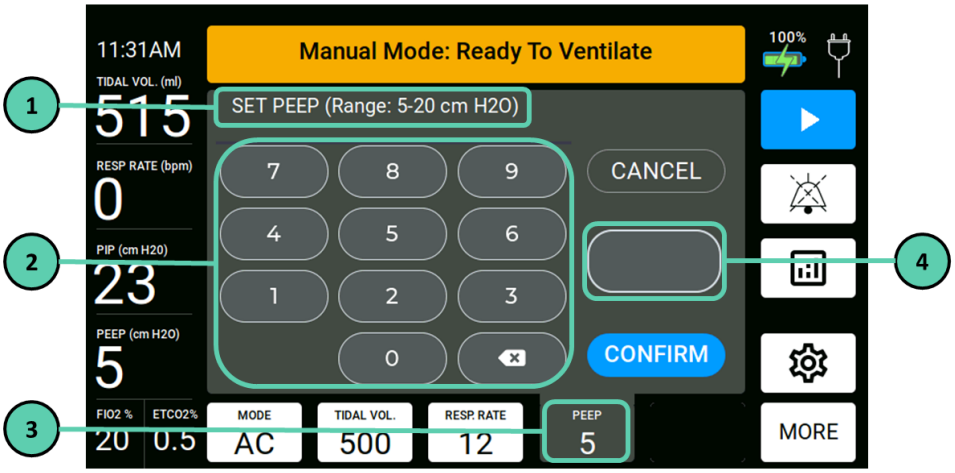


FIGURE 23: PEEP CONTROL WINDOW

1	Parameter and Range	**3**	Active Parameter Value
2	Keypad for Parameter Entry	**4**	Preview Parameter

1. To modify PEEP, select the PEEP Control on the Ventilatory Settings Pane to open the PEEP Control Window.
2. Use keypad to enter target PEEP
3. Once target PEEP value is set, select CONFIRM to apply change. If general action needs to be reverted, select CANCEL to exit screen.

5.2.6.4. *Modify T insp*

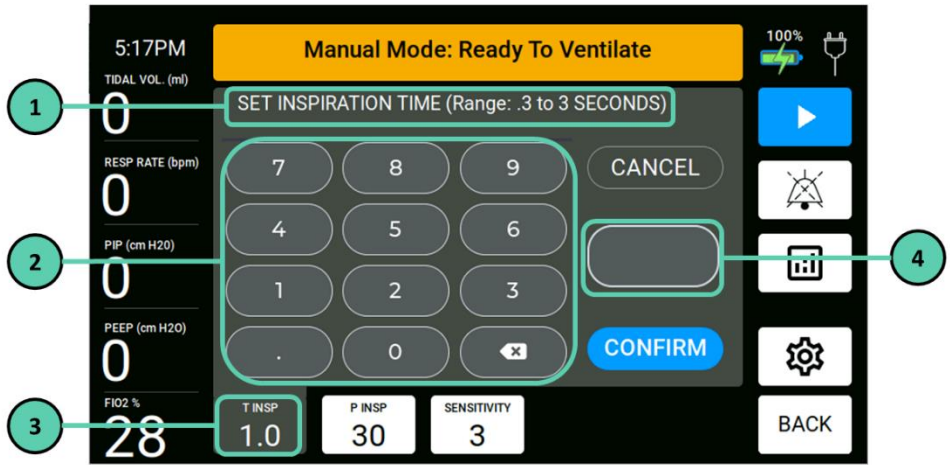


FIGURE 23: T INSP CONTROL WINDOW

1	Parameter and Range	**3**	Active Parameter Value
2	Keypad for Parameter Entry	**4**	Preview Parameter

1. To modify T insp, select the T insp Control on the Ventilatory Settings Pane.
2. Enter the desired T insp in seconds to the nearest tenth of a second between .3 and 2.0.
3. Once target T insp value is entered, select CONFIRM to apply change. If general action needs to be reverted, select CANCEL to exit screen.
4. Select Exit on the Ventilatory Settings Pane to return to main ventilator settings if desired.

5.2.6.5. *Modify P insp*

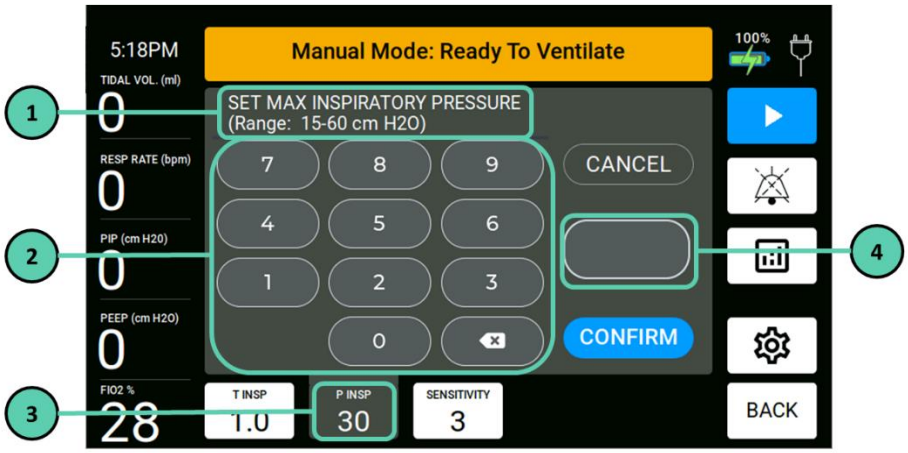


FIGURE 23: P INSP CONTROL WINDOW

1	Parameter and Range	**3**	Active Parameter Value
2	Keypad for Parameter Entry	**4**	Preview Parameter

1. To modify P insp, select the P insp on the Ventilatory Settings Pane to open the P insp Control Window.
2. Use keypad to enter target P insp Value.
3. Once target P insp value is set, select CONFIRM to apply change. If general action needs to be reverted, select CANCEL to exit screen.

5.2.6.6. *Modify P Support*

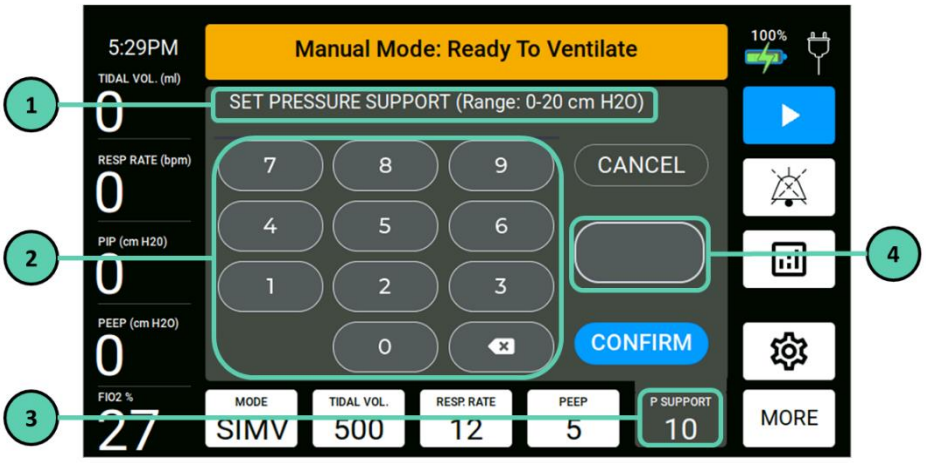


FIGURE 25: MODIFY P SUPPORT

1	Parameter and Range	**3**	Active Parameter Value
2	Keypad for Parameter Entry	**4**	Preview Parameter

1. To modify Pressure Support, select the P Support Control on the Ventilatory Settings Pane to open the P support Control Window. P Support will only be applied when the device is in SIMV mode.
2. Use keypad to enter target P Support Value.
3. Once target P Support value is set, select CONFIRM to apply change. If general action needs to be reverted, select CANCEL to exit screen.

5.2.6.7. Modify Sensitivity

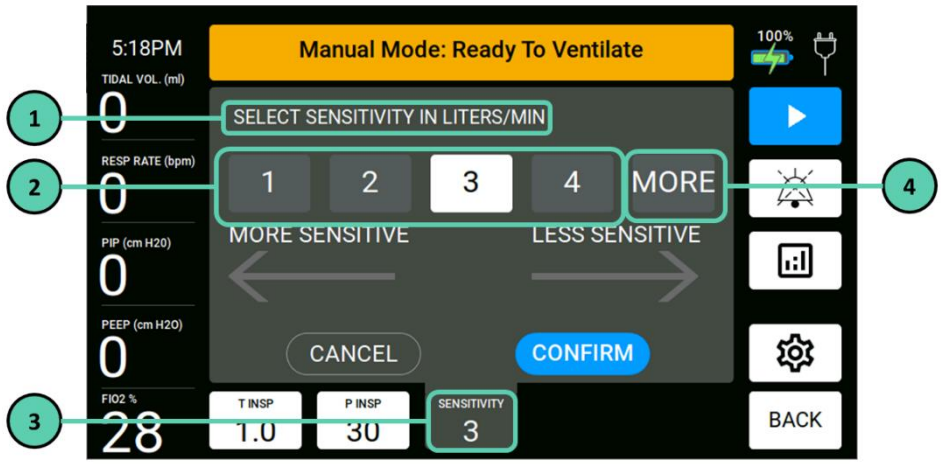


Figure 25: Modify Sensitivity

1	Parameter and Units	**3**	Active Parameter Value
2	Selection Options	**4**	More Options

1. To modify Sensitivity, select Sensitivity Control on the Ventilatory Settings Pane.
2. You will see the available options for Sensitivity. Tap on the desired setting.
3. SMALLER SENSITIVITY VALUES are MORE SENSITIVE (1 most sensitive, 4 least sensitive).
4. MORE allows selection of sensitivities 5 – 9 and OFF which DISABLES PATIENT TRIGGERING and is only active in AC mode.
5. Once target Sensitivity value is Selected, select CONFIRM to apply change. If general action needs to be reverted, select CANCEL to exit screen.
6. Select Exit on the Ventilatory Settings Pane to return to main ventilator settings if desired.

5.2.7. Modify Mode

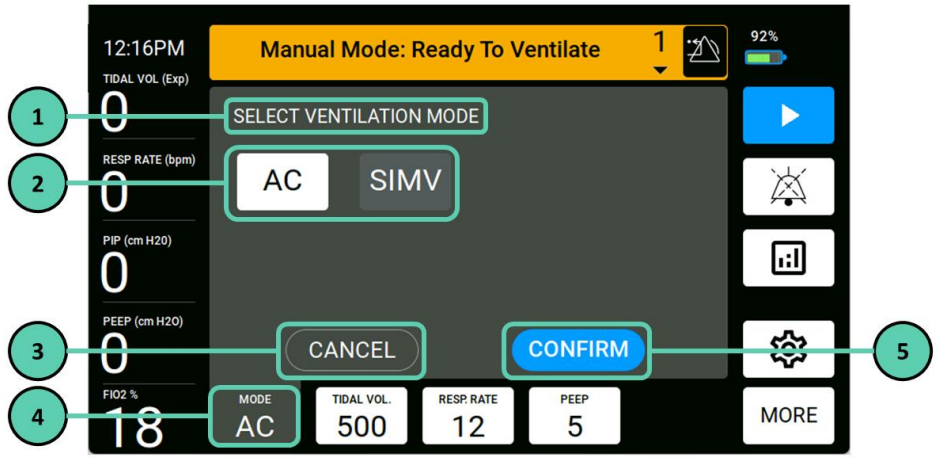


FIGURE 26: MODE CONTROL WINDOW

1	Parameter	**4**	Active Parameter Selection
2	Parameter Selection Options	**5**	Confirm
3	Cancel		

4. To modify Mode, select the Mode Control on the Ventilatory Settings Pane to open the Mode Control Window.
5. Use Selection buttons to enter target Mode.
6. Once target Mode is set, select CONFIRM to apply change. If general action needs to be reverted, select CANCEL to exit screen.

When first starting to ventilate a patient, the ventilator will default to AC mode. Adjust Mode, if needed, using the following instructions:

AC: AC Mode can be applied through the Mode control on the Ventilatory Settings Pane.

1. Select the Mode Control in the Ventilatory Settings Pane.
2. Select AC
3. Select CONFIRM to apply changes to the Mode. If previously selected settings not available in the new mode, the unit will default to the closest available allowed settings.
4. Updated Mode will only be applied when CONFIRM is selected.

SIMV: SIMV Mode can be applied through the Mode control on the Ventilatory Settings Pane.

1. Select the Mode Control in the Ventilatory Settings Pane.
2. Select SIMV
3. Select CONFIRM to apply changes to the Mode. *If previously selected settings not available in the new mode, the unit will default to the closest available allowed settings.*
   Updated Mode will only be applied when CONFIRM is selected.

CPAP: CPAP mode can be initiated when the VM-2000 is operating in SIMV mode, by modifying the P Support and Respiratory Rate values.

1. If not already operating in SIMV mode, select the Mode Control in the Ventilatory Settings Pane.
2. Select SIMV
3. Select CONFIRM to apply changes to the Mode (If previously selected settings not available in the new mode, the unit will default to the closest available allowed settings.).
4. Updated Mode will only be applied when CONFIRM is selected.
5. Select Resp Rate form the Ventilatory Settings Pane
6. Set Respiratory Rate to 0
7. Select CONFIRM to apply changes to the Respiratory Rate.
8. Select P Support from the Ventilatory Settings Pane
9. Select appropriate P Support value based on desired therapy
    - **For CPAP:** set P Support to 0
    - **For CPAP with Pressure Support:** Adjust P Support to the clinically appropriate value
10. Select CONFIRM to apply changes to P Support and apply CPAP mode

NPPV: Non invasive Ventilation is available in AC, SIMV, and CPAP modes by following the instructions outlined above for mode selection. No additional settings need to be applied to operate the VM-2000 using NPPV.

5.2.8. Modify Alarm Limit Settings

CAUTION

Alarm Limits: Setting the alarm limits to extreme values can render the alarm system useless.

The Alarm Limits for the following are settable:

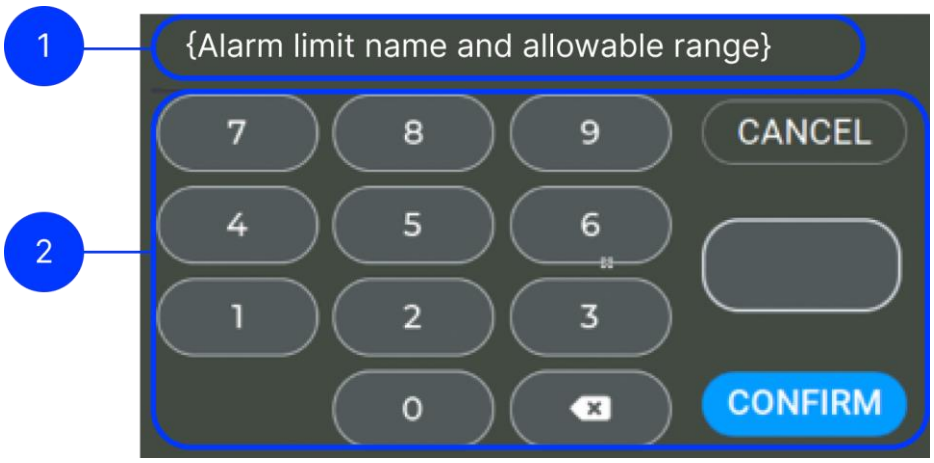
- Inspiratory Pressure
- Respiratory Rate
- Tidal Volume
- FIO2
- ETCO2
- Minute Ventilation

To modify these parameters, select the setting icon in the bottom righthand corner of the device screen. Next select the category of alarm limit that need to be set and modify the value using the numerical controls displayed in the screen.

To modify these parameters, select the setting icon in the bottom righthand corner of the device screen. Next select the category of alarm limit that need to be set and modify the value using the numerical controls displayed in the screen. To set an adjustable alarm limit:

- Navigate to the alarm settings screen
- Select the alarm that you want to adjust
- Adjust using the standard keypad interface as shown below

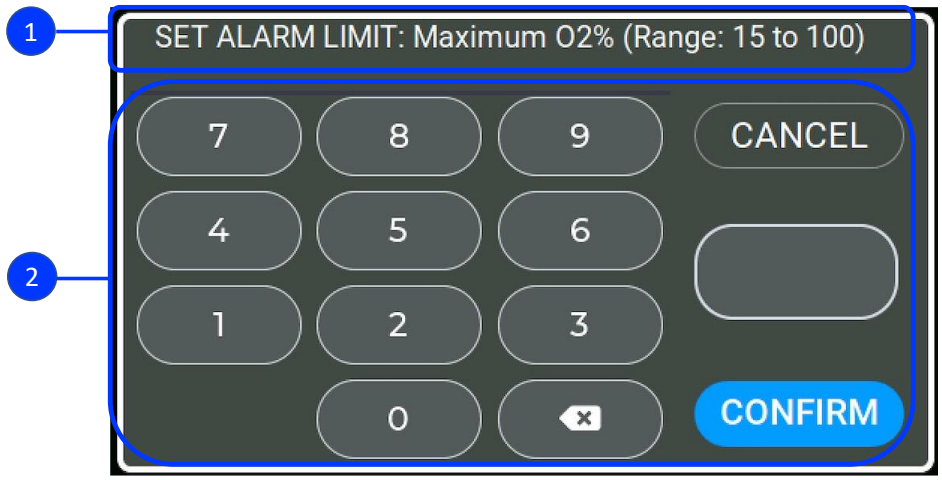
General format for VM-2000 alarm adjustment interface



All alarm limit adjustment interfaces adhere to the following format:

1. The name of the alarm limit to be adjusted, and the settable range
2. Use keypad to enter, confirm, or cancel the new alarm limit

Example of the Maximum O_2 alarm adjustment interface



The alarm limit adjustment interfaces showing:
1. The name of the alarm limit to be adjusted, and the settable range
2. The keypad to enter, confirm, or cancel the new alarm limit

Many of the alarm limits for the VM-2000 are calculated as a threshold above or below the set parameter. Others can be directly set by the user in the settings section.

ALARM DEFAULTS			
SETTABLE ALARMS			
LIMIT NAME	MESSAGE BAR	DEFAULT LIMIT	SETTABLE RANGE
Max Tidal Volume Exceeded	Maximum Tidal Volume Exceeded	115% of the set tidal volume	201 – 2000 ml
Minimum Tidal Volume Not Met	Minimum Tidal Volume Not Met	85% of the set tidal volume	200 – 2000 ml
High Respiratory Rate	High Respiratory Rate	40 BPM	1-41 BPM
Low Respiratory Rate	Low Respiratory Rate	0 BPM	0 – 40 BPM
FIO_2 Exceeds Maximum	FIO2 Exceeds Maximum	100%	27 – 100%
FIO_2 Below Minimum	FIO2 Below Minimum	19%	12 – 95%
$ETCO_2$ Exceeds Maximum	FIO2 Exceeds Maximum	6 kPa	0 – 14 kPa
$ETCO_2$ Below Minimum	FIO2 Below Minimum	0 kPa	0 – 14 kPa
High Minute Ventilation	High Minute Ventilation	30 L/min	1 - 30 L/min
Low Minute Ventilation	Low Minute Ventilation	0 L/min	0 - 30 L/min

ALARM DEFAULTS			
High Peak Inspiratory Pressure	Maximum Insp. Pressure Exceeded	30 cm H20	15-90 cm H20
Low Minimum Inspiratory Pressure	Minimum Inspiratory Pressure not met	6 cm H20	1 – 89 cm H20

ALARMS WITHOUT SETTABLE LIMITS		
LIMIT NAME	**MESSAGE BAR**	**LIMIT**
High PEEP	PEEP Exceeds Maximum	PEEP + 5 cm H2O
Low PEEP	PEEP Below Minimum	PEEP – 3 cm H2O

TABLE 14: ALARM LIMIT

5.3. Connect Supplemental Oxygen

WARNING

Turn off Supplemental Oxygen source when ventilator is shut down or in standby to avoid risk of dangerous O_2 levels.

The VM-2000 can be used when connected to an oxygen blender, or when connected directly to 100% supplemental oxygen.

NOTE

If medically required by protocol, do not delay therapy to connect supplemental Oxygen. In this case, connect the Air/Gas Reservoir tube only after the ventilator is providing air to the patient. However, if higher concentrations of FiO2 (>21%) are immediately required by medical protocol and the patient has an available supplemental Oxygen source, connect the Oxygen reservoir tube before connecting the patient to the ventilator.

VM-2000 is recommended for use with an oxygen blender to adjust concentration and flow of oxygen. Follow the steps outlined in **Instruction for Setup with Oxygen Blender** to attach the oxygen blender to the circuit.

If an oxygen blender is unavailable or impractical, the VM-2000 is compatible with a low flow supplemental Oxygen source using an Air/Gas Reservoir to provide >=90% FiO_2. The reservoir accumulates low-flow Oxygen for delivery in the inhalation phase. The operator can connect the Oxygen reservoir to the device using a straight connector as shown below in **Section 5.3.1: Instruction for Setup with Oxygen Reservoir**, and then connect to a flow-regulated Oxygen source, a low-flow wall source or an Oxygen concentrator capable of delivering supplemental Oxygen using a standard low pressure O_2 line.

All accessories can be independently purchased as standard off-the shelf components, intended for use with respiratory devices.

5.3.1. Instruction for Setup with Oxygen Blender

Ventis recommends that that a legally marketed oxygen blender capable of providing variable oxygen such as the MaxBlend 2 blender (R229P01-001) is used to adjust the concentration of oxygen delivered to the patient. Refer oxygen blender Instructions for Use for a complete, detailed set of instructions and specifications for this blender.

1. Set up the blender as described in the device's Instructions for Use.
2. Attach the Oxygen supply line, Air supply line, and DISS Barbed fitting as indicated in the user manual (shown in **Figure 26-A: Oxygen Blender**).

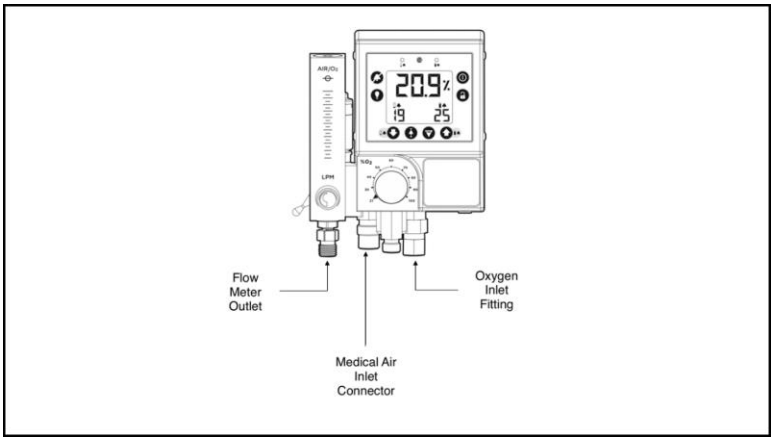


FIGURE 26-A: OXYGEN BLENDER

3. Assemble reservoir components using the following steps:

3.1 Connect one end of a ¼" low pressure tube to the DISS barbed fitting

3.2 Connect the other end of the ¼" pressure tube to the elbow on the reservoir connection.

3.3 Connect the reservoir tubing to the reservoir connection.

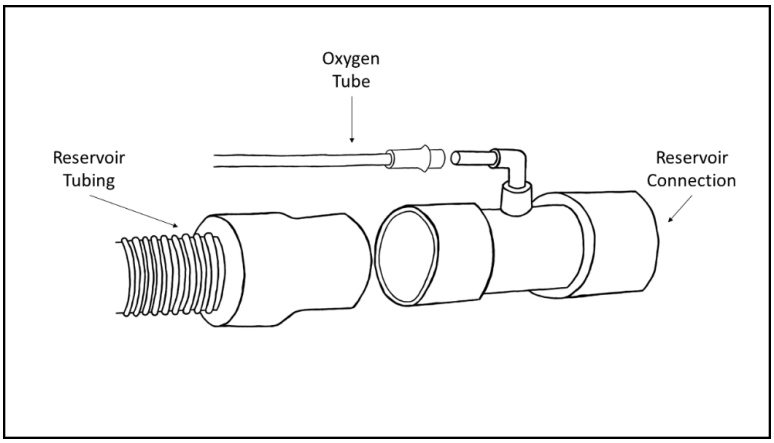


FIGURE 26-B: OXYGEN RESERVOIR COMPONENTS

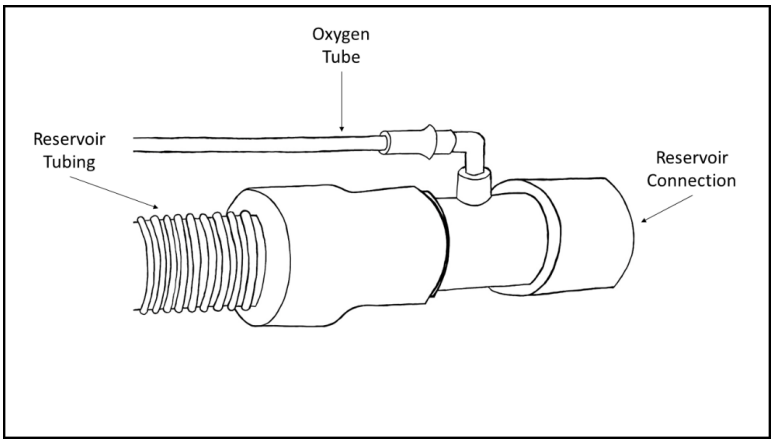


FIGURE 26-C: OXYGEN RESERVOIR ASSEMBLY

4. Connect the Oxygen Reservoir to the inlet of the ventilator.

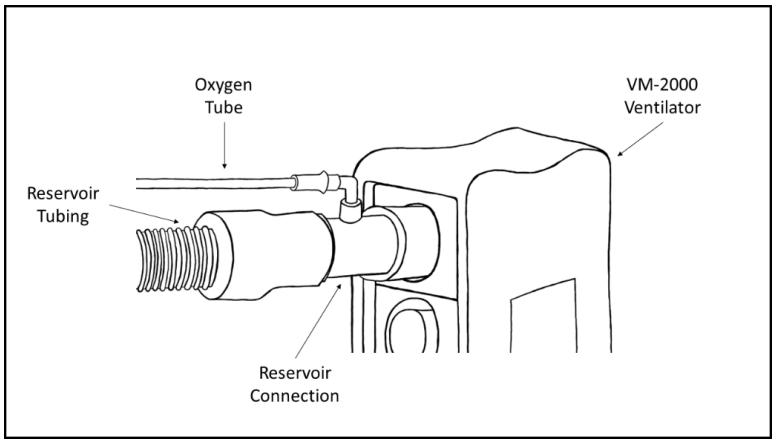


FIGURE 26-D: OXYGEN RESERVOIR CONNECTION

5. Attach reservoir to the Air/Gas inlet as shown in **Figure 26-D: Oxygen Reservoir Connection**
6. Ensure Oxygen tube is appropriately connected to flow regulated Oxygen source
7. Set the Oxygen flow rate at least 2 x minute ventilation rate in LPM (e.g., for a minute ventilation of 6LPM, set the O2 flow rate to at least 12 LPM).

WARNING

Take required precautions when using Oxygen. If using supplemental Oxygen, avoid smoking or open flames. Leaks at Oxygen connections can cause dangerous O_2 levels in the vicinity of the leak. To avoid the risk of ignition, visually inspect Oxygen connections before and after connecting supplemental O_2 and take measures to properly ventilate the area. Do not use oil, grease, or combustible lubricants (only those approved for Oxygen use) in contact with any part of the ventilator, regulator, or cylinder. Do NOT block the air intake port of the Air/Gas Reservoir.

The Oxygen supply must be shut off when ventilation is interrupted.

The hose connecting the ventilator to the Oxygen source must be designed exclusively for use with medical-grade Oxygen. Under no circumstances should the user modify the low pressure O_2 line. In addition, the line must be attached without the use of lubricants.

Do not use flow rates greater than 30 LPM.

NOTE

Setting the Oxygen source flow rate higher than the minute volume of the ventilator will unnecessarily deplete Oxygen supply.

5.4. Monitor Patient

CAUTION

It is the clinician's responsibility to ensure that all ventilator settings are appropriate even when "automatic" features, standard settings, or presets are used.

WARNING

Measured tidal volume in NPPV mode - During non-invasive ventilation, exhaled tidal volume of the patient can differ from the measured exhaled tidal volume due to leaks around the mask. Refer to inspired tidal volume reading during leak conditions.

During ventilation, monitor the patient and verify adequate chest rise and view patient data on the VM-2000 screen to monitor ventilatory delivery. As shown in **Figure 7-A: General Touch Screen Layout**, the Main Measured Parameters Pane on the left side of the display will display current values for measured Tidal Volume, Respiratory Rate, PIP, and PEEP. Reported patient parameters are in BTPS (37C 100% and local atmospheric pressure).

List of monitored/measured patient values, and how they are determined. For range and accuracies, please refer to **Appendix A: Specifications**.

VALUE	DESCRIPTION
Tidal Vol. (mL)	The Tidal Volume measures the volume of gas delivered to the patient with each breath. Tidal Volume is calculated by measuring the flow rate using the Flow Sensor during expiration to determine the total volume of air/gas delivered to the patient during the inspiratory window. Under leak conditions, the ventilation screen will additionally display the inspired Tidal Volume.
Resp. Rate (BPM)	The Respiratory Rate measures the number of breaths delivered to the patient in a minute. The system will initialize the Respiratory Rate once the user updates the machine settings and will determine a count the number of patient or machine-initiated inspiration triggers as a running average.
PEEP (cmH_2O)	The PEEP (Positive End Expiratory Pressure) measures the positive pressure that will remain in the airway at the end of a respiratory cycle. VM-2000 has the internal capability to measure PEEP using a pressure reading from the monitoring line to determine the proximal pressure on exhalation.
PIP (cmH_2O)	PIP measures the maximum inspiratory pressure delivered to the patient over the course of a breath. PIP is measured using a pressure reading from the monitoring line to determine the proximal pressure on inhalation.
$EtCO_2$	$ETCO_2$ measures the concentration of expired carbon dioxide detected over the course of a breath. This is measured by the $EtCO_2$ in-line sensor configured in the breathing circuit.
FiO_2	FiO_2 measures the concentration of oxygen delivered to the patient during inspiration. This is measured by the O_2 sensor within the device. Alarms will be triggered if the O_2 concentration deviates from the expected range.

TABLE 13: DESCRIPTIONS OF MONITORED/MEASURED PATIENT VALUES

Graphical Display

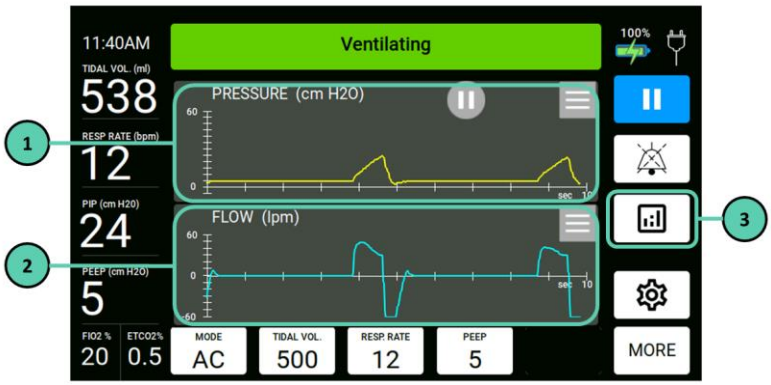


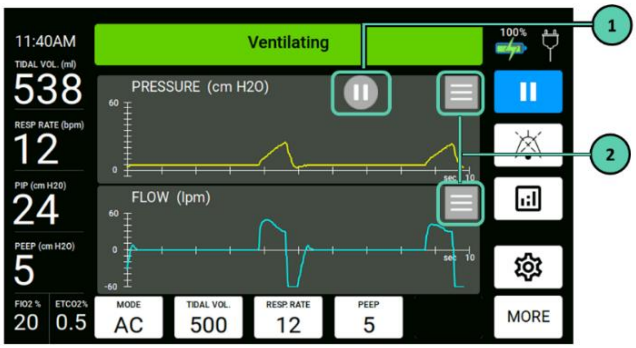
FIGURE 27-A: GRAPHICAL DISPLAY

1	Graph View 1	**3**	Graph View Button
2	Graph View 2		

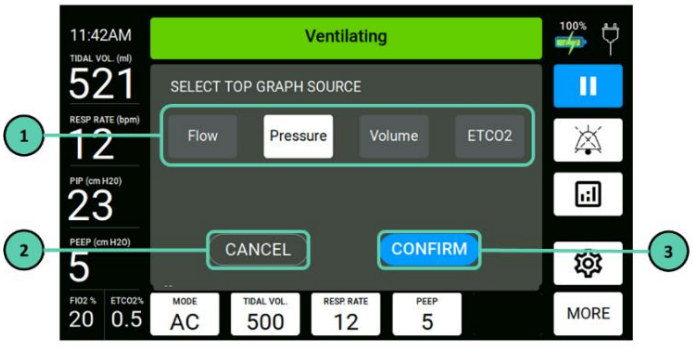
Users can access the graphical display at any time without affecting breath delivery by selecting Graphical View key. The VM-2000 can plot pressure, flow, Volume, and $ETCO_2$ against time. The four options for graphical plots are:

- **Flow:** Flow/time waveform
- **Pressure:** Pressure/time waveform
- **Volume:** Volume/time waveform
- **$ETCO_2$:** $ETCO_2$/time waveform (Only available if $ETCO_2$ accessory is connected)

1. Press the pause symbol to freeze the graph. Following this, the symbol will turn red, indicating that graph freeze is active.
2. To deactivate graph freeze and resume normal operation, press the red pause symbol.



To modify the graph source for either the top or bottom graph, select the chart symbol (2a, 2b) and select the desired parameter. Tap confirm to confirm your selection and cancel to return to the previous graph source.



See Appendix C: **Principles of Operation** for illustrative Pressure and Flow waveforms.

5.5. Respond to Alarms

When an alarm is triggered, the Alarm will be displayed in the Operational Status Bar, located at the top of the Ventis User Interface™, to alert the operator of various conditions. The Operational Status Bar, Alarm Key, and Measured Patient Parameter (if a displayed parameter caused the alarm condition) will illuminate in red. Refer to the **Quick Alarms Reference Guide** for details on alarm conditions, probable cause, and what to do. When an alarm occurs:

- Use standard operating procedures and standard of care to resolve alarm condition.
- If unsure how to respond, using alarm name, refer to Section 3.8.3: Quick Alarm Reference Guide for additional information about what to do.
- The alarm will resolve once the alarm condition is no longer present.

Alarms can indicate several conditions including clinical issues, technical faults, and/or that the system has not been assembled properly.

- Actions listed assume the appropriate alarm settings based on the patient's therapy. When an adjustable alarm is activated, evaluate the patient and re-confirm the alarm settings.
- When an alarm situation occurs, it is important to evaluate the patient. If a device alarm activates repeatedly, and if there is a concern that the alarm does not appropriately reflect the clinical situation, discontinue use, switch to a backup ventilator, and return the device for servicing.

  Alarm settings are restored automatically if power is interrupted for ≤ 5 minutes.

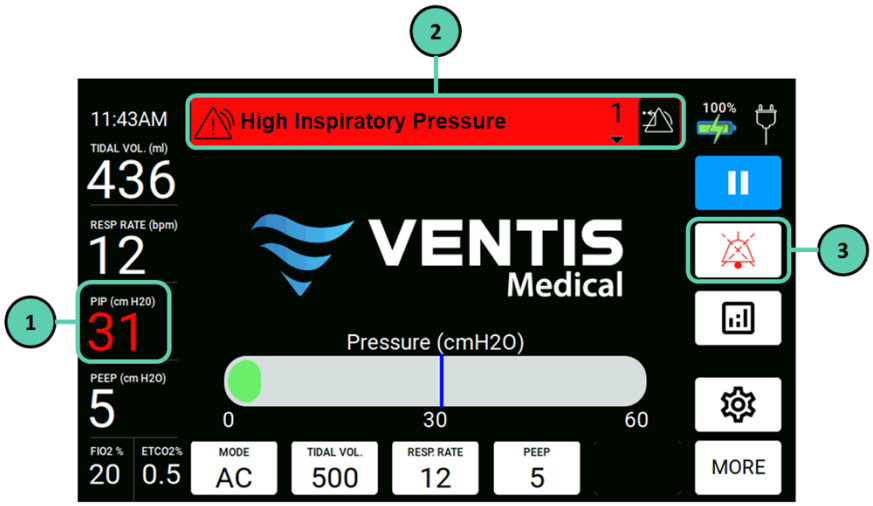


FIGURE 28-A: ALARM RESPONSE

1	Response to Alarm Criteria	**3**	Alarm Key – Press to pause auditory alarms
2	Alarm Name on Operational Status Bar		

To Pause Alarm Audio

The system enables the operator to temporarily pause the audio alarm on the VM-2000 device for a two-minute (120 second) period. During this period, the Alarm display and Alarm bar continue to display the alarm as usual. If after two minutes the alarm condition is still present, the audible alert will sound again.

5.6. Manual Trigger Breaths

The Respiratory Rate of the device can be controlled manually by pressing the Manual Breath Trigger Button. Manual trigger breaths can be initiated only when the device is turned on and ready to ventilate or in a paused state.

To avoid stacking breaths, the Manual Trigger button will not trigger a breath during the active inspiratory or expiratory phase.

FIGURE 29: PRESS MANUAL TRIGGER BUTTON

5.7. Clear Breathing Circuit of Debris

The VM-2000 Breathing Circuit is intended for a single patient use. If the breathing circuit becomes obstructed due to patient aspiration or other cause, a replacement circuit should be installed. If an appropriate replacement circuit is available, replace active circuit with new circuit according to local hospital protocol. Verify adequate chest rise and monitor pulse oximeter if available. If a replacement circuit is not available, then consider ventilating patient by other means.

5.8. Pause/Stop Ventilation

Ventilator operation is controlled by the Stop Ventilation key on the right-hand pane of the ventilator touch screen as shown in **Figure 29: Stop Ventilation**, which allows users to either pause or end ventilation.

5.8.1. Pause Ventilation

If ventilation is **paused**, the device Operational Status Bar will display “Paused: Press to Start.” Once the “PAUSE” button is pressed ventilation will be paused. In this state, the device will revert back to the last active state within 30 seconds.

Ventilation will stop completely If “STOP” is then pressed. When ventilation is **completely stopped**, the operational status bar will display “Manual Mode: Ready to Ventilate.” **The device will NOT resume ventilation unless the user selects to start ventilation in a continuous ventilation Mode.**

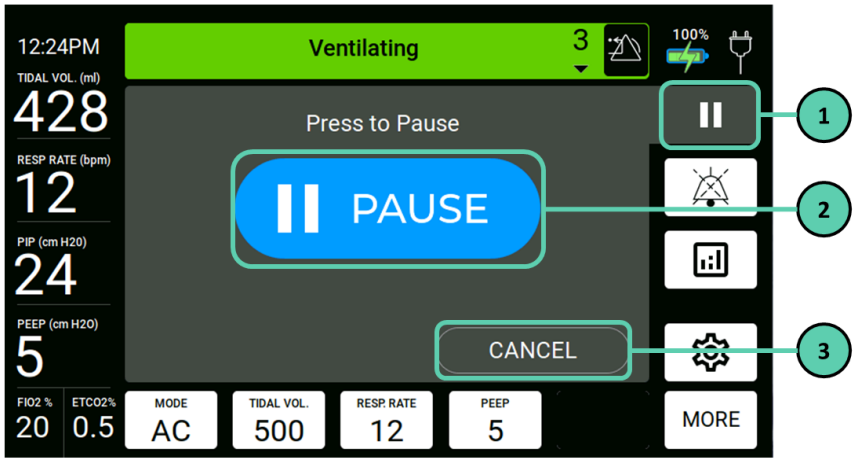


FIGURE 30: PAUSE VENTILATION

1	Pause Menu	**3**	Cancel
2	Pause Button		

To Pause Ventilation:

1. Select the Pause Ventilation Control on right side pane of the touch screen.
2. Select Pause to apply pause.
3. Manually deliver breath using the Manual Breath Key, as necessary.
4. Modify settings as necessary by following instructions described in 5.2.2: **Modify Settings.**
5. Select START to restart ventilation. After 30 seconds, the device will resume continuous ventilation.

5.8.2. Stop Ventilation

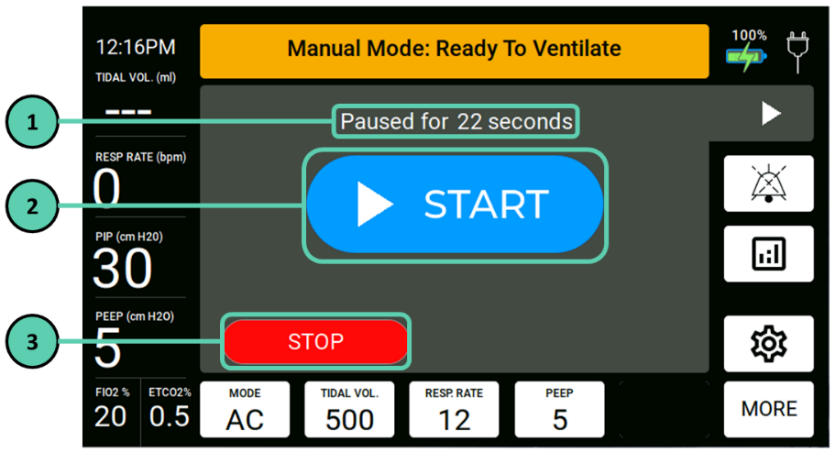


FIGURE 31: STOP VENTILATION

To Stop Ventilation:

1. Select the Pause key on the right side pane of the touch screen.
2. Select Stop to confirm

NOTE

If user stops ventilation, a patient will ONLY receive a breath when the caregiver provides one using the manual breath key. The backup ventilation and apnea alarm are disabled.

5.8.3. End Ventilation

To End using the device on the patient:

1. Disconnect the Patient Breathing Circuit from the patient.
2. Connect patient to alternative source of ventilation, as indicated.
3. Turn the device Off by pressing and holding the On/Off Power Button.
4. Remove Oxygen tubing from ventilator if supplemental Oxygen is in use.
5. Remove Breathing Circuit from ventilator
6. Dispose of single-use accessories following the institutional guidelines for biologically contaminated material.
7. Follow guidance outlined in Device: Maintenance for cleaning ventilator unit, before storing.

NOTE

If the VM-2000 has a rechargeable battery installed, and it is not anticipated to be used for long durations, maintain the battery as described in the battery maintenance section to prolong battery life and operational readiness.

6. Device Maintenance

WARNING

Maintenance Instructions – Failure to follow maintenance instructions could result in damage to the ventilator. This could reduce the life of the unit or lead to potential harm to the patient.

Personal Injury and Electrical Shock: To avoid electric shock hazard, do not open the enclosure casing. Do not use batteries, AC adapters, cables, or external power supplies with visible signs of damage. Only use power supplies approved by Ventis Medical.

Approved Parts/Accessories – Serious harm to the patient may result from the use of unauthorized parts or accessories. To ensure proper performance of the ventilator, only use accessories approved by Ventis Medical.

Sterilization --Do not attempt to sterilize the interior of the ventilator.

Use of EtO Gas - Do not attempt to sterilize the whole ventilator with EtO gas.

CAUTION

To minimize the risk of bacterial contamination or physical damage, handle bacteria filters with care.

To prevent patient exposure to sterilizing agents, as well as premature deterioration of parts, sterilize parts using the techniques recommended in this section only.

To reduce the risk of electrical shock, disconnect electrical power from the ventilator before cleaning.

Do not reuse single-use breathing circuit parts and other accessories, including Flow Sensors. They must be discarded after single use.

Annual Service – The VM-2000 must be serviced annually. Units outside the service dates may operate outside of specified tolerances.

Service Personnel Qualifications – To avoid ventilator malfunction and possible operator or patient injury, repair operations not included in this manual must be performed by a service technician certified by Ventis Medical. Contact Ventis Medical for service information and requirements.

NOTE

Because sanitation practices vary among institutions, Ventis Medical cannot provide specific practices that will meet all needs or be responsible for the effectiveness of these practices. This manual provides general guidelines with validated cleaning and disinfection methods only. It is the user's responsibility to ensure the validity and effectiveness of the actual methods used.

Exposure to sterilizing agents may reduce the lifetime of certain parts. Using more than one sterilization technique on a single part may damage that part.

6.1. Calibration and Preventative Maintenance Schedule

The FIO_2 sensor requires initial and periotic calibration. Ventis recommends calibration initially and on a **weekly** basis thereafter while in use. Additionally, Ventis recommends recalibration after:

- The temperature of the gas stream changes by more than 3 degrees Celsius
- There is a change in elevation of more than 500 feet (barometric pressure can affect the oxygen reading)

Recalibration is also recommended if the user is unsure when the last calibration was performed or if the measurement value is displayed as a question mark. More frequent calibration will not adversely affect performance.

To calibrate the FIO_2 sensor: Follow the instructions by selecting 'Calibrate Now' by navigating to Settings > Patient FIO_2 Sensor > Calibrate Now, and follow the directions on the screen.

The VM-2000 ventilator is designed to operate with minimal maintenance by qualified personnel on the following schedule:

	BEFORE USE	AFTER USE	ANNUALLY
Clean	X	X	X
Verify Performance*	X		X
Verify Functionality*	X		X

TABLE 15: RECOMMENDED MAINTENANCE SCHEDULE

* The device should be evaluated annually, or every 2,000 hours (whichever comes first), by an authorized service representative to verify performance is within specification. Contact Ventis Medical by sending an email to service@ventismed.com, or by calling (609) 373-6229 for more information.

6.2. Battery Maintenance

Runtime on a single battery depends on multiple factors, including Tidal Volume, Respiratory Rate, PEEP, patient compliance, environmental temperature, previous storage conditions, and age of battery.

- **Rechargeable Battery:** To maintain rechargeable battery while not in use, battery should be recharged every 6 months.
- **Primary Battery:** For long storage periods, the primary battery should be stored outside the ventilator unit.

CAUTION

Battery source requires replacement ahead of expiration date, as well as periodic checking to validate proper working conditions prior to use.

6.3. Software Maintenance

The current software version your device is running can be viewed in the Settings window. Ventis Medical will notify registered users of software updates, as well as software update instructions.

For questions about software versioning, please contact support@ventismed.com. There are no known software anomalies that can lead to the compromise of sensitive information or that can affect communication security.

6.4. Device Cleaning & Disinfecting, Storage, Repair

CAUTION

The system is approved for IP54 in operation mode with oxygen enrichment and accessory ports covered. Be careful of liquid spillage to avoid damage to the instrument and patient cable.

Do not expose the instrument, patient cable, or sensors to sprays or any other type of solvents except for those specifically instructed by Ventis Medical for the purpose of cleaning & disinfecting the VM-2000.

Be sure to power off the instrument and disconnect the AC power cord from the power source prior to conducting cleaning procedures

6.4.1. Device Surface Cleaning & Disinfecting

- The VM-2000 requires routine cleaning & disinfecting. A soft, lightly water dampened cloth should be used to remove any soil, debris, or dirt from the external surface.

Steps for Cleaning

1. Disconnect from device from power source
2. Wipe device with clean cloth damped with DI water to remove any visible debris
3. Spray entire exterior area with 0.25% Dawn Professional Dish detergent solution (UPC 030772087282)
4. Wipe device using lint free cloth until visibly free of soil
5. Using a 70% isopropyl alcohol wipe, wipe entire device exterior and allow solution to evaporate (~2 minutes)
6. After residual isopropyl alcohol has evaporated wipe entire surface using clean cloth damped with DI water
7. Wipe any excess DI water using lint free cloth

Steps for Disinfecting

1. Disconnect from device from power source
2. Wipe device with clean cloth damped with DI water to remove any visible debris
3. Spray entire exterior area with 0.25% Dawn Professional Dish detergent solution (UPC 030772087282)
4. Wipe device using lint free cloth until visibly free of soil
5. Using 70% isopropyl alcohol wipes, wipe entire device exterior and ensure that all surfaces remain wetted for 5 minutes
6. After all residual isopropyl alcohol has evaporated, wipe entire surface using clean cloth damped with DI water
7. Wipe any excess DI water using lint free cloth

NOTE

Never expose to an autoclave.

Do not remove inlet port cover or Inlet Filter while device is in use. Only qualified personnel should remove port cover and replace Inlet Filter.

The VM-2000 should be stored as a complete kit in a state of readiness. Ventis Medical recommends storing VM-2000 inside of a hard case which is both durable and waterproof. The device should be stored at room temperature at relative humidity (40% - 60%), per the requirements laid out in Appendix A: Specifications.

Under no circumstances should the VM-2000 or its accessories be immersed in liquid. If the VM-2000 becomes wet, the unit should be dried using a lint-free cloth immediately, or once the unit is no

longer in use. If the VM-2000 becomes immersed, discontinue use, and return to appropriate service facility for inspection. DO NOT expose the switch, external power jack, or audible alarm port directly to liquids.

To avoid damaging VM-2000 plastic components and User Interface, do not use cleaning agents containing ammonium chloride, other chloride compounds, more than 2% glutaraldehyde, phenols, or abrasive cleaners.

CAUTION

Repair/Replacement – Ventis Medical recommends performing service annually to verify the device continues to operate within specification. Do not reuse single-use breathing circuit parts and other accessories, including Flow Sensors. They must be discarded after single use.

Battery source – requires replacement ahead of expiration date, as well as periodic checking to validate proper working conditions prior to use.

Debris – Debris, particulate, or other sources of contamination inside the ventilator may significantly decrease the volume delivered to the patient.

6.4.2. Device Storage

The VM-2000 should be stored as a complete kit in a state of readiness. Ventis Medical recommends storing VM-2000 inside of a hard case which is both durable and waterproof. The device should be stored at room temperature at relative humidity (40% - 60%), per the requirements laid out in Appendix A: Specifications.

6.4.3. Device Repair

Ventis Medical recommends performing service annually to verify the device continues to operate within specification.

CAUTION

Repair/Replacement – Ventis Medical recommends performing service annually to verify the device continues to operate within specification. Do not reuse single use breathing circuit parts and other accessories, including Flow Sensors. They must be discarded after single use.

Repair/Replacement – Do not reuse single-use breathing circuit parts and other accessories, including Flow Sensors. They must be discarded after single use.

6.5. Accessory Cleaning, Storage, and Repair

6.5.1. Cleaning

Single use accessories: do not attempt to clean accessories intended for single patient use, including:

- Patient Breathing Circuit
- Breathing Filter
- HMEF Filter
- Flow Sensor
- Air/Gas Reservoir
- $ETCO_2$ Airway Adaptor

For outside accessories, refer to accessory manufacturer for cleaning procedure.

WARNING

Single-Use Accessories – Ventis Medical does not recommend attempting to clean or re-use single-use accessories.

Outside Accessories – Refer to accessory instructions for use for cleaning procedures.

Cross Contamination Risk – Ventis Medical does not recommend reusing the Breathing Circuit as it may cause cross contamination between patients. Reuse of single use components increases the risk of cross contamination between patients. A patient treated by mechanical ventilation is highly vulnerable to infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection.

6.5.2. Storage

Refer to the **Device: Maintenance – 2. Storage** section for details on storing device and device accessories.

6.5.3. Repair/Replacement

Replace any single-use device accessories with visible defects or are not functioning as expected. Ventis Medical does not recommend reusing single use breathing circuit parts and other accessories, including Flow Sensors. **The unit will notify the user upon startup if it detects that it is time to replace the inlet filter or time for routine service of the device**

ITEM	PART #	CYCLE TIME
VM-2000 Unit	VM-2000	2,000 hours of patient use or annual maintenance cycle, whichever comes first
FIO_2 Sensor	VM-522	500,000% O_2 hours or annual maintenance cycle, whichever comes first
Inlet Filter	VM-511	240 hours of patient use

Flow Sensor	VM-522	Single patient use
Flow Sensor Cable	VM-521	Repair/Replace based on annual maintenance cycle
Primary Battery Pack	VM-401	Replace when battery has been depleted or expires
Rechargeable Battery Pack	VM-402	Service life lesser of 5 years or 350 cycles where a cycle is 1 charge and 1 discharge at 23°C.
AC Power Supply	VM-420	Repair/replace based on annual maintenance cycle
ETCO2 Sensor	VM-701	5,000 hours of patient use

TABLE 16-A: VM-2000 VENTIS MEDICAL ACCESSORY REPAIR/REPLACEMENT

ITEM	CYCLE TIME
Patient Breathing Circuit	Single patient use
Breathing Filter	Single patient use
HMEF Filter	Single patient use
Air / Gas Reservoir	Single patient use
ETCO2 Airway Adaptor	Single patient use
Oxygen Blender	Refer to accessory manufacturer for maintenance & calibration

TABLE 16-B: COMPATIBLE ACCESSORY REPAIR/REPLACEMENT

To replace the Inlet Filter (to be performed by qualified service personnel):

1. Remove housing from device inlet by unscrewing four (4) inlet housing attachment screws.
2. Discard of existing inlet filter based on hospital protocol (being careful to prevent any particulate from entering the device housing).
3. Place a new filter onto the inlet, flush to the grill.
4. Replace the inlet housing and secure by tightly securing four (4) screws.

7. Appendix A: Specifications

7.1. Device Specifications

Ventilator Parameters		Operating Modes	AC, SIMV, CPAP, NPPV
		Primary Control	Time
		Secondary Control	Pressure
		Breath Target	Volume
	Rate	Flow Rate (LPM)	Up to 100
		Inspiratory Trigger Flow (LPM)	1 – 9, OFF
		Respiratory Rate (BPM)	• **AC:** 10-40 (+/- 1) • **SIMV:** 0-40 (+/- 1) • **CPAP**: 0
	Pressure (cmH_2O)	Peak Inspiratory Pressure Limit (P insp)	15 – 90 (+/- (2cmH2O + 4% of setting))
		Positive End Expiratory Pressure (PEEP)	5 – 20 (+/- (2cmH2O + 4% of setting))
		Inadvertent PEEP	<2
		Sensor Range	-60 to +100
	Volume (mL)	Tidal Volume[2]	200 – 2000
		Minute Volume	2000 – 30000
		Dead Space	<100
	Time (Seconds)	Inspiratory	.3 – 5.0 (+/-(.05 + 10% of setting))
		Expiratory	.3 – 5.7
	Resistance (cmH_2O)	Inspiratory	< 6.0 cmH_2O at 30 L/min
		Expiratory	< 6.0 cmH_2O at 30 L/min
	Compliance (mL / kpa)	Breathing Circuit	< 9
	Supplemental Oxygen	Input Flow Rate (LPM)	0 – 30
		FiO_2	21 – 100%
Monitored Values		Peak Inspiratory Pressure (PIP) (cmH_2O)	0 – 100 (+/- (2cmH2O + 4% of actual))
		Respiratory Rate (BPM)	0 – 100 (+/- 1)
		Tidal Volume (mL)	0 – 4000
		Positive End Expiratory Pressure (PEEP) (cmH_2O)	0 – 60 (+/- (2cmH2O + 4% of actual))
	Power Source	Input	100-240VAC, 50-60Hz, 1.5A
		Output	24VDC, 5A
Environmental	**Ranges**	Operating	-10°C – 40°C
		Storage	-40°C – 70°C
	Humidity	Operating	15% - 90% RH (non-condensing)
		Storage	up to 90% RH (non-condensing)
	Atmospheric Pressure	620 – 1060 hPa[3]	
	Drop	• MIL-STD-810G Method 51.6 Procedure 4 @ 48”	
	Shock & Vibration	Meets ISO 80601-2-12: 2020 clause: • 201.15.3.5.101.1 Shock and vibration (robustness) • 201.15.3.5.101.2 Shock and vibration for a transit-operable ventilator during operation	

	Ingress	Unit only without protection	IP54[4]
Other	**Audible Alarm**		Meets 60601-1-8 IEC Standard
	Dimensions	Size	8” x 6.5” x 2.25”
		Weight (Unit with Battery Installed)	3.0 lbs
		Other Accessories	See accessory labeling
	Shelf Life	Unit	5 years
	Warranty	Device	1 year
		Battery	1 year

[1]All specifications include a tolerance of +/- 10% of nominal value unless stated otherwise. Test conditions upon request.
[2] Delivered Tidal Volume may be materially affected by low lung compliance (<0.01 L / cm H_2O)
[3] Specifications have only been validated at or near sea level (2,000 ft), and maximum delivered pressure may degrade at higher altitude. Standard correction factors can be applied.
[4]IP54: With device operating with battery installed, oxygen accessory attached, and accessory ports covered -
(5) Ingress of dust is not entirely prevented, but it must not enter in sufficient quantity to interfere with the satisfactory operation of the equipment; complete protection against contact. (4) Water splashing against the enclosure from any direction shall have no harmful effect
NOTE: Transient operating conditions: -20°C – 50°C
NOTE: The time required for the ventilator to warm from the minimum storage temperature between uses until it is ready for intended use, is 1 HOUR in standard temperature and pressure conditions.
NOTE: The time required for the ventilator to cool from the maximum storage temperature between uses until it is ready for intended use, is 1 HOUR in standard temperature and pressure conditions.
NOTE: The maximum limited pressure (P_LIM) is 20cmH20 greater than the high pressure alarm limit.
NOTE: Measurement accuracy of calibration equipment may affect the respiratory parameters display by the following parameters:
• Volume calculation: +/-2% or 20 [cc]
• Inspiratory and expiratory times: +/- 0.02 [s]
• Pressure <1% Barometric / Airway pressure

7.2. Battery Specifications

TYPE	OPERATING TIME	SHELF LIFE	CHARGE TIME	NOTES
Primary Battery	6 hours (to 5% remaining)	10 years	N/A	At 5% of capacity, 20 minutes of power remain in the device Not Installed 5 years installed Operating Parameters: TV = 500, RR = 10, PEEP = 5, R5, C50 Meets IEC 60086-4 compliance
Rechargeable Battery	8 hours (to 5% remaining)	5 years	3 hours (off) 5 hours (ventilating)	At 5% of capacity, 20 minutes of power remain in the device Service life lesser of 5 years or 350 cycles where a cycle is 1 charge and 1 discharge at 23°C. Shelf life is with periodic charge interval of 6 months. Operating Parameters: TV = 500, RR = 10, PEEP = 5, R5, C50

7.3. Gas Sensor Specifications

ETCO2 AND FIO2[1]		
FIO_2	± (2.5% FiO2 + 2.5% of actual reading) within a 24-hour sensor calibration period, or a change in altitude Measurement is not automatically compensated for changes in altitude. 90% Response time: < 15 seconds Changes in elevation result in a reading error of approximately 1% of reading per 250 feet. A change in altitude greater than 500 feet will require sensor recalibration. The device does not automatically compensate for changes in barometric pressure or altitude. If the device is moved to a location of a different altitude, it must be recalibrated before use.	
Displayed $ETCO_2$	Upon connection, allow up to two minutes for data to appear. Displayed value is the peak of the expired CO2 waveform, updated on each breath. Displayed $ETCO_2$ waveform sample rate is 10 Hz. Measurement automatically compensates for changes in altitude. Accuracy is not impacted by the respiration rate. If breathing is not detected, then no value appears.	
Accuracy	0 - 40 mmHg:	± 3 mmHg
	41 - 70 mmHg:	± 5% of reading
	71 - 100 mmHg:	± 8% of reading
	101 - 150 mmHg:	± 10% of reading
Stability	Short Term Drift: Drift over four hours shall not exceed 0.8 mmHg maximum. Long Term Drift: Accuracy specification will be maintained over a 120-hour period.	
Total system response time	<2 seconds	

[1] $ETCO_2$ and FIO_2 specifications are for use in non-condensing environment and in specified humidity range

7.4. Audio Specifications

Alarm sound pressure level	77 dBA to 99 dBA for high and medium priority alarms
Sound pressure level	<=57 dBA *Ventilator, circuit, and exhalation device measured according to ISO 80601- 2-12 and 80601-2-84*
Sound power level	<=77 dBA *Ventilator, circuit, and exhalation device measured according to ISO 80601- 2-12 and 80601-2-84*

7.5. ISO 19223 Cross Referenced Modes

VM-2000 VENTILATION-MODE	ISO 19223:2020 CODE
AC	A/C-VC
SIMV	SIMV-VC\PS
CPAP	CPAP

8. Appendix B: Glossary

ACRONYM	WORD	ADDITIONAL DESCRIPTION
ARDS	Acute Respiratory Distress Syndrome	Respiratory condition wherein fluid accumulates in the air sacs of the lungs, inhibiting a patient's ability to breathe.
ARF	Acute Respiratory Failure	Respiratory condition wherein the respiratory system is unable to meet the oxygenation, ventilation, or metabolic requirements of the patient.
--	Air/Gas Reservoir	Reservoir to allow delivery of low flow Oxygen using a flow regulated Oxygen source.
AC Mode	Assist Control Mode – Volume Controlled	As a primary Mode of ventilation used in respiratory failure. Ventilator delivers a fully supported breath whether time or patient triggered.
AC Power	Alternating Current Power	Electric current which periodically reverses direction and changes its magnitude continuously with time.
--	Apnea	Cessation of breathing.
BPM	Breaths per Minute	Number of times a patient breathes in one minute.
BVD	Bag Valve Device	Handheld, manually operated resuscitator used to squeeze air into a patient's lungs.
--	Breathing Circuit	Circuit to channel air to and from the patient's airway. Includes pressure monitoring line to measure proximal pressure and control line to drive exhalatory valve, and flow sensor/breathing filter when assembled.
--	Breathing Filter	Disposable patient breathing filter to protect internal components and atmosphere from potential microbial contamination, dust, dirt, and other particles.
cmH_2O	Centimeters of water	Unit of pressure. 1 cmH_2O is approximately equal to 1 mbar, which equals 1 hPa.
--	Caution	Indication of potentially hazardous situations, which, if not avoided, could result in equipment damage. These situations could indirectly cause death or serious injury if the equipment damage causes the ventilator to operate improperly.
--	Control Line	Line to control the closing and opening of the exhalation valve of the gas exhaled by the patient.
DC	Direct Current	One-directional flow of electric charge.
ET	Endotracheal	Situated within or occurring within the trachea.
--	Exhalation Valve	Valve to control the respiratory phases and the positive end-expiratory pressure (PEEP), and it prevents internal ventilator components from encountering the patient's exhaled gas.

ACRONYM	WORD	ADDITIONAL DESCRIPTION
FiO_2	Fraction of inspired oxygen	Molar or volumetric fraction of oxygen in the inhaled gas.
--	Flow Sensor Cable	Line to connect air/gas flow sensor to ventilator unit.
--	Flow Sensor	Sensor to measures gas/flow at the patient connection end.
I:E	I:E Ratio	Unitless ratio between measured inspiratory time and measured exhalation time.
ID	Inner Diameter	Diameter of the inside of a tube, pipe, or other object.
IEC	International Electrotechnical Commission	International standards organization that prepares and publishes international standards for all electrical, electronic and related technologies
--	Inlet Debris Filter	Filter intended to protect the internal components of the system from dust, dirt, and other particles.
--	Mandatory Breath	Breath for which either the timing or size is controlled by the ventilator. That is, the machine triggers and/or cycles the breath.
--	Manual Breath	A user-triggered mandatory breath started by pressing the manual breath key.
O_2	Oxygen	Life supporting component of air
P insp	Inspiratory Pressure	Target pressure during inspiratory phase.
PIP	Peak Inspiratory Pressure Limit	Maximum acceptable pressure during the Inspiratory Phase before the pump shuts off.
PEEP	Positive End Expiratory Pressure	Positive pressure that will remain in the airway at the end of a respiratory cycle.
PPV	Positive Pressure Ventilation	A form of respiratory therapy that involves the delivery of air or a mixture of oxygen combined with other gases by positive pressure into the lungs.
--	Pressure Monitoring Line	Line to monitor patient pressure.
RR	Respiratory Rate / Resp. Rate	Target number of breaths delivered to the patient in a minute.
Sens	Sensitivity	Minimum flow threshold necessary to trigger a delivery.
SIMV	Synchronized Intermittent Mandatory Ventilation – Volume Controlled	As a Mode commonly used in surgical patients, Ventilator delivers a mandatory, fully supported, breath when time triggered. However, when the breath is patient-triggered, the ventilator allows a spontaneous breath.
TV	Tidal Volume / Tidal Vol	It controls the volume of gas delivered to the patient with each breath and measures the volume of gas delivered to the patient with each breath.

Acronym	Word	Additional Description
--	Warning	Warning statements alert the reader to potentially hazardous situations, which, if not avoided, could result in death or serious injury.

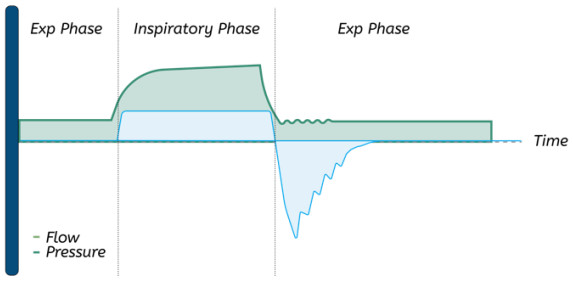
9. Appendix C: Principles of Operation

This section discusses VM-2000 ventilation modes, and breath delivery.

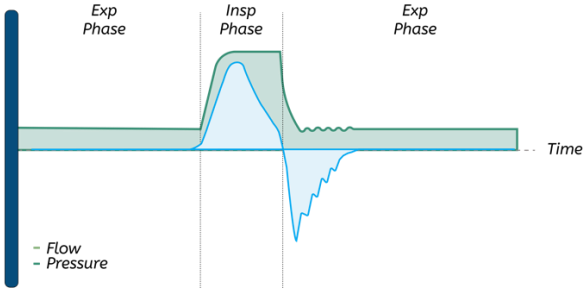
Inhalations can be machine (time) triggered or patient triggered. Triggering means the start of inhalation (start of positive flow into the airway opening) and cycling means the end of inhalation (start of negative flow out of the airway opening). Mandatory breaths are *either* machine triggered *or* machine cycled. Spontaneous breaths are *both* patient triggered *and* patient cycled.
The active inhalation phase completes expiration as follows:

- For *mandatory* breaths: after the Tidal Volume is delivered or the Inspiratory Time is reached. *Note: For mandatory breaths, the flow profile is constant flow. The flow profile is not adjustable by the operator.*
- For spontaneous breaths (e.g., pressure supported breaths in SIMV): when the inspiratory flow reaches the set percent of the peak inspiratory flow delivered, or the maximum time termination period is met

Characteristic breath waveforms produced by the ventilator are shown below. Pressure and Flow oscillations can be present during exhalation. Both breath profiles and all modes are further detailed in the sections below.



Mandatory Breath



Pressure supported breath

9.1. Assist Control (AC) Description

Parameter	Preset	Range	Increment
Tidal Vol	500 mL	200 - 2000 mL	1 mL
Resp Rate	12 BPM	10 - 40 BPM	1 BPM
PEEP	5 cmH2O	0 - 20 cmH2O	1 cmH2O
T insp	1.0 seconds	0.3 - 5.0 seconds	0.1 seconds
P insp	30 cmH2O	15 - 90 cmH2O	1 cmH2O
Sensitivity	3 LPM	1 - 9 LPM, OFF	1LPM

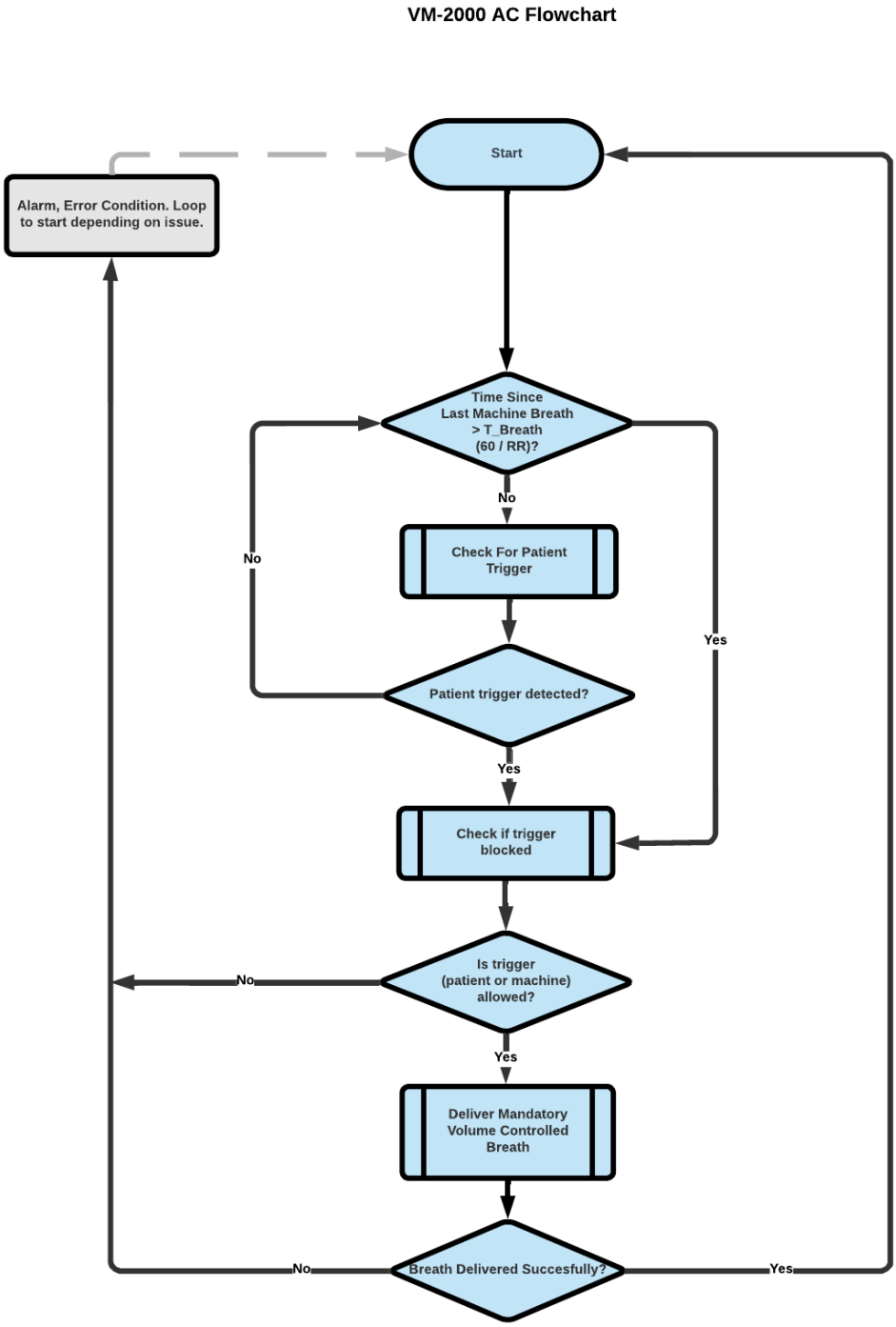
Default Values

The AC Mode provides volume-controlled assisted and controlled breaths with a clinician set PEEP level. Assisted breaths are flow triggered by patient efforts exceeding the flow threshold set by the clinician, while controlled breaths are time triggered by the ventilator. To allow the patient adequate time for expiration, there is a refractory period following a completed breath where an assisted breath cannot be initiated by the patient. Following this refractory period, there is a trigger window which allows for the patient to trigger an assisted breath. At the end of the trigger window, if the patient has not triggered an assisted breath, a controlled breath is applied to ensure a respiratory rate of at least the clinician set rate. Due to the existence of both patient triggered assisted breaths, and time triggered controlled breaths, this mode allows for a variable minute ventilation, but guarantees a minimum minute ventilation based on the set respiratory rate and tidal volume. Further details on the AC Mode are provided below.

Overview of Assist Control (AC)

BREATH TYPE	TRIGGER SOURCE	CONTROL	CYCLE
Assisted (VCV)	Patient (Flow)	Tidal Volume	Time
Controlled (VCV)	Ventilator (Time)		

9.2. Assist Control System Logic



9.3. Assist Control Delivered Wave Forms

Breaths are initiated either by the ventilator (time), or by a patient trigger (during the trigger window). The Patient Trigger is detected based on the sensitivity setting of 1 - 9 LPM flow. The inspiratory phase is controlled to deliver a set Tidal Volume, and limited by the maximum inspiratory time. See **Appendix C-4: Deliver Mandatory Volume Controlled Breath** for details.

9.4. Synchronized Intermittent Mandatory Ventilation (SIMV) Description

Parameter	Preset	Range	Increment
Tidal Vol	500 mL	200 - 2000 mL	1 mL
Resp Rate	12 BPM	0 - 40 BPM	1 BPM
PEEP	5 cmH2O	0 - 20 cmH2O	1 cmH2O
P Support	10 cmH2O	0 - 20 cmH2O	1 cmH2O
T insp	1.0 seconds	0.3 - 5.0 seconds	0.1 seconds
P insp	30 cmH2O	15 - 90 cmH2O	1 cmH2O
Sensitivity	3 LPM	1 - 9 LPM	1LPM

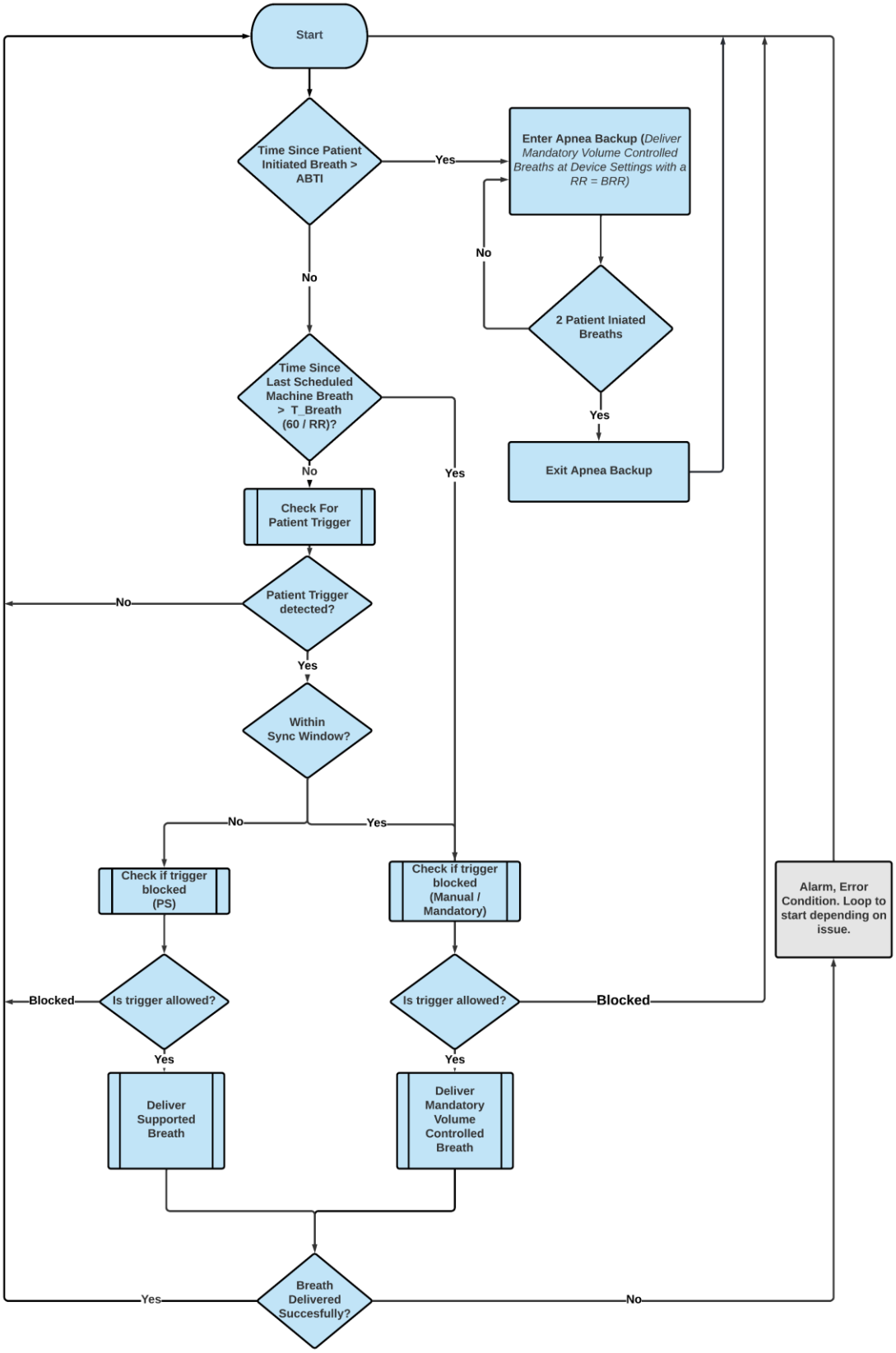
Default Values

SIMV Mode is a volume control mode that provides a mixture of mandatory and spontaneous breaths. The Respiratory Rate determines the length of the breath cycle (60/Resp Rate). SIMV Mode guarantees at least one breath is delivered over the course of each cycle. Pressure supported breaths can be triggered after the refractory period and before the sync window. If a patient trigger occurs within the sync window, the ventilator will deliver a mandatory breath.

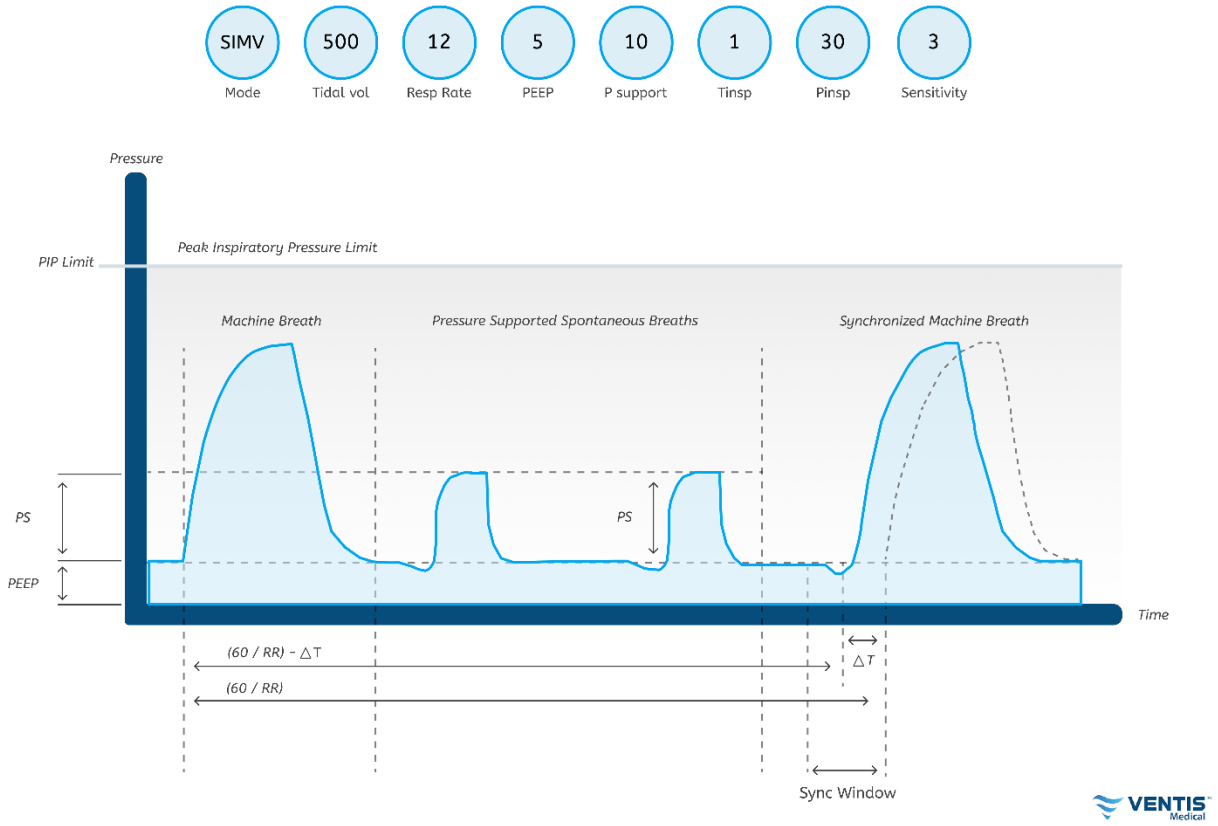
Overview of Synchronized Intermittent Mandatory Ventilation (SIMV)

BREATH TYPE	TRIGGER SOURCE	CONTROL	CYCLE
Assisted (VCV)	Patient (Flow)	Tidal Volume	Time
Controlled (VCV)	Ventilator (Time)		
Pressure Support	Patient (Flow)	Pressure	Flow (10-40% Peak Insp Flow)

9.5. SIMV System Logic



9.6. SIMV Mode Wave Forms



The inspiratory phase is initiated either by the ventilator (time), or by a patient trigger. The Patient Trigger is detected based on the sensitivity setting of 1 to 9 LPM flow.

For **Mandatory Volume Controlled Breath**, the inspiratory phase is controlled to deliver a set Tidal Volume and limited by the maximum inspiratory time. See **Appendix C-4: Deliver Mandatory Volume Controlled Breath** for details. For **Pressure Supported Breaths**, the inspiratory phase is triggered by patient flow. The **Pressure Supported Breaths** consist of four phases:

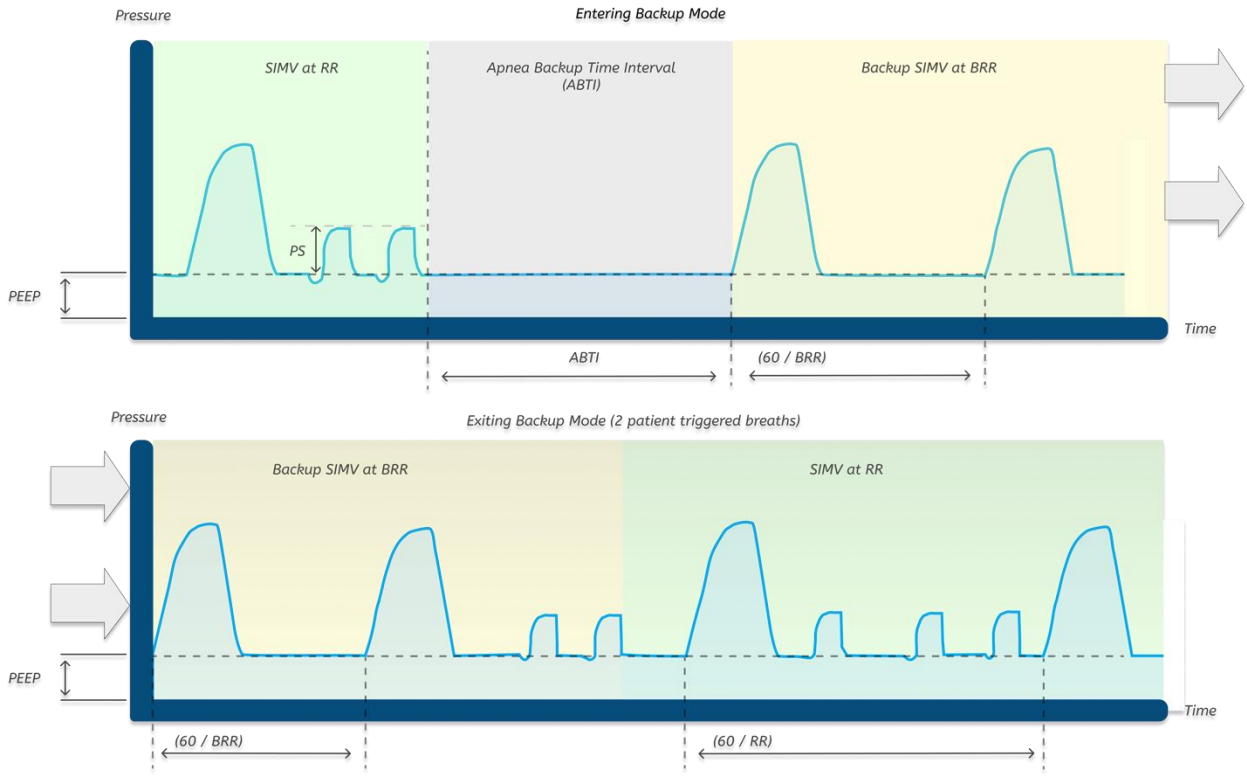
1. **Beginning of Inspiration** – Pressure Support breath has been triggered by an increase in flow due to patient effort.
2. **Pressurization –** VM-2000 pressurizes the patient from PEEP pressure to PEEP + PS.
3. **Beginning of Expiration –** As the patient receives pressure support, the flow eventually drops to expiratory cycle threshold (default 25%) of the peak inspiratory flow, or reaches the maximum inspiratory time, at which point the expiratory phase begins, at which point the expiratory phase begins.
4. **Expiration –** The VM-2000 allows for patient expiration through the exhalation control valve.

See **Appendix C-6: Deliver Supported Breath** for further details.

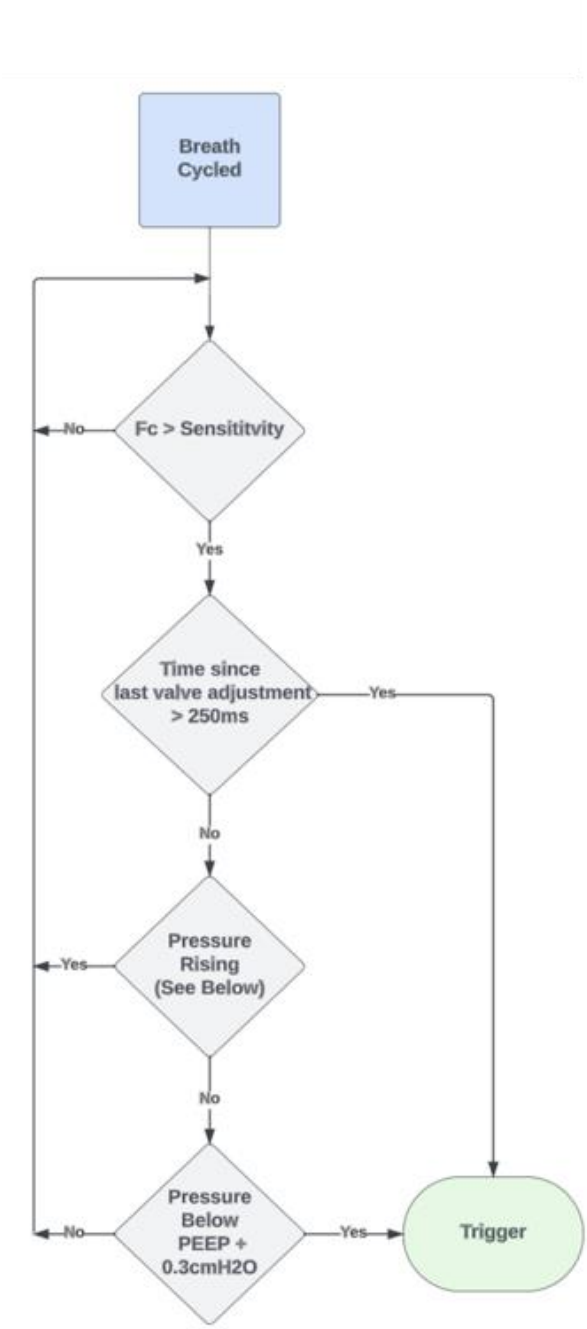
Expiration will begin when either the flow falls below the minimum threshold, or if the inspiration time is exceeded. During inspiration, the device will also check if the pressure exceeds the PIP Limit and alarm for Peak Inspiratory Limit and initiate expiration if the pressure exceeds the PIP Limit.

The device will monitor the patient breathing rate during SIMV mode, and alarm for Apnea and trigger a Backup Ventilation Mode if there has been no patient breath within the apnea interval (Default: 10 seconds, range: 5-60 seconds).

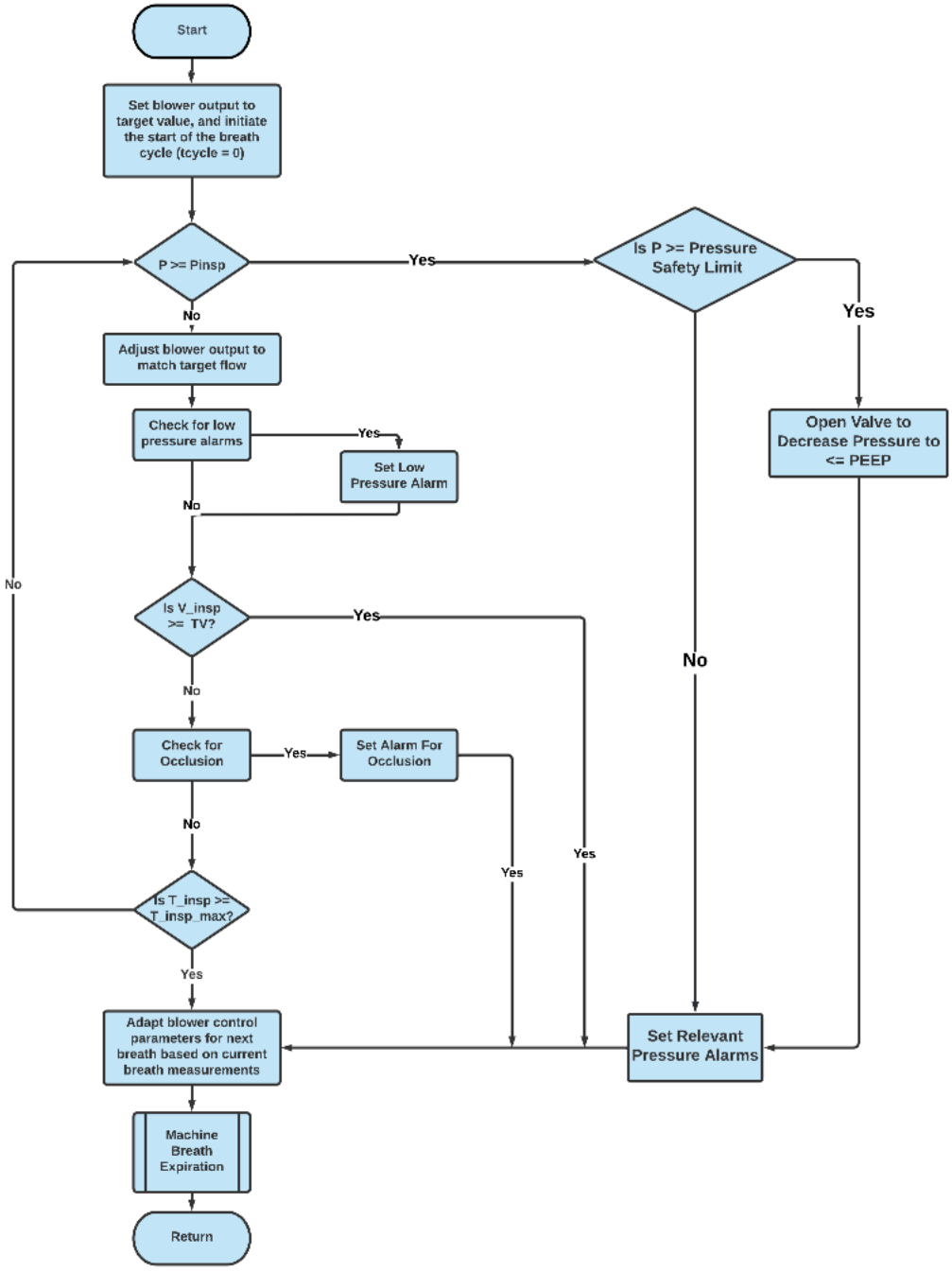
If no patient triggered breath occurs during the apnea interval, the ventilator will enter Backup Ventilation Mode. In Backup Ventilation Mode, the ventilator will provide mandatory volume controlled breaths at a respiratory rate of the backup respiratory rate (BRR) of 8 bpm. Once the ventilator has entered Backup Ventilation Mode, the device will only resume standard SIMV ventilation if two patient triggered breath are identified within the apnea interval.



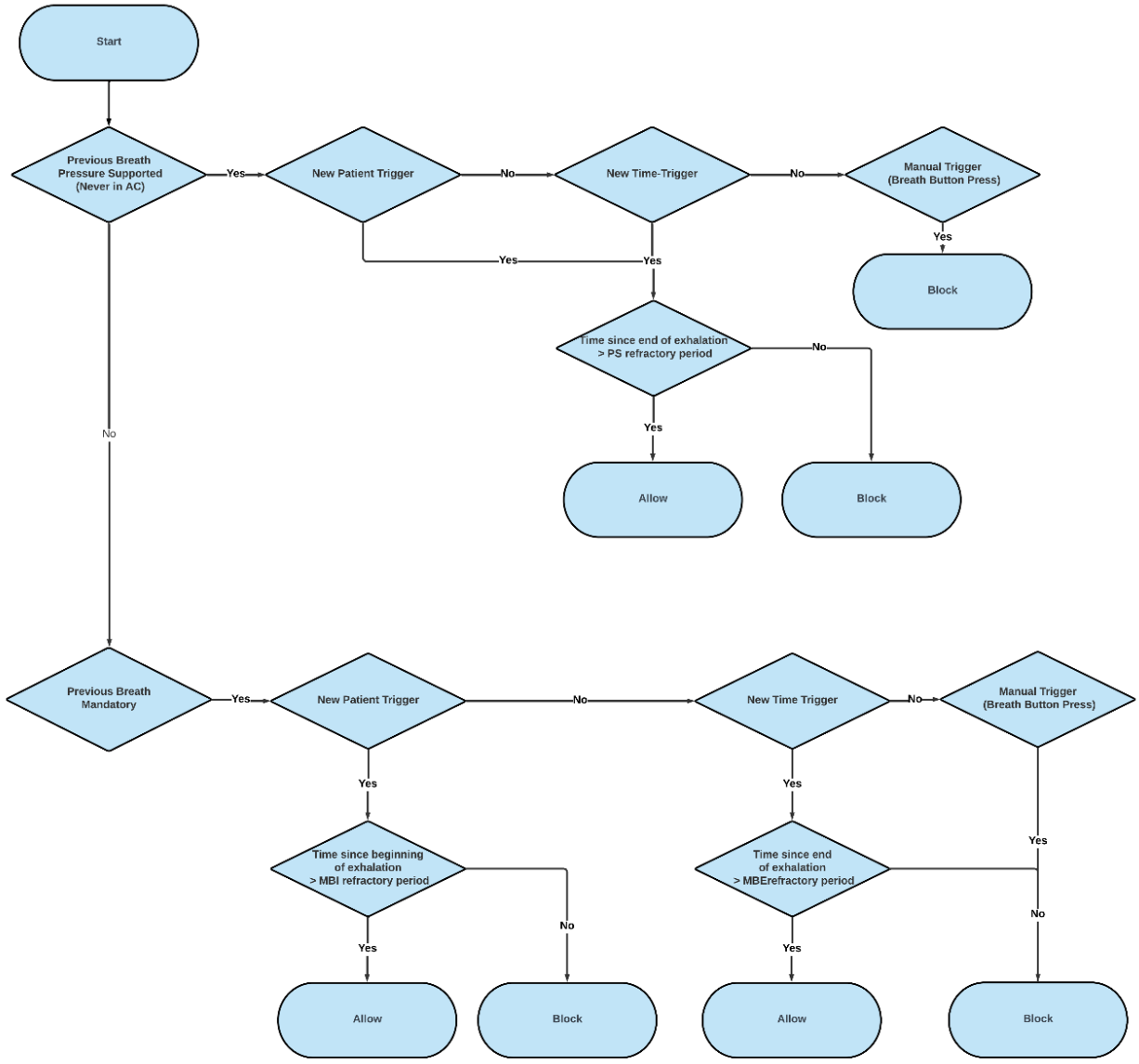
9.6.1. SIMV System Logic - Check for Patient Trigger



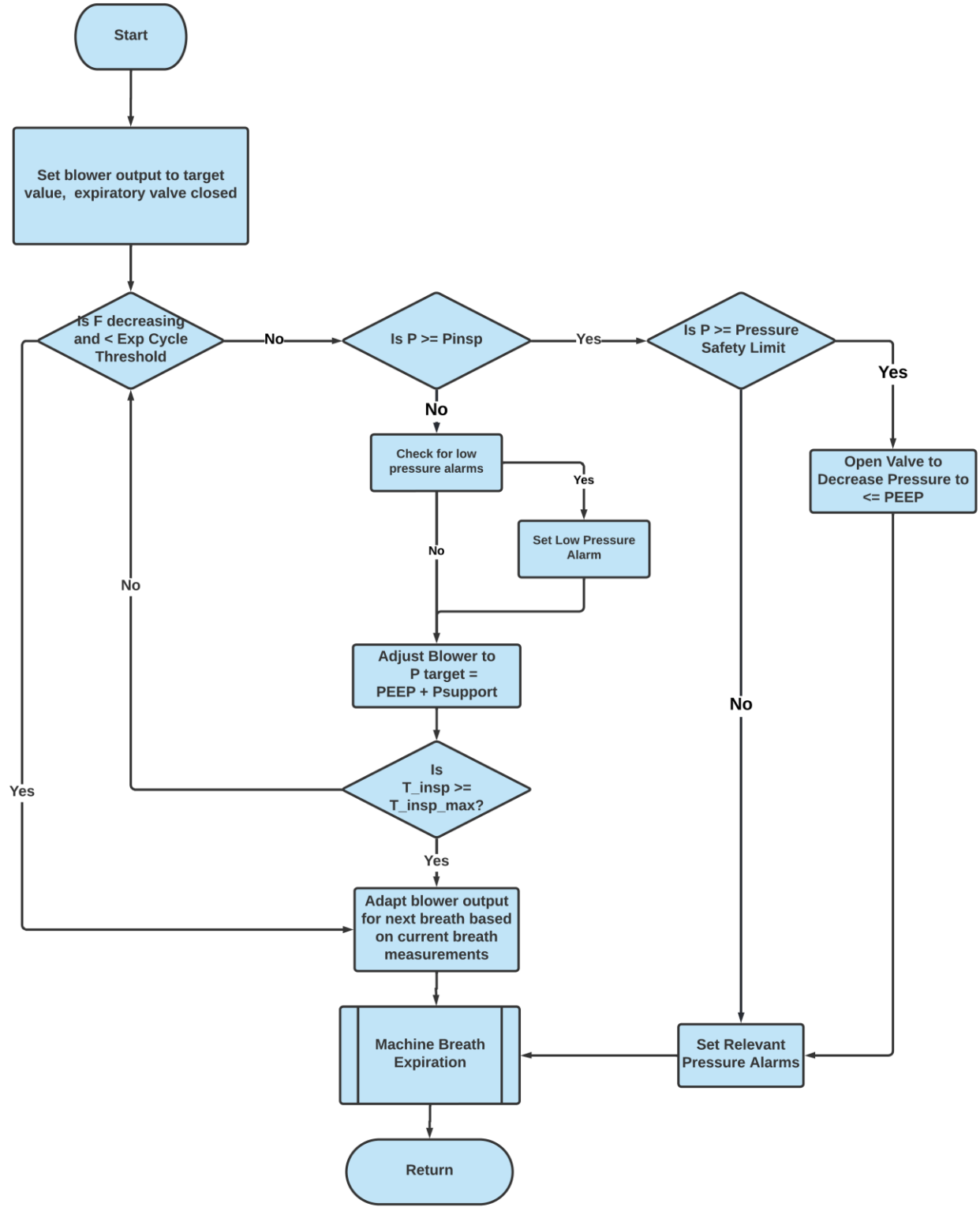
9.6.2. SIMV System Logic - Deliver Mandatory Volume Controlled Breath



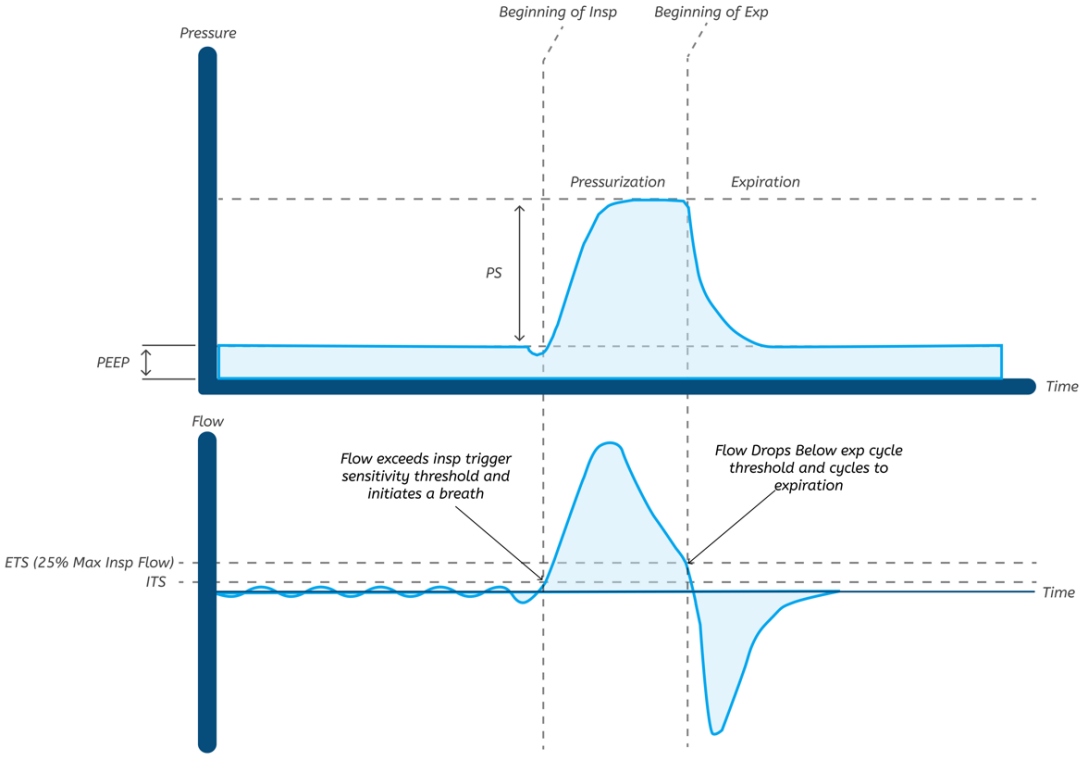
9.6.3. SIMV System Logic - Check if Patient Trigger Blocked



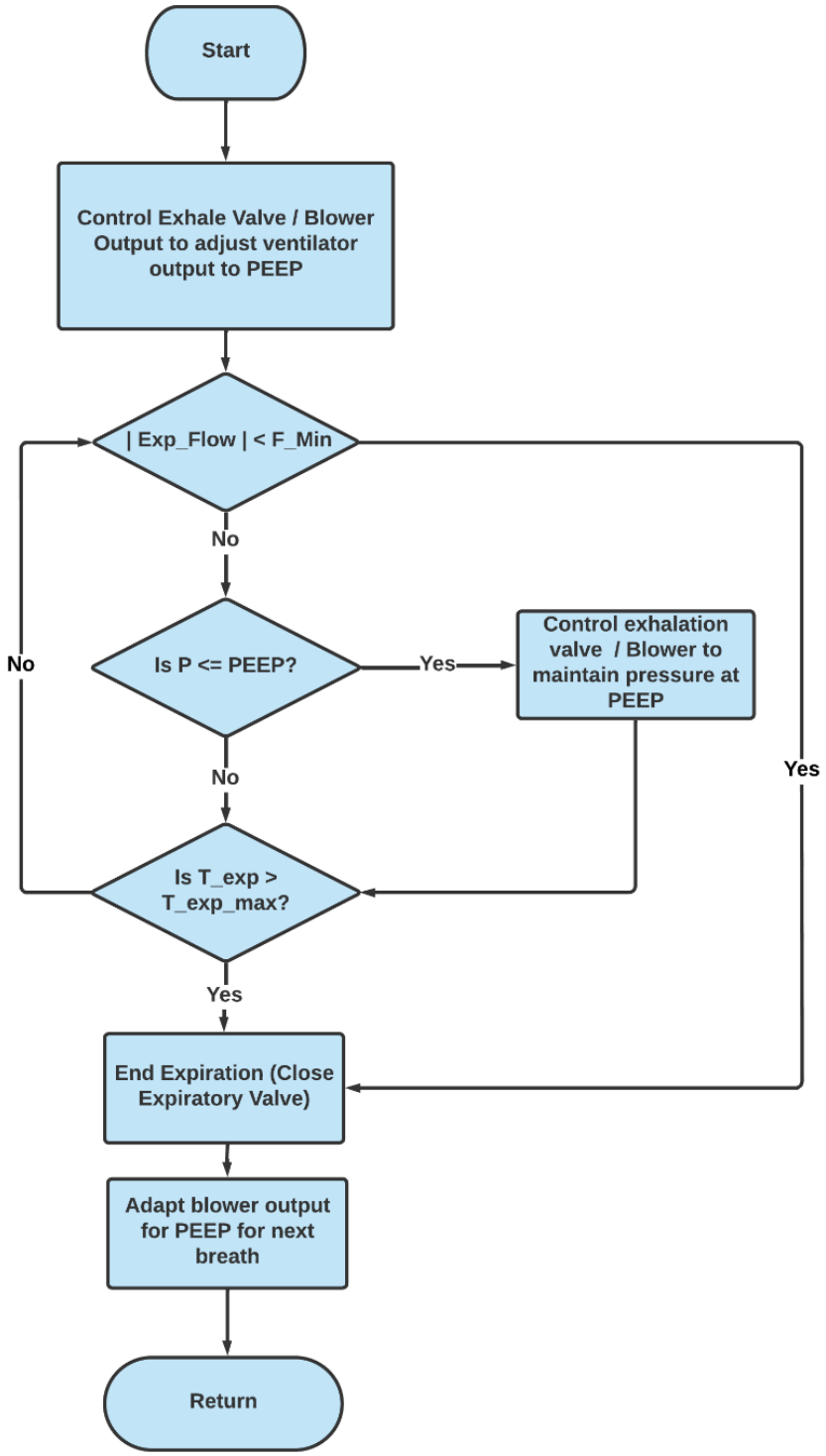
9.6.4. SIMV System Logic - Deliver Supported Breath



9.7. Pressure Support Breath Waveform



9.7.1. Pressure Support System Logic - Machine Breath Exhalation

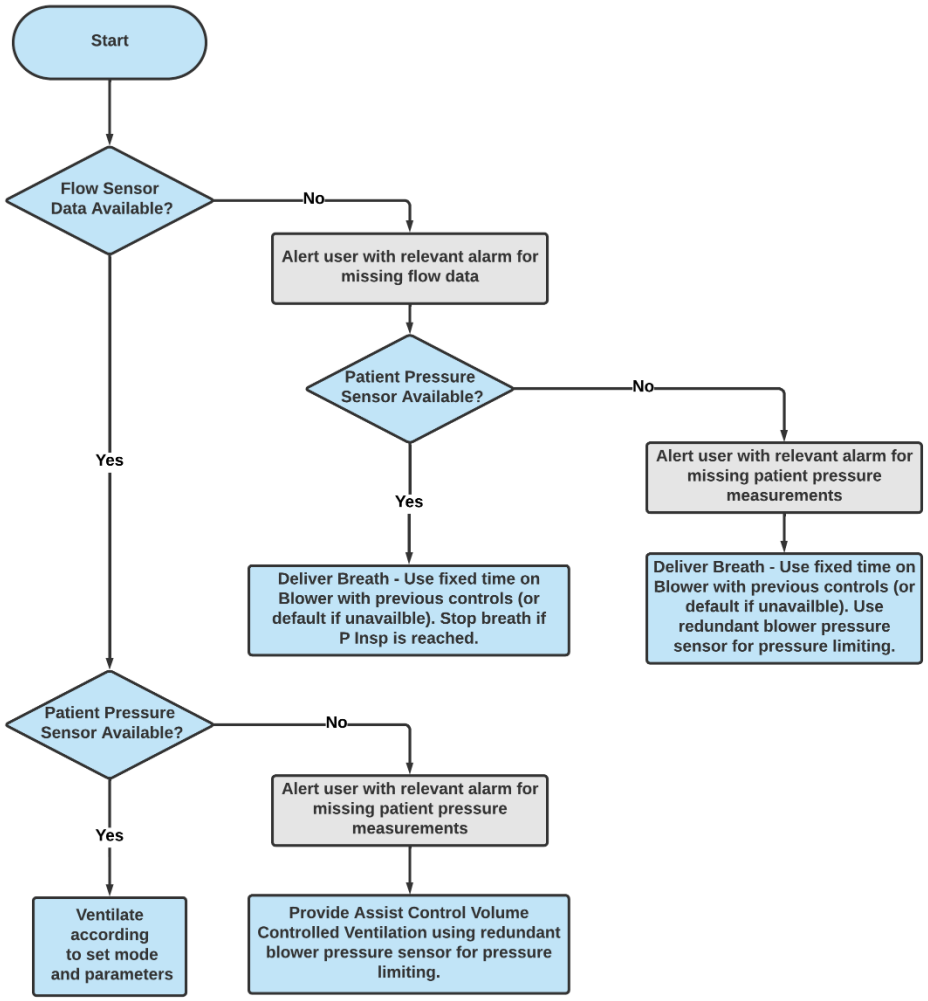


9.8. Safety Mode Description

In certain error conditions, including when pressure and/or flow sensor data become unavailable, the VM-2000 will enter safety mode and the user will be alerted. In safety mode, the ventilator will deliver ventilation to the patient using data from the most recent operational parameters. If the pressure sensor at the patient becomes unavailable, the VM-2000 will utilize data from the onboard pressure sensor to limit peak pressures while using the data from the flow sensor to deliver volume-controlled ventilation. If the flow sensor data becomes unavailable, the ventilator will use the most current motor and pressure parameters to deliver a pressure-controlled breath.

BREATH TYPE	TRIGGER SOURCE	INSPIRATION	CYCLE	EXHALATION
Mandatory	Ventilator (Time)	Tidal Volume	Inspiratory Time	PEEP
Mandatory (Assist – Control)	Patient			

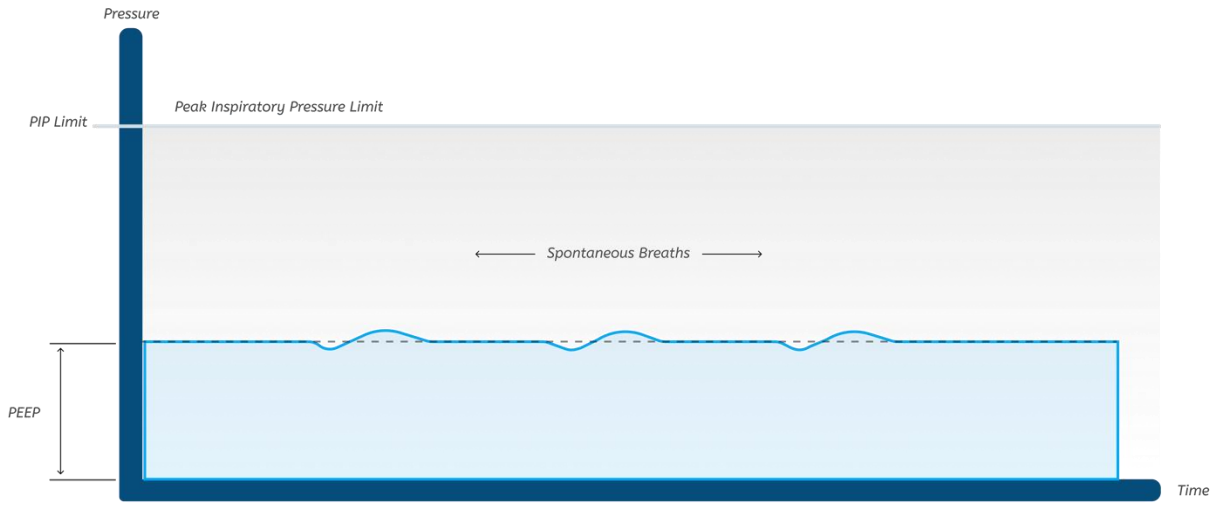
9.8.1. Safety Mode System Logic



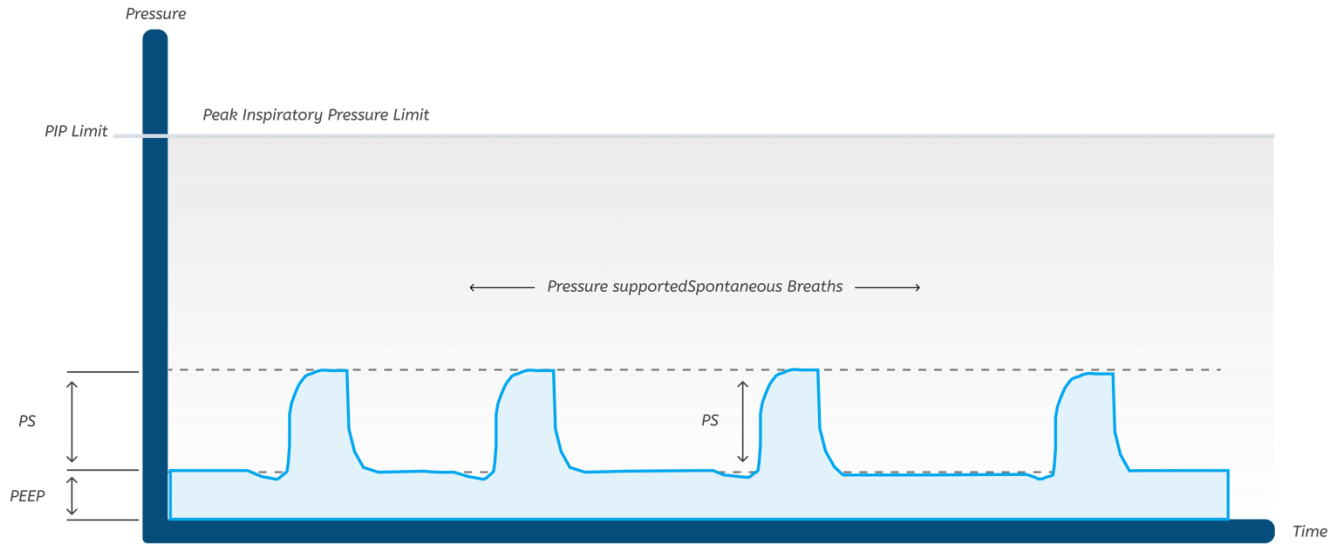
9.9. CPAP

CPAP is active when SIMV is selected, Respiratory Rate is set to 0, and Pressure Support is set to 0. In CPAP mode, when a patient trigger is detected, the VM-2000 will deliver the CPAP pressure setting (PEEP) during both inhalation and exhalation.

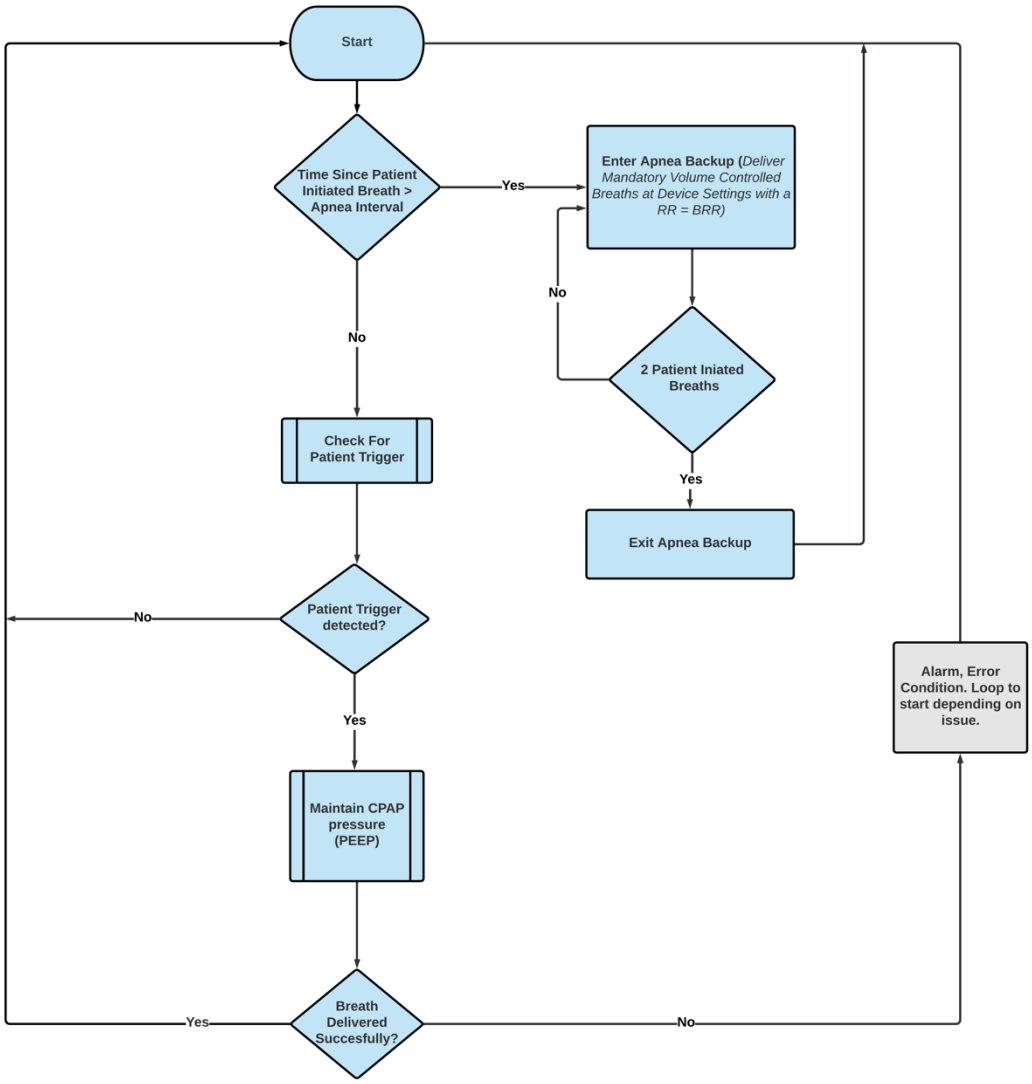
If no patient triggered breath occurs during the apnea interval, the ventilator will enter Backup Ventilation Mode. In Backup Ventilation Mode, the ventilator will provide mandatory volume controlled breaths at a respiratory rate of the backup respiratory rate (BRR) of 8 bpm. Once the ventilator has entered Backup Ventilation Mode, the device will only resume standard SIMV ventilation if two patient triggered breath are identified within the apnea interval. Read more about Backup Ventilation in the SIMV mode description (9.6).



When SIMV is selected, Respiratory Rate is set to 0 and PS is > 0 the ventilator will deliver pressure supported breaths. When a patient trigger is detected, the VM-2000 will deliver a supported breath.



9.9.1. CPAP Mode System Logic



10. Appendix D: Alarm History

When an alarm occurs, it is displayed in the information bar on the top of the display. The information bar allows access to all current and cleared alarms since an alarm history reset. The active alarms are listed by alarm priority and then by time. Active alarms are sorted by priority and time of occurrence. The alarm with the highest priority that occurred most recently appears at the top of the list. Once an alarm is resolved it is moves below the active alarms on the list and resorted by time of occurrence. A counter on the information bar shows the number of alarms. Tap the alarm history to expand it and view the list of alarms. Navigate through the list by tapping the up and down indicators.

SYMBOL	MEANING
	Audio Pause
	Low or Medium priority alarm
	High Priority Alarm
	Reset Alarm History

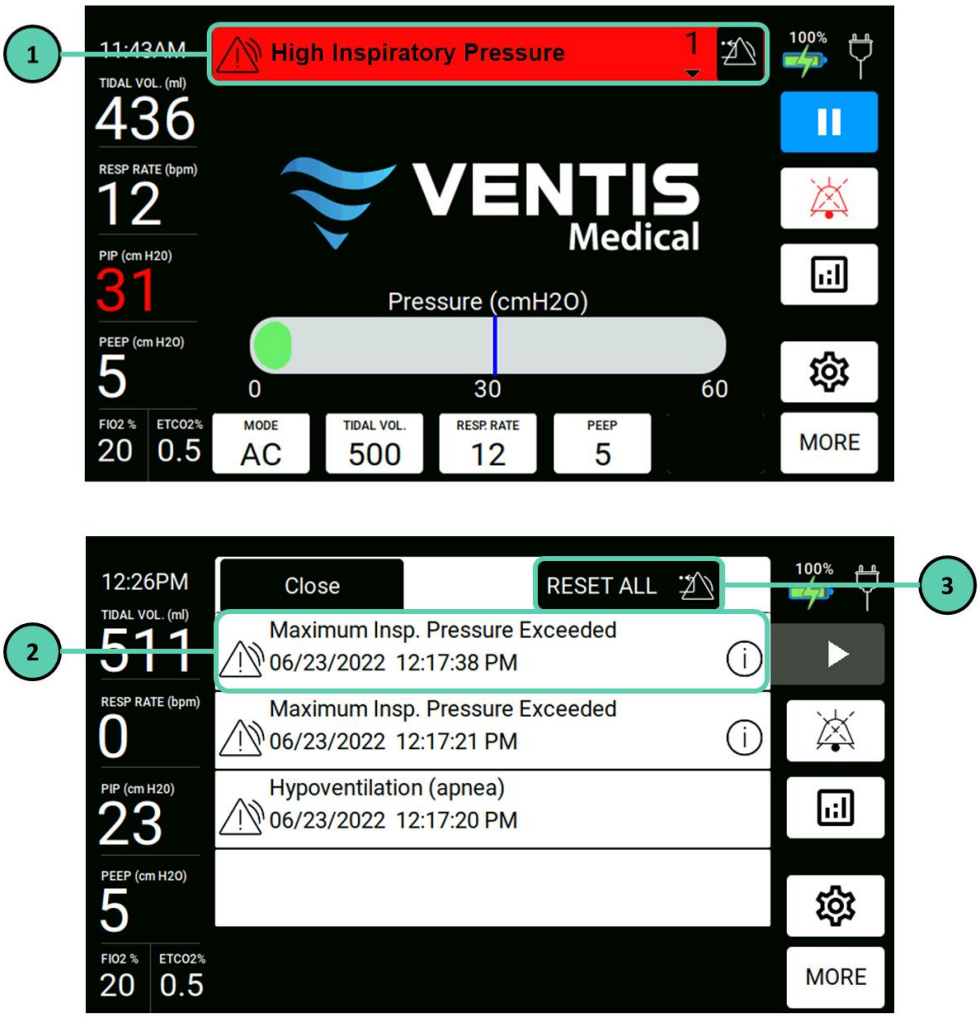


Figure 32: Resetting Alarm Logs

1	Status Bar (with alarm present)	**3**	'Reset All' button
2	Alarm History		

When an alarm-triggering condition (1) is no longer present, the alarm is resolved and the alarm text is no longer displayed. Resolved alarms or messages remain visible in the alarm history (2) after the active alarms/messages, but in an informational only state, until you reset the alarm history. The Alarm Reset icon (3) resets all active and resolved alarms.

To reset the alarm history, tap the Alarm Reset icon (3).

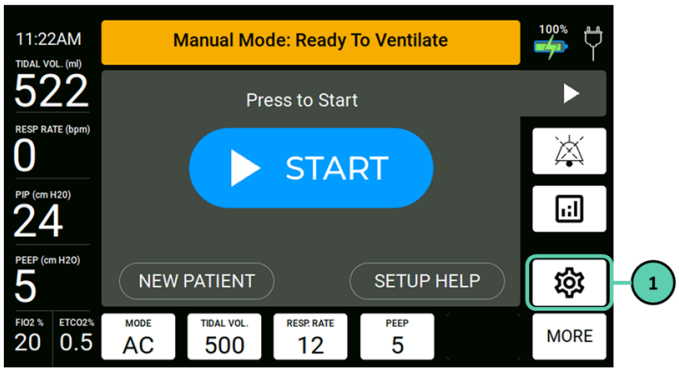
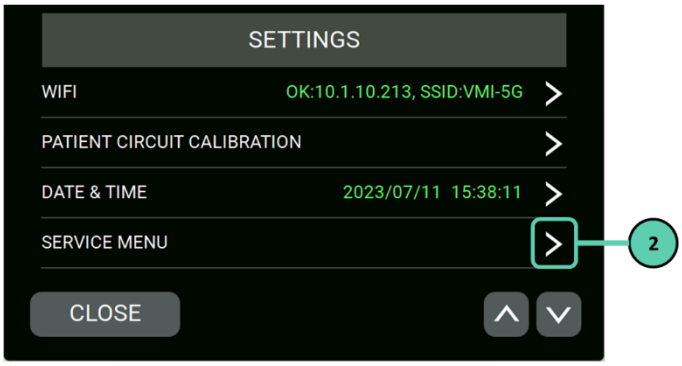
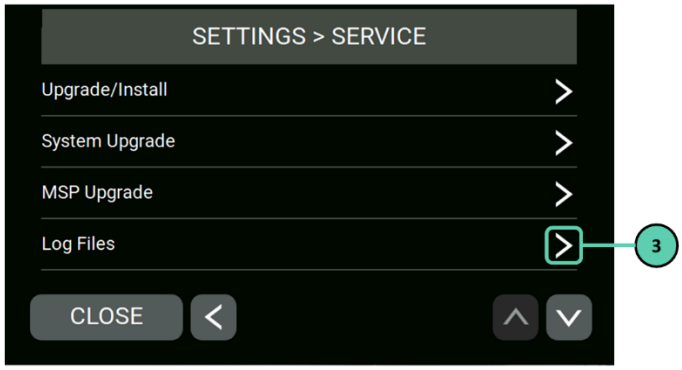
Alarm and Event Log

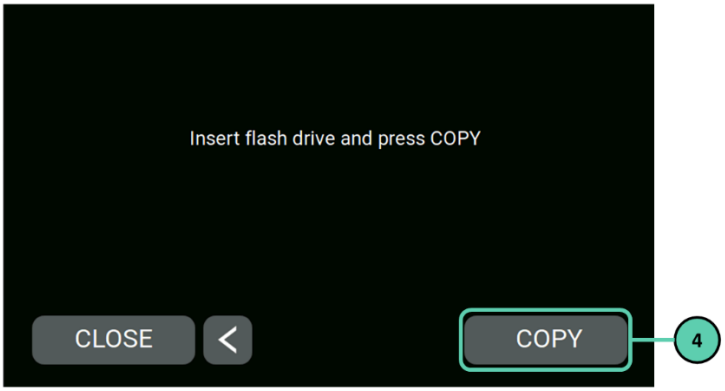
The Alarm and Event Log is a record of all events related to the device and to therapy. The log shows the event, when it occurred, and a brief description. Information is saved even when you shut off the device or when power is lost. The log stores the most recent 10,000 records. Older records are overwritten. When the operator powers down the unit, the power down is captured.

Where feasible, the alarm logs the alarm condition, including the date and time of beginning and end as well as the associated alarm limits, if operator-adjustable, for that alarm condition.

Where feasible, the alarm system logs technical alarm conditions for servicing and maintenance purposes. This log is not resettable or editable by operator action.

To export these logs, follow the workflow below.

1. Navigate to settings menu	
2. Navigate to service menu	
3. Navigate to log files export page: if required, enter the password to access this feature (talk to your responsible organization for more information)	

4. Insert a VM-2000 approved USB-C flash drive and select “copy” to transfer device logs	

11. Appendix E: Testing Alarms

Test alarms any time you make a significant change to the system. When testing alarms while ventilating a patient, assess the patient and confirm that the patient's clinical status is appropriate for the test. Have alternative ventilation means readily available.

11.1.1. Testing Circuit Disconnection Alarms

For ventilator-dependent patients, do not rely on any single alarm to detect when a circuit is disconnected. One or more of the following alarms may indicate a disconnected circuit.

- Circuit Disconnected
- Low Tidal Volume
- Low Minute Ventilation
- Low Peak Inspiratory Pressure

To test that these alarms detect a circuit disconnection:

1. Ensure that the patient is connected to the ventilator and that ventilation is stabilized. Ensure that none of the alarms above are active.
2. Disconnect the circuit at the patient end of the circuit.
3. Confirm that one or more of the above-listed alarms activate.
4. Reconnect the circuit and confirm that any active alarm automatically resets.

11.1.2. Testing Circuit Obstruction Alarms

For ventilator-dependent patients, do not rely on any single alarm to detect when a circuit is obstructed. One or more of the following alarms may indicate an obstructed circuit.

- Obstruction
- High Inspiratory Pressure
- Low Tidal Volume
- Low Peak Inspiratory Pressure alarms

To test that these alarms detect a circuit obstruction:

1. Ensure that the patient is connected to the ventilator and that ventilation is stabilized.
2. Disconnect the circuit at patient connection port and block the end of the circuit.
3. Confirm that one or more of the above-listed alarms activate.
4. Reconnect the circuit and confirm that any active alarm automatically resets.

11.1.3. Testing the Low FiO2 Alarm

The Low FiO2 alarm requires an FiO2 sensor to be connected and the FiO2 sensor setting to be turned on. To test the Low FiO2 alarm:

1. Ensure that the patient is connected to the ventilator and that ventilation is stabilized.
2. Disconnect the oxygen from the ventilator.
3. Confirm that the Low FiO2 alarm activates.

4. Reconnect the oxygen and confirm that the alarm automatically clears, which may take 30 seconds or more.

11.1.4. Testing Power Alarms

To test power alarms:

1. Connect to AC power and have a charged battery installed in the unit.
2. Ensure the VM-2000 is using AC power and has a battery. You should see both the battery and AC plug icon indicators.
3. Disconnect AC power (pull the power cord out of the outlet).
4. Confirm that the AC Disconnected alarm activates.
5. Confirm that the device continues to operate, the external battery icon appears in the Status Bar, and that AC Indicator changes to not present.

12. Appendix F: EMC Information

The VM2000 will deliver ventilation at the patient – connection port within its published accuracy and within the alarm limits set by the operator or generate an alarm condition for high pressure, high PEEP, low tidal volume, low breath rate, high and low FiO2, obstruction, and low power source.

This ventilator generates audible and visual alarms to alert you if it is not able to provide ventilation or if external monitoring is lost during an EMC disturbance.

NOTE

The use of accessories, transducers and/or cables other than those specified, except for those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

WARNING

Avoid using this equipment adjacent to or stacked with other equipment because it could result in improper operation. Although the other equipment may comply with EMC standard requirements, interference can occur. If such use is necessary, observe this equipment and the other equipment to verify that both are operating normally.

This device shall not be used near active high frequency (HF) surgical equipment, medical devices such as X-ray devices and diathermy, or in an RF shielded room of medical equipment or system for magnetic resonance imaging, where the intensity of electromagnetic (EM) disturbances is high.

This device shall not be used near RFID or electromagnetic security systems. The presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment, if possible, to maximize distances.

12.1.1. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11 Industrial, scientific, and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2 Electromagnetic compatibility (EMC). Part 3-2: Limits. Limits for harmonic current emissions (equipment input current smaller than or equal to 16 A per phase)	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3 Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low- voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection	Complies	

12.1.2. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment. During the immunity testing below the device will continue to ventilate the patient within specification. If these limits are exceeded the device may experience disturbance and will alarm

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
IEC 61000-4-2 Electromagnetic compatibility (EMC). Part 4-2: Testing and measurement techniques. Electrostatic discharge immunity test	±8 kV contact ±2 kV, ±4 kV, ±8 kV, and ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, and ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 35%.
IEC 61000-4-4 Electromagnetic compatibility (EMC). Part 4-4: Testing and measurement techniques. Electrical fast transient/burst immunity test	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for supply mains ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital environment.
IEC 61000-4-5 Electromagnetic compatibility (EMC) - Part 4-5 Testing and measurement techniques. Surge immunity test	±1 kV line to ground ±2 kV line to ground	±1 kV line to line N/A - this Class II device does not connect to earth ground	Mains power quality should be that of a typical home or hospital environment.
IEC 61000-4-11 Electromagnetic compatibility (EMC). Part 4-11: Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests	0% UT 0.5 cycle at 45 degree increments 0% UT 1 cycle 70% UT 25 cycles (30 cycles if US) 0% UT 5 sec	0% UT 0.5 cycle at 45 degree increments 0% UT 1 cycle 70% UT 25 cycles (30 cycles if US) 0% UT 5 sec	Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
IEC 61000-4-8 Electromagnetic compatibility (EMC). Part 4-8: Testing and measurement techniques. Power frequency (50/60 Hz) magnetic field immunity test	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment.
Conducted RF IEC 61000-4-6 Electromagnetic compatibility (EMC). Part 4-6: Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields.	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended 30 cm separation distance. Interference may occur in the vicinity of equipment marked with the following symbol: 
	6 Vrms Amateur Radio & ISM Bands between 150 kHz and 80 MHz	Vrms Amateur Radio & ISM Bands between 150 kHz and 80 MHz	
Radiated RF IEC 61000-4-3 Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	10 V/m 80 MHz to 2.7 GHz Telecommunication frequencies as specified in clause 8.10 of IEC 60601-1-2:2014	10 V/m	
	450, 810, 870, 930, 1720, 1845, 1970, and 2450 MHz at 28 V/m	28 V/m	
	385 MHz at 27 V/m	27 V/m	
	710, 745, 780. 5240, 5500, and 5785 MHz at 9 V/m	9 V/m	

Use of non-original manufacturer-approved accessories may violate your local RF exposure guidelines and should be avoided.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio, TV reception, or other devices which can be determined by turning the equipment on and off, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna (on the radio, TV, or other device).
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer of the device for help.

13. Appendix G: Software Licensing

This product contains software licensed under an open source license. Ventis hereby offers to deliver, upon request, a copy of the complete corresponding source code for the copyrighted open source software packages used in this product for which such delivery is requested by the respective licenses. This offer is valid for as long as the respective licenses require this offer to be valid. To obtain source code, please send your request in English with product type to open.source@Ventis.com.

14. Appendix H: Disclaimer of Warranties

Limited Warranty Applicable to the VM-2000
Ventis Medical warrants to the original purchaser ("Customer") of the VM-2000 that if there is a defect in material or workmanship in the VM-2000 and Ventis Medical is notified of such defect within one (1) year of Customer's original purchase, Ventis Medical shall, in its sole and absolute discretion, repair or provide a replacement of such defective part(s) at no charge to the Customer, provided that this warranty provision is not applicable to batteries or used consumables.

Limited Warranty Applicable to the Battery
The life of the battery, as noted, is materially affected by many factors. As such, Ventis Medical warrants to the Customer of the VM-2000 that, if there is a defect in material or workmanship in any battery contained in the VM-2000 and Ventis Medical is notified of such defect within one (1) year of Customer's original purchase, Ventis Medical shall, in its sole and absolute discretion, repair or provide a replacement of such defective battery at no charge to the Customer.

Sole Remedy
The sole remedy for a defect in materials or workmanship of the VM-2000 (or the battery or any other component of the VM-2000) shall be, at Ventis Medical's sole and exclusive discretion, repair or replacement of the defective VM-2000 or component thereof, as the case may be.

Exclusions
Ventis Medical's warranty shall not apply to defects or conditions resulting from: (a) repairs by an unauthorized party; (b) improper maintenance; (c) modifications made without written permission of Ventis Medical's; (d) damage by accident, abuse, misuse, or misapplication; or (e) operation otherwise than in accordance with this manual or other instructions furnished by Ventis Medical. Additionally, Ventis Medical's warranty shall not apply where no evidence is present that the occurrence of damage/repair happened within the certified warranty period. Ventis Medical's warranty shall not apply if the unit has been disassembled.

Replacements and/or repairs furnished under this Limited Warranty do not carry a new warranty, but carry only the unexpired portion of the original Limited Warranty. The warranty of repaired and/or replaced components does not exceed the Limited Warranty of the device. To obtain service under this Limited Warranty, claimant must promptly notify Ventis Medical or the authorized seller of the nature of the problem, serial number, and the date of purchase of the Product. Except as stated above, Ventis Medical shall not be liable for any damages, claims or liabilities including, but not limited to, personal bodily injury, or incidental, consequential, or special damages.

Disclaimer of Warranty and Limitation on Remedies
THE WARRANTY AND REMEDIES SET FORTH ABOVE ARE EXCLUSIVE AND IN LIEU OF ALL OTHERS, WHETHER ORAL OR WRITTEN, EXPRESS OR IMPLIED. VENTIS MEDICAL SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

VENTIS MEIDCAL IS NOT RESPONSIBLE FOR DIRECT, INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER LEGAL THEORY.

Limited Liability
To the maximum extent permitted by applicable law, in no event shall Ventis Medical or its Suppliers be liable for any special, incidental, indirect, physical, or consequential damages whatsoever arising out of the use or inability to use the VM-2000 product and or accessories. In any case, VM-2000's entire liability shall be limited to the amount actually paid for the purchase of the VM-2000 product. Valid proof of purchase required.

Disclaimer
Some countries, states, or provinces do not allow the exclusion or limitation of implied warranties or the limitation of incidental or consequential damages for certain products supplied to consumers, or the limitation of liability for personal injury, so the above limitations and exclusions may be limited in their application to you. When the implied warranties are not allowed to be excluded in their entirety, they will be limited to the duration of the applicable written warranty. This warranty gives you specific legal rights, which may vary depending on local law.

 The information contained in this manual is applicable to the product with which it was shipped. Product specifications and features are subject to change without notice.

Trademark Information

15. Appendix I: Cybersecurity

If a user becomes aware of or suspects any cybersecurity events, they should immediately contact support@ventismed.com.

Coordinated Vulnerability Disclosure:
- If a cybersecurity vulnerability affects the device safety or effectiveness, Ventis will disclose it by releasing an advisory to affected stakeholders and customers.
- The disclosure information will be published on the company website.
- In the event of a critical update, users shall be directly notified via email or phone.

- Following is the information disclosed:
    - Overview of the identified vulnerability, its nature, potential impact, affected devices and SW versions.
    - Actions taken to mitigate the vulnerability, including details on software updates, patches, or other remediation measures.
    - Risk assessment of vulnerability, outlining the potential risks to patient safety, data integrity, and overall device functionality if any.
    - Disclosure provides clear and concise guidance to end-users on any immediate actions they need to take to minimize potential risks associated with the vulnerability.
    - The disclosure of the vulnerability and its remediation shall be done at a specific scheduled UTC date and time.
    - Any message includes official communication channels to the company including point of contact as follows:
        - email addresses:
        - customer service:

End of Life

- At the end of support, the company may no longer be able to reasonably provide security patches or software updates. If the device remains in service following the end of support, the company will communicate through the coordinated vulnerability disclosure the potential cybersecurity risks that can be expected to increase over time.

Software Bill of Materials

- A Software Bill of Materials may be provided for certain customers. Contact Ventis for further information at support@ventismed.com.

The device hardware and software is encrypted to protect the device and ensure resiliency from cybersecurity events. The device has been validated to assure these cybersecurity protections.

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