Anesthesia Units

Procedure No. 400-20200410 COVID-19

Adapt Procedure For
Ventilators, Anesthesia [10-145]
Anesthesia Units [10-134]

Scope
Applies to anesthesia units and their ventilators; includes leak testing of vaporizers and should be used in conjunction with Anesthesia Unit Vaporizers Procedure 436; does not apply to oxygen monitors with an alarm, spirometers, or other monitors; see Multiparameter Physiologic Monitors Procedure 493.

Risk Level
High

Interval
6 Months

Time Required
2.4 Hours

Overview
Most surgical procedures are performed while the patient is under general anesthesia. Usually, the patient is anesthetized by a narcotic or barbiturate injection followed by administration of an inspired gas mixture of oxygen, air, and the vapor of a volatile liquid anesthetic, typically a halogenated hydrocarbon. The anesthesia unit administers this mixture of anesthetic gases and life-sustaining oxygen, varying the proportions to control the patient's level of consciousness. A ventilator, connected to the patient breathing system, forces the gas mixture into the patient's lungs.

Improperly modified or inadequately maintained anesthesia units have injured patients and hospital personnel, sometimes fatally. Gas leaks can adversely affect the accuracy of gas delivery to the patient, as well as add anesthetic agents to the OR atmosphere. Trace levels of anesthetics have been implicated as a health hazard to chronically exposed OR personnel and their unborn children. Failure of an alarm to respond to an excessively low oxygen pressure, and misconnected or improperly calibrated flowmeters have also caused anesthesia-related accidents.

Because mishandling and mistakes can have severe consequences, life-support devices such as anesthesia units should be operated and inspected only by qualified personnel who have a thorough knowledge of the units and their functions. If you are unsure of any aspect of the procedure, consult the manufacturer before inspecting an anesthesia unit.

Gas Supply. This system delivers a variety of gases to the patient. Cylinders containing oxygen and other gases at high pressure (see Table 1) are connected to the high-pressure system of the anesthesia unit by yoke fittings that comply with the Compressed Gas Association (CGA) pin-index safety system (see Figure 1). Unique placements of pins and mating holes on the pin-index fittings prevent connection of a gas cylinder to the wrong inlet. Inside the unit, each high-pressure gas flows through a filter, a check valve (for one-way flow), and a regulator that reduces the pressure to approximately 45 psi.

Table 1. Gases Used in Anesthesia Units

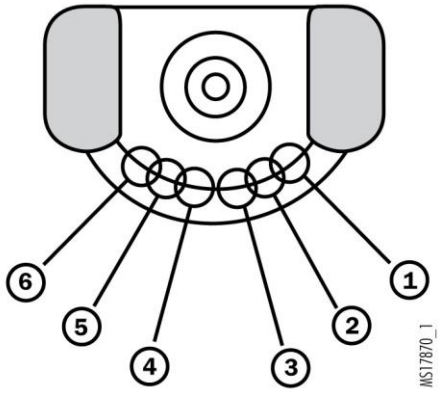
Gas	Chemical Formula	Color Code: U.S.	Color Code: International	Service Pressure, psi 21°C, Full Cylinder
Oxygen	O_2	Green	White	1,800–2,400*
Carbon Dioxide	CO_2	Gray	Gray	838
Nitrogen	N_2	Black	Black	2,200
Nitrous Oxide	N_2O	Blue	Blue	745
Helium	He	Brown	Brown	1,660–2,000*
Air		Yellow	White and Black	1,800

*Depends on cylinder size.

Because air, oxygen and nitrous oxide are used in relatively large quantities, they are usually drawn from the hospital's central gas supplies, which are more convenient and economical than compressed-gas cylinders. However, cylinders of these gases are also normally attached to the anesthesia unit as a reserve source if the central supply fails or if central supply outlets are not available.

Centrally supplied gases are delivered directly to the intermediate-pressure gas control system at approximately 50 psi through low-pressure hoses and connectors. These connectors should be of the DISS (diameter index safety system) to prevent mismating the gas supply and the unit inlet.

The anesthesia unit consists of five systems: the gas supply system, the gas control, the vaporizers, the ventilator, and the breathing system.



Gas Connector	Index Pins	CGA Number
Oxygen	2-5	870
Nitrous Oxide	3-5	910
O_2 - CO_2 (CO_2<7%)	2-6	880
O_2 - CO_2 (CO_2>7%)	1-6	940
O_2 - He (He>80%)	4-6	930
O_2 - He (He<80%)	2-4	890
Air	1-5	950

Figure 1. Pin-index safety system

Gas Control. This system regulates gas flow rates so that the gases can be mixed and delivered under accurate, constantly metered control. The operator must be able to adjust the ratios or make rapid gross changes in flow rates without inducing system interactions that cause temporary delivery of undesirable mixtures.

The flow of each gas is controlled by a valve and indicated by a flowmeter. After gases pass the control valve and enter the low-pressure system, they can be administered to the patient.

A fail-safe provision in anesthesia units protects the patient against a fall in pressure of life-sustaining oxygen. If the oxygen pressure drops below about 25 to 30 psi, some units shut off the flow of all other gases, while others reduce all gas flow rates in proportion to the drop in oxygen pressure. Anesthesia units have additional safety systems that provide a minimum percentage of oxygen (between 21% and 30%) and/or deliver a minimum flow of oxygen (usually 150 to 250 mL/min) (see the Minimum Oxygen Flow and Percentage task).

Vaporizers. These devices add the vapor of a volatile liquid anesthetic (e.g., halothane, isoflurane, enflurane) to the gas mixture, when desired, and aid in controlling the vapor concentration.

According to the American Society for Testing and Materials (ASTM) standard ASTM F1850-00, anesthetic agent vaporizers are required to be concentration calibrated (i.e., a calibrated knob controls the output concentration). Older vaporizers that do not have a single control for selecting the concentration of anesthetic vapor should be removed from service. Most contemporary concentration-calibrated vaporizers

are of two types: variable bypass and heated blender. See Anesthesia Unit Vaporizers Procedure 436 for additional background.

Ventilator. Anesthesia ventilators use positive pressure to inflate a patient's lungs and deliver a prescribed mixture of gases and vapors to them. This mixture is produced by the anesthesia machine. The ventilator is typically built into the anesthesia machine.

Although older anesthesia ventilators are less sophisticated than a critical care ventilator, current models include many features and advanced ventilation modes of critical care units. Several respiration parameters (e.g., inspiratory:expiratory [I:E] ratio, tidal volume, peak inspiratory pressure, minute volume, flow) are adjustable by the operator and controlled by the ventilator. Ventilators designed solely for anesthetic administration typically do not have compressors.

Breathing System. The components of the breathing system direct gases to the patient, remove CO_2 from exhaled gases, and provide positive end-expiratory pressure (PEEP), when required. The breathing system typically includes a scavenging system to remove waste gases.

Two types of breathing systems are used to deliver the anesthetic mixture from the unit to the patient, although they may assume a variety of configurations. The T-piece or open system may be a nonrebreathing system consisting of a reservoir bag and a gas-delivery hose connected through a nonrebreathing (one-way) valve to the face mask or endotracheal tube. The patient breathes the anesthetic mixture directly from the unit, and exhaled gas is vented out of the system. T-piece systems that do not include the nonrebreathing valve may allow partial rebreathing, depending on the inflow of fresh gas.

The more common (in North America) circle or closed system is a continuous loop in which check valves allow gas to flow in only one direction. The patient inhales from and exhales into the system. Fresh gases from the anesthesia unit enter at one point, mix with previously exhaled gases, and pass to the patient, who inhales the mixture. Newly exhaled gases are channeled to a carbon dioxide absorber, which removes almost all the carbon dioxide produced by body metabolism and routes the scrubbed gases back toward the patient. Enroute, the scrubbed gases become mixed with fresh gases.

A scavenging system should be included to remove waste gas from the vent port of a T-piece breathing system or from the adjustable pressure-limiting (APL) valve and relief valve of a ventilator of a circle system to reduce the quantity of gas that escapes into the OR. Such a scavenging system is necessary because trace levels of anesthetics are believed to cause an increased incidence of spontaneous abortion, congenital anomalies in offspring, and neoplastic disease and may affect the mental and physical abilities of exposed personnel. The breathing system should be checked before each use for leaking gases. The concentration of waste anesthetic gas should also be routinely surveyed; the facility's environmental survey program must document the survey interval, which should be based on past findings. The scavenging system must include pressure-relief mechanisms so that abnormal pressures cannot develop in the scavenging system and interfere with operation of the breathing system.

Anesthesia units either come with physiological monitors integrated into the unit or provide shelving to support such monitors. Most also provide mounting for a suction regulator and canister and other accessories, along with storage for drugs, supplies, and related items.

Special note concerning acceptance tasks during rapid deployment of anesthesia units 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 anesthesia unit 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 anesthesia unit that you are testing performs self-tests for the vital 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 anesthesia machines with unknown IPM history that all listed scheduled IPM tasks be performed before they are placed into use.*

Test Apparatus

Electrical safety analyzer [*Acceptance*]
Pressure gauge or meter, -10 to +80 cm H_2O (accuracy ±2 cm H_2O at 30 cm H_2O)
Digital flowmeter that can correct for mixed gases (0.1 to 20 L/min ±2%, 10 to 100 L/min ±10%)
Spirometer
Oxygen analyzer
Stopwatch or watch with a second hand
*Lung simulator with adjustable compliance or ventilator tester
Breathing/reservoir bag (adult)
Sphygmomanometer bulb with tubing and adapter

*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

Do not perform any procedures, adjustments, repairs, or modifications unless you thoroughly understand the unit and have verified the appropriateness of the intended actions. Resolve any questions or uncertainties with the manufacturer, the anesthetist, or ECRI Institute before placing a unit into use.
To avoid the adverse effects of exposure to anesthetic gases, all testing should be done with an operating scavenging system in place or an alternative means to vent excess gases from the vicinity of inspecting personnel. Check that all valves, including the gas cylinder valves, are turned off at the beginning of the inspection. Turn all valves off again when the inspection is complete.

When cleaning parts of the anesthesia unit with any organic solvent, allow time for the solvent to evaporate. When the parts appear dry, take the added precaution of briefly flushing them with a high flow rate of medical gas.

Procedure

Be sure that you understand how to operate the equipment, the significance of each control, indicator, and alarm. Before beginning an inspection, carefully read this procedure, the operators manual, and the inspection and preventive maintenance procedures recommended by the manufacturer (typically included in the service manual). Manufacturers' recommended procedures for inspection and preventive maintenance of anesthesia units vary in both methods and required accuracy. This procedure provides the basic framework for inspection and preventive maintenance; manufacturers' recommended procedures should be added where appropriate.

Procedure Note: Users of older units, which have an accessible common gas outlet (CGO), may be able to perform several of the qualitative and quantitative inspection tasks as provided in this procedure. These tasks are prefaced [See Procedure Note]. If the unit to be inspected does not have an accessible common gas outlet, delete the task description and substitute a model-specific task (and P/F criterion, for quantitative tasks).

On newer anesthesia units, tests for many of these inspection tasks are automated and performed as part of the pre-use check. Also, many newer units have an auxiliary CGO that can be used to perform these tests.

This procedure should be performed concurrently with Anesthesia Vaporizers Procedure 436, where leak testing of the vaporizer has been included with the anesthesia unit.

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.

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 anesthesia unit is suitably constructed to withstand normal hospital use and abuse. For instance, a unit with poorly protected or sealed controls and indicators may be prone to fluid entry.

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

*** Carbon Dioxide Absorber** [*Acceptance*] Check the carbon dioxide absorber housing for general physical condition. Verify proper operation of the elevating mechanism (if applicable) and clamps. Remove the canister from its holder, without inverting it, and check the gaskets.

Carbon Dioxide Absorber [*Scheduled*]
Check the carbon dioxide absorber housing for cracks or broken edges in the glass or plastic canister and in the inspiratory and expiratory valve domes. Verify proper operation of the elevating mechanism and clamps, if applicable. Remove the canister from its holder, without inverting it, and inspect the gaskets for any absorbent dust and wear. Remove any dust from the bottom of the absorber. If the amount of dust seems excessive or if the canister appears seriously pitted, check for dust in the inspiratory valve and piping, and report the condition to anesthesia personnel. If the absorber uses disposable canisters or cartridges, ensure that they latch firmly in place.

Labeling
Check that all necessary placards, labels, conversion charts, and instruction cards are present and legible. Check for proper color-coding for corresponding parts (e.g., green for oxygen, blue for nitrous oxide in the USA).

*** Mount** [*Acceptance*]
Ensure that the assembly and weight distribution is stable and that the anesthesia unit 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 anesthesia unit has a heating element, keep hoses, wires, and cables away from the unit and place the unit so that patients and staff are protected against contact with hot surfaces.
Check any shelves, brackets, or supporting structures. Check the security of the attachments.

Mount [*Scheduled*]
Check any shelves, brackets, or supporting structures. Check the security of the attachments.

*** Casters/Brakes** [*Acceptance*]
Verify that the correct casters have been supplied with the anesthesia unit (e.g., size, correct swivel). Verify caster and brake operation. Check that gas hoses do not lie on the floor or loop near the casters.

Casters/Brakes [*Scheduled*]
If the anesthesia unit moves on casters, check their condition. Look for accumulations of lint and thread around the casters, and be sure that the casters turn and swivel as appropriate. Check the operation of brakes and swivel locks, if the anesthesia unit is so equipped. Check that gas hoses do not lie on the floor or loop near the casters.

*** AC Plug/Receptacles** [*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.

If the anesthesia unit has electrical accessory outlets, inspect them for damage and insert an AC plug into each to check that it is held firmly. If the outlets are used for critical devices or devices are plugged and

unplugged frequently, consider more extensive testing. Use a tension tester to measure the tension of each contact. With the anesthesia unit plugged in, use an outlet test fixture to verify that the accessory outlet is energized and correctly wired. See Electrical Receptacles Procedure/Form 437 for more information.

AC Plug/Receptacles [*Scheduled*]
Examine the AC power plug for damage. Attempt to wiggle the blades to determine that they are secure. Shake the plug and listen for rattles that could indicate loose screws. If any damage is suspected, open the plug and inspect it.

If the anesthesia unit has electrical receptacles for accessories, insert an AC plug into each and check that it is held firmly. If accessories are plugged and unplugged often, consider a full inspection of the receptacle.

*** Line Cord** [*Acceptance*]
Ensure that the line cord is long enough for the unit's intended application; an extension cord should not be required. (A length of 10 ft [3 m] is suitable for most applications, although 18 ft [5.5 m] has been suggested for OR equipment.)

The cord should be of suitable quality and current-carrying capacity. Hard Service (SO, ST, or STO), Junior Hard Service (SJO, SJT, or SJTO), or an equivalent-quality cord should be used.

Verify that the anesthesia unit and ventilator have adequate protection against power loss (e.g., from accidental disconnection of a detachable power cord, disconnection of the power cord from the wall, or depleted battery if a battery-powered device is not plugged in). 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 anesthesia unit 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.

*** Tubes/Hoses** [*Acceptance*]
Check the condition of all tubing and hoses. Check that they are correctly connected and positioned so they will not kink, interfere with the operator, or be damaged during operation (i.e., that exposed tubing is guarded against strikes and accidental disconnection). Verify that color-coded hoses are the correct color for the gas that the hose carries.

Tubes/Hoses [*Scheduled*]
Check the condition of all tubing and hoses. Be sure that they are not cracked, kinked, discolored, or dirty. Verify that color-coded hoses are the correct color for the gas that the hose carries.

*** Cables** [*Scheduled*]
Inspect the cables (e.g., sensor, electrode) and their strain reliefs for general condition. Examine cables carefully to detect breaks in the insulation and to ensure that they are gripped securely in the connectors of each end to prevent rotation or other strain. Where appropriate, verify that there are no intermittent faults by flexing electrical cables near each end and looking for erratic operation or by using an ohmmeter.

*** Fittings/Connectors** [*Acceptance*]
Verify appropriate connectors are supplied. Devices 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 anesthesia unit so that adapters are not required.

Examine all gas and liquid fittings and connectors, as well as all electrical cable connectors and sockets, 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. Check the yoke clamping screw, and make sure empty yokes have plugs.

Fittings/Connectors [*Scheduled*]
Examine all gas and liquid fittings and connectors, as well as all electrical cable connectors and sockets, for general condition. Electrical contact pins or surfaces should be straight, clean, and bright. Check that pins used with the pin-index safety system comply with local standards/regulations and are intact. Check the yoke clamping screw, and make sure empty yokes have plugs. Check that appropriate keyed or indexed hose fittings are being used with corresponding gases.

*** Filters** [*Acceptance*]
Check the presence and condition of all compressed-gas filters.

Filters [*Scheduled*]
Check the condition of all compressed-gas filters. Clean or replace as needed. Check for corrosion residue indicative of liquid, gaseous, or solid particle contaminants in the gas supply; if found, notify appropriate personnel. Clean or replace if appropriate.

*** Controls/Switches** [*Acceptance*]
Verify that software setup parameters accessible through hidden or service menus are correctly set for the appropriate application and are consistent for all anesthesia units.

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

Check that the concentration dial on each vaporizer moves freely and that only one vaporizer can be on at a time.

Controls/Switches [*Scheduled*]
Examine all controls and switches for physical condition, secure mounting, and correct motion. Where a control should operate against fixed-limit stops, check for proper alignment, as well as positive stopping. During the course of the inspection, be sure to check that each control and switch performs its proper function. Membrane switches should be examined for dents, punctures, and sticking. Check that the concentration dial on each vaporizer moves freely and that only one vaporizer can be on at a time.

*** Indicators/Displays**
During the course of the inspection, confirm the operation of all lights, indicators, meters, gauges, and visual displays on the anesthesia unit, ventilator, and charger, if so equipped. Be sure that all segments of a digital display function. Record the reading of an hour meter, if present.

*** Self-Test**
For units with a self-test mode, activate it and determine if the expected response is produced.

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 (e.g., 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 (e.g., 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 configurable alarm features are appropriately set and consistent among all anesthesia units. 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.

Verify that alarms are loud, distinctive, and/or bright enough to be noticed in the environment in which the anesthesia unit 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 alarm conditions to activate audible and visual alarms. If the anesthesia unit has an alarm-silence feature, check the method of reset (i.e., manual or automatic) against the manufacturer's specifications.

Alarms [*Scheduled*]
Operate the unit and ventilator in such a way as to activate each audible and visual alarm. If the anesthesia unit has an alarm-silence feature, verify that alarms reset (i.e., manual or automatic) according to the manufacturer's specifications. It may not be possible to check out all alarms at this time since some may require special conditions that must be established according to the manufacturer's recommendations; include these in the Monitors and Alarms test.

*** Audible Signals**
Operate the unit in such a way as to activate all audible signals, such as advisory or cautionary tones. Confirm appropriate volume, as well as the operation of a volume control, if so equipped. Check that the audible signals are appropriate for the test conditions used and that they can be easily heard in the area on which the anesthesia unit will be used.

*** Flowmeters** [*Acceptance*]
Examine each flowmeter for general physical condition. If it has a mechanical float, observe the float motion as its associated flow control valve is turned on. The valve should turn smoothly with only slight drag, and the float, whether mechanical or virtual (e.g., LED, LCD), should rise and fall freely as the flow is increased or decreased.

At maximum flow, the float should still be visible at the top of the flow tube. Each valve (except O_2) should have a definite shutoff position at which the float should be motionless at its zero level. Check for free play in the control valve by pushing, pulling, and gently rocking the stem from side to side without rotation. The stem should feel firm, and the flowmeter float should not move. The control valve knob should require turning through at least 90° to change the flow rate from 10% to 100% of full scale.

Flowmeters [*Scheduled*]
Examine each flowmeter for signs of damage (e.g., internal nicks, scratches, cracks, condensation, debris). If it has a mechanical float, observe the float motion as its associated flow control valve is turned on. The valve should turn smoothly with only slight drag, and the float, whether mechanical or virtual (e.g., LED, LCD), should rise and fall freely as the flow is increased or decreased.

At maximum flow, the float should still be visible at the top of the flow tube. Each valve (except O_2) should have a definite shutoff position at which the float should be motionless at its zero level. Check for free play in the control valve by pushing, pulling, and gently rocking the stem from side to side without rotation. The stem should feel firm, and the flowmeter float should not move. The control valve knob should require turning through at least 90° to change the flow rate from 10% to 100% of full scale.

*** 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 if the anesthesia unit still operates on line power. Check the battery-operated power-loss alarms on AC and pneumatic devices, if so equipped.

Operate the anesthesia unit (including 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 the battery-operated power-loss alarms on AC and pneumatic devices, if so equipped. Operate the anesthesia unit (including the ventilator) on battery power for several minutes to check that the battery has an adequate charge.

Check remaining battery capacity by activating battery test function or measuring the output voltage. If appropriate, check the condition of the battery charger, and, to the extent possible, confirm that it does, in fact, charge the battery. When it is necessary to replace a battery, label the new battery with the installation date.

*** Fail-Safe Oxygen Valves**
With the unit in standby mode, close all control valves. Open all cylinder stem valves and external gas source valves. Connect the gas scavenging or other evacuation system. Connect a disposable breathing circuit to the inspiratory and expiratory ports of the absorber manifold. Attach an adult reservoir bag to the unit's bag mount and the test lung bag at the wye (or elbow) piece of the breathing circuit.

Turn on the main gas control, and open the flow control valves until the flowmeter for each gas reads midscale. Then disconnect or turn off all oxygen sources. The flow of other gases should fall proportionately as the oxygen flow decreases such that the oxygen flow is always greater than the flow of the other gases. All gas flow should cease when the oxygen flow reaches zero; however, air may be an exception.

In addition to the automatic shutoff or reduction of gas flow, audible or visual alarms signifying low oxygen pressure should have been activated. Silence the alarm by raising the oxygen pressure above the preset

alarm limit. If the unit has an alarm that does not respond, check for exhausted batteries or another source of the malfunction.

*** Directional Valves** [*Acceptance*]
Check the general physical condition of the inspiratory and expiratory valve disks and be sure that they fit smoothly against the valve seats. The valve disks should flutter up and down and should not stick to their seats.

Connect a disposable breathing circuit to the inspiratory and expiratory ports of the absorber manifold. Attach an adult reservoir bag to the unit's bag mount and the test lung bag at the wye (or elbow) piece of the breathing circuit. With the APL valve closed, increase the O_2 flow to 2 L/min and allow the reservoir bag to fill; then reduce the flow to its minimum. Repeatedly squeeze the bag to ventilate the test lung while observing the action of the inspiratory and expiratory valves.

Remove the breathing circuit from the expiratory port and cap both the port and the end of the hose. With the test lung bag inflated, turn off the unit to stop gas flow; then squeeze (or compress) the lung. The gauge on the absorber should not fluctuate. If substantial pressure fluctuation is observed, or if the test lung bag gradually empties, the inspiratory valve is permitting reverse flow and should be replaced by the manufacturer.

Disconnect the breathing circuit from the unit, cap the expiratory port, and cap the inspiratory port. Connect the -10 to +80 cm H_2O gauge to the expiratory port. Turn on the unit and fill the reservoir bag. Then, turn off the unit and squeeze the reservoir bag to produce increased pressure fluctuations in the absorber while monitoring for pressure changes at the expiratory port. If substantial pressure changes can be measured at the expiratory port, the valve is permitting reverse flow and should be replaced by the manufacturer.

Directional Valves [*Scheduled*]
Check that the inspiratory and expiratory valve disks are free from cracks and chips and fit smoothly against the valve seats. The valve disks should flutter up and down and should not stick to their seats. Discoloration or residue on the valve disk may indicate that the disk should be replaced. Some condensation in the expiratory valve dome is not unusual. If the condensation is excessive and prevents observation of valve function, excessive circuit humidification is being employed and may lead to valve malfunction.

Connect a disposable breathing circuit to the inspiratory and expiratory ports of the absorber manifold. Attach an adult reservoir bag to the unit's bag mount and the test lung bag at the wye (or elbow) piece of the breathing circuit. With the APL valve closed, increase the O_2 flow to 2 L/min and allow the reservoir bag to fill; then reduce the flow to its minimum. Repeatedly squeeze the bag to ventilate the test lung while observing the action of the inspiratory and expiratory valves.

Remove the breathing circuit from the expiratory port and cap both the port and the end of the hose. With the test lung bag inflated, turn off the unit to stop gas flow; then squeeze (or compress) the lung. The gauge on the absorber should not fluctuate. If substantial pressure fluctuation is observed, or if the test lung bag gradually empties, the inspiratory valve is permitting reverse flow and should be repaired.

Disconnect the breathing circuit from the unit, cap the expiratory port, and cap the inspiratory port. Connect the -10 to +80 cm H_2O gauge to the expiratory port. Turn on the unit and fill the reservoir bag. Then, turn off the unit and squeeze the reservoir bag to produce increased pressure fluctuations in the absorber while monitoring for pressure changes at the expiratory port. If substantial pressure changes can be measured at the expiratory port, the valve is permitting reverse flow and should be repaired.

*** Vaporizer Back-Pressure Check Valve** [*Acceptance*]
[See Procedure Note] For units without an accessible common gas outlet, open the vaporizer fill cap, occlude the circuit and run the pressure test. Note: This method may not be possible on units that always maintain a minimum flow of oxygen. On such devices, follow the manufacturer's instructions for testing the common outlet back-pressure check valve.

Attach the -10 to +80 cm H_2O pressure gauge or meter to the common gas outlet. Turn off all vaporizers. Adjust the oxygen flow control valve to maintain an outlet pressure of 30 cm H_2O. Turn on the vaporizer, and readjust, if necessary, to maintain 30 cm H_2O. Carefully open the vaporizer filler cap (to prevent a sudden flow of oxygen into the vaporizer), and observe the outlet gauge pressure. A sudden pressure drop

suggests a leaky check valve. If the check valve is missing or defective, contact the manufacturer for replacement.

Vaporizer Back-Pressure Check Valve [*Scheduled*]
[See Procedure Note] For units without an accessible common gas outlet, open the vaporizer fill cap, occlude the circuit and run the pressure test. Note: This method may not be possible on units that always maintain a minimum flow of oxygen. On such devices, follow the manufacturer's instructions for testing the common outlet back-pressure check valve.

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*** Bellows or Piston**
Check the physical condition and proper operation of the ventilator's bellows or piston. If the unit performs an automated leak test, initiate that test according to the manufacturer's instructions and observe the results. Otherwise, perform a leak test as follows: Fill the bellows and set the Vent/Bag valve to Bag to trap gas in the bellows. There should be no visible deflation after one minute. Follow manufacturer's instructions for testing a piston.

*** Breathing System (including filters)**
Verify that these components are compatible with the ventilator according to the manufacturer's recommendations. Check for leaks, the absence of obstructions, and proper flow direction in the system, ensuring the proper assembly and function of fittings, adapters, the CO_2 absorber, inspiratory and expiratory valves and PEEP valves, the APL valve, the scavenger, and other components. With the ventilator connected to the anesthesia system, check for leaks in the entire system, including the breathing circuit.

*** Pressure-Relief Mechanism**
Check the proper operation of the pressure-relief mechanism, by occluding the breathing circuit and observing the resulting peak pressure on the unit's pressure indicator. Verify that pressure is vented in the breathing system.

Fan [*Acceptance*]
Check physical condition and proper operation, if so equipped.

Fan [*Scheduled*]
Check physical condition and proper operation, if so equipped. Clean and lubricate if required, according to the manufacturer's instructions, and note this on the form.

*** Gas cylinders (and gauges and regulators)** [*Acceptance*]
Verify that these are present and securely mounted. Verify that one and only one washer is used to seal the tank to its yoke. Verify that all index pins are present and protruding to the proper length to engage the hole in the tank valve stem and in the correct positions for the gas to be supplied through the yoke.

Gas cylinders (and gauges and regulators) [*Scheduled*]
Verify that these are present, securely mounted, and in good condition and that there is an adequate gas supply. Verify that one and only one washer is used to seal the tank to its yoke. Verify that all index pins are present and protruding to the proper length to engage the hole in the tank valve stem and in the correct positions for the gas to be supplied through the yoke.

Humidifier
See Heated Humidifiers Procedure 431.

Accessories [*Acceptance*]
Verify that all necessary accessories (e.g., vaporizers, anesthetic gas monitors) have been supplied with the anesthesia unit. Inspect these accessories separately using the appropriate inspection procedures. A copy of the operators and service manuals (electronic or hard copy), including schematics, should be shipped with

the equipment. Manuals should be filed in the central equipment file and clinical instructions should be kept in the patient care area for easy access by clinicians.

Accessories [*Scheduled*]
Inspect vaporizers and anesthetic gas monitors (O_2, CO_2, N_2O, and anesthetic agents) separately using the appropriate inspection procedures. Ensure that a copy of the instruction manual is readily available.

Quantitative Tasks

*** Grounding Resistance** [*Acceptance*] ≤0.5 Ω
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 0.5 Ω. 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*] ≤500 μA
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 μA.

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 limits for the device touch current.

Oxygen Flush Valve [*Acceptance*] 35-75 L/min; O_2 flowmeter drop <1 L/min at 2 L/min; return to 2 L/min <2 sec
[See Procedure Note] Attach the digital flowmeter to the outlet. Set the oxygen flow rate to a 2 L/min indication on the unit's oxygen flowmeter, and actuate the oxygen flush control. Measured flow should rise to between 35 and 75 L/min. The unit flowmeter indication should remain near 2 L/min unless the manufacturer's specifications state otherwise. If it falls more than 1 L/min, check for an inadequate oxygen supply or a partially occluded oxygen line in the unit. If the problem cannot be corrected, contact the manufacturer for a replacement.

Cycle the flush control slowly several times; it should move smoothly and not have a tendency to stick. Check that the oxygen flow returns to 2 L/min within 2 sec each time the flush valve is closed.

Oxygen Flush Valve [*Scheduled*] 35-75 L/min; O_2 flowmeter drop <1 L/min at 2 L/min; return to 2 L/min <2 sec
[See Procedure Note] Attach the digital flowmeter to the common gas outlet. Set the oxygen flow rate to a 2 L/min indication on the unit's oxygen flowmeter and actuate the oxygen flush control. Measured flow should rise to between 35 and 75 L/min. The unit's flowmeter should remain near 2 L/min (unless the manufacturer's specifications state otherwise). If it falls below 1 L/min, check for an inadequate oxygen supply, a partially occluded oxygen line in the unit, and/or a dirty oxygen inlet filter.

Cycle the flush control slowly several times; it should move smoothly and not have a tendency to stick. Check that the oxygen flow returns to 2 L/min within 2 sec each time the flush valve is closed.

*** High-Pressure Leaks** [*Acceptance*] negligible pressure drop >30 sec
Close all flow control valves on the unit that can be closed. Disconnect the unit from the piped gas system. Open all cylinder valves one full turn, noting any motion of the flowmeter floats. Float movement with a closed valve indicates a leaky flowmeter valve. Record the unit's pressure gauge readings, verifying that they are close to the service pressure values listed in Table 1. Close the cylinder valves. The pressure drop over 30 sec should be negligible. Excess pressure drop indicates an unacceptable leak. Contact the manufacturer for repair or replacement.

With the unit off and all pressure gauges at zero, open the O_2 and N_2O cylinders to pressurize the gauges, then close the cylinder valves. After verifying that the O_2 pressure does not fall, fully open the N_2O flow control valve and turn on the gas machine. The N_2O pressure gauge should drop slightly but then stabilize. If the pressure reading on either gauge continues to fall, an unacceptable leak is present and the manufacturer should be contacted.

High-Pressure Leaks [*Scheduled*] negligible pressure drop >30 sec
[See Procedure Note] Close all flow control valves on the unit that can be closed. Disconnect the unit from the piped gas system. Open all cylinder valves one full turn, noting any motion of the flowmeter floats. Float movement with a closed valve indicates a leaky flowmeter valve. Record the unit's pressure gauge readings, verifying that they are close to the service pressure values listed in Table 1. Close the cylinder valves. The pressure drop over 30 sec should be negligible. Excess pressure drop indicates an unacceptable leak that should be located and repaired.

With the unit off and all pressure gauges at zero, open the O_2 and N_2O cylinders to pressurize the gauges, then close the cylinder valves. After verifying that the O_2 pressure does not fall, fully open the N_2O flow control valve and turn on the gas machine. The N_2O pressure gauge should drop slightly but then stabilize. If the pressure reading on either gauge continues to fall, an unacceptable leak is present and should be located and repaired.

Intermediate Pressure Leaks [*Acceptance*] no leakage
Connect the hoses to the external pipeline gas source, and test the supply line hoses with leak-detecting solution. If leaks are identified that cannot be eliminated by tightening the fittings, contact the manufacturer for repair or replacement.

Intermediate Pressure Leaks [*Scheduled*] no leakage
Connect the hoses to the external pipeline gas source, and test the supply line hoses with leak-detecting solution. If leaks are identified that cannot be eliminated by tightening the fittings, the fittings should be repaired, especially the N_2O fitting.

Low-Pressure Leaks [*Acceptance*] <30 mL/min at 30 cm H_2O
[See Procedure Note] With the unit off and vaporizer and flow control valves open, attach the -10 to +80 cm H_2O pressure gauge to the unit's common gas outlet using a three-way connector, and air pressurize the outlet to 30 cm H_2O with a sphygmomanometer squeeze bulb. If the pressure falls below 25 cm H_2O in 30 sec, the leakage rate is excessive. Contact the manufacturer for repair or replacement.

Low-Pressure Leaks [*Scheduled*] <30 mL/min at 30 cm H_2O
[See Procedure Note] With the unit off and vaporizer and flow control valves open, attach the -10 to +80 cm H_2O pressure gauge to the unit's common gas outlet using a three-way connector, and air pressurize the outlet to 30 cm H_2O with a sphygmomanometer squeeze bulb. If the pressure falls below 25 cm H_2O in 30 sec, the leakage rate is excessive. Locate the leak by shutting off all vaporizers and repeating the test with each vaporizer added in turn.

Breathing System [*Acceptance*] ≥30 cm H_2O, 30 sec
Turn the anesthesia unit off, and connect the -10 to +80 cm H_2O pressure gauge to a piece of breathing hose that connects the inspiratory port to the expiratory port. Close the APL valve. In place of the reservoir bag, insert a one-hole stopper with a fitting for the sphygmomanometer squeeze bulb.

Use the bulb to pressurize the breathing system to 50 cm H_2O. If the pressure falls below 30 cm H_2O within 30 sec, there is a leak in the breathing system that should be corrected. Contact the manufacturer for repair or replacement. During this test, verify the accuracy of the breathing system pressure gauge by comparing its readings with those of the test pressure gauge.

Breathing System [*Scheduled*] ≥30 cm H_2O, 30 sec
Turn the anesthesia unit off, and connect the -10 to +80 cm H_2O pressure gauge to a piece of breathing hose that connects the inspiratory port to the expiratory port. Close the APL valve. In place of the reservoir bag, insert a one-hole stopper with a fitting for the sphygmomanometer squeeze bulb.

Use the bulb to pressurize the breathing system to 50 cm H_2O. If the pressure falls below 30 cm H_2O within 30 sec, there is a leak in the breathing system that should be corrected. During this test, verify the accuracy of the breathing system pressure gauge by comparing its readings with those of the test pressure gauge.

APL Valve ~1 to ≥30 cm H_2O
Leave the setup as in the previous task, but replace the breathing bag, and restore the original pressure-limiting valve setting.

Turn on the unit and fill and squeeze the bag to verify that the valve holds pressure until the set pressure is exceeded and that it then opens. Check that the opening pressure is adjustable from approximately 1 to at least 30 cm H_2O.

*** Scavenging System** Max suction -0.5–0 cm H_2O @10 L/min O_2 near ambient; APL occluded ≤10 cm H_2O
Connect the pressure gauge between the APL valve exhaust port and the scavenging system intake hose. Leave the setup as in the previous test, with the APL valve closed.

With the scavenging system operating at maximum suction, the pressure gauge reading should be between -0.5 and 0 cm H_2O. Fully open the APL valve, and set a 10 L/min oxygen flow rate. With the scavenging system at the minimum vacuum, the gauge reading should not exceed 2 cm H_2O.

Repeat the last measurement with the APL valve fully open while occluding the APL valve outlet and activating the flush valve for 5 sec. The pressure should remain ≤10 cm H_2O.

*** Flowmeters** [*Acceptance*] ±10%
[See Procedure Note] In most cases, N_2O cannot be measured independently because of hypoxic mixture safety features. Once the accuracy of the O_2 flowmeter is determined, the N_2O meter can be indirectly tested by measuring the accuracy of a known mixture of O_2 and N_2O. For example, if a 1:1 mixture is delivered, the total flow should be the sum of the flow for each meter when measured with the digital flowmeter.

The following procedure applies to each flowmeter on the anesthesia unit. Connect the 1 to 20 L/min flowmeter to the common gas outlet, with its discharge directed into the scavenging or other gas evacuation system. Starting with oxygen, then for each gas in turn, set the flow rate at the highest and 1 L/min settings for each of the unit's flowmeters. Record the setting versus the reading of the test flowmeter.

The readings on the unit's flowmeters should agree with those of the test flowmeter to within 10% of set values or 20% when operating two flowmeters together (e.g., O_2 and N_2O). If the error is excessive, contact the manufacturer for repair or replacement.

Flowmeters [*Scheduled*] ±10%
[See Procedure Note] In most cases, N_2O cannot be measured independently because of hypoxic mixture safety features. Once the accuracy of the O_2 flowmeter is determined, the N_2O meter can be indirectly tested by measuring the accuracy of a known mixture of O_2 and N_2O. For example, if a 1:1 mixture is delivered, the total flow should be the sum of the flow for each meter when measured with the digital flowmeter.

The following procedure applies to each flowmeter on the anesthesia unit. Connect the digital flowmeter to the common gas outlet, with its discharge directed into the scavenging or other gas evacuation system. Starting with oxygen, then for each gas in turn, set the flow rate at the highest and 1 L/min settings for each of the unit's flowmeters. Record the setting versus the reading of the test flowmeter.

The readings on the unit's flowmeters should agree with those of the test flowmeter to within 10% of set values or 20% when operating two flowmeters together (e.g., O_2 and N_2O). If the error is excessive, check for damaged, inverted, or interchanged flowmeter tubes; condensation; or damaged floats.

*** Minimum Oxygen Flow and Percentage** 100–250 mL/min or mfr spec
Close, as far as possible, the valve to the anesthesia unit's oxygen flowmeter. Connect the 0.1 to 1.0 L/min flowmeter to the common gas outlet or the "patient outlet". The test flowmeter should indicate the minimum flow specified by the manufacturer (usually 100 to 250 mL/min).

Remove the flowmeter and, in its place, attach an O_2 monitor. Set the flow of oxygen to around 200 mL/min. Starting with the flow of nitrous oxide off, gradually increase the flow of N_2O. Verify that at least the minimum percentage of oxygen (specified by the manufacturer) is delivered as the flow of nitrous oxide is increased. Gas from the common gas outlet or the patient outlet should be scavenged.

PEEP Valve system pressures <1 cm H_2O and ±1.5 cm H_2O
Using a disposable breathing circuit and a test lung bag or lung simulator, use the -10 to +80 cm H_2O pressure gauge to measure the airway pressure at the test lung bag or lung simulator. The gauge can be connected at the Luer connector on the patient elbow or wye of the circuit.

Manually ventilate the test lung bag with the PEEP valve set at 0 cm H_2O water pressure. The end-exhalation pressure in the breathing system should be less than 1 cm H_2O at a fresh gas flow of 4 L/min and APL valve setting of 30 cm H_2O. Set PEEP to 5 cm H_2O water pressure. The pressure in the breathing system at the end of exhalation should be within 1.5 cm H_2O of the set value. Repeat the test with the PEEP valve set at 10 cm H_2O.

*** Exhaled Volume Monitor** ±15% test lung value; ±15% minute volume display
To test the function of the monitor, connect the inspiratory side of the breathing circuit to the unit. If necessary, attach the monitor's flow sensor at the appropriate location (e.g., expiratory port), making sure that it is oriented to measure flow into the expiratory port. Connect the spirometer between the expiratory port and expiratory limb of the circuit. Then connect the test lung bag to the wye of the circuit.

Set the test lung bag to accept a tidal volume of 500 mL, then ventilate the test lung bag by squeezing the reservoir bag, making sure that the test lung bag completely deflates before delivering another breath. The displayed tidal volume should be within 15% of the set value of the test lung. Next, deliver six breaths in a 1 min period. The minute volume display of the unit should be 3 L (3,000 mL) ±15%. An apnea alarm should occur when breaths are not delivered. Alternatively, this test can be performed by running the ventilator with tidal volume set to 500 mL.

Modes and Settings ±10% or mfr spec
The function of all modes as well as PEEP should be inspected and verified for proper operation. Check the operation and accuracy of ventilation controls, which may include tidal volume, breath rate, inspiratory time, expiratory time, I:E ratio, pressure limit, or flow. Typically, these tests are performed by attaching the ventilator to a lung simulator or ventilator tester and comparing measured values to settings on the ventilator. The manufacturer should recommend the appropriate ventilator settings (e.g., tidal volume, rate, inspiratory time, compliance) to verify proper operation and accuracy (generally within 10%).

Monitors and Alarms ±10% or mfr spec
[Note: This task should be customized into specific measurement tasks for each monitoring function.]

The following respiratory parameters may be monitored by the ventilator or by the system in which the ventilator is mounted. They should be inspected for accuracy (generally within 10%) according to the manufacturer's specifications:

- Breathing rate
- Inspiratory time
- Airway pressure (e.g., PIP, PEEP, MAP, apnea)
- Volume (e.g., tidal volume, minute volume, apnea)
- Fraction of inspired oxygen (FIO_2); see Oxygen Analyzers and Monitors Procedure 417)

Alarm settings (e.g., high PIP, low MAP, low pressure, low FIO_2) should be tested for proper and accurate activation.

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

Clean
Clean any excess leak-detection solution from the exterior and interior of the anesthesia unit; clean all compressed-gas filters, if needed.

Calibrate
Calibrate according to manufacturer's instructions.

Lubricate
Lubricate per the manufacturer's specifications.

Replace
Replace compressed-gas filters and alarm batteries, if needed.