

Adapt Procedure For

Ventilators, Intensive Care [17-429]

Ventilators, Intensive Care, Neonatal/Pediatric [14-361]

Scope

Applies to all ventilators except jet ventilators, negative-pressure ventilators, portable ventilators (see Procedure 471), and anesthesia unit ventilators (see Procedure 461)

Interval

12 Months

Time Required

2 Hours

Overview

Ventilators designed for use in critical care settings; most use positive pressure to deliver gas to the lungs at normal breathing rates and tidal volumes through an endotracheal tube or tracheostomy. These ventilators typically consist of a flexible breathing circuit, a control system, monitors, and alarms. The gas is typically delivered to the patient using a double-limb breathing circuit. The inhalation limb provides sites where the gas may be heated or humidified using appropriate devices, and the exhalation limb includes an exhaust valve to release the gas to the ambient air. Intensive care ventilators are usually connected to a wall gas (e.g., oxygen, air) supply. The method by which ventilators provide gas exchange into and out of the lungs is determined by the selected ventilation mode. Intensive care ventilators include both volume-controlled and pressure-controlled breathing modes. Depending upon the selected mode, ventilators will deliver mandatory breaths with or without spontaneous breathing. Different modes have different breath targeting schemes that typically utilize a feedback control system utilizing operator inputs and ventilator outputs to achieve a specific ventilatory pattern. Some intensive care ventilators can provide gases to the lungs at frequencies much higher than the normal breathing rates (100 or more times per minute is typical); negative-pressure ventilators are also used in intensive care as an alternative to positive-pressure ventilators for some selected patients.

Ventilators are composed of four basic subsystems: the ventilator and its controls, monitors and alarms, gas supply, and patient circuit (which includes the breathing circuit and may include a humidifier and nebulizer). Each subsystem requires its own inspection and preventive maintenance procedure.

Special note concerning acceptance tasks during rapid deployment of ventilators for the urgent treatment of patients during the Covid-19 pandemic:

*Ideally, all acceptance tasks in the procedure should be performed prior to placing any new ventilator into use, but there may be situations when they will need to be urgently placed into use. For these situations ECRI recommends that at minimum the acceptance tasks identified with an * be performed (we are assuming that the ventilator that you are testing performs self-tests for the vital ventilator functions. If you are not familiar with a particular model, you may want to first check the manual to confirm that assumption). However, ECRI recommends for used ventilators with unknown IPM history that all listed scheduled IPM tasks be performed before they are placed into use.*

Test Apparatus

Electrical safety analyzer [Acceptance]

*Lung simulator with adjustable compliance/ventilator tester

Stopwatch or a watch that displays seconds

Pressure gauge or meter with 2 cm H₂O resolution from -20 to +120 cm H₂OO₂ analyzer

*If you are using a ventilator tester, you need to use a filter between the tester and the ventilator to protect your tester from contamination.

Special Precautions

Ventilators may be contaminated with contagious microorganisms. Never place your mouth on any ventilator component to blow or suck as a qualitative task of operation or to blow dirt out of a part. Ventilators should be disassembled in a work area dedicated to servicing contaminated equipment. Wash hands thoroughly after inspection, especially if any accessories were disassembled.

Procedure

Be sure that you understand how to operate the equipment and the purpose of each control, indicator, and alarm. Before beginning an inspection, carefully read this procedure and the inspection and preventive maintenance procedure recommended by the manufacturer (typically included in the service manual). Use BiomedicalBenchmark's *Support Assessment Form* to document a scheduled maintenance interval and procedure that reflects past experience with this model and type of equipment and the environment where it is used. Also consider BiomedicalBenchmark *Maintenance Data* for this model and type of equipment.

The following procedure contains tasks for Acceptance and Scheduled inspections; tasks not labeled [*Acceptance*] or [*Scheduled*] apply to both types of inspections. The form provided for the General Devices IPM procedure can be used to develop a form for documenting performance of this procedure. Most ventilators have self-diagnostic programs. When the ventilator's hardware (e.g., solenoid valves, transducers) is checked by its own software, manual inspection tasks can be eliminated. Manufacturers' recommended procedures for inspection and preventive maintenance of mechanical ventilators vary in both methods and required accuracy. In addition, ventilation modes, controls, and algorithms for calculated variables vary greatly according to manufacturer and model. This procedure provides the basic framework for complete ventilator inspection and preventive maintenance. Manufacturers' recommended procedures should be added where appropriate. Several tasks, particularly Operational Modes, Controls, and Monitored Parameters and Alarms, should be customized to make a procedure that is model-specific.

Record the ventilator's hour meter reading; manufacturer recommendations for preventive maintenance are frequently based on hours of use. Note if any of the ventilator's settings, as received, will need to be restored at the completion of the procedure. Advise clinicians if any alarms or other settings are outside normal physiologic values and suggest the need to review and perhaps train appropriate personnel on alarm setting policy. Perform a self-test at the completion of the procedure.

Preventive maintenance intervals should be scheduled according to the manufacturer's recommendations, which may be related to hours of use. Pre-use checks should be performed by a respiratory therapist or respiratory equipment technician.

Qualitative Tasks

***Chassis/Housing** [*Acceptance*]

Check for shipping damage; report any damage to the manufacturer, shipper, or service organization, and arrange for repair or replacement.

Check that the ventilator is suitably constructed to withstand normal hospital use and abuse. For instance, a unit with venting on the top of the housing or poorly protected or sealed controls and indicators may be prone to fluid entry.

Examine the exterior of the ventilator for cleanliness and general physical condition. Ensure that plastic housings are intact, that all assembly hardware (e.g., screws, fasteners) is present and tight.

Chassis/Housing [*Scheduled*]

Examine the exterior of the ventilator for cleanliness and general physical condition. Be sure that plastic housings are intact, that all hardware is present and tight, and that there are no signs of spilled liquids or other serious abuse.

***Mount/Fasteners** [*Acceptance*]

Ensure that the ventilator will not tip over when pushed or when a caster is jammed on an obstacle (e.g., line cord, threshold), as may occur during transport. If the ventilator is designed to rest on a shelf, ensure that it has nonslip legs or supports.

If the ventilator is mounted on a stand or cart, examine the security of the mount. Check the mounting security of all components or attached monitors.

Mount/Fasteners [Scheduled]

If the ventilator is mounted on a stand or cart, examine the condition of the mount. If it is attached to a wall or rests on a shelf, check the security of this attachment. Check the mounting security of all components or attached monitors.

***Casters/Brakes** [Acceptance]

Verify that the correct casters have been supplied with the ventilator (e.g., size, correct swivel).

Casters/Brakes [Scheduled]

If the ventilator moves on casters, check their condition. Verify that they turn and swivel, as appropriate, and look for accumulations of lint and thread around the casters. Check the operation of brakes and swivel locks, if the ventilator is so equipped.

***AC Plug** [Acceptance]

A solidly constructed, good quality plug with adequate strain relief is acceptable, but the use of a Hospital Grade plug (identifiable by a green dot and/or labeling) will eliminate guesswork and ensure a plug of acceptable construction quality. Right-angle plugs are unacceptable for devices that are moved frequently. A good quality two-prong plug is acceptable for double-insulated devices. Replace the plug or have the supplier replace it if it is not Hospital Grade or otherwise suitable. Hospital Grade molded plugs are acceptable.

Examine the AC power plug for damage. Attempt to wiggle the blades to determine if they are secure. Shake non-molded plugs and listen for rattles that could indicate loose screws.

AC Plug [Scheduled]

Examine the AC power plug for damage. If any damage is suspected, open the plug and inspect it.

***Line Cord** [Acceptance]

Ensure that the line cord is long enough for the ventilator's intended application; an extension cord should not be required. (A length of 10 ft [3 m] is suitable for most applications.)

Equipment having a detachable power cord should also have adequate capture devices, cleats, or channels to hold the cord in place. If these are absent, request that the supplier provide suitable means of securing the cord. Verify that the ventilator has adequate alarms or indicators for line-power loss and battery depletion and an adequate battery-charging indicator.

Line Cord [Scheduled]

Inspect the cord for signs of damage. If damaged, replace the entire cord. Also, check line cords of battery chargers.

***Strain Reliefs**

Examine the strain reliefs at both ends of the line cord. Be sure that they hold the cord securely.

***Circuit Breaker/Fuse** [Acceptance]

If the ventilator has a switch-type circuit breaker, check that it moves freely. If the ventilator is protected by an external fuse, verify that the fuse type is labeled and that all fuses and spares are the proper current rating and type. If the value and type are not labeled, check the manual for the proper current rating and type and permanently mark this information on the ventilator housing near the fuse holder.

Especially for critical or life-support devices, verify that accessory outlets have independent overcurrent protection (fuse or circuit breaker) so that a short in a device plugged into the accessory outlet or an accessory overload will not disable the primary device. If this is not available, then consider labeling the primary device to clearly indicate where the ventilator's fuse or circuit breaker is located, and/or install a fused Hospital Grade (or similar quality) plug on any commonly used accessories that are not already provided with suitable overcurrent protection.

***Tubes/Hoses**

Check the condition of all tubing and hoses. They should be clean and intact.

***Cables** [Acceptance]

Inspect any cables and their strain reliefs for general condition.

Cables [Scheduled]

Inspect any cables and their strain reliefs for general condition. Carefully examine cables to detect breaks in the insulation and to ensure that they are securely gripped in the connectors at each end, which will prevent rotation or other strain. Where appropriate, verify that there are no intermittent faults by flexing cables near each end and looking for erratic operation or by using an ohmmeter.

***Fittings/Connectors** [Acceptance]

Verify that appropriate connectors are supplied if connection to other hospital equipment or systems is required. Ventilators that connect to the central piped medical gas system should have the matching DISS or quick-connect fitting for the appropriate gas. Verify that suitable connectors are supplied with the ventilator so that adapters are not required.

Examine all gas and liquid fittings and connectors, as well as all electrical cable connectors, for general condition. Electrical contacts should be straight, clean, and bright. Gas and liquid fittings should be tight and should not leak. If keyed connectors are used (e.g., pin-indexed gas connectors), ensure that no pins are missing and that the keying is correct. Keying pins should be securely seated in "blind" holes so that they cannot be forced in farther.

Fittings/Connectors [Scheduled]

Examine all gas fittings and connectors for general condition. Gas fittings should be tight and should not leak. Verify that keyed connectors (e.g., pin-indexed gas connectors) are used where appropriate, that all pins are in place and secure, and that keying is correct. Connectors to hospital central piped medical gas systems should have the appropriate DISS or quick-connect fitting to eliminate the need for adapters.

***Filters** [Acceptance]

Ensure that all gas filters are supplied. Check their condition.

Filters [Scheduled]

Check the condition of gas filters. Check for corrosion residue indicative of liquid, gaseous, or solid particle contaminants in the gas supply; advise appropriate personnel if found. Clean or replace if appropriate, and indicate this on the inspection form.

Retaining Clips [Scheduled]

Examine the retaining clip for damage/tightness. Verify that clip fits securely over plug or cord such that cord yanking will not loosen connection.

***Controls/Switches** [Acceptance]

Before changing any controls or alarm limits, check their positions. If any settings appear inordinate (e.g., alarm limits at the ends of their range), consider the possibility of inappropriate clinical use or of incipient device failure.

Examine all controls and switches for physical condition, secure mounting, and correct motion. Check that control knobs have not slipped on their shafts. Where a control should operate against fixed-limit stops, check for proper alignment, as well as positive stopping. Check membrane switches for damage (e.g., from fingernails, pens). During the inspection, be sure to check that each control and switch performs its proper function.

Controls/Switches [Scheduled]

Examine all controls and switches for physical condition, secure mounting, and correct motion. Check that control knobs have not slipped on their shafts. Where a control should operate against fixed-limit stops, check for proper alignment, as well as positive stopping. Check membrane switches for damage (e.g., from fingernails, pens). During the inspection, be sure to check that each control and switch performs its proper function.

***Pressure-Relief Mechanism**

Check the proper operation of the pressure-relief mechanism, if so equipped, by occluding the breathing circuit and observing the resulting peak pressure on the unit's pressure indicator. Verify that pressure is vented and does not exceed manufacturer specifications.

***Fan/Compressor** [Acceptance]

Check the physical condition and proper operation of these components, if so-equipped. Check for automatic activation of the compressor when the piped gas supply pressure falls below operating pressure.

Fan/Compressor [Scheduled]

Check the physical condition and proper operation of these components if so-equipped. Check for automatic activation of the compressor when the piped gas supply pressure falls below operating pressure. Clean or replace fan and/or compressor filters and lubricate as required, according to the manufacturer's instructions.

***Power Continuity** [Acceptance]

To ensure constant ventilation when line power is interrupted, ventilators should automatically switch to battery operation. If the unit is not equipped to do this, it should be connected to a compatible uninterruptible power supply (UPS). A UPS, however, is inconvenient, can be lost or overlooked, and must be accounted for in inventory control and equipment maintenance. A UPS should be periodically checked to ensure proper operation. Because of the added expense and the other disadvantages inherent in using a UPS, ventilators should be purchased with internal batteries when possible.

*** Battery/Charger** [Acceptance]

Determine the replacement interval for all batteries and document the interval(s). Be sure to include batteries/cells for clocks and/or memory logs. Disconnect the battery and determine that the ventilator still operates on line power.

Operate the ventilator on battery power for several minutes to verify that the battery is charged and can hold a charge. Activate the battery test function, if so equipped. Check the condition of the battery charger, and verify that battery charge indicators function. Provide users with instructions and/or checklist procedure to ensure adequate battery charging and performance.

Battery/Charger [Scheduled]

Inspect the physical condition of batteries and battery connectors if readily accessible. Check operation of battery-operated power-loss alarms, if so equipped. Operate the ventilator on battery power for several minutes to check that the battery is charged and can hold a charge. (The inspection can be carried out on battery power to help confirm adequate battery capacity.) Check battery condition by activating the battery test function or measuring the output voltage; for lead-acid batteries, measure the specific gravity and check the fluid level. Check the condition of the battery charger and, to the extent possible, confirm that it does, in fact, charge the battery. Be sure that the battery is recharged or charging when the inspection is complete. When it is necessary to replace a battery, label it with the date.

*** Indicators/Displays**

Confirm the operation of all lights, indicators, meters, gauges, and visual displays on the ventilator and charger (if so equipped). Be sure that all segments of a digital display function. Record reading of an hour meter, if present. If so equipped verify unit's internal altitude setting is properly set for your location.

*** Self-Test**

For units with a self-test mode, activate it and determine if the expected response is produced. (Scheduled, Acceptance)

*** Time/Date Settings**

Verify that the time and date settings on the unit are correct.

Cybersecurity [Acceptance]

This task applies to a variety of circumstances in which a medical device is connected to other devices or systems for data exchange or has other cybersecurity considerations.

Complete your facility's data security management form.

Record the following information in your computerized maintenance management system (CMMS) for each inventoried medical device, as applicable:
IP address, MAC address, configuration settings (ex: authentication and encryption protocols), the currently installed version of the software and whether it is networked (Y/N), wireless (Y/N), and or contains

Protected Health Information PHI (Y/N). Devices with wireless operation should indicate how they connect to the network. Identify equipment requiring deletion of PHI or other confidential information, before it leaves the hospital's control (e.g., for disposal, service by non-hospital employees or sale).

Assess potential risks and vulnerabilities to the confidentiality, integrity, and privacy of electronic information stored or transmitted by the device or system and take appropriate preventive measures including adherence to Health Insurance Portability and Accountability Act (HIPAA) requirements.

In particular, verify confidentiality and security measures (e.g., password protection, wireless security protocols, authentication, audit trails). Address cybersecurity issues such as software patches, anti-malware software, and firewalls. Deactivate USB ports that will not be used. Ensure that hospital policies address the risks and vulnerabilities you have documented.

Carry out pre-implementation testing as appropriate (e.g., performance, load testing). Confirm that data back-up processes are activated and verified. Confirm that data is correctly routed to and from the device and associated systems. Confirm that unnecessary communication channels (e.g. open communication ports) and other services are turned off.

Cybersecurity [*Scheduled*]

This task should be performed when the device is scheduled for routine inspection and as necessary when elements of the system that impact the device are changed (ex: upgrades to EMR software).

Review measures taken to ensure protection against potential risks to and vulnerabilities of the confidentiality, integrity, and availability of electronic information stored or transmitted by the device or system, and verify that preventive measures are still active. For example, ensure that passwords are utilized appropriately and that all necessary operating system upgrades and virus protection patches have been installed. Confirm that devices are operating on an appropriately segmented secure network, and deactivate any USB ports that are not being used.

Confirm that the appropriate information described in the acceptance inspection task has been recorded and is current in the CMMS.

Verify that data backup processes are activated and that data can be retrieved from backups. Confirm that data is correctly routed to and from the device and associated systems. Confirm that unnecessary communication channels (e.g. open communication ports) and other services are turned off.

Remove PHI and other confidential information before the device leaves the hospital's control, including for disposal, service by non-hospital employees or sale.

*** Audible Signals** [*Acceptance*]

Verify that alarms are loud, distinctive, and/or bright enough to be noticed in the environment in which the ventilator will normally be used. If a remote alarm-indicator is required, verify that it is available and functioning. Audible alarm-volume controls should not allow the alarm to be turned off or lowered to an indiscernible volume.

***Alarms** [*Acceptance*]

It should not be possible for critical alarms to be turned off, silenced, or defeated without adequate warning to the operator or automatic alarm reactivation after a short delay. If the ventilator has an alarm-silence feature, check the method of reset (i.e., manual or automatic) against the manufacturer's specifications.

Default Settings [*Scheduled*]

If the ventilator has back up ventilation or automatic default settings confirm that the values for tidal volume, respiratory rate are reasonable for intended patient population. Also verify (if so equipped) alarm defaults are reasonable values.

Operational Modes

This task should be customized into specific tasks for each mode. Verify proper operation of all installed modes per manufacturer's recommendations.

Compressor

Test according to the manufacturer's recommendations.

***Gas Cylinders, Gauges, and Regulators (for transport ventilators)**

Verify that these components are present, securely mounted, and in good condition and that there is adequate gas supply.

Humidifiers

See Procedure 431.

***Labeling**

Check that all necessary placards, labels, and instruction cards are present and legible.

***Accessories** [Acceptance]

Verify that all necessary features and accessories have been supplied with the ventilator. Verify that the breathing circuit and filters are compatible with the ventilator according to the manufacturer's recommendations. Check for leaks in the breathing circuit, ensuring that fittings, adapters, and other components (e.g., exhalation valves, flow sensors H-valves, proximal flow sensors, water traps, nebulizers) are properly assembled and functioning correctly.

Ensure the availability of printed and/or electronic operator and service manuals.

Accessories [Scheduled]

Confirm the presence and check the condition of accessories. Verify that the breathing circuit and filters are compatible with the ventilator, according to the manufacturer's recommendations. Check for leaks in the breathing circuit, ensuring that fittings, adapters, and other components (e.g., exhalation valves, H-valves, proximal flow sensors, PEEP valves, water traps, nebulizers) are properly assembled and functioning correctly. Oxygen-air proportioner. See Procedure 444.

Quantitative Tasks***Grounding Resistance** [Acceptance] $\leq 0.5 \Omega$

Measure the resistance between the grounding pin of the power cord (if so equipped) and exposed (unpainted and not anodized) metal on the chassis. Grounding resistance should not exceed 0.5Ω . Grounding resistance measurement is not applicable to double insulated devices.

Depending upon circumstances, including prior history of grounding failures or power cord damage, frequency of use, and environmental factors, this task should be considered for inclusion in scheduled inspections.

***Touch Current** [Acceptance] $\leq 500 \mu\text{A}$

Touch (chassis leakage) current must be measured with the device powered by a conventional (grounded) power system, even if it is normally used in an area with isolated power. ECRI Institute does not recommend touch current tests of double-insulated devices.

With the polarity of the power line normal and the equipment ground wire disconnected, measure touch current with the device operating in all normal modes, including on, standby, and off. Touch current should not exceed $500 \mu\text{A}$.

Inspect AC adapters used to power (or recharge) certain devices for CE mark or UL (or other testing laboratory) listing and to verify that it is labeled to identify the device with which it is to be used. ECRI Institute recommends testing of adapters, particularly those that are not listed, by measuring the leakage current from each secondary (low voltage) connection to ground. The leakage current should not exceed the limit for the device touch current.

Ventilation Controls $\pm 10\%$ of control settings

[Note: This task should be customized into specific measurement tasks for each control function.]

Verify proper operation and accuracy of ventilation settings, which may include:

- Tidal volume
- Pressure level
- Respiration rate

Inspiratory time
 Expiratory time
 Inspiratory: expiratory (I:E) ratio
 Inspiratory/expiratory hold
 Flow
 PEEP
 Trigger sensitivity
 100% oxygen delivery
 Manual breath
 Spontaneous breath
 Wave shape

Verify the operation and accuracy of ventilation settings and indicators. These tests are typically performed by attaching the ventilator to a lung simulator and ventilator tester and comparing measured values to settings on the ventilator. Follow manufacturer recommendations for appropriate ventilator settings at which to verify proper operation and accuracy. Measured values should typically be within 10% of settings. Record the tidal volume measured by the volume monitor. If the ventilator does not automatically compensate for breathing circuit compliance, determine the compliance and add that value to the measured volume.

Volume can also be confirmed by calculating the delivered tidal volume from the product of the test lung and breathing circuit compliance (C) and the peak inspiratory pressure (PIP) ($V = C \times PIP$). To determine the compliance, deliver a set volume (same volume that the ventilator is set to deliver) to the breathing circuit and test lung with a large syringe, and record the resultant change in pressure at the inlet of the test lung. The compliance is the delivered volume divided by the recorded pressure. The measured volume should be within 10% of the set tidal volume.

Record the number of breaths delivered during a one-minute period. Verify that the measured rate is within 1 breath/min of the set respiration rate (may be ± 2 breaths/min at high set rates).

Use the test lung to trigger a spontaneous breath and verify that: 1) the spontaneous breath indicator is working properly, and 2) the displayed respiratory rate adjusts correctly.

Monitored Parameters and Alarms monitored parameters: manufacturer specifications or $\pm 10\%$ simulated values; alarms: manufacturer specified accuracy or $\pm 10\%$ settings

[Note: This task should be customized into specific measurement tasks as recommended by the manufacturer for each monitored parameter and alarm.]

Verify proper monitoring of parameters and their associated alarms, which may include:

Respiratory rate (apnea alarm and high breath rate)

Inspiratory time (inspiratory time too long)

Peak inspiratory pressure (PIP) (high pressure alarm and low airway pressure)

Peak inspiratory flow

Positive end-expiratory pressure (PEEP) (loss of PEEP and high PEEP)

Mean airway pressure (MAP)

Volume (high and low minute and tidal volume)

Fraction of inspired oxygen (FIO₂); see Oxygen Analyzer Procedure 417 (FIO₂ alarm)

Attach the ventilator to a lung simulator or ventilator tester and verify that displayed values are within 10% of simulated values.

Induce alarm conditions to activate audible and visual alarms. Verify alarm messages on displays. If the ventilator has an alarm-silence feature, check the method of reset (i.e., manual or automatic) against the manufacturer's specifications. Confirm appropriate loudness as well as the operation of alarm loudness control, if so equipped. If audible alarms have been silenced or the loudness set too low, alert clinical staff to the importance of keeping alarms at the appropriate level. If the ventilator is used with a remote alarm, verify that the alarm and indicator function properly. Alarm activation (e.g., for high PIP, low pressure, low FIO₂) should also be within 10% of set values.

Verify equipment failure alarms:

Loss of AC power

Loss of battery power

Low battery

Loss of air supply

Loss of oxygen supply

Breathing circuit disconnection

Verify operation switchover:

- From AC to battery
- Air loss to 100% oxygen
- Oxygen loss to air

Preventive Maintenance [Does not apply to *Acceptance* procedure]

Clean

Clean the exterior, interior, and components if needed.

Calibrate

Calibrate according to the manufacturer's instructions.

Replace

Replace components (e.g. sensors, filters) according to the manufacturer's instructions. When it is necessary to replace a battery, label it with the date.

Lubricate

Lubricate the fan and/or motor, if required.