

Adapt Procedure For

Ventilators, Portable/Home Care [17-423]

Ventilators, Transport [18-098]

Scope

Applies to ventilators that are physically compact, have an internal turbine or compressor, and an AC line cord; these ventilators may use external O₂ source attachments for delivering supplemental O₂ therapy, external positive end-expiratory pressure (PEEP) valves, heated humidifiers, and/or external monitors or remote alarms; does not apply to intensive care ventilators (see Procedures 458)

Interval

12 Months

Time Required

0.9 Hours

Overview

As technological advances continue to prolong life for critically ill patients and make life possible for both children and adults with otherwise fatal conditions, a large, rapidly growing patient population needs long-term ventilatory support. To meet these needs, some hospitals have special care areas, such as intermediate care or long-term care where stable ventilator-dependent patients can remain indefinitely or be cared for until they are weaned from ventilatory support, moved to another facility, or sent home. These patients do not need to be in an ICU and do not require complex intensive care ventilators and are instead placed on portable ventilators.

Mechanical ventilators are used to compensate for deficiencies in normal breathing by aiding or augmenting spontaneous breathing or by completely regulating a prescribed breathing pattern for a patient who cannot breathe without assistance. Dependence on the amount and type of mechanical support varies according to the disorder and the presence of any pulmonary complications; therefore, ventilation needs may range from occasional ventilator use to complete ventilator dependency. Patients who require long-term mechanical ventilation include adults and children who have impaired or total loss of ventilatory function resulting from a variety of etiologies, such as neuromuscular diseases, restrictive and chronic obstructive lung diseases, and spinal cord injuries, as well as children who were born with premature or neonatal lung disease.

Portable ventilators are available with varying degrees of sophistication to meet the spectrum of needs of long-term ventilator users. For example, to control costs, some ventilators have limited capability for patients with limited needs. Other ventilators have additional features for pediatric use and for patients who may be more difficult to treat. Thus, some portable ventilators offer features that are usually available only on intensive care ventilators (e.g., non-physiologic breathing patterns, such as inverse inspiratory:expiratory [I:E] ratio), while retaining simplicity of operation, portability, and low cost.

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 expandable bellows or ventilator tester

Oxygen analyzer

Stopwatch or a watch that displays seconds

Pressure gauge or meter (2 cm H₂O resolution, -20 to +120 cm H₂O)

*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.

Manufacturers' recommended procedures for inspection and preventive maintenance of 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 tasks and specifications should be added where appropriate. Several tasks, particularly Operational Modes and Controls 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.

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 and/or home care use and abuse. For instance, a unit 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**

If the ventilator is mounted on a bracket or wheelchair tray, examine the condition of the mount. If it rests on a shelf, check the security of this attachment. Check the mounting security of all components, if so equipped (e.g., supplemental O₂ equipment, heated humidifiers) or attached monitors.

***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.

***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]

Verify that accessory outlets, if so equipped, 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.

Circuit Breaker/Fuse [Scheduled]

If the ventilator has a switch-type circuit breaker, check that it moves freely. If the ventilator is protected by an external fuse, check its value and type against that marked on the chassis and ensure that a spare is provided.

***Tubes/Hoses**

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

***Cables**

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 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 fittings and connectors, as well as all electrical cable connectors, for general condition. Electrical contacts should be straight, clean, and bright. Gas 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

Examine all gas fittings and connectors for general condition. Gas fittings should be tight and should not leak. Connectors to hospital central piped medical gas systems for delivering supplemental oxygen 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 (e.g., air-inlet) 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.

***Controls/Switches** [Acceptance]

Examine all controls and switches for physical condition, secure mounting, and correct motion. Assess membrane switches for sensitivity to pressure and errant operation. If a control has fixed-limit stops, check for proper alignment, as well as positive stopping.

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) and activation with appropriate finger-pressure. During the course of the inspection, be sure to check that each control and switch performs its proper function.

***Fan/Compressor or Turbine** [Acceptance]

Ensure the proper operation of these components.

Fan/Compressor or Turbine [Scheduled]

Check the physical condition and proper operation of these components. Clean and lubricate if required, according to the manufacturer's instructions.

***Power Sources/Internal 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.

Verify that, the ventilator operates on AC power and that the AC power indicator is lit. If an external battery is connected, switch the ventilator off and verify that it switches to its external battery and continues to operate without interruption. Verify that the external power and power switchover indicators light and that the audible alarm activates.

Disconnect the external battery and verify that the ventilator switches to its internal battery and continues to operate without interruption. Verify that the internal battery and power switchover indicators light and that the audible alarm activates.

Operate the ventilator on internal battery power. Activate the battery test function or measure the output voltage. Verify that the battery is charged and can hold a charge and that the ventilator operates for at least 30 minutes.

Reconnect the external battery, if available, then plug the ventilator back to AC power, and verify that the ventilator switches from internal to external battery and then to AC power. Turn the ventilator off and verify that the battery-charging indicator is lit. Be sure that the battery is recharged or charging when the test is complete.

Power Sources/Internal Battery Charger [Scheduled]

Inspect the physical condition of the internal battery and battery connectors.

Verify that the ventilator operates on AC power and that the AC power indicator is lit. Disconnect the ventilator from AC power.

If an external battery is connected, verify that the ventilator switches to its external battery and continues to operate without interruption. Verify that the external power and power switchover indicators light and that the audible alarm activates. Disconnect the external battery.

Verify that if no external battery is connected or if the external battery is disconnected, the ventilator switches to its internal battery and continues to operate without interruption. Verify that the internal battery and power switchover indicators light and that the audible alarm activates.

Operate the ventilator on internal battery power. Check battery condition by activating the battery test function or measuring the output voltage. Verify that the battery is charged and can hold a charge and that the ventilator operates for at least 30 minutes.

Reconnect the external battery, if available, then plug the ventilator back to AC power, and verify that the ventilator switches from internal to external battery and then to AC power. Turn the ventilator off and verify that the battery charging indicator is lit. Be sure that the battery is recharged or charging when the inspection is complete.

***Indicators/Displays**

Confirm the operation of all lights, indicators, meters, gauges, and visual displays on the ventilator. Be sure that all segments of a digital display function. Record the reading of an hour meter, if present.

***Self-Test**

Perform a self-test. Note any reported values including system leak and compliance and determine manufacturer-specified corrective actions.

***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.

***Alarms** [*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.

Induce all alarm conditions to activate audible and visual alarms. This includes equipment alarms such as power loss, low batter, operation on internal battery, as well as alarms for patients' condition such as high pressure, low pressure, circuit disconnect, apnea, high respiratory rate, continuous high pressure. Check that all associated interlocks or features function. Verify that the alarm-silence feature resets within 2 minutes.

Disconnect the breathing circuit at the tracheostomy tube connector to activate the low-pressure alarm. Verify that the low-pressure alarm and the breathing circuit disconnect (if so equipped) alarms activate audibly and visually. Reattach the breathing circuit and verify that the indicator remains lit until manually reset.

To activate the high-pressure alarm, adjust the high-pressure alarm limit to 5 cm H₂O below the peak inspiratory pressure (PIP). Verify that the high-pressure alarm activates audibly and visually and that the displayed pressure does not exceed the high-pressure alarm limit. Return the high-pressure alarm limit to its original setting and verify that the indicator remains lit until manually reset.

Alarms [*Scheduled*]

Audible alarm-volume controls should not be turned off or lowered to an indiscernible volume. If any alarms are disabled, check with clinical staff to determine if this is appropriate for the given alarm.

Induce all alarm conditions to activate audible and visual alarms. Check that any associated interlocks function. Verify reactivation of the alarm following alarm silence activation. If a remote alarm is used, verify that it functions properly.

Disconnect the breathing circuit at the tracheostomy tube connector to activate the low-pressure alarm. Verify that the low-pressure alarm activates audibly and visually and that the alarm activates within the manufacturer's specified time delay. Reattach the breathing circuit and verify that the indicator remains lit until manually reset.

To activate the high-pressure alarm, adjust the high-pressure alarm limit to 5 cm H₂O below the peak inspiratory pressure (PIP). Verify that the high-pressure alarm activates audibly and visually and that the

displayed pressure does not exceed the high-pressure alarm limit. Return the high-pressure alarm limit to its original setting and verify that the indicator remains lit until manually reset.

Operational Modes

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

***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. The pressure should not exceed manufacturer specifications.

***Labeling**

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

***Accessories** [Acceptance]

Verify that all necessary features and accessories, including the humidifier (see Heated Humidifiers Procedure 431) and the nebulizer, have been supplied with the ventilator. At least one copy each (two are generally preferred) of the instruction and service manuals, including schematics, should be shipped with the ventilator and filed in the central equipment file. Ensure the availability of printed and/or electronic operator and service manuals.

Verify that all external devices (e.g., proximal flow sensor) are connected into the breathing circuit or to the ventilator and functioning correctly. For single-limb breathing circuits, ensure that the exhalation valve is connected and functioning correctly.

Verify that all breathing circuit components (including filters) are compatible with the ventilator according to the manufacturer's recommendations. Check that all breathing circuit components are assembled correctly.

Accessories [Scheduled]

Confirm the presence and check the condition of accessories, including the humidifier (see Heated Humidifiers Procedure 431) and the nebulizer, if so equipped.

Verify that all external devices (e.g., proximal flow sensor) are connected into the breathing circuit or to the ventilator and functioning correctly. For single-limb breathing circuits, ensure that the exhalation valve is connected and functioning correctly.

Verify that all breathing circuit components (including filters) are compatible with the ventilator according to the manufacturer's recommendations. Check that all breathing circuit components that were retained are assembled correctly.

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. Maximum 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.

Pressure Display ±10%

Record the PIP from the ventilator's pressure display and from the pressure gauge or meter at the inlet of the test lung. The ventilator display should be within 10% of the pressure measured at the test lung. Verify that both pressure readings return to zero during exhalation.

Controls ±10%

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

Check the operation and accuracy of ventilation controls.

These tests are typically performed by attaching the ventilator to a lung simulator and comparing measured values to settings on the ventilator. Determine and use the manufacturer's recommended ventilator settings for tidal volume, rate, and inspiratory time to verify proper operation and accuracy.

Verify the operation and accuracy of the other controls, which may include expiratory time, I:E ratio, % O₂ concentration, flow, and pressure when present. Measurements should typically be within 10% of set values.

Respiration Rate ±1 breath/min

Record the number of breaths delivered during a 1-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).

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

Clean

Clean the exterior, interior, and components, if needed.

Lubricate

Lubricate the fan and/or motor, if required.

Calibrate

Calibrate, if needed, 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.