COVIDIEN

User's Manual

Puritan Bennett™

560 Ventilator

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Preface

Purpose of This Manual

This manual contains important information regarding the safe operation of your Puritan Bennett™ 560 Ventilator. Your ventilator is an electrical device that can provide years of useful service with the proper care, as described in this manual.
Ensure that you read and understand the instructions contained in this manual before operating the ventilator.

Warning

Before operating the ventilator, read, understand, and strictly follow the information contained in Chapter 1, "Safety Information".

Qualification of Personnel

Installation and maintenance of the device must be made by authorised and trained personnel. In particular, training for the handling of products sensitive to electrostatic discharges must include the use of Electrostatic Discharge (ESD) protection devices and knowledge of the following symbol's meaning: , as well as using original spare parts and respecting quality assurance and traceability rules approved by Covidien.

Warranty

Information regarding your product warranty is available from your sales representative or Covidien.

Extended Service

The Puritan Bennett™ 560 Ventilator offers extended service contracts/warranties for purchase when the ventilator is purchased. Please contact your local Covidien Sales or Service Representative for additional information.

SolvIT℠ CENTER *Knowledge base*

For online technical support, visit the SolvIT℠ Center Knowledge Base by clicking the link at http://www.covidien.com. Here, you will find answers to frequently asked questions about the product and other Covidien products 24 hours a day, 7 days a week. If you require further assistance, contact your local Covidien representative.

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1 Safety Information

1.1 Definitions

This manual uses three indicators to highlight critical information: Warning, Caution, and Note. They are defined as follows:

Warning

Indicates a condition that can endanger the patient or the ventilator operator.

Caution

Indicates a condition that can damage the equipment.

Note:

Indicates points of particular emphasis, that make operation of the ventilator more efficient or convenient.

It is essential to read, understand and follow these instructions before using the Puritan Bennett™ 560 Ventilator.
In order to use the ventilator correctly and efficiently and to help prevent incidents, please pay particular attention to sections 1.2, "Warnings", as well as all warnings and cautions contained throughout this manual.

Note:

Many of the functions of the ventilator are not accessible when the Locking key is enabled. For additional assistance contact your Clinician or equipment representative.

1.2 Warnings

General Warnings Regarding Use of Equipment

- **The ventilator must be used only under the responsibility and on the prescription of a doctor.**
- **The ventilator must be used according to its intended use. Refer to section 2.1, "Indications for Use".**
- **Be aware this manual describes how to respond to ventilator, but it does NOT tell you how to respond to the patient.**
- **While the ventilator is in use, an alternative means of ventilation should always be available in the event of a ventilator problem. This is particularly true for ventilator-dependent patients. Supplementary observation, appropriate for the patient's condition, is also recommended.**
- **To ensure that ventilation continues uninterrupted, ensure alternative power sources are available (AC power source, extra batteries, or an auxiliary DC car adapter). Be prepared for the possibility of power failure by having an alternative means of ventilation ready for use—particularly for ventilator-dependent patients.**

- **Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of exhalation gas, primarily carbon dioxide, may be inhaled by the patient. In some circumstances, inhaling carbon dioxide may lead to under-ventilation, suffocation, and serious injury or death.**
- **The ventilator must not be used with flammable anesthetic substances.**
- **Do not start ventilation until you ensure that the device is suitably assembled, that the air inlet filter is properly installed and is not obstructed, and that there is proper clearance all around the unit. Also ensure that the patient circuit is suitably connected to both the ventilator and the patient and that the patient circuit, including all hoses, is not damaged or obstructed.**
- **A ventilator-dependent patient should always be monitored by trained and competent medical personnel. Ensure that the patient's caregiver is able and prepared to take suitable action in the event the ventilator identifies an alarmed condition or experiences a problem.**
- **Do not use a patient circuit with a leak accessory for ventilator-dependent patients.**
- **Before dispensing the ventilator to caregivers or the patient for home use, ensure the Locking Key is activated so that critical ventilator settings are not modified.**
- **Do not perform ventilator alarm tests while the patient is connected to the ventilator. Provide the patient with an alternate means of ventilation before conducting these tests.**
- **Verify the functionality of the alarm conditions before connecting the patient to the ventilator.**
- **If the ventilator fails the alarm tests or if you cannot complete the tests, refer to chapter 3, "Troubleshooting" or call your equipment supplier or Covidien.**
- **When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.**
- **A continuous alarm condition will be activated if the ventilator power switch is turned off while ventilation is in progress. When the power switch is turned back on again, ventilation will resume without having to press the VENTILATION ON/OFF button.**
- **To reduce the risk of infection, wash your hands thoroughly before and after handling the ventilator or its accessories.**
- **A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet—or both ports if a double-limb circuit is used—is recommended. Refer to chapter 7, "Cleaning".**
- **Handle the ventilator with care during and after use, particularly when ambient temperatures are high. Some ventilator surfaces may become hot, even if safety specifications are not exceeded.**

Warnings Regarding Installation and Environment of Use

- **Even though the Puritan Bennett™ 560 Ventilator meets current safety standards, the internal Lithium-ion battery of the device exceeds the 100Wh threshold and is therefore considered to be Dangerous Goods (DG) Class 9 – Miscellaneous, when transported in commerce. As such, the Puritan Bennett™ 560 Ventilator and/or the associated Lithium-ion battery are subject to strict transport conditions under the Dangerous Goods Regulation for air transport (IATA: International Air Transport Association), International Maritime Dangerous Goods code for sea and the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) for Europe. Private individuals who transport the device are excluded from these regulations although for air transport some requirements apply. For air transport; the Puritan Bennett™ 560 Ventilator is permitted as checked-in or carry-on baggage. Two spare batteries per person may be taken on board as carry-on luggage only, with the prior approval of the airline. This classification and regulatory requirements may vary depending upon the country and mode of transport. Therefore it is recommended that users verify with the carrier / airline as to which measures to take before the voyage.**

- **To minimise the risk of damage, you must use the ventilator's Dual Bag to transport the ventilator. See Table F-1, List of Consumables and Accessories.**
- **Regularly clean the ventilator's Dual Bag according to manufacturer's recommendations.**
- **The ventilator should never be immersed in any liquid, and any liquid on the surface of the device should be wiped away immediately.**
- **To avoid damage to the ventilator, in particular the batteries or electrical components, fluids must not be allowed to enter the device, particularly through the air inlet filter or the cooling apertures located in the side, rear, and bottom panels of the ventilator.**
- **To ensure correct and lasting operation of the device, ensure that the ventilator is installed and operated in the environmental conditions recommended in Appendix A, "Specifications."**
- **Do not leave power cables lying on the ground where they may pose a hazard.**
- **Do not operate the ventilator in direct sunlight, near heat sources, outdoors, or near installations where liquid may pose a risk without first providing adequate protection for the device.**
- **Avoid using the ventilator, if possible, in dusty environments. Dusty environments may require more vigilant monitoring, cleaning, and/or replacement of air intake and other filters.**
- **Ensure that the ventilator's immediate surroundings allow for the proper operational connection of the device without folding, pinching, or damaging any of the required cables or tubes, and that the connection of the patient circuit to the patient provides for a secure, comfortable fit.**
- **Place the ventilator in a safe place when ventilating and according to the recommendations in this manual.**
- **Do not place the ventilator in a position where a child can reach it or in any position that might cause it to fall on the patient or someone else.**
- **To ensure correct and lasting operation of the ventilator, ensure that its air circulation holes (main inlet or cooling) are never obstructed. Place the device in an area where air can freely circulate around the ventilator and avoid installing it near floating fabrics, such as curtains.**
- **If the ventilator has been transported or stored at a temperature that differs more than ±20 °C (± 36 °F) from the temperature in which it will be operating, the ventilator should be allowed to stabilise in its operating environment for at least two (2) hours prior to use.**
- **If the ambient temperature where the device is operated is greater than 35 °C (95 °F), the flow supplied at the device outlet may exceed 41 °C (106 °F). This may lead to undesirable side effects for the patient. To avoid injury to the patient move the patient and the ventilator to a cooler location. For more information, contact Covidien.**
- **The default setting for altitude compensation is YES. Altitude compensation should always be set to YES for accurate volume delivery calculations at all elevations.**
- **To reduce the risk of a fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (such as flammable anesthetics and/or heaters) away from the ventilator and oxygen hoses.**
- **Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. If necessary, replace the filter before the recommended replacement period is over (see chapter 8, "Routine Maintenance"). This is particularly important when the ventilator is installed on a wheelchair, because environmental conditions may cause the filter to become dirty more rapidly.**
- **Handle the ventilator with care during and after use, particularly when ambient temperatures are high. Some ventilator surfaces may become hot, even if safety specifications are not exceeded.**

⚠ Warnings Regarding Electrical Power Supplies

- **Never connect your ventilator to an electrical outlet controlled by a wall switch because the power may be inadvertently turned off.**

- **The operator should connect the ventilator to an AC power source whenever available, for safer operation.**
- **The maximum recommended shelf life of the internal battery is two (2) years. Do not use a battery that has been stored for two years prior to its first use.**
- **Periodic recharging is important to help maximise useful life of the battery. Do not store the internal battery for extended periods, without recharging, as this may reduce the maximum life.**
- **For the AC ("mains") power cable to be properly secured, the attachment located on the power cable must be fitted into the power cable holder incorporated in the battery access cover and located under the AC (mains) power socket. Refer to section 4.2, "Connecting to External AC Power".**
- **The power supply to which the ventilator is connected (both AC and DC) must comply with all applicable standards and provide electrical power corresponding to the voltage characteristics inscribed on the rear of the ventilator to ensure correct operation. Refer also to the electrical specifications found in Appendix A, "Specifications".**
- **Ensure that the ventilator's internal battery is fully charged before connecting the ventilator to an external DC power source. Powering the ventilator using an external 12– 30 VDC power source (via the DC power cable) does not enable its internal battery to recharge.**
- **Due to its limited internal battery's reserve capacity, the ventilator should only be operated on the internal battery when no other power source is available. Ensure that the internal battery never becomes fully discharged.**
- **When using a car auxiliary adapter (cigarette lighter) ensure the car has been started prior to plugging in the ventilator's DC adapter. Refer to chapter 4.3, "Connecting to an External DC Power Source".**
- **Even if the "INTERNAL BATTERY" charging indicator is off, charging of the battery may sometimes be incomplete if the ambient temperature is above 40 °C (104 °F) because of the battery's internal heat safety device.**
- **When the "LOW BATTERY" alarm is triggered, immediately connect the ventilator to an AC power supply to maintain ventilation and recharge the internal battery.**
- **Batteries should be disposed of according to environmental legislation in your country and locality.**
- **Never expose any batteries to direct flame.**
- **Ensure that the AC power cable is in perfect condition and not compressed. The device should not be turned on if the AC power cable is damaged.**

⚠ Warnings Regarding Hoses and Accessories

- **The ventilator must not use, nor be connected to, any anti-static or electrically conductive hoses, tubing, or conduits.**
- **Minimum and maximum VTE alarm parameters must be properly set to warn in the event of patient disconnection.**
- **Before opening the packaging for the Patient Circuit, ensure that no damage is evident to the packaging or its contents. Do not use if evidence of damage exists.**
- **The patient circuit should not be changed during ventilation.**
- **On a DAILY basis, inspect the patient circuit to ensure that it shows no signs of damage, is properly connected, and is operating correctly without leakage.**
- **Single Use accessories should not be reused.**

- **The exhalation block is intended for single use by a single patient ②. It may periodically be cleaned, but it cannot be disinfected or sterilised. To maintain good measurement quality when used continuously, clean the exhalation block periodically (refer to section 7.3, "Cleaning the Exhalation Block"). The exhalation block should be changed every 4 months and cannot be reused with any other patient.**
- **During invasive ventilation (when an artificial airway bypasses the patient's upper respiratory system), the patient's upper respiratory system cannot humidify the incoming gas. For this reason, the use of a humidifier, to minimise drying of the patient's airway and subsequent irritation and discomfort, must be used.**
- **If exhaled tidal volume measurements are required to ensure correct patient ventilation a double limb patient circuit configuration must be used in order to detect leaks. In this case, both the minimum and maximum VTE alarm parameters must be properly set to warn in the event of patient disconnection.**
- **Failing to replace a dirty air inlet filter, or operating the ventilator without a filter, may cause serious damage to the ventilator.**
- **Before cleaning the ventilator, first disconnect the ventilator and the patient circuit.**
- **If the ventilator is used indoors, the condition of the air inlet filter should be checked monthly. If the ventilator is used outdoors or in a dusty environment, the filter should be checked weekly and replaced as necessary.**
- **The air inlet filter is not reusable; do not attempt to wash, clean, or reuse it.**
- **The patient circuit should always be positioned to avoid hindering the patient's movements, to prevent accidental disconnection or leakage, and to minimise the risk of patient strangulation.**
- **For pediatric use, ensure that the patient circuit type fits, and, in all respects, is suitable for use with a child. Use a pediatric circuit for patients that weigh under 53 lb. (23 kg). To ensure proper performance of the ventilator, See Table F-2, List of Circuits, on page F-2, for a list of recommended patient circuits.**
- **Resistance of the exhalation valve and accessories (water traps, filters, HMEs etc) must be as low as possible.**
- **Adding attachments to the ventilator breathing system can cause the pressure during exhalation at the patient connection port to increase.**
- **The exhalation valve must allow rapid discharge of the circuit pressure. Ensure that the exhalation valve is always clean and its evacuation aperture (exhaust port) is never obstructed.**
- **Users must always possess an additional breathing circuit and exhalation valve while using the Puritan Bennett™ 560 Ventilator.**
- **Always ensure that the humidification device is positioned lower than both the ventilator and the patient. Use water traps, if necessary, to limit water in the patient circuit and periodically empty these water traps.**
- **If a heated humidifier is used, you should always monitor the temperature of the gas delivered to the patient. Gas delivered from the ventilator that becomes too hot may burn the patient's airway.**
- **Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.**
- **The level of inspiratory resistance of the circuit and accessories (bacteria filter, humidifier, HMEs etc) must be as low as possible. Settings—particularly the PATIENT DISCONNECTION alarm, maximum inspired volume (Max VTI), and minimum inspired volume (Min VTI) settings—must be periodically adjusted according to changes in the patient circuit resistance—especially when filters are replaced.**

- **To ensure proper performance of the ventilator, use a patient circuit recommended by Covidien in this manual; refer to chapter 4, "Installation and Assembly" and Appendix F, "Parts and Accessories". The total specified length of the patient circuit tubing as measured from the ventilator outlet to the ventilator inlet is 1.1 metres (3.6 feet) to 2.0 metres (6.6 feet). The tubing must conform to all applicable standards and must be fitted with Ø 22 mm terminals that also conform to all applicable standards. Ensure that both the length and the internal volume of the patient circuit are appropriate for the tidal volume: a corrugated tube of Ø 22 mm for adult patients, and a corrugated tube of Ø 15 mm for pediatric patients with a tidal volume lower than 200 ml.**
- **To ensure proper performance of the ventilator, use only accessories (including oxygen accessories) approved and recommended by Covidien. See Appendix F, "Parts and Accessories" or contact your customer services.**
- **When using non-invasive ventilation (NIV) without an exhalation valve, use a vented nose or face mask or a non vented combined with a leak accessory. When using non-invasive ventilation (NIV) with an exhalation valve, use a non-vented mask.**
- **Before using the Nurse Call system, ensure that its connections are secure and it operates properly. For more information, contact Covidien or your equipment supplier.**
- **To connect the ventilator to a Nurse Call device, contact Covidien or your equipment supplier to check the ventilator's compatibility with the Nurse Call device and order a suitable connection cable.**
- **Do not use Nurse Call devices that operate based on the closure of an electrical circuit, because the devices often do not take into account possible cable disconnection or a total loss of power. Ensure that the Nurse Call device is always connected to the ventilator.**

⚠ Warnings Regarding Settings

- **Before starting ventilation, always verify that all settings are properly set in accordance with the required prescription.**
- **Before starting ventilation, ensure that the device is properly assembled and that the air inlet, cooling vents, and alarm sound diffusion holes are not obstructed. Ensure also that the patient circuit is of the proper configuration (double or single limb), properly connected to the ventilator, and that the circuit hoses are neither damaged nor compressed and contain no obstructions or foreign bodies.**
- **The CPAP mode does not provide a set respiratory rate. Do not use this mode for ventilator-dependent patients.**
- **Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of exhalation gas, primarily carbon dioxide, may be inhaled by the patient.**
- **Alarm volume should be adjusted with respect to the ventilator's operating environment and so that the patient's caretakers can hear the alarms. The audible alarm vents located at the front of the device should never be obstructed. The alarm can be paused with the Alarm Pause function by pressing the ALARM CONTROL key twice once the alarm has been declared.**
- **Ensure that the I Sens setting is not set to OFF when ventilating patients capable of triggering spontaneous breaths.**
- **Monitor the patient's state of health in order to ensure that the ventilator's settings are always suited to the patient's current physiological requirements.**
- **In adult or pediatric use ensure that the adjusted tidal volume is compatible with the needs of the patient.**
- **When changing the mode during ventilation, significant transitions of pressure, flow or cycling rate might occur, depending on the difference between the modes. Before setting the new mode, first ensure that the settings between the different modes are compatible. This reduces the risk of discomfort and harm to the patient.**

- **Do not conduct the ventilator alarm test while the patient is connected to the ventilator. Switch the patient to an alternate means of ventilation before testing.**
- **The setting of the Min PIP alarm must be adjusted for the patient, but must also be set high enough to allow the PATIENT DISCONNECTION alarm to trigger properly. Perform the Low Pressure Test to ensure the Min PIP alarm is properly set.**
- **If APNEA TIME is set to a value higher than 60/Control R then the APNEA alarm will not activate.**
- **If an APNEA alarm is required, set the APNEA setting to YES in the Preferences Menu.**
- **The Apnea Alarm should be set to YES for ventilator dependant patients.**
- **Setting Alarm limits to extreme values can cause the ventilator alarms to malfunction.**
- **Ensure the Insp Time setting is compatible with the physiological requirements of the patient.**
- **Adjustable alarms should not be systematically cancelled; instead, they should be adjusted according to the needs and condition of the patient.**
- **A continuous alarm condition will be activated if the ventilator power switch is turned off while ventilation is in progress. When the power switch is turned back on again, the ventilation will resume without having to press the VENTILATION ON/OFF button.**
- **In the SIMV mode the use of a double limb circuit is recommended. The Min VTE setting should remain active in the event that pressure losses are present on the patient circuit downstream from the proximal pressure link. In such cases the "PATIENT DISCONNECTION" alarm would not be systematically activated in case of a disconnection of the circuit.**
- **The inspiration trigger threshold should be carefully modified in order to avoid the risk of false triggering or "autotriggering" of the ventilator. For example, Level 1P, the most sensitive mode, is recommended for pediatric use. However, for an adult, this setting may result in autotriggering.**
- **The sound level of the alarms should be adjusted according to the installation environment and the size of the area monitored by the patient's caregiver. Ensure that the alarm sound apertures at the front of the device are never obstructed.**

⚠ Warnings Regarding USB Memory Device

- **Always verify the file ID before using a USB memory device to transfer data between the ventilator and a PC.**

⚠ Warnings Regarding Maintenance

- **Never use a ventilator or any components or accessories that appear to be damaged. If any signs of damage are evident, contact your equipment supplier or Covidien.**
- **To ensure proper servicing and avoid the possibility of physical injury to personnel or damage to the ventilator, only personnel authorised and qualified by Covidien should attempt to service or make authorised modifications to the Puritan Bennett™ 560 Ventilator.**
- **If you cannot determine the cause of a problem with your ventilator, contact your equipment supplier. Do not use the ventilator until the problem has been corrected.**
- **To ensure proper performance of the ventilator, the preventative maintenance schedule should be followed. For further information contact Covidien.**
- **On a daily basis, ensure the proper connection and operation of the patient circuit.**
- **If a problem with the ventilator is suspected, FIRST CHECK THAT THE PATIENT IS NOT IN DANGER. If necessary, remove the patient from the ventilator and provide an alternative means of ventilation.**
- **After assembling, cleaning, or reassembling the patient circuit, and on a daily basis, inspect the hoses and other components to ensure that there are no cracks or leaks and that all connections are secure.**

- **Use all cleaning solutions and products with caution. Read and follow the instructions associated with the cleaning solutions you use to clean your ventilator. Use only those solutions listed in Table 7-1.**
- **Never use a liquid cleaner inside the patient circuit, or on any component of a gas pathway. Clean the patient circuit only as specified by the manufacturer's instructions.**
- **Do not attempt to open, repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only personnel authorised and qualified by Covidien should repair, open or service the ventilator.**
- **If the ventilator is damaged or its external housing is not correctly closed or it behaves in a way that is not described in this manual (excessive noise, heat emission, unusual odour, alarms not triggered during the start-up procedure), the oxygen and power supplies should be disconnected and use of the device stopped immediately.**
- **The exhalation block is intended for single use by a single patient ②. It may periodically be cleaned, but it cannot be disinfected or sterilised. To maintain good measurement quality when used continuously, clean the exhalation block periodically (refer to section 7.3, "Cleaning the Exhalation Block"). The exhalation block should be changed every 4 months and cannot be reused with any other patient.**
- **Ensure that the exhalation block is completely dried after cleaning and prior to use.**
- **When an exhalation block is set up, each time it is removed, or after installing a new exhalation block on the machine, it is essential that the exhalation flow sensor be recalibrated before the exhalation block is used.**
- **The patient circuit is intended for single use by a single patient ② and should be changed according to the manufacturer's recommendations and according to the patient circuit lifetime. Refer to the instructions for use supplied by the manufacturer of the patient circuit (included with the ventilator) and chapter 4, "Installation and Assembly".**
- **A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet—or both ports if a double-limb circuit is used—is recommended. Refer to chapter 7, "Cleaning".**
- **Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. If necessary, replace the filter before the recommended replacement period is over (see chapter 8, "Routine Maintenance"). This is particularly important when the ventilator is installed on a wheelchair, because environmental conditions may cause the filter to become dirty more rapidly.**
- **For environmental protection, the ventilator and its components, whatever their respective conditions of operation, cannot be disposed of with household waste and must be submitted for suitable selective collection and possible recycling. Observe all applicable regulations when disposing of the ventilator and any of its components.**
- **If the device is damaged, its external housing is not correctly closed, or it behaves in a way that is not described in this manual (excessive noise, heat emission, unusual odour, alarms not triggered during the start-up procedure), the oxygen and power supplies should be disconnected and use of the device stopped immediately.**
- **Before using the ventilator's internal battery, ensure that the battery is fully charged and that the charge holds. Back up ventilators or those in storage should be connected to an AC power source to protect the integrity of the battery.**
- **The maximum recommended shelf life of the internal battery is two (2) years. Do not use a battery that has been stored for two years prior to its first use. Periodic recharging is important to help maximize useful life of the battery. Do not store the internal battery for extended periods, without recharging, as this may reduce the maximum life.**

- **To connect the ventilator to an external power source, first ensure the ventilator's I/O switch is off (O). Then, connect the desired power cable to the ventilator. Finally, connect the power cable to the external power source.**
- **To disconnect the ventilator from an external power source, first power-down the ventilator. Then, disconnect the power cable from the external power source and, finally, the ventilator.**
- **Connect the external DC power source by first connecting the power cable to the ventilator and then to the external DC source. Follow the reverse procedure to disconnect the device from the external DC power source.**
- **Connect the external electrical power source by first connecting the power cable to the ventilator and then to the external power source. Follow the reverse procedure to disconnect the device from electrical power sources.**

⚠ Warnings Regarding Oxygen

- **The ventilator must not be used with flammable anesthetic substances.**
- **Oxygen therapy for patients with respiratory failure is a common and effective medical prescription. However, be aware that inappropriate oxygen use may potentially lead to serious complications, including, but not limited to, patient injury.**
- **Strictly follow the instructions provided in section 4.8.2, "Connecting the Oxygen Supply", which include the use of a flow regulator and special oxygen connector.**
- **To avoid injury to the patient and/or possible damage to the ventilator: before connecting the ventilator to the oxygen supply, ensure a flow meter (flow regulator) is connected to the ventilator to regulate the oxygen supply to the required specification.**
- **The Puritan Bennett™ 560 Ventilator can be used with an optional oxygen analyser with minimum and maximum concentration alarms. Always measure the delivered oxygen with a calibrated oxygen analyser (FIO_2 kit) that features a minimum and maximum concentration alarm in order to ensure that the prescribed oxygen concentration is delivered to the patient.**
- **The Puritan Bennett™ 560 Ventilator is designed to deliver a percentage of oxygen equal or lower than 50%. Do not exceed this value as this may cause the ventilator to malfunction and put the patient at risk.**
- **Ensure that the oxygen supply pressure to the machine never exceeds 7 psi (50 kPa) or a flow of 15 lpm. Refer to Table A-8 on page A-3 for volume and sensitivity tolerances.**
- **In the event of an oxygen leak, shut down the supply of oxygen at its source. In addition, remove and/or keep any incandescent source away from the device, which may be enriched with oxygen. Circulate fresh air into the room to bring the oxygen level down to normal.**
- **The hose connecting the ventilator to the oxygen source must be designed exclusively for use with medical-grade oxygen. Under no circumstances should the oxygen hose be modified by the user. In addition, the hose must be installed without the use of lubricants.**
- **Ensure that the only gas supplied to the ventilator through the dedicated oxygen supply connector is medical-grade oxygen.**
- **The coupler must not remain connected to the oxygen connector unless it also connected to a leak-proof, external oxygen gas source. When an oxygen supply is not being used with the ventilator, disconnect the oxygen source completely from the ventilator.**
- **To prevent any interference with the internal sensors of the ventilator, do not install a humidifier upstream of the ventilator.**
- **To ensure stability, when the Puritan Bennett™ 560 Ventilator is mounted on a cart, the weight of the oxygen bottle should not exceed 14 kg (30 lbs).**
- **The oxygen supply hose ages even when it is not in use and should be replaced periodically. The expiration date may be located on the back of the hose end-piece.**
- **The oxygen supply must be regulated using a flow meter connected to the source gas outlet.**

- **The oxygen supply must be shut off when ventilation is interrupted. Before disconnecting the oxygen hose, allow the ventilator to continue for a few cycles without oxygen to flush the patient circuit of excess oxygen.**
- **Before connecting the oxygen supply, ensure that the stud on the oxygen connector is protruding outwards.**
- **Inspect the oxygen coupler before use to ensure it has its black O-ring attached and in good condition. Do not use an oxygen coupler with a missing, damaged, or worn O-ring.**

Warnings Regarding Electromagnetic Interference

- **The Puritan Bennett™ 560 requires special precautions for electromagnetic compatibility and should be installed and started according to the recommendations found in Appendix A, "Specifications." In particular, the use of nearby mobile and portable communications equipment using radio frequencies, such as mobile telephones or other systems exceeding the levels set in the IEC 60601-1-2 standard, may affect its operation. Refer to section A.10, "Manufacturer's Declaration".**
- **The use of any accessory other than those specified, with the exception of the power supplies or cables sold by Covidien, may lead to an increase in electromagnetic emissions or a decrease in the equipment protection against electromagnetic emissions. If the ventilator is used adjacent to such accessories or stacked with such devices, the ventilator's performance should be monitored to verify normal operation.**

1.3 Symbols and Markings

Table 1-1. Ventilator Symbols

Symbols	Descriptions
	It is essential to read, understand, and follow these instructions before using the Puritan Bennett™ 560 Ventilator (ISO 7000-0434A). This symbol appears on the ventilator's back panel, see Table 1-2, item 5.
	Type BF applied part (IEC 60417-5333). A regulatory standard classification for protection against electrical shock for the part of the device that contacts the patient. This symbol appears on the ventilator's back panel; see Table 1-2, item 5.
	Direct current, DC (IEC 60417-5031). This symbol appears on the ventilator's back panel and keyboard; see Figure 1-1 and Figure 1-3, item 9.
	Alternating current, AC (IEC 60417-5032). This symbol appears on the ventilator's back panel and keyboard; see Figure 1-4, item 8, and Figure 2-2 on page 2-5, item 10.
	Internal Battery. This symbol appears on the ventilator's keyboard; see Figure 2-3 on page 2-6, item 10.
	Insulation class II equipment (IEC 60417-5172). A regulatory standard classification for protection against electric shock. Class II equipment relies on double insulation rather than protective earthing. This symbol appears on the ventilator's back panel; see Table 1-2, item 5.
IP31	Index of Protection rating for the ventilator's enclosure, defined in IEC 60529 (BSEN60529:1991). The first digit, 3, indicates protection against the intrusion of small foreign bodies (including fingers, tools, wires, etc. with a diameter greater than 2.5 mm) into the ventilator. The second digit, 1, indicates protection against water dripping or falling vertically, as well as an environment featuring water vapour condensation and/or light rain. This rating appears on the ventilator's back panel; see Table 1-2, item 5.
	CSA – Canadian Standards Association. This symbol appears on the ventilator's back panel; see Table 1-2, item 5.
	CE - Conformity European Signifies compliance with the medical device directive 93/42/EEC as amended by 2007/47/EC. This symbol appears on the ventilator's back panel; see Table 1-2, item 5.
	This symbol appears on the ventilator's front panel UP/UNFREEZE key; see Figure 2-3 on page 2-6, item 4. This key is used to: move the LCD display's cursor upwards, line-by-line; increase the value of displayed and selected parameter settings; restart ("unfreeze") waveforms tracing.
	This symbol appears on the ventilator's front panel DOWN/FREEZE key; see Figure 2-3 on page 2-6, item 6. This key is used to: move the LCD display's cursor downwards, line-by-line; decrease the value of displayed and selected parameter settings; stop ("freeze") waveforms tracing.
	This symbol appears on the ventilator's front panel ENTER key; see Figure 2-3 on page 2-6, item 5. This key is used to confirm command actions.

Table 1-1. Ventilator Symbols (Continued)

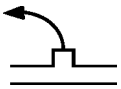
Symbols	Descriptions
	This symbol appears on the ventilator's front panel ALARM CONTROL key; see Figure 2-3 on page 2-6, item 3. This key is used to: cancel the audible portion of alarms for 60 seconds at a time; cancel an alarm. For more information, refer to section E, "Alarms Tests."
	This symbol appears on the ventilator's front panel MENU key; see Figure 2-2 on page 2-5, item 7. This key is used to access the ventilator's menus via the ventilator's front panel LCD display.
	This symbol (IEC 60417– 5009) appears on the ventilator's front panel VENTILATION ON/OFF button; see Figure 2-3 on page 2-6, item 8. This key is used to Start and Stop ventilation.
	To patient port. This symbol appears on the front right of the ventilator, adjacent to the To Patient port; see Figure 1-1 on page 1-16, item 1.
	From patient-port (double-limb option). This symbol appears on the front-left of the ventilator, adjacent to the From Patient port; see Figure 1-1 on page 1-16, item 4.
	Patient proximal pressure port. This symbol appears on the front right of the ventilator, adjacent to the From Patient port; see Figure 1-1 on page 1-16 and Figure 1-4 on page 1-18, item 3.
	Exhalation valve pilot port. This symbol appears on the front right of the ventilator, adjacent to the To Patient port indicating the connection of the tubing between the patient circuit exhalation valve; see Figure 1-1 on page 1-16, and Figure 1-4 on page 1-18, item 3.
	Oxygen inlet. This marking appears on the back panel of the ventilator, adjacent to the oxygen inlet port; see Figure 1-3 on page 1-17, item 2.
	Nurse Call connector. This symbol appears on the back panel of the ventilator, adjacent to the nurse call connector; see Figure 1-3 on page 1-17, item 2.
	Switch in "Off" position (IEC 60417-5008). This symbol appears on the I/O (power on/off) switch on the back panel of the ventilator to indicate the switch's "Off" position. See Figure 2-2 on page 2-5, item 2.
	Switch in "On" position (IEC 60417-5007). This symbol appears on the I/O (power on/off) switch on the back panel of the ventilator to indicate the switch's "On" position. See Figure 2-2 on page 2-5, item 2.
	Software Lock Enabled. This symbol appears on the upper-left of the ventilator's LCD display when the keyboard Locking Key is enabled.
	Internal Battery. This symbol appears on the top-center of ventilator's LCD display to indicate that the ventilator is being powered by its internal battery. See Figure 2-4 on page 2-7, item 1 and refer to chapter 6, "Internal Battery", for more information.
	Pressure rise times (inspiratory phase) parameter. These symbols appear on the ventilation mode menu screens. In pressure ventilation modes, you can select one of four rise times with setting 1 representing the fastest rise time and setting 4 representing the slowest.

Table 1-1. Ventilator Symbols (Continued)

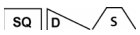
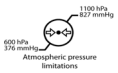
Symbols	Descriptions
	Flow shape ("flow distribution shape", inspiratory phase) parameter. These symbols appear on the ventilation mode menu screens; selectable for V A/C mode only. For more information, refer to chapter 5, "Operating Procedures". In volume ventilation mode you can select between Square (SQ), Descending (D) or Sinusoidal (S) flow patterns.
	Selected line (filled square). When making menu choices, this graphic indicates the line on which the cursor is currently positioned.
	Non-selected line (empty square). When making menu choices, this graphic indicates a line on which the cursor is currently not positioned.
	Locked parameter line. When making menu choices, this graphic indicates a line that cannot be selected (the Locking Key is enabled).
	Active parameter line. When making menu choices, this graphic indicates that the current parameter is selected and can be changed. See chapter 5, "Operating Procedures".
	Inspiratory Effort Detected. This symbol appears in the front panel display's Status window when the patient triggers a breath.
	Parameter adjustment bar. This graphic shows the current setting for parameters such as display contrast and alarm volume in the Preferences menu.
	WEEE (Waste Electrical and Electronic Equipment). This symbol means that this product must not be disposed of with household waste. Observe local ordinances for proper disposal. Refer to Table 1-2, item 5.
	Year of Manufacture.
	Manufacturer.
	Audio Paused. This symbol means the sounding of audible alarms is currently disabled. For more information, refer to section 3.4, "Silencing the Audible Portion of Alarms".
	Alarm Paused (reset/cancelled). This symbol means one or more alarms have been paused, or reset/cancelled. For more information, refer to section 3.5, "Pausing/Resetting Alarms".
	Apnea Alarm Deactivated. This symbol means that the Apnea Alarm has been deactivated. For more information, refer to section 3.5, "Pausing/Resetting Alarms".
	Exhalation Valve detected. This symbol means that an exhalation valve has been detected during ventilation.
	No Exhalation Valve detected. This symbol means that no exhalation valve has been detected during ventilation.

Table 1-1. Ventilator Symbols (Continued)

Symbols	Descriptions
	Single patient use only (ISO 7000-1051). This symbol means that the labeled device is for use by a single patient only.
	Freeze Waveforms. This symbol means the tracing of patient pressure and flow waveforms is currently paused or “frozen.”
	Follow instructions for use (ISO 7000-1641). This symbol directs the user to observe and adhere to the instructions contained in the product’s user manuals.
	USB port. This symbol indicates a communications port for interfacing with a USB connector. See Figure 2-2, item 11.
	PC connector. This symbol indicates a port that can be used by authorised Covidien product service personnel or Covidien service personnel for software maintenance. See Figure 2-2, item 10.
	Atmospheric pressure limitation.
	Humidity limitations.
	Temperature limitations.
	Fragile.
	Keep dry.
	Keep away from direct sunlight.
	This side up.

1.4 Labels / Identification and Instruction Information

Various labels or specific markings are affixed to the ventilator that describe precautions to be taken for the correct use of the ventilator and contribute to the traceability of the product. Refer to Table 1-2 and the figures on the following pages for illustrations of these labels and markings and their locations on the ventilator. Use the item numbers in the following tables to locate the labels in Figure 1-1 to Figure 1-4.

Table 1-2. Ventilator Labels and Markings

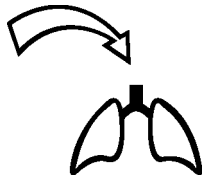
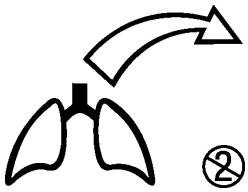
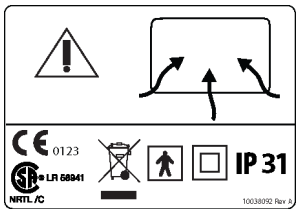
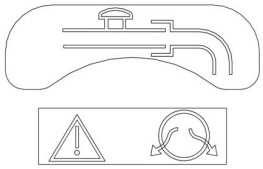
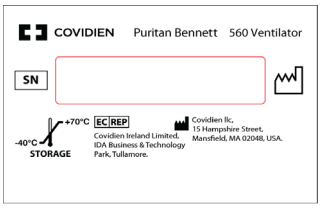
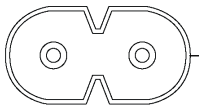
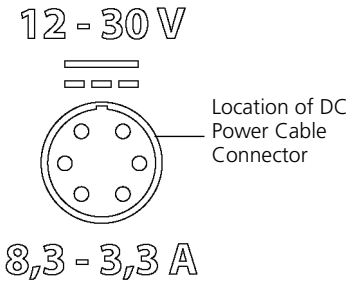
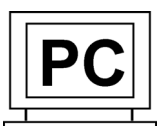
 **1.** Patient Gas Inlet Label (Figure 1-1, Figure 1-4)	 **2.** Oxygen Inlet Marking and Label (Figure 1-3)	 **3.** Exhalation Valve and Patient Pressure Connection Label (Figure 1-1, Figure 1-4)
 **4.** From Patient Port, Exhalation Limb Connection of Patient Circuit – Single Use Exhalation Block Label (Figure 1-1, Figure 1-2, Figure 1-4)	 **5.** Air Inlet Label (Figure 1-3)	 **6.** Exhaled Gas Outlet Label (Figure 1-2)
 **7.** Identification Label (Figure 1-4)	 Location of AC Power Cable Connector  **8.** AC Power (Mains) Cable Connector Marking (Figure 1-3)	 **9.** External Cable Connector Marking (Figure 1-3)
 **10.** PC Connection marking (Figure 1-3)	 **11.** USB Port marking (Figure 1-3)	 **12.** Nurse Call Cable Connector Marking (Figure 1-3)

Table 1-2. Ventilator Labels and Markings (Continued)

 **13.** FIO_2 Label (Figure 1-1, Figure 1-4)		

Note:
The item number callouts in the following figures refer to those listed in Table 1-2.

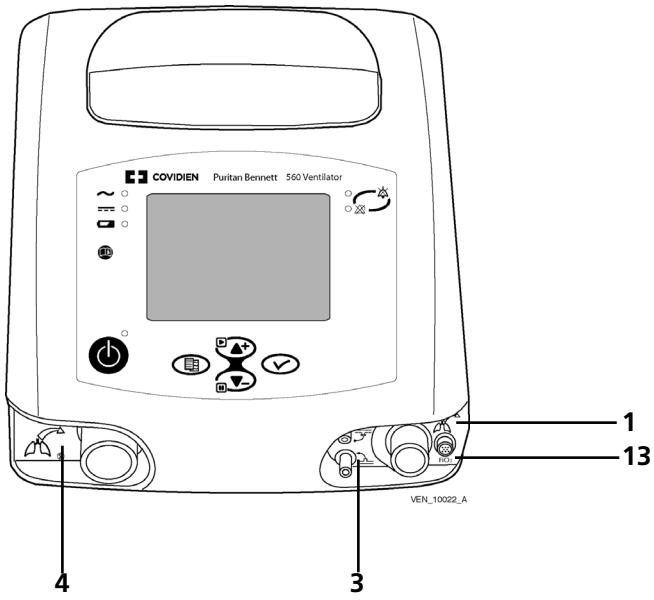


Figure 1-1. Locations of Labels – Top-Front View

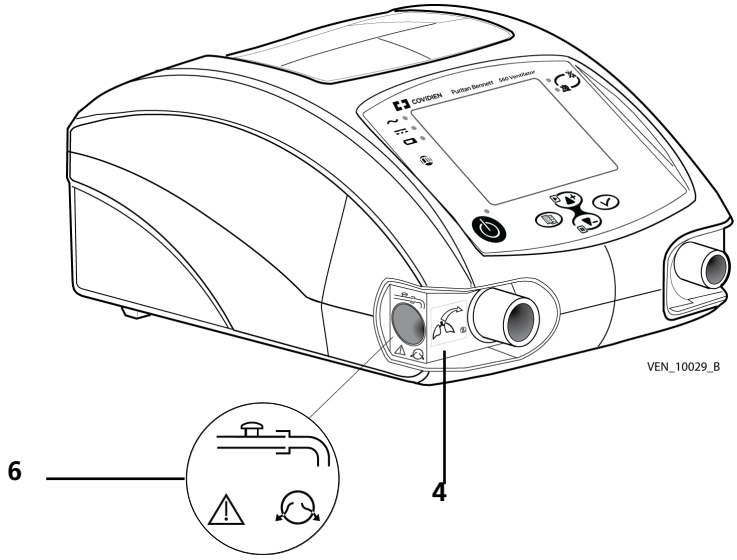


Figure 1-2. Locations of Labels – Front-Left View

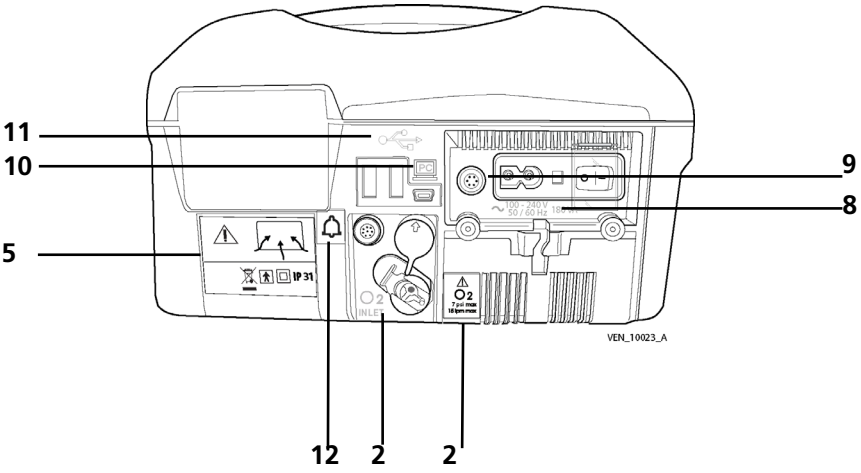


Figure 1-3. Location of Labels and Markings – Rear View

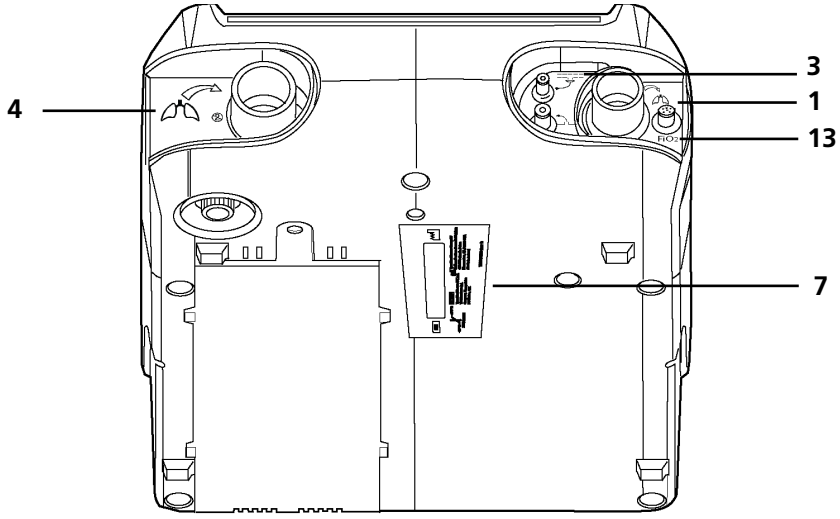


Figure 1-4. Location of Labels – Bottom View

2 Ventilator Overview

2.1 Indications for Use

The Device name is indicated for the continuous or intermittent mechanical ventilatory support of patients weighing at least 11 lb (5 kg) who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a doctor. It is essential to read, understand, and follow these instructions before using the Puritan Bennett™ 560 Ventilator.

Target Patients

Specifically, the ventilator is applicable for adult and pediatric patients who require the following general types of invasive or non-invasive ventilatory support, as prescribed by an attending doctor:

- Positive Pressure ventilation
- Assist/Control, SIMV, or CPAP modes of ventilation
- Breath types including Volume Control, Pressure Control, and Pressure Support

Target Environments

The ventilator is suitable for use in institutional, home, and portable settings. It is not intended for use as an emergency transport ventilator.

The Puritan Bennett™ 560 Ventilator is suitable for use on commercial aircraft, per FAA requirements. Refer to chapter A.11, "Standards Compliance and IEC Classification". Patients traveling with the Puritan Bennett™ 560 Ventilator may be required by their airline to demonstrate evidence of compliance with the RTCA/DO-160F standard, as well as other requirements. Contact your airline prior to travel to determine airline specific requirements and documentation.

Warning

Even though the Puritan Bennett™ 560 Ventilator meets current safety standards, the internal Lithium-ion battery of the device exceeds the 100Wh threshold and is therefore considered to be Dangerous Goods (DG) Class 9 – Miscellaneous, when transported in commerce. As such, the Puritan Bennett™ 560 Ventilator and/or the associated Lithium-ion battery are subject to strict transport conditions under the Dangerous Goods Regulation for air transport (IATA: International Air Transport Association), International Maritime Dangerous Goods code for sea and the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) for Europe. Private individuals who transport the device are excluded from these regulations although for air transport some requirements apply. For air transport; the Puritan Bennett™ 560 Ventilator is permitted as checked-in or carry-on baggage. Two spare batteries per person may be taken on board as carry-on luggage only, with the prior approval of the airline. This classification and regulatory requirements may vary depending upon the country and mode of transport. Therefore it is recommended that users verify with the carrier / airline as to which measures to take before the voyage.

Target Operators

The ventilator may be operated by:

- Respiratory therapists
- Doctors
- Nurses
- Homecare providers
- Patient and patient's families

Warning

This ventilator must be used only under the responsibility and on the prescription of a doctor.

2.2 Contraindications

This ventilator is not for use with anesthetic gases, and is not intended for use as an emergency transport ventilator.

2.3 Operational Use

The Puritan Bennett™ 560 Portable Ventilator uses a micro-turbine to provide ventilatory support to patients. Clinicians may use a variety of interfaces to connect patients to the ventilator: nasal masks or full face masks; endotracheal or tracheotomy tubes. User-selectable ventilation modes are:

- Assisted Controlled Volume (V A/C)
- Assisted Controlled Pressure (P A/C)
- Volume Synchronised Intermittent Mandatory Ventilation (V SIMV)
- Pressure Synchronised Intermittent Mandatory Ventilation (P SIMV)
- Continuous Positive Airway Pressure (CPAP)
- Pressure Support Ventilation with apnea ventilation (PSV/ST)

Safety Net

Incorporated in the ventilator design is an alarm system that continuously monitors both patient and machine for signs of specific errors or faults that could lead to an unsafe condition. Should any of these errors or faults be detected, the alarm system announces the specific alarm condition both audibly and visually. The machine-related alarm conditions are factory set, whereas the patient-related alarm conditions are defined by alarm-threshold values selected by an operator (a clinician
or a caregiver). For more information, refer to chapter 3, "Alarms and Troubleshooting"

Settings

A software key, known as the "Locking Key," restricts access to ventilation parameter settings and ventilation mode changes in order to distinguish between "clinician" usage and "patient" usage.

Oxygen Enrichment

Oxygen may be supplied from an external, low pressure source, but the oxygen flow must be limited to 15 lpm (50 kPa, 500 mbar). The ventilator automatically compensates for the extra flow created by the external oxygen supply (refer to chapter 4, "Installation and Assembly")

Breathing Circuit

The ventilator can be used with a single or double limb patient circuit. If exhaled volume monitoring is required (such as ventilator dependant patients), use the double-limb circuit for exhaled tidal volume monitoring. For more information, refer to section 4.4, "Patient Circuit".

Warning

Users must always possess an additional breathing circuit and exhalation valve while using the Device name.

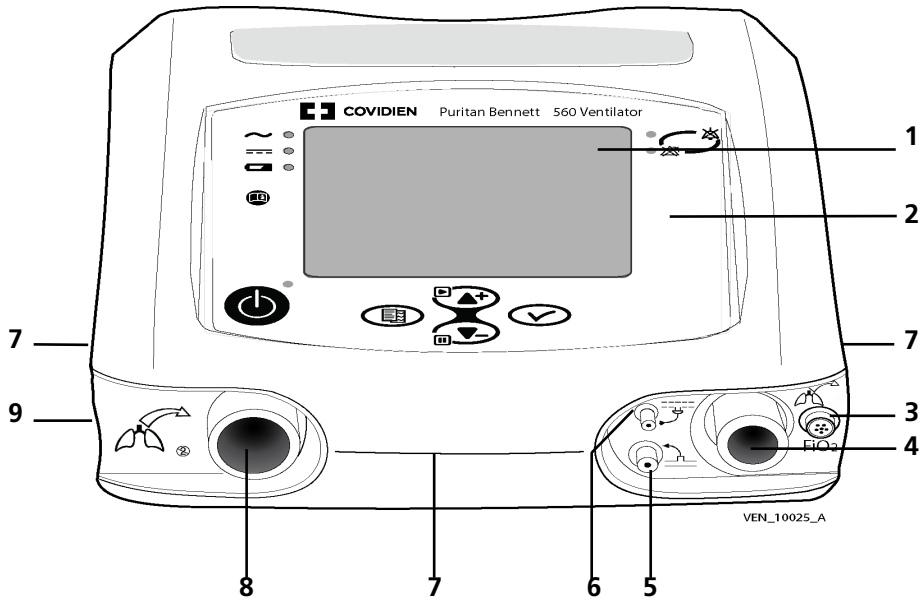
2.4 Device Classification

The ventilator's IEC / EN 60601-1classification is as follows:

- Protection/Insulation class (electric shock): Class II
- Protection index of enclosure: IP31
- Medical device directive classification: II B
- Degree of protection against risk of electric shock: BF
- Power: External (AC – mains, or DC – cigarette lighter) or internal (DC – battery)
- Operation mode: Continuous operation

For additional information, refer to section A, "Specifications."

2.5 Front Panel

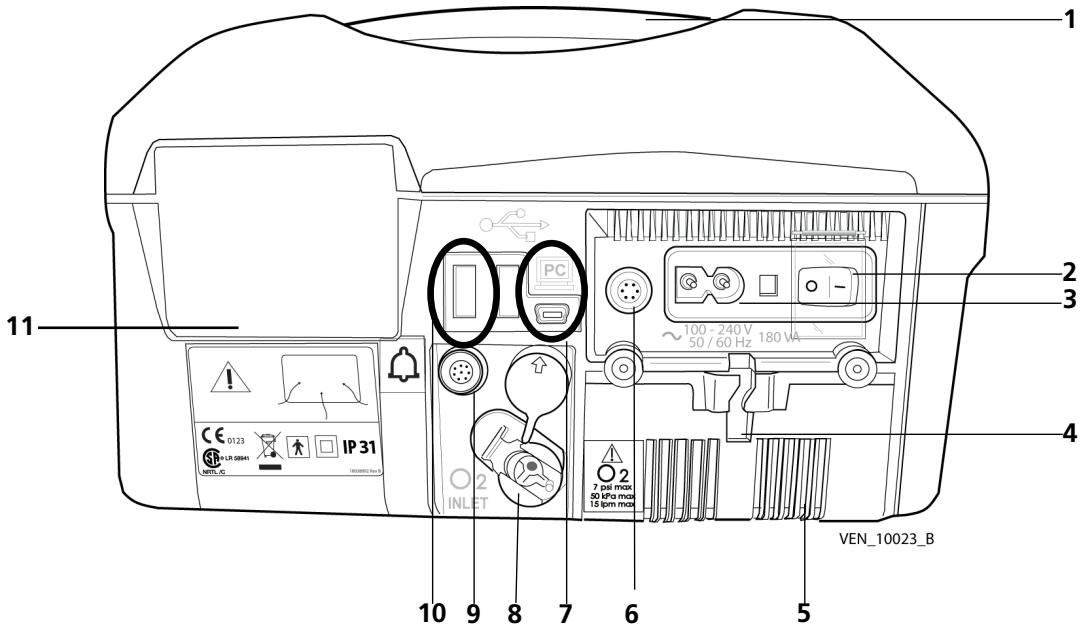


1	**LCD Display –** Displays information about the ventilator including patient hours and software version, ventilation modes and settings, and monitored and calculated patient data and waveforms. The display also allows the user to view and, using the Control Panel, adjust the ventilator's operating and alarm configuration settings.	**6**	**Exhalation Valve Port –** Nipple for providing piloting pressure to the exhalation valve. Controls the open-closed position of the exhalation valve.
2	**Control Panel –** Features the controls for setting up and operating the ventilator, and LEDs to indicate the ventilator's power source, ventilation On/Off status, and alarm priority level. Control functions include turning on and off the ventilation, configuring ventilation modes, silencing and cancelling alarms, and setting device and alarm parameters.	**7**	**Lateral and Front Openings –** Vents that allow for air circulation to cool the ventilator's internal components. In addition, these openings function as sound ports for audible alarms. ⚠ **Do not cover or obstruct these openings.**
3	**FIO_2 Sensor Connection -** Connection for FIO_2 sensor which monitors the amount of oxygen in the patient circuit.	**8**	**From Patient Port -** Exhaled volume measurements are taken from this port, through which a portion of the exhaled gas is diverted to the exhalation flow sensor. VTE is calculated from this flow measurement.[a]
4	**Patient Connection Port –** Provides an outlet for the gas to be delivered to the patient via the patient circuit.	**9**	**Exhaled Gas Outlet–** Exhalation Valve connects here.
5	**Patient Pressure Monitoring Port –** Nipple for monitoring proximal patient pressure.		

a. If exhaled tidal volume monitoring is required, use the double-limb circuit.

Figure 2-1. Front Panel

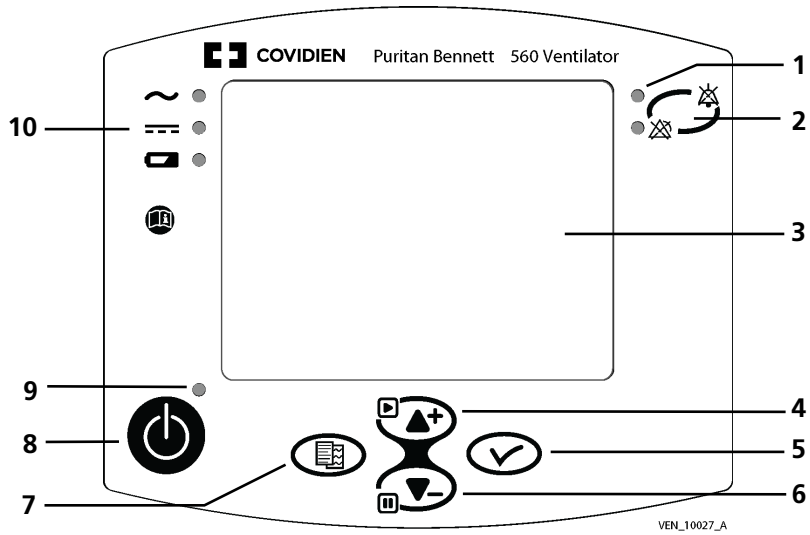
2.6 Back Panel



1	Ergonomic carrying handle.	**7**	PC Cable Connector: USB mini-B connector used for Puritan Bennett™ Ventilator Test Software.
2	On/Off (I/O) switch with protective cover: Device powered on in position I; device switched off in position 0.	**8**	O_2 Inlet Port: Connects the ventilator to a low pressure oxygen source via an adaptor connected to the O_2 Inlet (refer to section 4.8, "Oxygen").
3	AC power ("Mains") cable connector.	**9**	Nurse Call Output Connector: Used to connect the ventilator to the nurse call system.
4	AC power ("Mains") cable holding system: Secures AC power cable to avoid accidental disconnection.	**10**	USB Memory Device connection: USB connection to be used with Puritan Bennett™ Respiratory Insight Software. There are two USB type A ports.
5	Access cover for the internal battery.	11	Air Inlet Filter: Filters air as it enters the ventilator.
6	DC power cable connector with key.		

Figure 2-2. Back Panel

2.7 Control Panel

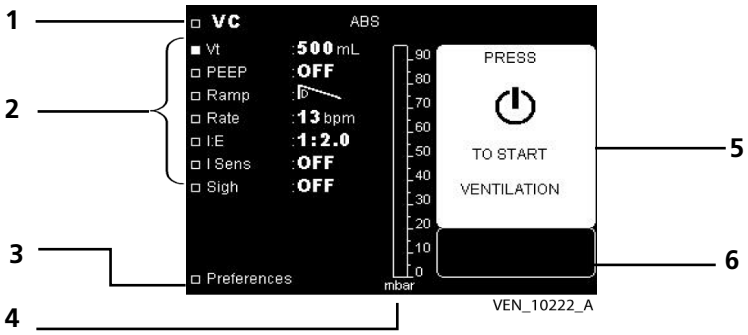


1	Alarm indicators (two LEDs): Red indicator: • Continuous: Very High Priority (VHP) alarm activated • High priority (HP) alarm activated. Yellow indicator: • Medium priority (MP) alarm activated.	**6**	DOWN/FREEZE key: • Moves the cursor down and decreases parameter values. • During ventilation, freezes displayed waveform in the Waveform menu.
2	ALARM CONTROL key: • Press once to silence an audible alarm for 60 seconds. • Press twice to halt visual and audible alarms. If alarm is remedied, the alarm is cancelled (other than the high pressure alarm).	**7**	MENU key: Changes the displayed menu. From the Ventilation menu screen, press this key to display the Alarm menu screen. When a USB memory device is inserted into the ventilator, press this key to display the USB memory device screen.
3	Display screen: Display of modes, ventilation settings, patient data and waveforms, configuration of the ventilator and alarm management.	**8**	VENTILATION ON/OFF button: • ON: Press briefly and release to start ventilation. • OFF: Press and hold for three (3) seconds,then press again to stop ventilation.
4	UP/UNFREEZE Key: • Moves the cursor up and increases parameter values. • During ventilation reactivates waveform tracing in the Waveform menu.	**9**	Ventilation status indicator: • Blue indicator illuminated: device is powered on and ventilation is off (on standby). • Blue indicator off: ventilation is on.
5	ENTER key: • Access to a setting value and validation of the modification of this setting. • Access to a sub-menu.	**10**	Electrical power source indicators: • AC POWER indicator lit: AC power source connected. • DC POWER indicator lit: DC power source connected. • INTERNAL BATTERY indicator lit continuously: Internal battery in use (no external power source connected.) • INTERNAL BATTERY indicator flashing: battery charging.

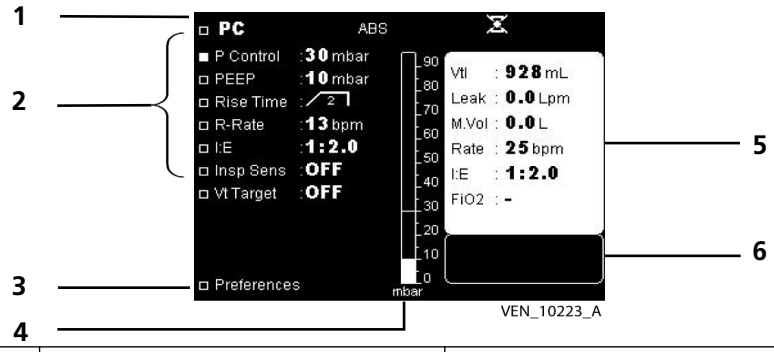
Figure 2-3. Control Panel

2.8 Ventilation Menu

Ventilation menu with ventilation on standby.



Ventilation menu during ventilation.

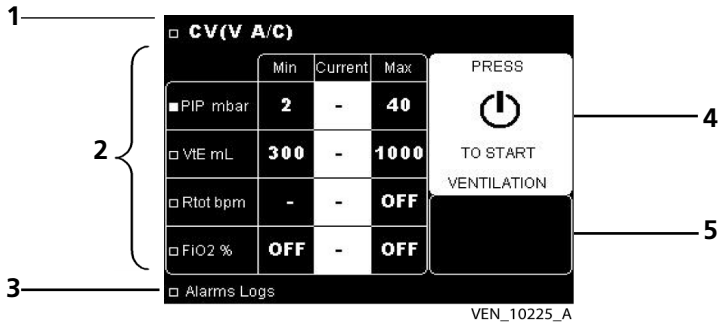


1 General information line: Displays the current ventilation mode, along with the following: • Battery symbol if the device is powered by the internal battery. • Audio paused symbol if an alarm is currently inhibited. • Alarm paused symbol if an alarm has been cancelled manually and the cause of the alarm remains. • Apnea Alarm deactivation • Exhalation valve symbol. • No exhalation valve symbol. • Absolute ABS symbol. • Relative REL symbol.	**2** Ventilation settings: Displays the specific ventilation parameter values for the currently selected ventilation mode.	**3** Preferences menu access line: Highlight this line and press the ENTER key to display the Preferences menu.
4 Bargraph: Displays pressure generation during ventilation.	**5** Status/monitored data window: • Ventilation stopped (Standby): displays the message, "PRESS TO START VENTILATION." • Ventilation on: parameters are monitored and displayed. • The Inspiratory Effort Detected symbol appears adjacent to the monitored I:E ratio when the patient actively triggers a breath.	**6** Alarm conditions window: • For Active alarms, scrolls through active alarm messages in flashing reverse video. • For Inactive alarms, displays the last alarm along with its trigger date and end-of-event time. Refer to chapter 3, "Alarms and Troubleshooting" for details.

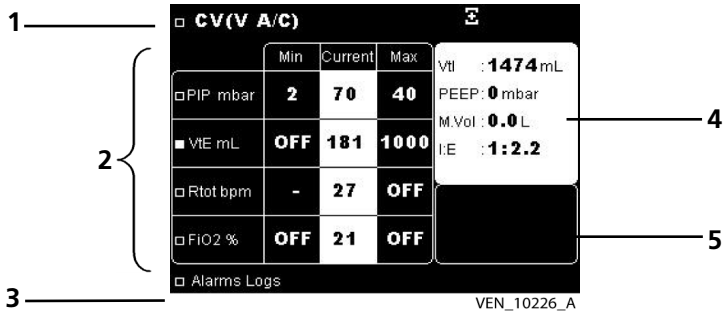
Figure 2-4. Ventilation Menu Display

2.9 Alarm Menu

Alarm menu with ventilation on standby.



Alarm menu when not in standby.

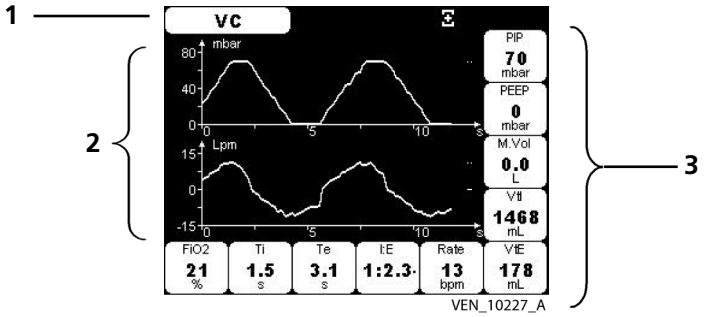


1 Title line: Displays ventilation mode and the following symbols: • Battery if the ventilator is powered by the internal battery. • Audio paused if an alarm is currently inhibited. • Alarm paused if an alarm has been cancelled manually and the cause of the alarm remains. • Apnea Alarm deactivation • Exhalation valve symbol. • No exhalation valve symbol.	**2** Alarm settings: Displays the specific alarm parameter values for the currently selected ventilation mode, which are: • Min and Max alarm threshold settings, and • Current monitored patient readings, or hyphen (-) when ventilation is in standby.	**3** Access line to Alarm Logs menu. Highlight this line and press the ENTER key to display the Alarm Logs menu. Refer to manual section 3.3, "Alarm Logs Menu".
4 Status/monitored data window: • Ventilation stopped (Standby): displays the message, "PRESS TO START VENTILATION." • Ventilation on: parameters are monitored and displayed. • The Inspiratory Effort Detected symbol appears adjacent to the monitored I:E ratio when the patient actively triggers a breath.	**5** Alarm message window: • For Active alarms, scrolls through active alarm messages in flashing reverse video. • For Inactive alarms, displays the last alarm along with its trigger date and end-of-event time. Refer to chapter 3, "Alarms and Troubleshooting" for more information.	

Figure 2-5. Alarm Menu

2.10 Waveforms Menu

The display of waveforms (Figure 2-6) is optional and can be selected using the Menu key The Waveform menu is only accessible when ventilation is active.



1	Title line: • Displays ventilation mode and the following symbols: • Battery if the ventilator is powered by the internal battery. • Audio paused if an alarm is currently inhibited. • Alarm paused if an alarm has been cancelled manually and the cause of the alarm remains. • Apnea Alarm deactivation. • Freeze Waveforms if the tracing of patient waveforms has been halted during ventilation. • Exhalation valve symbol. • No exhalation valve symbol.	**2**	Graphic zone: Displays the patient's pressure and flow waveforms as a function of time.	**3**	Numeric zone: Displays monitored data.

Figure 2-6. Waveforms Menu

2.11 USB Memory Device Menu

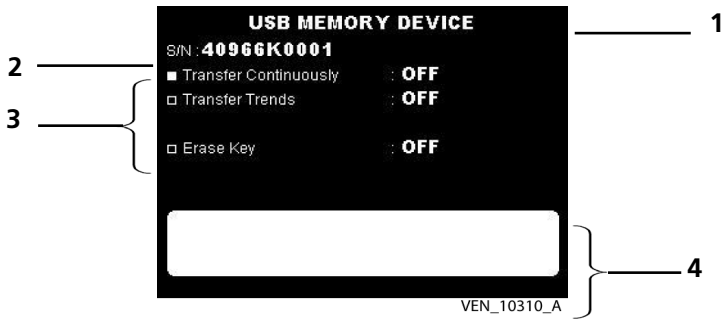


Figure 2-7. USB Memory Device Menu

1	Title line	**3**	USB Memory Device Menu
2	Ventilator serial number	**4**	Dialogue box

2.12 If Ventilator Failure Occurs

If a problem with the ventilator is suspected, FIRST CHECK THAT THE PATIENT IS NOT IN DANGER. If necessary, remove the patient from the ventilator and provide an alternate means of ventilation.

Keep in mind that troubleshooting information is available in this manual to assist you in the event of a problem. Refer to chapter 3, "Alarms and Troubleshooting".

If you cannot determine the cause of a problem, contact your equipment supplier or Covidien. Refer to chapter 8.3, "Service Assistance"

3 Alarms and Troubleshooting

Warning

Setting Alarm limits to extreme values can cause the ventilator alarms to malfunction.

When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.

Note:

Many of the functions of the ventilator are not accessible when the Locking key is enabled. For additional assistance contact your Clinician or equipment representative.

Default alarm setting preferences should be entered prior to using the ventilator.

The alarms or faults generated by your Puritan Bennett™ 560 Ventilator are classified into two categories:

- Ventilation (or utilisation) alarms
- Technical faults

Some of the ventilator alarms are adjustable, depending on ventilation modes. Automatic, non-adjustable alarms also exist to create a safety net for safer patient ventilation.
Alarms indicate events likely to affect the ventilation in the short term and necessitate rapid intervention (refer to section 3.8, "Troubleshooting").
Technical faults do not directly affect machine operation. Therefore, the user is not alerted to technical faults. Only authorised and trained technicians may consult the maintenance menu (refer to the Puritan Bennett™ 560 Service Manual).

3.1 Alarm Level of Priority

The alarm hierarchy for signalling the level of alarm criticality is listed below.

- **Very High Priority (VHP): Immediate critical situation; ventilation is impossible:**

  Continuous Sound Signaling / With or Without Continuous Red LED Illumination / With or Without Message / With or Without Display Lighting (it is possible for an alarm condition to occur that may not have **both** a message and lighting).

- **High Priority (HP): Critical situation in the short term; ventilation is potentially compromised:**

  High Speed Intermittent Sound Signaling / Flashing Red LED Illumination / With Message / With Display Lighting

- **Medium Priority (MP): Critical situation in the long term; ventilation is not affected in the short term:**

  Medium Speed Intermittent Sound Signaling / Flashing Yellow LED Illumination / With Message / With Display Lighting

Note:

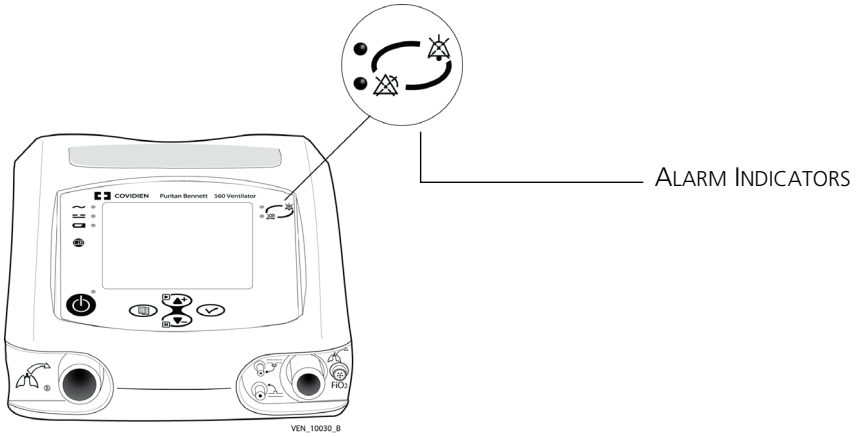
If there is no corrective action and if the audible alarm is not inhibited (Audio Paused) or reset (Alarm Reset) within 60 seconds, High Priority alarms will sound at the maximum level of 85 dB(A).

There are currently no Low Priority (LP) Alarms.

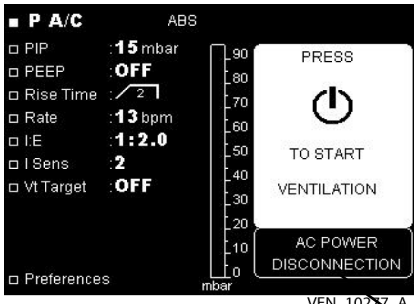
3.2 Alarm Display

During operation, when an alarm is activated:

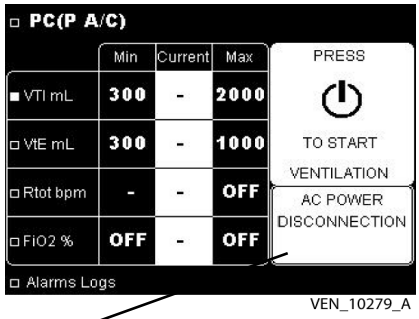
- One of the red or yellow alarm indicators to the left of the **ALARM CONTROL** key illuminates and flashes.
- An alarm tone sounds.
- A message is displayed and flashes in reverse video at the bottom of the Ventilation Menu or Alarm Menu.



VENTILATION MENU



ALARM MENU



ALARM MESSAGES

Note:

There are currently no Low Priority (LP) Alarms.

When an alarm is triggered, if the current menu displayed is not the Ventilation parameters or Alarm menu, the display automatically switches to one of these menus to display the alarm message.

In the event several alarms are activated at the same time, the highest priority audible and visual alarm is highlighted; however, all active messages are displayed, in the sequence in which they occurred.

3.3 Alarm Logs Menu

All alarms are recorded in the internal memory of the ventilator at the time they are activated.
The Alarm Logs menu is used to display the last eight (8) alarms activated, along with their date and time of activation.

To access the Alarm Logs menu, do the following:

1. Press the **MENU** key to access the alarm setting menu (if this is not the menu currently displayed).
2. Press the **DOWN** key several times or press until the cursor is on the "Alarm Logs" line at the bottom of the page. The display appears as follows:

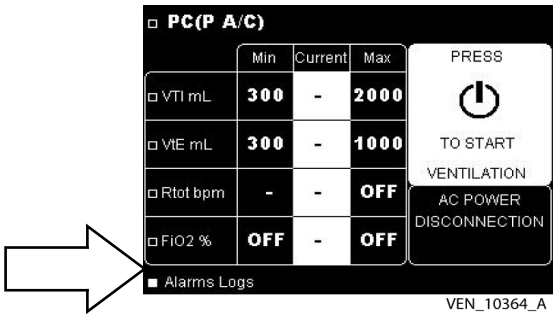


Figure 3-1. Accessing Alarm Logs Menu

3. Press the **ENTER** key. The Alarm Logs screen is displayed.

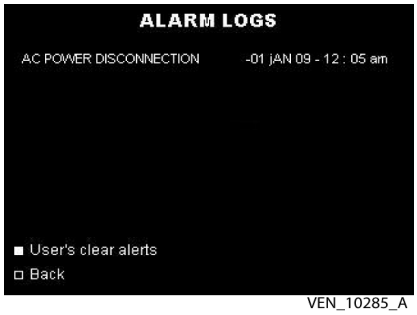


Figure 3-2. Displaying the Alarm Logs Screen

Note:
When no alarm has been activated, "NO DATA" is displayed on the screen (see graphic below).

Figure 3-3. Alarm Logs Display when No Alarm Activated

For more information on the "USER'S CLEAR ALERTS" line, refer to section 3.6, "Re-activating Alarms".

To dismiss the Alarm Logs screen manually:

Press the **ENTER** key when the cursor is on the "Back" line.

The Alarm Logs screen is dismissed automatically:

- After 15 seconds if no keyboard action is detected
- When a High Priority alarm is triggered

Note:

Only qualified service personnel may access all alarms and events recorded by the ventilator. Qualified personnel should refer to the Puritan Bennett™ 560 Service Manual for further information.

3.4 Silencing the Audible Portion of Alarms

You may silence the audible portion of alarms for 60 seconds at a time. This is referred to as the Audio Paused function.

To silence the audible portion of activated alarms:

Press the **ALARM CONTROL** key.

- The audible portion of all activated alarms is paused.
- The visual portions (light indicator and message) of activated alarms remain visible.
- The Audio Paused symbol is displayed at the top right of the screen while the audio pause function is active.

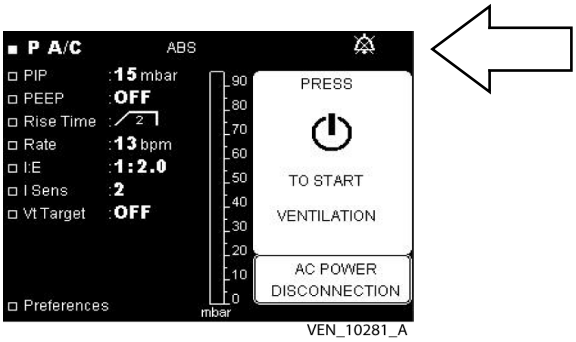


Figure 3-4. Silencing the Audible Portion of Alarms

If several alarms are activated at the same time, pressing the **ALARM CONTROL** key affects all current alarms.

The audible portion of activated alarms is automatically reactivated:

- After 60 seconds, if the cause(s) of the alarm(s) persist(s)
- Whenever a new alarm is activated

Note:

If a key is stuck or held down for 45 seconds a keypad alarm will occur.

3.5 Pausing/Resetting Alarms

Warning

Alarm volume should be adjusted with respect to the ventilator's operating environment and so that the patient's caretakers can hear the alarms. The audible alarm vents located at the front of the device should never be obstructed. The alarm can be paused with the Alarm Pause function by pressing the ALARM CONTROL key twice once the alarm has been declared.

When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.

Some alarms are not automatically cancelled when the condition causing the alarm clears e.g. HIGH PRESSURE. Some alarms can be paused manually even if the cause(s) of their activation remain(s).

To manually pause an alarm, proceed as follows:

Press the **ALARM CONTROL** key twice.

- The alarm is paused until the alarm condition is corrected and the condition reoccurs: the audible portion, light indicator, and message are all halted (for the alarms which can be paused manually).
- The Alarm Paused symbol is displayed at the top right of the Ventilation, Alarms, and Waveforms screens. Refer to the following graphic:

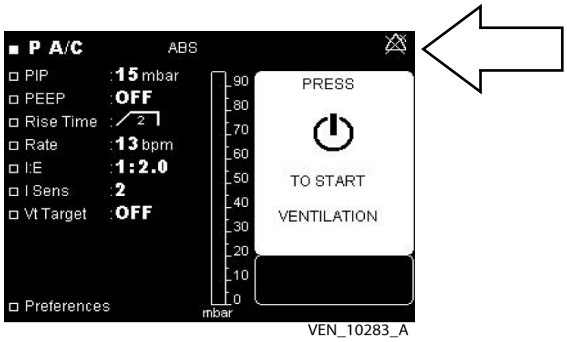


Figure 3-5. Manually Pausing Alarms

When no other alarms are currently activated, the last alarm cancelled is displayed continuously in the alarm message window in the Alarms menu, along with the date and time of its activation. The High Pressure alarm must be manually reset. Refer to section 3.7, "Overview of Alarms".

To manually reset the High Pressure Alarm, proceed as follows:

Press the **ALARM CONTROL** key twice.

- The visual alarms will be reset.

3.6 Re-activating Alarms

Alarms that have been paused and whose activation conditions continue to exist can be reactivated.

To reactivate alarms, proceed as follows:

1. Press the **MENU** key to access the Alarm Setting menu, if this is not the menu currently displayed.
2. Press the **DOWN** key to position the cursor on the "Alarm Logs" line, if this is not already
   the case. Refer to the following graphic:

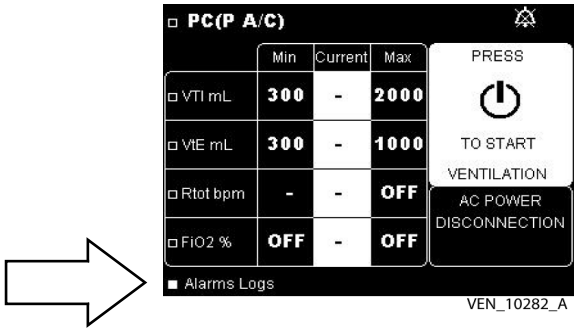


Figure 3-6. Reactivating Alarms

3. Press the **ENTER** key, to confirm access to the "Alarm Logs" menu.
4. Press the **UP** key to position the cursor on the "USER'S CLEAR ALERTS" line. Refer to the following graphic:

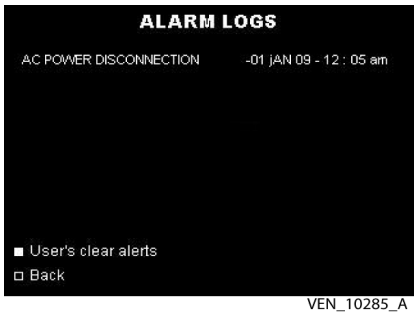


Figure 3-7. Alarm Logs

5. Press the **ENTER** key for at least three (3) seconds. The following events occur:
   - A "beep" sounds.
   - An audible alarm sounds.
   - An alarm indicator illuminates.
   - The messages of all active alarms are displayed in a loop in the Ventilation and Alarm menus.
   - The Audio Paused symbol disappears (if it was displayed).
   - The Alarm Paused symbol disappears.

3.7 Overview of Alarms

Note:

The message: "*IF PERSISTS RESTART/SRVC" will occur only if the alarm condition continues for longer than 30 seconds.

Note:

Many of the functions of the ventilator are not accessible when the Locking key is enabled. For additional assistance contact your Clinician or equipment representative.

Table 3-1. Overview of Alarms

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
AC POWER DISCONNECTION	Cut-off of the AC (mains) power supply. Alarm activation occurs: • After 5 seconds if ventilation is stopped • At the start of a ventilation cycle when ventilation is in progress. Consequence: switch over to external DC power supply if present, otherwise to the internal battery.	MP	Yes	Yes
APNEA	No inspiratory trigger detected by the ventilator after the apnea time set in PSV, CPAP, P SIMV and V SIMV modes. Automatically clears itself after two successive patient breaths.	MP	Yes	Yes – except for CPAP
BATTERY FAULT1 RESTART/SRVC	Ventilator has detected an internal battery fault. Consequence: the internal battery is disabled from use.	MP	Yes	No
BATTERY FAULT2 RESTART/SRVC	No internal battery detected.	MP	Yes	No
BUZZER LOW BATTERY	Occurs when the buzzer battery is too low to sound the POWER SUPPLY LOSS alarm.	MP	Yes	Yes
BUZZER FAULT1 RESTART/SRVC	Defective operation of the buzzers.	MP	Yes	No
BUZZER FAULT2 RESTART/SRVC	Failure detected in the Very High Priority buzzer. Consequence: no audible alarm in case of POWER SUPPLY LOSS alarm.	MP	Yes	Yes
BUZZER FAULT3 RESTART/SRVC	Battery Charge Failure due to incorrect voltage. Contact your service representative for assistance.	HP	Yes	No

Table 3-1. Overview of Alarms (Continued)

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
BUZZER FAULT4 RESTART/SRVC	Buzzer Battery Failure. The Battery Buzzer Voltage is too low. Internal technical problem that prevents the battery sounding the POWER SUPPLY LOSS alarm.	MP	Yes	Yes
CALIBRATE FIO_2	An FIO_2 sensor is detected and has not been calibrated.	MP	Yes	Yes
CALIBRATION FAIL	Failure of one calibration point of the internal exhaled flow sensor. Consequence: failed calibration point is replaced by the default point.	MP	Yes	Yes
CHECK BATTERY CHARGE IF PERSISTS RESTART/SRVC	Internal battery charging failure. Consequence: charging of the internal battery impossible.	MP	Yes	Yes
CHECK EXH VALVE* *IF PERSISTS RESTART/SRVC	Inspired tidal volume during exhalation < 20% of Inspired tidal volume and Inspired tidal volume > 20mL. Exhalation valve obstructed.	HP	Yes	No
CHECK EXH VALVE PRESSURE	Internal ventilation fault related to exhalation valve detection sensor. (pressure sensor)	HP	Yes	Yes
CHECK FIO_2 SENSOR	FIO_2 measurement is less than 18%. Recalibrate or change FIO_2 sensor.	HP	Yes	No
CHECK PROXIMAL LINE1* *IF PERSISTS RESTART/SRVC	1. Loss of signal from the proximal pressure sensor Consequence: switch to internal pressure sensor for the pressure measurement. Alarm activation occurs: In the event of signal loss (1): After one ventilation cycle or In the event of signal loss (2) and after the 17^{th} breath cycle: After 17 seconds for P A/C and V A/C modes, or after the maximum time between 17 seconds and Apnea Time + 4 seconds for CPAP, PSV, P SIMV, and V SIMV modes	MP	Yes	No
CHECK REMOTE ALARM	No activation of Nurse Call or remote alarm system when an alarm is in progress.	MP	Yes	Yes

Table 3-1. Overview of Alarms (Continued)

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
CHECK SETTINGS	Alarm activation occurs: • Systematically after software versions have changed. • Loss of memorised parameters Consequence: • Locking Key disabled • Out-of-range settings are replaced by their default values	MP	Yes	Yes
CONNECT VALVE OR CHANGE PRESS	No exhalation valve connected with PEEP set to less than 4 mbar or PIP set to more than 30 mbar when relative pressure is set to OFF.	HP	Yes	No
CONTROLLED CYCLES	The ventilator is delivering apnea ventilation at set back up rate.	NA	No	No
COOLING FAN RESTART/SRVC	Ventilator cooling fan operating speed not suited to the internal ambient temperature of the device.	MP	Yes	Yes
DC POWER DISCONNECTION	Cut-off of the external DC power supply. Consequence: switch-over to the internal battery.	MP	Yes	Yes
DEVICE FAULT3 RESTART/SRVC	Failure in the 24 V power supply.	HP	Yes	No
DEVICE FAULT5 RESTART/SRVC	Detection of a fault in the electrical power supply system. Consequence: the internal battery capacity is not displayed beside the battery symbol.	MP	Yes	Yes
DEVICE FAULT7 RESTART/SRVC	Detection of a fault in internal voltage measurement.	HP	Yes	No
DEVICE FAULT9 RESTART/SRVC	POST RAM Error. RAM Read/Write does not match memory setting.	VHP	No	No
DEVICE FAULT10 RESTART/SRVC	POST FLASH Checksum Error. Startup FLASH computed checksum does not match memory setting.	VHP	No	No
DEVICE FAULT11 RESTART/SRVC	POST EEPROM Error. Startup EEPROM does not match memory setting.	VHP	No	No
DEVICE FAULT12 RESTART/SRVC	POST Reference Voltage Error. 5V or 10V reference voltage error.	VHP	No	No
DEVICE FAULT13 RESTART/SRVC	Software Version Error	VHP	No	No
E SENS FAULT OR CIRC LEAK	At least four of the last six spontaneous breaths are terminated by time.	MP	Yes	No

Table 3-1. Overview of Alarms (Continued)

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
EMPTY BATTERY	Internal battery capacity < 10 min. or 3%. (battery voltage < 22.5V) Consequence: ventilation comes to a halt.	HP	No	No
EXH VALVE LEAKAGE	Abnormally high expired flow during the inspiratory phase of three consecutive breaths (in double-limb setup). Alarm activation occurs: After three consecutive breaths.	MP	Yes	No
FIO_2 SENSOR MISSING	No FIO_2 sensor detected and the FIO_2 alarm is active.	HP	Yes	Yes
HIGH / LOW BATTERY TEMP* *IF PERSISTS RESTART/SRVC	Battery temperature out of tolerance. Consequence: battery charging stops.	MP	Yes	Yes
HIGH FIO_2	The level of oxygen delivered by the ventilator exceeds the Max FIO_2 level set.	MP	Yes	No
HIGH INT TEMP COOL VENT* *IF PERSISTS RESTART/SRVC	Device internal ambient temperature out of tolerance range.	MP	Yes	Yes
HIGH LEAKAGE	The LEAK estimated by the ventilator exceeds the Max LEAK alarm threshold.	MP	Yes	No
HIGH PRESSURE	• In V A/C or V SIMV modes, if Inspiratory Pressure is higher than Max PIP during three consecutive cycles. or • In PSV, CPAP, P A/C, or P SIMV modes, if Inspiratory Pressure is higher than (P Support or P Control + PEEP) + 5 mbar up to 29 mbar or + 10 mbar over 30 mbar during three consecutive cycles. or • In PSV or CPAP mode and P Support is set to off, if Inspiratory Pressure is higher than PEEP + 10 mbar during three consecutive cycles. Alarm activation occurs: • After three consecutive breaths. Consequence: • Switch to exhalation phase.	HP Note: When alarm condition clears, alarm priority indicator must be manually reset by pressing the key.	Yes	No (The visual portion of the alarm may be paused)

Table 3-1. Overview of Alarms (Continued)

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
HIGH RATE	Rate measured greater than Max Rtot set during three consecutive breaths. Alarm activation occurs: • After three consecutive breaths.	MP	Yes	No
HIGH VTE	Expired tidal volume greater than Max VTE set during three consecutive breaths (in double limb setup). Alarm activation occurs: • After three consecutive breaths.	MP	Yes	No
HIGH VTI	Inspired tidal volume greater than Max VTI set during three consecutive breaths in PSV, CPAP, P A/C, P SIMV, and V SIMV modes. Alarm activation occurs: • After three consecutive breaths.	HP	Yes	No
INSP FLOW RESTART/SRVC	Inspiratory flow is constant (± 1 lpm) with normal turbine temperature and speed conditions. Contact your service representative for assistance.	HP	Yes	No
INTENTIONAL VENT STOP	Ventilation has been stopped voluntarily by the caregiver or patient.	HP	Yes	Yes
KEYPAD FAULT RESTART/SRVC* *IF PERSISTS RESTART/SRVC	Keyboard key held down for more than 45 seconds.	HP	No	No
LOW BATTERY	Internal battery capacity < 30 min. or 8%.	HP	Yes	No
LOW FIO_2	The level of oxygen delivered by the ventilator is below the Min FIO_2 level set.	MP	Yes	No
LOW VTE	Expired tidal volume less than Min VTE set during three consecutive breaths (in double-limb setup). Alarm activation occurs: • After three consecutive breaths.	MP	Yes	No
LOW VTI	Inspired tidal volume less than Min VTI set during three consecutive breaths in PSV, CPAP, P A/C, P SIMV and V SIMV modes. Alarm activation occurs: • After three consecutive breaths.	MP	Yes	No
NO PROXIMAL LINE2* *IF PERSISTS RESTART/SRVC	Proximal pressure < 0.6 mbar for 100 ms during inspiration phase of 3^{rd} breath cycle. Ventilator response: Switch to internal pressure sensor for pressure measurement.	MP	Yes	No

Table 3-1. Overview of Alarms (Continued)

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
OCCLUSION CHECK CIRCUIT* *IF PERSISTS RESTART/SRVC	Occurs in VALVE configuration when the tidal volume is measured below 20ml during three consecutive breaths for PSV, CPAP, PA/C and P SIMV modes. Alarm activation occurs after three consecutive breaths if the tidal volume is less than 20 mL.	HP	Yes	No
OCCLUSION CHECK CIRCUIT	Occurs in LEAK configuration when the LEAK level is not sufficient to flush the CO_2 from patient exhalation. The built-in LEAK in the mask may be obstructed. The built-in leak for the mask is not sufficient for the settings.	HP	Yes	No
PATIENT DISCONNECTION* *IF PERSISTS RESTART/SRVC	Alarm activation occurs if conditions remain for the maximum time between: • disconnection time and 60/R-Rate in P A/C and V A/C mode • disconnection time and (Apnea time +2 sec) in CPAP and PSV mode • disconnection time and (60/R-Rate + Insp time) in P SIMV and V SIMV mode.	HP	Yes	No
	If the flow is greater than 130 lpm during the inspiratory phase.			
	In V A/C and V SIMV modes, if patient pressure is lower than Min PIP.			
	In PSV, CPAP, P A/C modes and P SIMV if patient pressure is lower than (P Support + PEEP) - 20% or (P Control + PEEP) - 20%.			
POWER FAULT RESTART/SRVC	Detection of a fault in the electrical power supply system.	MP	Yes	Yes
POWER SUPPLY LOSS (no message)	1. Electrical power supply to the machine is interrupted with the I/O switch when ventilation is in progress or 2. Battery fully discharged when it was the only source of power to the ventilator. Consequence: ventilation stops immediately. Ventilation restarts immediately when the switch is pressed in case 1 (above) or after restoration of the AC or DC supply in case 2 (above).	VHP	No	Yes

Table 3-1. Overview of Alarms (Continued)

Alarm Message	Cause/Ventilator Response	Priority	Audio Paused Avail.	Alarm Paused Avail.
PRES SENS FLT1 RESTART/SRVC	Faulty internal pressure sensor signal. Alarm activation occurs: • After 15 seconds.	HP	Yes	No
PROX SENS FLT2 RESTART/SRVC	Faulty proximal pressure sensor signal. Alarm activation occurs: • After 15 seconds.	MP	Yes	Yes
REMOVE VALVE CPAP MODE	The ventilation settings are not compatible with the type of patient circuit used. Remove exhalation valve to start CPAP ventilation.	HP	Yes	No
REMOVE VALVE OR CHANGE PRES	The ventilation settings are not compatible with the type of patient circuit used. With a valve circuit, the difference between PIP and PEEP should not be less than 5 mbar.	HP	Yes	No
SOFTWARE VERSION ERROR	Detection of a wrong software version.	NA	NA	NA
TURB OVERHEAT RESTART/SRVC	Turbine speed too low and temperature too high. Consequence: ventilation stops immediately and O_2 supply stops.	HP	No	No
UNKNOWN BATTERY	The internal battery is not recognised as a Puritan Bennett™ product battery.	MP	Yes	No
VALVE MISSING CONNECT VALVE	Connect exhalation valve to start ventilation in V A/C or V SIMV / P SIMV modes.	HP	Yes	No
VTI NOT REACHED* *IF PERSISTS RESTART/SRVC	Measurement and calculation of tidal volume do not match Vt set during six consecutive breaths in VOL inspired and V SIMV modes. Alarm activation occurs: • After six consecutive breaths—once the ventilator has reached its performance limits.	HP	Yes	No

3.8 Troubleshooting

Warning

This manual tells you how to respond to ventilator alarms, but it does NOT tell you how to respond to the patient.

To ensure proper servicing and avoid the possibility of physical injury to personnel or damage to the ventilator, only personnel authorised and qualified by Covidien should attempt to service or make authorised modifications to the Puritan Bennett™ 560 Ventilator.

3.8.1 Alarms

Table 3-2 offers a guide to the most likely ventilator alarms, possible reasons for the alarms, and corrective actions.

Warning

Do not attempt to open, repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only personnel authorised and qualified by Covidien should repair, open or service the ventilator.

When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.

Note:

The ventilator screen must be unlocked before setting and parameters can be changed.

Many of the functions of the ventilator are not accessible when the Locking key is enabled. For additional assistance contact your Clinician or equipment representative.

Table 3-2. Alarms and Corrective Actions

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
AC POWER DISCONNECTION	AC (“mains”) power source cut off.	Cancel the alarm then check the supply cable and/or the effective availability of a voltage on the AC power (“mains”) port. Cancel the alarm then check the power cable availability of a voltage on the AC power (“mains”) outlet.
	Starting with 12 – 30 VDC external power supply.	Cancel the alarm.
	Current-limiting fuse of the device blown.	Replace the ventilator and call for the maintenance technician.
APNEA	Patient’s breathing effort less than the Sensitivity control setting.	Ensure the patient is breathing and adjust the inspiratory setting appropriately based on patient’s respiratory needs.
	Patient apnea.	Examine the patient for breathing effort and stimulate if necessary. If patient status has changed adjust the ventilator settings based on patient’s respiratory needs.
	Defective sensors.	Have a qualified technician replace the defective component(s) and call your customer service representative.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
BATTERY FAULT1 RESTART/SRVC	Battery problem that prevents it from operating.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
BATTERY FAULT2 RESTART/SRVC	Internal battery missing or not detected.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
BUZZER FAULT1 RESTART/SRVC	Defective operation of the buzzers. Consequence: no audible tone when an alarm is activated.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
BUZZER FAULT2 RESTART/SRVC	Internal technical problem that prevents the very high priority "POWER SUPPLY LOSS" alarm from triggering.	Ensure that the protective cover over the I/O switch located on the rear of the device is intact and functioning properly. This cover helps prevent accidental pressing of the I/O switch and stoppage of the ventilation. Ensure that the device is stabilised. Call your customer service representative.
BUZZER FAULT3 RESTART/SRVC	Internal technical problem that prevents the battery from correctly charging.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
BUZZER FAULT4 RESTART/SRVC	Internal technical problem that prevents the battery warning buzzer from sounding POWER SUPPLY LOSS alarm.	Connect the ventilator to AC power and switch on the device using the on/off at the rear of the ventilator (I/O). Leave to charge for at least 15 minutes. If persists restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
BUZZER LOW BATTERY	Buzzer battery is too low to sound POWER SUPPLY LOSS alarm.	Connect the ventilator to AC power and switch on the device using the on/off at the rear of the ventilator (I/O). Leave to charge for at least 15 minutes.
CALIBRATE FIO_2	An FIO_2 sensor is detected and has not been calibrated.	Calibrate FIO_2 sensor.
CALIBRATION FAIL	Too large a difference between a calibration point and its tolerance range.	Restart calibration. There may be a leak in the circuit. Ensure an approved circuit is in use (refer to circuit documentation).
	Incorrect circuit type selected in the Preferences menu.	Verify the circuit selection in the Preferences menu matches the circuit in use.
	Exhalation block defective or not properly aligned.	Reset alarm message and ensure all connections are secure, verify circuit integrity, and verify the exhalation block is properly seated.
	Defective exhalation flow sensor.	Have a qualified technician replace the defective component(s) and call your customer service representative.
CHECK BATTERY CHARGE	Battery charging impossible.	Do not disconnect the ventilator from the AC power supply. Ensure that the power cable is installed according to the instructions in chapter 4, "Installation and Assembly", so that the power cable cannot be involuntarily disconnected. In the event the internal battery capacity is low, use an alternate device to ventilate the patient. Call your customer service representative.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
CHECK EXH VALVE	Obstruction or abnormal damage of the exhalation valve.	Clean or replace the exhalation valve and/or its control tube.
	Excessive moisture in the exhalation block.	Remove moisture from exhalation block and valve. Verify exhalation valve is seated properly. Reduce temperature of the humidifier.
	Defective connection or defective exhalation valve tubing.	Reconnect the valve or replace the exhalation valve and/or the exhalation valve pilot pressure tube.
	Defective inspiratory flow sensor.	Have a qualified technician replace the defective component(s) and call your customer service representative.
CHECK EXH VALVE PRESSURE	The exhalation valve may not be detected by the ventilator when ventilation is started. Or the exhalation valve may be falsely detected when ventilation is started.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
CHECK FIO_2 SENSOR	FIO_2 measured is less than 18%.	Check that FIO_2 sensor is properly connected or Recalibrate FIO_2 sensor or Replace FIO_2 sensor.
CHECK PROXIMAL LINE1* *IF PERSISTS RESTART/SRVC	No connection of the proximal pressure tube when ventilation starts.	Reconnect the proximal pressure line.
	Proximal pressure line disconnected or obstructed.	Reconnect the connection line or replace it if obstructed. Check for moisture or occlusion of the proximal line. Reduce humidifier temperature. Switch to a heated wire circuit.
	Defective proximal pressure sensor or internal leak of the machine.	Restart ventilator to see if alarm clears. If not, have a qualified technician replace the defective component(s) and call your customer service representative.
CHECK REMOTE ALARM	Nurse Call or remote alarm system is disconnected.	Connect the Nurse Call or remote alarm cable to the ventilator.
	Relay control voltage problem.	Carefully monitor the patient to detect possible alarm triggering and call for the maintenance technician.
CHECK SETTINGS	Loss of memorised parameters.	Check and adjust the prescribed parameters, if necessary.
	Software versions have changed.	Check and adjust the prescribed parameters, if necessary.
CONNECT VALVE OR CHANGE PRESS	The ventilation settings are not compatible with the type of patient circuit used. No exhalation valve connected with PEEP set to less than 4 mbar or PIP set to more than 30 mbar when relative pressure is set to OFF.	Connect exhalation valve Decrease PIP to less than 30 mbar in absolute pressure. Increase PEEP to more than 3 mbar. **Note:** Always consult the clinician before changing PEEP, FIO_2, pressure, volume or Rate settings.
CONTROLLED CYCLES	The ventilator is delivering apnea ventilation at set back up rate.	Check that the patient circuit is correctly attached and the patient is correctly ventilated.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
COOLING FAN RESTART/SRVC	Operating speed of the cooling fan not properly adjusted for the internal ambient temperature of the device.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
DC POWER DISCONNECTION	12 – 30 VDC power supply cut off when there is no AC ("mains") power supply.	Cancel the alarm then check the supply wiring and/or the effective availability of voltage on the external source.
	Ventilator's current-limiting fuse blown.	Replace the ventilator and call your customer service representative.
DEVICE FAULT3 IF PERSISTS RESTART/SRVC	24 V supply failure.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
DEVICE FAULT5 IF PERSISTS RESTART/SRVC	Internal problem in the electrical power supply.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
DEVICE FAULT7 IF PERSISTS RESTART/SRVC	Internal technical problem.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
DEVICE FAULT9 IF PERSISTS RESTART/SRVC	POST RAM Error. RAM Read/Write does not match memory setting.	If patient has been disconnected, reconnect patient to reset the fault. If persists restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
DEVICE FAULT10 IF PERSISTS RESTART/SRVC	POST FLASH Checksum Error. Startup FLASH computed checksum does not match memory setting.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
DEVICE FAULT11 IF PERSISTS RESTART/SRVC	POST EEPROM Error. Startup EEPROM does not match memory setting.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
DEVICE FAULT12 IF PERSISTS RESTART/SRVC	POST Reference Voltage Error. 5V or 10V reference voltage error.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
DEVICE FAULT13 IF PERSISTS RESTART/SRVC	Incorrect software version detected.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
EMPTY BATTERY	Internal battery capacity is less than 10 min. (or 3%) —battery operation overextended.	Reconnect the device to an AC power outlet, connect it to an external DC power source, or replace the battery. Reminder: the internal battery can be charged only when the ventilator connected to an AC power supply.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
E SENS FAULT OR CIRC LEAK	Leak in the patient circuit, leak in patient artificial airway or vented mask interface.	**Note:** Always consult the clinician before changing PEEP, FIO_2, pressure, volume or Rate settings. Check and properly connect the patient circuit connections. Minimise the leak. Ensure O_2 connector is removed. Reduce inspiratory time. Increase E-Sensitivity setting. Check tracheotomy cuff. Refit mask. Use non-vented mask.
	E sensitivity setting not properly adjusted.	Check E Sensitivity setting **Note:** Always consult the clinician before changing PEEP, FIO_2, pressure, volume or Rate settings.
EXH VALVE LEAKAGE	Large leakage detected on the patient circuit return limb during the inspiratory phase.	Replace the exhalation valve and/or its control tube.
	Contaminated or defective exhalation flow sensor.	Restart ventilator to see if alarm clears. If not, have a qualified technician replace the defective component(s) and call your customer service representative.
FIO_2 SENSOR MISSING	There is no FIO_2 sensor and FIO_2 alarms are active.	If oxygen is to be delivered to the patient, connect FIO_2 sensor. If no oxygen is to be delivered to the patient, deactivate FIO_2 alarms.
HIGH FIO_2	The level of oxygen being delivered to the patient is higher than the Max FIO_2 limit set.	Check the level of oxygen corresponds to the patient's prescription or Increase the FIO_2 alarm threshold. **Note:** Always consult the clinician before changing PEEP, FIO_2, pressure, volume or Rate settings.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
HIGH INT TEMP COOL VENT	Internal ambient temperature of the device out of the tolerance ranges.	**Note:** Ensure that you are operating the ventilator within the proper temperature range (refer to Appendix A, "Specifications"). Put the device in a warmer environment (if the ambient temperature is too low) or in a cooler environment (if the ambient temperature is too high). For example, ensure the ventilator is not in direct sunlight or next to an air conditioning vent. ⚠ In case of operation in a high ambient temperature, handle the ventilator with care; some portions of the device may have high surface temperatures. ⚠ In the case of high ambient temperatures, it may take a significant period of time to cool the internal temperature of the ventilator to the proper operating range. To avoid injury to the patient, ensure that the air inspired by the patient does not exceed 41 °C (106 °F). If in doubt, replace the ventilator.
	Defective internal temperature probe or any other technical anomaly.	Replace the ventilator and call your customer service representative.
HIGH/LOW BATTERY TEMP* *IF PERSISTS RESTART/SRVC	Battery temperature out of the tolerance ranges. Defective internal temperature probe or any other technical anomaly inside the battery.	**Note:** Ensure that ventilator is being used according to the operating instructions found in Appendix A, "Specifications". If the ambient temperature is too low, place the device in a warmer environment. If the ambient temperature is too high, place the ventilator in a cooler environment. For example, ensure the ventilator is not in direct sunlight or next to an air conditioning vent. The temperature fault alarm does not interfere with the operation of the ventilator. ⚠ In case of operation in a high ambient temperature, handle the ventilator with care; some portions of the device may have high surface temperatures. Restart ventilator to see if alarm clears. if the alarm message persists, please contact technical services. **CAUTION:** Do not attempt to charge a defective battery; such a battery cannot be charged.
HIGH LEAKAGE	The LEAK estimated by the ventilator exceeds the Max LEAK alarm threshold.	Readjust mask to reduce leakage or Increase the alarm settings.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
HIGH PRESSURE	Adjustment of Max PIP too low (only for V A/C and V SIMV modes).	**Note:** Always consult the clinician before changing PEEP, FIO_2, pressure, volume or Rate settings. Increase the Max PIP threshold.
	Airway obstruction.	Check patient's trachea and clear the obstruction. If the filter is obstructed, replace the filter.
	Proximal pressure tube or patient circuit obstructed.	Clean the proximal pressure tube or the patient circuit or replace them.
	Coughing or other high-flow exhalation efforts.	Treat patient's cough. Silence the alarm, if necessary.
	Patient inspiratory resistance or compliance changes.	Have physician determine if ventilator settings are appropriate for the patient.
	Defective internal circuits of the machine or pressure sensor.	Replace the ventilator and call your customer service representative.
HIGH RATE	Adjustment of the Max Rtot level too low.	Re-adjust Max Rtot.
	Adjustment of the I Sens level too low.	Adjust I Sens according to the patient.
	Patient hyperventilating.	Silence the alarm and call for a medical team if the symptoms persist. Check for auto-cycling and adjust inspiratory sensitivity, manage leaks or drain condensation from patient circuit.
	Defective inspiratory flow sensor.	Have a qualified technician replace the defective component(s) and call your customer service representative.
HIGH VTE	Adjustment of the Max VTE level too low.	**Note:** Always consult the clinician before changing PEEP, FIO_2, pressure, volume or Rate settings. Modify the Max VTE level.
	Inappropriate patient circuit.	Replace the patient circuit. Ensure there is not excessive airflow near the exhalation block (such as a fan).
	Exhalation flow sensor not calibrated properly.	Calibrate the exhalation flow sensor.
	Defective exhalation flow sensor.	Replace the exhalation block and calibrate the exhalation flow sensor. Call your customer service representative.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
HIGH VTI	Adjustment of the Max VTI level too low (for PSV, CPAP, P A/C, P SIMV and V SIMV modes).	**Note:** Always consult the clinician before changing PEEP, FIO_2, pressure, volume or Rate settings. Modify the Max VTI level.
	Adjustment of the pressure level too high for the volume required (for PSV, CPAP, P A/C, P SIMV and V SIMV modes).	**Note:** Always consult the clinician before changing PEEP, FIO_2, pressure, volume or Rate settings. Modify the pressure level.
	A leak in the patient circuit causing increased bias flow.	Check and properly connect the patient circuit.
	Inappropriate patient circuit.	Replace the patient circuit.
	Defective flow sensor or internal leak in the machine.	Have a qualified technician replace the defective component(s) and call your customer service representative.
INSP FLOW RESTART/SRVC	Inspiratory flow is constant (± 1 lpm) with normal turbine temperature and speed conditions.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
INTENTIONAL VENT STOP	The user / caregiver has stopped ventilation using the **VENTILATION ON/OFF** key. Ventilation is in stand-by.	Check that the ventilation was switched off on purpose.
KEYPAD FAULT RESTART/SRVC	Pressing a key for more than 45 seconds.	Press and release keys in the normal, prescribed manner. Do not press keys for 45 seconds or more.
	A key on the keyboard is stuck.	If unsuccessful in releasing the stuck key(s), restart ventilator to see if alarm clears. If not, replace the device and call your customer service representative if the situation persists.
LOW BATTERY	Internal battery capacity is less than 30 min. (or 8%)—battery operation overextended.	Immediately connect the ventilator to an AC power outlet, or connect it to an external DC power source. Reminder: the internal battery can be charged only when the ventilator is connected to an AC power supply.
LOW FIO_2	The level of oxygen being delivered to the patient is below the Min FIO_2 limit set.	**Note:** Always consult the clinician before changing PEEP, FIO_2, pressure, volume or Rate settings. Check the level of oxygen corresponds to the patient's prescription or Decrease the FIO_2 alarm threshold.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
LOW VTE	Patient circuit obstructed.	Clean, unblock, and/or properly connect the patient circuit.
	Leak in the patient circuit.	Check and properly connect the patient circuit connections. May be caused by increased resistance across exhalation filter (such as excessive moisture).
	Exhalation block missing or disconnected.	Restore or connect the exhalation block (refer to section 4.7, "Exhalation Block"). If the exhalation block has been removed or replaced, calibrate the exhalation flow sensor. Call your customer service representative.
	Adjustment of a Min VTE threshold when the patient circuit is in a single-limb configuration.	Set the Min VTE alarm limit to OFF. ⚠ If exhaled tidal volume monitoring is required, use the double-limb circuit.
	Inappropriate patient circuit.	Replace the patient circuit with an appropriate one.
	Exhalation flow sensor not properly calibrated.	Calibrate the exhalation flow sensor.
	Defective exhalation flow sensor.	Replace the defective component(s) and calibrate the exhalation flow sensor. (Call your customer service representative.
	Adjustment of the Min VTE level too high.	Modify the Min VTE level.
LOW VTI	Adjustment of the Min VTI level too high (for PSV, CPAP, P A/C, P SIMV and V SIMV modes)	Modify the Min VTI level.
	Adjustment of the pressure level not enough to reach the volume required (for PSV, CPAP, P A/C, P SIMV and V SIMV modes).	Modify the pressure level according to the physician's prescription.
	Patient circuit obstructed or disconnected.	Clean, unblock, and/or reconnect the patient circuit.
	Inappropriate patient circuit.	Replace the patient circuit.
	Defective flow sensor or internal leak in the machine.	Check patient, replace the device and call your technician or customer service representative.
NO PROXIMAL LINE2	The proximal pressure line is disconnected.	Connect proximal pressure line.
PATIENT DISCONNECTION *IF PERSISTS RESTART/SRVC	Adjustment of Min PIP too high.	Decrease the Min PIP threshold.
	Leak or loose connection in the patient circuit. Circuit disconnection from patient or ventilator.	Check the patient circuit connections to the ventilator; examine all connections for leakage and tightness. Replace the patient circuit if necessary.
	Inspiratory flow exceeds 130 LPM.	Check Min PIP alarm setting. Adjust Apnea alarm setting.
	Inappropriate patient circuit.	Replace the patient circuit.
	Defective internal circuits of the machine or pressure sensor.	Restart ventilator to see if alarm clears. If not, have a qualified technician replace the defective component(s) or call your customer service representative.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
OCCLUSION CHECK CIRCUIT *IF PERSISTS RESTART/SRVC	Patient circuit obstructed.	Clean, unblock, and/or properly connect the patient circuit.
OCCLUSION CHECK CIRCUIT	A non-vented configuration is being used or the built-in leak in the mask or in the circuit may be obstructed or insufficient for the settings. Note that a high patient or backup respiratory rate may not sufficiently flush out CO2 in some vented pediatric masks.	Replace the non-vented circuit with a vented one. Clean, unblock the mask or the circuit of the vented system or switch to a vented system with a larger leak configuration. Try to reduce patient's backup rate if possible.
POWER FAULT RESTART/SRVC	Internal problem in the electrical power supply.	Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
POWER SUPPLY LOSS (without message)	Electrical power supply cut off by the main switch when ventilation is in progress.	Press the **I/O** switch to restore electrical power to the ventilator and allow ventilation to continue. To stop ventilation, press the VENTILATION ON/OFF key for three seconds.Press the VENTILATION ON/OFF key again to confirm stop. (refer to chapter 5, "Operating Procedures").
	The internal battery that supplies the ventilator is entirely discharged.	Immediately connect the ventilator to an AC power outlet or an external DC power source; otherwise, use an alternate device to ventilate the patient.
PRES SENS FLT1 RESTART/SRVC	Defective internal pressure sensor.	Restart ventilator to see if alarm clears. If not, have a qualified technician replace the defective component(s) and call your customer service representative.
PROX SENS FLT2 RESTART/SRVC	Defective proximal pressure sensor or internal leak of the machine.	Restart ventilator to see if alarm clears. If not, have a qualified technician replace the defective component(s) and call your customer service representative.
REMOVE VALVE OR CHANGE PRES	The ventilation settings are not compatible with the type of patient circuit used.	Remove exhalation valve to start ventilation with less than 5 mbar of difference between PEEP and PIP or Increase the difference between PEEP and PIP to a minimum of 5 mbar.
REMOVE VALVE CPAP MODE	The ventilation settings are not compatible with the type of patient circuit used.	Remove exhalation valve to start CPAP ventilation.
SOFTWARE VERSION ERROR	Incorrect software version detected.	Call your customer service representative.
TURB OVERHEAT RESTART/SRVC	Turbine overheated because of blockage during operation.	Ensure lateral and front openings are not obstructed. Check air inlet filter. Restart ventilator to see if alarm clears. If not, replace the ventilator and call your customer service representative.
UNKNOWN BATTERY	Internal battery not recognised as a Puritan Bennett™ product battery.	Call your customer service representative.
VALVE MISSING CONNECT VALVE	The ventilation settings are not compatible with the type of patient circuit used.	Connect exhalation valve.

Table 3-2. Alarms and Corrective Actions (Continued)

Alarm Message or Symptom	Possible Reason(s) For The Alarm Event	Corrective Action(s)
VTI NOT REACHED *IF PERSISTS RESTART/SRVC	Defective inspiratory flow sensor or internal leak of the machine.	Restart ventilator to see if alarm clears. If not, replace the defective device(s) and have a skilled technician check them.
	I time is not long enough to deliver set VT.	Call your customer service representative.

3.8.2 Additional Troubleshooting

Table 3-3 provides other possible ventilator problems, causes, and corrective actions.

Warning

If the device is damaged, its external housing is not correctly closed, or it behaves in a way that is not described in this manual (excessive noise, heat emission, unusual odour, alarms not triggered during the start-up procedure), the oxygen and power supplies should be disconnected and use of the device stopped immediately.

If you cannot determine the cause of the problem, contact your equipment supplier. Do not use the ventilator until the problem has been corrected.

Note:

Buzzer and battery alarms may occur when the unit is first powered on after the internal battery has been completely drained. Connect to an AC power source and recycle power.

Many of the functions of the ventilator are not accessible when the Locking key is enabled. For additional assistance contact your Clinician or equipment representative.

Table 3-3. Additional Troubleshooting and Corrective Actions

Conditions	Possible Causes	Corrective Actions
No access to the waveforms	Display waveform set to OFF in Preferences menu.	Set Display waveform to YES in Preferences menu.
The screen backlight never switches off during ventilation	Backlight set to OFF in Preferences menu.	Set Backlight to YES in Preferences menu.
Alarm sound level too low or too high	Adjustment of the alarm sound level is incompatible with the patient's environment.	Re-adjust sound level.
Poor visibility of the displays	Contrast adjustment is incompatible with the luminosity of the environment.	Re-adjust contrast.
Unusual display on the screen	Problem with the display unit.	Adjust contrast or call your customer service representative if the problem persists. Ensure that the ventilator is not exposed to direct radiation from the sun.
The ventilator does not operate after pressing I/O switch	No external power source and the internal battery is completely discharged.	Connect the ventilator to the AC power source.

Table 3-3. Additional Troubleshooting and Corrective Actions (Continued)

Conditions	Possible Causes	Corrective Actions
Light noise	Turbine noise.	Replace the ventilator and call your customer service representative.
Whistling noise or vibrations	Filter and/or turbine silencer deteriorated.	Replace the ventilator and call your customer service representative.
	Valve membranes damaged.	Replace the ventilator and call your customer service representative.
Excessive heat emitted	Obstruction of main or secondary air inlets of the casings.	Remove obstructions from all blocked ventilator air inlets and outlets.
Condensation inside the device	Liquid entered the device.	Replace the ventilator and call your customer service representative.

4 Installation and Assembly

Warning

Before operating the ventilator, read, understand, and strictly follow the information contained in Chapter 1, "Safety Information".

A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet—or both ports if a double-limb circuit is used—is highly recommended. Refer to chapter 7, "Cleaning".

4.1 Installing the Ventilator

To install your Puritan Bennett™ 560 Ventilator:

- Choose an area where air can circulate freely; avoid proximity to loose fabrics such as curtains.
- Avoid direct exposure to sunlight.
- Set the ventilator on a flat and stable surface so that its feet are all in contact with the surface. The ventilator may operate in any position, provided that the air inlets are not obstructed and the device cannot fall and possibly cause damage and/or personal injury.

Warning

The operator should connect the ventilator to an AC power source whenever available, for safer operation.

To ensure correct and lasting operation of the ventilator, ensure that its air circulation holes (main inlet or cooling) are never obstructed. Place the device in an area where air can freely circulate around the ventilator and avoid installing it near floating fabrics, such as curtains.

Do not place the ventilator in a position where a child can reach it or in any position that might cause it to fall on the patient or someone else.

Ensure that the ventilator's immediate surroundings allow for the proper operational connection of the device without folding, pinching, or damaging any of the required cables or tubes, and that the connection of the patient circuit to the patient provides for a secure, comfortable fit.

Do not operate the ventilator in direct sunlight, near heat sources, outdoors, or near installations where liquid may pose a risk without first providing adequate protection for the device.

If the ambient temperature where the device is operated is greater than 35 °C (95 °F), the flow supplied at the device outlet may exceed 41 °C (106 °F). This may lead to undesirable side effects for the patient. To avoid injury to the patient move the patient and the ventilator to a cooler location. For more information, contact Covidien.

To reduce the risk of a fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (such as flammable anesthetics and/or heaters) away from the ventilator and oxygen hoses.

Never connect your ventilator to an electrical outlet controlled by a wall switch because the power may be inadvertently turned off.

Even if the "INTERNAL BATTERY" charging indicator is off, charging of the battery may sometimes be incomplete if the ambient temperature is above 40 °C (104 °F) because of the battery's internal heat safety device.

The use of any accessory other than those specified, with the exception of the power supplies or cables sold by Covidien, may lead to an increase in electromagnetic emissions or a decrease in the equipment protection against electromagnetic emissions. If the ventilator is used adjacent to such accessories or stacked with such devices, the ventilator's performance should be monitored to verify normal operation.

The Puritan Bennett™ 560 Ventilatorrequires special precautions for electromagnetic compatibility and should be installed and started according to the recommendations found in Appendix A, "Specifications." In particular, the use of nearby mobile and portable communications equipment using radio frequencies, such as mobile telephones or other systems exceeding the levels set in the IEC / EN 60601-1-2 standard, may affect its operation. Refer to section A.10, "Manufacturer's Declaration".

The ventilator must not use, nor be connected to, any anti-static or electrically conductive hoses, tubing, or conduits.

4.2 Connecting to External AC Power

Any of four power sources: AC power, 12 – 30 VDC power, Internal Battery power, or Auxiliary DC car adapter (cigarette lighter) can be used to power the ventilator. But when AC power is available, the ventilator will automatically select AC power as its operating power source.

⚠ **Warning**

The power supply to which the ventilator is connected (both AC and DC) must comply with all current and applicable standards and provide electrical power corresponding to the voltage characteristics inscribed on the rear of the ventilator to ensure correct operation.

Ensure that the AC power cable is in perfect condition and not compressed. The device should not be turned on if the AC power cable is damaged.

Connect the external electrical power source by first connecting the power cable to the ventilator and then to the external power source. Follow the reverse procedure to disconnect the device from electrical power sources.

Do not leave power cables lying on the ground where they may pose a hazard.

To prevent accidental disconnection of the AC power cable, use the power cable holder (Figure 4-1, item 1)

that is inserted into the notch (Figure 4-1, item 2) of the battery cover: AC Power Cable Holder

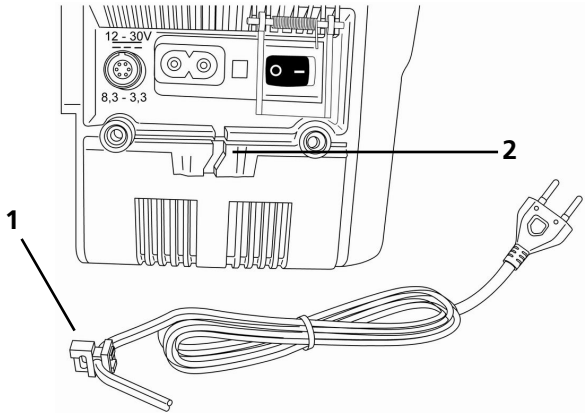


Figure 4-1. The Power Cable Holder

To secure the AC power cable:

1. Insert the power cable holder (Figure 4-2, item 1) into the notch of the battery cover.

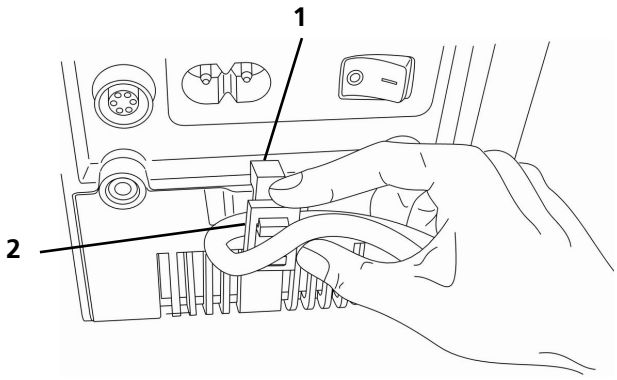


Figure 4-2. Inserting the Power Cable Holder Into the Notch

2. Push the AC power cable into the power cable holder (Figure 4-2, item 2).
3. Connect the female end of the ventilator's AC power cable to the AC connector on the back of the ventilator.

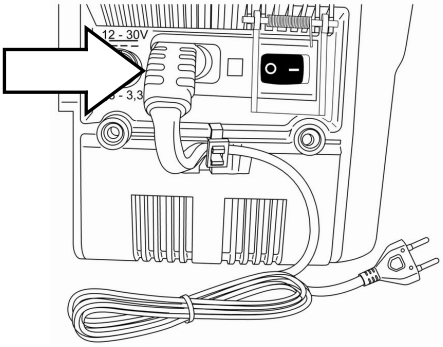


Figure 4-3. Power Cable Connected to the Ventilator

4. Connect the male end of the AC power cable to the AC power outlet.

- The **AC POWER** ~ indicator on the top left corner of the ventilator illuminates.
- The indicator ▭ flashes while the battery charges and then turns off when the battery is fully charged.

Refer to Figure 4-4 on page 4-4.

If the AC power cable becomes disconnected or the AC power source fails, an "AC POWER DISCONNECTION" alarm signals an automatic switch to the external DC power source (if the DC power cable is connected) or to the ventilator's internal battery.
One of three power indicators, located on the upper-left of the ventilator's front panel, illuminates to signal which of the three possible power sources are currently in use by the device (refer to Figure 4-4).

Note:

The only time the AC POWER and indicators are illuminated at the same time is when the ventilator is connected to an AC supply and the battery is charging (indicator is flashing).

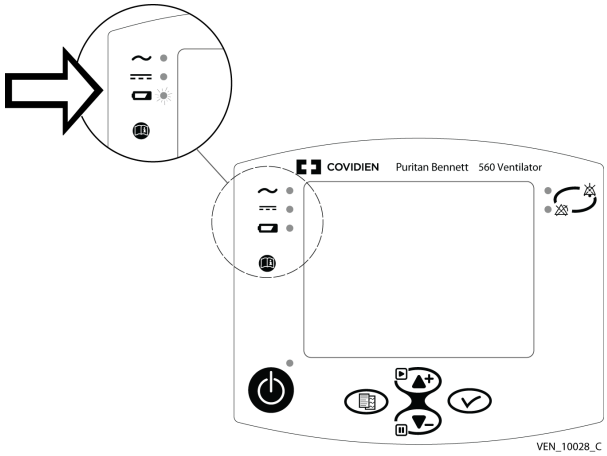


Figure 4-4. Power Indicators

To disconnect the AC power cable:

1. Disconnect the AC power cable from the AC power outlet.
2. Disconnect the AC power cable from the ventilator's AC connector at the rear of the device.
3. Grasp the AC power cable at the level of the power cable holder and turn the cable counterclockwise while lifting it upwards and out of the holder.

4.3 Connecting to an External DC Power Source

⚠ **Warning**

Ensure that the ventilator's internal battery is fully charged before connecting the ventilator to an external DC power source. Powering the ventilator using an external 12– 30 VDC power source (via the DC power cable) does not enable charging of its internal battery.

When using a car auxiliary adapter (cigarette lighter) ensure the car has been started prior to plugging in the ventilator's DC adapter.

Note:

An alternative means of ventilation should always be available, particularly when the patient is in transit or away from wall power.

While using the ventilator on external battery power it is vital that a qualified caregiver (capable of providing necessary corrective actions in the event of alarm conditions) is present.

When AC power is not available use an external DC power prior to using internal battery power.

To connect the ventilator to an external power source do the following:

1. Ensure the car's engine is started prior to connecting the ventilator.
2. Firstly connect the DC power cable into the ventilator.
3. Then connect the DC power cable into the car auxiliary adapter.

Note:

Whenever AC power is unavailable, the ventilator can operate from a continuously powered external 12 – 30 VDC power source via a DC power cable (Figure 4-5, item 1) that connects to the ventilator's rear panel DC power input connector (Figure 4-5, item 2). The DC power cable is optional; refer to Appendix F, "Parts and Accessories", for more information. It is possible to use the DC auxiliary port (cigarette lighter) in a car as a power source as well.

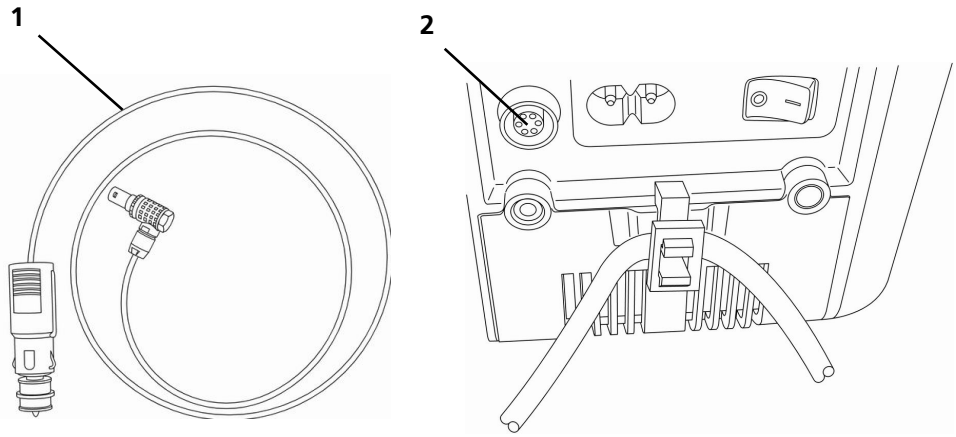


Figure 4-5. Connecting the Ventilator to an External DC Power Source

⚠ **Warning**

Connect the external DC power source by first connecting the power cable to the ventilator and then to the external DC source. Follow the reverse procedure to disconnect the device from the external DC power source.

To connect the DC power cable to the ventilator:

1. Line up the red marker dot on the ventilator's DC power connector with the marker on the DC power cable (Figure 4-6, item 1).

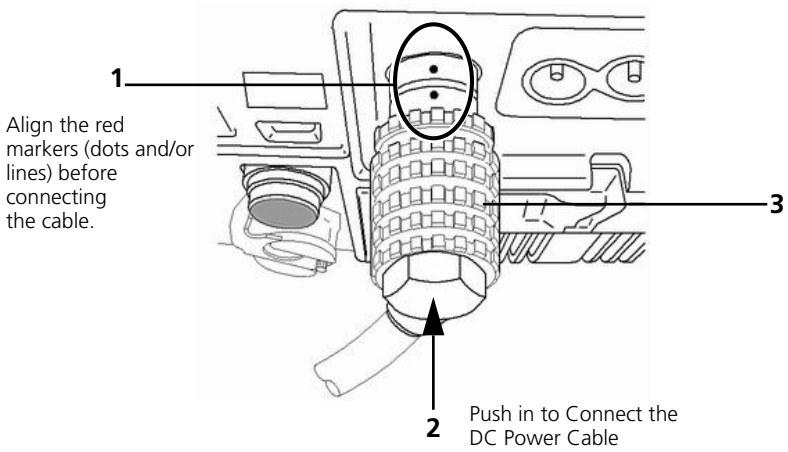


Figure 4-6. Connecting the DC Power Cable to the Ventilator

2. Push the DC power cable onto the ventilator's DC power connector (Figure 4-6, item 2).
   - You will hear a locking "click".
   - The **DC POWER** ⎓ indicator on the top left corner of the ventilator illuminates (see Figure 4-4).

To disconnect the DC power cable from the ventilator, slide the locking ring (Figure 4-6, item 3) back and pull the plug away from the ventilator's rear panel to disengage it.
An "DC POWER DISCONNECTION" alarm signals an automatic switch to the internal battery in case the external DC power source fails or becomes disconnected.

4.4 Patient Circuit

⚠ **Warning**

Before opening the packaging for the Patient Circuit, ensure that no damage is evident to the packaging or its contents. Do not use if evidence of damage exists.

For pediatric use, ensure that the patient circuit type fits, and, in all respects, is suitable for use with a child. Use a pediatric circuit for patients that weigh under 53 lb. (23 kg). See Table F-2, List of Circuits, on page F-2 for a list of recommended patient circuits.

If exhaled tidal volume measurements are required to ensure correct patient ventilation a double limb patient circuit configuration must be used in order to detect leaks. In this case, both the minimum and maximum VTE alarm parameters must be properly set to warn in the event of patient disconnection.

The patient circuit should always be positioned to avoid hindering the patient's movements, to prevent accidental disconnection or leakage, and to minimise the risk of patient strangulation.

Ensure that the ventilator's immediate surroundings allow for the proper operational connection of the device without folding, pinching, or damaging any of the required cables or tubes, and that the connection of the patient circuit to the patient provides for a secure, comfortable fit.

The patient circuit is intended for single use by a single patient ② and should be changed according to the manufacturer's recommendations and according to the patient circuit lifetime. Refer to the instructions for use supplied by the manufacturer of the patient circuit (included with the ventilator) and chapter 4, "Installation and Assembly".

After assembling, cleaning, or reassembling the patient circuit, and on a daily basis, inspect the hoses and other components to ensure that there are no cracks or leaks and that all connections are secure.

To ensure proper performance of the ventilator, use a patient circuit recommended by Covidien in this manual; refer to chapter 4, "Installation and Assembly" and Appendix F, "Parts and Accessories". The total specified length of the patient circuit tubing as measured from the ventilator outlet to the ventilator inlet is 1.1 metres (3.6 feet) to 2.0 metres (6.6 feet). The tubing must conform to all applicable standards and must be fitted with Ø 22 mm terminals that also conform to all applicable standards. Ensure that both the length and the internal volume of the patient circuit are appropriate for the tidal volume: a corrugated tube of Ø 22 mm for adult patients, and a corrugated tube of Ø 15 mm for pediatric patients with a tidal volume lower than 200 ml.

Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.

Users must always possess an additional breathing circuit and exhalation valve while using the Puritan Bennett™ 560 Ventilator.

4.4.1 Choosing the Patient Circuit Type

Single limb circuits are used with breathing modes where spirometry measurements are not required, and double limb circuits are used with breathing modes where spirometry is required. Be sure to choose the appropriate circuit in the menu preferences; in particular, ensure that Pediatric Circuit Yes/No is set to YES when using a pediatric circuit (refer to chapter F, "Parts and Accessories").

For information regarding validated circuits, visit the SolvIT^{SM} Center Knowledge Base by clicking the link at http://www.puritanbennett.com or contact you customer representative.

4.4.2 Installing the Patient Circuit

The patient circuit is mounted depending on the setup of the circuit used and the accessories used.
The following procedures describe the installation of the patient circuit with a humidifier. To add other accessories, refer to the installation instructions for the specific accessories used.

To connect a single limb circuit with an exhalation valve: (refer to Figure 4-7)

1. Inspect the components of the patient circuit for any signs of damage, such as cracks (which might cause leakage). Do not use damaged components to assemble the patient circuit.
2. Install the bacteria filter (item 1) on the TO PATIENT outlet port, as shown.
3. Attach one end of the short circuit tubing (item 2) to the bacteria filter (item 1).
4. Attach the other end of the circuit tubing (item 2) to the inlet port of the humidifier (item 3).
5. Place a water trap (item 4) between the outlet port of the humidifier and the inlet of the exhalation valve (item 5).
6. Ensure the exhalation valve (item 5) is placed as close as possible to the patient.
7. Connect one end of the proximal pressure tubing (item 7) to the proximal pressure port on the exhalation valve (item 5) and the other end onto the ventilator patient pressure port (item 8).
8. Connect one end of the exhalation valve tubing (item 6) to the exhalation valve port on the exhalation valve (item 5) and the other end onto the ventilator exhalation valve port (item 9).
9. To protect the exhalation port (as it will not be used in this configuration), place the cap (if provided with the breathing circuit) over the exhalation port opening (item 10).

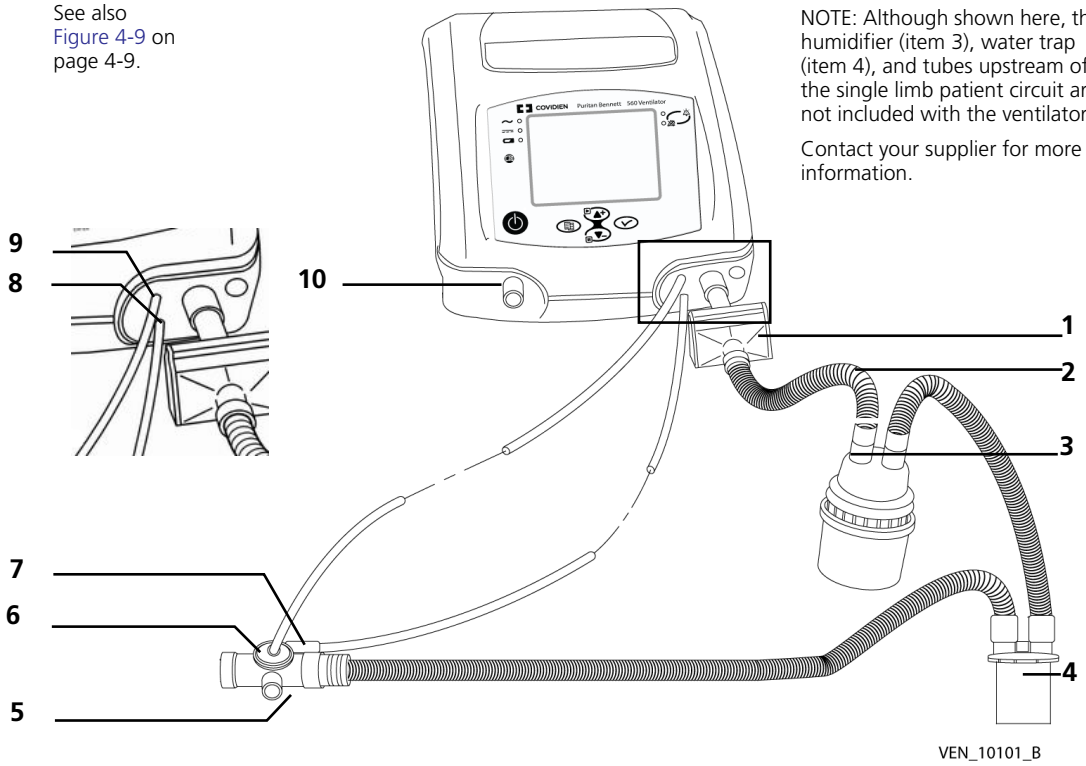


Figure 4-7. Single Limb Patient Circuit With Exhalation Valve

To connect a double limb circuit: (refer to Figure 4-8)

1. Inspect the components of the patient circuit for any signs of damage, such as cracks (which might cause leakage). Do not use damaged components to assemble the patient circuit.
2. Install the bacteria filter (item 1) on the TO PATIENT outlet port.
3. Attach one end of the short circuit tubing (item 4) to the filter (item 1).
4. Attach the other end of the circuit tubing to the inlet port of the humidifier (item 2).
5. Place a water trap (item 3) between the outlet port of the humidifier and the patient wye (item 5) on the double limb circuit.
6. Place a second water trap (item 3) between the patient wye (item 5) and the inlet port of exhalation bacteria filter (item 12).
7. Connect the exhalation bacterial filter (item 12) between the FROM PATIENT inlet port (item 10) and the exhalation limb of the patient circuit.
8. Connect one end of the small proximal pressure tubing (item 6) to the double limb patient wye circuit connection (item 5) and the other end on the ventilator patient pressure port (item 13).
9. Place the exhalation valve assembly (item 9) on the exhaust port.
10. Connect the tubing (item 8) from the exhalation valve assembly to the exhalation valve port (item 14) of the ventilator.

Note:

When shipped, the proximal pressure tube may already be connected to the patient wye. If so, simply verify that the connection is secure and the tube shows no signs of damage, kinks, or obstructions.

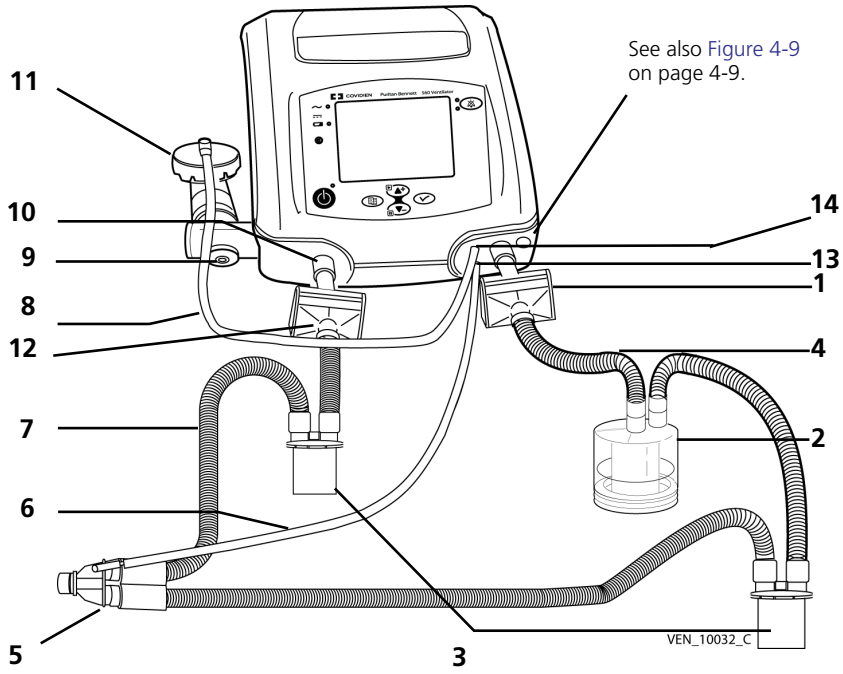


Figure 4-8. Double Limb Patient Circuit

Note:

Although shown here, the humidifier (item 2), water traps (item 3), and their connecting tubes are not included with the patient circuit or ventilator. Contact your supplier for more information.

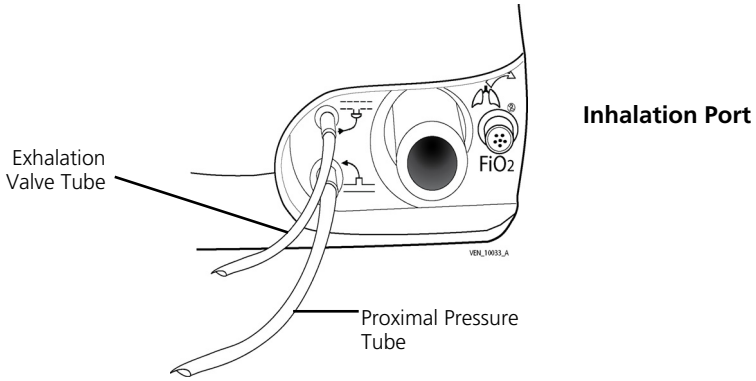


Figure 4-9. Close-up of Exhalation Valve Tube and Proximal Pressure Tube

Figure 4-9 shows details of the connections of the proximal pressure tube (Figure 4-8, item 6) and the exhalation valve tube (Figure 4-8, item 8).

To connect a single limb circuit without an exhalation valve (NIV only):

refer to Figure 4-10.

1. Inspect the components of the patient circuit for any signs of damage, such as cracks (which might cause leakage). Do not use damaged components to assemble the patient circuit.
2. Install the bacteria filter (item 1) on the TO PATIENT outlet port, as shown.
3. Attach one end of the short circuit tubing (item 4) to the filter (item 1)
4. Attach the other end of the circuit tubing (item 4) to the inlet port of the humidifier (item 2).

5. Place a water trap (item 3) between the outlet port of the humidifier and the patient end.
6. Place a vented (NIV) interface to the end of the patient circuit. (item 5)

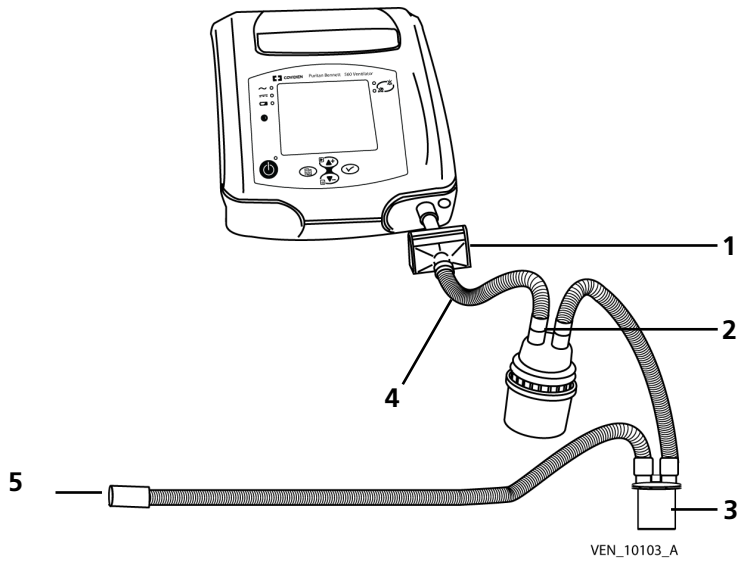


Figure 4-10. Single limb Patient Circuit Without Exhalation Valve

For both types of circuits, shown previously, you should connect the end of the proximal pressure tube as close as possible to the patient (at the mask or cannula entry, if possible) so that the ventilator can account for all load losses due to the circuit and its potential accessories. If this is not possible, it is best to modify the PATIENT DISCONNECTION triggering threshold by doing one of the following: set a Max VTI alarm limit for pressure modes or a Min VTE alarm limit for all ventilation modes if using a dual limb circuit.
As a reminder: Ensure that the length and the internal volume of the patient circuit are compatible with the tidal volume: ringed tube Ø 22 mm for adults and ringed tube Ø 15 mm for pediatric patients with tidal volumes lower than 200 ml. Use, if necessary, a 22F-15M link on the outlet and a 15M-22M link on the exhalation block for a double limb circuit.

Warning

When using non-invasive ventilation (NIV), without an exhalation valve, use a vented nose or face mask or a non vented combined with a leak accessory. When using non-invasive ventilation (NIV), with an exhalation valve, use a non vented mask.

The level of inspiratory resistance of the circuit and accessories (bacteria filter, humidifier, and so on) must be as low as possible. Settings—particularly the PATIENT DISCONNECTION alarm, High inspired volume (High VTI), and Low inspired volume (Low VTI) settings—must be periodically adjusted according to changes in the patient circuit resistance—especially when filters are replaced.

Resistance of the exhalation valve and accessories (water traps, filters, HMEs etc) must be as low as possible.

The exhalation valve must allow rapid discharge of the circuit pressure. Ensure that the exhalation valve is always clean and its evacuation aperture (exhaust port) is never obstructed.

Do not start ventilation until you ensure that the device is suitably assembled, that the air inlet filter is properly installed and is not obstructed, and that there is proper clearance all around the unit. Also ensure that the patient circuit is suitably connected to both the ventilator and the patient and that the patient circuit, including all hoses, is not damaged or obstructed.

Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.

4.5 Filters

Warning

Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. If necessary, replace the filter before the recommended replacement period is over (see chapter 8, "Routine Maintenance"). This is particularly important when the ventilator is installed on a wheelchair, because environmental conditions may cause the filter to become dirty more rapidly.

The ventilator features two filter types:

- air inlet filter
- bacteria filter

Air Inlet Filter

Consisting of foam and fine particle filter media and located at the rear of the ventilator, this filters the air as it enters the ventilator.

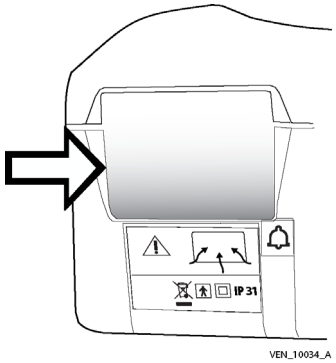


Figure 4-11. Air Inlet Filter

Warning

The air inlet filter is not reusable; do not attempt to wash, clean, or reuse it.

Failing to replace a dirty air inlet filter, or operating the ventilator without a filter, may cause serious damage to the ventilator.

Bacteria Filter

It is highly recommended that you install a bacteria filter (see Figure 4-12) on both single and double limb circuits. In a double limb configuration, two bacteria filters are used: one at the

TO PATIENT port, and the other at the FROM PATIENT port.

- Connected to the TO PATIENT port:

  This filter protects the ventilator from contamination by the patient (primarily, rebreathed gas). Refer to Figure 4-8, item 1.

- Connected to the FROM PATIENT port:

  This filter protects the internal exhalation flow sensor from the gases exhaled by the patient. Refer to Figure 4-8, item 10.

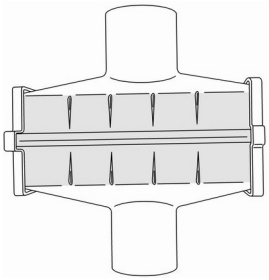


Figure 4-12. Bacteria Filter

Refer to the manufacturer's instructions for more information about the use and maintenance of the bacteria filter(s).

4.6 Humidifier

The humidifier (Figure 4-13) adds moisture (water vapour) and warms the gas in the patient circuit. It is inserted into the patient circuit between the main outlet and the patient (refer to Figure 4-7 and Figure 4-8).

Warning

During invasive ventilation (when an artificial airway bypasses the patient's upper respiratory system), the patient's upper respiratory system cannot humidify the incoming gas. For this reason, the use of a humidifier, to minimise drying of the patient's airways and subsequent irritation and discomfort, must be used.

Always position a humidification device so that it is lower than both the ventilator and the patient. Use water traps, if necessary, to limit water in the patient circuit and periodically empty these water traps.

If a heated humidifier is used, you should always monitor the temperature of the gas delivered to the patient. Gas delivered from the ventilator that becomes too hot may burn the patient's airway.

Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.

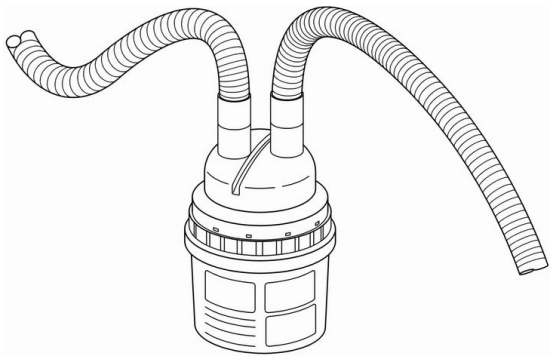


Figure 4-13. Humidifier

When a humidification device is used, any condensation that forms in the patient circuit is collected in the

water trap. If you notice any moisture in the patient circuit, you need to replace the wet circuit components with dry ones.
Refer to the humidification device's instruction for information on operating, cleaning, and sterilising the humidifier.

4.7 Exhalation Block

Warning

The exhalation block is intended for single use by a single patient ②. It may periodically be cleaned, but it cannot be disinfected or sterilised. To maintain good measurement quality when used continuously, change it every 4 months.

Ensure that the exhalation block is completely dried after cleaning and prior to use.

Warning

When an exhalation block is set up, each time it is removed, or after installing a new exhalation block on the machine, it is essential that the exhalation flow sensor be recalibrated before the exhalation block is used.

The exhalation block requires calibration and should only be removed or cleaned by qualified personnel.

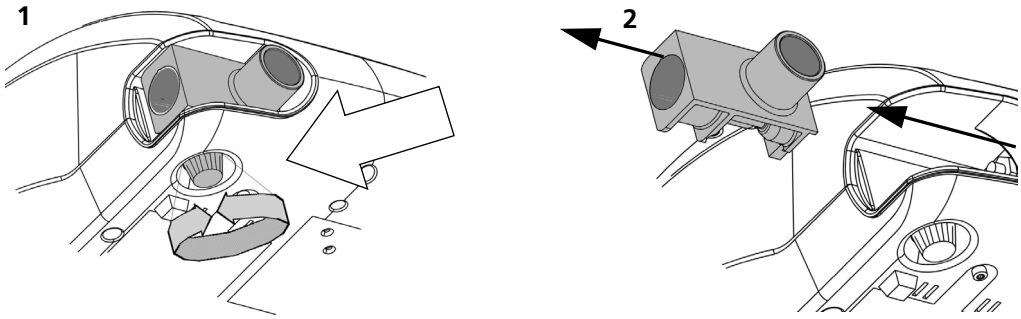


Figure 4-14. Removing the Exhalation Block

4.8 Oxygen

4.8.1 Administering Oxygen

Warning

The ventilator must not be used with flammable anesthetic substances.

Oxygen therapy for patients with respiratory failure is a common and effective medical prescription. However, be aware that inappropriate oxygen use may potentially lead to serious complications, including, but not limited to, patient injury.

To avoid injury to the patient and/or possible damage to the ventilator: before using the ventilator, use a flow meter (flow regulator) to regulate the oxygen supply to specifications before connecting the ventilator to the oxygen supply.

Ensure that the oxygen supply pressure to the machine never exceeds 7 psi (50 kPa) or a flow of 15 lpm. Refer to Table A-8 on page A-3 for volume and sensitivity tolerances.

The Puritan Bennett™ 560 Ventilator can be used with an optional oxygen analyser with minimum and maximum concentration alarms. Always measure the delivered oxygen with a calibrated oxygen analyser (FIO_2 kit) that features a minimum and maximum concentration alarm in order to ensure that the prescribed oxygen concentration is delivered to the patient.

Oxygen administered to the patient is introduced from an external source into the machine through the oxygen connector at the rear of the ventilator. It is then integrated into the total volume of delivered gas. Remove the oxygen inlet connector from the back of the ventilator when external oxygen is not in use.
The specific oxygen flow to the patient depends on the physiological characteristics of the patient and the ventilator settings.
The oxygen flow setting should be adjusted for *each* patient and established in relation to a *calibrated* oxygen monitor measurement. Since the factors that affect administered oxygen flow may change over time, you must ensure that these settings always correspond to the *current* oxygen therapy objectives specified by the physician.

4.8.2 Connecting the Oxygen Supply

Warning

Ensure that the only gas supplied to the ventilator through the dedicated oxygen supply connector is medical-grade oxygen.

The hose connecting the ventilator to the oxygen source must be designed exclusively for use with medical-grade oxygen. Under no circumstances should the oxygen hose be modified by the user. In addition, the hose must be installed without the use of lubricants.

A connector (Figure 4-15, item 1) for an external low pressure oxygen source is available at the rear of the ventilator. It is essential that you also use the special coupler (item 2) supplied with the ventilator to attach the external low pressure oxygen source to the connector. The connector is also fitted with a non-return airtight valve system. The non-return airtight valve system includes a stud (item 3) and a locking tab (item 4).

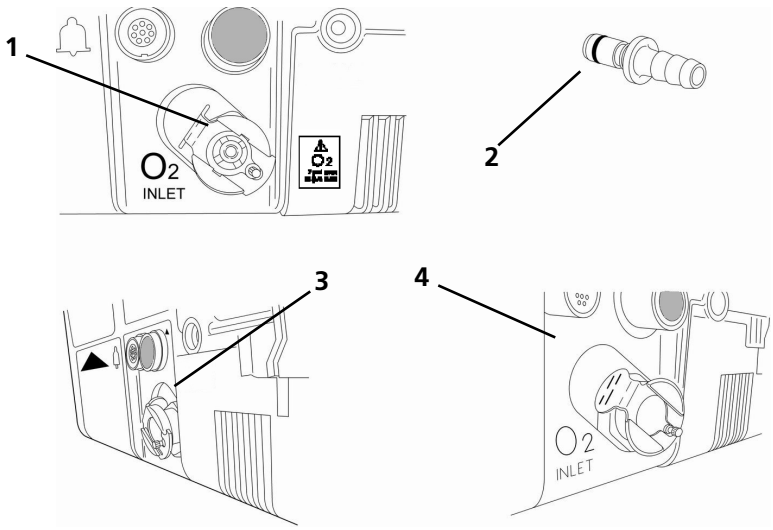


Figure 4-15. Rear Panel Oxygen Connector

Warning

Before connecting the oxygen supply, ensure that the stud on the oxygen connector (Figure 4-15, item 3) is protruding outwards.

Inspect the oxygen coupler (Figure 4-16, item 2) before use to ensure it has its black O-ring attached and in good condition. Do not use an oxygen coupler with a missing, damaged, or worn O-ring.

To connect the oxygen supply system to the ventilator:

Refer to Figure 4-16 as required:

1. Inspect the oxygen supply's connector (Figure 4-16, item 1) to ensure that connector's black O-ring (item 2) is not missing.
2. Push the oxygen supply's oxygen connector (item 1) into the ventilator's oxygen connector (Figure 4-16, item 3).
   - the ventilator's oxygen connector's locking stud (item 4) retracts.
   - the ventilator's oxygen connector's locking tab (item 5) is released, ensuring that the oxygen connection is locked and secured in place.

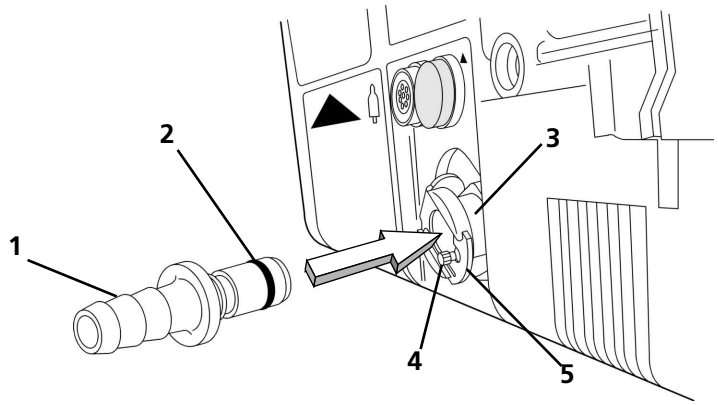


Figure 4-16. Connecting the Oxygen Supply System

To disconnect the oxygen supply system from the ventilator:

Note:

Ensure the oxygen source is turned off prior to placing the ventilator in Standby or turning off the ventilator.

1. Stop the oxygen flow from the oxygen supply.
2. Press the locking tab of the ventilator's oxygen connector, as shown in Figure 4-17, to unlock the oxygen connection.

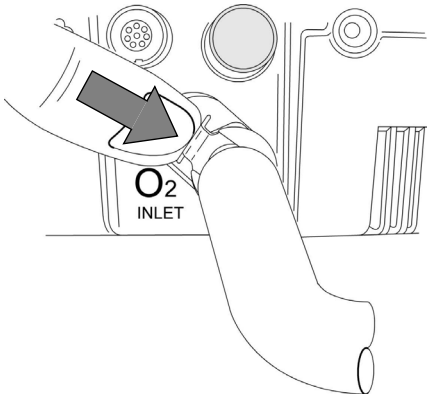


Figure 4-17. Disconnecting the Oxygen Supply System

3. Disconnect the oxygen supply's oxygen connector by pulling it towards you.

   The ventilator's oxygen connector's locking stud (Figure 4-16, item 4) will then extend outwards,
   which is required before the oxygen connector can be reconnected.

Warning

The coupler must not remain connected to the oxygen connector unless it also connected to a leak-proof, external oxygen gas source. When an oxygen supply is not being used with the ventilator, disconnect the oxygen source completely from the ventilator.

In the event of an oxygen leak, shut down the supply of oxygen at its source. In addition, remove and/or keep any incandescent source away from the device, which may be enriched with oxygen. Circulate fresh air into the room to bring the oxygen level down to normal.

To prevent any interference with the internal sensors of the ventilator, do not install a humidifier upstream of the ventilator.

4.8.3 Connecting the FIO_2 sensor

When administering oxygen it is recommended to use a FIO_2 oxygen sensor that can be connected to the front of the apparatus by means of a FIO_2 measurement kit.

Note:

The FIO_2 sensor requires calibration and should only be removed or cleaned by qualified personnel.

When using a new sensor, allow its temperature to become stable for about 20 minutes in ambient air before installing it, calibrating it and starting ventilation.

To install the FIO_2 sensor:

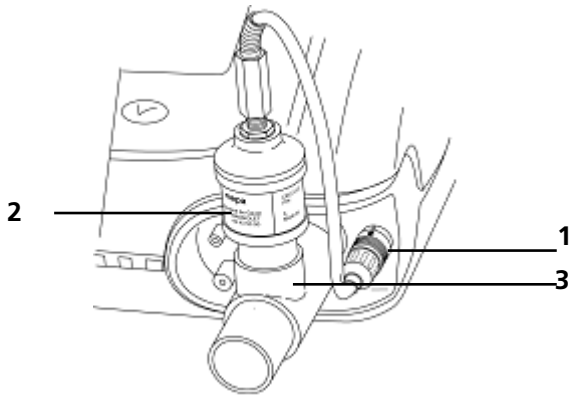


Figure 4-18. Connecting the FIO_2 sensor

1. Remove the sensor from the airtight packaging.
2. Install the FIO_2 connector to the FIO_2 socket on the ventilator (item 1)
3. Connect the FIO_2 sensor (item 2) onto Ø15mm adaptor (item 3).
4. Install the adaptor on the TO PATIENT outlet port, as shown.

Fit the patient circuit after the adaptor.

4.9 Fitting the Ventilator into the Dual Bag

The Dual Bag is a carrying bag with a dual function. It allows the Puritan Bennett™ 560 Ventilator to either be mounted onto a wheelchair or carried as a backpack. (see Figure 4-19)

Warning

Ensure that the ventilator is switched off and disconnected from all external power supplies before installation.

To fit the ventilator into the Dual Bag do the following:

1. Open the rear panel of the Dual Bag.
2. Slip the ventilator into the Dual Bag, pushing it in completely to ensure a snug fit.
3. Shut the rear panel of the Dual Bag ensuring that the hook and loop fastener strips are securely fastened.

4.10 Mounting the Ventilator on a Wheelchair

Warning

Due to its limited internal battery's reserve capacity, the ventilator should only be operated on the internal battery when no other power source is available. Ensure that the internal battery never becomes fully discharged.

Do not operate the ventilator in direct sunlight, near heat sources, outdoors, or near installations where liquid may pose a risk without first providing adequate protection for the device.

To avoid damage to the ventilator, in particular the batteries or electrical components, fluids must not be allowed to enter the device, particularly through the air inlet filter or the cooling apertures located in the side, rear, and bottom panels of the ventilator.

If exhaled tidal volume measurements are required to ensure correct patient ventilation a double limb patient circuit configuration must be used in order to detect leaks. In this case, both the minimum and maximum VTE alarm parameters must be properly set to warn in the event of patient disconnection.

To minimise the risk of damage, you must use the ventilator's Dual Bag to transport the ventilator. See Table F-1, List of Consumables and Accessories.

Before using the ventilator's internal battery, ensure that the battery is fully charged and that the charge holds. Back up ventilators or those in storage should be connected to an AC power source to protect the integrity of the battery.

Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. If necessary, replace the filter before the recommended replacement period is over. This is particularly important when the ventilator is installed on a wheelchair, because environmental conditions may cause the filter to become dirty more rapidly.

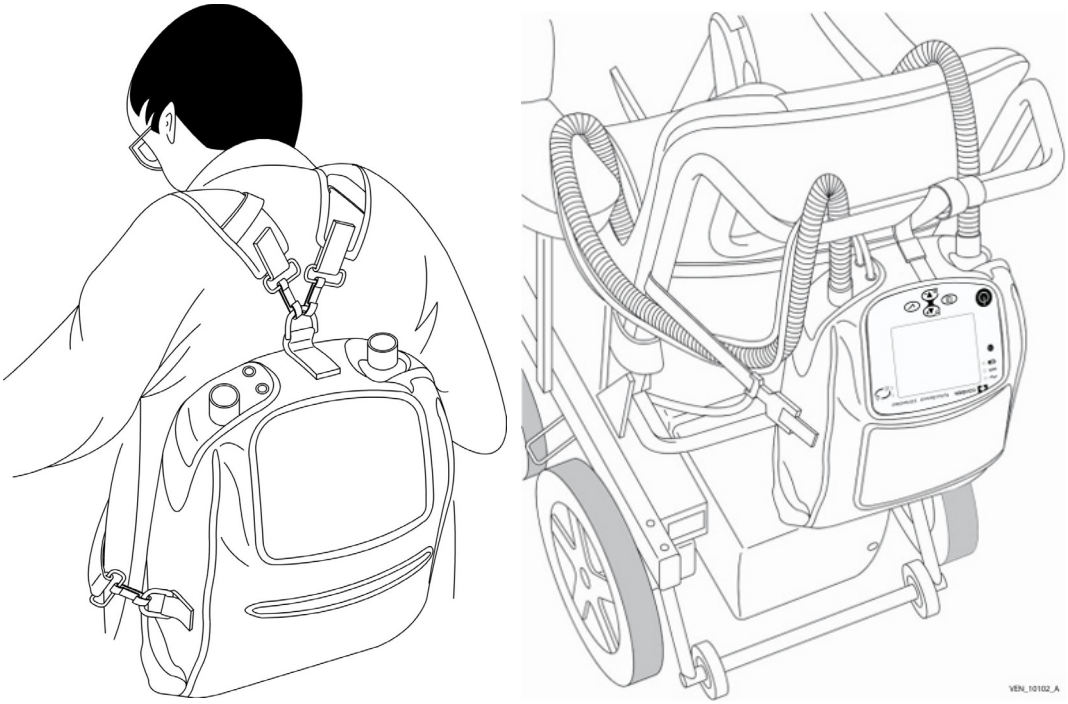


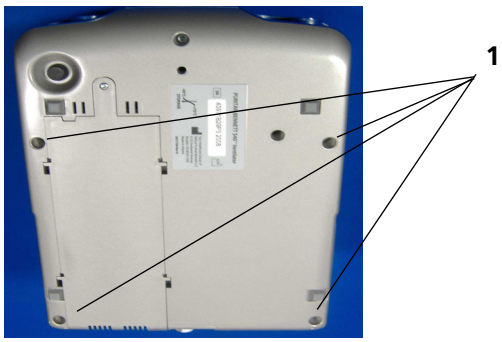
Figure 4-19. Using the Dual Bag Accessory

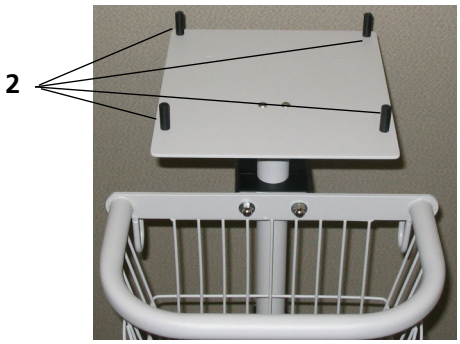
To install the Dual Bag onto a wheelchair do the following:

1. Unclip the two backpack straps from the side clips.
2. Clip the suspension belt onto the central ring.
3. Secure the Dual Bag on the wheelchair's push handle.
4. Attach the non adjustable side of the maintaining belt to the side clip of the Dual Bag.
5. Pass the maintaining belt around the back of the wheelchair.
6. Adjust the length of the maintaining belt and attach the adjustable side of the belt to the clip on the other side of the Dual Bag.

4.11 Mounting the Ventilator on the Utility Cart

Match the mounting holes (item 1) on the bottom of the Puritan Bennett™ 560 Ventilator to the mounting studs (item 2) on the top of the utility cart platform.





4.12 Connecting the Nurse Call Cable

Connect the Nurse Call cable (Figure 4-20, item 1) to the Nurse Call Monitor Connector (item 2).

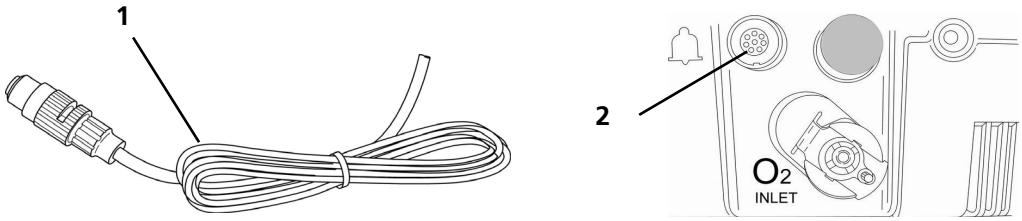


Figure 4-20. Connecting the Nurse Call Cable

Warning

Before using the Nurse Call system, ensure that its connections are secure and it operates properly. For more information, contact Covidien.

To connect the ventilator to a Nurse Call device, contact Covidien to check the ventilator's compatibility with the Nurse Call device and order a suitable connection cable.

Do not use Nurse Call devices that operate based on the closure of an electrical circuit, because the devices often do not take into account possible cable disconnection or a total loss of power. Ensure that the Nurse Call device is always connected to the ventilator.

The Nurse call function provides for remote alerts of ventilator alarm conditions (for example, when the ventilator is used in an isolation room), and features the following:

- The ventilator signals an alarm using a normally open (NO) or a normally closed (NC) signal.
- A remote alarm is activated when an alarm condition occurs, unless either of the following is true:
  - The audio paused function is active.
  - The ventilator power switch is OFF.
- The remote alarm port is an 8-pin female connector; allowable current is 100mA at 24VDC (max).

5 Operating Procedures

5.1 Turning on the Ventilator

Warning

Before operating the ventilator, read, understand, and strictly follow the information contained in Chapter 1, "Safety Information".

If the ventilator has been transported or stored at a temperature that differs more than ±20 °C (± 36 °F) from the temperature in which it will be operating, the ventilator should be allowed to stabilise in its operating environment for at least two (2) hours prior to use.

To reduce the risk of a fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (such as flammable anesthetics and/or heaters) away from the ventilator and oxygen hoses.

While the ventilator is in use, an alternative means of ventilation should always be available in the event of a ventilator problem. This is particularly true for ventilator-dependent patients. Supplementary observation, appropriate for the patient's condition, is also recommended.

To ensure that ventilation continues uninterrupted, ensure alternative power sources are available (AC power source, extra batteries, or an auxiliary DC car adapter). Be prepared for the possibility of power failure by having an alternative means of ventilation ready for use—particularly for ventilator-dependent patients.

Do not start ventilation until you ensure that the device is suitably assembled, that the air inlet filter is properly installed and is not obstructed, and that there is proper clearance all around the unit. Also ensure that the patient circuit is suitably connected to both the ventilator and the patient and that the patient circuit, including all hoses, is not damaged or obstructed.

Users must always possess an additional breathing circuit and exhalation valve while using the Puritan Bennett™ 560 Ventilator.

Verify the functionality of the alarm conditions before connecting the patient to the ventilator.

Before starting ventilation, always verify that all settings are properly set in accordance with the required prescription.

If the ventilator fails the alarm tests or if you cannot complete the tests, refer to section 3.8, "Troubleshooting" or call your equipment supplier or Covidien.

Due to its limited internal battery's reserve capacity, the ventilator should only be operated on the internal battery when no other power source is available. Ensure that the internal battery never becomes fully discharged.

To turn the ventilator on:

- Set the **I/O** switch (a covered, rocker-type switch located at the rear of the ventilator) to the **I** position, as shown in Figure 5-1 below.

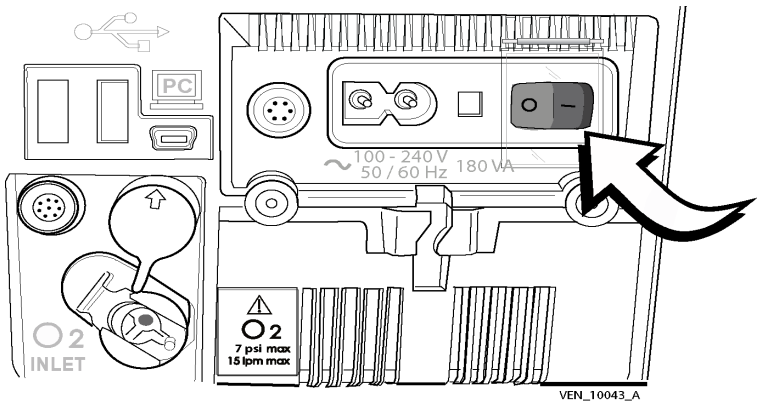


Figure 5-1. Turning on the Ventilator

The following events occur:

- The ventilator is powered on.
- A Power On Self Test (POST) is carried out (when plugged in to an AC power source).
- The front panel indicators flash (except for the indicator showing the type of power supply in use, which remains lit).
- The audible alarms briefly sound.
- The display's backlight turns on.
- The PURITAN BENNETT™ logo is displayed momentarily.
- The blue **VENT STDBY** indicator to the right of the **VENTILATION ON/OFF** key illuminates, indicating the device is in standby mode.
- A Welcome Menu screen is displayed for about five (5) seconds, which includes the machine counter and the patient counter, as shown in Figure 5-2.

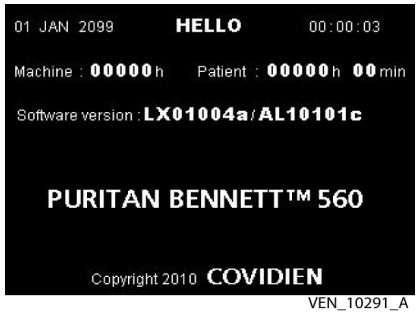


Figure 5-2. Welcome Menu Screen

Note:

If the ventilator had been previously stopped by use of the **I/O** switch while ventilation was in progress, the ventilator starts directly in ventilation mode and does not show the Welcome Menu screen.

The Alarm, Technical Fault, and Event logs are stored in non-volatile memory on the Main CPU PCB, ensuring that the information is retained when the ventilator is powered off and during power loss conditions.

To skip the Welcome Menu:

- Press **VENTILATION ON/OFF** ⏻ to start ventilation immediately.

  The Ventilation menu is then displayed.

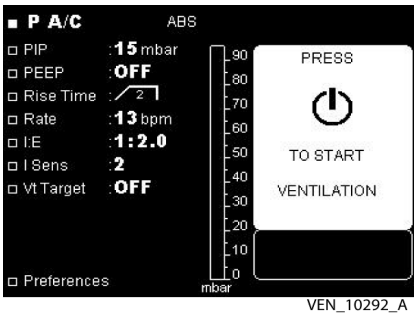


Figure 5-3. Ventilation Menu Parameters

By default, the starting ventilation mode is the last one used, the settings being those that were active when the machine was last stopped.If the ventilator's memory of the settings is faulty, a "CHECK SETTINGS" alarm is activated. If this occurs, the desired parameters should be reset and saved; otherwise the machine will operate on default parameter values.

5.2 USB Menu Parameters

The USB menu is accessible even if the Locking Key has been enabled. The USB menu is automatically displayed when the USB memory device is connected to the ventilator, when ventilation is either on or off.
Only one USB memory device shall be connected at any time, otherwise an error message will be displayed.
The USB Menu is not accessible from the Setup Menu or Maintenance menu.
To access patient data via a PC, a dedicated software package, Puritan Bennett™ Respiratory Insight Software, is available for Clinicians. Contact Covidien or your Puritan Bennett™ product representative for further information.

5.2.1 USB Memory Device Specifications

Table 5-1. USB Memory Device Specifications

Characteristics	Supported Formats
USB compatibility	USB flash memory USB 2.0 or USB 1.1, 32 bit format
Number of files	Maximum 999 (sector size: 512-2,048 bytes)
USB size	128 MB to 4Gb (To guarantee accuracy of transfer time, at least 10% of the USB memory device capacity must be free).

5.2.2 USB Menu

To access the USB menu when a USB memory device is connected:

Press the **MENU** key several times, until the USB Menu appears:

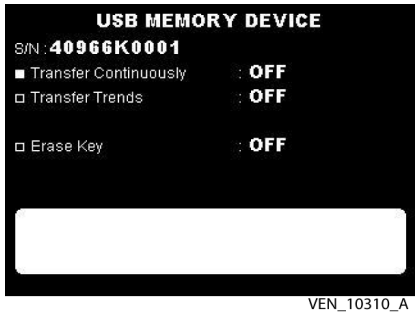


Figure 5-4. Selecting the USB Menu

In case of high priority alarm activation the ventilator will automatically display the alarm page. To return to the USB Menu, press the MENU key.
The adjustable parameters in this menu are:

- Transfer continuously
- Transfer trends
- Erase key

5.2.3 Transfer Continuously

Up to 48 hours worth of data can be transferred from a ventilator to a USB memory device.
To record continuously, the USB memory device must be permanently connected to the ventilator and ventilation is active.
The following data will be recorded to the USB memory device:

- Monitoring: pressure, inspired flow, exhaled flow and leak waveforms.
- Trends: leaks, VTI, VTE, Rate, I:E, M. Vol, PIP and PEEP measurements.

The data can be accessed by a doctor or service provider using the Puritan Bennett™ Respiratory Insight Software.

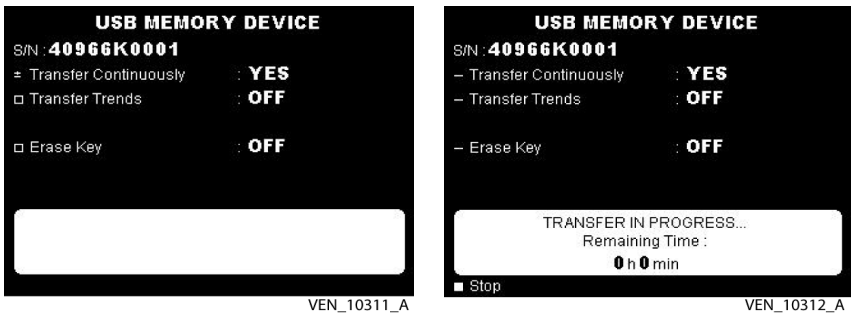


Figure 5-5. Selecting Transfer Continuously

To transfer continuous data from a ventilator to a USB memory device:

1. Use the **UP** or **DOWN** arrow keys to place the cursor at the "Transfer Continuously" position.
2. Press **ENTER** .

- The cursor changes to the plus/minus symbol.
- The parameter selected to be modified flashes.

3. Press **UP** or **DOWN** to change the selected parameter's value.
4. Press **ENTER** to confirm the new parameter setting.

- The new parameter setting is displayed continuously.
- The cursor is placed at the **STOP** position.

5. To manually stop continuous transfer, press the **ENTER** key.

If a parameter change is not confirmed by pressing **ENTER** before seven (7) seconds elapse, the ventilator resets the parameter to its previous value.

Note:

All ventilator menus remain accessible during transfer time.

The message "TRANSFER IN PROGRESS... REMAINING TIME" is displayed during the transfer time.

Other functions of the USB memory device are not available during continuous recording,

If the memory capacity on the USB memory device is insufficient the message "TRANSFER NOT ALLOWED - USB CAPACITY INSUFFICIENT" is displayed and data transfer is not allowed. Delete the data on the USB memory device before restarting data transfer.

In case of USB memory device disconnection or transfer error, the message "TRANSFER ERROR - USB DISCONNECTION" or "TRANSFER ERROR - TECHNICAL PROBLEM" is displayed. In this case restart the transfer process. If the problem persists contact your technical service.

5.2.4 Transfer Trends

Up to one year's worth of trend data can be transferred from a ventilator to a USB memory device.
Ventilation trends such as leaks, VTI, VTE, Rate, I:E, M. Vol, PIP and PEEP measurements can be transferred from the ventilator to a USB memory device.
The data can be accessed by a doctor or service provider using the Puritan Bennett™ Respiratory Insight Software.

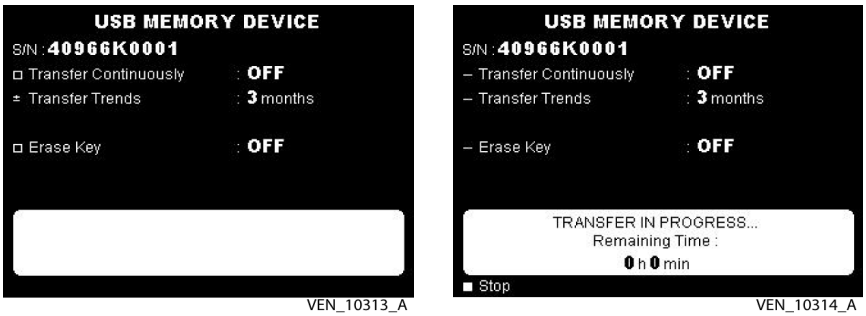


Figure 5-6. Selecting Transfer Trends

To transfer trend data from a ventilator to a USB memory device:

1. Use the **UP** or **DOWN** arrow keys to place the cursor at the "Transfer Trends" position.
2. Press **ENTER** .

- The cursor changes to the plus/minus symbol.

- The parameter selected to be modified flashes.

3. Press **UP** or **DOWN** to change the selected parameter's value.
4. Press **ENTER** to confirm the new parameter setting.

- The new parameter setting is displayed continuously.
- The cursor is placed at the **STOP** position.

5. To manually stop trend transfer, press **ENTER** .

If a parameter change is not confirmed by pressing **ENTER** before seven (7) seconds elapse, the ventilator resets the parameter to its previous value.

Table 5-2. Time taken to transfer trends data from the ventilator to a USB memory device

Amount of trends data (in months)	Transfer time from ventilator to USB memory device
3 months	Approximately 2 minutes
6 months	Approximately 4 minutes
9 months	Approximately 6 minutes
12 months	Approximately 8 minutes

Note:

The message "TRANSFER IN PROGRESS... REMAINING TIME" is displayed during the transfer time.

Other USB memory device functions are available during transfer of trends.

If the memory capacity on the USB memory device is insufficient the message "TRANSFER NOT ALLOWED - USB CAPACITY INSUFFICIENT" is displayed and data transfer is not allowed. Delete the data on the USB memory device before restarting data transfer.

In case of USB memory device disconnection or transfer error, the message "TRANSFER ERROR - USB DISCONNECTION" or "TRANSFER ERROR - TECHNICAL PROBLEM" is displayed. In this case restart the transfer process. If the problem persists contact your technical service.

5.3 Starting Ventilation

Before starting ventilation, refer to Appendix C, "Operational Verification Checklist", and set the parameter values in the Preferences menu.)

Warning

Verify the functionality of the alarm conditions before connecting the patient to the ventilator.

Before starting ventilation, ensure that the device is properly assembled and that the air inlet, cooling vents, and alarm sound diffusion holes are not obstructed. Ensure also that the patient circuit is of the proper configuration (double or single limb), properly connected to the ventilator, and that the circuit hoses are neither damaged nor compressed and contain no obstructions or foreign bodies.

Note:

Many of the functions of the ventilator are not accessible when the Locking key is enabled. For additional assistance contact your Clinician or equipment representative.

When the ventilator is in standby (the ventilator is on, but ventilation has not started), a message that prompts the ventilator operator to press **VENTILATION ON/OFF** to start ventilation is displayed in the right-hand window of the ventilation and alarm menus (Figure 5-7).

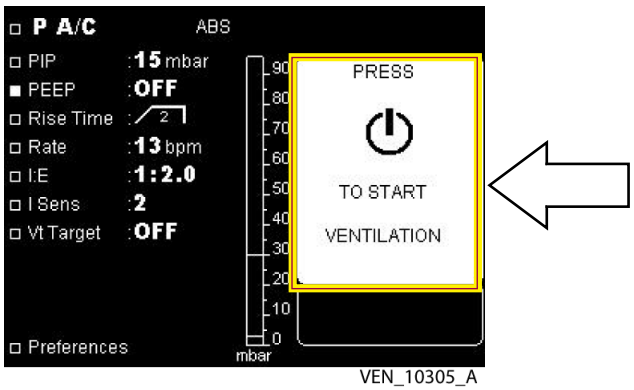


Figure 5-7. Prompt to Start Ventilation

To start ventilation:

Press and release **VENTILATION ON/OFF** (Figure 5-8, item 1).

- The blue light indicator, at the upper right of the **VENTILATION ON/OFF** key (see Figure 5-8, item 2), turns off.
- A "beep" sounds.
- The ventilation starts.
- The values of the monitored parameters are displayed in the right-hand window.

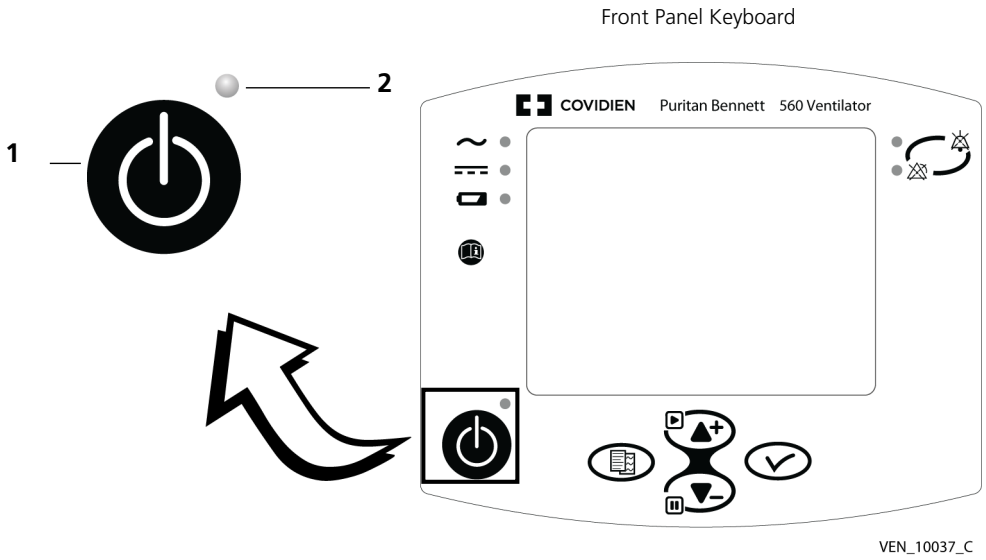


Figure 5-8. Starting Ventilation

5.4 Stopping Ventilation

Warning

Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of expiratory gas, primarily carbon dioxide, may be inhaled by the patient. In some circumstances, inhaling carbon dioxide may lead to under-ventilation, suffocation, and serious injury or death.

You can stop your ventilator at any time.

To stop the ventilator:

1. Press and hold the **VENTILATION ON/OFF** key (Figure 5-8, item 1) for three (3) seconds.
   - A message prompting the user to keep the button pressed appears on the monitoring window, as shown in the graphic below:

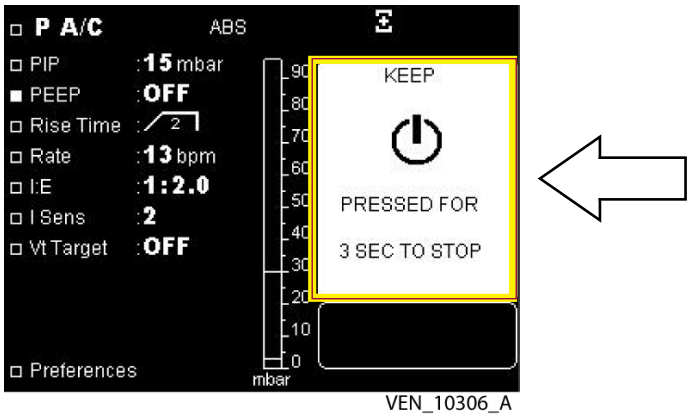


Figure 5-9. Stopping Ventilation (1)

2. While keeping the **VENTILATION ON/OFF** key pressed:

- A new message appears that directs the user to press the key again to confirm ventilation stop. (shown in the graphic below).

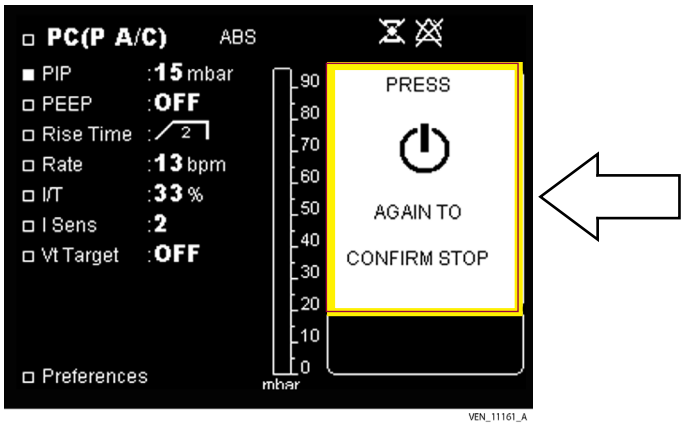


Figure 5-10. Stopping Ventilation (2)

- A double "beep" sounds.

3. Release the **VENTILATION ON/OFF** key.
4. Press the **VENTILATION ON/OFF** key within 5 seconds to confirm stop, otherwise ventilation will continue.
   - Ventilation stops.
   - The blue LED located to the upper-right of the **VENTILATION ON/OFF** key (Figure 5-8, item 2) illuminates to indicate ventilation is on Standby.
   - A prompt for a new start of ventilation is displayed (see Figure 5-7 on page 5-7).

5.5 Turning Off the Ventilator

Warning

When the ventilator is switched back on, it will immediately begin ventilating—without the user first having to press the VENTILATION ON/OFF key.

Handle the ventilator with care after use, particularly when ambient temperatures are high. Some ventilator surfaces may be very hot, even if safety specifications are not exceeded.

Set the **I/O** switch to the **O** position to power off the ventilator.

- The blue LED to the right of the **VENTILATION ON/OFF** key turns off.
- The ventilator screen switches off.

Note:

When the ventilator is completely stopped, but is still connected to the AC power source (the green AC POWER indicator is illuminated), the internal battery continues charging.

A continuous alarm condition will be activated if the ventilator power switch is turned off while ventilation is in progress. When the power switch is turned back on again, the ventilation will resume without having to press the VENTILATION ON/OFF button.

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6 Internal Battery

Warning

Even though the Puritan Bennett™ 560 Ventilator meets current safety standards, the internal Lithium-ion battery of the device exceeds the 100Wh threshold and is therefore considered to be Dangerous Goods (DG) Class 9 – Miscellaneous, when transported in commerce. As such, the Puritan Bennett™ 560 Ventilator and/or the associated Lithium-ion battery are subject to strict transport conditions under the Dangerous Goods Regulation for air transport (IATA: International Air Transport Association), International Maritime Dangerous Goods code for sea and the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) for Europe. Private individuals who transport the device are excluded from these regulations although for air transport some requirements apply. For air transport; the Puritan Bennett™ 560 Ventilator is permitted as checked-in or carry-on baggage. Two spare batteries per person may be taken on board as carry-on luggage only, with the prior approval of the airline. This classification and regulatory requirements may vary depending upon the country and mode of transport. Therefore it is recommended that users verify with the carrier / airline as to which measures to take before the voyage.

Ensure that the ventilator's internal battery is fully charged before connecting the ventilator to an external DC power source. Powering the ventilator using an external 12– 30 VDC power source (via the DC power cable) does not enable charging of its internal battery.

The maximum recommended shelf life of the internal battery is two (2) years. Do not use a battery that has been stored for two years prior to its first use.

Periodic recharging is important to help maximize useful life of the battery. Do not store the internal battery for extended periods, without recharging, as this may reduce the maximum life.

6.1 Battery Capacity

The reserve capacity offered by the internal battery depends on the level of ventilation parameters, the environmental conditions (primarily in terms of temperature) and the physiological characteristics of the patient. With a fully charged battery at a normal room temperature of 25 °C (± 5 °C), the ventilator can be expected to operate on internal battery power for the average durations shown in Table 6-1.

Checking the battery charge level requires that the ventilator be running on battery power at the time of the battery check. To check the battery charge level, temporarily disconnect the ventilator from AC power (while in Stand By mode or while providing ventilation) and read the percent charge level displayed adjacent to the battery icon displayed at the top of the ventilator's display screen.

Table 6-1. Internal Battery Reserve Capacity

Displayed Values	Average Operating Time on Internal Battery Power[a]
Vt = 200 ml (± 5 ml) PIP = 10 mbar (± 2 mbar) Rtot = 20 bpm	11 hours (–10%)
Vt = 300ml (± 5 ml) PIP = 20 mbar (± 2 mbar) Rtot = 15 bpm	9 hours (–10%)
Vt = 500 ml (± 5 ml) PIP = 30 mbar (± 2 mbar) Rtot = 15 bpm	6.5 hours (–10%)
Vt = 750 ml (± 5 ml) PIP = 45 mbar (± 2 mbar) Rtot = 20 bpm (Maximum Ventilation Parameters)	4.5 hours (–10%)

a. Average durations shown are with a fully charged battery having less than 50 charge/recharge cycles.

6.2 Battery Operation

Warning

Before using the ventilator's internal battery, ensure that the battery is fully charged and that the charge holds. Back up ventilators or those in storage should be connected to an AC power source to protect the integrity of the battery.

Note:

Buzzer and battery alarms may occur when the unit is first powered on after the internal battery has been completely drained. Connect to an AC power source and recycle power.

In the event of AC power interruption or disconnection of the external AC or DC power supply, the ventilator automatically switches to its internal battery and the following events occur:

- The Battery symbol is displayed at the top on the general information line.
- Battery reserve capacity is displayed on the right of the symbol.
- The "INTERNAL BATTERY" indicator at the top left of the ventilator's front panel is continuously lit (Figure 6-1).

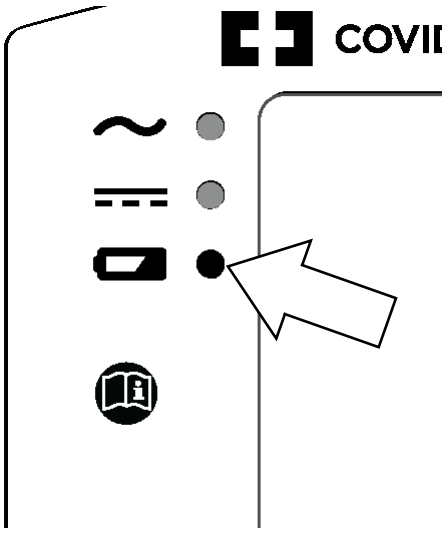


Figure 6-1. Internal Battery Indicator

- A loss of external supply alarm is activated.

If ventilation is *stopped*, the internal battery reserve capacity is displayed as a percentage of battery charge. Refer to Figure 6-2.

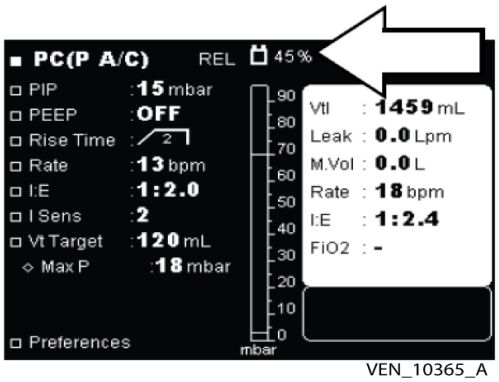


Figure 6-2. Battery Reserve Capacity as a Percentage

If the ventilator is *running*, the internal battery reserve is momentarily displayed as a percentage. Then, after the ventilator calculates the battery time remaining (which takes about two minutes, depending on the power consumption of the ventilator), the internal battery reserve is then displayed in hours and minutes (rounded to the nearest fifteen minutes). Refer to Figure 6-3.

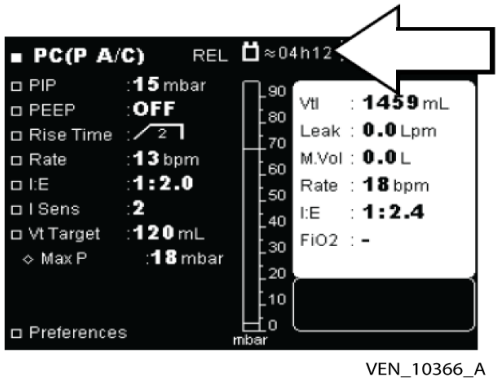


Figure 6-3. Battery Reserve Capacity in Hours and Minutes

The "LOW BATTERY" and "EMPTY BATTERY" alarms (refer to chapter 3, "Alarms and Troubleshooting") are triggered when the internal battery reserve is reduced.

Warning

Due to its limited internal battery's reserve capacity, the ventilator should only be operated on the internal battery when no other power source is available. Ensure that the internal battery never becomes fully discharged.

When the "LOW BATTERY" alarm is triggered, immediately connect the ventilator to an AC power supply to maintain ventilation and recharge the internal battery.

From the time that an "EMPTY BATTERY" alarm is activated, if no external supply is connected to the ventilator, other alarms may be triggered due to insufficient supply voltage.
In the final discharge phase, the "EMPTY BATTERY" alarm will become continuous, and ventilation may be interrupted at any time during this phase.

Note:

The "EMPTY BATTERY" alarm symbol may disappear shortly before the ventilator completely stops, but it always triggers a final, continuous alarm.

6.3 Testing the Battery

Your ventilator continuously and automatically checks the state of the internal battery, even when the battery is not used as the main source of energy. The "BATTERY FAULT1" alarm is activated whenever a problem is detected in the battery or the charger.
However, on a monthly basis you should disconnect the ventilator from the external power supply to check the integrity of the connections linking the internal battery to other ventilator components.

6.4 Recharging the Battery

In the event that the battery charge level is considered insufficient, as per the reserve capacity display, recharge of the internal battery is necessary. In general, it is recommended that the ventilator be allowed to charge when the battery drops below 80%, and that the ventilator be recharged systematically after storage and before using it again.

Note:

To avoid cycling and extend battery life while connected to an AC power source, the battery will not begin charging until it has dropped below an 85%-90% charge.

TTo charge the internal battery, do the following:

Connect the ventilator to the AC power source.

- The "AC POWER" indicator illuminates (Figure 6-4, item 1).

- The "INTERNAL BATTERY" indicator flashes (Figure 6-4, item 2).

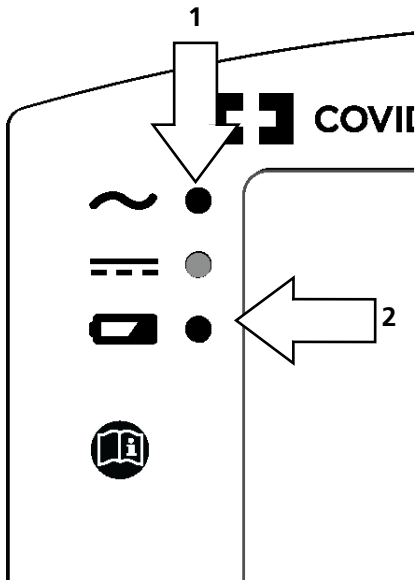


Figure 6-4. Power Indicators When Charging the Battery

When the battery charge is complete, the "INTERNAL BATTERY" indicator turns off.

Warning

Even if the "INTERNAL BATTERY" indicator is off, charge of the battery may sometimes be incomplete regardless of charge time when the ambient temperature is above 40 °C (104 °F). This is due to the characteristics of the battery's internal heat safety device.

Although it is not necessary to start the ventilator to charge the battery, charging the battery during operation will increase the time required to fully charge the internal battery.
When recharging a depleted internal battery, it may be necessary to leave the ventilator on charge for up to six (6) hours if the ventilator is on standby and about 13 hours if ventilation is operating.

Warning

Ensure that the ventilator's internal battery is fully charged before connecting the ventilator to an external DC power source. Powering the ventilator using an external 12–30 VDC power source (via the DC power cable) does not enable charging of its internal battery.

6.5 Storage

If the ventilator is to be stored for an extended period of time, it is not necessary to remove the battery. However, the ventilator should be stored in cool, dry, well-ventilated environment, as follows:

- Temperature: approximately 21 °C (70 °F)
- Humidity: less than 80% RH

Note:

When the device is in storage it should be recharged monthly to maximise battery life.

If the battery is stored for more than one month at a temperature greater than 21 °C (70 °F), or for more than one or two weeks at a temperature greater than 45 °C (113 °F), the reserve capacity of the battery may be affected. It will then be necessary to recharge the battery before using it again.

If the ventilator has been in storage for longer than 30 days connect it to an AC power source, turn on the unit by the I/O switch at the rear of the ventilator, and let it charge for 15 minutes prior to starting ventilation.

Note:

Fully charge the internal battery prior to disconnecting from AC Power source ("mains").

The battery should not be stored for more than two years, whatever the conditions.

7 Cleaning

Warning

A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet—or both ports if a double-limb circuit is used—is highly recommended.

To reduce the risk of infection, wash your hands thoroughly before and after handling the ventilator or its accessories.

7.1 Cleaning the Ventilator

Clean all external panels and surfaces before and after each patient use and as often as necessary to keep the ventilator clean. You should clean the ventilator periodically, whenever it is soiled or dirty, before any maintenance operation, and before storing the ventilator.

Warning

Use all cleaning solutions and products with caution. Read and follow the instructions associated with the cleaning solutions you use to clean your ventilator. Use only those solutions listed in Table 7-1.

The ventilator should never be immersed in any liquid, and any liquid on the surface of the device should be wiped away immediately.

To avoid damage to the ventilator, in particular the batteries or electrical components, fluids must not be allowed to enter the device, particularly through the air inlet filter or the cooling apertures located in the side, rear, and bottom panels of the ventilator.

To clean the surface of the ventilator:

1. Dip a clean, soft cloth into a mixture of mild soap and water, or other approved cleaning solution. Refer to Table 7-1 for a list of approved cleaning solutions.
2. Squeeze the cloth thoroughly to remove excess liquid.
3. Lightly wipe the external casing of the ventilator, taking care not to allow excess moisture to enter any of the openings on the ventilator's surface. See the warning, above.
4. Dry the ventilator surface with a clean, soft, lint-free cloth.

Table 7-1. Approved Cleaning Solutions for Exterior Ventilator Surfaces

Description
Mild dishwashing detergent
70% isopropyl alcohol (rubbing alcohol)
10% chlorine bleach (90% tap water)
Glutaraldehyde
Hospital disinfectant cleaners
Hydrogen peroxide
15% ammonia (85% tap water)
Ammonia-based household cleaners
Household cleaners

7.2 Cleaning the Accessories

Follow the accessory manufacturer's instructions for cleaning the ventilator's accessories and components, including the patient circuit.

⚠ **Warning**

After assembling, cleaning, or reassembling the patient circuit, and on a daily basis, inspect the hoses and other components to ensure that there are no cracks or leaks and that all connections are secure.

Never use a liquid cleaner inside the patient circuit, or on any component of a gas pathway. Clean the patient circuit only as specified by the manufacturer's instructions.

7.3 Cleaning the Exhalation Block

⚠ **Warning**

The exhalation block is intended for single use by a single patient ②. It may periodically be cleaned, but it cannot be disinfected or sterilised. To maintain good measurement quality when used continuously, clean the exhalation block periodically. The exhalation block should be changed every 4 months and cannot be reused with any other patient.

Ensure that the exhalation block is completely dried after cleaning and prior to use.

When an exhalation block is set up, each time it is removed, or after installing a new exhalation block on the machine, it is essential that the exhalation flow sensor be recalibrated before the exhalation block is used.

Note:

Many of the functions of the ventilator are not accessible when the Locking key is enabled. For additional assistance contact your Clinician or equipment representative.

8 Routine Maintenance

Warning

On a DAILY basis, inspect the patient circuit to ensure that it shows no signs of damage, is properly connected, and is operating correctly without leakage.

Do not attempt to open, repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only personnel authorised and qualified by Covidien should repair, open or service the ventilator.

8.1 Replacing the Air Inlet Filter

Warning

Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. If necessary, replace the filter before the recommended replacement period is over. This is particularly important when the ventilator is installed on a wheelchair, because environmental conditions may cause the filter to become dirty more rapidly.

Failing to replace a dirty air inlet filter, or operating the ventilator without a filter, may cause serious damage to the ventilator.

The air inlet filter is not reusable; do not attempt to wash, clean, or reuse it.

If the ventilator is used indoors, the condition of the air inlet filter should be checked monthly. If the ventilator is used outdoors or in a dusty environment, the air inlet filter should be checked weekly and replaced as necessary.

To replace the air inlet filter:

1. Hold the filter between your fingers (see Figure 8-1, item 1).
2. Remove the filter (Figure 8-1, item 2) and discard it.
3. Place the new filter in the device, while ensuring that:
   a. The fine particle side of the filter faces *outwards*, away from the ventilator.

b. The filter is properly installed in its housing. Proper installation of the filter prevents particles from entering the device.

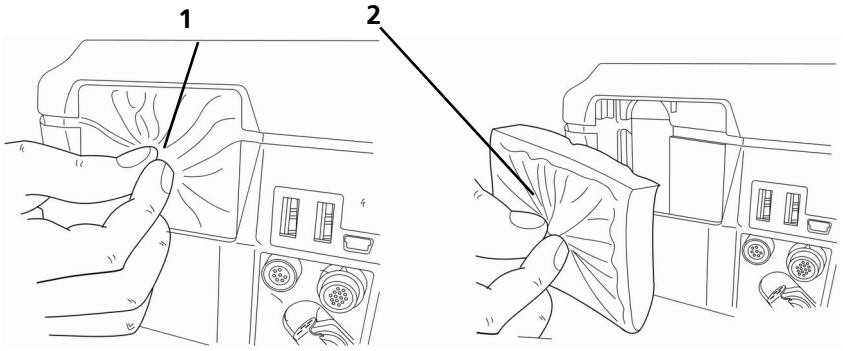


Figure 8-1. Replacing the Air Inlet filter

8.2 Recommended Schedule of Maintenance

Consumables and Replacement Intervals

When used under normal circumstances - a relatively dust-free atmosphere, and without damage to the device and its components (shocks, cracks, significant dirt) - the intervals for replacing the ventilator's consumable elements are as follows:

Table 8-1. Consumables and Replacement Intervals

Elements	Recommended Replacement Intervals
Air Inlet Filter (Foam + Fine Particle)	Once a month or more often, depending on the extent of soiling
Inspirited Bacteria Filter	See manufacturer's recommendation
Patient Circuit	See manufacturer's recommendation Single use Single patient (2)
FIO_2 Sensor	14 to 18 months or more often in case of persistent calibration failure
Exhalation Block	4 months(*) (and for each new patient)

Note:

For a list of parts and accessories, refer to Appendix F, "Parts and Accessories" or contact your service representative or consult www.puritanbennett.com.

* The exhalation block replacement frequency may be 3 months (**) for patients ventilated by tracheotomy > 12 hours / day. The replacement frequency may be extended to 6 months for patients ventilated < 12hours / day depending on the frequency of technician visits

** This minimum replacement period is based on bench test validation performed under 24/24 continuous ventilation and active humidification conditions over a period of 3 months. (Test report N°08DE265). Test report results show that no condensation or drops of water that would affect flow measurement were found in the exhalation block or the Piezzo valve.

Note:

For all additional accessories not necessarily considered as consumables consult the manufacturer's recommendations.

To prevent any risk of cross contamination we recommend the use of DAR™ filters (Ref: 351/5856 or equivalent) to protect the patient outlet port and the exhalation block port.

Warning

Regularly check the cleanliness of the air inlet filter located on the rear of the ventilator. Replace it when necessary—even before the recommended replacement period has elapsed, and particularly when the ventilator is installed on the wheelchair. Environmental conditions may cause the filter to become dirty more rapidly.

The exhalation block is intended for single use by a single patient ② . It may periodically be cleaned, but it cannot be disinfected or sterilised. To maintain good measurement quality when used continuously, clean the exhalation block periodically (refer to section 7.3, "Cleaning the Exhalation Block"). The exhalation block should be changed every 4 months and cannot be reused with any other patient.

Failure to observe these recommendations may result in a loss of performance, excessive overheating, a loss of certain functions and, in the long term, compromise the longevity of the ventilator.

Maintenance of the Internal Battery

The internal battery does not need to be removed to verify its correct operation.

Periodic Test of the Internal Battery

Your ventilator continuously and automatically checks the state of the internal battery, even when the internal battery is not used as the main power source.
However, the battery charge status should be checked MONTHLY by disconnecting the ventilator from external power supplies (refer to section 6, "Battery Operation."). Such a test is *imperative* after opening the ventilator or after a prolonged period of non-use (one month or more), in order to ensure the correct operation of internal connections linking the battery to other components.

Warning

The maximum recommended shelf life of the internal battery is two (2) years. Do not use a battery that has been stored for two years prior to its first use.

Periodic recharging is important to help maximise useful life of the battery. Do not store the internal battery for extended periods, without recharging, as this may reduce the maximum life.

Replacement of the Internal Battery

The internal battery should be replaced when the battery capacity drops below 3840 mAh. Keep in mind that, for environmental protection, the ventilator and its components—including its internal battery—cannot be disposed of with household waste. You must submit the ventilator and its components for suitable selective collection and possible recycling and observe all applicable regulations.

Note:

As the total number of battery charge/discharge cycles approaches 300, a drop in potential of as much as 20% may be detected.

8.3 Service Assistance

Warning

If a problem with the ventilator is suspected, FIRST CHECK THAT THE PATIENT IS NOT IN DANGER. If necessary, remove the patient from the ventilator and provide an alternative means of ventilation.

Do not attempt to open, repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only qualified service personnel should open, repair or service the ventilator.

In the event of a problem with the ventilator, refer to chapter 3, "Alarms and Troubleshooting". If you cannot determine the cause of the problem, contact your equipment supplier or Covidien.
For more information and local Covidien Technical Service Contact details, See "Technical Support" on page Preface-2.

A Specifications

A.1 Physical

Table A-1. Physical Description (Excluding Accessories)

Ventilator Weight	9.9 lb. (4.5 kg)
Ventilator Dimensions	9.25 in wide x 12.40 in deep x 6.0 in high (235 mm wide x 315 mm deep x 154 mm high)
Connectors	Inspiratory limb connector: ISO 22 mm (OD) conical Exhalation limb connector (on exhalation block): ISO 22 mm (ID) conical Oxygen inlet: Female Connector with valve
Device airway volume	2000 ml
Breathing circuit volume	
• Adult, dual limb	1150 ml
• Pediatric, dual limb	670 ml
• Adult, single limb	550 ml
• Pediatric, single limb	300 ml
Air Inlet Filter	Dimensions: 70 mm long x 60 mm wide Composition: Polypropylene fiber electrostatic filter material, which is laminated onto polyurethane open-celled foam. Efficiency: 99.999982% at 30 lpm (filtering microbes 3.3 µm)
Inspiratory Bacteria Filter Requirement	Maximum allowable flow resistance: 4mbar at 60 lpm

A.2 Electrical

Table A-2. AC Electrical Supply

Voltage	Frequency	Consumption
100 VAC to 240 VAC	50 Hz / 60 Hz	180 VA max
12 VDC	NA	8.3 A
30 VDC	NA	3.3 A

Table A-3. Internal Lithium Ion Battery

Voltage	25.2 VDC
Full-load capacity	4.8 Ah
Ampere-hour rating	On standby: 1.5 Ah
	During ventilation: 0.5 Ah
Watt hour rating	124Wh to 126Wh
Charging current • Standby mode • Ventilation mode	 1.5 A/hr. (duration: < 6 hr.) 0.5 A/hr. (duration: < 13 hr.)
Average operating time at 25 °C (± 5 °C) with a fully charged battery (having less than 50 charge/discharge cycles) at the following displayed values:	
Vt = 200 ml (± 5 ml), PIP = 10 mbar (± 2 mbar), Rtot = 20 bpm	11 hr. (–10%)
Vt = 300 ml (± 5 ml), PIP = 20 mbar (± 2 mbar), Rtot = 15 bpm	9 hr. (–10%)
Vt = 500 ml (± 5 ml), PIP = 30 mbar (± 2 mbar), Rtot = 15 bpm	6.5 hr. (–10%)
Vt = 750 ml (± 5 ml), PIP = 45 mbar (± 2 mbar), Rtot = 20 bpm (maximum settings)	4.5 hr. (–10%)

Table A-4. Remote Alarm

Remote Alarm Port:

Also known as the Nurse's Call port, it provides for remote alerts of ventilator alarm conditions.

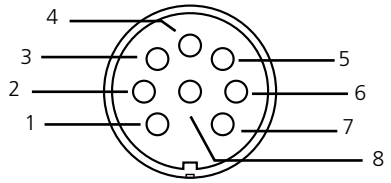
An example of a setting that requires such a feature is when the ventilator is used in an isolation room.

The ventilator signals an alarm using a normally open (NO) or a normally closed (NC) signal.

A remote alarm is activated when an alarm condition occurs, unless either of the following is true:

- Audio paused function is active
- Ventilator power switch is turned off

The remote alarm port is an 8-pin female connector. Allowable current is 100 mA at 24 VDC (maximum).



Nurse call pin-out (view from back of ventilator)

Pin	Signal	Remote Alarm Wire color
1	relay common	black
2	normally open (NO)	brown
3	normally closed (NC)	orange
4	remote supply - (not used)	
5	RX Signal (not used)	
6	TX Signal (not used)	
7	remote supply + (not used)	

A.3 Indicators and Alarms

Table A-5. Power Indicators

Ventilation ON/OFF	AC power	DC power	Internal Battery
• Blue in standby mode • Not lit if ventilation is in progress.	Green	Green	• Flashing if the battery charge is in progress. • Continuously lit if the ventilator is powered by the internal battery.

Table A-6. Alarm Indicators

High Priority	Medium Priority
Red flashing LED	Yellow flashing LED

Table A-7. Audio Alarms

Audio Paused	Alarm Volume
60 s ± 1 s	65 to 85 dBA ± 10% at 1 meter

A.4 Performance

A.4.1 Specifications

Table A-8. Performance Parameter Specifications and Tolerances

Settings	Range	Tolerances
Volume	50 to 2000 ml	± (10 ml + 10%)
Pressure	5 to 55 mbar	± (1 mbar +10%)
Time	0.3 to 2.4 s	± 50 ms or 10%, whichever is greater
Rate	1 to 60 bpm	± 1 bpm
Inspiratory Sensitivity	1 P to 5	N/A
Exhalation Sensitivity	5 to 95%	± (4 lpm + 10%) of target exhalation flow based on E Sens within 50ms
Vt Sigh	Vt x1 to Vt x 2	± (20ml + 20%)
I:E	1:4 to 1:1	± 50 ms or 10%, whichever is greater
I/T	20% to 50%	± 50 ms or 10%, whichever is greater

A.5 Monitored Parameters

Table A-9. Monitored Parameter Tolerances

Ventilator Parameters	Tolerances
Peak Inspiratory Pressure (PIP)	± (2 mbar + 8%)
Positive End Expiratory Pressure (PEEP)[a]	± (2 mbar + 8%)
Inspiratory Tidal Volume (VTI)	± (10 ml + 10%VTI)*Rate

Table A-9. Monitored Parameter Tolerances (Continued)

Ventilator Parameters	Tolerances
Exhalation Tidal Volume (VTE)	± (10 ml + 10%VTE)*VTE
Total Breath Rate (Rtot)	± 1 bpm
I:E Ratio (I:E) I/T Ratio (I/T)	± 50 ms or 10%, whichever is greater ± 50 ms or 10%, whichever is greater
Inspiratory Time (I Time)	± 100 ms
Exhalation Time (E Time)	± 100 ms
Inspiratory Minute Volume (M Vol)	± (10ml + 10%)
Vt Sigh	± (20ml + 20%)
FIO_2	± (2.5% + 2.5% FIO_2)
Leak	± (3 lpm + 20%)
Apnea Index (AI)	± 1 ev/h
Apnea Time	± 1 s
% Spontaneous (Spont)	± 1 %

a. The Puritan Bennett™ 560 Ventilator does not have the capability to reduce pressure below the PEEP pressure during the exhalation phase.

A.6 Range, Resolution, and Accuracy

Table A-10 lists the ranges, resolutions, and accuracies for ventilator settings, alarm settings, and patient data.

Table A-10. Ventilator Range, Resolution, and Accuracy

Ventilator Settings	Range, Resolution, and Accuracy
Mode	Range: V A/C, P A/C, V SIMV, P SIMV, PSV, CPAP Resolution: N/A Accuracy: N/A Default value: P A/C
Tidal volume (Vt)	Range: 50 mL to 2000 mL Resolution: 10 mL Accuracy: ± (10 ml + 10%) of setting Default value: 500 mL Depends on: Insp time, R-Rate in V SIMV and P SIMV Depends on: Rate and I:E (I/T) in V A/C
Peak Inspiratory Pressure (PIP)	Range: 5 mbar to 55 mbar in valve configuration Range: 6 mbar to 30 mbar in leak configuration Resolution: 1 mbar Accuracy: ± (1 mbar + 10%) of P Control + PEEP setting Default value: 15 mbar Depends on PEEP when Relative Pressure is set to YES
Pressure control (P Control)	Range: 5 mbar to 55 mbar in valve configuration Range: 6 mbar to 30 mbar in leak configuration Resolution: 1 mbar Accuracy: ± (1 mbar + 10%) of P Control + PEEP setting Default value: 15 mbar Depends on PEEP when Relative Pressure is set to YES

Table A-10. Ventilator Range, Resolution, and Accuracy (Continued)

Ventilator Settings	Range, Resolution, and Accuracy
Pressure support (P Support)	Range: OFF or 5 mbar to 55 mbar in valve configuration Range: 6 mbar to 30 mbar in leak in valve configuration Resolution: 1 mbar Accuracy: ± (1 mbar + 10%) of P Support + PEEP setting Default value: 15 mbar Depends on PEEP when Relative Pressure is set to YES
I:E Ratio (I:E)	Range: from 1:1 to 1:4 Resolution: 1/0.1 s Accuracy: ± 50 ms or 10%, whichever is greater Default value: 1/2
I/T Ratio (I/T)	Range: 20% to 50% Resolution: 1% Accuracy: ± 50 ms or 10%, whichever is greater Default value: 33%
Inspiratory time (Insp Time)	Range: 0.3 s to 2.4 s Resolution: 0.1 s Accuracy: ± 50 ms or 10%, whichever is greater Default value: 1.5 s Depends on: R-Rate, Vt in V SIMV mode Depends on: R-Rate in P SIMV mode
Respiratory rate (R-Rate)	Range: 5 bpm to 60 bpm in V A/C and P A/C modes 1 bpm to 40 bpm in P SIMV and V SIMV modes Resolution: 1 bpm Accuracy: ± 1 bpm Default value: 13 Depends on: Insp Time and Vt in V SIMV mode Depends on: Insp Time in P SIMV modes Depends on: Vt in V A/C mode
Inspiratory sensitivity (I Sens)	Range: 1P-5 Resolution: 1 Accuracy: NA Default value: 2 in CPAP, I Sens is set to 2 and is not adjustable
Exhalation sensitivity (E Sens)	Range: 5% to 95% of peak flow Resolution: 5% Accuracy: ± (4 lpm +10%) of target exhalation flow based on E Sens within 50ms Default value: 25% In CPAP, E Sens is fixed at 25% and is not adjustable.
Ramp (Flow Pattern)	Range: Square (SQ), descending ramp (D), sinusoidal (S) Resolution: N/A Default value: Descending ramp (D) In V SIMV, flow pattern is set to square and is not adjustable

Table A-10. Ventilator Range, Resolution, and Accuracy (Continued)

Ventilator Settings	Range, Resolution, and Accuracy
PEEP	Range: OFF (0.5 mbar) to 20 mbar Resolution: 1 mbar Accuracy: ± (1 mbar + 10%) mbar Default value: OFF Depends on: PIP in P A/C and PSV modes when Relative Pressure is set to YES Depends on: P Support and P Control in P SIMV mode when Relative Pressure is set to YES Depends on: P Support in V SIMV mode when Relative Pressure is set to YES
Rise time	Range: 1-4 Resolution: 1 Default value: 2 Depends on: Insp time
Backup rate	Range: OFF or 4-40 bpm Resolution: 1 bpm Default value: 13 Depends on: Min I time In P SIMV and V SIMV, Backup rate = Max (8, R-Rate)
Apnea time	Range: AUTO or 1-60 s Resolution: 1 s Default value: AUTO Depends on: Backup R In PSV, Apnea time: AUTO = 60/Backup R In V SIMV or P SIMV, Apnea Time: AUTO = 12 In CPAP, Apnea Time: AUTO = 30
Minimum Inspired Tidal Volume (Min VTI)	Range: 30 mL to 1990mL Resolution: 10 mL Default value: 300 Depends on: Max VTI
Maximum Inspired Tidal Volume (Max VTI)	Range: 80 mL to 3000 mL Resolution: 10 mL Default value: 2000 mL Depends on: Min VTI
Minimum Exhaled Tidal Volume (Min VTE)	Range: 30 mL to 1990 mL Resolution: 10 mL Default value: 300 Depends on: Max VTE
Maximum Exhaled Tidal Volume (Max VTE)	Range: 80 mL to 3000 mL Resolution: 10 mL Default value: 1000 Depends on: Min VTE
Maximum Respiratory Rate (Max Rtot)	Range: 10 bpm to 70 bpm Resolution: 1 bpm Default value: OFF Depends on: R-Rate

Table A-10. Ventilator Range, Resolution, and Accuracy (Continued)

Ventilator Settings	Range, Resolution, and Accuracy
Minimum Peak Inspiratory Pressure (Min PIP)	Range: PIP- 20% (not adjustable in pressure breath) Range: 2-52 in volume breath Resolution: N/A
Maximum Peak Inspiratory Pressure (Max PIP)	Range: PIP+ 20 % (not adjustable in pressure breath) Range: 12-60 in volume breath Resolution: N/A
Minimum inspiratory time (Min I time)	Range: 0.1 to 2.8 s Resolution: 0.1 s Default value: AUTO (Rise time + 300 ms) Depends on: Max I Time, Backup R, Rise time
Maximum inspiratory time (Max I time)	Range: 0.8 to 3 s Resolution: 0.1 s Default value: AUTO {Min [3 s; (30/R-Rate)]} Depends on: Min I Time, R-Rate
Minimum Fraction of Inspired Oxygen (Min FIO_2)	Range: 18 to 90 % Resolution: 1 % Default value: OFF Depends on: Max FIO_2
Maximum Fraction of Inspired Oxygen (Max FIO_2)	Range: 30 to 100 % Resolution: 1 % Default value: OFF Depends on: Min FIO_2

A.7 Environmental

The following environmental conditions shall be observed:

Table A-11. Environmental Conditions for Storage or Transport

Temperature	Humidity	Atmospheric pressure	Altitude
-40 °C to +70 °C (-40 °F to +158 °F)	10% to 95% RH	500 hPa to 1060 hPa (7 psi to 15.4 psi)	-152 m to 3964 m (500 ft to 13,000 ft)

Table A-12. Environmental Conditions for Operation

Temperature	Humidity	Atmospheric pressure	Altitude
+5 °C to 40 °C (+41 °F to 104 °F)	10% to 95% RH	600 hPa to 1100 hPa (8.7 psi to 16.0 psi)	-152 m to 3964 m (-500 ft to 13,000 ft)

Under extreme conditions of use that are beyond the recommendations above but within the limits of a supply voltage of –20%, compared to the nominal temperature or the combination of a temperature of 45 °C (113 °F) and humidity of 75% RH, the ventilator should not malfunction nor endanger the user. However, operating the device for prolonged periods or repeatedly under such extreme conditions could result in premature aging of components and more frequent maintenance.

A.8 USB

Table A-13. USB Memory Device Specifications

Characteristics	Supported formats
USB compatibility	USB flash memory USB 2.0 or USB 1.1
Memory file format	USB 32 bit format (sector size: 512 - 2,048 bytes)
Number of files	Maximum 999
USB size	128 MB to 4 GB

Table A-14. Data Transfer Characteristics

Ventilator data description	Capacity
Trends capacity	86 MB
Events capacity	512 KB or 5,500 events
Monitorings capacity	42 MB / 48 hours

A.9 Pneumatic

Table A-15. Airway Resistances

Inspiratory	Exhalation
1.0 mbar at 30 lpm flow ± 0.1 mbar	0.5 mbar at 30 lpm ± 0.1 mbar
3.7 mbar at 60 lpm flow ± 0.1 mbar	1.1 mbar at 60 lpm ± 0.1 mbar

Table A-16. Patient Circuit Resistances[a]

Adult Double Limb	Pediatric Double Limb
≤ 2 mbar at 60 lpm flow[b]	≤ 2 mbar at 30 lpm flow

a. Includes exhalation valve
b. Values obtained from the manufacturer's directions for use.

Table A-17. Air Inlet Resistance (Filter)

1.1 cmH_2O (1.079 mbar) at 30 lpm flow

Table A-18. Oxygen Inlet Specifications

Maximum pressure	Maximum flow
50 kPa (7 psi)	15 lpm

Table A-19. Performance Specifications

Working pressure	Sound pressure level	Maximum pressure limit	Internal compliance (ventilator)	Inspiratory triggering response time (Ttr)
5 mbar – 55 mbar	30 dBA (per NF EN ISO 17510-1 test conditions)	60 mbar	.0001 l/mbar	100 ms

A.10 Manufacturer's Declaration

The following tables, Table A-20 through Table A-23, contain the manufacturer's declarations for the ventilator's electromagnetic emissions, electromagnetic immunity, and recommended separation distances between the ventilator and portable and mobile RF communications equipment, as well as a list of compliant cables.

Warning

Portable and mobile RF communications equipment can affect the performance of the Puritan Bennett™ 560 Ventilator. Install and use this device according to the information contained in this manual.

The ventilator should not be used adjacent to or stacked with other equipment, except as specified in this manual. If adjacent or stacked use is necessary, the ventilator should be observed to verify normal operation in the configurations in which it will be used.

Table A-20. Electromagnetic Emissions

The Puritan Bennett™ 560 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should assure that it is used in such an environment.		
RF emissions CISPR 11 / EN 55011	Group 1	The ventilator uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 / EN 55011	Class B	The ventilator is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC / EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC / EN 61000-3-3	Complies	

Table A-21. Electromagnetic Immunity

The ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should ensure that it is used in such an environment.			
Immunity Test	**IEC / EN 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment–Guidance**
Electrostatic discharge (ESD) IEC / EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC / EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	AC power ("mains") quality should be that of a typical commercial or hospital environment.
Surge IEC / EN 61000-4-5	± 1 kV lines/lines ± 2 kV lines/earth	± 1 kV lines/lines ± 2 kV lines/earth	AC power ("mains") power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC / EN 61000-4-11	< 5% U_T (> 95% dip in U_T for 0.5 cycle) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) < 5% U_T (> 95% dip in U_T for 5 s)	< 5% U_T (> 95% dip in U_T for 0.5 cycle) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) < 5% U_T (> 95% dip in U_T for 5 s)	AC power ("mains") power quality should be that of a typical commercial or hospital environment. If the user of the ventilator requires continued operation during power mains interruptions, it is recommended that the ventilator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC/ EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Table A-22. Electromagnetic Immunity – Conducted and Radiated RF

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

Immunity Test	IEC / EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment– Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC / EN 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms inside ISM bands[a]	3 Vrms 150 kHz to 80 MHz outside ISM bands 10 Vrms inside ISM bands	**Recommended separation distance** $d = 0{,}35\sqrt{P}$ $d = 1{,}2\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Table A-22. Electromagnetic Immunity – Conducted and Radiated RF (Continued)

Note:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ventilator is used exceeds the applicable RF compliance level above, the Puritan Bennett™ 560 Ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Puritan Bennett™ 560 Ventilator.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Table A-23. Recommended Separation Distances

The ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ventilator as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter**			
	150 kHz to 80 MHz (outside ISM bands) $d = 0{,}35\sqrt{P}$	**150 kHz to 80 MHz** (in ISM bands) $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2{,}3\sqrt{P}$
0.01	0.035 m	0.12 m	0.12 m	0.23 m
0.1	0.11 m	0.38 m	0.38 m	0.73 m
1	.35 m	1.2 m	1.2 m	2.3 m
10	1.1 m	3.8 m	3.8 m	7.3 m
100	3.5 m	12 m	12 m	23 m

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

Note:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
- An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table A-24. Compliant Cables and Accessories

Cable or Accessory	Maximum length
UK AC power cable assembly	1.8 m (5.9 ft)
Japan AC power cable assembly	1.8 m (5.9 ft)
China AC power cable assembly	1.8 m (5.9 ft)
South Africa AC power cable assembly	1.8 m (5.9 ft)
India AC power cable assembly	1.8 m (5.9 ft)
Australia AC power cable assembly	1.8 m (5.9 ft)
Europe AC power cable assembly	1.8 m (5.9 ft)
Canada AC power cable assembly	1.8 m (5.9 ft)
Nurse call cable	5 m (16.4 ft)
12V DC car adapter cable	5 m (16.4 ft)
Oxygen inlet connector	-

A.11 Standards Compliance and IEC Classification

General Standards

- Medical Electrical Equipment: General Requirements for Safety IEC 60601-1:1990 and EN 60601-1:1990 and all its amendments up to 1995.
- The ventilator will be constructed to comply with the following product Classifications as detailed in Clause 5 of 60601-1:
  - Class II Equipment
  - Internally Powered Equipment
  - Type BF Applied Parts
  - IP31 with respect to access to hazardous parts and ingress of moisture
  - Not suitable for use in the presence of flammable anesthetic mixtures
  - Not suitable for sterilisation
  - Suitable for continuous operation
  - Detachable power supply cable
- Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment - Part 1: General Requirements for Safety.
- UL 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety: 2003.

Collateral Standards

- Medical Electrical Equipment - Part 1: General Requirements for Safety -2- Collateral standard Electro-Magnetic Compatibility requirements and tests IEC 60601-1-2:2007 and EN 60601-1-2: 2007.
- Medical Electrical Equipment - Part 1: General Requirements for Safety -2- Collateral standard: Programmable Electrical Medical Systems IEC 60601-1-4:2000 and EN 60601-1-4:2004.
- Medical Electrical Equipment - Part 1: General Requirements for Safety -2- Collateral standard: Usability IEC 60601-1-6:2006 and EN 60601-1-6:2007.
- General Requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-8:2003 and EN 60601-1-8:2007.

Particular Standards

- Lung Ventilators for Medical Use- Particular Requirements for Basic Safety and Essential Performance Part 2: Home Care Ventilators for Ventilator-Dependent Patient EN ISO10651-2:2009.
- Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 2: Home care ventilators for ventilator – dependent patients YY 0600.2-2007 (ISO 10651-2:2004, MOD).
- Medical electrical equipment – Part 2: Particular requirements for the safety of lung ventilators – Critical care ventilators GB 9706.28-2006 (IEC / EN 60601-2-12:2006, MOD)
- Anesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets EN ISO 5356-1:2004.

Air Transportation Standards

- Environmental Conditions and Test Procedures for Airborne Equipment - RTCA/DO-160:2007.

B Modes of Ventilation

B.1 Modes of Ventilation

This chapter is a general description of the various modes of ventilation and breath types available with the Device name.

Note:
The default ventilation mode setting is P A/C; for more information, see below.

B.1.1 Assist/Control (A/C) Modes

When set to an Assist/Control mode, machine-initiated breaths are delivered at a clinician-set volume or pressure, inspiratory time, and rate. If the patient triggers a spontaneous breath between machine breaths, the ventilator will deliver a breath based on the volume or pressure settings and inspiratory time.
Whether initiated by the patient or the ventilator, all breaths are delivered at the same preset volume or pressure and inspiratory time.

The names of the Assist/Control modes are:

- V A/C, if the breaths are based on a volume setting
- P A/C, if the breaths are based on a pressure setting

B.1.2 SIMV Modes

When set to a SIMV (Synchronised Intermittent Mandatory Ventilation) Mode, machine-initiated breaths are delivered at a clinician-set volume or pressure, inspiratory time, and rate. These mandatory breaths are synchronised with patient effort. If the patient triggers a spontaneous breath between machine breaths, the ventilator will deliver a spontaneous breath, which is pressure-supported.
CPAP spontaneous breaths are not available in SIMV modes.

The names of the SIMV modes are:

- V SIMV, if mandatory breaths are based on a volume setting
- P SIMV, if mandatory breaths are based on a pressure setting

B.1.3 CPAP Mode

In CPAP, the ventilator maintains a constant level of pressure in the patient's airway.

B.1.4 PSV Mode

PSV mode maintains a constant level of pressure in the patient's airway during exhalation. In addition, the ventilator applies a clinician-set pressure (Pressure Support) to each of the patient's breaths. This has the same benefits as CPAP, with the additional benefit of assisting the patient in moving gas into his or her lungs.

C Operational Verification Checklist

The operational verification and safety checks listed in Table C-1 below should be performed to ensure the ventilator is operating properly in the following circumstances:

- Prior to using the ventilator with a patient
- Monthly while the ventilator is in use
- Following maintenance or changes in ventilator settings

If the ventilator fails any of the safety checks below, or if you cannot complete these checks, refer to section 3.8, "Troubleshooting" or call the equipment supplier or Covidien (refer to section 8.3, "Service Assistance").

Warning

Provide the patient with an alternate means of ventilation before conducting these tests.

To reduce the risk of infection, wash your hands thoroughly before and after handling the ventilator or its accessories.

Table C-1. Operational Verification Checklist

1	Verify the proper appearance and cleanliness of the ventilator.	☐ Pass
2	Verify all of the labels and markings on the ventilator are clear and legible.	☐ Pass
3	Confirm the air inlet filter is clean and correctly installed.	☐ Pass
4	Ensure the AC power cable does not exhibit any signs of damage, such as kinks, breaks, or damaged insulation.	☐ Pass
5	Connect the AC power cable. Ensure that all power supply indicators on the front panel flash, except for the AC power supply (mains) indicator, which should remain lit.	☐ Pass
6	Push the power switch **I/O** to the **I** position to activate the ventilator test: Check that the two alarm indicators and the Standby indicator (located close to the **VENTILATOR ON/OFF** ⏻ key) flash. Ensure also that the two alarm buzzers sound.	☐ Pass
7	Perform the Functioning Alarms Test. Refer to Appendix E, "Alarms Tests."	☐ Pass
8	Verify the alarm volume is adapted to the patient environment.	☐ Pass
9	Verify that the preventive maintenance schedule for the ventilator is followed. Refer to chapter 8, "Routine Maintenance".	☐ Pass
10	Ensure the patient breathing circuit is correctly attached to the ventilator, with all the necessary components, and is free from any signs of damage and leaks. If exhaled volume monitoring is required, use the double-limb circuit for exhaled tidal volume monitoring.	☐ Pass

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D Unpacking and Preparation

The Puritan Bennett™ 560 Ventilator is delivered with the following items:
(1) Printed User's Manual (language as requested by the customer)
(1) Clinician's Manual on CD (a print copy is available upon request by the customer)
(1) Patient circuit and valve
(1) Set of six (6) combination foam/fine particle air inlet filters
(1) Carrying bag
(1) Oxygen connector
(1) AC power cable

Warning

Users must always possess an additional circuit and valve while using the Puritan Bennett™ 560 Ventilator.

To minimise the risk of damage, you must use the Dual Bag to transport the Puritan Bennett™ 560 Ventilator. See Figure D-2, Dual Bag.

To unpack and prepare the ventilator, follow the steps below.

1. From the plastic bag, remove the following:
   - Plastic pocket containing the Clinician's Manual.
   - The ventilator and its components and/or accessories.
2. Remove the patient circuit, the AC ("Mains") power cable, and the set of fine-particle air inlet filters
3. Inspect the ventilator and ensure that:
   - the ventilator's outer casing and the **I/O** switch's protective cover do not have any dents or scratches, which may indicate possible damage.
   - the ventilator's labels and markings are clear and legible.
   - the AC power cable does not exhibit any signs of damage, such as kinks, breaks, or cuts.

Warning

Never use a ventilator or any components or accessories that appear to be damaged. If any signs of damage are evident, contact your equipment supplier or Covidien.

4. Clean the ventilator with a mild soap solution, if necessary (refer to chapter 7, "Cleaning").
5. Ensure that the air inlet filter is installed.

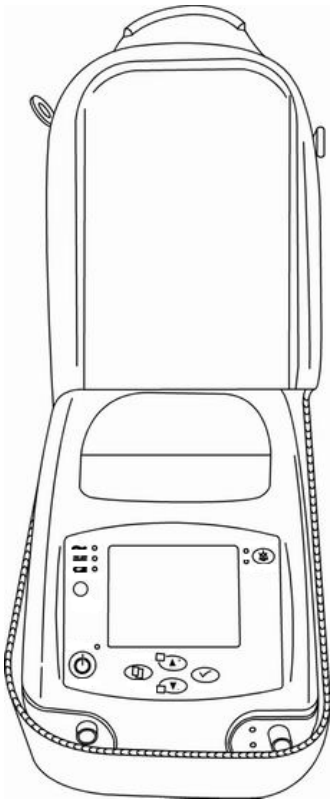

Figure D-1. Puritan Bennett™ 560 Ventilator

Figure D-2. Dual Bag

E Alarms Tests

Before connecting the ventilator to the patient, perform the following tests to ensure the ventilator's alarms are working properly.

Warning

Do not perform ventilator alarm tests while the patient is connected to the ventilator. Provide the patient with an alternate means of ventilation before conducting these tests.

If the ventilator fails any alarm test or if you cannot complete these tests, see the Troubleshooting section (refer to chapter 3, "Alarms and Troubleshooting") of this manual or call your equipment supplier or Covidien (refer to section 8.3, "Service Assistance").

The setting of the Min PIP alarm must be adjusted for the patient, but must also be set high enough to allow the PATIENT DISCONNECTION alarm to trigger properly. Perform the Low Pressure Test (refer to section E.1, "Low Pressure Test") to ensure the Min PIP alarm is properly set.

Note:

Many of the functions of the ventilator are not accessible when the Locking key is enabled. For additional assistance contact your Clinician or equipment representative.

Most of these tests require that an approved patient circuit be connected to the ventilator. Ensure that your patient circuit is properly connected prior to performing these tests.

E.1 Low Pressure Test

Warning

The setting of the Min PIP alarm must be adjusted for the patient, but must also be set high enough to allow the PATIENT DISCONNECTION alarm to trigger properly. Perform the following test to ensure the Low PIP alarm is properly set.

1. Before proceeding, set the ventilation and alarm parameters specified by the patient's clinician and specify a single or dual circuit setup.
2. Press the **VENTILATION ON/OFF** key to start ventilation.
3. Keep the patient's end of the breathing circuit open and allow ventilation to continue.
4. Wait for (Apnea Time + 2 seconds; Apnea time is not always 5 seconds), then ensure that:
   - the High priority indicator (red colour) lights up
   - the "PATIENT DISCONNECTION" alarm is displayed
   - the audible alarm sounds
5. Press the **ALARM CONTROL** key once to silence the alarm.
6. Press and hold the **VENTILATION ON/OFF** key for three (3) seconds, then release it. Press the **VENTILATION ON/OFF** key again to confirm stop.The ventilator will switch to Standby mode and cancel the alarms.

E.2 Power Failure Test

Note:

If the ventilator is operating on either the external power supply or the internal battery, you must plug it in to an AC power source before beginning this test.

1. Disconnect the ventilator from its AC power supply. Ensure that the following events occur:
   - the Medium priority indicator (yellow colour) illuminates
   - the "AC POWER DISCONNECTION" alarm activates
   - an audible alarm sounds
   - the **DC POWER** indicator illuminates if the DC power source is connected; otherwise, the INTERNAL BATTERY indicator illuminates
2. Press the **ALARM CONTROL** key *twice* to reset the alarm.
3. Reconnect the ventilator to its AC power supply.

E.3 Occlusion Test

Note:

Occlusion testing can only be done in Pressure modes.

1. Verify that the pressure tube of the patient circuit is properly connected to the appropriate fitting on both the ventilator and the proximal pressure port (refer to section 4.4, "Patient Circuit").
2. Block the patient wye at the end of the patient circuit. Refer to Figure E-1 on page E-2.

Figure E-1. Blocking the Patient End of a Patient Circuit

3. Press the **VENTILATION ON/OFF** key to start ventilation.
4. Allow the ventilator to deliver three (3) consecutive breaths. At the beginning of the fourth breath, ensure that the following events occur:
   - the High priority indicator (red colour) illuminates
   - the "Occlusion" alarm activates
   - an audible alarm sounds
5. Press the **ALARM CONTROL** key to silence the alarm.
6. Unblock the patient wye.
   - The alarm is cancelled.

7. Press and hold the **VENTILATION ON/OFF** key for three (3) seconds, then release it. Press the **VENTILATION ON/OFF** key again to confirm stop.
   - Ventilation stops.

E.4 Testing the Battery

The ventilator is capable of testing the power of the battery (refer to chapter 6, "Internal Battery"). You can determine which power source the ventilator is using by checking the power indicator, located on the top panel. The indicator light will be lit to indicate which power source is currently available.

1. Disconnect the AC power supply cable and the DC power cable (if it is connected) from the ventilator.
   - a POWER DISCONNECTION alarm will trigger.
2. Press the **ALARM CONTROL** key twice to pause the alarm. Ensure that the following events occur:
   - the INTERNAL BATTERY indicator to the upper-left of the display illuminates
   - the BATTERY symbol is displayed at the top of the screen (along with its reserve capacity)
3. Connect the AC (mains) power supply. Ensure that the following events occur:
   - the AC POWER indicator to the upper-left of the display illuminates
   - the indicator to the upper-left of the display is flashing, which indicates that the battery is charging (this only occurs if the ventilator has run on battery power long enough to lose enough charge that the charger will turn on)
   - the BATTERY symbol is no longer displayed at the top of the screen

E.5 Involuntary Stop Test

To verify proper functioning of the Very High Priority audible alarm, perform the following.

1. Press the VENTILATION ON/OFF key to start ventilation.
2. Set the **I/O** switch to the **O** (off) position to power-down the ventilator during ventilation. Ensure that the following events occur:
   - An audible alarm sounds continuously
   - The ventilator turns off. There should be no alarm indicators illuminated and no alarm messages displayed.
3. Press the **ALARM CONTROL** key once to silence the audible alarm.

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F Parts and Accessories

Table F-1 provides a list of accessories that are available for the Device name.
To order parts or accessories, contact your equipment supplier or Covidien representative.

Note:

The ventilator is delivered with the following items: a printed User's Manual, a CD with Clinician's Manual (printed copy available upon request); one patient circuit with valve; one set of six (6) combination foam/fine particle air inlet filters; one carrying bag; one O_2 connector; and one AC power cable.

Table F-1. List of Consumables and Accessories

Description
Carrying bag (grey)
Oxygen inlet connector
Ventilator Cart
Dual Bag (blue or pink) delivered with: Backpack Padded Straps, 2 ea. Suspension belt Carrying belt ⚠ **Warning** **To minimise the risk of damage, you must use the ventilator's Dual Bag to transport the ventilator.**
AC (mains) power cable
DC power cable (for connection to an external DC power source, such as a car 12 volt DC outlet)
Remote Alarm cable (5 metres)
Exhalation block, single-patient use (blue)
Inlet air combi-filter, fine (pack of 6) **Note:** This is the "foam plus fine particle" filter listed in See Table 8-1, Consumables and Replacement Intervals, on page 8-2).
Internal battery
External battery
FIO_2 measurement kit
FIO_2 sensor
2-way and 3-way DAR™ valves

Table F-1. List of Consumables and Accessories (Continued)

Description
DAR™ Inspiratory Bacteria Filters
Electrostatic Filter, Large (formerly Barrierbac)
Electrostatic Filter, Small (formerly Barrierbac S)
Electrostatic Filter; Small, Angled Port (formerly Barrierbac S Angled)
Adult-Pediatric Electrostatic Filter HME, Large (formerly Hygrobac)
Adult-Pediatric Electrostatic Filter HME, Small (formerly Hygrobac S)
Adult-Pediatric Electrostatic Filter HME; Small, Angled Port (formerly Hygrobac S Angled)
Infant-Pediatric Electrostatic Filter HME, Small (formerly Hygroboy)
Adult-Pediatric Mechanical Filter HME, Large (formerly Hygroster)
Adult-Pediatric Mechanical Filter HME, Compact (formerly Hygroster Mini)
Mechanical Filter, Large (formerly Sterivent)
Mechanical Filter, Compact (formerly Sterivent S)
Mechanical Filter, Small (formerly Sterivent Mini)
Adult-Pediatric HME (formerly Hygrolife II)

Table F-2 provides a list of consumable parts available for the ventilator.

Warning

To ensure proper performance of the ventilator, use a patient circuit recommended by Covidien in this manual; refer to chapter 4, "Installation and Assembly" and Appendix F, "Parts and Accessories". The total specified length of the patient circuit tubing as measured from the ventilator outlet to the ventilator inlet is 1.1 metres (3.6 ft) to 2.0 metres (6.6 feet). The tubing must conform to all applicable standards and must be fitted with Ø 22 mm terminals that also conform to all applicable standards. Ensure that both the length and the internal volume of the patient circuit are appropriate for the tidal volume: a corrugated tube of Ø 22 mm for adult patients, and a corrugated tube of Ø 15 mm for pediatric patients with a tidal volume lower than 200 ml.

Table F-2. List of Circuits

Description	Part Number
DAR™ Double limb patient circuit with exhalation valve, 180 cm, PVC, ADULT	5094000
DAR™ Double limb patient circuit with exhalation valve, 180 cm, PVC, PEDIATRIC	5093900
DAR™ Single limb patient circuit with exhalation valve, 180 cm, PVC, ADULT	5093600
DAR™ Single limb patient circuit with exhalation valve, 180 cm, PVC, PEDIATRIC	5093500
DAR™ Single limb patient circuit without exhalation valve, 180 cm, PVC, ADULT	5093300
DAR™ Single limb patient circuit without exhalation valve, 180 cm, PVC, PEDIATRIC	5093100

For more information regarding parts and accessories for the Device name contact your service representative or www.covidien.com.

G Glossary

AC Power

Alternating current.

Alarm Pause

The audible and visual alarms cease and the  symbol appears. The symbol will remain until the cause of the alarm is addressed. For example, when the ventilator is running on internal battery, the AC Disconnection alarm may be paused, and the alarm paused symbol will appear until the device is plugged into AC. The paused alarm will be captured in the alarm log screen and can be reactivated.

Alarm Reset

Used only for the High Pressure alarm, this function resets the visual alarm message.

Apnea

The absence of breathing or a breathing pattern capable of supporting an individual's respiratory needs.

AI - Apnea Index

The Apnea index is average number of apnea events per hour of ventilation. It is based on the Apnea Alarm.

Apnea Time

Time allowed between breath starts before APNEA alarm occurs when no patient effort is detected.

Assist/Control

In Assist/Control mode, the ventilator delivers an assisted breath of a set volume or set pressure when the patient's breathing effort creates a flow or pressure drop that is greater than the SENSITIVITY setting. In absence of patient breathing effort, the ventilator will deliver a controlled breath of the set volume or pressure. (Does not apply in PSV/CPAP mode).

Assisted Breath

A volume or pressure breath triggered by the patient but then controlled and terminated by the ventilator.

Audio Pause

Pauses the audible alarm for 60 seconds at a time and shows the  symbol; often referred to as "Alarm Silence."

Back Up Rate

Rate of control cycles in PSV or SIMV modes during apnea phase.

Battery Level

Display of the remaining battery capacity; located adjacent to the battery symbol.

Bias flow

Turbine flow during exhalation phase through the patient circuit to avoid rebreathing.

bpm

An abbreviation for "breaths per minute," which is the unit of measure for breath rate (see below).

Breath Rate (Back Up R)

The total number of breaths, both machine and spontaneous, delivered by a ventilator in one minute.

Caregiver

An individual who assists a patient with the tasks of daily living. This may be a family member, a live-in assistant, or the nursing staff of a health care facility.

cmH_2O

An abbreviation for "centimetres of water," which is a unit of measure for pressure.

CPAP (Continuous Positive Airway Pressure)

Continuous airway pressure maintained throughout a spontaneous breath cycle.

Controlled breath

A volume or pressure breath triggered, controlled and terminated by the ventilator.

DC Power

Direct current.

Double Limb Patient Circuit

Patient circuit with a tube between the ventilator gas outlet and the patient for inspiratory gas and another tube between the patient and the exhalation block for exhalation gas.

Exhalation Block

Part of the ventilator that allows the connection of the exhalation limb of the patient circuit. The exhalation block is for single-patient use only.

Exhalation Phase

Phase of the breath cycle during which the patient exhales.

Exhaled Tidal Volume (VTE)

Exhaled volume measured for all breath types through the exhalation block. Monitored value available only with double limb patient circuit.

Exhalation Sensitivity

The exhalation sensitivity (E Sens) level is a percentage of peak flow at which a pressure-supported breath will be terminated.

Exhalation Tidal Volume (VTE)

Volume exhaled by the patient at each exhalation phase.

Fraction of Inspired Oxygen (FIO_2)

Amount of oxygen delivered to the patient.

FIO_2 Sensor

The sensor which measures the amount of oxygen being delivered to the patient.

Flow

Volume of gas delivered by the ventilator compared to time, expressed in litres per minute (lpm).

Flow Pattern (Ramp Setting)

This is the flow distribution shape during the inspiration phase. There are three flow patterns available: Square waveform or constant flow, Decelerated (sawtooth waveform) or decreasing flow and Sinusoidal flow.

Freeze

Interruption of the waveform plot tracing on the ventilator's display.

hPa

An abbreviation for "hectopascal" which is a unit of measure for atmospheric pressure.

I:E ratio

Inspiratory time versus exhalation time ratio.

Inspiratory Phase

Phase of the breath cycle during which the patient inspires.

Inspiratory Sensitivity (I Sens)

Level of inspiratory effort the patient has to provide during the initiation of a machine breath. The sensitivity levels (from 1P to 5) correspond to differences in flow compared to the bias flow. Level 1P is the most sensitive (for a pediatric use) and requires the least effort to trigger a breath. Level 5 requires the most amount of effort to trigger a breath.

Inspiratory Tidal Volume (VTI)

Volume delivered to the patient at each inspiratory phase.

I Time (Inspiratory Time)

Inspiratory time measure.

Intentional Vent Stop Alarm

Intentional Ventilation Stop Alarm - Ventilation has been switched off by the user / caregiver and the ventilator is in stand-by.

I/T Ratio

Inspiratory time versus total breath time ratio.

L

litres (a unit of volume).

Leak

When ventilating with a double limb circuit in leak configuration, it is the average unexpected leak during each cycle and over the past 24 hour period. When ventilating with a single limb circuit there is no average leak.

LED

Light Emitting Diode; used as indicator lights on the ventilator's front panel.

lpm

Litres Per Minute (a unit of volume flow rate).

Machine Hours

Counter for the total ventilation time since manufacture or the last CPU board change.

Mains

AC power supply.

Max Leak

The maximum alarm setting of a high leakage threshold. An alarm will be triggered in the event the calculated leakage is exceeded.

Max Rtot (Total breath rate)

The maximum alarm setting to prevent hyperventilation or ventilator autotriggering. The HIGH RATE alarm will be triggered if the total breath rate exceeds the maximum limit set.

Max P (Maximum Inspiration Pressure)

Max P allows the ventilator to adjust the inspiratory pressure up to a maximum limit in order to reach the target tidal volume (Vt Target).

Mbar

An abbreviation for "millibar" which is a unit of measure for atmospheric pressure.

Mean Airway Pressure

Average patient pressure during each breath.

Minimum Exhalation Time

Minimum exhalation time before allowing the patient inspiratory trigger.

Minimum Inspiratory Time

Minimum inspiratory time before allowing the patient to exhale.

M Vol (Minute Volume)

Flow delivered at each breath to the patient is measured by the inspiratory flow sensor and that measurement is used to calculate minute volume (Vt x Rtot)

Nurse Call

This function allows for remote alerts of ventilator alarm conditions (for example, when the ventilator is in an isolation room)

P A/C (Pressure Assist /Control)

A ventilator mode which provides machine-initiated breaths delivered at a clinician-set pressure, inspiratory time, and rate.

Patient Breath

Breathing cycle initiated by the patient.

Patient Counter

Counter of ventilation time for the patient.

Patient effort

Inspiratory effort initiated by the patient.

Patient circuit

Tubing between the ventilator and the patient.

Pause

Waveforms freezing function.

PAW (Peak Airway Pressure)

The Peak Airway Pressure is the average peak pressure during the inspiratory phase, measured by each cycle and over the previous 24 hour period.

Peak Inspiratory Pressure (PIP)

The highest pressure measured in the patient circuit during the inspiration phase.

Positive End Expiratory Pressure (PEEP)

Pressure in the patient circuit at the end of expiration.

Pressure Control (P Control)

Augmentation of the patient's ventilation synchronously with inspiratory effort until a preset pressure is met. Pressure is maintained throughout patient inspiratory flow, and is cycled to expiration by time (controlled by the selected Inspiratory Time setting). Used in Assist/Control mode.

Pressure Support (P Support)

Augmentation of the patient’s ventilation synchronously with inspiratory effort until a preset pressure is met. Pressure is maintained until inspiratory flow is reduced to a percentage of peak flow that depends on the exhalation sensitivity setting for the inspiration, when the ventilator cycles into exhalation. Available in SIMV or Spontaneous modes.

PSI

Pounds Per Square Inch.

PSV (Pressure Support Ventilation)

Pressure support ventilation.

Rebreathing

The patient breathes his/her exhaled gas.

Respiration rate

The number of breath cycles (inspiration + expiration) completed within one minute. Normal resting adult respiratory rates are from 12 – 20 breaths per minute (bpm).

Rise Time

This determines how the target pressure will be reached, and indirectly defines the minimum inspiration time.

Rtot

Parameter measured by the ventilator equal to the total number of breaths per minute (bpm).

Sensitivity

This adjustable parameter determines the amount of inspiratory effort required by the patient before the ventilator delivers an assisted breath, or demands flow in the case of a spontaneous breath.

The Puritan Bennett™ 560 Ventilator is flow-triggered, with sensitivity levels in the range from 1 to 5: the lower the number, the more sensitive the trigger.

Sigh

A sigh is an increased volume of gas delivered to the patient at a set rate. i.e. every 50 breaths.

Spont Cyc (Spontaneous Cycling)

This is the percentage of ventilation cycles initiated by the patient over the previous 24 hour period.

Spontaneous

A ventilation mode that delivers assisted breaths only. Spontaneous mode does not provide breaths if the patient does not make an inspiratory effort greater than the sensitivity settings and there is no apnea backup rate.

Standby

The operational mode of the ventilator where it is powered (power supply **I/O** button set to the **I** position), but is not ventilating the patient.

SIMV (Synchronised Intermittent Mandatory Ventilation)

A ventilator mode which provides a mechanism for synchronising the ventilator-delivered breaths with a patient's inspiration, as detected by the ventilator.

Tidal volume (Vt)

Volume of gas delivered to the patient in a breath.

Unfreeze

Resumption of the waveform plot tracing on the ventilator’s display.

V A/C (Volume Assist / Control)

A ventilator mode which provides machine-initiated breaths are delivered at a clinician-set volume inspiratory time, and rate.

Vent Time (Ventilation Time)

The ventilation duration data is based on the patient counter and shows the total ventilation time in hours and minutes over the previous 24 hour period.

Volume breath

Inspiration of the selected volume, delivered over the selected inspiratory time.

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