# English

# The RESPOND 19 Ventilator


CORVENT™

## User Manual

REF 3461-03-9001

CE 0459

**Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.**

The RESPOND 19 Ventilator is under US patent protection (patent pending)

**RESPOND 19 Ventilator** is a Registered Trademark of the CorVent Medical Corporation



Uncontrolled Document: IFU112 rev K1 with revised Cleaning Procedure for Cleaning and Disinfection Validation11-9-21

**CorVent Medical Inc.**
2326 Walsh Ave
Santa Clara, CA 95051
USA

EC REP

**MedPass International**
95 bis Boulevard Pereire
75017 Paris
France

## ⚠ WARNINGS – Healthcare Providers

**Device Usage, Patient Monitoring and Alternative Ventilation**:

The CorVent RESPOND 19 Ventilator is intended to be used in institution/hospital applications for invasive and non-invasive mechanical ventilation support. It requires a robust external monitoring system be in place inclusive of functionality and alarms required for monitoring critically ill and mechanically ventilated patients.

The RESPOND 19 Ventilator is NOT intended for multiplexing (supporting more than one patient at one time).

DO NOT use the ventilator at an altitude above 3000m or outside a temperature of 10 Deg C to 30 Deg C. Using the ventilator outside of this temperature range or above this altitude can compromise the ventilator performance which consequently can result in degradation of the health of the patient. The Ventilator has only been tested at sea level and degradations in performance may occur at higher altitudes.

An alternative means of ventilation should always be available whenever the ventilator is in use (back up ventilator, alternative ventilation equipment, manual resuscitator, or similar device). Ventilator dependent patients should be continuously monitored by qualified personnel. These personnel should be prepared to provide alternative therapy in the event of ventilator failure or inoperative equipment.

**Oxygen**:

The RESPOND 19 Ventilator is not equipped with an alarm to indicate interruption of the oxygen supply to the ventilator. If the supply is interrupted, it could result in the $FiO_2$ being lower than the amount set on the unit (down to 21%). Appropriate patient monitoring should be used, as medically indicated, such as an alarming pulse oximeter and the required external Oxygen monitor. Check that the supply is still operational when assessing the patient.

When administering fixed flow supplemental oxygen, the oxygen concentration may not be constant. The inspired oxygen concentration will vary and depend primarily on the minute ventilation. If the minute ventilation increases the delivered FiO2 will be reduced and if the minute ventilation decreases the delivered FiO2 will increase.

There is a risk of fire if $O_2$ buildup within the unit is 25% or higher. The system is designed to limit the build-up of oxygen within the ventilator to less than 25% via hardware design.

Turn the device on before turning on the oxygen. Turn the oxygen off before turning the device off. This will prevent oxygen accumulation in the device.

**Loss of Power**

Upon loss of power the device will alarm and stop working. The Total Loss of Power alarm will annunciate for greater than two minutes or until the device is properly powered back on. There is NO internal backup battery. There should be continuous monitoring by

qualified personnel and an alternative means of ventilation is recommended whenever the ventilator is in use. A UPS (see section 6.3 for UPS required features) must be used with the Ventilator to provide up to 30 mins of backup power upon total loss of mains power supply. *Note: This UPS is not supplied by CorVent Medical.*

When a UPS is connected, the Ventilator will NOT indicate when the UPS has switched from mains supply to backup battery supply. The user must rely upon the UPS alarms to understand the status of their mains supply and backup battery life using the audio and visual cues from the UPS. When using a UPS, the UPS will alarm upon:

- A mains supply loss (switchover to internal backup battery) with four beeps every 30 seconds with battery symbol on UPS LCD
- Low battery Condition (battery run-time low) with continuous beeping and symbol on UPS LCD), as well as overload alarms
- The depletion of the UPS backup battery.

When the UPS battery is completely depleted, the Ventilator Total Loss of Power alarm will annunciate for >2 minutes.

The RESPOND 19 **MUST** be used with an external Uninterruptible Power Supply (UPS) and be plugged into the Hospitals Uninterruptible Backup power supply system (red outlet or equivalent).

**Viral Bacterial filter, Patient Circuit, HME:**

The device comes with a proprietary patient circuit, HME and viral bacterial filters – only replace with CorVent supplied parts. Operating this device with incompatible products could lead to fatal or other serious injury due to incompatibility.

The system **MUST** use both the inhalation and exhalation filters at all times to prevent contamination of the environment and the unit.

**Alarms:**

The RESPOND 19 utilizes a ranked alarm system. This means that it only displays the highest ranked alarm to the user. Once the highest ranked alarm is resolved, any remaining alarms of lower ranking will annunciate after if their condition persists. Please refer to the Alarm section of this manual for additional alarm information on ranking and priorities *(Section 7).*

**PLEASE READ THIS MANUAL BEFORE OPERATING THE SYSTEM**

## Table of Contents

# 1.0 Introduction

The RESPOND 19 Ventilator is a light weight, mechanical ventilator that provides Mandatory, Assist, and Spontaneous breath types for ventilator dependent adult patients. It is electro-pneumatically operated, providing invasive, and non-invasive mechanical ventilation with a built-in PEEP demand flow system. It requires a robust external monitoring system be in place, inclusive of functionality and alarms required for monitoring critically ill and mechanically ventilated patients.

The system is designed to operate in pressure controlled and pressure support modes to facilitate ease of use. Clinicians can optimize oxygenation and ventilation via standard inputs: Respiratory Rate, Inspiratory Time, Pressure Targets, Oxygen, and PEEP. The patient may be ventilated spontaneously, with mandatory/assist modes, or a combination therein. Safety features include adjustable patient alarms such as High and Low Inspiratory Pressure Limits, Disconnect, High and Low Exhaled Tidal Volume, High and Low PEEP, Apnea, and High Respiratory Rate. These features constitute the basic functionality needed for the ventilator to provide a life-supporting capacity.

The RESPOND 19 system design leverages known technology in ventilators. The Ventilator supports patients by controlling the speed of a micro-blower motor. It is electrically powered and does not require external supply of compressed air. Basic operating specifications are provided in this manual and are consistent with other currently available ventilators operating ranges for Mandatory and Spontaneous methods of Ventilation. The ventilator has an air pathway specifically designed to minimize the spread of airborne contaminants.

# 2.0 Intended Use

The RESPOND 19 Ventilator is intended to provide continuous, invasive, or non-invasive ventilatory support for the care of adult patients (of at least 60 lbs.) who require mechanical ventilation.

The RESPOND 19 Ventilator is intended for use in a hospital including intra-hospital transport. The RESPOND 19 Ventilator is intended for use by qualified, trained personnel under the direction of a licensed physician.

Personnel must become thoroughly familiar with these instructions prior to using the RESPOND 19 Ventilator.

It is recommended for the personnel that use the RESPOND-19 Ventilator to contact CorVent Medical at +1 (833) 770 - VENT, at support@CorVentmedical.com, and/or online at CorVentMedical.com for additional training.

# 3.0 Safety Information

## 3.1 Warnings, Cautions, Notes

⚠ **Warning:** Indicates the possibility for injury to the patient or the operator

| System Characteristic | Warning |
|---|---|
| Device Usage | Operating this device for unintended purposes or with incompatible products could lead to fatal or other serious injury. |
| | The RESPOND 19 Ventilator is NOT intended for multiplexing (supporting more than one patient at one time). |
| | DO NOT use a sharp object when pressing keypad to adjust Ventilation settings. |
| | Do NOT cover the ventilator or place in a position that affects proper operation |
| | Do NOT position next to a curtain that blocks the flow of cooling air, thereby causing the equipment to overheat, thereby interfering with patient ventilation. |
| | Do NOT block the gas intake port or emergency intake port, thereby interfering with patient ventilation |
| | Do NOT block the fan intake or otherwise cover or position the ventilator in a way that adversely affects its operation or performance. For example, positioning the ventilator next to a curtain that blocks the flow of cooling air can cause the ventilator to overheat and shut down, resulting in patient injury. |
| | Use of accessories, transducers and cables other than those specified or provided by CorVent Medical could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. |
| Patient Monitoring | A clinical assessment (per clinician institutional standards) should be made prior to placing a patient on the ventilator to determine:<br>• Device alarm settings<br>• Alternative ventilation equipment needed<br>• Additional external monitors to be used (oximeter ($SpO_2$), blood pressure)<br>• Required External Oxygen Monitor<br>• Required External $CO_2$ Monitor for NIV (Capnography) |

| System Characteristic | Warning |
|---|---|
| Backup Ventilation | An alternative means of ventilation should always be available whenever the ventilator is in use (back up ventilator, alternative ventilation equipment, manual resuscitator or similar device).<br>Ventilator dependent patients should be continuously monitored by qualified personnel. These personnel should be prepared to provide alternative therapy in the event of ventilator failure or inoperative equipment. |
| Qualified Personnel | The RESPOND 19 Ventilator is intended for use by properly trained personnel under the direct supervision of a licensed medical Physician or Practitioner only. Personnel must become thoroughly familiar with this Operators Manual prior to using the RESPOND 19 Ventilator on a patient. |
| | This manual serves as a reference. The instructions in this manual are not intended to supersede the physician's instructions regarding the use of the RESPOND 19 Ventilator. |
| | The RESPOND 19 Ventilator is not intended to be operated by patients or laypersons. |
| Adults only | The RESPOND 19 Ventilator has been designed for use on adult patients greater than 60 lb. DO NOT use on neonatal, infant, or pediatric patients. |
| Alarm<br>High-Medium Priority | The high priority and medium priority alarms have similar auditory indications. These two alarm priorities are mainly differentiated by their visual indicator of LED color (Red – High, Yellow – Medium) and frequency (1.5 Hz - High, 0.7 Hz – Medium) at a 50% duty cycle. |
| Alarms | Setting any alarm limits to extreme high or low values, can cause the associated alarm not to activate during ventilation, which reduces its efficacy for monitoring the patient and alerting the clinician to situations that may require intervention. |
| | The operator should check to ensure current alarm settings are appropriate prior to use on each patient. If not properly adjusted, this could effectively disable the alarm, and could lead to missing the detection of hazardous situations. This could occur if the user is trying to disable a nuisance alarm. |
| | The Alarm settings are not maintained when the system is powered down. They revert to default values upon power on. |

| System Characteristic | Warning |
|---|---|
| Loss of power | Upon loss of power the device will alarm and stop working. |
| | Immediately after power interruption the alarm system is unable to restore the alarm settings and the subsequent behavior of the alarm system. The time of powering down is not captured upon loss of power. |
| | There is NO internal backup battery. Upon loss of power the device will alarm and stop working. There should be continuous monitoring by qualified personnel and an alternative means of ventilation is recommended whenever the ventilator is in use. The ventilator must be used with an Uninterruptible Power Supply (UPS) and be plugged into the hospital's uninterruptible emergency power system. |
| Obstruction | There is no protection device in place to allow spontaneous breathing when obstruction occurs at a pressure drop less than 6,0 hPa (6,0 cmH2O). |
| Uninterruptible Power Supply | The UPS is not intended to be used to power your RESPOND 19 Ventilator, but for backup power purposes in the event of an unexpected loss of power. |
| | When a UPS is connected, the Ventilator will NOT indicate when the UPS has switched from mains supply to backup battery supply. The user must rely upon the UPS alarms to understand the status of their mains supply and backup battery life using the audio and visual cues from the UPS. When using a UPS, the UPS will alarm upon:<br>• A mains supply loss (switchover to internal backup battery) with four beeps every 30 seconds with battery symbol on UPS LCD<br>• Low battery Condition (battery run-time low) with continuous beeping and symbol on UPS LCD), as well as overload alarms<br>• The depletion of the UPS backup battery. When the UPS battery is completely depleted, the Ventilator Total Loss of Power alarm will annunciate for >2 minutes. |
| | The UPS must be placed at least 2 m (6.5 ft) away from the RESPOND 19 Ventilator and patient. |
| | Be certain to plug the UPS power cord directly into a wall outlet and not into a surge protector. |
| | Do NOT plug any other device into the UPS to ensure that the indicated backup battery life can be achieved. |

| System Characteristic | Warning |
|---|---|
| | The Uninterruptible Power Supply is **NOT** automatically maintained in a fully usable condition, it must be periodically checked per manufacturer recommendations, with replacement of power source as needed. |
| Oxygen | When administering fixed flow supplemental oxygen, the oxygen concentration may not be constant. The inspired oxygen concentration will vary and depend primarily on the minute ventilation. If the minute ventilation increases the delivered $FiO_2$ will be reduced and if the minute ventilation decreases the delivered $FiO_2$ will increase. Appropriate patient monitoring should be used, as medically indicated, such as an alarming pulse oximeter. Check that the supply is still operational when assessing the patient. |
| | It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration as marked on the ventilator and indicated in the instructions for use as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health. |
| | An alarm will not sound on the Ventilator if there is an interruption to the O2 supply. If the supply is interrupted, it could result in the FiO2 being lower than the amount set on the unit (down to 21%). Appropriate patient monitoring should be used, as medically indicated, such as an alarming pulse oximeter and the required external alarming Oxygen monitor. |
| | There is a risk of fire if $O_2$ buildup within the unit is 25% or higher. The system is designed to limit the build-up of oxygen within the ventilator to less than 25% via hardware design. |
| | Turn the device on before turning on the oxygen. Turn the oxygen off before turning the device off. This will prevent oxygen accumulation in the device. **Explanation of the warning**: When the device is not in operation and the oxygen flow is left on, oxygen delivered into the tubing may accumulate within the device's enclosure. Oxygen accumulated in the device enclosure will create a risk of fire. The design of the hardware and component selection minimizes the risk of fire; however, it is necessary to follow good practices when working with Oxygen. |

| System Characteristic | Warning |
|---|---|
| | Use an $SpO_2$ monitor to verify patient's oxygenation level. |
| | The oxygen supply must comply with local regulations for medical oxygen. Ensure the oxygen connector is connected an oxygen supply and not another gas. Follow the oxygen connection instructions carefully. |
| | DO NOT connect the device to an unregulated or high-pressure oxygen source. The Supply pressure to the Flowmeter must be within recommended tolerances for the flowmeter (typically, 50-55 PSI). |
| | Oxygen supports combustion. DO NOT use in the presence of an open flame or while smoking. |
| | DO NOT use the device near a source of toxic or harmful vapors. |
| | DO NOT use the device in the presence of a flammable anesthetic mixture in combination with oxygen or air, in the presence of nitrous oxide, or in an oxygen rich environment. |
| | To reduce the risk of fire, use the ventilator in well-ventilated areas. |
| | To reduce patient risk of oxygen toxicity, keep free-flowing oxygen away from air inlet of ventilator. |
| Interdependent Functions | Due to the design of the ventilator (see Appendix 1-Principles of Operation) the patient settings are interdependent. The Pressure Target, Inspiratory Time, and Respiratory Rate controls are all calibrated controls however the system will ensure that the output is physically possible due to the constraints of the system design. To ensure that the system is not incapable of reaching the settings desired, the ranges on all other patient settings will update in relation to any proposed change to ensure that the user is aware of the systems capability. |
| $CO_2$ rebreathing | DO NOT block the exhalation port which is located in the center of the Ventilator front panel. This can reduce airflow and result in rebreathing of exhaled air. |
| | DO NOT position next to curtains, bedding, clothing that could block the air inlet. Blocking the flow of air could lead the device to interfere with patient ventilation, potentially leading to $CO_2$ rebreathing. |

| System Characteristic | Warning |
|---|---|
| | Failure to use the patient circuit, Flow Sensor, filters, and HME provided by the company that minimize the risk of rebreathing of carbon dioxide or permit spontaneous breathing can cause asphyxiation. |
| Nebulization or Humidification | Caution when using a nebulizer as it may cause aerosolization of pathogens. If used, place after the HME, proximal to the patient. |
| | When using nebulization, the breathing system filter will require more frequent replacement to prevent increased resistance or blockage. |
| | The Ventilator accuracy can be adversely affected by the gas added to the Ventilator breathing system by the use of a pneumatic nebulizer. |
| | DO NOT use heated humidifiers as they may compromise the filter efficacy. |
| | Humidification can increase the resistance of breathing system filters, and the operator must monitor the breathing system filter frequently for increased resistance and blockage to ensure the delivery of the therapeutic pressure. |
| Other Gases | DO NOT use the ventilator with other gases other than room air and wall oxygen. |
| Device Startup | Make sure the device is working properly at startup by following the instructions in section 6. Contact CorVent if the listed testing does not work. |
| Biocompatibility | All ventilator components comprising the airway, and the means of attachment to the patient are comprised of commercial off the shelf (COTS) components. Material Safety Data Sheets (MSDS) Sheets are on file with the Manufacturer. |
| Non Invasive (Mask Based Ventilation) | The exhaled volume and exhaled CO2 of the patient can differ from the measured exhaled volume and exhaled CO2 due to leaks around the mask. |
| Patient Circuit | DO NOT use electrically conductive or antistatic patient breathing circuits. The only approved and compatible patient circuit for use with RESPOND 19 Ventilator is the circuit listed this manual. Any other patient circuit could result in degraded ventilator performance which could lead to patient injury. |

| System Characteristic | Warning |
|---|---|
| | DO NOT attempt to sterilize or reuse single use complete patient circuit or its components (Flow Sensor, Patient Circuit Tubing, Filters, and HME) as it could lead to patient infection, degraded performance, and system contamination. |
| | DO NOT add any attachments or accessories to the ventilator that are not intended for use in combination with the ventilator, as the ventilator might not function correctly leading to the risk of patient death or serious degradation of patient health |
| | Inspect the Patient Breathing Circuit, Filters, and HME for wear or damage. DO NOT use if damaged. Only replace with CorVent supplied Patient Breathing Circuit, Filters, or HMEs. |
| | DO NOT pull or stretch the tubing – this could result in circuit leaks. |
| | The RESPOND 19 Ventilator has not been tested for safety during defibrillation. |
| | To reduce the likelihood of disconnection and to prevent adverse ventilator performance use only accessories compatible with the ventilator. |
| | DO NOT place the Flow Sensor in contact with the patient. The Flow Sensor is heated to prevent condensation and may exceed 30°C depending on ambient temperature. The maximum temperature rise is less than 5°C above ambient temperature. Ensure the Flow Sensor is not in direct contact with the patients' skin. |
| | Do not use this device if the room temperature is warmer than 104˚F (30˚C) because the temperature of the airflow may exceed 109˚F (43˚C). This could cause thermal irritation or injury to the patient's airway. |
| | The system will alarm if the Luer connections on filters and HME are not sealed. Ensure that they are sealed at all times or an alarm state can occur. |
| HME | An HME is included with the ventilator for use in the patient circuit and MUST be placed as instructed in this manual to humidify air and have the unit function as intended. |
| | Only replace with CorVent supplied HME's per the instructions in this manual. Use of non CorVent supplied HME's may lead to the ventilator not functioning properly and subsequent patient harm. |

| System Characteristic | Warning |
|---|---|
| Viral Filters/ Contamination Protection | Viral bacterial filters are included with the ventilator to prevent contamination. These filters MUST be installed in the patient circuit in the TO and FROM patient port connections per the setup instructions to prevent contamination of the environment and the unit. |
| | Only replace with CorVent supplied viral bacterial filters – use of alternative filters could negatively impact the performance of the device, serious injury and/or contamination of the environment and unit. |
| | DO NOT remove, reverse orientation, or reuse filters as it may contaminate the environment or ventilator, and/or degrade the performance. |
| | DO NOT switch the inhalation and exhalation patient circuit limbs once patient ventilation has begun to minimize the risk of aerosolizing exhaled bacterial & viral particulates. |
| | DO NOT install Viral Filters or HMEs that are wet. Replace any wet filter before continuing operation. |
| Flow Sensor | Use ONLY CorVent provided Flow Sensor components. |
| | The system will Alarm for “Flow Sensor Reversed” if the Flow Sensor is placed incorrectly. |
| Improperly functioning Ventilator | If a fault is detected in the ventilator, disconnect the patient from it and immediately start ventilation with alternative device. The defective ventilator must be removed from clinical use and sent back to CorVent if possible. |
| | If any unexplained changes in the performance of the device are noticed, if it is making unusual or harsh sounds, or if the device or power supply are dropped or mishandled, discontinue use and contact CorVent support. |
| Power Supply | ONLY use the power supply provided by CorVent. |
| | The main plug of the power supply is used as a means of isolation/disconnection. DO NOT position the ventilator so that it is difficult to unplug the power cord from the wall outlet. |
| | Route the power cord to the outlet in such a manner that will prevent the cord form being tripped over or interfered with by chairs or other furniture. |
| | This device is activated when the power cord is connected. |

| System Characteristic | Warning |
|---|---|
| | Ensure that an Audible click is heard when connecting the locking external 24V universal power supply cable to the RESPOND 19 Ventilator. This ensures a locked connection, lowering the risk of unintended power cable exertion which could lead to Ventilator Total Loss of Power. |
| | The Ventilator DOES NOT have an internal battery. |
| | The RESPOND 19 MUST be used with an external Uninterruptible Power Supply (UPS) and be plugged into the Hospitals Uninterruptible Backup power supply system (red outlet or equivalent). |
| EMC | Care must be taken when operating this equipment around other equipment to avoid reciprocal interference. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with this device. |
| | This Medical Equipment is designed to comply with IEC 60601-1-2: 2014. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following:<br>• Reorient or relocate the receiving device<br>• Increase the separation between the equipment<br>• Connect the equipment to an outlet on a different circuit from that to which the other device(s) are connected<br>• Consult your authorized dealer for help |
| | Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RESPOND 19 Ventilator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. |
| Maintenance | DO NOT attempt to service the unit. If any defects are present, contact CorVent Medical support. |

| System Characteristic | Warning |
|---|---|
| | DO NOT operate the ventilator or use any of the accessories if there are signs of damage or it is not working properly. Periodically inspect power cord, patient circuit, filters, HME, and Flow Sensor for damage and replace if necessary. |
| | NO modification of this equipment is allowed. |
| Cleaning | DO NOT spray the device with any water or cleaners or immerse in any fluids. If necessary, wipe the device with a cloth dampened with an approved cleaner. To avoid electrical shock, always unplug the power cord from the wall outlet and/or external power supply module before cleaning the device. |
| | DO NOT attempt to sterilize the ventilator with autoclave or ethylene oxide. Doing so will destroy the ventilator. |
| | DO NOT immerse the ventilator in water or any fluids |
| | DO NOT allow liquid or sprays to penetrate the ventilator openings or cable connections |
| | DO NOT use pressurized air to clean or dry the ventilator |
| | DO NOT spray the air intake or the patient ports with cleaning solutions immediately before or during operation. The cleaning solutions may aerosolize and enter the patient's airway creating the potential to cause lung damage. |
| Not MRI safe | The RESPOND 19 Ventilator is not intended for use within Magnetic Radiation (MR) environment. |
| Operating Environment | DO NOT use the ventilator at an altitude above 3000m or outside a temperature of 10 Deg C to 30Deg C. Using the ventilator outside of this temperature range or above this altitude can compromise the ventilator performance which consequently can result in degradation of the health of the patient. The Ventilator has only been tested at sea level and degradations in performance may occur at higher altitudes. |
| | Condensation may damage the device. If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (operating temperature) before starting therapy. Do not operate the device outside of the operating temperature range shown in the Specifications chapter in the Operator Manual. |

| System Characteristic | Warning |
|---|---|
| | DO NOT use the RESPOND 19 Ventilator in conjunction with anesthetics or in contaminated (hazardous, explosive) atmospheres. Only compressed oxygen may be used. |
| | This ventilator is portable meaning it is intended to be carried but not operating from one location to another. |
| | The RESPOND 19 Ventilator is not intended for use as an emergency transport ventilator. |
| | DO NOT stack the ventilator on other equipment. Place on flat surface large and strong enough to support the weight and stability of the device. |
| | Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. |
| Hyperbaric Use | DO NOT use the ventilator in a hyperbaric chamber or other similarly oxygen-enriched environments. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health. |
| High Altitude | The RESPOND 19 is not suitable for use at high altitudes (above 3000m). The Ventilator has only been tested at sea level and degradations in performance may occur at higher altitudes. |
| Latex | The RESPOND 19 Ventilator and its accessories are not made with Natural Rubber Latex. |
| Electric Shock | To reduce the risk of electric shock from liquid entering the device, DO NOT put a container filled with a liquid on or near the ventilator. |
| | To avoid the risk of electric shock this equipment must be connected to a supply main with a protective earth. |
| EM Interference | The RESPOND 19 Ventilator may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ventilator or shielding the location. |
| Software | There are no known unresolved software anomalies and workarounds. |

| System Characteristic | Warning |
|---|---|
| | The CorVent System will not be subject to digital cyberattacks because there are no data ports that the user may access without the use of a tool. It will take dismantling the device to gain access to a port. The device also does not contain any wireless devices. |
| | There are no known or unresolved anomalies that can lead to the compromise of sensitive information or that can affect communication security due to system not having capability to interface with external systems. |
| EMC | Use of non-approved accessories, transducers or cables may increase EMC emissions or decrease the EMC immunity performance of the equipment. |
| Nitric Oxide | The ventilator shall not be used with nitric oxide. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health |
| Helium Gas Mixtures | The ventilator shall not be used with inlet gases, which are not specified for use (e.g. helium or mixtures with helium). Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health. |

**Caution**: indicates the possibility of damage to the device

| System Characteristic | Caution |
|---|---|
| Condensation | Condensation may damage the device. If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (operating temperature) before starting. DO NOT operate the device outside of the temperature range shown in the specifications section later in this manual. |
| Device Placement | DO NOT place the device in or on any container that can collect or hold water |
| | DO NOT place the device directly onto carpet, fabric or other flammable materials |
| | DO NOT plug the device into an outlet controlled by a wall switch |
| | Ensure the ventilator is placed on a flat stable surface or secured to a stand |
| | DO NOT use extension cords with this ventilator. |
| Cleaning | DO NOT immerse the device in any liquid or allow any liquid to enter the vent or inlets |

| System Characteristic | Caution |
|---|---|
| | DO NOT use harsh detergents, abrasives or brushes to clean the ventilator. Refer to recommended cleaning procedures in Section 8. |
| Alarms | The alarm changes are NOT STORED upon powering down or at total loss of power. |
| | The alarm pre-sets (Defaults) are the same for each RESPOND-19 ventilator, are un-editable, and reset to Default upon power cycling. |

See the Limited Warranty section of this manual for information on warranty coverage

## 3.2 Patient Population

The intended patient population includes adult patients who require pressure-based continuous respiratory support with tidal volumes as low as 50 ml and inspiratory pressures as low as 1 cmH20.

## 3.3 Contraindications

The RESPOND 19 Ventilator is contraindicated in the following situations:

- Active Pneumothorax
- Neonatal, Infant, and Pediatric patients
- Use of this device may be contraindicated depending on the status of DNR type instructions in your location. Please consult your legal advisor for specific guidelines in this matter.

## 3.4 Environments of Use

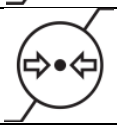
The RESPOND 19 Ventilator is intended for use in a hospital setting or similar clinical environments such as an Intensive Care Unit (ICU) or Long-Term Acute Care (LTAC) unit. The hospital and most clinical units are a non-sterile environment, where the Ventilator and its components are non-sterile as per standard of respiratory care. The patient circuit is disposable; the Ventilator, its power supply and flow sensor cable are reusable.

Users will interact with the Ventilator while wearing various levels of PPE from bare hands with no mask/face shield up to complete biohazard suits in the case of infectious respiratory viruses and bacteria.

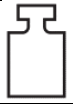
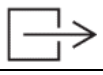
| Hospital and Clinical Environment Characteristics | |
|---|---|
| Architectural | • A majority of care units consists of a central clinician workstation surrounded by PATIENT rooms or bays.<br>• A central clinician workstation usually has counters and desks to serve as standing and sitting workstations, respectively.<br>• Floors are usually covered by smooth tile or vinyl. |

| Hospital and Clinical Environment Characteristics | |
|---|---|
| Equipment, furniture, and supplies | • PATIENT rooms or bays are typically equipped with a movable hospital bed, an over-bed table, and one or more chairs to accommodate visitors.<br>• Headwalls provide medical gases (e.g. air, oxygen), electrical receptacles, mounting points or shelves for equipment (e.g. multi-parameter PATIENT monitor), and storage for emergency supplies.<br>• Equipment is often exposed to rough handling during emergencies.<br>• Equipment might be splashed with fluids (e.g. blood, urine, IV solutions, cleaning solutions). |
| Personnel | • A central station can be occupied by multiple physicians, nurses, and nurse assistants.<br>• Additional hospital personnel, such as technicians and PATIENT transporters, enter and exit an intensive care unit frequently.<br>• PATIENTS can have multiple visitors (e.g. family members, friends) of any age. |
| Lighting | • At various times of day, a PATIENT room or bay can be brightly lit (e.g. 150 lx), less brightly lit (e.g. 50 lx to 100 lx), or dimly lit (e.g. 10 lx) such as during medical PROCEDURES performed at the bedside, daytime care, and nigh- time care, respectively.<br>• Overhead lighting is often complemented with headwall lights.<br>• Some intensive care units receive direct sunlight via windows and skylights. |
| Noise | • Sound level variance is partly a function of the time of day, daytime usually being noisier time of day than night-time.<br>• Steady background (i.e. ambient) noise sources include people communicating and moving throughout the intensive care unit, ventilation noise, overhead pages, various MEDICAL DEVICES, and televisions.<br>• Ambient sound level range at the central station is normally 50 dBA to 70 dBA.<br>• Ambient sound level range in a PATIENT room or bay is normally 50 dBA to 65 dBA. |
| Climate | • Temperature range is normally 18 °C to 21 °C.<br>• Relative humidity range is normally 10 % to 50 % |
| Potential distractions | • Personnel might be distracted by PATIENT care emergencies, hallway meeting, telephone calls, overhead pages, and other events. |

# 4.0 Symbols Glossary and Abbreviations

| Symbol | Description |
|---|---|
|  | Medical Device<br>Indicates that the item is a medical device. |
| IP22 | IP22: N1=2, Protected against solid foreign objects of 12.5 mm Ø and greater; N2=2, Protection against vertically falling water drops when ENCLOSURE tilted up to 15° |
|  | (MR) Unsafe. Not intended to be used within an MR environment. |
|  | To indicate packages containing electrostatic sensitive devices, or to identify a device or a connector that has not been tested for immunity to electrostatic discharge. |
|  | Temperature limitation to which the medical device can be safely exposed |
|  | Humidity limitation to which the medical device can be safely exposed |
|  | Atmospheric pressure limitation to which the medical device can be safely exposed |
|  | TYPE BF APPLIED PART.<br>The Flow Sensor, flow sensor cable, Inhalation/Exhalation filters, HME, and patient circuit are the patient applied parts. |
| SN | Indicates the manufacturer's serial number so that a specific medical device can be identified |
| REF | Model (part) number |
| LOT | Lot Number |
| EC REP | European Authorized Representative |
|  | DO NOT Reuse<br>Indicates a medical device that is intended for one single use only |
|  | Manufacturer |
|  | Manufactured Date |

| | Description |
|---|---|
|  | Use by Date, Indicates the date after which the medical device is not to be used. |
|  | Keep Dry, avoid moisture |
|  | Caution, serious injury or device damage may occur by disregarding the instructions accompanying this warning symbol. |
|  | General Warning |
|  | Non-Sterile Device |
|  | Alternating Current |
|  | Direct Current |
|  | Mandatory action sign |
|  | Operators manual must be read prior to use |
|  | Reference Operators manual |
|  | Explosion Risk (Oxygen rich environment) |
|  | Fire Risk (Oxygen rich environment). Keep away from flame. |
|  | Not made with natural rubber latex |
|  | Electric Shock Hazard |

| Symbol | Description |
|---|---|
|  | Waste Electrical and Electronic Equipment Directive (WEEE). The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. |
| CE 0459 | CE marking is an administrative marking that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area. 0459 = GMED SAS Code |
| Rx Only | Intended for use only by the order of a physician (prescription) |
|  | Do not use if package or device is damaged |
|  | Alarm Pause – Pause the audio indication of an alarm for a short period of time |
|  | Alarm Silence – Reset an alarm if it continues to annunciate even though the condition causing the alarm is no longer present. |
|   | Altitude Limitation |
|  | Keep out of Sunlight |
|  | This way up |
|  | Fragile. Handle with care. |
|   | Stacking weight limitation. |
|  | Stacking limitation of the same box vertically |
|  | Weight of Device |
|  | To Patient Port – Inhalation limb connection |
|  | From Patient Port – Exhalation limb connection |
|  | Distributor – Distributed By |

**ACV –** Assist control ventilation
**A/C** – Assist Control
**ATPD** – Atmospheric Temperature and Pressure Dry
**BIOT** – Built in Ongoing Test
**BPM/BR/RR/f** – Breaths per minute (Breaths per minute)
**BTPS** – Body Temperature and Pressure Saturated
**CMV** – Continuous Mandatory Ventilation
**ES/$E_{SENS}$** – Exhalation Sensitivity
**ETT** – EndoTracheal Tube
**HME –** Heat Moisture Exchanger
**HP/ HIP** – High Pressure/ High Inspiratory Pressure (cmH2O)
**HR** - High respiratory Rate Limit (bpm)
**LP/LIP** – Low Pressure (cmH2O)
**MAP** Mean Airway Pressure (cmH2O)
**MV -** Minute Ventilation (L/min)
**NIV –** Non-Invasive Ventilation
**$O_2$% -** Percent Oxygen
**PCV** – Pressure Control Ventilation
**PEEP** – Positive End Expiratory Pressure
**PF** – Peak Flow Rate (L/min)
**$P_I$** – Inspiratory Pressure Target
**POST** – Power On Self-Test
**PP** - Peak Pressure (cmH2O)
**$P_{SUPP}$** – Pressure Support Target
**$P_{Target}$** – Pressure Target
**PSV** – Pressure Support Ventilation
**$Q_i$** – Inspiratory Flow
**$Q_{aw}$** – Flow at Patient Wye
**SIMV** – Spontaneous Intermittent Mandatory Ventilation
**SPONT** – Spontaneous Ventilation
**TV** – Tidal Volume
**UPS** – Uninterruptible Power Supply
**VAC –** Voltage, Alternating Current
**VDC –** Voltage, Direct Current
**Ve** - Expiratory Volume measured by airway Flow Sensor (mL)
**Vi -** Inspiratory Volume measured by airway Flow Sensor (mL)
**$\dot{V}_{SENS}$** – Inspiratory Trigger Sensitivity

# 5.0 System Components, Overview and Performance

## 5.1 Package Contents

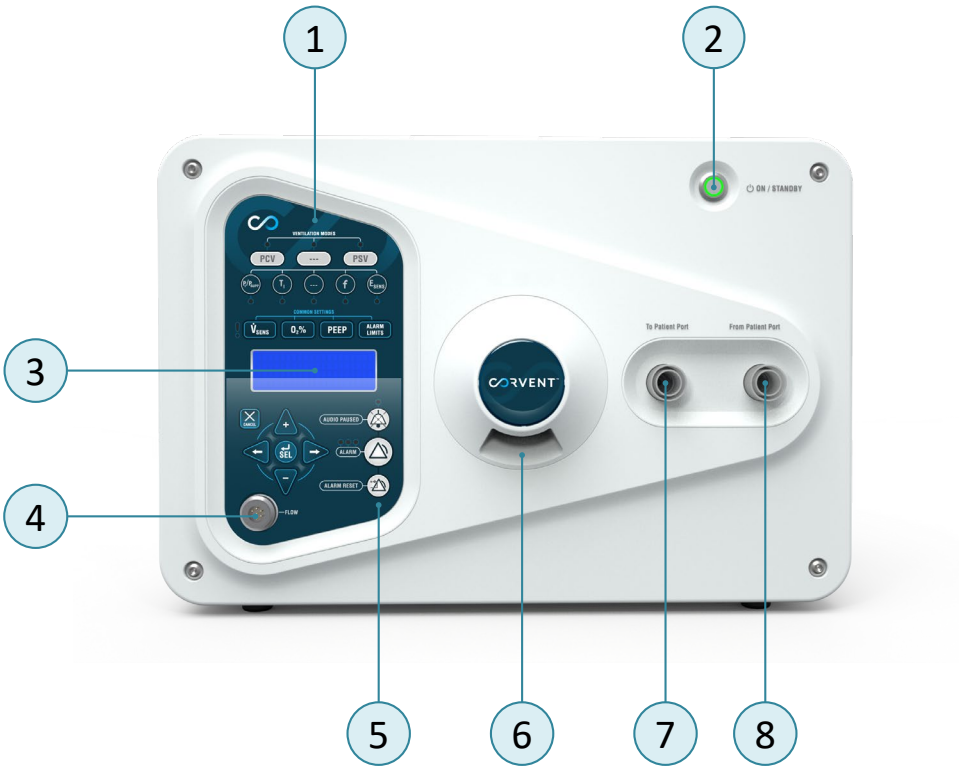
The RESPOND 19 ventilator is supplied with all the components needed to support a patient right out of the box. This includes:

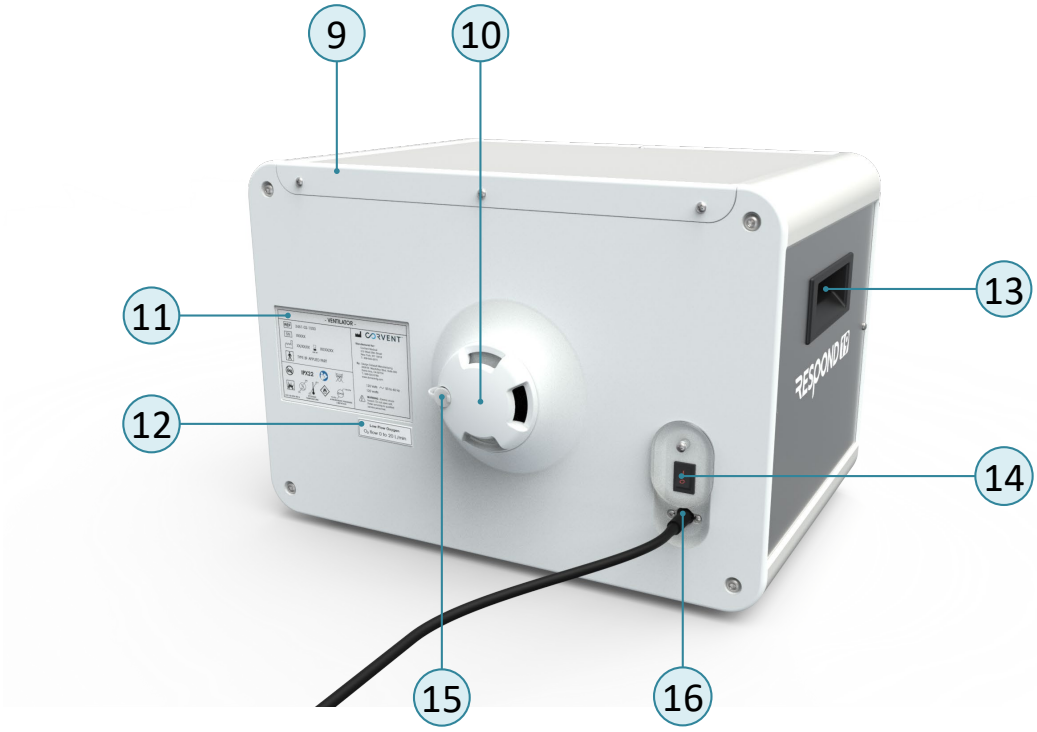
- RESPOND 19 Ventilator
- External 24V power supply with 6 ft. power cord
    - Uninterruptible Power Supply (UPS) available separately
- Single Use RESPOND 19 Patient Circuit
- Single Use Heat Moisture Exchanger (HME)
- Single Use Bacterial / Viral Filters
- Single Use Flow Sensor
- Reusable Flow Sensor Cable
- Operators Manual
- Quick Start Guide
- Quick User Interface Reference Guide


The system is provided in a non-sterile state without cleaning required, as is standard of care.

Carefully unpack the items and set up on a stable level surface. Inspect items for signs or damage, DO NOT use if damaged, replace if necessary.

## 5.2 System Overview and Key Performance Specifications




17
18
19
20
21
22
23
24

The key features of the CorVent RESPOND 19 Ventilator are described below:

| No. | Feature | Description |
|---|---|---|
| 1 | Membrane Panel User Interface | Refer to Section 6.6 for User Interface details |
| 2 | Standby/Start Ventilation Therapy Button | Green Light LED indicates ventilation on. Flashing Green LED indicates standby mode. |
| 3 | Display LCD | Refer to Section 6.6 for display features |
| 4 | Flow Sensor Connection | Connect during setup per Section 6.3 |
| 5 | Patient and Technical Alarms | Refer to Section 7.0 for alarm details |
| 6 | Exhalation Port | |
| 7 | From Patient Inlet Port | Standard 22mm |
| 8 | To Patient Outlet Port | Standard 22mm |
| 9 | Ventilator Enclosure | |
| 10 | Ventilator Air Inlet Port | |
| 11 | Ventilator Label | |
| 12 | Oxygen Flow Rate Label | 0 - 15 SLPM, Low Flow Oxygen |
| 13 | Ventilator Carrying Handles | |
| 14 | Covered Power On/Off Switch | Use per Section 6.5 |
| 15 | Blended Oxygen Inlet Connection | Connect during setup per Section 6.4, Cap when not in use. |
| 16 | Power Supply | Connect during setup per Section 6.2 |
| 17 | Expiratory Viral/Bacterial Filter | Clear Body with White Internals, From Patient, Single Patient Use |
| 18 | Inspiratory Viral/Bacterial Filter | Clear Body with White Internals, To Patient, Single Patient Use |
| 19 | Flow Sensor Cable | Reusable |
| 20 | Patient ET Tube Connection | |
| 21 | HMEF | Clear Body with Blue Internals, Single Patient Use |
| 22 | Flow Sensor | Single-patient Use |
| 23 | Patient Circuit Wye | Single-patient Use |
| 24 | Patient Circuit | Single-patient Use |

| Key Performance Specifications | |
|---|---|
| ***Ventilation Modes*** | |
| Available Breath Modes | PCV, PSV/CPAP, P SIMV |
| ***Ventilation Types*** | |
| Available Types | Invasive and Non-Invasive (NIV) |
| ***Patient Settings*** | |
| Breath Rate (f) | 3 to 70 bpm |
| Inspiratory Pressure Target ($P_I$)* | 5 to 40 $cmH_2O$ – PEEP |
| Inspiratory Time ($T_I$) | 0.4 to 3.0 sec |
| Pressure Support Target ($P_{SUPP}$)* | 0 to 40 $cmH_2O$ – PEEP |
| Exhalation Sensitivity($E_{SENS}$) | 5 – 80% |
| Tidal Volume | 50 – 2,000 mL– *not a direct setting on ventilator* |
| ***Common Settings*** | |
| PEEP | 0 - 20 $cmH_2O$ |
| % $O_2$ | 21 - 95%* Set via MV – not a direct setting on ventilator |
| Invasive Trigger Sensitivity ($\dot{V}$) | 0.5 - 20 L/min |
| NIV Trigger Sensitivity ($\dot{V}$) | 1 - 10 |
| ***Alarm Settings*** | |
| High Inspiratory Pressure Limit | 20 – 50 $cmH_2O$ |
| Low Inspiratory Pressure Limit | 1 – 35 $cmH_2O$ |
| High Respiratory Rate Limit | 20 – 80 BPM |
| Apnea/Hypoventilation Limit | 10 – 40 secs |
| Disconnect Limit | 10 – 90% of delivered Tidal Volume |
| High Exhaled Tidal Volume Limit | 100 – 3,000 mL |
| Low Exhaled Tidal Volume Limit | 50 – 1,000 mL |
| High PEEP Limit | 5 – 25 $cmH_2O$ |
| Low PEEP Limit | -1 – 15 $cmH_2O$ |
| ***General Specifications*** | |
| Flow Rate | Max 120 L/min BTPS |
| Oxygen Supply (flow meter) | 0 - 15 SLPM |
| Circuit Compliance | 2 ml/$cmH_2O$ |
| Bacterial/Viral Filtration | >99.99% on inhalation and exhalation |
| Inspiratory Ratio (measured) | 3:1 to 1:5 |
| Humidified Air | Yes - HME |
| Alarms | High Inspiratory Pressure, Occlusion, Disconnect, High Exhaled Tidal Volume, Low Exhaled Tidal Volume, Low Inspiratory Pressure, Apnea, Hi Respiratory Rate, High PEEP, Low PEEP, Flow Sensor Disconnect/ Failure, Key Stuck, Flow Sensor Reversed, Total Loss of Power, Ventilation Stopped, System Inoperable |

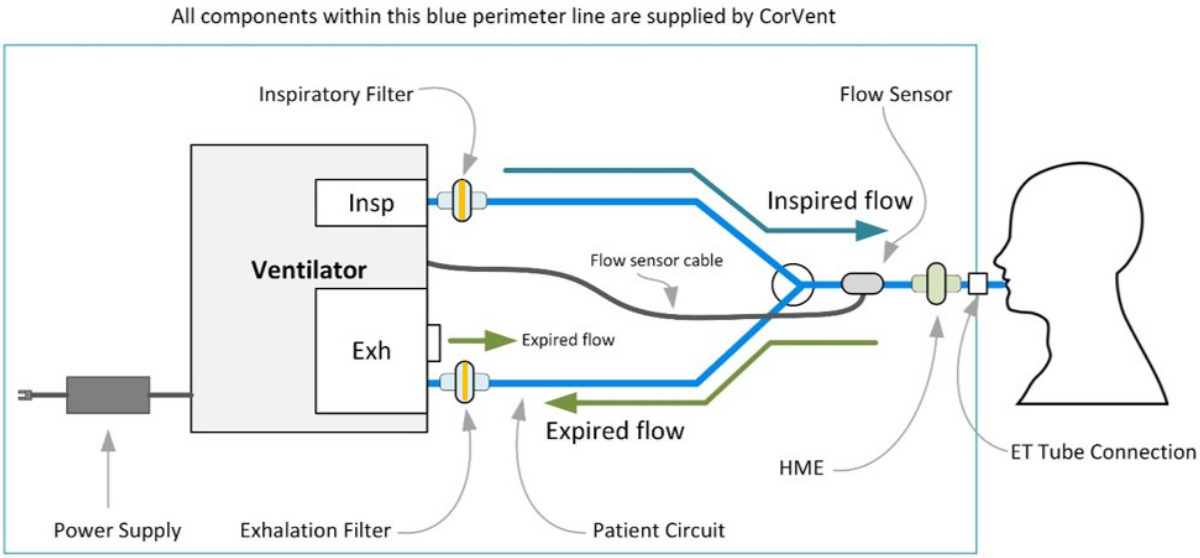
**Max Pressure Target capability may be affected by altitude, Refer to Section 10: Specifications, Subsection: Effects of Altitude on Ventilation Parameters, for more details.*

## 5.3 Ventilator Components and Accessories

| Part Description | Part # | Picture of Part |
|---|---|---|
| **RESPOND 19 Complete Ventilator Kit (MDD)** | **3461-03-9001**<br>*This Kit Includes:*<br>1x 3461-03-1001<br>1x 3461-03-9121<br>1x 3461-03-9200<br>1x 3461-03-9300<br>1x 3461-03-9410<br>1x 3461-03-9421 or 9422 |  |
| **RESPOND 19 Base Ventilator Kit (MDD)** | **3461-03-9111**<br>*This Kit Includes:*<br>1x 3461-03-1001<br>1x 3461-03-9121 |  |
| **RESPOND 19 Ventilator (MDD)** | **3461-03-1001*** |  |
| **Complete Patient Circuit Kit** | **3461-03-9200**<br>*This Kit Includes:*<br>1x 3461-03-9210<br>1x 3461-03-9220<br>2x 3461-03-9230<br>1x 3461-03-9240<br>1x 3461-03-9280 |  |
| **Patient Circuit** | **3461-03-9210** |  |
| **HME** | **3461-03-9220** |  |

| Part Description | Part # | |
|---|---|---|
| **Inhalation/Exhalation Filter** | **3461-03-9230** |  |
| **Flow Sensor** | **3461-03-9240** |  |
| **Filter Port Adapter** | **3461-03-9280** |  |
| **Flow Sensor Cable** | **3461-03-9300** |  |
| **24V Universal Power Supply** | **3461-03-9410** |  |
| **Power Supply Cable (North America)** | **3461-03-9421** |  |
| **Power Supply Cable (EU)** | **3461-03-9422** |  |
| **Literature Kit** | **3461-03-9121** | Operators Manual, Quick-Start Guide, Quick User Interface Reference |

**The RESPOND 19 Ventilator must be purchased as part of the Complete Ventilator Kit (3461-03-9001) or the Base Ventilator Kit (3461-03-9111)*


All components within this blue perimeter line are supplied by CorVent
Inspiratory Filter
Flow Sensor
Insp
Inspired flow
Ventilator
Flow sensor cable
Exh
Expired flow
Expired flow
HME
ET Tube Connection
Power Supply
Exhalation Filter
Patient Circuit

# 6.0 Using the RESPOND 19 Ventilator

## 6.1 Setting Up the Ventilator

Place the device on a clean, flat, stable surface. Make sure the area around the device is dry, clean, and clear of bedding, clothing, or curtains that could block the air inlet. Air must flow freely around the device for the system to work properly.

Examine the device for any damage before use.

⚠ Warnings

DO NOT position next to curtains, bedding, clothing that could block the air inlet. Blocking the flow of cooling air could lead the device to overheat thereby interfering with patient ventilation.

DO NOT block the exhalation port which is located in the center of the front panel of the Ventilator. This can reduce air flow and result in rebreathing of exhaled air.

DO NOT place the device in or on any container that can collect or hold water.

DO NOT place the Flow Sensor in contact with the patient. The Flow Sensor is heated to prevent condensation rainout and may exceed 30°C depending on ambient temperature. The maximum temperature rise is less than 5°C above ambient temperature. Ensure the Flow Sensor is not in direct contact with the patients' skin.

**Caution**

DO NOT place ventilator directly onto carpet, fabric or other flammable materials

## 6.2 Supplying Power

1. The RESPOND 19 must be connected to a hospital dedicated circuit that will continue AC supply even in the event of an external main AC supply failure. These mains sockets are typically marked with a red outlet plate and are backed up by UPS and in-house generators.
2. Before connecting the ventilator to such a socket, test the AC voltage is within the power supply operational limits. Refer to the Specification section for these limits.
3. Typically, the RESPOND 19 will not be affected when AC power is lost when connected to such hospital dedicated circuit because these switchovers happen instantaneously. In the event, that AC power is lost momentarily, the RESPOND 19 has been designed to restart ventilation even after a temporary loss of AC power of up to 2 minutes. The RESPOND 19 will reestablish all user settings and alarm limits present before the loss of power and come back up ventilating 10 seconds (when it is performing POST) after power is restored annunciating a high priority TEMP LOSS OF POWER alarm. The user will be required to press the ALARM RESET key to acknowledge this event has occurred to reset the alarm.

**⚠ Warnings**

Upon loss of power the device will alarm and stop working. The Total Loss of Power alarm will annunciate for greater than two minutes or until the device is reconnected to AC power. There is NO internal backup battery. There should be continuous monitoring by qualified personnel and an alternative means of ventilation is recommended whenever the ventilator is in use. A UPS or a hospital dedicated circuit must be used with the Ventilator to provide up to 30 mins of backup power upon total loss of mains power supply. DO NOT plug the ventilator into an outlet controlled by a wall switch.

The main plug of the power supply is used as a means of isolation/disconnection. DO NOT position the ventilator so that it is difficult to unplug the power cord from the wall outlet

ONLY use the power supply provided by CorVent.

To avoid the risk of electric shock this equipment must be connected to a supply main with a protective earth.

Inspect electrical cords for damage or signs of wear and DO NOT use if damaged.

Ensure that an **Audible click** is heard when connecting the locking external 24V universal power supply cable to the RESPOND 19 Ventilator. This ensures a locked connection, lowering the risk of unintended power cable exertion which could lead to Ventilator Total Loss of Power.

**Caution**

DO NOT use extension cords with this device.

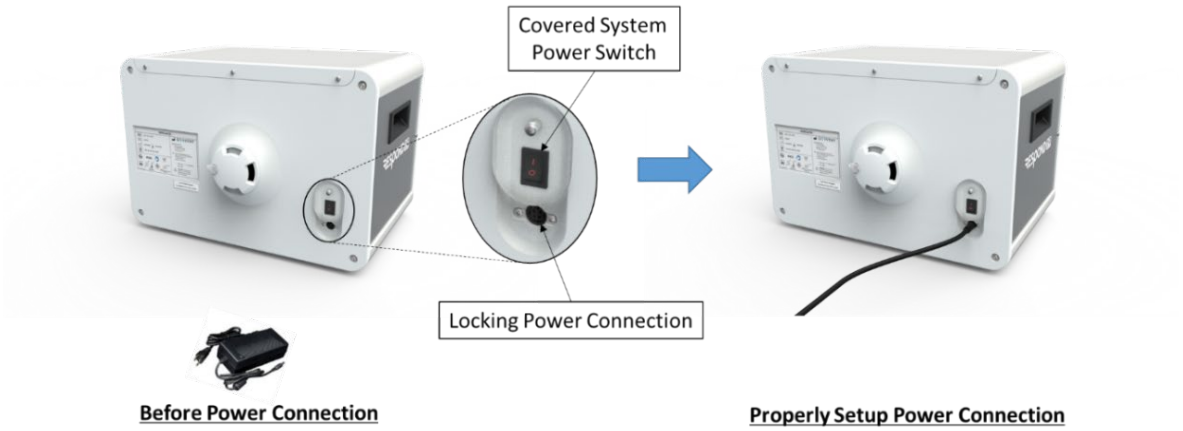
## Connecting to Power

The power supply is medical grade (IEC 60601-1 compliant). It is external to the unit and is not in contact with the ventilator. The power supply is outside of the system and strictly provides DC voltage, minimizing the risk of leakage.

To connect the ventilator to power, ensure the system power switch is in the OFF position. Align the power connection with the Locking power connection on the rear of the unit. Press firmly until an auditory click is heard, this ensures a locked connection, lowering the risk of unintended power cable exertion.

Once the ventilator locking power connection is attached, the system can be plugged into to a hospital power outlet. Verify that all connections are fully inserted and locked in before turning on the system power switch**.** This will help to ensure that a secure, reliable electrical connection has been made.

A **UPS or a hospital dedicated circuit is required for use** to provide up to 30 mins of backup power. Plug the UPS into the hospital uninterruptible power outlets first (red outlet or equivalent), and then plug the ventilator into the battery backup plugs on the UPS (Refer to Section 6.3 for more details). Before connecting the ventilator to such a socket, test the AC voltage is within the power supply operational limits. Refer to the Specification section for these limits.




The system power switch is covered with a rotating plate to protect from unintended shutoff. This cover will need to be rotated out of the way in order to turn on/off the system.

## 6.3 Connecting to an Uninterruptible Power Supply (UPS)

See manufacturer instructions accompanying the UPS selected for setup, accessory alarms, service intervals, and other additional operational details. *Note: This UPS is not supplied by CorVent Medical.*

⚠ Warnings

The RESPOND 19 **MUST** be used with an external Uninterruptible Power Supply (UPS) and be plugged into the Hospitals Uninterruptible Backup power supply system (red outlet or equivalent).

The UPS is not intended to be used to power your RESPOND 19 Ventilator, but for backup power purposes in the event of an unexpected loss of power.

The UPS must be placed at least 2 m (6.5 ft) away from the RESPOND 19 Ventilator and patient.

Be certain to plug the UPS power cord directly into a wall outlet and not into a surge protector.

When a UPS is connected, the Ventilator will NOT indicate when the UPS has switched from mains supply to backup battery supply. The user must rely upon the UPS alarms to understand the status of their mains supply and backup battery life using the audio and visual cues from the UPS. When using a UPS, the UPS will alarm upon a mains supply loss (switchover to internal backup battery) with four beeps every 30 seconds with battery symbol on UPS LCD, a Low battery Condition (battery run-time low) with continuous beeping and symbol on UPS LCD), as well as overload alarms, and the depletion of the UPS backup battery.

When the UPS battery is completely depleted, the Ventilator Total Loss of Power alarm will annunciate for >2 minutes.

**Do NOT** plug any other device into the UPS to ensure that the indicated backup battery life can be achieved.

The Uninterruptible Power Supply is **NOT** automatically maintained in a fully usable condition, it must be periodically checked per manufacturer recommendations, with replacement of power source as needed.

UPS outlets are powered whenever a UPS is switched ON. During a power outage, UPS outlets will be powered for a limited time. Charging the UPS for at least 20 minutes before use will support back-up of a 2-minute brown-out. The UPS selected may take up to 24 hours to complete a full charge. Once fully charged, the UPS (will provide up to 30 mins of backup power in the event of a mains total loss of power). In order to achieve up to 30 mins of backup power with the UPS, no other equipment shall be plugged into the UPS.

A secondary adapter cable may be necessary to use some UPS's with the RESPOND 19 Ventilator. Below are the requirements for selecting a UPS and the instructions for how to set it up with the RESPOND 19 Ventilator:

UPS Requirements:

Uninterruptible Power Supply Power In: 120 to 240 VAC

Volt-Amp Rating: ≥700VA

Operation time: >30 minutes

Standard Compliance (at Minimum):

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-6
- IEC 60601-1-8

Alarms Available (at Minimum):

- **Medium Priority -** Total Loss of Mains Supply + Switchover to Internal Battery
- **Medium Priority** - Battery Close to Depletion alarm (at least 10 mins prior to losing power)
- **High Priority** - Battery Nearing Complete Depletion alarm ( at least 5 mins prior to losing power)

Indicators (at Minimum):

- Means of measuring the battery operational time left (can be qualitative)
- Means to indicate that the system is running off of the backup battery

UPS Setup with the Ventilator:

1. Ensure the Ventilator is turned off.

2. Test the red wall outlet voltage is within the expected AC limits.

3. Plug the UPS into the red wall outlet (or equivalent).

4. Plug the RESPOND 19 ventilator power supply into the UPS, ensuring that you plug into the UPS battery backup outlets. Press the power button on the UPS to turn it on.

5. Verify that the RESPOND 19 Ventilator and UPS are operating properly.

## 6.4 Connecting the Breathing Circuit, HME, Viral Filters, and Flow Sensor to Ventilator and Patient

⚠ Warnings

Inspect the breathing circuit and HME for wear or damage. DO NOT use if damaged. Only replace with CorVent supplied Breathing Circuit or HME
DO NOT pull or stretch the tubing – this could result in circuit leaks.

The RESPOND 19 Ventilator has not been tested for safety during defibrillation.

### 6.4.1 Connecting the Viral Inhalation and Viral Exhalation Filters

⚠ Warning

Viral bacterial filters are included with the ventilator to prevent contamination. These filters MUST be installed in the patient circuit in the TO and FROM patient port connections per the setup instructions to prevent contamination of the environment and the unit.

DO NOT remove, reverse orientation, or reuse filters as it may contaminate the environment or ventilator, and/or degrade the performance.

Only replace with CorVent supplied viral bacterial filters – use of alternative filters could negatively impact the performance of the device, serious injury and/or contamination of the environment and unit.

DO NOT switch the inhalation and exhalation patient circuit limbs once patient ventilation has begun to minimize the risk of aerosolizing exhaled bacterial & viral particulates

The system will alarm if the Luer connections on filters and HME are not sealed. Ensure that they are sealed at all times or an alarm state can occur.

The filters have unidirectional connections and are the same for both the inhalation limb and the exhalation limb. Each patient circuit limb can be connected to either ventilator port upon setting up the ventilator, however, the limbs should never be switched once patient ventilation has begun. Ensure complete connection to both the ventilator ports and the distal circuit connections provided in the patient circuit.


1. **Firmly Press Patient Circuit into the replaced Filter Connections until Fully Seated**

2. **Firmly Press Replaced Filter Connections into the Patient Ports until Fully Seated**

### 6.4.2 Connecting the Breathing Circuit

Use ONLY CorVent provided patient circuit components and attach the 22 mm connections as shown below. If an external Oxygen monitor is not used, then a port adapter (3461-03-9280) is required to allow for inspiratory filter connection to the "To patient port". This component is supplied with every complete patient circuit.

**Before Patient Circuit Connection** **Properly Setup Patient Circuit Connection**

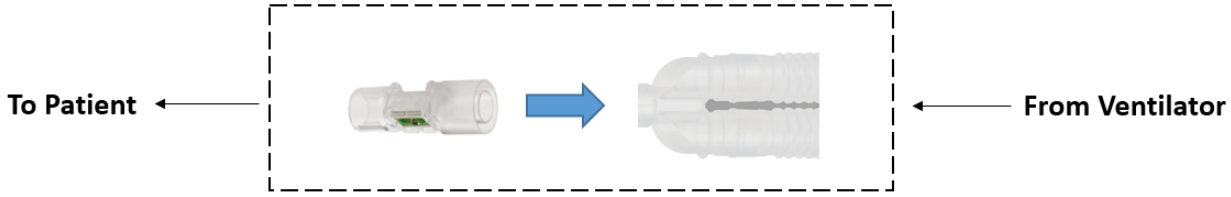
**Firmly Press Patient Circuit into Ventilator Port Connections until Fully Seated**

### 6.4.3 Connecting the Flow Sensor to Patient Circuit

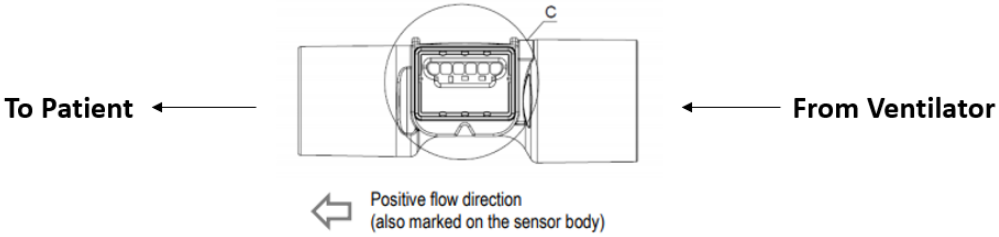
⚠ Warning

| |
|---|
| Use ONLY CorVent provided Flow Sensor components.<br><br>The system will Alarm for "Flow Sensor Reversed" if the Flow Sensor is placed incorrectly. |

Ensure the Flow Sensor is placed in the proper orientation as indicated in the images below.



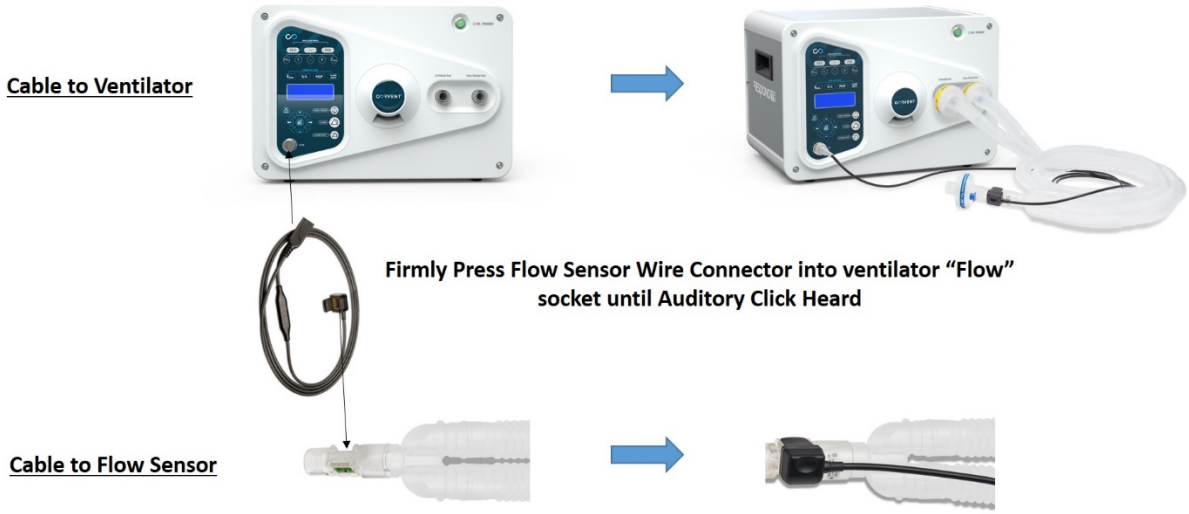

**Firmly Press Flow Sensor into patient circuit Wye Connection until Fully Seated**




**Ensure Flow Sensor is placed in proper flow direction as shown above**

### 6.4.4 Connecting the Flow Sensor Cable to Flow Sensor and Ventilator

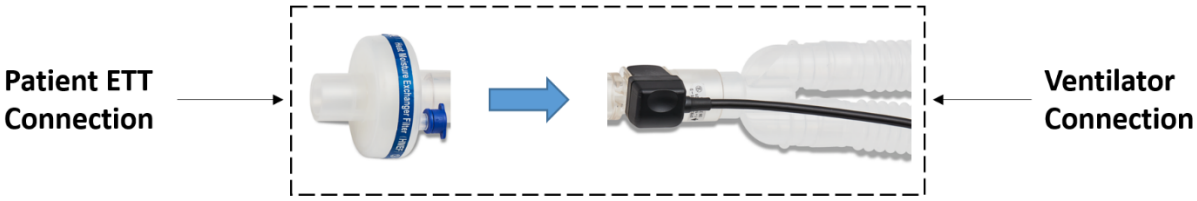
Use ONLY CorVent provided Flow Sensor components. After assembly, apply light pulling pressure at Flow Sensor cable connections to verify their correct assembly.




**Before Flow Sensor Connections** **Properly Setup Flow Sensor Connections**

### 6.4.5 Connecting the HME

Use ONLY CorVent provided HME's and attach standard connections as per standard of care.




**Firmly Press HME into Flow Sensor Connection until Fully Seated**

### 6.4.6 Connecting to Patient

Using the assembled respiratory circuit, press the open end of the HME into the standard ETT 22mm adapter until securely connected as per standard of care. Verify functionality visually and with the system functionality (Alarms will sound if improperly connected). The HME must be between the patient and the Flow sensor as shown below.

## 6.5 Powering the Ventilator On and Operational Verification

*Upon powering the Ventilator, a Power on Self-Test (POST) will run a check of all Ventilator systems to ensure proper operating conditions are met.* The system will auto-calibrate and test itself. If any error is present, it will show the fault on the LCD with potential methods of troubleshooting and both a visual and audio alarm to alert the user.

The user must stand in front of the ventilator and be capable of viewing the entire user interface (membrane panel, LCD display, and Run/Standby Button) and the patient while making ventilator setting adjustments.

During POST, ensure that all the User Interface LED's light up, that the buzzer beeps once, and that the Speaker beeps three times. The following screen will be displayed upon POST pass.

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | **l** | **l** | | **P** | **O** | **S** | **T** | | **t** | **e** | **s** | **t** | **s** | | **h** | **a** | **v** | **e** | |
| **s** | **u** | **c** | **c** | **e** | **s** | **s** | **f** | **u** | **l** | **l** | **y** | | **p** | **a** | **s** | **s** | **e** | **d** | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |

*After POST passes, the user is asked if they are Ventilating a new patient or an old patient in order for the Ventilator to log this event. The following screen will be displayed:*

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **V** | **e** | **n** | **t** | **i** | **l** | **a** | **t** | **i** | **n** | **g** | | **a** | | **N** | **E** | **W** | | |
| | **P** | **a** | **t** | **i** | **e** | **n** | **t** | **?** | | **P** | **R** | **E** | **S** | **S** | | **S** | **E** | **L** | |
| | | | | | | | | | | | | | | | | | | | |
| **S** | **A** | **M** | **E** | | **P** | **a** | **t** | **i** | **e** | **n** | **t** | **?** | | **C** | **A** | **N** | **C** | **E** | **L** |

*After the Ventilator has passed POST and patient information has been entered, the system will enter Standby mode (Green Run/Standby Button will begin to Flash).*

*Once in Standby mode, the following screen will be displayed, indicating how long they have been in standby mode, what the total Operational time of the Ventilator is, and the Service life left on the Ventilator:*

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **I** | **n** | | **S** | **t** | **a** | **n** | **d** | **b** | **y** | **:** | **X** | **X** | **X** | | **m** | **i** | **n** | | |
| **T** | **o** | **t** | **a** | **l** | | **O** | **p** | | **T** | **i** | **m** | **e** | | | | | | | |
| **X** | **X** | | **D** | **a** | **y** | | **X** | **X** | | **H** | **r** | | **X** | **X** | | **m** | **i** | **n** | |
| **O** | **p** | | **l** | **i** | **f** | **e** | | **l** | **e** | **f** | **t** | **:** | **X** | **X** | **X** | **D** | **a** | **y** | **s** |

*The ventilator has two modes of operation available to the user when power is present:*

1. *<u>Standby Mode:</u> ventilator setup and ventilator settings may be made. The system does not deliver breaths.* ***The patient should never be attached in this mode.***

The LCD will display that the device is in Standby Mode after successfully passing POST and the standby button LED and Alarm/Status LED will flash green. The following screen will be shown:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **I** | **n** | | **S** | **t** | **a** | **n** | **d** | **b** | **y** | **:** | **X** | **X** | **X** | | **m** | **i** | **n** | | |
| **T** | **o** | **t** | **a** | **l** | | **O** | **p** | | **T** | **i** | **m** | **e** | | | | | | | |
| **X** | **X** | | **D** | **a** | **y** | | **X** | **X** | | **H** | **r** | | **X** | **X** | | **m** | **i** | **n** | |
| **O** | **p** | | **l** | **i** | **f** | **e** | | **l** | **e** | **f** | **t** | **:** | **X** | **X** | **X** | **D** | **a** | **y** | **s** |

If needed, a secondary screen can be scrolled to with the Left and Right Arrows that displays relevant Ventilator information.

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **C** | **O** | **R** | **V** | **E** | **N** | **T** | | **M** | **E** | **D** | **I** | **C** | **A** | **L** | | | |
| | | **S** | **W** | | **R** | **E** | **V** | **:** | | **X** | **X** | **X** | **X** | **X** | **X** | **X** | | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |

2. *<u>Run Mode:</u> The ventilator delivers breaths in this mode at the prescribed breath settings but will also deliver assist breaths if patient triggers are detected.*

Depress the Standby key for 1 second to enter Run Mode. When the system enters run mode it will be in exhalation phase. The standby button LED will now be solid green. The LCD will now display the settings that are set and the measured ventilation parameters.

When the system enters Run mode, the unit will verify its functionality, if any errors occur, the details will be displayed on the LCD, with both a visual and audio alarm to alert the user.

## 6.6 Selecting Ventilation Type

In order to toggle Invasive and Non-Invasive Ventilation (NIV), the system must be in standby mode to ensure patient safety, i.e. Invasive and NIV would not be switched while actively ventilating a patient without other steps in between.

While in standby mode, the following screen shows on the LCD when Trigger Sensitivity is pressed. The currently active type of ventilation is displayed as well. The user can use Cancel (x) at any-time to revert and leave the adjustment screen. They also may use the scroll (Left and Right Arrows) in order to show the trigger sensitivity setting screen.

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **V** | **e** | **n** | **t** | **i** | **l** | **a** | **t** | **i** | **o** | **n** | | **t** | **y** | **p** | **e** | **:** | | | |
| **N** | **I** | **V** | | **A** | **c** | **t** | **i** | **v** | **e** | | | | | | | | | | |
| **P** | **R** | **E** | **S** | **S** | | **+** | | **f** | **o** | **r** | | **I** | **n** | **v** | **a** | **s** | **i** | **v** | **e** |
| **P** | **R** | **E** | **S** | **S** | | **C** | **A** | **N** | **C** | **E** | **L** | | **t** | **o** | | **E** | **X** | **I** | **T** |

or

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **V** | **e** | **n** | **t** | **i** | **l** | **a** | **t** | **i** | **o** | **n** | | **t** | **y** | **p** | **e** | **:** | | | |
| **I** | **n** | **v** | **a** | **s** | **i** | **v** | **e** | | **A** | **c** | **t** | **i** | **v** | **e** | | | | | |
| **P** | **R** | **E** | **S** | **S** | | **+** | | **f** | **o** | **r** | | **N** | **I** | **V** | | | | | |
| **P** | **R** | **E** | **S** | **S** | | **C** | **A** | **N** | **C** | **E** | **L** | | **t** | **o** | | **E** | **X** | **I** | **T** |

Prior to beginning Non-Invasive Support, the ventilator shall be provided with CO2 monitoring equipment for the measurement of expiratory carbon dioxide concentration, (e.g., in the expiratory limb or at the patient connection port) in accordance with ISO 80601-2-55 before being put into service.

*Note:* For Non-invasive (Mask based) ventilation, the system MUST be used with a Non-Vented face mask. This is to ensure that the exhaled particulates are thoroughly filtered from the patient and not aerosolized into the room.

This change must be confirmed with a secondary screen as follows:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| P | R | E | S | S | | S | E | L | | t | o | | C | O | N | F | I | R | M |
| | | | | | | C | h | a | n | g | e | | | | | | | | |
| | | I | n | v | a | s | i | v | e | | t | o | | N | I | V | | | |
| P | R | E | S | S | | C | A | N | C | E | L | | T | O | | E | X | I | T |

or

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| P | R | E | S | S | | S | E | L | | t | o | | C | O | N | F | I | R | M |
| | | | | | | C | h | a | n | g | e | | | | | | | | |
| | | N | I | V | | t | o | | I | n | v | a | s | i | v | e | | | |
| P | R | E | S | S | | C | A | N | C | E | L | | T | O | | E | X | I | T |

When the system is in NIV, the center --- Breath type LED is lit solid green. When the --- button is pressed, the screen shown below is displayed on the following LCD screen:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | N | I | V | | - | | N | O | N | I | N | V | A | S | I | V | E | | |
| | V | e | n | t | i | l | a | t | i | o | n | | A | C | T | I | V | E | |
| | | | | | | | | | | | | | | | | | | | |
| | C | h | a | n | g | e | | i | n | | S | t | a | n | d | b | y | | |


*Center --- LED lit to show that system is in NIV*

## 6.7 Connecting to Oxygen

⚠ Warnings

When administering fixed flow supplemental oxygen, the oxygen concentration may not be constant. The inspired oxygen concentration will vary and depend primarily on the minute ventilation. If the minute ventilation increases the delivered $FiO_2$ will be reduced and if the minute ventilation decreases the delivered $FiO_2$ will increase. Appropriate patient monitoring should be used, as medically indicated, such as an alarming pulse oximeter. Check that the supply is still operational when assessing the patient.

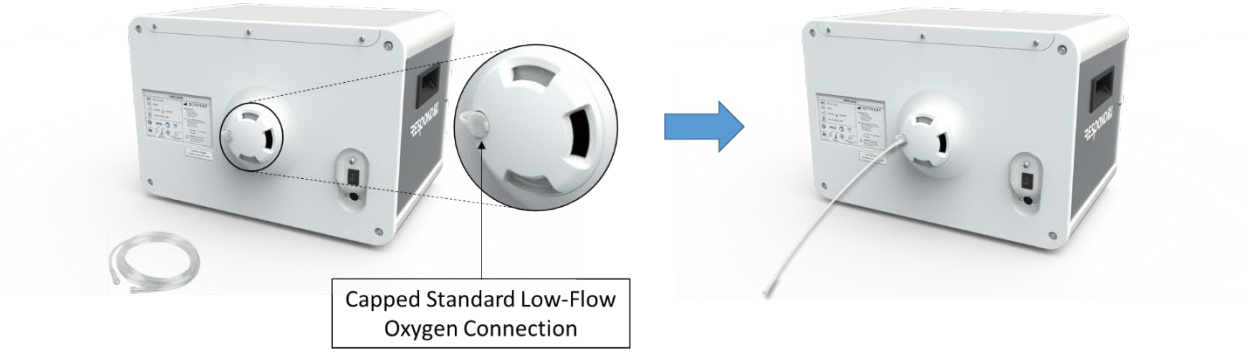
An alarm will not sound on the Ventilator if there is an interruption to the $O_2$ supply. If the supply is interrupted, it could result in the $FiO_2$ being lower than the amount set on the unit (down to 21%). Appropriate patient monitoring should be used, as medically indicated, such as an alarming pulse oximeter and the required external alarming Oxygen monitor.

There is a risk of fire if O2 buildup within the unit is 25% or higher. The system is designed to limit the build-up of oxygen within the ventilator to less than 25% via hardware design.

Turn the device on before turning on the oxygen. Turn the oxygen off before turning the device off. This will prevent oxygen accumulation in the device.

### 6.7.1 Connecting to Oxygen

To connect the Oxygen supply properly, utilize the standard taper low flow $O_2$ connection on the rear of the ventilator as shown below. Ensure the connection is well seated; re-check for proper mounting after Oxygen flow has begun to minimize the risk of leaks. If Oxygen is not in use, ensure that the low flow $O_2$ connection is covered with provided cap. Section 6.7.4 details the supply types compatible with the RESPOND 19.




**Before Oxygen Connections** **Properly Setup Oxygen Connection**

### 6.7.2 Delivering Oxygen

The delivered Minute Ventilation will be displayed to the user on the LCD. The required External Oxygen flow rate will be calculated using the following formula:

$$\text{External } O_2 \text{ Flow Rate} = \text{Delivered Minute Ventilation} * (\%O_2 - 21)/79$$

Utilizing the $O_2$% button, the user inputs desired setting, and the system calculates for them what flow rate to set the Oxygen to. This $O_2$ flow rate adjustment will be performed by the user based upon a set desired $O_2$ level by adjusting the $O_2$ flow rate into the reservoir. Refer to section 6.7 for more detail.

For example, if the user aims to deliver 50% $O_2$ to the patient with a Delivered Minute Ventilation of 8 L/min the user must set the $O_2$ flow meter to 2.9 L/min.

Adjustments must be made for variations in Minute Ventilation. The measured MV may be affected by the addition of Oxygen Flow and may require the system to stabilize at the initially recommended Oxygen flow rate, and then be altered once the new MV has stabilized.

### 6.7.3 External Oxygen Monitor

An external Oxygen monitor is **required for use** with the RESPOND 19 Ventilator to provide the user with direct feedback that the delivered Oxygen percent is within a prescribed range. This external monitor **MUST** be used to verify Oxygen accuracy and can be used to finely adjust the input flow rate for the targeted O2%. This monitor will also indicate a loss of gas supply via the low oxygen alarm target that is user set.

*The Oxygen Monitor selected must conform to the following requirements:*

Oxygen Range: < 21% - >95%

Operation time (battery): >1,000 hours

Standard Compliance (at Minimum):

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-6
- IEC 60601-1-8
- ISO 80601-2-55

Alarms Available (at Minimum):

- **Medium Priority –** Oxygen Percent too High
- **Medium Priority** – Oxygen Percent too Low + Loss of Gas Supply

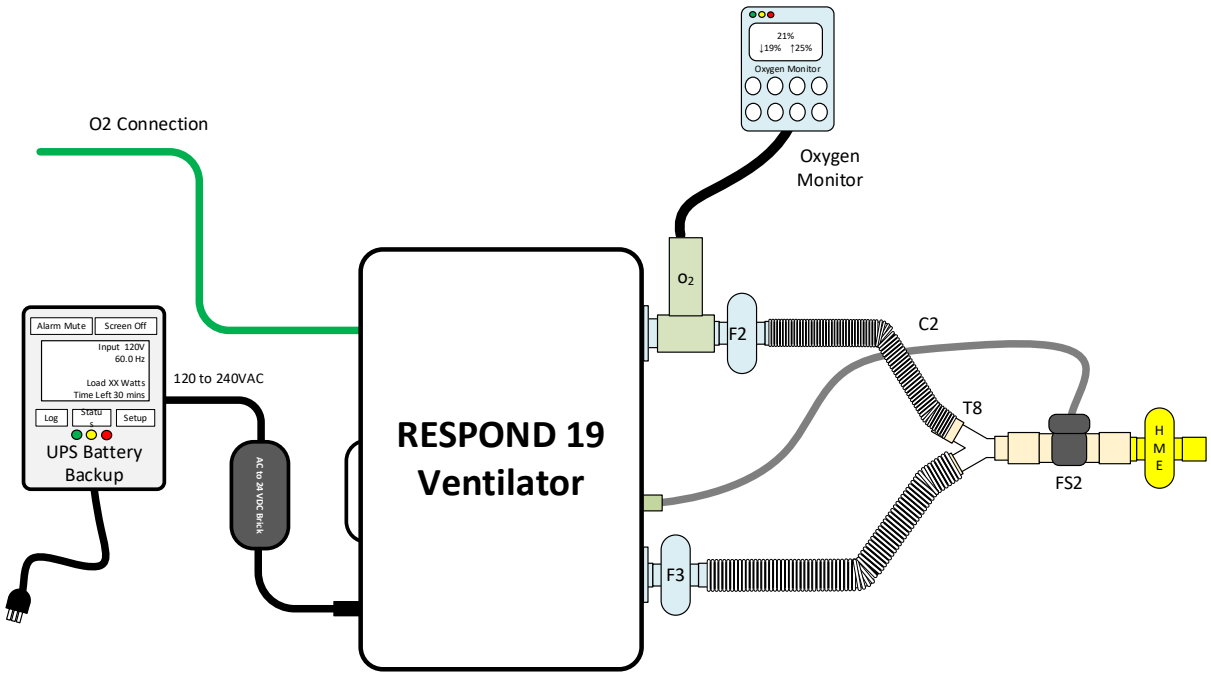
Indicators (at Minimum):

- Means of measuring the Oxygen Percent at anytime

Oxygen Monitor Setup with the Ventilator:

To mount the Oxygen monitor, a standard sensor adapter (shown below in green, 22M/22F) are provided to place it on the inhalation limb between the “To Patient” port of the Ventilator and the Inhalation limb filter. This protects the Oxygen monitor from contamination while providing accurate measurement of inspired Oxygen percent.

Set the monitor’s Oxygen High and Low alarms to 5% above and below the intended oxygen percent target to indicate that the gas supply is not properly set or has lost supply. When at 25% Oxygen, set the Low alarm to 23% Oxygen percent to ensure that a supply loss can be detected. The Oxygen on the Ventilator can only be set in 5% intervals, starting at 25%, with the exception of the ambient Oxygen concentration of 21%.

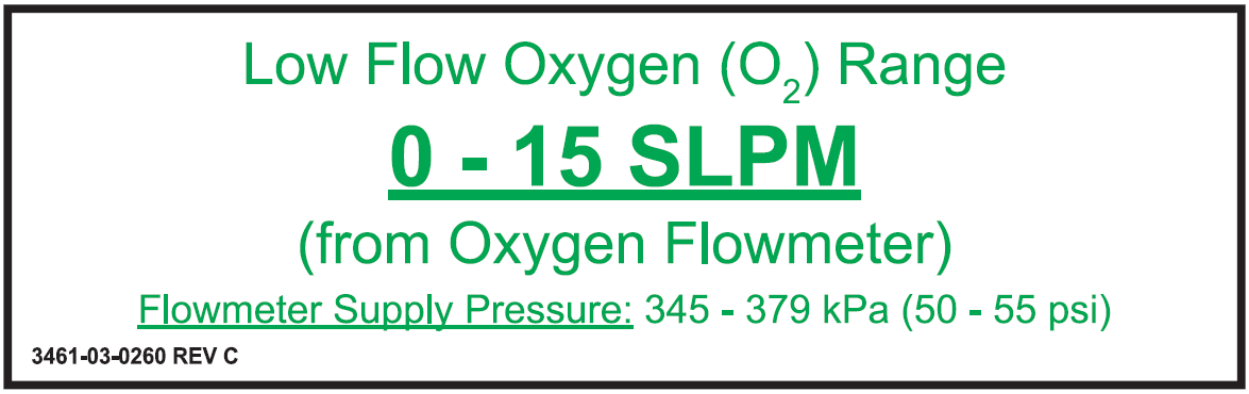



It is recommended that the batteries on the external Oxygen monitor be replaced between each patient to ensure that the system can provide continuous monitoring for the duration of Ventilation. Refer to the Oxygen monitor Operators manual for complete instructions for use.

An Oxygen Monitor that conforms to these requirements is the Maxtec Max$O_2$ME (R230P01).

### 6.7.4 Oxygen Supply

The RESPOND 19 can be supplied with low flow oxygen from multiple sources. The supplies and their compliance requirements are as follows (sticker shown below is on rear of RESPOND 19 Ventilator):




- Oxygen Flow Meter connected to Medical Gas Pipeline System (i.e. $O_2$ Tree)
    - Flow meter Must comply with ISO 15002
    - Medical Gas Pipeline System must comply with ISO 7396-1
    - Maximum supply flowrate of 15 SLPM.
    - Supply Pressure to Flow Meter set to between 345-379 kPa
- Oxygen Flow Meter connected to Pressure Regulator on Oxygen Bottle
    - Flow meter Must comply with ISO 15002
    - Low Pressure Regulator on supply side must comply with ISO 10524-4
    - Maximum supply flowrate of 15 SLPM.
    - Supply Pressure to Flow Meter set to between 345-379 kPa
- Oxygen Flow Meter connected to Oxygen Concentrator
    - Oxygen concentrator must comply with ISO 80601-2-69
    - Maximum supply flowrate of 15 SLPM.

## 6.8 Setting Parameters and Patient Ventilation

### 6.8.1 Ventilator User Interface

*The User Interface (UI) consists of 18 press button keys, an 80-character 4-line LCD, and a tri color LED to denote the status of the ventilator.*

*<u>In Pressure Control Ventilation (PCV) the user may set:</u>*

1. *Inspiratory Pressure Target ($P_I$)*
2. *Inspiratory Time ($T_I$)*
3. *Breath Rate (f)*

*<u>In Pressure Support Ventilation (PSV) the user may set:</u>*

1. *Pressure Support Target ($P_{SUPP}$)*
2. *Exhalation Sensitivity ($E_{SENS}$)*

*<u>In SIMV (PCV + PSV) the user may set:</u>*

1. *Inspiratory Pressure Target ($P_I$)*
2. *Inspiratory Time ($T_I$)*
3. *Breath Rate (f)*
4. *Pressure Support Target ($P_{SUPP}$)*
5. *Exhalation Sensitivity ($E_{SENS}$)*

*<u>The user may always set (Common Settings):</u>*

1. *Trigger Sensitivity ($\dot{V}_{SENS}$)*
2. *$O_2$% (Based on Minute Ventilation and set externally by wall $O_2$ flow)*
3. *PEEP*
4. *Alarm settings*
    a. *High Exhaled Tidal Volume*
    b. *Low Exhaled Tidal Volume*
    c. *High Respiratory Rate (HRR)*
    d. *Low Exhaled Tidal Volume %/ Disconnect*
    e. *High Pressure Limit*
    f. *Low Pressure Limit*
    g. *Apnea Limit*
    h. *Disconnect Limit*
    i. *High PEEP*
    j. *Low PEEP*
    k. *Short Self-Test (SST), (Standby only)*


*RESPOND 19 User Interface*

The following units are displayed to the user to signify the units

| Unit | Display | Description |
|---|---|---|
| Flow | L/min | Liters per minute (BTPS) |
| Inspiratory Time | s | Seconds |
| Breath rate | BPM | Breath per minute |
| Volume | mL | Milliliters |
| Pressure | cmH2O | cm of water |
| Compliance | mL/cmH2O | Milliliters per cm of water |
| Resistance | cmH2O/Lps | cm of water per liter per second |

The user must stand in front of the ventilator and be capable of viewing the entire user interface (membrane panel, LCD display, and Run/Standby Button) and the patient while making ventilator setting adjustments.

### 6.8.2 Monitored and Displayed Parameters

The Current Settings (screen displayed corresponds to active breath type) and Monitored Parameters (common across breath types) will be displayed to the user during Run mode. The two screens displayed are shown below and are referred to as the “Main Menu”. This is a manual cycling of displays. The user can utilize the Left and Right arrow keys on the membrane panel user interface to scroll between screens.

**Displayed Settings (screen displayed corresponds to active breath type):**

PCV Settings Value Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **P** | **R** | **E** | **S** | **S** | **U** | **R** | **E** | | **C** | **O** | **N** | **T** | **R** | **O** | **L** | | | |
| **P** | **I** | | **X** | **X** | | | **P** | **E** | **E** | **P** | | **X** | **X** | | **c** | **m** | **H** | **2** | **0** |
| **T** | **I** | | **X** | **.** | **X** | | **s** | **e** | **c** | | | | | | | | | | |
| **B** | **P** | **M** | | **X** | **X** | | | | **T** | **S** | | **X** | **X** | | **L** | **/** | **m** | **i** | **n** |

1. **PI** = Inspiratory Pressure ($P_I$)
2. **PEEP** = Peak End Expiratory Pressure (PEEP)
3. **TI** = Inspiratory Time ($T_I$)
4. **BPM** = Breath Rate (f)
5. **TS** = Trigger Sensitivity ($\dot{V}_{SENS}$)

PSV Settings Value Display:

| P | R | E | S | S | U | R | E | | S | U | P | P | O | R | T | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| P | S | | X | X | | | P | E | E | P | | X | X | | c | m | H | 2 | 0 |
| E | S | | X | X | | % | | P | F | | X | X | X | | L | / | m | i | n |
| T | S | | X | X | | L | / | m | i | n | | | | | | | | | |

1. **PS** = Pressure Support Target ($P_{SUPP}$)
2. **PEEP** = Peak End Expiratory Pressure (PEEP)
3. **ES** = Exhalation Sensitivity ($E_{SENS}$)
4. **TS** = Trigger Sensitivity ($V_{SENS}$)
5. **PF** = Peak Flow during inspiration

P SIMV Settings Value Display:

| S | I | M | V | ( | P | C | V | + | P | S | V | ) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| P | I | | X | X | | T | I | | X | . | X | s | | B | P | M | | X | X |
| P | S | | X | X | c | m | H | 2 | O | | E | S | | X | X | | p | c | t |
| P | E | E | P | | X | X | | | T | S | | X | X | | L | / | m | i | n |

1. **TI** = Inspiratory Time ($T_I$)
2. **BPM** = Breath Rate (f)
3. **PS** = Pressure Support Target ($P_{SUPP}$)
4. **ES** = Exhalation Sensitivity ($E_{SENS}$)
5. **PEEP** = Peak End Expiratory Pressure (PEEP)
6. **TS** = Trigger Sensitivity ($\dot{V}_{SENS}$)

NIV Settings Value Display:

When in Non-Invasive, the Settings value display for each Ventilation Mode will update its top display line to indicate that the system is in the NIV Ventilation Type as follows:

| N | I | V | | S | I | M | V | ( | P | C | V | + | P | S | V | ) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| N | I | V | | P | R | E | S | S | U | R | E | | S | U | P | P | O | R | T |
| N | I | V | | P | R | E | S | S | U | R | E | | C | O | N | T | R | O | L |

**Displayed Monitored Values (common across breath types):**

During Ventilation, the monitored values displayed as shown below:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| M | V | : | X | X | . | X | L | / | m | i | n | | B | P | M | : | X | X | |
| V | i | / | V | e | : | | X | X | X | / | X | X | X | | m | L | | P | P |
| : | X | X | | P | E | E | P | : | X | . | X | | M | A | P | : | X | . | X |
| P | F | : | X | X | | L | / | m | | | I | : | E | | X | : | X | . | X |

1. **MV** = Minute Ventilation (L/min)
2. **PP** = Peak Pressure (cmH2O)
3. **Vi** = Inspiratory Volume measured by airway flow sensor (mL)
4. **Ve** = Expiratory Volume measured by airway flow sensor (mL)
5. **BPM** = measured breath rate (bpm)
6. **PEEP** = Positive End Expiratory Pressure (cmH2O)
7. **PF** = Peak Flow (L/min)
8. **MAP** = Mean Airway Pressure (cmH2O)
9. **I:E** = Inspiratory/Expiratory Ratio

### 6.8.3 Changing Ventilator Mode

The RESPOND 19 Ventilator defaults to Pressure Control Ventilation (PCV) upon system startup. The Ventilator requires that a Ventilation mode to always be active, i.e., the user cannot disable all modes. The user may change Ventilation modes in either Run Mode or Standby Mode

To ensure continuous and sufficient patient support, the Ventilator requires the user to enter, into SIMV (PCV+PSV) from PCV or PSV, before allowing the user to disable one mode. *i.e., if the user desires to switch from PCV to PSV, they must enter SIMV (PCV +PSV) first in order to maintain a safe ventilation environment for the patient.*


*Ventilation Mode Keys on User Interface*

The displayed LCD screens and required user key input functions for each breath type upon user ventilation mode key press are shown in the following table:

| Active Ventilation Mode | User Presses Ventilation Mode Key | LCD Screen to Display |
|---|---|---|
| PCV | PCV | PRESSURE CONTROL<br><br><br>PRESS CANCEL TO EXIT |
| | PSV | PRESSURE SUPPORT<br>PRESS SEL to enable<br>SIMV (PCV+PSV)<br>PRESS CANCEL TO EXIT |
| PSV | PCV | PRESSURE CONTROL<br>PRESS SEL to enable<br>SIMV (PCV+PSV)<br>PRESS CANCEL TO EXIT |
| | PSV | PRESSURE SUPPORT<br><br><br>PRESS CANCEL TO EXIT |
| SIMV (PCV + PSV) | PCV | SIMV (PCV+PSV)<br>PRESS + for PCV only<br>PRESS - for PSV only<br>PRESS CANCEL TO EXIT |
| | PSV | SIMV (PCV+PSV)<br>PRESS + for PCV only<br>PRESS - for PSV only<br>PRESS CANCEL TO EXIT |
| Breath Type Change Confirmation | | PRESS SEL to CONFIRM<br>Breath Type Change<br>XXXX to XXXX<br>PRESS CANCEL TO EXIT |

| Active Ventilation Mode | User Presses Ventilation Mode Key | LCD Screen to Display |
|---|---|---|
| ***Notes*** | | (+) key is only used to enter PCV from SIMV, disabling PSV<br>(-) key is only used to enter PSV from SIMV, disabling PCV<br>(SEL) key is only used to enter SIMV from either PCV or PSV<br>(Cancel) key is only used to exit back to Main menu<br>(XXXX) denotes a breath type abbreviation that will be displayed when confirming a breath type change |
| ***Non-Invasive Ventilation*** | | When in Non-Invasive Mode, NIV will be displayed in the front of the first line of each breath type screen:<br>**NIV SIMV (PCV+PSV)**<br>**NIV PRESS SUPPORT**<br>**NIV PRESSURE CONTROL** |

When a ventilation breath type screen is shown, the user is capable of exiting to the “Main Menu” of settings and monitored values at any time. *Note: This can be accomplished with the Cancel (X) key or by waiting 10 seconds for the screen to timeout.*

The user is required to press a discrete key *(key defined in the LCD screen display table shown above, i.e., + key in SIMV to enter PCV only, and disable PSV),* to confirm breath type enable/disable. An additional screen is displayed in order to confirm that user intends to change the breath type.

After the user confirms a breath type change, the screen will update to that corresponding breath type screen (*defined in the LCD screen display settings section shown above). Note:* When the user requests a breath type to be enabled/disabled, the change will take effect upon the next exhalation

### 6.8.4 Changing Ventilator Settings

In order to communicate how settings are changed and to prevent false setting changes, the user is required to depress the confirm key both on and off for the device to increment a setting change. The system cannot be adjusted by only using the up and down the arrow keys, a confirmation or cancellation is required. For each setting the range and current related settings will be displayed on the LCD along with the current setting to be adjusted. The user is able to adjust ventilator and alarm settings at any time, even when an alarm is active, or the ventilator is in standby mode.


*Ventilator Setting Adjustment Keys*

Setting Changes

The first key depression (setting key) for each setting will display the corresponding details on the LCD screen. Up (+) and Down (-) arrow key presses will adjust the settings with the Enter (SEL) key used to approve a setting change. When a setting is confirmed, the following screen will be displayed for 2 seconds.

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **S** | **E** | **T** | **T** | **I** | **N** | **G** | | **C** | **O** | **N** | **F** | **I** | **R** | **M** | **E** | **D** | | |
| | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | |

If the Cancel (X) key is used or no adjustments are made after 10 seconds, the system will cancel the adjustment and return to its home screen.

For keys with multiple settings, [i.e., the “PI/PSUPP” key, or “Alarm Limits” key], after the user presses the key and the initial setting is displayed on the LCD, depress the same key again or use the scroll arrows (left/right) to cycle through the potential settings if SIMV has been selected. *For Example: PI is only available in PCV and SIMV(PCV + PSV) and therefore the setting screen can only be displayed to the user when those breath types are active. The PI/PSUPP key will only annunciate the relevant setting of each breath type; PI for PCV, PSUPP for PSV, and PI/PSUPP for SIMV (PCV+PSV). Alarm limits are always available to the user and can be scrolled through at user will.*

*Note:* Setting changes are limited to those settings the ventilator is capable of delivering. There are natural limitations on settable respiratory rate (f), inspiratory time ($T_I$), pressure target ($P_I$) combinations, and associated operating envelope. For instance, if the inspiratory time were set to 2 secs and the breath rate to 30 bpm there would be no time left for exhalation.

Available Settings

The user can only adjust the “patient settings” that are relevant to the active breath type.

To aid the user in knowing what patient settings are available to them, dependent on the mode of Ventilation chosen, the relevant ventilation settings are backlit to display to the user that they are available for edit.


*Backlit LED keys are used to elucidate relevant settings for user. A: PCV, B: PSV, C: SIMV (PCV+PSV)*

If a key is pressed that is not active, then the following screen will annunciate.

| | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | S | E | T | T | I | N | G | | N | O | T | | | | | |
| | | | | | A | V | A | I | L | A | B | L | E | | | | | | |
| i | n | | t | h | i | s | | b | r | e | a | t | h | | t | y | p | e | |
| | | | | | | | | | | | | | | | | | | | |

Common settings are always available to the user.

### 6.8.5 Patient Ventilation Settings

Setting details shown in example display screens as XXX are measured or calculated values that change based on current interdependent settings.


*Patient Ventilation Setting Keys on User Interface*

1. **Inspiratory Pressure Target ($P_I$)**

The Inspiratory Pressure Target setting details are as follows:

| | |
|---|---|
| Units: | $cmH_2O$ |
| Breath Types: | PCV only |

| | |
|---|---|
| Range: | $P_I$ can range from (5 to 40 cmH2O – PEEP), thus with $P_{TARGET} = P_I$ + PEEP having a maximum of 40 cmH2O. Therefore the maximum $P_I$ the user can set: $P_I$Max = (40 – PEEP) |
| Increments: | 1 (total of 36 possible settings) |
| Default: | 15 |
| Accuracy: | ± (2 +4% of setting) cmH2O |
| Setting Change: | Implemented at the start of the next inspiration |
| Active Mode: | Only active in PCV and SIMV (PCV+PSV) modes |

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **P** | **C** | **V** | **:** | | **P** | **I** | **:** | | **X** | **X** | | **c** | **m** | **H** | **2** | **O** | | |
| **R** | **a** | **n** | **g** | **e** | **:** | | | **5** | | **t** | **o** | | **X** | **X** | **c** | **m** | **H** | **2** | **O** |
| **P** | **E** | **E** | **P** | **:** | | **X** | **X** | | **c** | **m** | **H** | **2** | **O** | | | | | |
| **V** | **i** | **/** | **V** | **e** | **:** | | **X** | **X** | **X** | **/** | **X** | **X** | **X** | **m** | **L** | | | |

### 2. Inspiratory Time ($T_I$)

The Inspiratory Time setting details are as follows:

| | |
|---|---|
| Units: | sec |
| Breath Types: | PCV only |
| Range: | 0.4 – 3.0 |
| Increments: | 0.1 (total of 27 possible settings) |
| Default: | 0.8 |
| Accuracy: | ± (0.1+1% of setting) /minute |
| Setting Change: | Implemented at the start of the next inspiration |
| Active Mode: | Only active in PCV and SIMV (PCV+PSV) modes |

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **P** | **C** | **V** | **:** | | **I** | **n** | **s** | **p** | | **t** | **:** | **X** | **.** | **X** | **s** | **e** | **c** | | |
| **R** | **a** | **n** | **g** | **e** | **:** | | **0** | **.** | **4** | | **t** | **o** | | **X** | **X** | **X** | **s** | **e** | **c** |
| **I** | **:** | **E** | | **R** | **a** | **t** | **i** | **o** | **:** | | **1** | **:** | **X** | **X** | **X** | | | | |
| **V** | **i** | **/** | **V** | **e** | **:** | | **X** | **X** | **X** | **/** | **X** | **X** | **X** | **m** | **L** | | | | |

### 3. Breath Rate (f)

The Breath Rate setting details are as follows:

| | |
|---|---|
| Units: | bpm |
| Breath Types: | PCV only |
| Range: | 3 to 70 |
| Increments: | 1 (total of 68 possible settings) |
| Default: | 20 |
| Accuracy: | ±1 bpm |
| Setting Change: | Implemented at the start of the next inspiration |
| Active Mode: | Only active in PCV and SIMV (PCV+PSV) modes |

LCD Display:

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **P** | **C** | **V** | **:** | | **B** | **P** | **M** | **:** | | **X** | **X** | **b** | **p** | **m** | | | |
| **R** | **a** | **n** | **g** | **e** | **:** | **X** | **X** | | **t** | **o** | | **X** | **X** | | | | |
| **I** | **:** | **E** | | **R** | **a** | **t** | **i** | **o** | **:** | | **X** | **:** | **X** | **X** | **X** | | |
| **M** | **i** | **n** | | **V** | **e** | **n** | **t** | **:** | | **X** | **X** | **.** | **X** | **L** | **/** | **m** | **i** | **n** | |

### 4. Pressure Support Target ($P_{SUPP}$)

The Inspiratory Pressure Target setting details are as follows:

| | |
|---|---|
| Units: | $cmH_2O$ |
| Breath Types: | PSV only |
| Range: | PSUPP can range from (0 to 40 cmH2O – PEEP). Thus PTARGET = PSUPP + PEEP having a maximum of 40 cmH2O. Therefore the maximum PSUPP the user can set: PSUPPMAX = (40 – PEEP) |
| Increments: | 1 (total of 41 possible settings) |
| Default: | 10 |
| Accuracy: | ± (2 +4% of setting) cmH2O |
| Setting Change: | Implemented at the start of the next inspiration |
| Active Mode: | Only active in PSV and SIMV (PCV+PSV) modes |

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **P** | **S** | **V** | **:** | | **P** | **S** | **U** | **P** | **P** | **:** | | | **X** | **X** | **c** | **m** | **H** | **2** | **O** |
| **R** | **a** | **n** | **g** | **e** | **:** | | | **0** | | **t** | **o** | | **X** | **X** | **c** | **m** | **H** | **2** | **O** |
| **P** | **E** | **E** | **P** | **:** | | **X** | **X** | | **c** | **m** | **H** | **2** | **O** | | | | | | |
| **V** | **i** | **/** | **V** | **e** | **:** | | **X** | **X** | **X** | **/** | **X** | **X** | **X** | **m** | **L** | | | | |

### 5. Exhalation Sensitivity ($E_{SENS}$)

The Exhalation Sensitivity setting details are as follows:

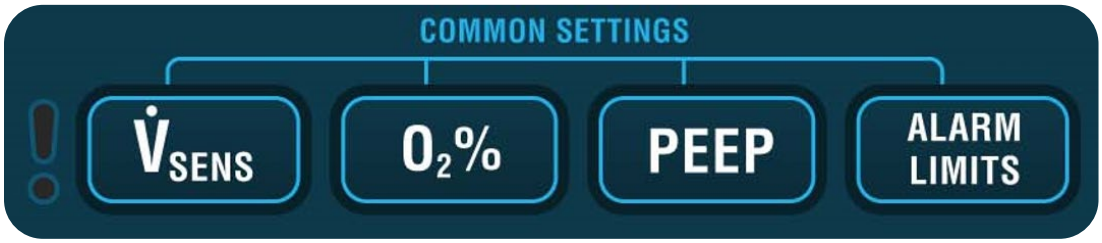
| | |
|---|---|
| Units: | % of peak flow |
| Breath Types: | PSV only |
| Range: | 5 - 80 |
| Increments: | 5% (16 settings) |
| Default: | 25 |
| Accuracy: | ±10% of peak flow or +/- 5L/min whichever is greater |
| Setting Change: | Implemented at the start of the next inspiration |
| Active Mode: | Only active in PCV and SIMV (PCV+PSV) modes |

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **P** | **S** | **V** | **:** | | **E** | **X** | **H** | | **S** | **E** | **N** | **S** | **:** | | **X** | **X** | | **%** | |
| **R** | **a** | **n** | **g** | **e** | **:** | | **5** | | **t** | **o** | | **8** | **0** | **%** | | | | | |
| **M** | **e** | **a** | **s** | | **V** | **i** | **/** | **V** | **e** | | **X** | **X** | **X** | **/** | **X** | **X** | **X** | **m** | **l** |
| **P** | **e** | **a** | **k** | | **F** | **l** | **o** | **w** | **:** | | **X** | **X** | **X** | | **L** | **/** | **m** | **i** | **n** |

### 6.8.6 Common Ventilation Settings

Setting details shown in example display screens as XXX are measured or calculated values that change based on current interdependent settings.




*Common Ventilation Setting Keys*

1. **Invasive Inspiratory Trigger Sensitivity ($\dot{V}_{SENS}$)**

The Trigger Sensitivity setting details are as follows:

| | |
|---|---|
| Units: | L/min |
| Breath Types: | PCV only |
| Range: | 0.5 to 20 |
| Increments: | 0.5 L/min increments between 0.5 and 5Lpm, 1 Lpm, thereafter (25 settings) |
| Default: | 2 |
| Accuracy: | ± (1 L/min + 5% of setting) of delivered set pressure |
| Setting Change: | Implemented immediately |
| Active Mode: | Always active in Invasive |

When a patient takes an assist breath, the corresponding LED to Trigger Sensitivity will flash in conjunction with the patient's inspiration.

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **T** | **r** | **i** | **g** | | **S** | **e** | **n** | **:** | | **X** | **X** | | **L** | **/** | **m** | **i** | **n** | | |
| **R** | **a** | **n** | **g** | **e** | **:** | | **0** | **.** | **5** | | **t** | **o** | | **2** | **0** | | **%** | | |
| **P** | **e** | **a** | **k** | | **F** | **l** | **o** | **w** | **:** | | **X** | **X** | **X** | | **L** | **/** | **m** | **i** | **n** |
| **M** | **e** | **a** | **s** | | **B** | **P** | **M** | **:** | | **X** | **X** | | **b** | **p** | **m** | | | | |

### 2. NIV Inspiratory Trigger Sensitivity ($\dot{V}_{SENS}$)

The V̇SENS setting shall have the following:

| | |
|---|---|
| Units: | Unitless |
| Mode(s) | PCV only (Non-Invasive) |
| Range: | 1 to 10 |
| Increments: | 1 (10 settings) |
| Default: | 5 |
| Accuracy: | Not applicable |
| Setting Change: | implemented at the start of the next expiration. |
| Active Mode: | Always active in NIV |

When a patient takes an assist breath, the corresponding LED to Trigger Sensitivity will flash in conjunction with the patient's inspiration.

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **N** | **I** | **V** | | **T** | **r** | **i** | **g** | | **S** | **e** | **n** | **:** | | | **X** | **X** | | | |
| **R** | **a** | **n** | **g** | **e** | **:** | | **1** | | **t** | **o** | | **1** | **0** | | | | | | |
| **P** | **e** | **a** | **k** | | **F** | **l** | **o** | **w** | **:** | | **X** | **X** | **X** | | **L** | **/** | **m** | **i** | **n** |
| **M** | **e** | **a** | **s** | | **B** | **P** | **M** | **:** | | **X** | **X** | | **b** | **p** | **m** | | | | |

### 3. $O_2$%

The $O_2$% setting details are as follows:

*Note:* This is a calculation done for the user and does not directly alter the delivered Oxygen. The user is required to externally set the wall $O_2$ flow to achieve the desired $O_2$%. The O2% can only be set while in Run Mode in order for MV to update to provide an accurate calculation of Oxygen flow rate setting.

| | |
|---|---|
| Units: | % |
| Breath Types: | PCV, PSV, SIMV (PCV+PSV) |
| Range: | 21 - 95 |
| Increments: | 21, 25, 30 to 95 in increments of 5 (16 settings). |
| Default: | 21 |
| Accuracy: | ± (2 +4% of setting) cmH2O |
| Setting Change: | Is a function of the minute ventilation and accuracy of the delivered O2 flow. |
| Active Mode: | Always active. |

Run Mode LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| S | e | t | | D | e | s | i | r | e | d | | O | 2 | % | : | | X | X | % |
| M | i | n | u | t | e | | V | e | n | t | : | | X | X | L | / | m | i | n |
| S | e | t | | O | x | y | g | e | n | | F | l | o | w | | T | o | : | |
| | X | X | . | X | L | / | m | i | n | | | | | | | | | | |

Standby Mode LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| O | 2 | | F | l | o | w | | C | A | N | | O | N | L | Y | | b | e | |
| s | e | t | | i | n | | R | U | N | | M | O | D | E | | o | n | c | e |
| | M | i | n | u | t | e | | V | e | n | t | i | l | a | t | i | o | n | |
| | | | | i | s | | M | e | a | s | u | r | e | d | | | | | |

### 4. PEEP

The PEEP setting details are as follows:

| | |
|---|---|
| Units: | $cmH_2O$ |
| Breath Types: | PCV, PSV, SIMV (PCV+PSV) |
| Range: | 0 to 20. Therefore, the Maximum PEEP = MIN(40 – PI, 40 - PSUPP, 20) |
| Increments: | 1 (total of 21 possible settings) |
| Default: | 5 |
| Accuracy: | ± (2 +4% of setting) cmH2O |
| Setting Change: | Implemented at the start of the next expiration |
| Active Mode: | Always active |

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| P | E | E | P | : | | X | X | | c | m | H | 2 | O | | | | | | |
| R | a | n | g | e | : | | 0 | | t | o | | X | X | c | m | H | 2 | O | |
| C | u | r | r | . | | P | E | E | P | : | | | X | X | c | m | H | 2 | O |
| P | I | : | | X | X | | P | S | U | P | P | : | | X | X | | | | |

### 6.8.7 Alarm Limit Setting Ranges, Units and Resolution

The alarm limits should not need to be adjusted from default as they are automatically set to optimize patient safety. If needed due to a recurring nuisance alarm state during homeostatic patient ventilatory support, the following patient alarm limits can be adjusted.


To adjust alarm limits, depress the “Alarm Limits” Key to cycle between alarm settings. The left and right arrow keys may also be used to scroll between alarm setting screens. Once the desired setting is displayed, utilize the Up (+) and Down (-) to adjust the corresponding alarm settings. Confirm alarm limit adjustment with the Enter (SEL) key.

**Caution**

The alarm pre-sets (Defaults) are the same for each RESPOND-19 ventilator, are un-editable, and reset to Default upon power cycling.

*Note:* Alarm limits are always active while in Run Mode (all breath types)

1. **High Exhaled Tidal Volume Limit**

The High Exhaled Tidal Volume alarm is annunciated based on the exhaled tidal volume being greater than the setting for 3 out of 4 of the previous breaths. The High Exhaled Tidal Volume alarm setting has the following:

| | |
|---|---|
| Units: | ml |
| Range: | 100 to 3,000 |
| Breath Types: | PCV, PSV, SIMV (PCV+PSV) |
| Increments: | 50 (59 settings) |
| Default: | 550 |
| Setting Change: | After user confirmation, alarm detection is deferred for two breaths after a PEEP, PI, or PSUPP change. |

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **H** | **i** | **g** | **h** | | **E** | **x** | **h** | | **T** | **V** | **:** | **X** | **X** | **X** | **X** | | **m** | **l** |
| **R** | **a** | **n** | **g** | **e** | **:** | | **1** | **0** | **0** | | **t** | **o** | | **3** | **0** | **0** | **0** | **m** | **l** |
| **M** | **e** | **a** | **s** | | **V** | **e** | **:** | | **X** | **X** | **X** | | **m** | **l** | | | | | |
| | | | | | | | | | | | | | | | | | | | |

### 2. Low Exhaled Tidal Volume Limit

The Low Exhaled Tidal Volume alarm is annunciated based on the exhaled tidal volume being less than the setting for 3 out of 4 of the previous breaths. The Low Exhaled Tidal Volume alarm setting has the following:

| | |
|---|---|
| Units: | ml |
| Range: | 25 to 1,000 |
| Breath Types: | PCV, PSV, SIMV (PCV+PSV) |
| Increments: | 50 (20 settings); except 25 to 50, 25 (1 setting) |
| Default: | 150 |
| Setting Change: | After user confirmation, alarm detection is deferred for two breaths after a PEEP, PI, or PSUPP change. |

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **L** | **o** | **w** | | **E** | **x** | **h** | | **T** | **V** | **:** | **X** | **X** | **X** | | **m** | **l** | | | |
| **R** | **a** | **n** | **g** | **e** | **:** | | **2** | **5** | | **t** | **o** | | **1** | **0** | **0** | **0** | | **m** | **l** |
| **M** | **e** | **a** | **s** | | **V** | **e** | **:** | | **X** | **X** | **X** | | **m** | **l** | | | | | |
| | | | | | | | | | | | | | | | | | | | |

### 3. Apnea Limit (automatically set & user adjustable)

The Apnea alarm is annunciated when the time since the initiation of the last inspiration is greater than set apnea interval. The user may adjust this Apnea setting. The Apnea Limit setting shall have the following:

| | |
|---|---|
| Units: | seconds |
| Range: | 10 to 40 |
| Breath Types: | PCV, PSV, SIMV (PCV+PSV) |
| Increments: | 1 (31 settings) |
| Default: | For PCV and SIMV: Apnea = MIN [20.1, (((60 * 1.6) / set breath rate) + 0.1)]<br>For PSV: Apnea = 15 |
| Setting Change: | After user confirmation |

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | **p** | **n** | **e** | **a** | **:** | **X** | **X** | | | **S** | **e** | **t** | **:** | **X** | **X** | | **s** | **e** | **c** |
| **R** | **a** | **n** | **g** | **e** | **:** | | **1** | **0** | | **t** | **o** | | **4** | **0** | | **s** | **e** | **c** | |
| **M** | **e** | **a** | | **B** | **P** | **M** | **:** | | **X** | **X** | | **b** | **p** | **m** | | | | | |
| **M** | **e** | **a** | | **B** | **r** | **t** | **h** | | **P** | **r** | **d** | **:** | **X** | **X** | **.** | **X** | **s** | **e** | **c** |

### 4. HRR (High Respiratory Rate) Limit (automatically set & user adjustable)

The HRR alarm is annunciated based on the sensed respiratory rate being higher than that of the ventilator for the previous 4 breaths. The High Respiratory Rate Limit setting shall have the following:

| | |
|---|---|
| Units: | bpm |
| Breath Types: | PCV, PSV, SIMV (PCV+PSV) |
| Range: | 20 to 80 |
| Increments: | 5 (13 settings) |
| Default: | PCV and SIMV: HRR = MAX ((f + 10), 40)<br>For PSV: HRR = 40 |
| Setting Change: | Implemented at the start of the next inspiration. |

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **H** | **i** | | **R** | **e** | **s** | **p** | | **R** | **a** | **t** | **e** | **:** | | **X** | **X** | | **b** | **p** | **m** |
| **R** | **a** | **n** | **g** | **e** | **:** | | | **2** | **0** | | **t** | **o** | | **8** | **0** | | **b** | **p** | **m** |
| **S** | **e** | **t** | | **H** | **R** | **R** | **:** | | | **X** | **X** | **b** | **p** | **m** | | | | | |
| **M** | **e** | **a** | **s** | | **B** | **P** | **M** | **:** | | **X** | **X** | **b** | **p** | **m** | | | | | |

### 5. Disconnect Limit

The Disconnect Limit is annunciated based upon the Inhaled and Exhaled tidal volume percent difference. For example: Vi/Ve = 400/350, the percent difference would be (Vi-Ve)/Vi) = (400-350)/(400) = 12.5%. In order to get a disconnect the % difference must be greater than the disconnect limit.

| | |
|---|---|
| Units: | % drop |
| Breath Types: | PCV, PSV, SIMV (PCV+PSV) |
| Range: | 10 to 90 |
| Increments: | 5 (14 settings) |
| Default: | Invasive: 20<br>NIV: 40 |
| Setting Change: | After user confirmation, alarm detection is deferred for two breaths after a PEEP, PI, or PSUPP change. |

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **D** | **i** | **s** | **c** | **o** | **n** | **n** | **e** | **c** | **t** | | **L** | **i** | **m** | **i** | **t:** | | **X** | **X** | **%** |
| **R** | **a** | **n** | **g** | **e** | **:** | | | **X** | **X** | | **t** | **o** | | **X** | **X** | **%** | | | |
| | | | | | | | | | | | | | | | | | | | |
| **V** | **i** | **/** | **V** | **e** | **:** | | **X** | **X** | **X** | **/** | **X** | **X** | **X** | | **m** | **l** | | | |

### 6. HP Limit (automatically set & user adjustable)

The High-Pressure Limit is automatically set with respect to the Pressure Target [$P_{Target}$ = PEEP + $P_I$] for PCV and [$P_{Target}$ = PEEP + $P_{SUPP}$] for PSV. The HP setting details are as follows:

| | |
|---|---|
| Units: | $cmH_2O$ |
| Breath Types: | PCV, PSV, SIMV (PCV+PSV) |
| Range: | 20 - 50 |
| Increments: | 1 (31 settings) |
| Default: | PCV and SIMV Mandatory Breaths:<br>HP = MIN [(MAX ((PEEP + PI + 5), 20)), 50]. This will be overridden by the user set value.<br>PSV and SIMV Support Breaths:<br>HP = MIN [(MAX ((PEEP + PSUPP + 5), 20)), 50]. This will be overridden by the user set value. |
| Setting Change: | Shall be immediately implemented after a Pressure Target setting update in PSV, PCV and SIMV |

* The HP Limit can-not be set less than the LP Limit. The HP limit will be immediately implemented after a HP limit change. For more information on how the HP and LP limit are automatically set, refer to the Appendix I, Principles of Operation.

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **R** | **e** | **l** | **a** | **t** | **i** | **v** | **e** | | **H** | **P** | **:** | **+** | **X** | **X** | **c** | **m** | **H** | **2** | **O** |
| **t** | **o** | | **P** | **t** | **a** | **r** | **g** | **e** | **t** | | **+** | **X** | | **t** | **o** | | **+** | **X** | **X** |
| **P** | **C** | **V** | | **t** | **a** | **r** | **g** | **e** | **t** | **:** | | **X** | **X** | | **c** | **m** | **H** | **2** | **O** |
| **P** | **S** | **V** | | **t** | **a** | **r** | **g** | **e** | **t** | **:** | | **X** | **X** | | **c** | **m** | **H** | **2** | **O** |

### 7. LP Limit (automatically set & user adjustable)

The Low-Pressure Limit is automatically set with respect to the Pressure Target [$P_{Target}$ = PEEP + $P_I$] for PCV and [$P_{Target}$ = PEEP + $P_{SUPP}$] for PSV. The LP setting details are as follows:

| | |
|---|---|
| Units: | $cmH_2O$ |
| Breath Types: | PCV, PSV, SIMV (PCV+PSV) |
| Range: | 1 to 35 |
| Increments: | 1 (35 settings) |
| Default: | 1) If PCV, MIN [(MAX (PEEP + PI – 5, 1)), 35].This will be overridden by the user set value. |

2) If PSV, MIN [(MAX (PEEP + PSUPP – 5, 1)), 35].This will be overridden by the user set value.
3) LP limit will switch between breaths in SIMV

Setting Change: Shall be implemented at the start of the next inspiration

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| R | e | l | a | t | i | v | e | | L | P | : | + | X | X | c | m | H | 2 | O |
| t | o | | P | t | a | r | g | e | t | | - | X | X | | t | o | | - | X |
| P | C | V | | t | a | r | g | e | t | : | | X | X | | c | m | H | 2 | O |
| P | S | V | | t | a | r | g | e | t | : | | X | X | | c | m | H | 2 | O |

### 8. High PEEP Limit (automatically set & user adjustable)

The High PEEP setting is as follows:

Units: cmH2O
Breath Types: PCV, PSV, SIMV (PCV+PSV)
Range: 5 to 25.
Increments: 1 (21 settings)
Default: High PEEP = MAX (MIN((PEEP +3), 25), 5)
Accuracy: ± (2 +4% of setting) cmH2O
Setting Change: implemented at the start of the next expiration.
Active Mode: Only active in exhalation.

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| H | i | g | h | | P | E | E | P | : | | X | X | | | c | m | H | 2 | O |
| R | a | n | g | e | : | | 5 | | t | o | | 2 | 5 | | c | m | H | 2 | O |
| P | E | E | P | : | X | X | | C | u | r | r | H | P | E | E | P | : | X | X |
| P | I | : | | X | X | | P | S | U | P | P | : | | X | X | | | | |

### 9. Low PEEP Limit (automatically set & user adjustable)

The Low PEEP setting shall have the following:

Units: cmH2O
Breath Types: PCV, PSV, SIMV (PCV+PSV)
Range: -1 to 15.
Increments: 1 (17 settings)
Default: Low PEEP = MIN (MAX((PEEP-3), -1), 15)

Accuracy: ± (2 +4% of setting) cmH2O
Setting Change: implemented at the start of the next expiration.
Active Mode: Only active in exhalation.

LCD Display:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| L | o | w | | P | E | E | P | : | | | X | X | | | c | m | H | 2 | O |
| R | a | n | g | e | : | - | 1 | | t | o | | 1 | 5 | | c | m | H | 2 | O |
| P | E | E | P | : | X | X | | C | u | r | r | L | P | E | E | P | : | X | X |
| P | I | : | | X | X | | P | S | U | P | P | : | | X | X | | | | |

## 6.9 Shutting Down the Ventilator

**To Stop ventilation** (go from Run mode to Standby Mode) depress the standby button for 1 second continuously.

Upon standby request, the system will declare an alarm (LCD display shown below) alerting the user that a Ventilation stop has been requested. The user is required to press the “Alarm Pause” key twice to confirm that they wish to stop ventilation and enter standby mode. This alarm will be annunciated as a medium priority alarm given that the user is present. If the alarm pause key is not depressed twice in rapid succession, the Ventilation Stop request alarm will clear and the system will continue to ventilate.

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | R | E | Q | U | E | S | T | | V | E | N | T | | S | T | O | P | | |
| | P | R | E | S | S | | A | U | D | I | O | | P | A | U | S | E | | |
| | | | T | W | I | C | E | | t | o | | S | T | O | P | | | | |
| | | | | V | E | N | T | I | L | A | T | I | O | N | | | | | |

**To Power down the unit**, turn off the Oxygen supply BEFORE turning off the power switch to the unit. This will prevent oxygen accumulation in the device and reduce the risk of fire. The power switch cover must be rotated out of the way before proceeding to depress the switch on the rear panel of the ventilator to the OFF state, at which time the unit can be safely unplugged. This requires the user to perform two discrete movements to power off the ventilator.

## 6.10 Replacing the Patient Circuit, HME, Viral Filters,

### ⚠ Warnings

Viral bacterial filters are included with the ventilator to prevent contamination. These filters MUST be installed in the patient circuit in the TO and FROM patient port connections per the setup instructions to prevent contamination of the environment and the unit.

Only replace with CorVent supplied parts – using other incompatible parts could result in serious personal injury or death.

**Replacing the Circuit or HME**

The Patient breathing circuit and/or HME should be replaced if damaged, soiled or occluded or in intervals determined per institutional recommended guidelines. Replace as per standard of care. Check visually that the filters are not clogged/waterlogged and replace as necessary.

**Replacing the Viral Filters**

The Viral Filters should be replaced when/if the airway resistance progressively increases, lowering the ventilation efficacy, due to build-up of copious secretions. This can be indicated by alarm states of high inspiratory pressure or by external monitoring. Otherwise, it is recommended to minimize changing frequency to minimize provider exposure to aerosolized pathogens when opening the patient circuit.

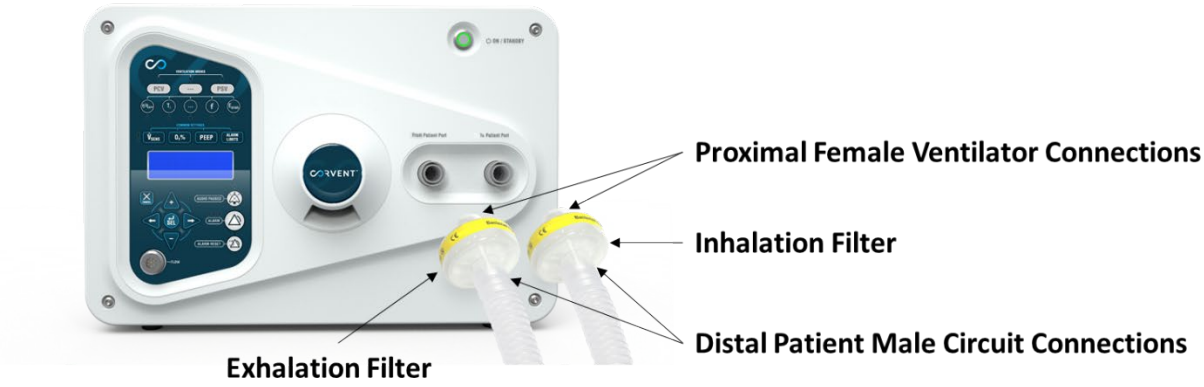
To replace filters (same filter for inhalation and exhalation), ensure the patient is in a stable breathing pattern and can tolerate the momentary lapse in support.

Pull the patient circuit tubing connection from the filter and replace in line. Push 22mm conical fittings until fully seated as per standard of care.

It is recommended to disconnect only one limb at a time while servicing the filters. This is to ensure that the patient limbs are never switched after patient ventilation begins, to minimize the risk of rebreathing exhaled viral or bacterial particles.

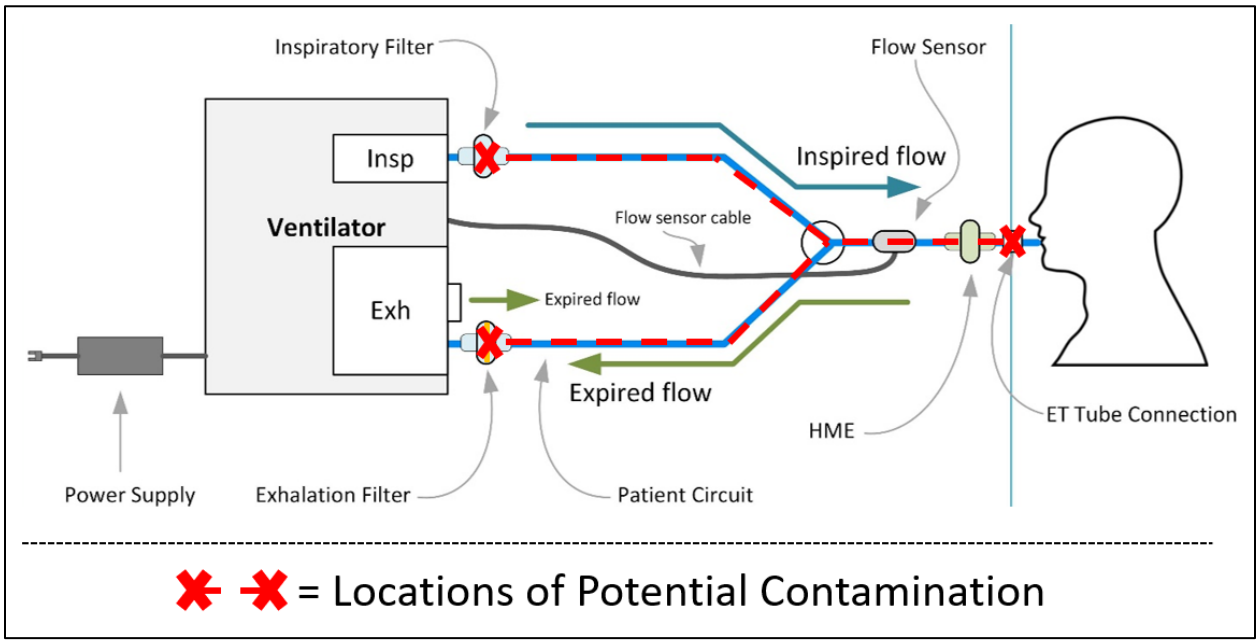
The filters have unidirectional connections and can physically only be attached in one orientation via the male and female connections in the patient circuit.

An alarm will sound when it senses the open patient circuit. Reset the alarm after completing the new filter connections and wait to ensure that the system is properly functioning.




1. **Firmly Press Patient Circuit into Male Filter Connections until Fully Seated**
2. **Firmly Press the Female Filter Connection into the Patient Port until Fully Seated**

## 6.11 Possible Locations of Contamination




Care must be taken not to switch the filters between inspiration and expiration or to reverse their direction after use has initiated. The HMEF provides sufficient bacterial and viral filtration with the exhalation filter providing additional safety and preventing contamination of the environment with exhaled gas. Reversing the orientation of the exhalation filter during use will only result in the environment being contaminated if the HMEF is not filtering correctly or is not present. Care must be taken not to reverse orientation and to ensure all filters are in place during operation. If disconnecting, make note of the position of each line.

During normal operation and under single fault failure (i.e. HMEF missing), the insides of the Ventilator are not contaminated due to redundant filtration.

## 6.12 Suctioning

Suctioning is required to remove mucus from the patient lungs during mechanical ventilation. This is associated with the risks of false triggers or erroneous false technical faults.

During patient suctioning, which typically interrupts ventilation for less than 10 seconds, the risk exists that false triggers will be detected and that a disconnect alarm may be annunciated. Breath delivery will continue during suctioning. If a disconnect alarm is annunciated, triggering will be disabled for 4 seconds and will reset automatically.

In order to begin suction, set the $\%O_2$ to 100% for a few minutes before initiating suctioning, if in the medical opinion of the physician this is necessary.

*To Begin Suctioning:*

1. Set Trigger Sensitivity to maximum setting. (The recommended breath type for suctioning is Noninvasive (NIV) at the highest trigger sensitivity (10) to prevent false triggering while suctioning.)
2. Begin suctioning.

# 7.0 Alarms, Event Logs, and Troubleshooting

This section describes the alarms and what you should do if an alarm occurs. Refer to the Troubleshooting section if you experience any problems while using this device. It also describes the methods to view the Active Alarm log and the Event log.

## 7.1 Device Alarms

The RESPOND-19 uses a ranked alarm system. This means that it only displays the highest ranked alarm to the user. Once the highest ranked alarm is resolved, any remaining alarms of lower ranking will annunciate after if their condition persists. If a higher ranked alarm were to be triggered, it would supersede the alarm condition that was currently being annunciated. The order of ranking is shown in Section 7.6.

The alarm system determines the alarm to annunciate based on a ranking system where each alarm is assigned a number from 1 to 16, with 1 being the highest ranking, and 16 being the lowest ranked. The ranking system is fixed and cannot be adjusted. The alarm signal generation delay (fixed at 5ms) and alarm condition annunciation delay are not adjustable. More detail on the alarm annunciation delays can be found in *Section 10: Alarm Setting Ranges and Detection Times.*

The RESPOND-19 alarm system suppresses an active alarm condition when a related alarm condition of higher ranking has recently generated an alarm signal *(I.e. a Flow Sensor Disconnected (Rank 4) alarm superseding a Disconnect Alarm (Rank 5)).* The most relevant alarm will be shown to the user. All other active alarms (if any) can be inspected by the operator by scrolling to up and down through ranking (Up to the highest, Down to the lowest).

This ranking technique is used to reduce the number of alarm signals that an operator is required to respond to on alarm systems with multiple, related alarm conditions. The use of a ranked alarm system is an effective way of reducing the number of alarm signals that are generated during transient events, thus reducing the number of nuisance, false positive, or false negative alarm conditions.

Some alarms are the same priority, and therefore they are displayed based upon their ranking, which have been assigned based on patient safety. If two alarms of the same priority were annunciated at once, the higher ranked alarm would be displayed.

*There are three types of alarms:*

**High Priority** – Requires immediate response by the Operator

**Medium Priority –** Requires prompt response by the Operator

**Low Priority/Information** – Only Occurs in Standby Mode and requires resolution by Operator to begin ventilation. This primarily indicates that the system is in standby mode.

*When an alarm condition occurs:*

- The audible alarm sounds
- A visual indicator LED flashes a color at a specific frequency and duty cycle
- A message appears on the LCD display indicating the type of alarm

*Exceptions to the ranking of Alarms:*

- If a REQUEST VENT STOPPED alarm (medium priority) is displayed it supersedes all other alarms so the user can exit Run Mode.
- If a higher priority alarm occurs it supersedes all other alarms except under the conditions stated above.

*Non-Latching and Latching Alarms:*

All patient and technical alarms are Non-Latching. This means that all annunciated alarm states will self-resolve if the condition that has triggered the alarm, has been resolved.

If the alarm condition is quickly resolved, a Medium Priority auditory alarm signal will complete at least one full burst and a High Priority auditory alarm signal will complete one half of one full burst, unless inactivated by the operator.

POST and BIOT failures are latching as they require the user to power cycle the ventilator in order to resolve them. POST and BIOT Failures are outlined in Appendix 1. Principles of Operation.

*Alarm Setting Storage:*

Alarm changes are not stored upon powering down or at total loss of power. All pressure-based alarm settings are automatically set by the system based on set pressure parameters, streamlining the need to adjust them and store them actively.

*System Alarm & Event Logging:*

The RESPOND 19 ventilator logs all alarms, POST, and BIOT failure codes as they arise with a time stamp from the beginning of patient ventilation since power on. The system also logs when a new patient has been placed on the Ventilator. It is stored in non-volatile memory allowing it to be stored for the lifetime of the ventilator, or until the storage capacity is exceeded (8,000 events) at which point the system will overwrite the earliest logs to continue logging the most recent events. This complete log is not user accessible. Partial logs can be accessed to aid in ventilation and troubleshooting; detail on these logs can be found in section 7.10. The contents of the user accessible logs will not be maintained after total loss of power.

## 7.2 Alarm Audible Indicators

An audible indicator sounds when a High or Medium priority alarm condition occurs, which can include device inoperable conditions and patient ventilation mismatch. A complete list of alarms is listed below.

**⚠ WARNING**

The high priority and medium priority alarms have similar auditory indications. These two alarm priorities are mainly differentiated by their visual indicator of LED color (Red – High, Yellow – Medium) and frequency (1.5 Hz - High, 0.7 Hz – Medium) at a 50% duty cycle.

Setting any alarm limits to extreme high or low values, can cause the associated alarm not to activate during ventilation, which reduces its efficacy for monitoring the patient and alerting the clinician to situations that may require intervention.

The operator should check to ensure current alarm settings are appropriate prior to use on each patient. If not properly adjusted, this could effectively disable the alarm, and could lead to missing the detection of hazardous situations. This could occur if the user is trying to disable a nuisance alarm.

**Caution**

The alarm changes are NOT STORED upon powering down or at total loss of power.

The ventilator adheres to IEC60601-1-8 alarm standard. The console will display the system status using the following LED indicator colors, flashing frequency and duty cycle and sounds in Run Mode and Standby Mode.

## Status indicators / Sounds

The table below indicates what is seen and heard when an alarm is activated:

| Status category | Indicator Color | Mode | Indicator Flashing Frequency | Indicator Duty Cycle (on/off time) | Buzzer Sound File | Speaker Sound File | Decibel Level | Interburst Interval |
|---|---|---|---|---|---|---|---|---|
| High Priority | Red | Run | 2 Hz | 50% | B B B space B B | C4 A4 F4 - A4 F4 VEN-TI-LA-TI-ON; VEN-TI-LATE A-LARM | 50-85 dBA | 4 - 5 s |
| Medium Priority | Yellow | Run | 0.7 Hz | 50% | B B B | C4 A4 F4 VEN-TI-LATE; RISE AND FALL | 50-85 dBA | 6 - 10 s |
| Normal | Green | Run | Constant on | 100% on | None | None | NA | NA |
| High Priority - POST Failure | Red | Standby | 2 Hz | 50% | B B B space B B | C4 A4 F4 - A4 F4 VEN-TI-LA-TI-ON; VEN-TI-LATE A-LARM | 50-85 dBA | 4 - 5 s |
| Normal – POST Passed | Green | Standby | 2 Hz | 50% | None | None | NA | NA |

Where B = Beep, Interburst Interval = period of time between the end of the last PULSE of a BURST and the start of the first PULSE of the next BURST of the same ALARM SIGNAL

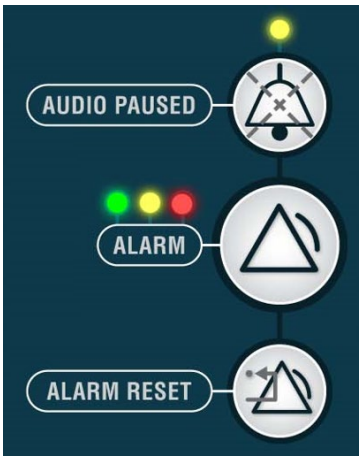
The system will default to using the speaker as the alarm audio annunciator. If a speaker failure is detected, the ventilator will annunciate alarms states with the backup buzzer.

### Temporarily Silencing an Alarm (Audio Paused Key)

The ventilator will pause an audible alarm annunciation for up to two minutes when the AUDIO PAUSED key is pressured.

The AUDIO PAUSED will be cleared in the event of a mode transition. There are two mode transitions Standby to Run Mode and Run Mode to Standby Mode.

While the AUDIO PAUSED is active, the corresponding LED will indicate as a solid yellow LED on. The operator can terminate any alarm signal inactivation state by pressing the AUDIO PAUSED button a second time (re-annunciating the alarm).




*Alarm Section of User Interface*

### Resetting Alarm (Alarm Reset Key)

The ventilator will reset (resolve) the active alarm if the Alarm Reset key is held for 2 seconds continuously.

*Note:* Upon entry to Standby mode from Run Mode all alarms will be reset.

## 7.3 Alarm Message Screens

Multiple alarms will not be displayed to the operator to aid in direct troubleshooting. The highest ranked alarm active will be the primary display; once resolved the next highest-ranking alarm, if still applicable, will then display. If the operator wishes to see the lower ranked alarms that are active, they may scroll to the right to view the Active Alarm List. More detail on the Active Alarm List can be found in Section 7.10.

Each alarm state is listed below with the corresponding LCD display and details regarding how and when the alarm will be resolved:

**Request Ventilation Stop**

The REQUEST VENT STOP alarm will occur in Run Mode when the user requests the ventilation to stop:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **R** | **E** | **Q** | **U** | **E** | **S** | **T** | | **V** | **E** | **N** | **T** | | **S** | **T** | **O** | **P** | | |
| | **P** | **R** | **E** | **S** | **S** | | **A** | **U** | **D** | **I** | **O** | | **P** | **A** | **U** | **S** | **E** | | |
| | | | **T** | **W** | **I** | **C** | **E** | | **t** | **o** | | **S** | **T** | **O** | **P** | | | | |
| | | | | **V** | **E** | **N** | **T** | **I** | **L** | **A** | **T** | **I** | **O** | **N** | | | | | |

The REQUEST VENT STOP alarm will allow entry to standby mode when the AUDIO PAUSED Key is pressed twice in quick succession. The alarm shall clear automatically in 5 seconds if the AUDIO PAUSED Key is not pressed twice in quick succession and the ventilator will continue in Run Mode.

*Note: this will force two actions to by the user to stop ventilating.*

**System Inoperable**

The SYSTEM INOPERABLE alarm occurs in Run Mode when the Ventilator has failed BIOT or in Standby mode when the Ventilator has failed to pass POST.

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **S** | **Y** | **S** | **T** | **E** | **M** | | **I** | **N** | **O** | **P** | **E** | **R** | **A** | **B** | **L** | **E** | | |
| | | **P** | **O** | **W** | **E** | **R** | | **C** | **Y** | **C** | **L** | **E** | | **V** | **E** | **N** | **T** | | |
| | **R** | **e** | **p** | **l** | **a** | **c** | **e** | | **V** | **e** | **n** | **t** | **i** | **l** | **a** | **t** | **o** | **r** | |
| | **I** | **f** | | **a** | **l** | **a** | **r** | **m** | | **p** | **e** | **r** | **s** | **i** | **s** | **t** | **s** | | |

The SYSTEM INOPERABLE alarm will annunciate immediately upon POST Failure or BIOT Failure in either run mode or standby mode. The SYSTEM INOPERABLE alarm can only be reset by power cycling the Ventilator and subsequent POST pass and BIOT monitoring demonstrating system operation within expected limits.

### High Pressure (HP)

The HIGH-PRESSURE alarm will annunciate when two consecutive breaths are truncated because the pressure exceeded HIGH PRESSURE setting.

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| H | I | G | H | | P | R | E | S | S | U | R | E | | A | L | A | R | M | |
| C | h | e | c | k | | f | o | r | | k | i | n | k | i | n | g | | | |
| I | n | c | r | e | a | s | e | | I | n | s | p | | T | i | m | e | | |
| R | e | d | u | c | e | | T | i | d | a | l | | V | o | l | u | m | e | |

The HIGH-PRESSURE alarm will auto-reset the alarm when the peak pressure is less than the alarm setting for 5 breaths.

### Flow Sensor Not Connected

The FLOW SENSOR NOT CONNECTED alarm is annunciated when the Flow Sensor ceases to output data, the rate is too slow, or data is missing from the Flow Sensor data received.

The following text strings are displayed when a FLOW SENSOR NOT CONNECTED Alarm is annunciated.

| | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| F | L | O | W | | S | E | N | S | | N | O | T | | C | O | N | N | E | C |
| C | h | e | c | k | | s | e | n | s | | c | o | n | n | e | c | t | e | d |
| C | h | e | c | k | | e | l | e | c | t | | c | o | n | n | | a | t | |
| s | e | n | s | o | r | | & | | a | i | r | w | a | y | | | | | |

The FLOW SENSOR NOT CONNECTED Alarm will auto-reset when the measured Flow Sensor reads correctly for 2 seconds.

### Disconnect

The DISCONNECT alarm is annunciated when the measured inspired or expired Tidal Volume is less than Delivered Tidal Volume multiplied by the Ve Limit for four consecutive breaths.

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| D | I | S | C | O | N | N | E | C | T | | D | E | T | E | C | T | E | D | |
| C | h | e | c | k | | i | n | s | p | / | E | x | p | | l | i | m | b | |
| C | h | e | c | k | | f | l | o | w | | s | e | n | s | o | r | | | |
| C | h | e | c | k | | V | e | | l | i | m | i | t | | | | | | |

The DISCONNECT alarm will auto-reset when the exhaled tidal volume is greater than the set percent of the delivered Tidal Volume.

**Occlusion**

The OCCLUSION alarm will annunciate when inspiratory and expiratory pressures sensors differ greatly from each other for a given flow demonstrating the presence of high resistance. The same alarm will occur for a partial or complete occlusion.

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **O** | **C** | **C** | **L** | **U** | **S** | **I** | **O** | **N** | | **A** | **L** | **A** | **R** | **M** | | | | |
| **C** | **h** | **e** | **c** | **k** | | **f** | **o** | **r** | | **k** | **i** | **n** | **k** | **i** | **n** | **g** | | |
| **C** | **h** | **e** | **c** | **k** | | **f** | **o** | **r** | | **b** | **l** | **o** | **c** | **k** | **e** | **d** | | |
| **f** | **i** | **l** | **t** | **e** | **r** | | **o** | **r** | | **w** | **a** | **t** | **e** | **r** | | | | |

The OCCLUSION alarm will auto-reset when the alarm condition is no longer present for a new breath period.

**Low Inspiratory Pressure (LP)**

The LOW INSP PRESSURE alarm will annunciate when the monitored pressure never rises above LOW INSP PRESSURE setting during inspiration for a single breath.

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **L** | **O** | **W** | | **A** | **I** | **R** | **W** | **A** | **Y** | | **P** | **R** | **E** | **S** | **S** | **U** | **R** | **E** |
| **C** | **h** | **e** | **c** | **k** | | **p** | **a** | **t** | **i** | **e** | **n** | **t** | | | | | | |
| **C** | **h** | **e** | **c** | **k** | | **f** | **o** | **r** | | **d** | **i** | **s** | **c** | **o** | **n** | **n** | **e** | **c** | **t** |
| | | | | | | | | | | | | | | | | | | |

The LOW INSP PRESSURE alarm will auto-reset when the circuit pressure is at least equal to alarm limit setting during inspiration for a single breath.

### Low Exhaled Tidal Volume

The LOW EXHALED TIDAL VOL alarm is annunciated when the measured expired Tidal Volume is less than the Ve Limit for 3 out of four consecutive breaths

The following text strings are displayed when a LOW EXHALED TIDAL VOL Alarm is annunciated.

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| L | O | W | | E | X | H | | T | I | D | A | L | | V | O | L | | | |
| C | h | e | c | k | | I | n | s | p | / | E | x | p | | l | i | m | b | |
| C | h | e | c | k | | f | l | o | w | | s | e | n | s | o | r | | | |
| C | h | e | c | k | | L | o | w | | V | e | | l | i | m | i | t | | |

The LOW EXHALED TIDAL VOL alarm will auto-reset when the exhaled tidal volume is greater than the user set low exhaled tidal volume limit for 3 out of 4 consecutive breaths.

### High Respiratory Rate

The HIGH RESP RATE alarm will annunciate when the measured breath rate is higher than the set High Respiratory Rate breath rate limit.

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| H | I | G | H | | R | E | S | P | | R | A | T | E | | | | | | |
| C | h | e | c | k | | f | o | r | | c | u | f | f | | l | e | a | k | |
| C | h | e | c | k | | t | r | i | g | | s | e | n | s | i | v | i | t | y |
| M | e | a | s | | B | P | M | : | | X | X | b | p | m | | | | | |

When a HIGH RESP RATE alarm is annunciated, the measured Breath rate shall be displayed to the user.

The HIGH RESP RATE alarm will auto-reset when the measured bpm is less than 50 bpm.

### Apnea Alarm

The APNEA alarm is annunciated when the measured respiratory rate is lower than the set Apnea limit.

When an APNEA alarm is annunciated, the measured and set Breath rate is displayed to the user.

The following text strings are displayed when an APNEA Alarm is annunciated.

| A | P | N | E | A |  | A | L | A | R | M |  |  |  |  |  |  |  |  |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| B | r | e | a | t | h |  | r | a | t | e |  | l | o | w |  |  |  |  |
| I | n | c | r | e | a | s | e |  | b | r | e | a | t | h |  | r | a | t | e |
| M | e | a | s | / | s | e | t | : |  | X | X | / | X | X | b | p | m |  |  |

The APNEA Alarm will auto-reset when the measured Breath Rate is equal to or exceeds the set apnea limit.

**High Exhaled Tidal Volume**

The HIGH EXHALED TIDAL VOL alarm is annunciated when the measured expired Tidal Volume is greater than the Ve Limit for 3 out of four consecutive breaths

The following text strings are displayed when a HIGH EXHALED TIDAL VOL Alarm is annunciated.

| H | I | G | H |  | E | X | H |  | T | I | D | A | L |  | V | O | L |  |  |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| C | h | e | c | k |  | i | n | s | p | / | E | x | p |  | l | i | m | b |  |
| C | h | e | c | k |  | P | r | e | s | s | . | S | e | t | t | i | n | g |  |
| C | h | e | c | k |  | H | i | g | h |  | V | e |  | l | i | m | i | t |  |

The HIGH EXHALED TIDAL VOL alarm will auto-reset when the exhaled tidal volume is less than the user set high exhaled tidal volume limit for 3 out of 4 consecutive breaths.

**High PEEP**

The HIGH PEEP alarm is annunciated when the measured PEEP is higher than the High PEEP setting for 3 out of 4 breaths.

The following text strings are displayed when a HIGH PEEP Alarm is annunciated.

| H | I | G | H |  | P | E | E | P |  | A | L | A | R | M |  |  |  |  |  |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| C | h | e | c | k |  | f | o | r |  | k | i | n | k | i | n | g |  |  |  |
| D | e | c | r | e | a | s | e |  | P | E | E | P |  |  |  |  |  |  |  |
| C | h | e | c | k |  | H | i | g | h | P | E | E | P |  | l | i | m | i | t |

The HIGH PEEP alarm shall auto-reset the alarm when the measured PEEP is less than the alarm setting for 5 breaths.

**Low PEEP**

The LOW PEEP alarm is annunciated when the measured PEEP is lower than the LOW PEEP setting for 3 out of 4 breaths.

The following text strings are displayed when a LOW PEEP Alarm is annunciated.

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| L | O | W | | P | E | E | P | | A | L | A | R | M | | | | | |
| C | h | e | c | k | | f | o | r | | l | e | a | k | | | | | |
| I | n | c | r | e | a | s | e | | P | E | E | P | | | | | | |
| C | h | e | c | k | | L | o | w | | P | E | E | P | | l | i | m | i | t |

The LOW PEEP alarm shall auto-reset the alarm when the measured PEEP is greater than the alarm setting for 5 breaths.

**Flow Sensor Reversed**

The FLOW SENSOR REVERSED alarm is annunciated when the Flow Sensor is inserted in the wrong direction. *Note: We will only need this alarm because user can reverse the direction of the Flow Sensor.*

The following text strings are displayed when a FLOW SENSOR REVERSED Alarm is annunciated.

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| F | L | O | W | | S | E | N | S | O | R | | R | E | V | E | R | S | E | D |
| R | e | v | e | r | s | e | | d | i | r | e | c | t | i | o | n | | | |
| o | f | | t | h | e | | f | l | o | w | | s | e | n | s | o | r | | |
| | | | | | | | | | | | | | | | | | | | |

The FLOW SENSOR REVERSED Alarm will auto-reset when the measured and delivered flow demonstrate flow in the same direction for two breaths.

### Key Board Failure

When a KEYBOARD FAILURE alarm is annunciated the ventilator will continue to ventilate.

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| K | E | Y | | S | T | U | C | K | | | | | | | | | | |
| C | h | e | c | k | | p | a | t | i | e | n | t | | | | | | |
| P | o | w | e | r | | c | y | c | l | e | | v | e | n | t | | | |
| | | | | | | | | | | | | | | | | | | |

To reset the KEYBOARD FAILURE alarm, power cycle the ventilator.

*Note:* If the Keyboard “Stuck Key” alarm annunciates, the system will continue to provide ventilation at user set rates. Check the patient first. The Unit must be power cycled to reset system to clear the alarm. Replace Ventilator if keyboard failure persists.

### Life Exceeded

The LIFE EXCEEDED alarm occurs in Run Mode when the Ventilator has surpassed its indicated life of cumulative total use. This is cumulative use and only counts while the system is ventilating a patient.

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | L | I | F | E | | E | X | C | E | E | D | E | D | | | |
| 1 | 8 | 0 | / | 1 | 8 | 0 | | D | a | y | s | | o | f | | u | s | e |
| | | | | | | | | | | | | | | | | | | |
| | R | E | P | L | A | C | E | | V | E | N | T | I | L | A | T | O | R |

The LIFE EXCEEDED alarm annunciates only once while in Run Mode.

The LIFE EXCEEDED alarm requires the user to hold the “Alarm Reset” key for 2 seconds to reset the alarm for the remaining ventilation time so they are aware that they are operating past the indicated lifetime of the Ventilator.

After Ventilation has ended and the Ventilator is turned off, upon every subsequent powerup the LIFE EXCEEDED alarm will annunciate.

**Temporary Loss of Power**

During a TOTAL LOSS OF POWER alarm, the following will occur:

1. The RED led and buzzer alarm shall annunciate
2. After Power comes back on, the user will be prompted to acknowledge the loss of power via the LCD screen:
    a. *The user will be required to press the SEL switch via the LCD once and wait for normal operation to recover. The user will be presented with the following message:*

When power is lost, the ventilator settings and ALARM SETTINGS prior to the power loss **will be restored automatically if the power is turned on within 2 minutes**. *The LCD displays the following message if a total loss of power is still active when power is re-enabled:*

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | T | E | M | P | | L | O | S | S | | O | F | | P | O | W | E | R | |
| | A | C | | p | o | w | e | r | | w | a | s | | l | o | s | t | | |
| | S | y | s | t | e | m | | V | e | n | t | i | l | a | t | i | n | g | |
| | P | r | e | s | s | | A | L | A | R | M | | R | E | S | E | T | | |

When SEL is pressed, ventilation will begin at the previous settings and at the previous alarm limits. If CANCEL is pressed, the ventilator will return to the default settings and enter Standby Mode.

**When power is lost for an extended period of time, the ventilator settings and ALARM SETTINGS prior to the power loss will NOT be restored automatically.**

**Oxygen Supply**

⚠ WARNING

| |
|---|
| An alarm will not sound on the Ventilator if there is an interruption to the $O_2$ supply. If the supply is interrupted, it could result in the $FiO_2$ being lower than the amount set on the unit (down to 21%). Appropriate patient monitoring should be used, as medically indicated, such as an alarming pulse oximeter and the use of the required external alarming Oxygen monitor. |

## 7.4 When an Alarm Occurs

When an alarm occurs do the following:

1. Observe the patient and ensure that they are receiving adequate ventilation and oxygenation.
2. Listen to the audible alarm and look at alarm indicators (colored LED)
3. Look at the display to check the alarm message that appears on the display
4. As per standard of care in clinical decision making, mute and then resolve the alarm. If alarm fault source is fixed and alarm persists, reset the alarm. Continue cycle of troubleshooting as outlined in alarm table to ensure patient safety and ventilation efficacy is maintained.
5. Note the alarm and refer to the alarm descriptions in this section to determine the cause of the alarm and the appropriate action

## 7.5 External Power Failure

⚠ **WARNING**

Upon loss of power the device will alarm and stop working. There is NO internal backup battery. There should be continuous monitoring by qualified personnel and an alternative means of ventilation is recommended whenever the ventilator is in use.

If power to the ventilator fails, the system allows for spontaneous breathing. Upon supply mains loss, the Total Loss of Power alarm will annunciate for greater than two minutes or until the device is properly powered back on.

During the total loss of power alarm annunciation, if supply mains return to operation and reapplies power to the ventilator, the ventilator will come up ventilating with the previous alarm/ventilation settings and will display the Temp Loss of Power alarm asking the operator to continue with current settings or cancel to enter standby.

When the Total Loss of Power alarm sounds, first ensure that the power supply is plugged into the outlet.

If plugged in, check to see if outlet is live with secondary system. If not, move power plug to active outlet and cycle the ventilators power to ensure operability. If system still not functional, replace power supply first and then ventilator. Contact CorVent support if Ventilator non-functional.

## 7.6 Alarm Summary Table

The following table summarizes the alarms. Note the previous section for the audible and visual indicators for each alarm priority and corresponding screen.

The alarms have delays before generation dependent on the time it takes for the system to recognize an alarm state via its algorithm of sensing *(i.e. the maximum delay time for high respiratory rate is the average over 12 breaths, with the minimum setting being 20 BPM, therefore it would take 36 seconds to alarm at worst case; the maximum delay time for apnea is 40 seconds (the largest setting) at worst case. Once* an alarm state is sensed, the alarm is generated after a 5 ms signal delay.

When you enter standby mode all the active alarms will be disabled, and the ventilation stopped alarm will be shown.

| *Alarm* | *Description* | *User Actions* | *Ranking* |
|---|---|---|---|
| ***REQUEST VENTILATION STOP*** | ***Medium-priority alarm.***<br>*Upon request of entry to Standby Mode from Run Mode the system will declare an alarm alerting the user that the device has been requested to stop ventilation. The user will be required to press the AUDIO PAUSED key twice to enter Standby Mode and reset the alarm. If pressed in error the user may wait 5 seconds before the request is cleared (alarm is auto reset) and the ventilator continues in Run Mode.*<br>***Reset***<br>*User waits 5 seconds* | *Check Patient*<br>*System enters Standby Mode*<br>*Reset Alarm.* | *1* |
| ***SYSTEM INOPERABLE*** | ***High-Priority alarm.***<br>*Upon POST or BIOT failure, the Ventilator will declare an alarm alerting the user that the system has a technical fault requiring power cycle. If a POST failure occurs ventilation shall not be allowed. If a BIOT failure occurs the system will only stop ventilation if necessary and attempt to ventilate the patient.*<br>***Action***<br>*Ventilator must be power cycled.* | *Power cycle.*<br>*Replace Ventilator if POST or BIOT Fails three times.* | *2* |

| Alarm | Description | User Actions | Ranking |
|---|---|---|---|
| | ***Reset***<br><br>*Can only be reset by power cycle and subsequent successful POST pass and BIOT monitoring demonstrating system operation within expected limits.* | | |
| ***HIGH PRESSURE***<br><br>***(user adjustable)*** | ***High-priority alarm.***<br><br>*High pressure limit is automatically set to 5 cmH2O higher than the MAXIMUM (PEEP + PI , PEEP + PSUPP). (the user may override):*<br><br>*A High-Pressure alarm is unlikely in PSV because PSV breath will be terminated during inspiration because of pressure excursions.*<br><br>*Two consecutive breaths were truncated because ventilator breathing circuit pressure reached HIGH PRESSURE setting (Inspiration phase ends and exhalation valve opens to prevent excessive pressure).*<br><br>***Action***<br><br>*Ventilator continues ventilation at user set breath rate. Triggering is disabled for 4 seconds when in PSV.*<br><br>***Auto-reset***<br><br>*When circuit pressure is less than alarm setting for 5 breaths. Cannot be silenced if alarm condition persists.* | *Check patient.*<br><br>*Check for water in inspiratory limb or for kinked tubing.*<br><br>*Consider appropriate HIGH-PRESSURE LIMIT and ventilator settings.* | *3* |
| ***FLOW SENSOR NOT CONNECTED*** | ***Medium-priority alarm.***<br><br>*The console is not reading the flow sensor.*<br><br>***Action***<br><br>*Ventilator continues ventilation at user set breath rate. Triggering is disabled.*<br><br>***Auto-reset***<br><br>*When console starts to read the flow sensor again.* | *Check patient*<br><br>*Connect flow sensor* | *4* |

| Alarm | Description | User Actions | Ranking |
|---|---|---|---|
| ***DISCONNECT*** <br><br> ***(user adjustable)*** | ***Medium-priority alarm.*** <br><br> *Measured exhaled tidal volume is XX% less of delivered tidal volume for 4 consecutive breaths.* <br><br> ***Action*** <br><br> *Ventilator continues ventilation at user set breath rate. Triggering is disabled for 4 seconds when in PSV.* <br><br> ***Auto-reset*** <br><br> *When exhaled tidal volume is greater than XX% of the delivered tidal volume for one breath.* | *Check patient.* <br><br> *Check ventilator breathing circuit connections.* | *5* |
| ***OCCLUSION*** | ***High-priority alarm.*** <br><br> *Ventilator breathing circuit or inspiratory or expiratory filters occluded. Ventilator detects above-normal difference between inspiratory and expiratory pressure transducers. This could be a partial or complete occlusion.* <br><br> ***Action*** <br><br> *Ventilator continues ventilation at user set breath rate. Triggering is disabled for 4 seconds when in PSV.* <br><br> ***Auto-reset*** <br><br> *When the ventilator no longer detects an occlusion on the next breath.* | *Check patient.* <br><br> *Check ventilator breathing circuit and inspiratory and expiratory filters for occlusions or kinks. Empty excess water* <br><br> *from tubes.* | *6* |
| ***LOW INSP PRESSURE*** <br><br> ***(user adjustable)*** | ***Medium-priority alarm.*** <br><br> *Low pressure limit is automatically set to a default setting (the user may override): For PCV: maximum (PEEP + PI – 5 cmH2O) setting (Min = 1 cmH2O)* <br><br> *For PSV: maximum (PEEP + PSUPP – 5 cmH2O) setting (Min = 1 cmH2O)* <br><br> *Depending upon the breath being delivered. This will update between two levels in SIMV if the PI and PSUPP are different.* | *Check patient.* <br><br> *Check for circuit disconnect.* | *7* |

| Alarm | Description | User Actions | Ranking |
|---|---|---|---|
| | ***Action***<br><br>*Ventilator continues ventilation at user set breath rate. Triggering is disabled for 4 seconds when in PSV.*<br><br>***Auto-reset***<br><br>*When circuit pressure is at least equal to alarm setting during inspiration for a single breath* | | |
| ***LOW EXHALED TIDAL VOL***<br><br>***(user adjustable)*** | ***Medium-priority alarm.***<br><br>*When the measured exhaled tidal volume is less than the user set for 3 out of 4 consecutive breaths*<br><br>***Action***<br><br>*Ventilator continues ventilation at user set breath rate.*<br><br>***Auto-reset***<br><br>*Resets when the monitored value at least equals the alarm setting for 3 out 4 consecutive breaths.* | *Check patient.*<br><br>*Consider appropriate exhaled tidal volume limit.*<br><br>*Consider increasing pressure.* | *8* |
| ***HI RESP RATE***<br><br>***(user adjustable)*** | ***Medium-priority alarm.***<br><br>*Monitored respiratory rate higher than HIGH RATE setting.*<br><br>***Action***<br><br>*Ventilator continues ventilation at user set breath rate. Triggering is disabled for 4 seconds when in PSV.*<br><br>***Auto-reset***<br><br>*When monitored respiratory rate is less than or equal to the breath rate limit* | *Check patient.*<br><br>*Check for cuff leak*<br><br>*Check TRIGGER SENSITIVITY settings.* | *9* |
| ***APNEA***<br><br>***(user adjustable)*** | ***Medium-priority alarm.***<br><br>*The APNEA alarm shall be annunciated when the time elapsed since the initiation of the inspiratory phase is greater than the apnea alarm limit.*<br><br>***Action*** | *Check patient.*<br><br>*Check trigger sensitivity*<br><br>*Check apnea interval setting* | *10* |

| Alarm | Description | User Actions | Ranking |
|---|---|---|---|
| | *Ventilator switches to apnea ventilation.*<br>***Auto-reset***<br>*Resets when the user triggers two consecutive breaths at intervals lower than the apnea interval.* | | |
| ***HIGH EXHALED TIDAL VOL (user adjustable)*** | ***Medium-priority alarm.***<br>*When the measured exhaled tidal volume is greater than the user set for 3 out of 4 consecutive breaths*<br>***Action***<br>*Ventilator continues ventilation at user set breath rate.*<br>***Auto-reset***<br>*Resets when the monitored value at least equals the alarm setting for 3 out 4 consecutive breaths.* | *Check patient.*<br>*Consider appropriate exhaled tidal volume limit.*<br>*Consider decreasing pressure.* | *11* |
| ***HIGH PEEP (user adjustable)*** | ***Medium-priority alarm.***<br>*High PEEP limit is automatically set to 3 cmH2O higher than the PEEP Setting (the user may override):*<br>*The monitored PEEP pressure rises above HIGH PEEP setting during exhalation for 3 out of 4 breaths. The user may adjust this HIGH PEEP setting.*<br>***Action***<br>*Ventilator continues ventilation at user set breath rate. Triggering is disabled for 4 seconds when in PSV.*<br>***Auto-reset***<br>*Resets when the monitored valve at least equals the alarm setting for 3 out of 4 breaths.* | *Check patient.*<br>*Check for water in expiratory limb or for kinked tubing.*<br>*Consider appropriate HIGH PEEP LIMIT and ventilator settings.* | *12* |
| ***LOW PEEP***<br>***(user adjustable)*** | ***Medium-priority alarm.***<br>*The LOW PEEP limit is automatically set to 3 cmH2O lower than the set PEEP and is not used for PEEPs less than 4 cmH2O.* | *Check patient.*<br>*Check for circuit disconnect.* | *13* |

| Alarm | Description | User Actions | Ranking |
|---|---|---|---|
| | *The user may adjust the LOW PEEP setting.*<br><br>*The monitored PEEP pressure never rises above LOW PEEP setting during exhalation for 3 out of 4 breaths. The user may adjust this LOW PEEP setting.*<br><br>***Action***<br><br>*Ventilator continues ventilation at user set breath rate.*<br><br>***Auto-reset***<br><br>*Resets when the monitored valve at least equals the alarm setting for 3 out of 4 breaths.* | *Check for occlusion of exhalation port* | |
| ***FLOW SENSOR REVERSED*** | ***Medium-priority alarm.***<br><br>*The flow sensor was placed in the wrong orientation and should be reversed.*<br><br>***Action***<br><br>*Ventilator continues ventilation at user set breath rate.*<br><br>*The sensor reading is multiplied by -1.0 and triggering is enabled until the flow sensor is reversed.*<br><br>***Auto-reset***<br><br>*When console see the flow sensor in the correct direction.* | *Check patient*<br><br>*Reverse connection of flow sensor* | *14* |
| ***KEYBOARD FAILED*** | ***Medium-priority alarm.***<br><br>*Technical alert. A key was held down longer than expected.*<br><br>***Action***<br><br>*Ventilator continues ventilation.*<br><br>*Unit Must be power cycled.*<br><br>***Alarm does not auto-reset.*** | *Check patient.*<br><br>*Power cycle ventilator.*<br><br>*Replace ventilator if keyboard failure persists.* | *15* |

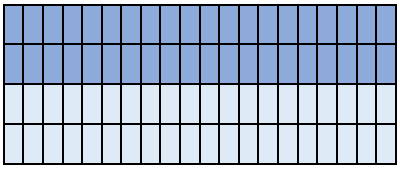
| Alarm | Description | User Actions | Ranking |
|---|---|---|---|
| ***LIFE EXCEEDED*** | ***Medium-priority alarm.***<br><br>*Upon the internal EEPROM stored operational time surpassing the indicated lifetime of the Ventilator, the Ventilator will declare and alarm alerting the user that the device has surpassed its operational lifetime.*<br><br>***Action***<br><br>*Ventilator continues ventilation at user set breath rate.*<br><br>***Reset***<br><br>*User must depress Alarm reset key for 2 seconds to signal that they understand that the ventilator has surpassed its operational lifetime.*<br><br>*<u>Note</u>: the passing of the indicated operational lifetime in no way represents a risk to the patient at present, it simply means that the ventilator has surpassed the indicated (allowed) lifetime under the authorized labeling of the ventilator.* | *Check Patient*<br><br>*Reset Alarm.*<br><br>*Replace Ventilator after patient support complete.* | *16* |
| ***TEMP LOSS OF POWER*** | ***HIGH-priority alarm.***<br><br>*This is both a hardware and software generated alarm.*<br><br>*When power is lost the alarm is generated by hardware. When power is reestablished within a few minutes the system is able to determine that power was temporarily and restart ventilation with a high priority alarm.*<br><br>***Action***<br><br>*Ventilator continues ventilation at user previous settings and alarm limits.*<br><br>***Reset***<br><br>*User must depress Alarm reset key to acknowledge alarm.* | *Check Patient*<br><br>*Reset Alarm.*<br><br>*Check that the power supply is correctly connected.* | *17* |

| Alarm | Description | User Actions | Ranking |
|---|---|---|---|
| ***TOTAL LOSS OF POWER*** | ***HIGH-priority alarm.***<br>*This is a hardware alarm.* | *Power cycle ventilator.*<br>*If intended, turn off Ventilator solely in standby mode to.*<br>*If not intended shutoff, find alternative mains supply or use charged external UPS.* | *NA* |
| ***GAS SUPPLY FAILURE (OXYGEN)***<br>***(user adjustable)*** | ***Medium-priority alarm.***<br>*This is an alarm integrated into external hardware.*<br>*Refer to external Oxygen Sensor for details on oxygen concentration range.* | *Check patient external monitoring.*<br>*Check Oxygen Supply.* | *NA* |
| ***INTERNAL BATTERY NEARING DEPLETION***<br>***(user adjustable)*** | ***Medium-priority alarm.***<br>*This is an alarm integrated into external hardware.*<br>*Refer to external UPS for more details. Must be set to alarm when battery has <10 mins left of battery life at system load.* | *Find alternative MAINS to reinstate power input or alternative method of backup patient ventilation support* | *NA* |
| ***LOSS OF MAINS/ SWITCHOVER TO INTERNAL BATTERY*** | ***Medium-priority alarm.***<br>*This is an alarm integrated into external hardware.*<br>*Refer to external UPS for more details. This is a hardware alarm.* | *Check mains plug.*<br>*Find alternative MAINS to reinstate power input* | *NA* |

## 7.7 Troubleshooting

The table below lists some of the problems you may experience with the ventilator and possible solutions:

| ***Problem*** | ***Why it Occurred*** | ***What to Do*** |
|---|---|---|
| Nothing happens when device is plugged in and power is turned on | Potential power failure at wall, transformer, or within device. | Check power to the system (plug outlet)<br>Check multiple outlets.<br>Try different power supply.<br>Ensure switch on rear of unit is turned to 'On' state when attempting to run ventilator.<br>If still unable to power on unit, contact CorVent Service and replace unit. |
| Ventilator airflow does not begin | Potential hardware or software error. | Check power to the system (plug outlet)<br>Depress On/Standby button, ensure green light is solid on power button and LCD displays settings of ventilation.<br>If occurs 3 times, contact CorVent Service and replace unit. |
| Device display is erratic | Potential hardware or software error.<br>Potential Interference from external device. | First press any setting adjustment button.<br>If display does not self-fix. Momentarily press the Run/Standby button quickly (<0.2 sec). This will reset the LCD and membrane panel<br>Power cycle unit to reset system if problem persists.<br>If occurs 3 times, contact CorVent Service and replace unit. |

| *Problem* | *Why it Occurred* | *What to Do* |
|---|---|---|
| Leak or high-pitched sound coming from unit | Potential hardware or software error. | Power cycle unit to reset system.<br><br>If occurs 3 times, contact CorVent Service and replace unit. |
| Cannot adjust parameter settings on keypad | Potential hardware or software error. | Power cycle unit to reset system.<br><br>If occurs 3 times, contact CorVent Service and replace unit. |
| Liquid accidentally spilled on unit | User error | Check for ventilator functionality.<br><br>If system does not power on after checking multiple plugs and power supplies, contact CorVent Service and replace unit. |
| POST or BIOT Failure | Internal Electronic Self-Test Failure | Cycle power to reset system.<br><br>If occurs 3 times, contact CorVent Service and replace unit. |
| Screen Blank or Solid White Boxes show up Blocking rows<br><br>  | Internal Communication Error | Momentarily press the Run/Standby button quickly (<0.2 sec). This will reset the LCD and membrane panel.<br><br>Power cycle unit to reset system if problem persists.<br><br>If occurs 3 times, contact CorVent Service and replace unit. |

| ***Problem*** | ***Why it Occurred*** | ***What to Do*** |
|---|---|---|
| Membrane Panel not working (button presses not adjusting items on screen) | Internal Communication Error | Momentarily press the Run/Standby button quickly (0.2 sec). This will reset the LCD and membrane panel<br><br>Power cycle unit to reset system if problem persists.<br><br>If occurs 3 times, contact CorVent Service and replace unit. |
| Disconnect Alarm that will not clear | External Communication Error | Replace Flow Sensor Cable.<br><br>Replace Flow Sensor<br><br>Momentarily press the Run/Standby button quickly (0.2 sec). This will reset the LCD and membrane panel<br><br>Power cycle unit to reset system if problem persists.<br><br>If occurs after replacing cables and flow sensors 3 times, contact CorVent Service and replace unit. |
| Occlusion alarm that will not clear | Potential blockage or low system output | Check that Peak Flow is above 5 L/min<br><br>Check circuit for occlusion or excess fluid.<br><br>Hold Alarm reset for 2 seconds to clear active alarm<br><br>Power cycle unit to reset system if problem persists. |

## 7.8 Software

The software was developed under a controlled life cycle process (IEC 62304)

The CorVent System will not be subject to digital cyberattacks because there are no data ports that the user may access without the use of a tool. It will take dismantling the device to gain access to a port. The device also does not contain any wireless devices.

There are no known unresolved software anomalies and workarounds.

There are no known unresolved software anomalies that can lead to the compromise of sensitive information or that can affect communication security as there is no method for interface with external systems.

## 7.9 System Checkout Procedure

Between each patient, run through system self-checkout procedure. No maintenance is required between each patient.

The RESPOND 19 System is a continuous blower-based gas delivery system that regulates pressure primarily based upon blower velocity. The blower is naturally limited in the pressure it can generate to 50 cmH2O due to limitations in the motor torque constant, back EMF constant, motor velocity, supply voltage and current available from the power supply.

Between each patient, run through system self-checkout procedure. No maintenance is required between each patient.

### 7.9.1 Verifying Power on Self-Test (POST)

In order to ensure that the Ventilator has successfully powered on and is ready for patient ventilation, check for the following functionality after turning the power switch on:

1. Check that LCD lights up and text appears (SW Revision and HW Revision)
2. All LEDs on the membrane panel User Interface light up
3. Buzzer Beeps Once
4. Speaker Beeps Three Times
5. POST PASSED screen is displayed (Reference Section 6.5)
6. Audible sound of Fan Turning on
7. System Defaults to Pressure Control Ventilation (PCV, $T_I$, $P_I$, and f LED are lit)
8. Select a New Patient or Same Patient (Reference Section 6.5)
9. Standby Button and alarm status LED should now be flashing green and LCD will display Standby time and Operational Life (Reference Section 6.5)

System is ready for patient ventilation.

### 7.9.2 Verifying Ventilation Output with Accessory Self-Check, Short Self-Test (SST):

The system has internal feedback functionality to ensure that the Output is directly correlated to the Input. The primary monitoring mechanisms of the ventilator are volume based upon an independent airway Flow Sensor and pressure. From these measurements the correct operation of the system may be derived. For more details on system architecture, refer to Appendix I.

If required to independently verify the system output, connect the system to a standard test lung (ideally instrumented) to ensure that the ventilator is functioning properly.

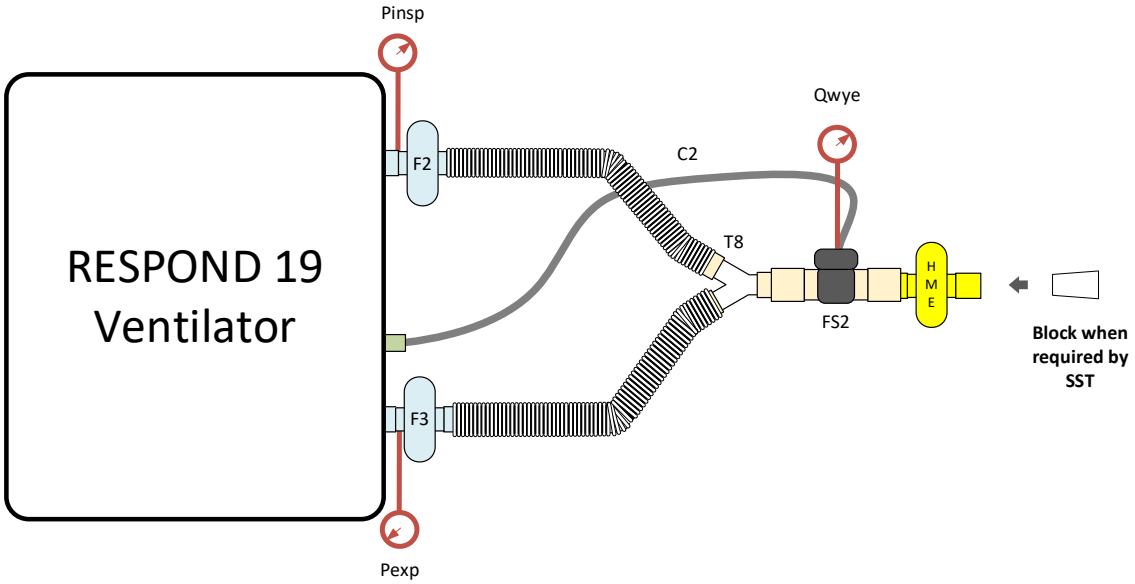
The SST takes less than one minute to complete when a user is fully prepared to run the test and can be canceled at any time by pressing the Cancel key.

In standby mode, the user is capable of running a short system self-test (SST) for the ventilator to ensure that the VBS (Ventilator Breathing System) is in normal ranges of resistances and compliances as well as checking for any system leaks. This test will require the user to block off the patient circuit wye with either their gloved finger or a #1 rubber stopper for the duration of the test.

*For reference, ISO 80601-2-12 201.15.103 Accessory self-check: requires the ventilator shall be equipped with means that allow the determination of whether or not the VBS resistance and compliance characteristics fall outside the values necessary to maintain normal operation.*

In order to enter the short self-test, the system must be in standby mode and NOT connected to a patient. The user will be required to press the “Alarm Limits” key and the first screen that will show when scrolled through is the following. This screen option available by pressing the ALARM LIMITS key shall only be available in Standby Mode:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **R** | **u** | **n** | | **S** | **h** | **o** | **r** | **t** | | **S** | **e** | **l** | **f** | **-** | **T** | **e** | **s** | **t** | **?** |
| **W** | **A** | **R** | **N** | **I** | **N** | **G** | **!** | | **C** | **o** | **n** | **f** | **i** | **r** | **m** | | **P** | **a** | **t** |
| | **i** | **s** | | **N** | **O** | **T** | | **C** | **o** | **n** | **n** | **e** | **c** | **t** | **e** | **d** | **!** | | |
| | | **P** | **R** | **E** | **S** | **S** | | **S** | **E** | **L** | | **t** | **o** | | **r** | **u** | **n** | | |




The user will be guided through the SST and requires the patient to block and unblock the patient wye in order for the test to properly run. The screens for the SST are as follows; the first test that will run is Compliance:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | l | o | c | k | | P | a | t | i | e | n | t | | W | y | e | |
| f | o | r | | e | n | t | i | r | e | t | y | | o | f | | t | e | s | t |
| | | | | T | e | s | t | | 1 | | o | f | | 3 | | | | | |
| | | | R | e | a | d | y | ? | | P | r | e | s | s | | + | | | |

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | S | S | T | | R | u | n | n | i | n | g | | | | |
| | | | | T | e | s | t | | 1 | | o | f | | 3 | | | | | |
| P | i | X | X | | P | e | X | X | | Q | i | X | X | | Q | a | w | X | X |
| | E | n | s | u | r | e | | W | y | e | | B | l | o | c | k | e | d | |

The second test that will run is Leakage:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| U | n | b | l | o | c | k | | P | a | t | i | e | n | t | | W | y | e | |
| f | o | r | | e | n | t | i | r | e | t | y | | o | f | | t | e | s | t |
| | | | | T | e | s | t | | 2 | | o | f | | 3 | | | | | |
| | | | R | e | a | d | y | ? | | P | r | e | s | s | | + | | | |

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | S | S | T | | R | u | n | n | i | n | g | | | | | |
| | | | | T | e | s | t | | 2 | | o | f | | 3 | | | | | |
| P | i | X | X | | P | e | X | X | | Q | i | X | X | | Q | a | w | X | X |
| E | n | s | u | r | e | | W | y | e | | U | n | b | l | o | c | k | e | d |

The third and final test that will run is Resistance:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | B | l | o | c | k | | P | a | t | i | e | n | t | | W | y | e | | |
| f | o | r | | e | n | t | i | r | e | t | y | | o | f | | t | e | s | t |
| | | | | T | e | s | t | | 3 | | o | f | | 3 | | | | | |
| | | | R | e | a | d | y | ? | | P | r | e | s | s | | + | | | |

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | S | S | T | | R | u | n | n | i | n | g | | | | | |
| | | | | T | e | s | t | | 3 | | o | f | | 3 | | | | | |
| P | i | X | X | | P | e | X | X | | Q | i | X | X | | Q | a | w | X | X |
| | E | n | s | u | r | e | | W | y | e | | B | l | o | c | k | e | d | |

After running the SST, the system logs the results and displays the following screens dependent upon SST outcome:

| Final Outcome | LCD |
|---|---|
| PASS | |
| FAILED | |

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | S | S | T | | P | A | S | S | E | D | | | | | |
| C | = | X | . | X | | m | L | / | c | m | H | 2 | O | | L | e | a | k | = |
| X | X | X | m | L | / | m | i | n | | R | i | X | . | X | | R | e | X | . |
| X | | R | h | m | e | X | . | X | | c | m | H | 2 | O | / | L | p | s | |

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | S | S | T | | F | A | I | L | E | D | | | | | |
| C | = | X | . | X | | m | L | / | c | m | H | 2 | O | | L | e | a | k | = |
| X | X | X | m | L | / | m | i | n | * | R | i | X | . | X | | R | e | X | . |
| X | | R | h | m | e | X | . | X | | c | m | H | 2 | O | / | L | p | s | |

| Final Outcome | LCD |
|---|---|
| | Note: Where the * follows the failed test parameter; in the example shown above the system has found a leak failure<br><br>Troubleshooting Information:<br>*C (Compliance) Failure may mean an incorrect patient circuit is used (CorVent only)<br>*Leak Failure may mean a disconnect is present<br>*Ri (Inspiratory Resistance) Failure may mean Inspiratory filter is missing<br>*Re (Expiratory Resistance) Failure may mean Expiratory filter is missing<br>*Rhme (HME Resistance) may mean HMEF is missing |

### 7.9.3 Verifying the Alarms:

Test Setup Procedure:

1. Set test lung compliance to 50 mL/cmH2O.
2. Set test lung resistance to 5 cmH2O/Lps.
3. Connect patient circuit on ventilator to test lung.
4. Turn on Ventilator and Confirm device passes POST.
5. Set ventilator Inspiratory Pressure Target to 20 cm H2O.
6. Set ventilator Respiratory Rate to 20 BPM.
7. Set ventilator Inspiratory Time to 1.0 sec.
8. Set ventilator PEEP to 5 cmH20.
9. Press On/Standby Key for 1 second to enter Run Mode.
10. Confirm the system has entered Run mode.
11. Allow system to operate in Run mode for 30 seconds.
12. Confirm that measured peak inspiratory pressure (PIP) is within +/- 4 $cmH_2O$ + 4% of set pressure target (PI + PEEP)
13. Confirm no alarms present.

| Alarm | Description | Test Procedure |
|---|---|---|
| ***REQUEST VENTILATION STOP*** | ***Medium-priority alarm.***<br>*Upon request of entry to Standby Mode from Run Mode the system will declare an alarm alerting the user that the device has been requested to stop ventilation. The user will be required to press the AUDIO PAUSED key twice to enter Standby Mode and reset the alarm. If pressed in error the user may wait 5 seconds before the request is cleared (alarm is auto reset) and the ventilator continues in Run Mode.*<br>***Reset***<br>*User waits 5 seconds* | 1. *Depress standby button for two seconds*<br>2. *Confirm Request Ventilation Stop alarm is generated*<br>3. *Wait 5 seconds*<br>*Confirm alarm is no longer present* |
| ***SYSTEM INOPERABLE*** | ***High-Priority alarm.***<br>*Upon POST or BIOT failure, the Ventilator will declare an alarm alerting the user that the system has a technical fault requiring power cycle. The system will immediately stop Ventilation due to potential risk to the patient.*<br>***Action***<br>*Ventilator must be power cycled.*<br>***Reset***<br>*Can only be reset by power cycle and subsequent successful POST pass and BIOT monitoring demonstrating system operation within expected limits.* | *Confirm system passes POST and allows system to enter Run Mode from Standby Mode.* |

| Alarm | Description | Test Procedure |
|---|---|---|
| ***HIGH PRESSURE***<br><br>***(user adjustable)*** | ***High-priority alarm.***<br><br>*High pressure limit is automatically set to 5 cmH2O higher than the MAXIMUM (PEEP + PI , PEEP + PSUPP). (the user may override):*<br><br>*A High-Pressure alarm is unlikely in PSV because PSV breath will be terminated during inspiration because of pressure excursions.*<br><br>*Two consecutive breaths were truncated because ventilator breathing circuit pressure reached HIGH PRESSURE setting. (Inspiration phase ends and exhalation valve opens to prevent excessive pressure.)*<br><br>***Action***<br><br>*Ventilator continues ventilation at user set breath rate. Triggering is disabled for 4 seconds.*<br><br>***Auto-reset***<br><br>*When circuit pressure is less than alarm setting for 5 breaths. Cannot be silenced if alarm condition persists.* | 1. *While in Run Mode, Press Down sharply on the connected Test Lung at the end of inspiration for more than 2 breaths in a row (This will force the air to exit the lung at a high pressure)*<br>2. *Confirm high pressure alarm is generated*<br><br>*Confirm alarm is auto reset after 30 seconds* |
| ***FLOW SENSOR NOT CONNECTED*** | ***Medium-priority alarm.***<br><br>*The console is not reading the flow sensor.*<br><br>***Action***<br><br>*Ventilator continues ventilation at user set breath rate. Triggering is disabled.*<br><br>***Auto-reset***<br><br>*When console starts to read the flow sensor again.* | 1. *Disconnect Flow Sensor cable from Flow Sensor*<br>2. *Confirm Flow Sensor not connected alarm is generated*<br>3. *Reconnect Flow Sensor cable to Flow Sensor*<br><br>*Confirm alarm is auto reset after 30 seconds* |

| Alarm | Description | Test Procedure |
|---|---|---|
| ***DISCONNECT*** <br> ***(user adjustable)*** | ***Medium-priority alarm.*** <br> *Measured exhaled tidal volume is XX% less of delivered tidal volume for 4 consecutive breaths.* <br> ***Action*** <br> *Ventilator continues ventilation at user set breath rate. Triggering is disabled for 4 seconds* <br> ***Auto-reset*** <br> *When exhaled tidal volume is greater than XX% of the delivered tidal volume for one breath.* | 1. *Disconnect the patient circuit at the Wye* <br> 2. *Confirm Disconnect alarm is generated* <br> 3. *Reconnect patient circuit to test lung* <br> *Confirm alarm is auto-reset after 30 seconds* |
| ***OCCLUSION*** | ***High-priority alarm.*** <br> *Ventilator breathing circuit or inspiratory or expiratory filters occluded. Ventilator detects above-normal difference between inspiratory and expiratory pressure transducers. The same alarm will occur for a partial or complete occlusion.* <br> ***Action*** <br> *Ventilator continues ventilation at user set breath rate. Triggering is disabled for 4 seconds.* <br> ***Auto-reset*** <br> *When the ventilator no longer detects an occlusion on the next breath* | *For Complete Occlusion:* <br> 1. *Occlude the inspiratory or expiratory limb of the patient circuit by clamping circuit shut by folding a segmented section over on itself, effectively kinking it* <br> 2. *Confirm occlusion alarm is generated* <br> 3. *Unclamp circuit* <br> *Confirm alarm is auto-reset after 30 seconds* <br> *For Partial Occlusion:* <br> 1. *Partially Occlude the inspiratory or expiratory limb of by squeezing a segmented section shut, but maintain a base flow which may be visualized by seeing a test lung inflating and deflating or via measurement of exhaled tidal volumes on the monitor* <br> 2. *Confirm occlusion alarm is generated* <br> 3. *Unclamp circuit* <br> *Confirm alarm is auto-reset after 30 seconds* |

| Alarm | Description | Test Procedure |
|---|---|---|
| ***LOW INSP PRESSURE*** <br> ***(user adjustable)*** | ***Medium-priority alarm.*** <br> *Low pressure limit is automatically set to a default setting (the user may override):* <br> *For PCV: maximum (PEEP + PI – 5 cmH2O) setting (Min = 1 cmH2O)* <br> *For PSV: maximum (PEEP + PSUPP – 5 cmH2O) setting (Min = 1 cmH2O)* <br> *Depending upon the breath being delivered. This will update between two levels in SIMV if the PI and PSUPP are different.* <br> ***Action*** <br> *Ventilator continues ventilation at user set breath rate. Triggering is disabled for 4 seconds* <br> ***Auto-reset*** <br> *When circuit pressure is at least equal to alarm setting during inspiration for a single breath* | 1. *Disconnect the inspiratory patient circuit while in Run mode* <br> 2. *Clear the Disconnect Alarm with Alarm Reset (Hold for two seconds)* <br> 3. *Confirm low pressure alarm is generated* <br> 4. *Reconnect inspiratory limb* <br> *Confirm alarm is auto-reset after 30 seconds* |
| ***LOW EXHALED TIDAL VOL*** <br> ***(user adjustable)*** | ***Medium-priority alarm.*** <br> *When the measured exhaled tidal volume is less than the user set for 3 out of 4 consecutive breaths* <br> ***Action*** <br> *Ventilator continues ventilation at user set breath rate.* <br> ***Auto-reset*** <br> *Resets when the monitored value at least equals the alarm setting for 3 out 4 consecutive breaths.* | 1. *Set the Inspiratory Pressure to 5 $cmH_2O$ and confirm measured Tidal Volume is now under 150 mL (default alarm limit)* <br> 2. *Confirm Low Exhaled TV alarm is generated* <br> 3. *Set Inspiratory Pressure to 30 $cmH_2O$ and confirm measured Tidal Volume is now greater than 150 mL (default alarm limit)* <br> *Confirm alarm is auto-reset after 30 seconds* |

| Alarm | Description | Test Procedure |
|---|---|---|
| ***HI RESP RATE*** ***(user adjustable)*** | ***Medium-priority alarm.*** *Monitored respiratory rate higher than HIGH RATE setting.* ***Action*** *Ventilator continues ventilation at user set breath rate. Triggering is disabled for 4 seconds* ***Auto-reset*** *When monitored respiratory rate is less than or equal to the breath rate limit* | 1. *Use ALARM LIMITS key to adjust high respiratory rate alarm to 20 BPM*<br>2. *Set trigger sensitivity to 0.5 LPM*<br>3. *Squeeze or extend the patient circuit tubing to create patient triggers during exhalation*<br>4. *Confirm High respiratory rate is generated*<br>5. *Adjust High respiratory rate limit back to default 40 BPM*<br>*Confirm alarm is auto-reset after 30 seconds* |
| ***APNEA*** ***(user adjustable)*** | ***Medium-priority alarm.*** *When the measured breath interval is lower than that set apnea interval.* ***Action*** *Ventilator switches to apnea ventilation.* ***Auto-reset*** *Resets when the user triggers two consecutive breaths at intervals lower than the apnea interval.* | 1. *Set System to PSV mode*<br>2. *Begin Ventilation on test lung*<br>*Wait 30 seconds and Confirm apnea alarm is generated*<br>3. *Return system to SIMV mode*<br>*Confirm alarm is auto-reset after 30 seconds* |
| ***High Exhaled Tidal Volume (user adjustable)*** | ***Medium-priority alarm.*** *When the measured exhaled tidal volume is greater than the user set for 3 out of 4 consecutive breaths* ***Action*** *Ventilator continues ventilation at user set breath rate.* ***Auto-reset*** *Resets when the monitored value at least equals the alarm setting for 3 out 4 consecutive breaths.* | 1. *Use ALARM LIMITS key to adjust high exhaled tidal volume alarm to 100 ml*<br>2. *Set target pressure to 30 cmH2O and Test lung compliance to 50 ml/cmH2O*<br>3. *System tidal volume should now be greater than 550 ml*<br>4. *Confirm High exhaled tidal volume is generated*<br>5. *Set high exhaled tidal volume alarm to 1500 ml and return target pressure to default*<br>*Confirm alarm is auto-reset after 30 seconds* |

| Alarm | Description | Test Procedure |
|---|---|---|
| ***High PEEP (user adjustable)*** | ***Medium-priority alarm.***<br>*High PEEP limit is automatically set to 5 cmH2O higher than the PEEP Setting (the user may override):*<br>***Action***<br>*Ventilator continues ventilation at user set breath rate.* ***Triggering is disabled for 4 seconds.***<br>***Auto-reset***<br>*When circuit pressure is less than alarm setting for 5 breaths. Cannot be silenced if alarm condition persists.* | 1. *Use ALARM LIMITS key to adjust High PEEP alarm to 5 cmH2O*<br>2. *Set PEEP to 20 cmH2O*<br>3. *Confirm High PEEP alarm is generated*<br>4. *Reset PEEP to 5 cmH2O and Reset High PEEP alarm to 25 cmH2O*<br>*Confirm alarm is auto-reset after 30 seconds* |
| ***LOW PEEP (user adjustable)*** | ***Medium-priority alarm.***<br>*The LOW PEEP limit is automatically set to 3 cmH2O lower than the set PEEP. The user may adjust the LOW PEEP setting.*<br>*The monitored PEEP pressure never rises above LOW PEEP setting during exhalation for 3 out of 4 breaths. The user may adjust this LOW PEEP setting.*<br>***Action***<br>*Ventilator continues ventilation at user set breath rate.*<br>***Auto-reset***<br>*Resets when the monitored valve at least equals the alarm setting for 3 out of 4 breaths.* | 1. *Use ALARM LIMITS key to adjust Low PEEP alarm to 10 cmH2O*<br>2. *Set PEEP to 0 cmH2O*<br>3. *Confirm Low PEEP alarm is generated*<br>4. *Reset PEEP to 10 cmH2O and Reset Low PEEP alarm to 5 cmH2O*<br>*Confirm alarm is auto-reset after 30 seconds* |

| Alarm | Description | Test Procedure |
|---|---|---|
| ***FLOW SENSOR REVERSED*** | ***Medium-priority alarm.***<br>*The flow sensor was placed in the wrong orientation and should be reversed.*<br>***Action***<br>*Ventilator continues ventilation at user set breath rate. Triggering is disabled for 4 seconds.*<br>***Auto-reset***<br>*When console see the flow sensor in the correct direction.* | 1. *Reverse direction of Flow Sensor*<br>2. *Confirm alarm is generated*<br>3. *Reverse Flow Sensor back to correct orientation*<br>*Confirm alarm is auto-reset after 30 seconds* |
| ***KEYBOARD FAILED*** | ***Medium-priority alarm.***<br>*Technical alert. A key was held down longer than expected.*<br>***Action***<br>*Ventilator continues ventilation.*<br>***Unit Must be power cycled. Alarm does not auto-reset.*** | 1. *Depress any key for greater than 20 seconds*<br>2. *Confirm alarm is generated*<br>3. *Power cycle system to reset*<br>*Confirm alarm is reset upon turning it back on* |
| ***TEMP LOSS OF POWER*** | ***HIGH-priority alarm.***<br>*This is both a hardware and software generated alarm.*<br>*When power is lost the alarm is generated by hardware. When power is reestablished within a few minutes the system is able to determine that power was temporarily and restart ventilation with a high priority alarm.*<br>***Action***<br>*Ventilator continues ventilation at user previous settings and alarm limits.*<br>***Reset***<br>*User must depress Alarm reset key to acknowledge alarm.* | 1. *Switch off or unplug ventilator power while in run mode*<br>2. *Wait 30 seconds*<br>3. *Plug back in ventilator*<br>4. *Wait 30 seconds*<br>5. *System will come back up ventilating and display Temp Loss of Power Warning*<br>6. *Confirm Alarm is generated*<br>*Confirm alarm is auto-reset after resolving alarm screen with Alarm Reset* |

| Alarm | Description | Test Procedure |
|---|---|---|
| ***OXYGEN SUPPLY INSUFFICIENT (if no O2 monitor used)*** | *An alarm will not sound if there is an interruption to the $O_2$ supply. If the supply is interrupted, it could result in the $FiO_2$ being lower than the amount set on the unit (down to 21%). Appropriate patient monitoring should be used, as medically indicated, such as an alarming pulse oximeter.* | *Use external monitoring to manage oxygen delivery efficacy and safety* |
| ***TOTAL LOSS OF POWER*** | *This is a hardware alarm.* | 1. *Run the system for 5 minutes*<br>2. *While the ventilator is running in Run mode, pull the power cord from the wall*<br>3. *Confirm alarm is generated*<br>4. *Plug Ventilator back-in*<br>5. *Ensure Power ON/OFF switch is in ON position*<br>*Confirm system passes POST* |
| ***GAS SUPPLY FAILURE (OXYGEN)***<br>***(user adjustable)*** | ***Medium-priority alarm.***<br>*This is an alarm integrated into external hardware.*<br>*Refer to external Oxygen Sensor for details on oxygen concentration range.* | 1. *Supply oxygen at 15L/min to ventilator*<br>2. *Connect external oxygen monitor and set low oxygen percent alarm limit to 50% O2*<br>3. *Turn off Oxygen supply (0 L/min)*<br>4. *Confirm alarm is generated*<br>5. *Reconnect supply oxygen at 15L/min to ventilator*<br>*Confirm alarm is reset upon turning oxygen back on* |
| ***INTERNAL BATTERY NEARING DEPLETION***<br>***(user adjustable)*** | ***Medium-priority alarm.***<br>*This is an alarm integrated into external hardware.*<br>*Refer to external UPS for more details. Automatically set to alarm when battery has <10 mins left of battery life at system load.* | 1. *Connect ventilator to external UPS and begin ventilation*<br>2. *Unplug UPS from mains supply*<br>3. *Let the system ventilate for 30 mins*<br>4. *Ensure a low battery alarm is generated before depleting*<br>5. *Plug UPS back into mains*<br>*Confirm alarm is reset upon plugging UPS back into mains* |

| Alarm | Description | Test Procedure |
|---|---|---|
| ***LOSS OF MAINS/ SWITCHOVER TO INTERNAL BATTERY*** | ***Medium-priority alarm.***<br>*This is an alarm integrated into external hardware.*<br><br>*Refer to external UPS for more details. This is a hardware alarm.* | 1. *Connect ventilator to external UPS and begin ventilation*<br>2. *Unplug UPS from mains supply*<br>3. *Ensure a switchover to battery alarm/loss of mains alarm is generated*<br>4. *Plug UPS back into mains*<br>*Confirm alarm is reset upon plugging UPS back into mains* |

If any of the alarm states DO NOT trigger when clearly in an insufficient ventilation state, cycle power on the unit and attempt the test again. If after three attempts, the system does not respond adequately, contact CorVent Service and replace the unit.

## 7.10 Active Alarm List and Event Log

The RESPOND 19 Ventilator maintains logs of all events that the system experiences since power on. The RESPOND 19 maintains two logs, an Active alarm List, and an Event log since power on. The Active alarm list is available only when more than one alarm is active. The Event log is always accessible to the user and encompasses all alarms, events, and technical indicators on a minute basis since power on. If power is reset, the alarm list and event log will be cleared.

### 7.10.1 Active Alarm List

The Active alarm list may be accessed when an alarm is annunciating by pressing the RIGHT ARROW key to navigate to the log. An example of the list is shown below:

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **A** | **c** | **t** | **i** | **v** | **e** | | **A** | **l** | **a** | **r** | **m** | | **L** | **i** | **s** | **t** | | |
| | **S** | **e** | **c** | **s** | | **D** | **e** | **s** | **c** | **r** | **i** | **p** | **t** | **i** | **o** | **n** | | |
| **M** | **0** | **0** | **9** | **0** | | **R** | **E** | **Q** | | **V** | **E** | **N** | **T** | | **S** | **T** | **O** | **P** |
| **H** | **0** | **0** | **8** | **5** | | **H** | **I** | **G** | **H** | | **P** | **R** | **E** | **S** | **S** | **U** | **R** | **E** |

When displayed, new alarms will not eject the user from the list, they will be added to the list as they occur. The audio and LED visual indication will continue to annunciate using the highest ranked alarm priority. The side ARROW keys may be used to move between the active alarm list, the highest ranked alarm, the user settings, and the measurements screen. The Cancel (X) key may also be used to revert back to the highest ranked alarm screen. The Active Alarm List is displayed with a second indicator from the last alarm annunciated (first alarm = 0000 seconds). This allows up to ~3 hours of alarm event history. There are a maximum of 16 alarms that could annunciate simultaneously.

| Active Alarm List Abbreviation | Definition |
|---|---|
| **M** | Medium Priority Alarm |
| **H** | High Priority Alarm |
| **Secs** | Seconds. Time from first active alarm annunciated. When all alarms are cleared this time will reset to 0 seconds. |
| **Alarm Abbreviation** | **Definition** |
| **REQ VENT STOP** | Request Ventilator Stop |
| **FLW SEN NOT CO** | Flow Sensor Not Connected |
| **DISCONNECT** | Patient Circuit Disconnect |
| **HI EXH TID VOL** | High Exhaled Tidal Volume |
| **LO EXH TID VOL** | Low Exhaled Tidal Volume |
| **HIGH RESP RATE** | High Respiratory Rate (Hyperventilation) |
| **FLW SEN REVRSD** | Flow Sensor Reversed |

*Alarm States not listed in the table above are not abbreviated and will be directly displayed as the title (*i.e. High Pressure, Low Pressure, High PEEP, Low PEEP, APNEA, Life Exceeded, Key Stuck*)

### 7.10.2 Event Log

The Event log may be accessed at any time by selecting the ALARM LIMITS key and scrolling left or right to the Event log screen. An Example of the event log screen is shown below:


| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| E | v | e | n | t | | L | o | g | | | | | | | | | | |
| | M | i | n | s | | D | e | s | c | r | i | p | t | i | o | n | | |
| M | 0 | 0 | 9 | 0 | | R | E | Q | | V | E | N | T | | S | T | O | P |
| H | 0 | 0 | 8 | 5 | | H | I | G | H | | P | R | E | S | S | U | R | E |

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | M | i | n | s | | D | e | s | c | r | i | p | t | i | o | n | | |
| M | 0 | 1 | 8 | 1 | | D | I | S | C | O | N | N | E | C | T | | | |
| E | 0 | 1 | 7 | 0 | | D | I | S | C | O | N | N | E | C | T | | 2 | 5 |
| E | 0 | 1 | 4 | 4 | | P | E | E | P | | 1 | 0 | | | | | | |

| Event Log Abbreviation | Definition |
|---|---|
| **M** | Medium Priority Alarm |
| **H** | High Priority Alarm |
| **E** | Event. An event could be breath mode change, breath type change, setting change, alarm setting change, etc. |
| **Mins** | Minutes. Time from first Ventilation start. When the system is powered down, the time is reset to 0. |

The Event log will display all events including alarms, setting changes, alarm silences/pauses, and technical indicators. The contents of the event log will not be maintained upon power down or Total Loss of Power. It is generated from the time of last power on. Up to 1,000 events may be viewed.

# 8.0 Cleaning, Disinfection, Maintenance, Disposal, and Storage

The ventilator does not require routine servicing or preventative maintenance other than inspection for damage or wear.

### ⚠ Warnings

- **DO NOT** immerse the ventilator in water or any fluids
- **DO NOT** allow liquid or sprays to penetrate the ventilator openings or cable connections
- **DO NOT** attempt to sterilize the ventilator with autoclave or ethylene oxide.
- **DO NOT** attempt to clean and disinfect when the ventilator is powered on.
- **DO NOT** use pressurized air to clean or dry the ventilator
- **DO NOT** overspray the device with any water or cleaners. The cleaning solutions may aerosolize and enter the patient's airway creating the potential to cause lung damage.
- **NO** modification of this equipment is allowed.

**Cleaning and Disinfecting the Ventilator**

The ventilator surfaces may be disinfected using the recommended cleaning and disinfection agent listed below. Certain areas of the ventilator will be contacted frequently during use while others such as the handles will not be regularly used while ventilating patients.

Care should be taken to avoid contacting areas that may be soiled in use and difficult to disinfect thoroughly during therapy such as:

- Membrane Panel
- Flow Sensor Cable
- Standby Switch

CorVent recommends changing gloves after touching these areas, if required. The areas most likely to be touched during use are the membrane panel, Oxygen inlet barb, patient ports and ON/Standby Switch. Particular care should be taken to ensure that these areas are cleaned and disinfected.

- The internals of the ventilator are not contaminated by the exhaled air if the filters are used as instructed during normal operation. Wiping down the outside of the system is sufficient.
- In the case of a single fault failure (i.e., Filter is missing/damaged/torn), refer to Section 6.11 for details on the gas pathways through the Ventilator that can become contaminated with body fluids or expired gases
- Clean and disinfect system between each patient or after any spill.
- We recommend cleaning the ventilator while it is powered off and with the ports capped.

**RECOMMENDED CLEANING and DISINFECTION AGENT**

CaviWipes1* or equivalent

Manufactured by Metrix Research LLC.
Safety Data Sheets are available at www.metrex.com/en-us/caviwipes1

*Note**:** The effectiveness of the cleaning and disinfection processes recommended below have been validated with CaviWipes1. Test reports are on file at CorVent Medical (www.corventmedical.com).

**Note: Follow the institution's infection control protocol for handling, storage, and disposal of potentially bio-contaminated waste

| Part | Procedure |
|---|---|
| Cleaning Ventilator Exterior | **Ensure the ventilator is turned off and unplugged to prevent electrocution.**<br>- Examine all surfaces of the Ventilator<br>- When gross debris/soiling is observed, pull one CaviWipe1 towelette from the cannister.<br>- Remove the visible debris by wiping with the towelette.<br>- Repeat with another towelette if necessary.<br>- If necessary, use a new small soft bristle brush (i.e. tooth brush) to clean recesses if necessary. Ensure the new brush is dampened with a CaviWipe1 and not excessively wet.<br>- When all visible debris is removed perform a final cleaning of all surfaces with a clean towelette.<br>- Once the surfaces are clean, dispose of the towelettes as biological waste**. |
| Disinfecting ventilator exterior | **Ensure the ventilator is turned off and unplugged to prevent electrocution.**<br>**Note: Disinfection is to be performed after the Respond Ventilator is cleaned via the above procedure.**<br>- Dispense one clean CaviWipe1 towelette.<br>- Thoroughly wipe the surfaces to be disinfected with the towelette.<br>- If necessary, use a new small soft bristle brush (i.e. tooth brush) to clean recesses if necessary. Ensure the new brush is dampened with a CaviWipe1 and not excessively wet.<br>- Assure all the treated surfaces remain visibly wet for a minimum of 3 minutes.<br>- If surfaces do not appear wet for at least one minute, wipe again with a clean towelette.<br>- Let the ventilator surfaces air dry before plugging the ventilator into the electrical outlet.<br>- Dispose of the towelettes as biological waste**. |

| | |
|---|---|
| Ventilator Cooling Vent | Vacuum the vent on the bottom of the unit to remove any dust present. Wipe with a CaviWipe1 towelette to remove residue and disinfect as needed per the above instructions. |

**Cleaning / Disinfecting the Patient Circuit**

The RESPOND 19 patient circuit and its components are disposable, single use devices. This circuit must not be cleaned, disinfected, or reused. It should be strictly disposed of per institutional guidelines. Replace only with a CorVent supplied patient circuit.

**DO NOT** attempt to sterilize or reuse single use complete patient circuit or its components (Flow Sensor, Patient Circuit Tubing, Filters, and HME) as it could lead to patient infection, degraded performance, and system contamination.

**Maintenance**

No user serviceable parts inside the Ventilator.
**DO NOT** attempt to service the unit.

**Disposal**

- **DO NOT** attempt to reuse the ventilator after its functional lifetime. Dispose of the ventilator in accordance with local regulations after use.

- Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste. It must be collected separately and must be disposed as per local regulations. Contact your authorized representative for information concerning the decommissioning of the RESPOND 19 ventilator and its related accessories (UPS Batteries, Oxygen Sensor, etc.)
- The patient circuit is to be removed and placed in biohazard waste container**.

**Storage**

Store per environmental conditions as specified in Section 10, Environmental and Physical Characteristics.

# 9.0: CorVent Support

If service, training, or troubleshooting support is required, please contact the CorVent Support Hotline at +1 (833) 770 - VENT and/or at support@CorVentmedical.com. Refer to labeling on Ventilator for up-to-date contact information.

⚠ **DO NOT** attempt to service the unit.

To return RESPOND 19 Ventilator to manufacturer, contact the support hotline for instructions on how and where to send the unit.

Any attempts to modify the hardware of this device will void all warranties and liabilities.

# 10.0 Specifications

## Environmental and Physical Characteristics

### ⚠ Warnings

DO NOT use the ventilator at an altitude above 3000m or outside a temperature of 10 Deg C to 30Deg C. Using the ventilator outside of this temperature range or above this altitude can compromise the ventilator performance which consequently can result in degradation of the health of the patient. The Ventilator has only been tested at sea level and degradations in performance may occur at higher altitudes.

| Characteristic | Specification |
|---|---|
| Operating Temperature | 10 – 30 °C (50 - 86 °F) |
| Operating Relative Humidity | 15 – 90% noncondensing |
| Operating Atmospheric Pressure Range | 700 – 1060 hPa |
| Operating Altitude* | Up to 3000m |
| Short Term Storage (< 2 months)/ Transport Temperature | -34 – 70 °C (-29 - 158 °F)** |
| Long Term Storage ( >2 months) Temperature | 15 – 25 °C (59 – 77 °F) |
| Storage/Transport Relative Humidity | 0 – 95% non-condensing |
| Storage/Transport Atmospheric Pressure Range | 510 – 1081 hPa |
| Shelf Life *(Within required Storage Conditions)* | < 5 years |
| Dimensions | < 45.7 cm x 30.5 x 30.5 (18” x 12” x 12”) |
| Weight including power supply | < 9.1 kg (20 lbs) |
| Sound Pressure Level of Ventilator *(while operating per 201.102 of ISO 80601-2-12 )* | < 65 dBA |

**Reference Effects of Altitude on Ventilation Parameters section below*

**Service Life**: The system is rated for operation of **up to 5 years of normal use** after beginning patient support. The system must be checked out for functionality at regular intervals for proper functionality as per institutional guidelines to confirm this service life. After this service lifetime is exceeded, the system must be disposed of as per institutional guidelines. If the Ventilator is used beyond this service lifetime, degraded performance parameters may occur.

The Ventilator has been developed using a risk management process ISO 14971.

The power supply is medical grade. The patient is also electrically isolated from the ventilator and only connected via plastic pneumatic tubing. The Flow Sensor is electrically isolated up to 2.5kV continuously.

## Standards Compliance

This device is designed to conform to the following standards:

### General Standards

| Standard | Description |
|---|---|
| IEC 60601-1:2005/A1:2012 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2:2014 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014) |
| EN 60601-1-8:2007 | Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006) |
| EN ISO 10993-1:2009/AC:2010 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009) |
| ISO 18562-1 First Edition 2017-03: | Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 1: Evaluation and Testing Within a Risk Management Process |
| ISO 18562-2 First Edition 2017-03: | Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 2: Tests for Emissions of Particulate Matter |
| ISO 18562-3 First Edition 2017: | Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 3: Tests for Emissions of Volatile Organic Compounds |
| ISO 18562-4 First Edition 2017-03: | Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 4: Tests for Leachables in Condensate |

This device is tested to conform to the following standards:

**Particular Standards**

| Standard | Description |
|---|---|
| ISO 80601-2-12 Second Edition 2020-02: | *Medical Electrical Equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators* |
| EN ISO 9360-1:2000 | *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml* |
| ISO 5367 | *Anaesthetic and respiratory equipment — Breathing sets and connectors* |
| ISO 5356-1 | *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets* |
| EN ISO 23328-1 | *Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance (ISO 23328- 1:2003)* |
| EN ISO 23328-2 | *Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects (ISO 23328-2:2002)* |
| ISO 80369-1 | *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements* |

## IEC 60601-1 Classification

| Characteristic | Classification |
|---|---|
| Type of Protection Against Electric Shock | Class I, Internally Powered* |
| Degree of Protection Against Electric Shock | Type BF |
| Defibrillation Safety | The RESPOND 19 Ventilator does not have any Defibrillator proof applied parts |
| Degree of Protection against Ingress of Water | Ventilator: IP22 (Protection against touch by fingers and objects greater than 12 Millimeters. Protected from water spray less than 15 degrees from vertical) |
| Modes of Operation | Continuous |
| Sterilization | The ventilator, power supply, and flow sensor cable are not intended to be sterilized. The patient circuit tubing, HME, Filters, and Flow Sensor are not intended to be sterilized. |
| Oxygen Rich Environment | Not intended for use in Oxygen rich environment |

**Achieved with external UPS*

## Electrical

| Characteristic | Specification |
|---|---|
| External AC/DC Power Supply Rating | 120 - 240 VAC, 60 Hz to 24 VDC, 120 Watt |
| Fuses | No User replaceable fuses, contact CorVent Service if system has electrical failure. |
| Backup Power Life *(For All Delivered Volumes per Table 201.102, ISO80601-2-12)* | >2 minutes of audio/visual alarm annunciation upon mains total loss of power (Ventilation will stop); Up to 30 mins of power with required, aged and fully charged, External UPS |
| Behavior After switchover to internal electrical source *(with Required External UPS)* | The system will operate normally, with no reduction in performance, until the UPS is depleted. This depletion will be annunciated by multiple UPS alarms (integrated into the UPS) prior to Complete loss of power. |
| Behavior During Internal Power Source Recharging *(with Required External UPS)* | The system will operate normally, with no reduction in performance, if UPS is plugged into Mains Supply |

## Gas Supply

| Characteristic | Specification |
|---|---|
| Low Flow Oxygen Supply (from Oxygen Flow Meter) | 0 – 15 SLPM* |
| Supply Pressure to Oxygen Flow Meter | 50 - 55 psi (345 - 379 kPa) |
| Air Flow | Generated by Micro blower and is a function of a set pressure and the patient demand |

**Ten second average, Constant flow rate*

## Patient Circuit Specifications

| Characteristic | Specification |
|---|---|
| Inspiratory side filter | Materials: Polypropylene housing, Hydrophobic Coated Glass Fibers<br>B/V Efficacy: >99.99% at 0.3 microns<br>Dead Space Volume: 34 mL |
| Exhalation side filter | Materials: Polypropylene housing, Hydrophobic Coated Glass Fibers<br>B/V Efficacy: >99.99% at 0.3 microns<br>Dead Space Volume: 34 mL |
| HMEF* | Materials: Polypropylene housing, Polyurethane Foam, Hydrophobic Coated Glass Fibers<br>B/V Efficacy: >99.99% at 0.3 microns<br>Humidity Output: 32mg H2O/L<br>Dead Space Volume: 15 mL |
| Rebreathing | A one-way valve is used to direct airflow out of the micro turbine blower, minimizing the risk of rebreathing. The dead volume that is potentially being rebreathed is <5 mL. At worst case it is <10% CO2 rebreathing at the lowest tidal volumes. |
| Inspiratory Limb Resistance* | <1.9 $cmH_2O$ at 15L/min<br><4.6 $cmH_2O$ at 30L/min<br><10.2 $cmH_2O$ at 60L/min |
| Expiratory Limb Resistance* | <3.3 $cmH_2O$ at 15L/min<br><5.4 $cmH_2O$ at 30L/min<br><10.8 $cmH_2O$ at 60L/min |
| VBS (Patient Circuit) Compliance* | <2.1 mL/$cmH_2O$ |
| NIV Mask Specification | <10L/min Leak rate @ 20 cmH2O, Non-Vented Only |
| NIV Masks to Use with the RESPOND 19 (Non-Vented) | Phillips Respironics AF811 & PerforMax Full Face Mask<br>Hamilton Medical BiTrac MaxShield & BiTrac NIV Full Face<br>Resmed Quattro non-vented & Ultra-Mirage non-vented<br>Salter Labs Utopia and Hybrid Full Face |

**Available for operational measurement through SST at 60 L/min*

## Setting Range and Control Accuracy

| Modes of Ventilation | | | |
|---|---|---|---|
| Continuous Mandatory Ventilation (CMV), Assist Control Ventilation (ACV), Spontaneous Ventilation (SPONT) | | | |
| **Types of Ventilation** | | | |
| Invasive (*Default Type*), Non-Invasive (NIV) | | | |
| **Parameter** | **Range** | **Accuracy** | **Default** |
| Tidal Volume (TV) | 50 – 2,000 ml | ± (10 + 10%) ml of measured value. This is not a direct setting on the ventilator. **This is exclusive of the volumes lost to tubing compliance.* | NA |
| Maximum Limited Pressure ($P_{LIMmax}$) | 50 $cmH_2O$ | This is not a direct setting on the ventilator. Limited by hardware and software. | NA |
| Maximum Working Pressure ($P_{Wmax}$) | 0 - 40 $cmH_2O$ | ± (2 + 4% of setting) $cmH_2O$. Achieved by pressure generation. | NA |
| **Patient Settings (PCV, *Default Breath Type)*** | | | |
| Breath Rate (f) | 3 – 70 bpm | ± 1 bpm | 20 bpm |
| Inspiratory Time ($T_I$) | 0.4 – 3.0 sec | ± (0.1 + 1% of setting) sec | 0.8 sec |
| Inspiratory Pressure Target ($P_I$)* | 5 – (40 $cmH_2O$ - PEEP) | ± (2 + 4% of setting) $cmH_2O$ | 15 $cmH_2O$ |
| **Patient Settings (PSV)** | | | |
| Pressure Support Target ($P_{SUPP}$)* | 0 – (40 $cmH_2O$ – PEEP) | ± (2 + 4% of setting) $cmH_2O$ | 10 $cmH_2O$ |
| Exhalation Sensitivity ($E_{SENS}$) | 5 - 80% | ±10% of peak flow or +/- 5L/min whichever is greater | 25% |
| **Common Settings** | | | |
| PEEP* | 0 – 20 $cmH_2O$ | ±(2 + 4% of setting) $cmH_2O$ | 5 $cmH_2O$ |
| Inspiratory Trigger Sensitivity (Invasive) | 0.5 – 20 L/min | ± (1 + 5% of setting) l/min | 2 L/min |
| Inspiratory Trigger Sensitivity (NIV) | 1 – 10 | NA | 5 |
| $O_2$% ($FiO_2$) | 21 – 95% | ±5% up to 70% O2<br>±10% 70 - 95%<br>*(Increments are in 5%)*** | 21% (*ambient room air*) |

*Max Pressure Target capability may be affected by altitude

** At patient connection port in relation to the setting. Adjustments must be made for variations in Minute Ventilation. The $O_2$% accuracy is a function of the minute ventilation and accuracy of the delivered O2 flow. (*Accuracy must be operationally verified and adjusted with use of external alarming Oxygen monitor)*

***To achieve these accuracies, the system must be used within its service life and be used with CorVent supplied parts (Complete Patient Circuit and accessories). No system calibration is required, SST is recommended to ensure the Ventilator is operating correctly before each patient is attached.

****These accuracies were determined for the only VBS configuration that the Ventilator has, and is therefore also the worst case VBS configuration at all intended delivered volumes.

*****The first value of each accuracy is the Maximum Bias Error, and the second value is the Maximum linearity error (%).The declared tolerances have been adjusted to encompass the measurement uncertainty, which are declared in the technical description.

******The maximum error of the Airway Pressure ($P_{AW}$) at the end of the inspiratory phase in relation to the setting is the same as $P_I$ or $P_{SUPP}$, which are ± (2 + 4% of setting) $cmH_2O$

## Response Time of the Ventilator (Worst case VBS)

| Oxygen Concentration Rise Target | Set $O_2$ % | Set Insp. Time ($T_I$) | Set Nominal Breath Rate (f) | Target $O_2$ % Range | Target Tidal Vol. (TV) | Length of time required for the Oxygen concentration in the Delivered Volume to change from a volume fraction of 21% to 90% of the maximum settable oxygen concentration (95% Max*90% = 85.5% Target) |
|---|---|---|---|---|---|---|
| 21% (ambient) to 85.5% (90% of Max) | 95% | 1.0 sec | 10 bpm | ≥85.5% | 500 ml | 360 seconds |
| 21% (ambient) to 85.5% (90% of Max) | 95% | 1.0 sec | 10 bpm | ≥85.5% | 150 ml | 1200 seconds |

*In order to achieve relatively fast Oxygen rise times during patient ventilation, set the Oxygen flow rate substantially above the requested $O_2$ flow rate to quickly flush the system with a higher concentration of Oxygen prior to tapering back to the requested flow rate.

## Effects of Altitude on Ventilation Parameters

The RESPOND 19 ventilator includes a barometric pressure sensor which is used to compensate for altitude changes automatically. The maximum static pressure that the blower can generate will lower with altitude, therefore the settable $P_{Target}$ will vary with altitude as shown in the table below.

$$P_{maxBlower} = 50\ cmH2O * P_{atm} / 1{,}013.25\ hPa$$

$$\mathbf{P_{Target}\ (PCV)} = P_I + PEEP\ \underline{or}\ \mathbf{P_{Target}\ (PSV)} = P_{SUPP} + PEEP$$

| Altitude (m) | Indicated Maximum Pressure Target [$P_{Target}$] ($cmH_2O$) | Nominal Barometric Pressure (hPa) | Max Blower Pressure [$P_{maxBlower}$] ($cmH_2O$) |
|---|---|---|---|
| 0 | 40 | 1013.25 | 50.0 |
| 1000 | 40 | 902.15 | 44.5 |
| 2000 | 37 | 803.22 | 39.6 |
| 3000 | 32 | 715.15 | 35.3 |

## Alarm Setting Ranges and Detection Times

| Parameter | Range | Default | Maximum Alarm Condition Annunciation Delay |
|---|---|---|---|
| High Inspiratory Pressure Limit | 20 – 50 $cmH_2O$ | Auto-Set, User Over-rideable | 80 sec + 5 ms (at 3 BPM)<br>16 sec + 5 ms (at 15 BPM) |
| Low Inspiratory Pressure Limit | 1 – 35 $cmH_2O$ | Auto-Set, User Over-rideable | 80 sec + 5 ms (at 3 BPM)<br>16 sec + 5 ms (at 15 BPM) |
| High Respiratory Rate | 20 – 70 BPM | Auto-Set, User Over-rideable (PCV, SIMV)<br>40 BPM (PSV) | 36 sec + 5 ms (set to 20 BPM) |
| Disconnect Limit | 10 – 90 % | 20 % (Invasive)<br>40% (NIV) | 80 sec + 5 ms (at 3 BPM)<br>16 sec + 5 ms (at 15 BPM) |
| High Exhaled Tidal Volume | 100 – 3,000 mL | 550 mL | 20 sec + 5 ms (at 3 BPM)<br>4 sec + 5 ms (at 15 BPM) |
| Low Exhaled Tidal Volume | 50 - 1,000 mL | 150 mL | 20 sec + 5 ms (at 3 BPM)<br>4 sec + 5 ms (at 15 BPM) |
| Apnea | 10 – 40 sec | Auto-Set, User Over-rideable (PCV, SIMV)<br>15 seconds (PSV) | 40 sec + 5 ms (set to 40 sec) |
| High PEEP | 5 – 25 $cmH_2O$ | Auto-Set, User Over-rideable | 80 sec + 5 ms (at 3 BPM)<br>16 sec + 5 ms (at 15 BPM) |
| Low PEEP | -1 – 15 $cmH_2O$ | Auto-Set, User Over-rideable | 80 sec + 5 ms (at 3 BPM)<br>16 sec + 5 ms (at 15 BPM) |
| Flow Sensor Reversed | Fixed Setting. | Fixed Setting. | 20 sec + 5 ms (at 3 BPM)<br>4 sec + 5 ms (at 15 BPM) |
| Flow Sensor Not Connected | Fixed Setting. | Fixed Setting. | 15 ms |
| Occlusion | Fixed Setting. | Fixed Setting. The resistance of Inspiratory or Expiratory limb are above a defined level. | 20 sec + 5 ms (at 3 BPM)<br>4 sec + 5 ms (at 15 BPM) |
| Keyboard Failed | Fixed Setting. | Fixed Setting. 20 seconds of button depression. | 20 sec + 5 ms |
| System Inoperable | Fixed Setting. | Fixed Setting. | 180 secs + 5 ms |

| Parameter | Range | Default | Maximum Alarm Condition Annunciation Delay |
|---|---|---|---|
| Total/Temporary Loss of Power | Fixed Setting. | Fixed Setting. When power is lost during run mode, alarm is enabled. | 5 ms |
| Request Ventilation Stop | Fixed Setting. | Fixed Setting. Always occurs immediately upon entry into standby mode from run mode. | 5 ms |
| Life Exceeded | Fixed Setting. | Fixed Setting. 5 Years of cumulative operational time. | 5 ms |

** Breath Type and/or Ventilation Type specified if not universal default*
***The 5ms addition to the maximum alarm condition annunciation delay column is the fixed electronic signal delay that the system takes to annunciate the alarm to the LCD and speaker*

**Displayed Parameter Accuracy**

| Parameter | Accuracy | Resolution | Range |
|---|---|---|---|
| Minute Ventilation Flow Rate | ± (10 ml + 10% of reading) | 0.1 L/min | 0-999 L/min |
| Breath Rate | ± 1% | 1 BPM | 0-99 BPM |
| Inspiration Volume** | ± (10 ml + 10% of reading) | 1 ml | 0-9999 ml |
| Expiration Volume** | ± (10 ml + 10% of reading) | 1 ml | 0-9999 ml |
| Peak Pressure | ± (2 $cmH_2O$ + 4% of reading) | 0.1 $cmH_2O$ | 0-99 $cmH_2O$ |
| I:E Ratio | ± (20 ms of inspiratory time) | 0.1 | 99:1 – 1:99 |
| Mean Airway Pressure | ± (2 $cmH_2O$ + 4% of reading) | 0.1 $cmH_2O$ | 0-99 $cmH_2O$ |
| PEEP | ± (2 $cmH_2O$ + 4% of reading) | 0.1 $cmH_2O$ | 0-99 $cmH_2O$ |
| Low Pressure | ± (2 $cmH_2O$ + 4% of reading) | 0.1 $cmH_2O$ | 0-99 $cmH_2O$ |

*See appendix for principles of operation and measurement processes.
**Since the Flow Sensor is placed at the patient airway, this volume is independent of tubing compliance losses. These volumes accurately reflect what is actually delivered to the patient and exhaled by the patient.
***The declared tolerances have been adjusted to encompass the measurement uncertainty. The measurement uncertainty is declared in the technical description.

## Cross Reference between Manufacturer Specific Modes and Annex E of ISO 19223

| RESPOND19 Ventilation Mode | Ventilation Group Mode* | | Note | Ventilation-mode systematic code | Ventilation- mode full systematic mode |
|---|---|---|---|---|---|
| PCV | Group 1 | Group 1a | | CMV-PC | Continuous mandatory ventilation with pressure-control |
| | | Group 1b | Note 1 | A/C-PC | Assist/Control Ventilation with Pressure Control |
| SIMV | Group 2 | Group 2b | Note 1 | SIMV-PC/PS | Synchronized Intermittent mandatory Ventilation with Pressure Control and Pressure Support |
| PSV/CPAP | Group 4 | Group 4a | | CSV-PS | Continuous spontaneous ventilation with pressure support |
| | | Group 4b | | CPAP | Continuous positive airway pressure |

**Table E.1- Typical examples of ventilation-mode systematic coding scheme for ventilators without an ACAP adjunct*

***Note 1: The settings may be adapted as appropriate for NIV (non-invasive ventilation)*

# EMC/ Declarations information

The Respond 19, Model 3461-03-9001 is suitable for the electromagnetic environment of typical hospital settings.

During the immunity testing described below, the Respond 19, Model 3461-03-9001, continues to operate normally.

### ⚠ Warnings

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Respond 19, Model 3461-03-9001 System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."
- The Respond 19, Model 3461-03-9001 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Respond 19 Ventilator should be observed to verify normal operation. If operation is not normal, the Respond 19 Ventilator or the other equipment should be moved.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment if possible, to maximize distances.
- Care must be taken when operating this equipment around other equipment to avoid reciprocal interference. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with this device.

This Medical Equipment is designed to comply IEC 60601-1-2: 2014. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Connect the equipment to an outlet on a different circuit from that to which the other device(s) are connected
- Consult your authorized dealer for help

## ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES FOR RF EMISSIONS

| Guidance and Manufacturer's Declaration - Electromagnetic Emissions | | |
|---|---|---|
| The Respond 19, Model 3461-03-9001 is intended for use in the electromagnetic environment of typical hospital environments. The customer or the user of the "Respond 19, Model 3461-03-9001" should assure that it is used in such an environment | | |
| **Emissions Tests** | **Compliance** | **Electromagnetic Environment - Guidance** |
| RF emissions CISPR 11 | Group 1 | The Respond 19, Model 3461-03-9001 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 A | The Respond 19, Model 3461-03-9001 is suitable for use in all establishments excluding domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations IEC 61000-3-3 | Complies | |

**ELECTROMAGNETIC IMMUNITY (EMI) TABLES FOR RF SUSCEPTIBILITY**

| Guidance and Manufacturer's Declaration - Electromagnetic Immunity | | |
|---|---|---|
| The Respond 19, Model 3461-03-9001 is intended for use in the electromagnetic environment of typical hospital environment. The customer or the user of the Respond 19, Model 3461-03-9001 should assure that it is used in such an environment. | | |
| **Immunity Test** | **Compliance Level** | **Electromagnetic Environment – Guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±2 kV, ±4 kV & ± 8 kV for Contact Discharge<br><br>±2 kV, ±4 kV, ±8 kV and± 15kV for Air Discharge | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ±2kV for power supply lines<br>±1kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | AC Mains Line to Ground ±0.5kV, ±1kV and ±2kV<br>AC Mains Line to Line ±0.5kV and ±1kV | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | <5% UT (100% dip in UT) for 0.5 cycles<br>0% UT (100% dip in UT) for 1 cycle<br>70% UT (30% dip in UT) for 25/30 cycles<br><5% UT (100% dip in UT) for 250/300 cycles | Mains power quality should be that of a typical commercial or hospital environment., It is required that the Respond 19, Model 3461-03-9001 be powered from an uninterrupted power supply for continued operation during power mains interruptions |
| Power frequency (50/60Hz) magnetic field<br>IEC 61000-4-8 | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Conducted RF IEC 61000-4-6 | 3 V rms<br><br>6 V rms in ISM bands | The Respond 19, Model 3461-03-9001 is suitable for the electromagnetic environment of typical commercial or hospital settings |
| Radiated RF IEC 61000-4-3 | 3 V/m | The Respond 19, Model 3461-03-9001 is suitable for the electromagnetic environment of typical commercial or hospital settings |
| NOTE: UT is the a.c mains voltage prior to application of the test level. | | |

# 11.0 Limited Warranty

Contact CorVent Medical for up-to-date warranty information at:

Address:
CorVent Medical Inc.
2326 Walsh Avenue,
Santa Clara, CA, 95051

Telephone:
+1 (833) 770 - VENT

Email:
Support@CorVentmedical.com

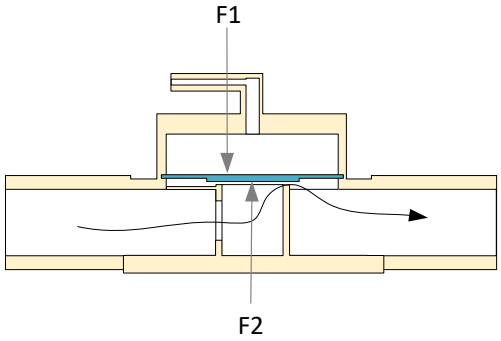
# Appendix 1. Principles of Operation

### System Technical Description

The Ventilator is electro-mechanically and pneumatically operated, providing mechanical ventilation using:

- Two blowers in the generation of pressure and flow,
  - the Main blower to control inspiration pressure and
  - the PEEP blower to control the PEEP pilot pressure which controls exhalation pressure during exhalation,
- Exhalation System
  - An exhalation solenoid valve is used to switch the pilot pressure from the inspiratory limb during inspiration to the PEEP blower during exhalation to the exhalation valve. This ensures the exhalation valve is closed during inspiration and open during exhalation.
  - An area ratio exhalation valve is used to perform two functions:
    - Prevent gas venting through the exhalation valve during inspiration.
    - Control PEEP expiratory pressure during exhalation.
- Safety System
  - A safety solenoid valve is used to switch the pilot pressure from the inspiratory limb to atmosphere to the area ration safety valve in the event of a sustained occlusion.
  - An area ratio safety valve is used to perform two functions:
    - Prevent gas venting through the exhalation valve during normal operation.
    - Direct gas from the inspiratory limb to atmosphere in the event of a sustained occlusion via the Safety Valve.

The exhalation valve shown below shows the area ratio between the pilot pressure generating a closing force F1 and the exhalation pressure of the patient generating an opening force F2. During inspiration since the pilot pressure equals the exhalation pressure the valve is forced closed due to F1>F2. During exhalation, the pilot pressure is set to the PEEP pressure divided by area ratio to control the expiratory pressure at PEEP. This means the exhalation pressure will have to exceed the PEEP pilot pressure x area ration which equals PEEP for gas to vent through the exhalation valve.




**Area Ratio Exhalation Valve**

The ventilator is rated for 5 years of normal use after starting patient support. The system must be disposed of as per institutional guidelines after the intended service lifetime is exceeded.

The ventilator is built around a common ventilator engine, a blower driven by a DC brushless blower motor with Hall sensors used for velocity feedback. This basic “engine” is attractive because it does not require an external supply of compressed air and it is limited in the pressure it may generate by the physics of the blower. It does not emit toxic volatiles into the breathing circuit (e.g. oil, particles, volatile organic compounds (VOC), mold release agents are avoided in the GAS PATHWAYS, and it is built for oxygen use. Clinicians can optimize patient ventilation oxygenation using the following settings and breath types:

In standby the user may select:

- Invasive Ventilation
- Non-Invasive Ventilation

The user may always select breath modes:

- Pressure Control Ventilation (PCV)
- Pressure Support Ventilation (PSV)
- Spontaneous Intermittent Mandatory Ventilation (SIMV)

In Pressure Control Ventilation (PCV) the user may set:

- Inspiratory Pressure Target ($P_I$)
- Inspiratory Time ($T_I$)
- Breath Rate (f)

In Pressure Support Ventilation (PSV) the user may set:

- Pressure Support Target ($P_{SUPP}$)
- Exhalation Sensitivity ($E_{SENS}$)

In SIMV (PCV + PSV) the user may set:

- Inspiratory Pressure Target (P*I*)
- Inspiratory Time (T*I*)
- Breath Rate (f)
- Pressure Support Target (P*SUPP*)
- Exhalation Sensitivity (E*SENS*)

The user may always set (Common Settings):

- Trigger Sensitivity (A/C)
- O2% - RESPOND 19 calculates and displays the required external O2 flow rate based upon minute ventilation. (The user sets this manually).
- PEEP

Alarm settings:

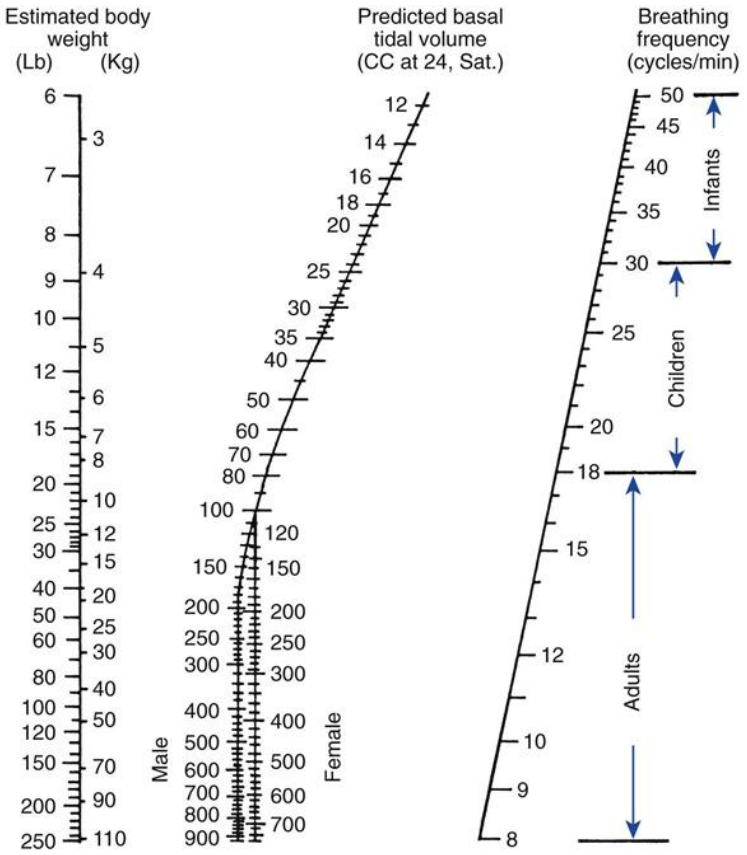
- Low Exhaled Tidal Volume Limit

- High Exhaled Tidal Volume Limit
- Apnea Limit
- High PEEP
- Low PEEP
- Relative High Pressure Limit (relative to $P_I$ / $P_{SUPP}$)
- Relative Low Pressure Limit (relative to $P_I$ / $P_{SUPP}$)
- High Respiratory Rate Limit
- Disconnect Limit
- Short Self-Test (Standby Mode Only)

These user settable features constitute the basic functionality needed for the ventilator to provide a life-supporting capacity.

These ventilation parameters are set by a trained physician as per standard of care.

*The Radford diagram is included below for reference:*




***Radford Nomogram used to predict necessary tidal volume for artificial respiration on the basis of respiratory rate body weight and sex.***

In addition to these basic features, the ventilator is able to detect a number of patient hazardous conditions which the user is altered to via the following alarms

1. High pressure alarm – This alarm is annunciated when the circuit pressure exceeds a user set limit. Priority High. This is a not latch alarm and will reset if another breath is given that does not cause a high-pressure alarm. The ventilator will continue to deliver breaths. In the event of a high-pressure alarm, the ventilator will enter exhalation and both the safety valve and exhalation valve will be open to atmosphere to allow the system to drop to PEEP in order to mitigate any potentially dangerous scenario for the patient.
2. Circuit occlusion – This alarm is annunciated when the inspired or expired limb is occluded. Priority Medium. This is not a latch alarm and may be reset by the user. The ventilator will continue to deliver breaths. The same alarm will occur for a partial or complete occlusion. In the event of the occlusion, the ventilator will enter exhalation and both the safety valve and exhalation valve will be open to atmosphere to allow the system to drop to PEEP in order to mitigate any potentially dangerous scenario for the patient.
3. Circuit Disconnect – This alarm is annunciated when there is low exhaled tidal volume, or the set delivered volume does not match with measured delivered volume. Priority Medium. This is not a latch alarm and will may only be reset by the user. The ventilator will continue to deliver breaths.
4. Low pressure alarm – This alarm is annunciated when the circuit pressure falls below a user set limit. Priority Medium. This is not a latch alarm and may be reset by the user. The ventilator will continue to deliver breaths.
5. Apnea – this alarm is annunciated when the measured breath rate does not match the set breath rate. Priority Medium. This is not a latch alarm and may be reset by the user. The ventilator will continue to deliver breaths.
6. High Exhaled Tidal Volume – This alarm will be annunciated when the measured expired Tidal Volume is higher than the Ve Limit for 3 out of four consecutive breaths. Priority Medium. This is not a latch alarm and may be reset by the user. The ventilator will continue to deliver breaths.
7. Low Exhaled Tidal Volume – This alarm will be annunciated when the measured expired Tidal Volume is less than the Ve Limit for 3 out of four consecutive breaths. Priority Medium. This is not a latch alarm and may be reset by the user. The ventilator will continue to deliver breaths.
8. High PEEP – This alarm is annunciated when the circuit pressure during exhalation (PEEP) rises above a user set limit. Priority Medium. This is not a latch alarm and may be reset by the user. The ventilator will continue to deliver breaths.
9. Low PEEP – This alarm is annunciated when the circuit pressure during exhalation (PEEP) falls below a user set limit. Priority Medium. This is not a latch alarm and may be reset by the user. The ventilator will continue to deliver breaths.

10. Flow Sensor Not Connected – The system relies on the flow sensor for feedback and volume information. Therefore, this alarm will annunciate when it has been electrically disconnected from the system. Priority Medium.
11. Key Stuck – This alarm is annunciated if the user interface key-pad has a switch failure. This requires the user to reset the system to get the system out of the failure mode. Priority Medium.
12. Flow Sensor Reversed – Although not physically possible with the connectors provided to the user in the patient circuit. The system is capable of sensing when the flow sensor sees flow in the incorrect direction in relation to inhalation/exhalation. This will alarm to ensure that the user has the patient circuit set up correctly. Priority Medium.
13. Life Exceeded Alarm - This alarm is annunciated when the system operational time has surpassed its indicated lifetime. This is not a latch alarm and may be reset by the user. The ventilator will continue to deliver breaths.
14. Request Ventilation Stop – This alarm is annunciated when the user requests to go from Run mode to Standby mode. This is intended to alert the user and provide assurance that they meant to stop ventilation. Priority Medium.
15. Oxygen Supply – There is no oxygen supply alarm. External monitoring is required to ensure sufficient patient oxygenation.
16. Total Loss of Power Alarm – This alarm is annunciated when DC power is lost to the ventilator. This is a latch alarm and will may only be reset by the user after power is turned back on. Priority High.
17. Temporary Loss of Power Alarm – This alarm is annunciated when DC power is lost to the ventilator and the system is resupplied with power while the Total Loss of Power is annunciating. Priority High. This is a latch alarm and will may only be reset by the user after power is turned back on. Priority High.
18. System Inoperable Alarm – This alarm is annunciated when the ventilator has exited normal operating conditions in Run mode or failed to pass Power on Self-Test in standby mode. This is a latch alarm and may be reset by the user. The ventilator will continue to deliver breaths.

The console adheres to IEC60601-1-8 alarm standard. The console displays the system status using the following indicator colors, flashing frequency and duty cycle:

## Status indicators / Sounds

The table below indicates what is seen and heard when an alarm is activated:

| Status category | Indicator Color | Mode | Indicator Flashing Frequency | Indicator Duty Cycle (on/off time) | Buzzer Sound File | Speaker Sound File | Decibel Level | Interburst Interval |
|---|---|---|---|---|---|---|---|---|
| High Priority | Red | Run | 2 Hz | 50% | B B B space B B | C4 A4 F4 - A4 F4 VEN-TI-LA-TI-ON; VEN-TI-LATE A-LARM | 50-85 dBA | 4 - 5 s |
| Medium Priority | Yellow | Run | 0.7 Hz | 50% | B B B | C4 A4 F4 VEN-TI-LATE; RISE AND FALL | 50-85 dBA | 6 - 10 s |
| Normal | Green | Run | Constant on | 100% on | None | None | NA | NA |
| High Priority - POST Failure | Red | Standby | 2 Hz | 50% | B B B space B B | C4 A4 F4 - A4 F4 VEN-TI-LA-TI-ON; VEN-TI-LATE A-LARM | 50-85 dBA | 4 - 5 s |
| Normal – POST Passed | Green | Standby | 2 Hz | 50% | None | None | NA | NA |

Where B = Beep, Interburst Interval = period of time between the end of the last PULSE of a BURST and the start of the first PULSE of the next BURST of the same ALARM SIGNAL

The system will default to using the speaker as the alarm audio annunciator. If a speaker failure is detected, the ventilator will annunciate alarms states with the backup buzzer.

After power on and when no alarm conditions are present the status bar displays Normal operation (flashing Green).

During power on the system performs a self-check known as Power ON Self-Test (POST) and when no failure conditions are detected, the status bar displays Normal operation in Standby Mode as a flashing green LED.

The ventilator, during use, continuously tests for correct device operation using a Built In Ongoing Test (BIOT) series of tests that looks for technical alarm conditions that may bring the device to a safe state as well as a number of patient alarms that the user may rectify.

The ventilator has been specifically designed to minimize the spread of airborne and surface infection and risks to users. The ventilator is separated from the patient by five feet of tubing. The tubing system is equipped with filters designed to create a replaceable pneumatic system and capture infectious material inside the HME and exhalation filter and prevent virus aerosolization. All the surfaces exposed to the patient's exhaled air are self-contained minimize the possibility of infection.

The ventilator components have been sourced from readily available parts that are used in medical ventilator products today including: Blower Motors, Heat and Moisture Exchanger (HME), Exhalation Filters (virus filter), bulkhead connectors, one-way valve, exhalation valve, Y adapter, 22mm tubing, flow sensors and pressure sensors. The system is provided ready to use and includes the patient circuit, supplied in a non-sterile state without cleaning required, as is standard of care

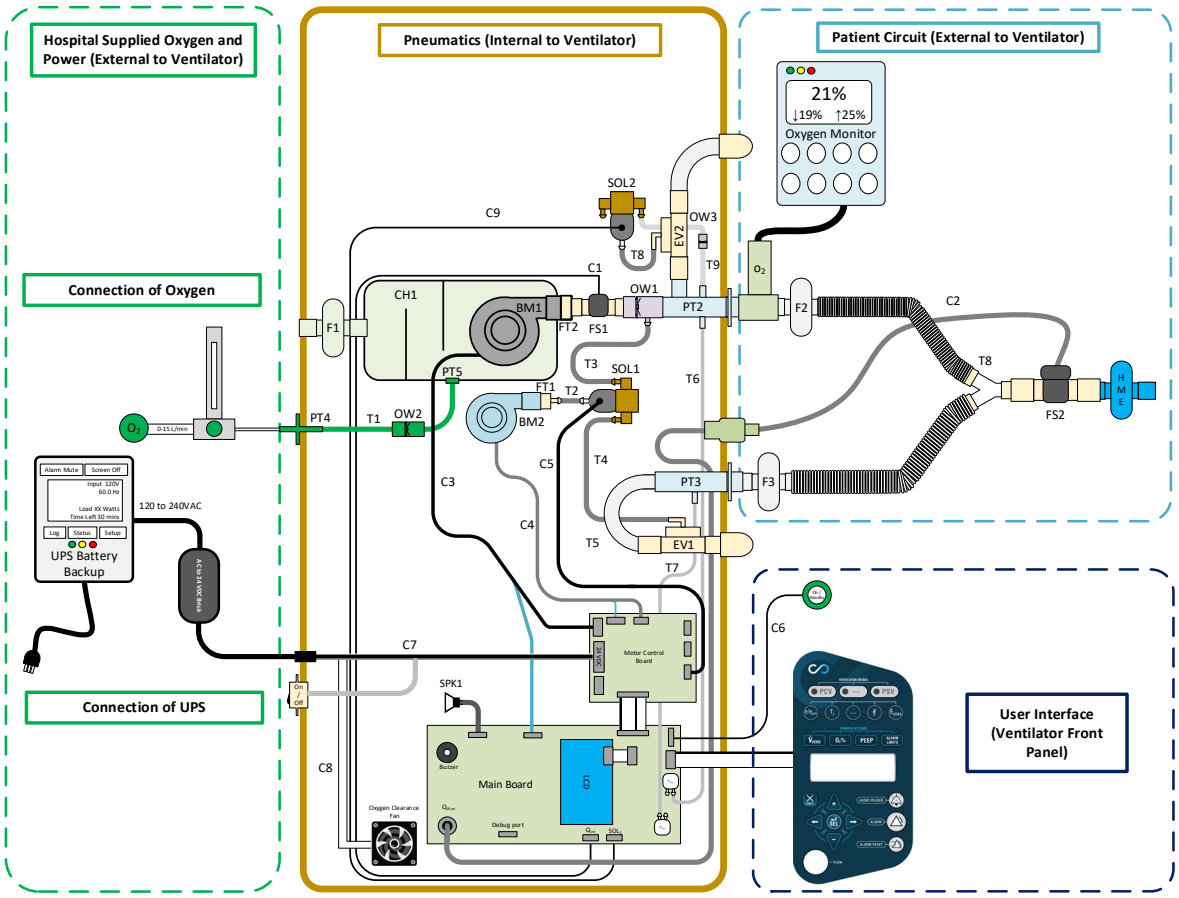
The ventilator includes the following components:

- **Power:** The ventilator uses a 120-watt DC 24 VDC input and connects to a 6ft 3-prong US medical grade power supply that converts AC to DC. The system must be used with a backup battery that provides up to 30 mins of backup power is available to comply the internal battery requirements of ISO 80601-2-12.
- **UI:** User interface consisting of:
  - 18 input keys (+2 for future expansion) on a membrane switch panel with status LED capable of displaying green, yellow and red
  - 4-line LCD with a total of 80 character (20 characters per line)
  - ON/OFF switch located at the rear of the console
  - ON/Standby switch with LED
  - Flow sensor serial line connection (C1)
  - Piezo alarm and speaker for sound annunciation
- **Electronics:** 2 PCBAs
  - Ventilator Main Board
    - Microprocessor with internal watchdog
    - 2 pressure sensors for measuring inspiratory and expiratory pressure
    - Barometric pressure for measuring atmospheric pressure and box temperature
    - Safety Valve Solenoid Control Line (C9)
    - Internal I2C flow sensor Connection
  - Motor Controller Board
    - PMD Juno motor controller processor
    - Brushless DC blower motor hall connection + NTC for main breaths (BM1)
    - PWM Controlled DC blower motor for PEEP (BM2)
    - Solenoid Control line (C5)
- **Internal Pneumatics:**
  - **Inspiratory Limb:** during inspiration air passes through the air intake filter into the mixing reservoir where it is mixed with the oxygen if it is flowing into the reservoir. The main blower delivered gas through the one-way valve, inspiratory pressure pilot tap, inspiratory flow sensor and inspiratory pressure tap, through the inspiratory filter, patient circuit tubing, airway flow sensor, optional alarming oxygen meter, and HME into the patient lungs. A safety valve (EV2) placed in the inspiratory limb is Normally Open in the event of a system failure or high priority alarm, i.e., total loss of power, Occlusion.

- **Expiratory Limb:** During exhalation the patient breaths through the HME, through the airway flow sensor, exhalation limb and filter through the expiratory pressure sensor tap, one-way valve and exhalation valve.

- **External Pneumatics:** Single Use patient circuit containing HME with two bacterial/viral filters, patient circuit, flow sensor cable, and a flow sensor which are also available separately as separate replacement Field Replacement Unit (FRU) replacing.

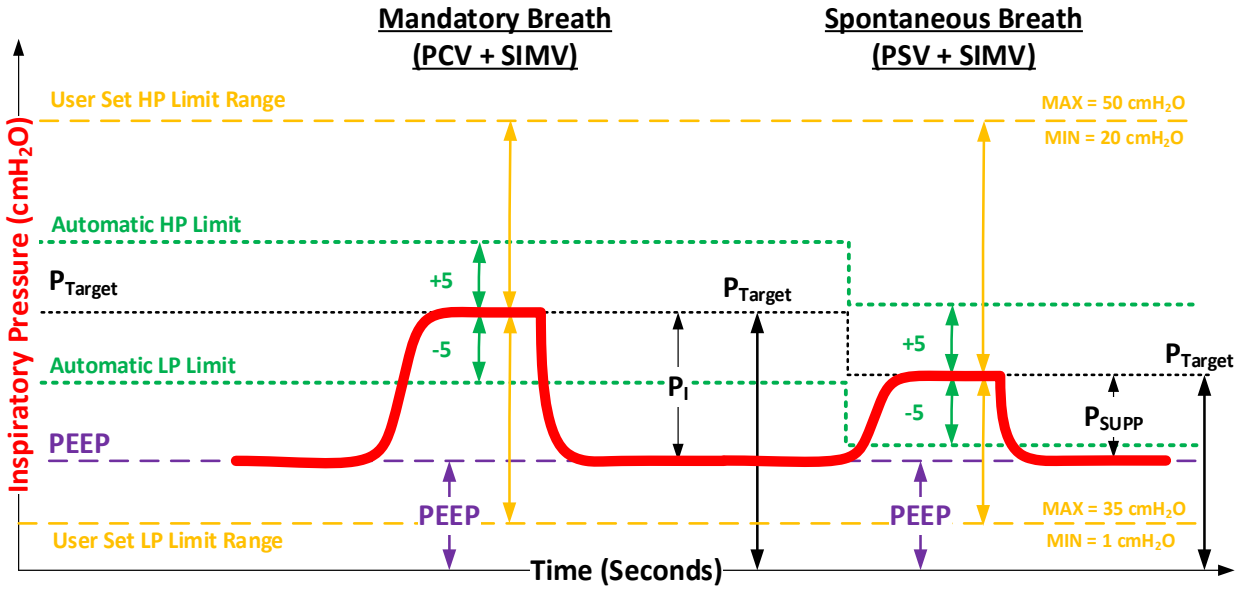
# RESPOND 19 Ventilator Electro-Pneumatic Diagram




**Electronics and Pneumatic diagram RESPOND 19 Ventilator**

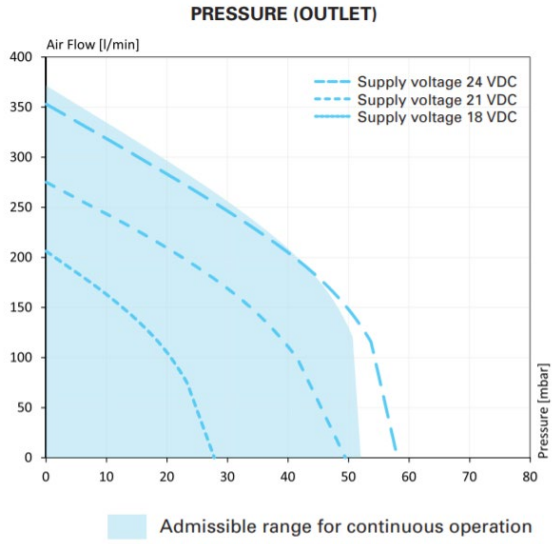
*The ventilator design has some inherent "by design" safety features:*

**Pressure Limitation:** The system is unable to fail in such a way as to generate extremely high pressures. The user settable maximum pressure that may be generated is limited to 40 cmH2O during normal operation. The system is limited in its pressure generation by BLDC motor Kv and Kt constants and power supply and motor controller ability to deliver current to a maximum inspiratory pressure of 50 cmH2O. Delivered breath volume/pressure is correlated to motor RPM as feedback by HALL sensor (3 pole). For additional safety, the High and Low Inspiratory Pressure alarm limits are automatically set to be +5 and -5 $cmH_2O$ of the user set pressure target ($P_I$ + PEEP, or $P_{SUPP}$ + PEEP), which can be overridden by the user if desired. The following figure illustrates the HP and LP settings in relation to a delivered mandatory and spontaneous breath (The same method is used to automatically set the High and Low PEEP limits for exhalation):




If the Ventilator were to experience an occlusion of either the inhalation or exhalation limb, the system will drop to PEEP within one breath cycle. The system will continue to attempt supplying breaths with the safety valve and exhalation valve open to ensure that the patient is protected.

**Rebreathing:** Rebreathing is prevented by the inclusion of a one-way valve. The patient is unable to exhale into the inspiratory limb during exhalation and unable to inhale through the expiratory limb using inspiration. Thus, in the event of a total loss of power the patient has the ability to inhale and exhale through the pneumatic circuit.




*U65MN Blower flow Vs Pressure. RESPOND-19 ventilator will use 24 VDC.*

The internal inspiratory flow sensor connected to the output of the main blower is used to ensure accurate flow monitoring from the main blower. The external airway flow sensor is used only for triggering of breaths by the control system of the ventilator. It is used primarily by the monitoring system to detect disconnects, occlusions and low exhaled tidal volumes.

A 30% error in the measurement of flow will have little effect on the ventilators ability to trigger. The user can adjust the inspiratory trigger sensitivity to achieve the desired triggering effect if the default setting of 3 L/min is not satisfactory. Current and motor velocity are continuously monitored enabling detection of fault conditions.

The sensors in the system such as pressure and flow are used to detect fault conditions. Redundant sensors are used where one of the sensors is used for feedback.

## POST & BIOT:

During Power On the system tests (POST) the following functions:

1. Software integrity via Cyclic Redundancy Check (CRC)
2. Random Access Memory(RAM) via pattern reads/writes
3. Motor Functionality, ability to disable motor
4. System Voltage and Current Limits
5. Buzzer alarm Integrity via Current test
6. LCD and LED Functionality via enabling and writing to them, allowing the user to view functionality
7. Watchdog Timeout Test Feature
8. ADC reading correctly
9. System Temperatures
10. Barometric Pressure within limits
11. Flow Sensors operational

POST Codes, Causes, and Corrective Actions:

| Code | Software | Possible Cause | Corrective Action |
|---|---|---|---|
| P001 | SW Code CRC Incorrect | SW corrupt | Power cycle if three failure contact CorVent Medical. |
| P002 | RAM Test failure | Corruption of RAM | Power cycle if three failure contact CorVent Medical. |
| P003 | 24 volts too low | 24 volt regulator damaged | Power cycle if three failure contact CorVent Medical. |
| P004 | 24 volts too high | 24 volt regulator damaged | Power cycle if three failure contact CorVent Medical. |
| P005 | 24V current too low | 24 volt regulator damaged | Power cycle if three failure contact CorVent Medical. |
| P006 | 24V current too high | 24 volt regulator damaged | Power cycle if three failure contact CorVent Medical. |
| P007 | 8 volts too low | 8 volt regulator damaged | Power cycle if three failure contact CorVent Medical. |
| P008 | 8 volts too high | 8 volt regulator damaged | Power cycle if three failure contact CorVent Medical. |
| P009 | 5 Volt Ref too high | 5 volt ref regulator damaged | Power cycle if three failure contact CorVent Medical. |
| P010 | 5 Volt Ref too low | 5 volt ref regulator damaged | Power cycle if three failure contact CorVent Medical. |
| P011 | 5 volts too high | 5 volt regulator damaged | Power cycle if three failure contact CorVent Medical. |
| P012 | 5 volts too low | 5 volt regulator damaged | Power cycle if three failure contact CorVent Medical. |
| P013 | 3.3 volts too high | 3.3 volt regulator damaged | Power cycle if three failure contact CorVent Medical. |
| P014 | 3.3 volts loo low | 3.3 volt regulator damaged | Power cycle if three failure contact CorVent Medical. |
| P015 | Barometric pressure not reading | Failure to read barometric pressure. | Power cycle if three failure contact CorVent Medical. |

| Code | Software | Possible Cause | Corrective Action |
|---|---|---|---|
| P016 | Console Temperature too low (measured from barometric pressure sensor) | Temperature is < 5°C | Power cycle if three failure contact CorVent Medical. |
| P017 | Console Temperature too high (measured from barometric pressure sensor) | Temperature is > 50°C | Power cycle if three failure contact CorVent Medical. |
| P018 | External Watchdog Failed | Motor supply voltage enabled despite not strobing external watchdog for 4 seconds. | Power cycle if three failure contact CorVent Medical. |
| P019 | Code Not used | | |
| P020 | Motor Braking Current too low | Sensed motor supply current too low for shunt resistor active test. | Power cycle if three failure contact CorVent Medical. |
| P021 | SPI connection to motor not working | SPI line disconnected | Power cycle if three failure contact CorVent Medical. |
| P022 | Buzzer current low | Buzzer not functional | Power cycle if three failure contact CorVent Medical. |
| P023 | Buzzer current high | Buzzer not functional | Power cycle if three failure contact CorVent Medical. |
| P024 | Motor disable line not working | Independent motor disable function not working. | Power cycle if three failure contact CorVent Medical. |
| P025 | Watchdog not working | Watchdog not working | Power cycle if three failure contact CorVent Medical. |
| P026 | Main blower will not move | Motor disconnected | Power cycle if three failure contact CorVent Medical. |
| P027 | Main blower moved | Motor moved during disable test | Power cycle if three failure contact CorVent Medical. |
| P028 | PEEP blower will not move | Motor disconnected | Power cycle if three failure contact CorVent Medical. |
| P029 | PEEP blower moved | Motor moved during disable test | Power cycle if three failure contact CorVent Medical. |
| P030 | 24SW Current Too High | Excessive current draw after enabling motor supply voltage. | Power cycle if three failure contact CorVent Medical. |
| P031 | Solenoid will not energize | Solenoid Disconnected | Power cycle if three failure contact CorVent Medical. |
| P032 | Speaker Current too Low | Speaker disconnected | When speaker is run. Power cycle if three failure contact CorVent Medical. |
| P033 | Speaker Current too high | Speaker failure | When speaker is run. Power cycle if three failure contact CorVent Medical. |
| P034 | Motor Temperature too low | Temperature is < 5°C | Power cycle if three failure contact CorVent Medical. |
| P035 | Motor Temperature too high | Temperature is > 70°C | Power cycle if three failure contact CorVent Medical. |
| P036 | Internal Flow Sensor Communication Error | I2C communication error | Cannot communicate with internal flow sensor. Three power resets should be attempted. |

| Code | Software | Possible Cause | Corrective Action |
|---|---|---|---|
| P037 | 24V_SW Voltage too high | Motor supply voltage too high | Power cycle if three failure contact CorVent Medical. |
| P038 | 24V_SW Voltage too low | Motor supply voltage too low | Power cycle if three failure contact CorVent Medical. |
| P039 | Processor for Total Loss of Power Communication error | Processor for Total Loss of Power issue | Power cycle if three failure contact CorVent Medical. |
| P040 | S-Sol curr too high | Solenoid energized during disable test | Power cycle if three failure contact CorVent Medical. |
| P041 | S-Sol curr too low | Solenoid Disconnected | Power cycle if three failure contact CorVent Medical. |

Built-In Ongoing Test (BIOT):

1. During operation the system continually tests that the ventilator is operating within safe parameters.
2. System Voltage and Current limits
3. System Temperatures
4. Motor Communication
5. ADC is reading correctly
6. Pressure Sensor comparison
7. Barometric Pressure within limits
8. Ambient Temperatures within limits
9. Ventilator Temperatures within limits.

BIOT Codes, Causes, and Ventilator Actions:

BIOT has two actions when a fault is detected:

1. Continue ventilation with alarm annunciating.
2. Stop ventilation and enter standby mode with alarm annunciating.

**In both cases it is necessary to power cycle the ventilator.**

| Code | Software | Possible Cause | Sample Rate | Ventilation Action |
|---|---|---|---|---|
| B001 | Code Not Used | | | |
| B002 | Code Not Used | | | |
| B003 | 24 volts too low | 24 volt regulator damaged | 0.1 sec | STOP Ventilation |
| B004 | 24 volts too high | 24 volt regulator damaged | 0.1 sec | STOP Ventilation |
| B005 | 24 volts current too low | 24 volt regulator damaged | 0.1 sec | STOP Ventilation |
| B006 | 24 volts current too high | 24 volt regulator damaged | 0.1 sec | STOP Ventilation |
| B007 | 8 volts too low | 12 volt regulator damaged | 0.1 sec | STOP Ventilation |
| B008 | 8 volts too high | 12 volt regulator damaged | 0.1 sec | STOP Ventilation |
| B009 | 5 Volt Ref too high | 5 volt ref regulator damaged | 0.1 sec | STOP Ventilation |
| B010 | 5 Volt Ref too low | 5 volt ref regulator damaged | 0.1 sec | STOP Ventilation |
| B011 | 5 volts too high | 5 volt regulator damaged | 0.1 sec | STOP Ventilation |
| B012 | 5 volts too low | 5 volt regulator damaged | 0.1 sec | STOP Ventilation |

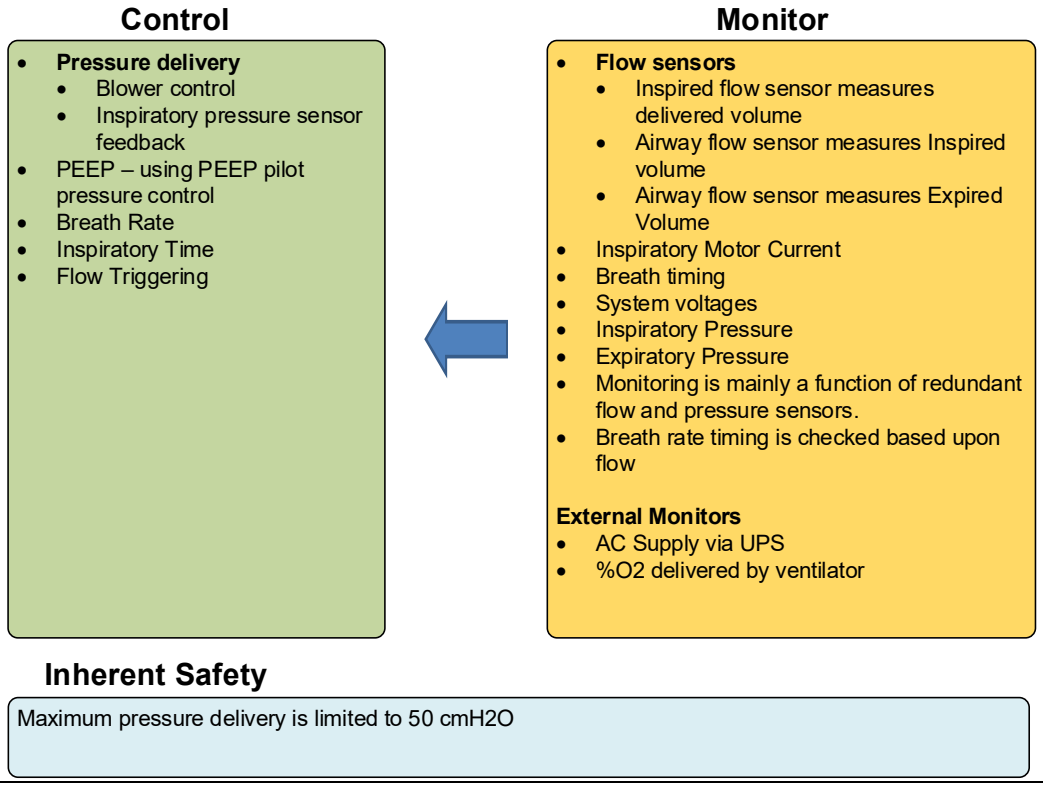
| Code | Software | Possible Cause | Sample Rate | Ventilation Action |
|---|---|---|---|---|
| B013 | 3.3 volts too high | 3.3 volt regulator damaged | 0.1 sec | STOP Ventilation |
| B014 | 3.3 volts loo low | 3.3 volt regulator damaged | 0.1 sec | STOP Ventilation |
| B015 | Barometric pressure not reading | Failure to read barometric pressure. | 1 min | Continue Ventilation Assume 1033 cmH2O |
| B016 | Console Temperature too low (measured from barometric pressure sensor) | Temperature is < 5°C | 1 min | Continue Ventilation |
| B017 | Console Temperature too high (measured from barometric pressure sensor) | Temperature is > 50°C | 1 min | Continue Ventilation |
| B018 | Expiration Pressure Higher than Inspiration Pressure | Failure of inspiratory or expiratory pressure measuring system | Per Breath | STOP Ventilation |
| B019 | Ambient temperature too low (measured from SFM3300 flow sensor) | Temperature is < 10°C | 1 min | Continue Ventilation |
| B020 | Ambient temperature too high (measured from flow sensor) | Temperature is > 45°C | 1 min | STOP Ventilation |
| B021 | SPI connection to motor not working | SPI disconnected | 0.005 secs | STOP Ventilation |
| B022 | Buzzer current low | Buzzer not functional | During alarm | Continue Ventilation |
| B023 | Buzzer current High | Buzzer not functional | During alarm | Continue Ventilation |
| B024 | Motor shunt on too long | Shunt is on for > 1.0 secs | 0.005 secs | STOP Ventilation |
| B025 | Watchdog Triggered | Watchdog triggered and reset the system | NA | STOP Ventilation |
| B026 | Main blower communication error | Motor disconnected | 0.005 secs | STOP Ventilation |
| B027 | Main blower Hall Sensor error | Motor moved during disable test | 0.005 secs | STOP Ventilation |
| B028 | Main blower drive error | Motor controller reports Current Foldback or Drive Exception error. | 0.005 secs | STOP Ventilation |
| B029 | Main blower velocity error | Motor moved during disable test | 0.005 secs | STOP Ventilation |
| B030 | Diff Pinsp & Pexp error | Pressure sensors have drifted or are damaged and measure different PEEPs | Per breath | STOP Ventilation |
| B031 | PEEP blower velocity error | Motor moved during disable test | 0.005 secs | STOP Ventilation |
| B032 | Speaker Current too Low | Speaker disconnected | When speaker is run | Continue Ventilation Switch to buzzer. |
| B033 | Speaker Current too high | Speaker failure | When speaker is run | Continue Ventilation Switch to buzzer. |
| B034 | Motor Temperature too low | Temperature is < 5°C | 1 min | Continue Ventilation |

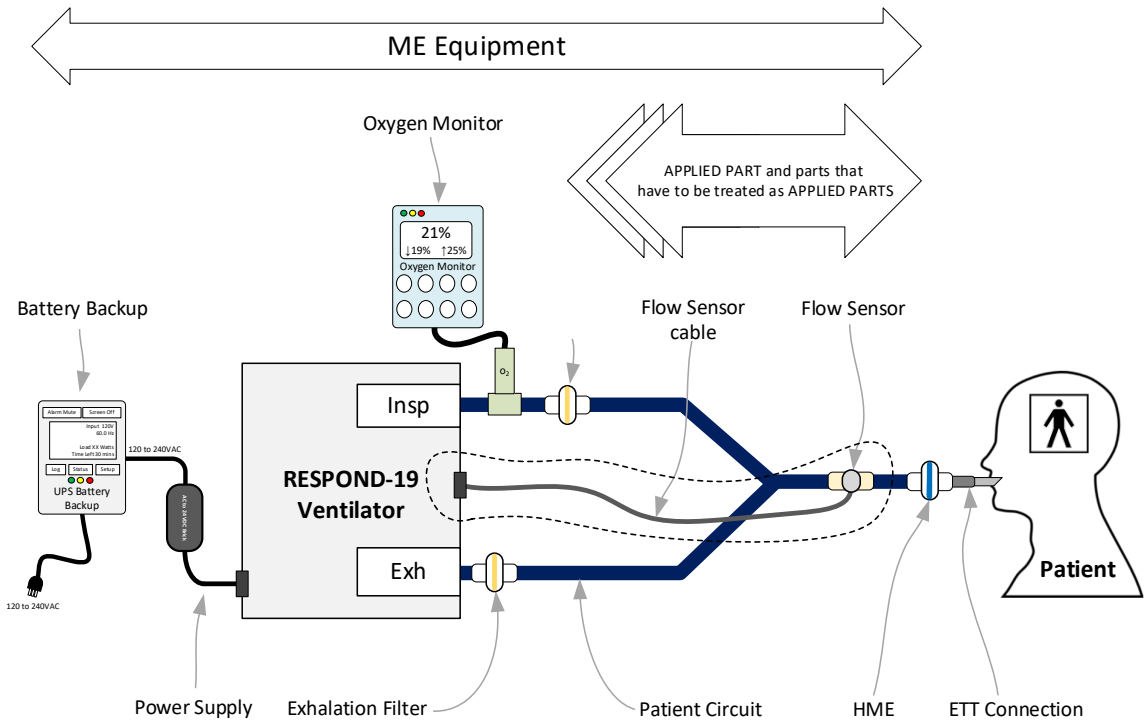
| Code | Software | Possible Cause | Sample Rate | Ventilation Action |
|---|---|---|---|---|
| B035 | Motor Temperature too high | Temperature is > 70°C | 1 min | Continue Ventilation up to 70°C.<br>STOP Ventilation if temp is > 70°C. |
| B036 | Internal Flow Sensor Communication Error | I2C communication error | 0.005 secs | Continue Ventilation |
| B037 | 24V_SW Voltage too high | Motor supply voltage too high | 0.1 sec | Continue Ventilation |
| B038 | 24V-SW Voltage too low | Motor supply voltage too low | 0.1 sec | Continue Ventilation<br>Assume 1033 cmH2O |
| B039 | Processor for Total Loss of Power communication error | Processor for Total Loss of Power issue | 0.1 sec | Continue Ventilation |

## Separation of Control and Monitor

The primary control function of the ventilator is pressure delivery. Breaths may be delivered as mandatory, assist or spontaneous breath. In Pressure Control Ventilation (PCV) pressure is controlled at the patient airway for the designated inspiratory time at the user set breath rate. Both delivered pressure and breath rate are a function of the ventilators timing accuracy. Volume is also measured using the integral of the inspiratory flow measured by the inspiratory flow sensor at the output of the blower.

The primary monitoring mechanisms of the ventilator are based upon the airway flow sensor and the inspiratory and expiratory pressure sensor. From these sensors, the correct operation of the system may be assessed.






**RESPOND 19 Ventilator ME Diagram**

## Data Logging

When the data log is full, the oldest entries are overwritten with the latest entries. The total data entries available are 4,000. The hours of use are stored. This is an internal counter based upon the number of minutes elapsed while the system is turned on. The ventilator also logs POST and BIOT failure codes as they arise. The ventilator logs all alarms as they arise along with the count in minutes from the start of ventilation. This log is not accessible to the user.

## Inspiration Phase

Inspiratory Pneumatics:

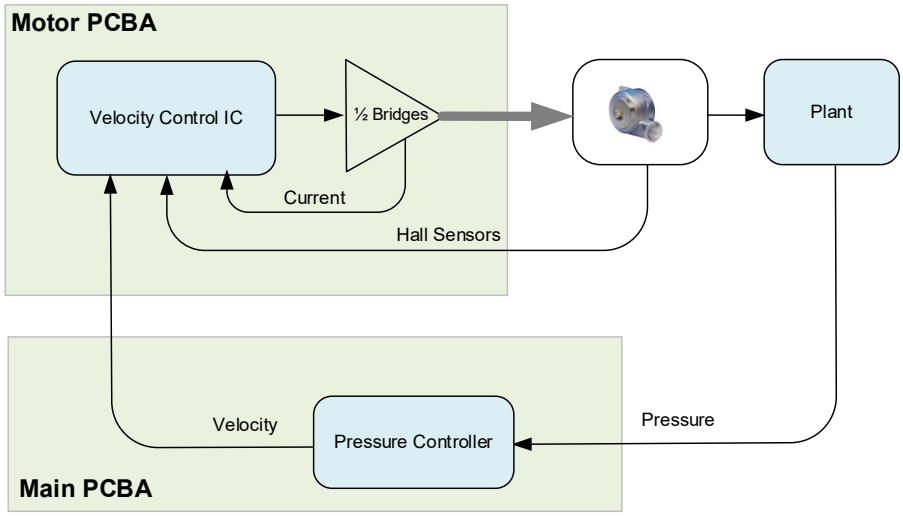
Gas is entrained though the air intake filter F1 as the blower motor BM1 delivers flow to the patient. The gas passes into the reservoir and muffler CH1, mixing with oxygen before it exits the blower single turbine where it is compressed. Oxygen mixing occurs in the reservoir when the manually set oxygen flow rate mixes with the entrained air based upon the patient inspired minute volume.

The air first passes through the one-way valve OW1 which prevents exhaled gas passing through the blower during the exhalation cycle. Next the gas passes through the inspiratory flow sensor FS1 where the volume displaced by the blower and the inspiratory pressure is measured by the inspiratory pressure sensor at pressure tap PT1. Gas then passes through the inspiratory filter F2 and is delivered to the patient through the patient circuit, airway flow sensor FS2 and HME.

During inspiration, the Pressure Tap on OW1 allows pressurized gas to pass through the energized exhalation solenoid SOL1 and pressurize the area ratio exhalation valve EV1 pilot pressure, preventing gas from exiting the exhalation valve. This valve has an area ratio of approximately 2, where the force to close the valve is twice that to open it during inspiration. The same pressure exists on both sides of the valve, but the area ratio is in favor of the pilot pressure. This ensures that gas being delivered via the inspiratory limb during inspiration is delivered to the patient.

Inspiration may be initiated based upon a specific breath period elapsing or based upon a patient trigger. This timing will be discussed later. In SIMV the breath period is divided up into a mandatory breath period and a spontaneous breath period. 60% of the breath period is devoted to waiting for an assist breath at which point a mandatory breath is initiated.

The airway flow sensor FS2 is used for flow triggering to detect inspiration efforts by the patient based upon a user defined trigger flow setting, ranging from 0.5 to 20 Lpm. An inspiratory trigger can only be detected during the exhalation breath phase. Upon the detection of an inspiratory trigger the breath phase will be switched from exhalation to inspiration. To deliver a breath, the blower motor must respond with either a PCV or PSV breath which is based upon the mode selected and the timing of the breaths being delivered. The blower produces a static pressure based upon specific motor velocity. The blower motor is controlled using three control loops which rely on current measurement, velocity measurement using the BLDC Hall sensors and pressure measurement. The first loop controls current using motor current as feedback, the second loop controls velocity using the Hall sensors as feedback and the third loop controls pressure using pressure feedback.



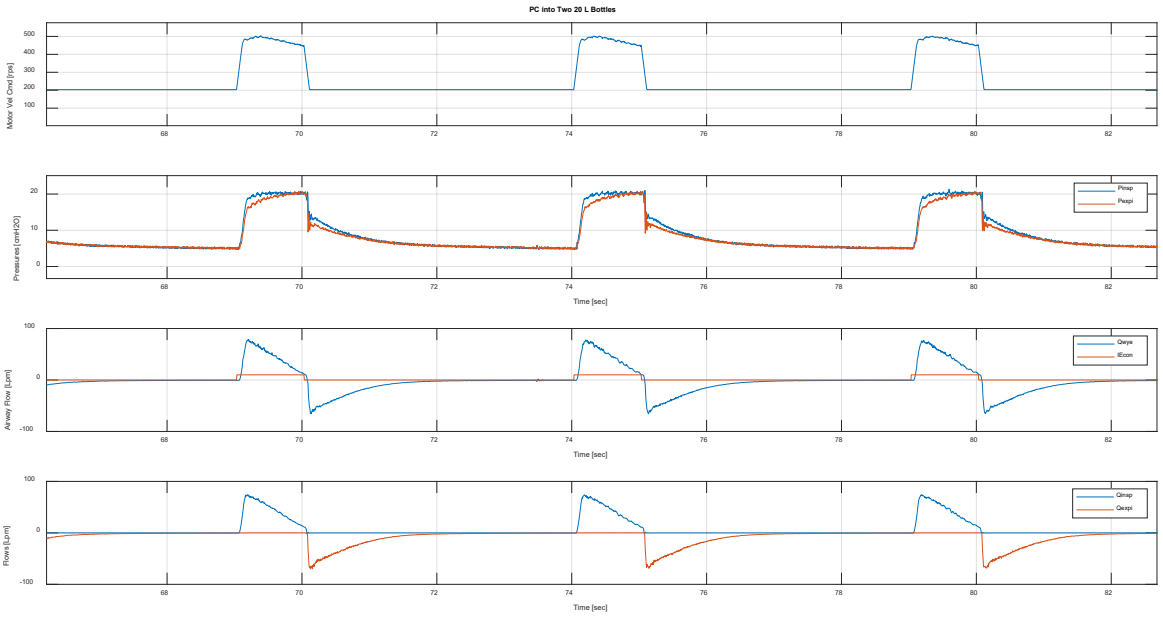

*Blower motor uses HALL sensors for feedback and uses both current and velocity control*

During inspiration, the motor is controlled to deliver a pressure for a timed duration or based upon the exhalation sensitivity $E_{SENS}$ which is a function of the peak inspired flow

of the patient. Inspiration is stopped when the inspired flow is less than the peak inspired flow multiplied by the ESENS.

PCV breaths are time based once initiated whereas PSV breaths are both initiated and terminated by the patient. Breaths may also be truncated based upon specific alarms occurring:

- The high-pressure limit is exceeded
- An occlusion is declared
- A technical alarm occurs (this will be discussed later)




*50 ml/cmH2O R = 5 cmH2O/Lps, $P_I$ = 15 cmH2O, PEEP = 5 cmH2O, $T_I$ = 1 sec, f = 12 bpm. Trace 1: velocity command to blower, Trace 2: Insp and Exp Pressure cmH2O, Trace 3 Air way flow and IE signal, and Trace 4 Inspiratory flow sensor and Expiratory flow sensor.*

### Detecting Inspiratory Triggering

In PCV Mode, an inspiration will be declared if the breath period is exceeded. Thus, if the set breath rate is 20 bpm, the allowable period between breaths is 3 seconds. The breath period is measured from the start of the last inspiration even if the last breath was a patient triggered breath (patient-initiated). Inspiratory triggers are only detected during exhalation. Since we are using the airway flow sensor for the detection of a patient trigger, we are guaranteed that patient is no longer in exhalation when air is flowing into the patient's lungs. Exhaled air flows out of the patient's lungs and is measured as negative flow. By convention inspired air is positive and exhaled air is negative. If the cumulated breath period from the last trigger exceeds the user set breath period a ventilator-initiated breath is delivered. This is by convention called a mandatory breath or ventilator-initiated breath. Inspiratory triggers are detected using the air way flow sensor when 6 out of 7 flows measurements measure > than the trigger flow. This detection period takes 35 msecs assuming the sampling rate is 200Hz or 5 msecs.

In PSV Mode, an inspiration is only declared when the patient triggers a breath. This mode is only used on patient can regularly trigger breaths and maintain their own oxygenation.

*PSV a spontaneous mode of ventilation that is both initiated and terminated by the patient. Compliance 50 ml/cmH2O Resistance 5 cmH2O/Lps, PSUPP 10 cmH2O, PEEP 5 cmH2O, Trigger sensitivity 2 Lpm, Exh Sen 25%, Volume ~ 420 mL per breath and Trigger times < 100 msecs*

### Operation of Safety Valve

The safety valve is normally open and is kept closed during normal operation in both inspiratory and expiratory phase. Power is cut to SOL2 to open the safety valve when required. This is done in the presence of a sustained high pressure or occlusion of the exhalation limb. SOL1 is cycled open during exhalation and closed during inspiration until the occlusion is eliminated. The same solenoid and area ratio valve are used for both the exhalation and safety valve. The OW3 is used to trap the peak pressure in the inspiratory limb and feed it to the area ratio pilot line ensuring minimal leak occurs when closed. The operation of the safety valve is tested during POST and use of the valve is expected to be low during ventilator use.

### Inspiration Monitoring

During Inspiration the exhalation valve and safety valve are kept closed. Both SOL 1 and SOL2 are energized forcing the gas delivered by BM1 into the patient.

During inspiration, the wye flow FS2 and inspiratory flow sensor FS1 measure the flows into the lung and exiting the blower BM1 in terms of Standard Temperature and Pressure Dry (STPD) and the monitoring system integrates these flows to determine the ventilator delivered and patient inspired volume. These volumes are compared with each other to determine the presence of a leak or disconnect. In ventilation all flow and volumes related to the patient are measured in terms of the lung conditions Body Temperature and Pressure Saturated (BTPS).

The response to the measured Pexh pressure exceeding the user set high-pressure limit is to immediately switch to exhalation. If the Pinsp pressure ever exceeds 50 cmH2O the system also immediately switches to exhalation. The Pinsp will always be higher than the Pexh pressure during inspiration due to the flow resistance of the inspiratory limb and inspiratory filter. The patient during ventilation will also experiences the additional resistance of the airway flows sensor, HME and their own lung resistance. The response to immediately switching to exhalation prevents the airway pressure from further rising and reduces the circuit pressure to PEEP.

In the event of an occlusion of the inspiratory limb the system will also switch to exhalation and cease inspiration.

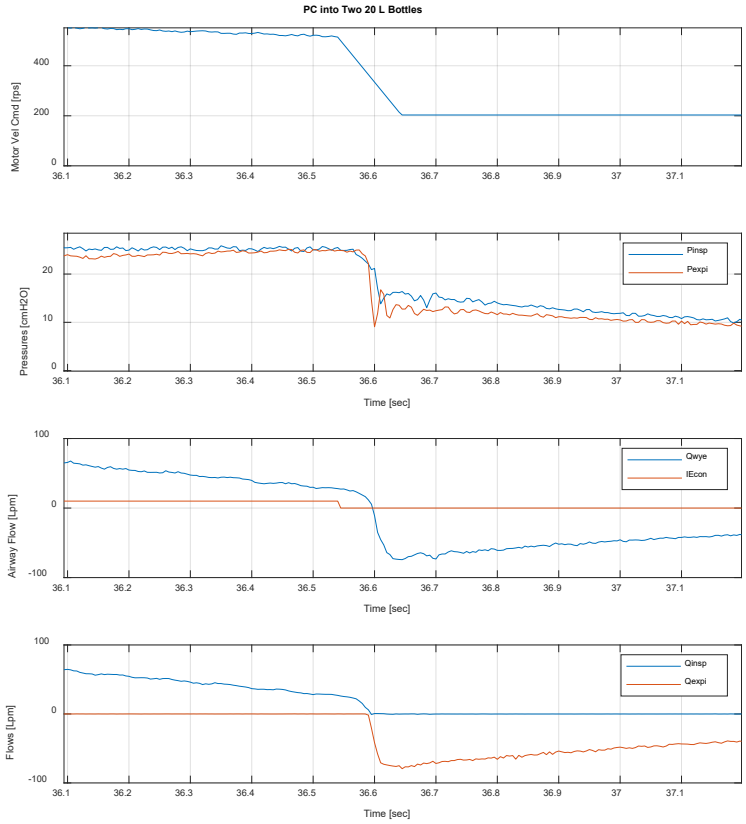
### Expiration Phase

During Inspiration the exhalation valve is opened SOL1 is de-energized and the safety valve SOL2 is kept closed. The Main Blower is decelerated to a pressure just below PEEP and the exhalation valve is opened. Because the exhalation valve is under PEEP pilot pressure the exhalation pressure is kept at PEEP.

During exhalation, the wye flow FS2 and measures flow out of the lung in terms of Standard Temperature and Pressure Dry (STPD) and the monitoring system integrates these flows to determine the patient expired volume. This volume is compared with the inspired volume to detect the presence of a leak or disconnect. In ventilation all flow and

volumes related to the patient are measured in terms of the lung conditions Body Temperature and Pressure Saturated (BTPS).

The blower circuit airway pressure must drop below the PEEP pressure to ensure extra volume is not displaced into the patient circuit during exhalation. To stop inspiration the circuit pressure must drop below the lung pressure which lags the airway pressure due to the lung compliance and resistance during inspiration. The time for the circuit pressure to drop to PEEP is a function of the tubing compliance, lung compliance, lung resistance and expiratory circuit resistance.




*Pressure drop form end inspiratory pressure to PEEP during exhalation.*

Once expiration occurs the air way pressure in the patient circuit will drop and plateau at PEEP. In the case of the RESPOND-19 ventilator PEEP this is achieved by the PEEP Blower generating a PEEP pilot pressure applied to the exhalation valve. The rate of this pressure drop in the patient circuit is a function of the exhalation flow and exhalation

resistance of the ventilator. These resistances are designed to be as low as possible otherwise they prevent the patient from exhaling quickly.

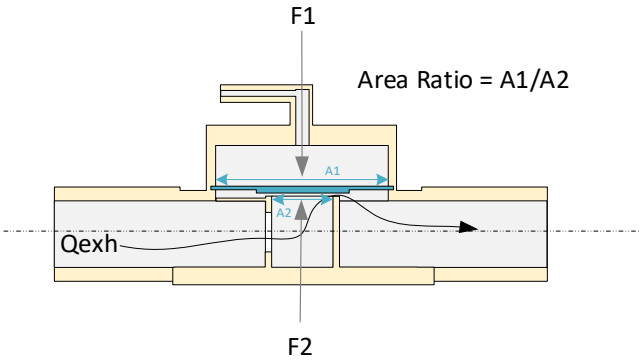



*Figure 13: Exhalation valve showing area ratio*

The user can adjust the PEEP setting directly on the user interface of the console. This is achieved by adjusting the PEEP Pilot pressure which is connected to the F1 above to PEEP * A2/A1.

In the event of an occlusion of the expiratory limb the patient will be prevented from exhaling even if the exhalation valve is opened. Under these circumstances the Safety Valve EV2 on the inspiratory limb is opened allowing the circuit pressure to be depressurized to below the PEEP pressure. This is achieved by deenergizing SOL2 which opens EV2 allowing the patient to exhale through EV2. The one-way valve, OW1 prevents gas from being exhaled through the Main Blower BM1.

**Pneumatic Performance**

The response and operational performance of the pneumatics is mainly a function of the following components:

1. The main blower BM1 ability to accelerate quickly. This will determine how quickly the blower can pressurize the circuit and patient.
2. The switching time of the exhalation solenoid valve will dictate how quick the exhalation valve closes and opens because the exhalation valve directs the pilot pressure from the inspiratory limb to the PEEP pilot pressure.
3. The Cv value of the exhalation valve will dictate how fast pressure is released from the pilot pressure of the exhalation valve.
4. The exhalation resistance of the expiratory pneumatics will dictate how quickly the patient is able to exhale.
5. The Cv value of the safety valve will dictate how fast pressure is reduced in the inspiratory limb during an occlusion of the exhalation limb.

## Breath Timing

All breath modes are classified as mandatory, spontaneous or synchronized intermittent mandatory ventilation (SIMV) which is a mix of mandatory and spontaneous breath types. Ventilator Initiated Mandatory (VIM) breaths are delivered at a rate determined by the respiratory rate (f). Patient Initiated Mandatory (PIM) breaths are delivered as an assist breath when the patient triggers a mandatory breath. The following breath types are available in Invasive and Non-Invasive. When Non-Invasive is active, the system triggering will automatically compensate for leaks associated with mask-based ventilation. The ventilator has three ventilation breath types:

1. Mandatory: PCV
2. Spontaneous: PSV
3. Mixed: SIMV.

The user is be able to select the mode of ventilation between

1. Pressure Control Ventilation (PCV),
2. Pressure Support Ventilation (PSV), and
3. SIMV (PCV+PSV)

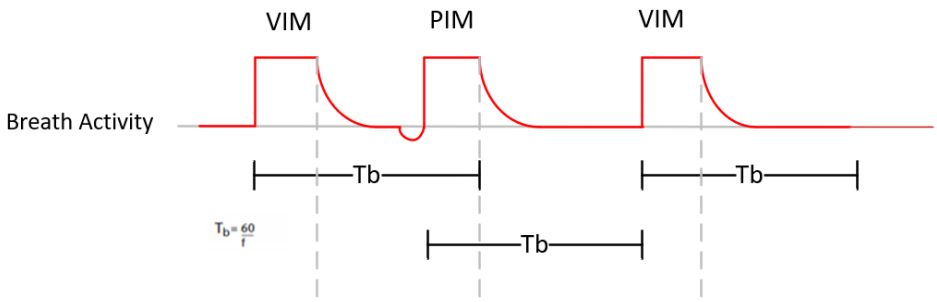
The ventilator uses three different breath timing schemes which depends upon the mode of ventilation being run:

1. Time Cycled – PCV exclusively
2. Patient Cycled – PSV exclusively
3. SIMV (a combination of time cycled, and patient cycled)

The time-cycling method uses a specified inspiratory time to terminate inspiration and transition to exhalation. The ventilator terminates inspiration based on the set or computed value for inspiratory time. The time-cycling method operates during PCV.

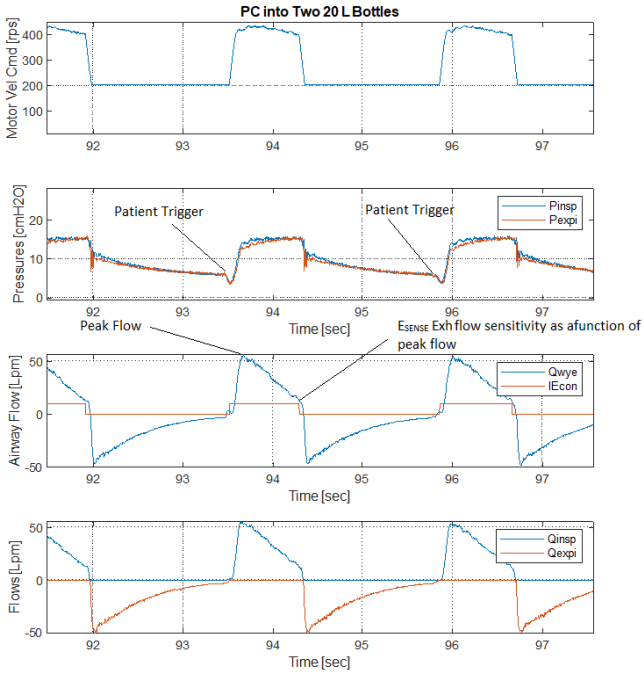
<u>PCV Breath Timing:</u>

In the PCV ventilation the ventilator monitors time intervals from a specific event (for example, triggering a Patient Initiated Mandatory (PIM) breath or the transition from inspiration to exhalation). During PCV in the absence of patient effort, the ventilator delivers one inspiration at the beginning of next breath period, as shown below. Such a breath is called a ventilator-initiated mandatory (VIM) breath. If the patient's inspiratory efforts generate a flow trigger before the breath cycle has elapsed, the ventilator delivers a PIM breath. The breath period Tb is calculated from the user set respiratory rate f, Tb = 60/f. This breath period is restarted from a PIM as shown below:




## PSV Breath Timing:

When using PSV (Spontaneous mode) the breath will be both initiated and terminated based by the patient based upon specific flow criteria and at times, pressure criteria. The ESENS terminates inspiration when the inspired flow drops below the Peak flow x ESENS/100. Thus if the Peak flow was measured to be 100 Lpm and the ESENS was set to 20% of peak flow, inspiration would be terminated when the inspired flow dropped below 20 Lpm.

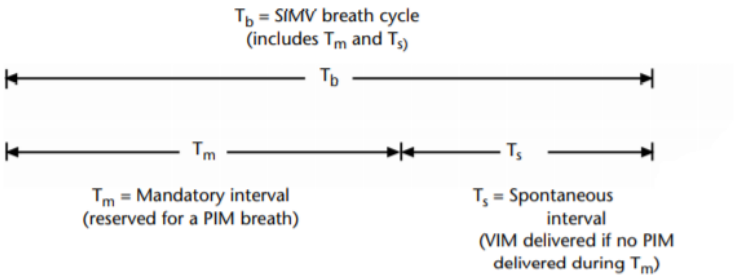



*PSV Breath Timing based upon patient triggers*

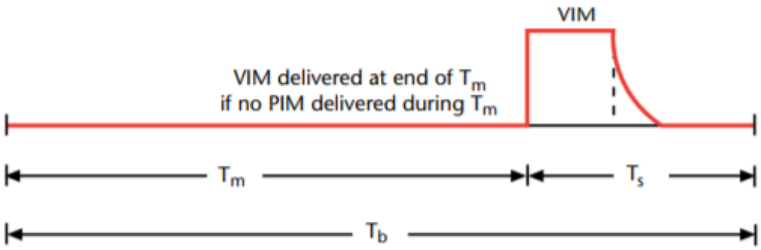
## SIMV Breath Timing:

SIMV is a mixed ventilatory mode allowing both mandatory and spontaneous breaths. The mandatory breaths and the spontaneous breaths are pressure assisted. The SIMV algorithm is designed to guarantee one mandatory breath each SIMV breath cycle. This mandatory breath is either a patient-initiated mandatory (PIM) breath (also called an

As the figure below shows, each SIMV breath cycle (Tb) has two parts: the first part of the cycle is the mandatory interval (Tm) and is reserved for a PIM. If a PIM is delivered, the Tm interval ends and the ventilator switches to the second part of the cycle, the spontaneous interval (Ts), which is reserved for spontaneous breathing throughout the remainder of the breath cycle. At the end of an SIMV breath cycle, the cycle repeats. If a PIM is not delivered, the RESPOND-19 System delivers a VIM at the end of the mandatory interval, then switches to the spontaneous interval.




*SIMV breath cycle (mandatory and spontaneous intervals)*




*SIMV breath cycle, PIM not delivered within mandatory interval*

Mandatory breaths in SIMV are identical to mandatory breaths in assist mode, and spontaneous breaths in SIMV are identical to spontaneous breaths in SPONT mode. Patient triggering must meet the requirements for flow and pressure sensitivity. The procedure for setting the SIMV respiratory rate is the same as in assist. Once the respiratory rate (f) is set, the SIMV interval cycle (Tb) in seconds is:

$$Tb = 60 / f$$

$$Tm = 0.6 * Tb$$

The SIMV breathing algorithm delivers one mandatory breath each cycle interval, regardless of the patient's ability to breath spontaneously. Once a PIM or VIM is delivered, all successful patient efforts yield spontaneous breaths until the cycle interval ends. The ventilator delivers one mandatory breath during the mandatory interval, regardless of the number of successful patient efforts detected during the spontaneous interval. A PIM delivered during the mandatory interval satisfies the mandatory breath requirement and causes Tm to transition to Ts. During the mandatory interval, if the patient triggers a breath according to the current setting for flow sensitivity, the ventilator delivers a PIM.

Once a mandatory breath is triggered, Tm ends, Ts begins, and any further trigger efforts yield spontaneous breaths. During the spontaneous interval, the patient can take an unlimited number of spontaneous breaths. If no PIM is delivered by the end of the mandatory interval, the ventilator delivers a VIM and transitions to the spontaneous interval at the beginning of the VIM.

The maximum mandatory interval, Tm for any valid respiratory rate setting in SIMV is defined as whichever is less:

*0.6 x the SIMV interval cycle (Tb), or 10 seconds.*

In SIMV, the interval from mandatory breath to mandatory breath can be as long as 1.6 x the SIMV cycle interval (but no longer than the cycle interval + 10 seconds). At high respiratory rates and too large tidal volumes, breath stacking (the delivery of a second inspiration before the first exhalation is complete) is inevitable. In pressure control ventilation (with inspiratory pressure remaining constant), breath stacking leads to reduced tidal volumes, which can be detected by the low exhaled tidal volume alarms. If a spontaneous breath occurs toward the end of the spontaneous interval, inspiration or exhalation can still be in progress when the SIMV interval ends. No VIM, or PIM, is allowed during the restricted phase of exhalation. In the extreme, one or more expected mandatory breaths could be omitted. When the expiratory phase of the spontaneous breath ends, the ventilator reverts to its normal criteria for delivering mandatory breaths. In SIMV mode it is possible for the respiratory rate to drop temporarily below the f setting. If the patient triggers a breath at the beginning of a breath cycle, then does not trigger another breath until the maximum mandatory interval for the following breath has elapsed, a monitored respiratory rate less than the respiratory rate setting can result.

**Oxygen Mixing**

The O2% delivered to the patient is a function of the O2 flow rate into the reservoir and delivered minute ventilation as measured by the inspiratory flow sensor in L/min. Any flow delivered by the blower depletes the oxygen in the reservoir. Once the reservoir is full which is a volume of approximately equal to 2.5 L any excess oxygen delivered will be vented to atmosphere, The O2 flow rate must be adjusted by the user at the wall air supply and is not a function provided by the ventilator. For example, Table 3.0 shows that if a user desired as 60% O2 and the ventilator minute ventilation is 8 Lpm then the O2 flow must be set to 3.9 Lpm on the wall. When the user sets press the O2% key on the user interface the user may adjust the desired O2% and the following calculation is run which displays to the user the O2 flow they must set to get the desired O2%.

The External Oxygen flow rate in L/min will be displayed to the user, using the following formula.

*ExternalO2FlowRate = delMinVent*(%O2-21)/79*

Table for setting wall O2 flow based upon desired %O2 deliver and ventilator minute ventilation:

| Minute Ventilation (Lpm) | % | % | % | % | % | % | % | % | % | |
|---|---|---|---|---|---|---|---|---|---|---|
| BPM x Tidal Vol | 21 | 30 | 40 | 50 | 60 | 70 | 80 | 90 | 100 | Desired % O2 |
| **2.0** | 0.0 | 0.2 | 0.5 | 0.7 | 1.0 | 1.2 | 1.5 | 1.7 | 2.0 | |
| **4.0** | 0.0 | 0.5 | 1.0 | 1.5 | 2.0 | 2.5 | 3.0 | 3.5 | 4.0 | |
| **6.0** | 0.0 | 0.7 | 1.4 | 2.2 | 3.0 | 3.7 | 4.5 | 5.2 | 6.0 | |
| **8.0** | 0.0 | 0.9 | 1.9 | 2.9 | 3.9 | 5.0 | 6.0 | 7.0 | 8.0 | |
| **10.0** | 0.0 | 1.1 | 2.4 | 3.7 | 4.9 | 6.2 | 7.5 | 8.7 | 10.0 | |
| **12.0** | 0.0 | 1.4 | 2.9 | 4.4 | 5.9 | 7.4 | 9.0 | 10.5 | 12.0 | |
| **14.0** | 0.0 | 1.6 | 3.4 | 5.1 | 6.9 | 8.7 | 10.5 | 12.2 | 14.0 | |
| **16.0** | 0.0 | 1.8 | 3.8 | 5.9 | 7.9 | 9.9 | 11.9 | 14.0 | 16.0 | |

To verify the accuracy of the delivered oxygen, an external Oxygen monitor is recommended for use with the Ventilator that can alarm when the delivered Oxygen is above or below the user set oxygen range. The recommended Oxygen monitor is FDA cleared and is compliant with *ISO 80601-2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors.* This Oxygen monitor is to be used for the entirety of patient Ventilation to indicate to the user that Oxygen is within range, as well as to verify the robustness of the Oxygen supply in the case that a gas supply loss will lower the Oxygen percent below the alarm limit set on the monitor.

**Biocompatibility for Patient Contacting Materials (RTA 30)**

When used as intended, patient breathing circuit ET tube portion of the device will be placed in indirect contact with the patient's respiratory tract; the total cumulative exposure of the device is expected to be prolonged (>30 days). The device is therefore categorized according to ISO 10993-1 as: External Communicating Device with Prolonged Tissue Contact. The ET tube is not supplied by CorVent Medical, Inc. If the patient's chest area is exposed it possible that the patient circuit tubing or its components in direct contact with the patient's skin.

The device has undergone air testing for volatile organic compounds (VOCs), carbon monoxide (CO), carbon dioxide (CO2), ozone (O3), and particulates per ISO 18562 in order to examine any toxicological hazards and demonstrate the device's overall biological safety. Test Results and toxicological risk assessment as documented in TR213 concluded that all compounds detected from air testing were either below the TTC of 120 µg/day for prolonged contacting devices per ISO 8562 or their respective USP <467> PDE, published toxicological threshold (RfC or NIOSH REL), or TE value derived per ISO 10993-17.

Flow sensor of the RESPOND-19 Ventilator was evaluated based on the nature, degree, frequency, and duration of its exposure to the body for Cytotoxicity, Sensitization, and Irritation per Table A.1 of ISO 10993-1:2018 and Attachment A of the FDA guidance document.

**Measured Ventilation Values**

| Measured Value | Displayed Yes/No | Description |
|---|---|---|
| PEEP | Yes | PEEP is measured based upon the airway pressure and Flow Sensor: 200 msecs before the end of exhalation the measured exhaled airway pressure filtered with a 5 Hz low pass filter is taken as the PEEP value. This is displayed to allow the user to see what the actual PEEP value is. |
| Breath Rate | Yes | Based upon the airway Flow Sensor: 60 seconds is divided by the average period of time for the last 12 breaths (the minimum set breath rate for 12bpm). This average filters the measured breath period and is used in the APNEA alarm. |
| Inspiratory Time | Yes* (via derivative I:E ratio) | Time tidal volume is delivered over. Based upon the airway flow sensor: The period of time between the times the flow exceeds the trigger sensitivity and the exhaled flow is less than -5 Lpm. When flow drops below -5Lpm exhalation has considered to have started. Flow is sampled at 200 Hz and 6 out of 7 samples must be above the trigger sensitivity to be considered the start of inspiration and 4 out of 5 flows must be below the exhalation trigger sensitivity to be considered the start of exhalation. |
| Exhaled Tidal Volume | Yes | Based upon the airway Flow Sensor: This is the volume integrated between beginning of exhalation and the start of inspiration. |
| Inspired Tidal Volume | Yes | Based upon the airway Flow Sensor: This is the volume integrated between the beginning of inspiration and the start of exhalation. |
| Delivered Tidal Volume | No | Based upon the patient lung compliance, resistance, delivered pressure and inspiratory time: This is the measured volume based upon the volume delivered by the pump. The volume could be prematurely shortened in terms of its delivery in the event of a high-pressure alarm or other such alarm. |
| Minute ventilation | Yes | This is the average of the last 12 breaths of delivered tidal volume. This is displayed to the user to aid in the setting of the oxygen flow rate. |
| Peak Airway pressure | Yes | This is the peak air way pressure measured during the entire respiratory cycle. This is important when the user is setting the peak inspiratory pressure. |

| Measured Value | Displayed Yes/No | Description |
|---|---|---|
| Mean Airway Pressure | Yes | Mean Airway Pressure. This is the average pressure across each breath period (expiration and inspiration). |
| Inspiratory Pressure | No | The Inspiratory pressure transducer is filtered in hardware with a 15 Hz lowpass filter and in software with a 11Hz lowpass filter. |
| Expiratory Pressure | No | The expiratory pressure transducer is filtered in hardware with a 15 Hz lowpass filter and in software with a 11Hz lowpass filter. |
| Peak Flow | Yes | Based upon the airway Flow Sensor: This is the direct flow sensor measurement measured on breath by breath basis. |

**Measurement Uncertainty**

Measurement uncertainties and the manner in which they are applied are listed below:

| Measured Parameter | Max Offset | Max Gain |
|---|---|---|
| Flow | +/- 0.2 slpm | +/- 5% of reading < 100 slpm<br>+/- 10% of reading > = 100 slpm |
| Pressure | +/- 0.5 cmH2O | +/- 2.5% of reading |
| Oxygen Concentration | NA - External monitoring used to verify | |
| Temperature | +/- 2 deg C | +/- 2% of reading |
| Atmospheric Pressure | +/- 0.15 kPa | NA |

**Internal measurement, not available to user*

Breath delivery performance verification for flow and pressure based measurements and their derived parameters, such as volume, compliance, etc., the individual sensor uncertainties are combined and applied as applicable to determine the acceptance limits.

## Essential Performance

1. Micro-Blower Maximum Pressure Limit
    a. The microblower is physically limited to produce a maximum pressure generated to 50 $cmH_2O$
2. Detection of Excessive Pressures
    a. The system is able to detect high- and low-pressure conditions which could result in barotrauma or hypoventilation.
    b. There requirements are:
        i. The system has a user-settable high-pressure limit
        ii. The system has a user-settable low-pressure limit
        iii. The system is able to detect occlusions on the inspiratory and expiratory limb
3. Detection of Hypoventilation
    a. The system is able to detect that adequate volume is being delivered or the excessive volume is being lost before delivery to the patient
        i. The system is able to detect a circuit disconnect, a low exhaled tidal volume, and an apnea event
4. Detection of Cessation of Ventilation – Detection of Total Loss of Power
    a. The system is able to detect the ventilation has ceased
        i. The system is able to detect a total loss of power and annunciate an alarm in the event CPU function is lost
        ii. The system shall be able to detect patient apnea
5. Alerting User – Generation of Alarm Sound
        i. The system is able to generate an alarm sound and the volume will be in the range of 65-85 dBA at 1 meter