Procedure No. 436-20200410 COVID 19

Adapt Procedure For

Anesthesia Unit Vaporizers [10-144]

Scope

Applies to the various anesthesia vaporizers used to deliver a known concentration of vaporized liquid anesthetic

Interval

6 Months

Time Required

0.7 Hour

Overview

Anesthesia vaporizers are used to vaporize a liquid anesthetic agent and deliver a controlled amount to the patient. There are three types of concentration-calibrated vaporizers: variable bypass, heated blender, and electronically controlled vapor cassettes. These devices are used in operating rooms, emergency departments, delivery rooms, trauma departments, ambulatory surgical centers, and any areas requiring the administration of an inhalation agent. In the vast majority of cases, vaporizers will be mounted on anesthesia machines; however, vaporizers can also be associated with cardiopulmonary bypass consoles by the use of special mounting blocks.

Conventional (variable-bypass) vaporizers. In a variable-bypass vaporizer, the total background gas flow that enters the unit is split into two streams. The smaller stream, which acts as the carrier gas, passes through the vaporizing chamber containing the anesthetic agent and becomes saturated with agent vapor; the remainder of the gas bypasses this chamber. A wick may be used in the vaporizing chamber to provide increased surface area for efficient evaporation of the drug and saturation of the carrier gas. The saturated carrier gas leaves the chamber and mixes with the bypass gas. One adjustment is made to set the desired concentration. This adjustment simultaneously balances the carrier and bypass flows to produce the blend required for the set concentration. The mixture exits the vaporizer and is delivered from the anesthesia machine in the fresh gas to be inspired by the patient. Figure 1 presents a schematic of a variable-bypass vaporizer.

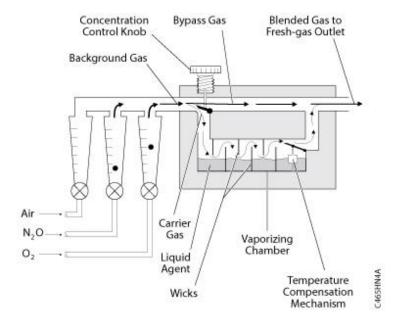


Figure 1. Schematic illustrating the basic elements of a variable-bypass vaporizer



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Heated-blender vaporizers are presently only needed for desflurane, marketed by Baxter Pharmaceutical Products Division under the trade name Suprane $^{\text{TM}}$.

Due to the higher volatility of desflurane as compared to other agents, the vapor concentration could not be adequately controlled using the variable-bypass vaporizer concept. As a result, Datex-Ohmeda (now GE Healthcare) developed the Tec 6 vaporizer, based on a heated-blender design, which maintains a constant desflurane vapor pressure and allows accurate delivery. Figure 2 shows a schematic of this vaporizer. Datex-Ohmeda has since released the Tec 6 Plus, which is similar in design.

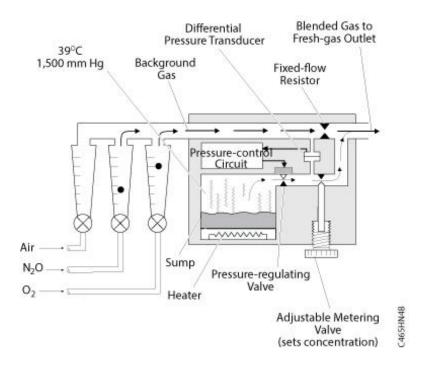


Figure 2. Schematic illustrating the basic elements of the Datex-Ohmeda Tec 6 vaporizer

A desflurane vaporizer requires electrical power to heat the agent to a thermostatically controlled 39°C, producing a stable, saturated vapor pressure of approximately 1,500 mm Hg. No wick is used, and no carrier gas enters the sump chamber. Instead, a stream of vapor under pressure flows out of the sump; this stream blends with the background gas stream from the anesthesia machine's flowmeters to achieve the desired concentration.

The control circuits and heating elements in the vaporizer are turned when connected to electrical power. The unit then heats to and remains at operating temperature as long as it receives power, whether it is delivering agent or is in the standby mode. Consequently, it is warm to the touch while plugged into a live socket. Heated vaporizers typically require at least a 10 minute warm up time from a cold start.

GE Healthcare has developed a cassette-based, electronically-controlled vaporizer system. The cassettes, which are filled with the agent solution, are deliver vapor at the concentration set by the user from the anesthesia machine control panel. The cassettes have both a gas interface and electronic interface with the anesthesia machine. Cassettes for sevoflurane, isoflurane, and desflurane are available. These cannot be used as free-standing vaporizers.

Test Apparatus and Supplies

Electrical safety analyzer (line powered vaporizers) [Acceptance] Halogenated anesthetics analyzer Anesthetic gas scavenging system



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Special note concerning acceptance tasks during rapid deployment of anesthesia vaporizers 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 vaporizer 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. 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 vaporizers or vaporizers with unknown IPM history that all listed scheduled IPM tasks be performed before they are placed into use.

Special Precautions

Always use a scavenging system when inspecting vaporizers. For personal safety, when inspecting vaporizers alone, notify other personnel of your location. Be sure that fill ports are tightly capped before passing gas through the vaporizer.

Anesthesia vaporizers should only be disassembled and repaired by persons qualified by manufacturer training to do so. If damage or deficiencies are identified during inspection and testing of the vaporizer, the vaporizer should be returned to the manufacturer or manufacturer qualified servicer.

As a general precaution, older vaporizers containing an anesthetic agent should not be tilted substantially or laid on their side. If such occurs, follow the manufacturer's recommended procedures for airing or drying the vaporizer.

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.

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.

Note: This procedure should be performed concurrently with Anesthesia Units Procedure 400, 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.

Examine the exterior of the vaporizer for cleanliness and general physical condition. Ensure that the setting dial is secure, the sight tube is not cracked, housings are intact, and all assembly hardware (e.g., fill port caps) is present and tight.

Chassis/Housing [Scheduled]

Examine the exterior of the vaporizer for cleanliness and general physical condition. Ensure that the setting dial is secure, the fill tube is not cracked, plastic housings are intact, and that all assembly hardware (e.g., fill port cap) is present and tight. Examine for signs of leaks or evidence of damage such as dents or cracks that suggest dropping.



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* Mount/Fasteners

Check security of mounts or support mechanisms. Verify that the vaporizer is firmly mounted on the anesthesia unit (or CPBPM) and the presence, condition and appropriate number of O-rings between the vaporizer and its mount, if applicable.

* 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.

If the vaporizer has an AC power plug, examine it for damage. Attempt to wiggle the blades to determine if they are secure. Shake nonmolded plugs and listen for rattles that could indicate loose screws.

AC Plug [Scheduled]

If the vaporizer has an AC plug, examine it for damage. Shake the plug and listen for rattles that could indicate loose screws. If any damage is suspected, open the plug and inspect it.

* Line Cord [Acceptance]

Ensure that the line cord, if so equipped, is long enough for the vaporizer's intended application. 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.

Line Cord [Scheduled]

Inspect the cord, if so equipped, for signs of damage. If damaged, replace the entire cord.

* Strain Reliefs

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

* Fittings/Connectors [Acceptance]

Verify appropriate connectors are supplied if connection to other hospital equipment or systems is required. Verify that suitable connectors are supplied with the vaporizer 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 on vaporizer cassettes should be straight, clean, and bright. Gas and liquid fittings should be tight and should not leak. If keyed connectors are used, ensure that the keying is correct. Verify that the latching mechanism and its lever operates smoothly and securely engages the vaporizer in the mounting block or cassette receptacle.

Fittings/Connectors [Scheduled]

Examine all gas and liquid fittings and connectors, as well as all electrical cable connectors, for general condition. Electrical contacts on vaporizer cassettes 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. Verify that the latching mechanism and its lever operates smoothly and securely engages the vaporizer in the mounting block or cassette receptacle.

* Controls [Acceptance]

For vaporizers that are manually set, verify smooth rotation of the vapor concentration dial from maximum to OFF position. If a control has fixed-limit stops, check for proper alignment, as well as positive stopping.

Controls [Scheduled]

For vaporizers that are manually set, verify smooth rotation of the vapor concentration dial from maximum to OFF position. 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.



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Indicators/Displays

Confirm the operation of all indicators and visual displays on the vaporizer, if so equipped.

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.

Alarms [Acceptance]

If the vaporizer itself has alarms, it should not be possible for them 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 vaporizer will normally be used. Audible alarm-volume controls should not allow the alarm to be turned off or lowered to an indiscernible volume. Operate the vaporizer in such a way as to activate each audible and visual alarm, if so equipped. If the vaporizer has an alarm-silence feature, check the method of reset (i.e., manual or automatic) against the manufacturer's specifications.

Alarms [Scheduled]

If the vaporizer itself has alarms, operate it in such a way as to activate each audible and visual alarm. If the vaporizer has an alarm-silence feature, check the method of reset (i.e., manual or automatic) against the manufacturer's specifications.

Audible Signals

If the vaporizer has audible signals, operate it in such a way as to activate the signals. Confirm appropriate volume, as well as the operation of a volume control, if so equipped.

* Interlocks

Check that the vaporizer interlock allows activation of only one vaporizer at a time.

<u>Labeling</u>

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

* Site Glass, O-Rings, Keyed Filler Mechanism

Examine the physical condition of the site glass, O-rings, and keyed filler mechanism, if so equipped.

Accessories

Verify that all necessary features and accessories have been supplied with the vaporizer. 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.

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 0.5 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 μ A.



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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.

* Concentration Check ±0.3% vapor or ±15% of the selected value, whichever is greater Record the type and control number of each vaporizer. Because there are various types of halogenated anesthetic analyzers, follow the manufacturer's procedure for setup and use of the analyzer.

Vaporizers should usually be tested with an oxygen flow of 4 L/min. Nitrous oxide may affect the readings of some vapor analyzers and should not be used). Test the vaporizers at OFF, low, mid and maximum concentration settings. At one concentration setting (e.g., 1.0% for halothane, 10% for desflurane), test the vaporizer at 1 L/min. The concentration should be $\pm 0.3\%$ vapor or $\pm 15\%$ of the selected value, whichever is greater. [If errors in concentration are observed, allow the vaporizer to operate for a minute or two and recheck the unit. Some units may require a short stabilization period.]

Preventive Maintenance [Does not apply to *Acceptance* procedure] <u>Clean</u>

Clean the exterior.

Replace

Replace the battery, if indicated.

Change

Change CO2 absorbent if the procedure or investigation results in excessive gas flow through the carbon dioxide absorber.

Calibrate

If needed, calibrate according to manufacturer's instructions.

