

Anesthesia Units

EXECUTIVE SUMMARY



This Product Comparison covers complete anesthesia systems capable of delivering anesthetic agents, ventilating the patient, and monitoring ventilation variables (and possibly gas and physiologic variables). Excluded are separate analyzers designed to measure concentrations of halogenated anesthetics and gases supplied to the unit or to detect levels present in the operating room; also excluded are separate stand-alone physiologic monitoring systems.

Anesthesia units dispense a mixture of gases and vapors and vary the proportions to control a patient's level of consciousness and/or analgesia during surgical procedures. Anesthesia units primarily perform the following four functions:

- Provide oxygen (O₂) to the patient
- Blend gas mixtures, in addition to O₂, that include air or nitrous oxide (N₂O) along with an anesthetic vapor
- Facilitate spontaneous, controlled, or assisted ventilation while using these gas mixtures Reduce, if
- not eliminate, anesthesia-related risks to the patient and clinical staff

The patient is anesthetized by inspiring a mixture of O₂, the vapor of a volatile liquid halogenated hydrocarbon anesthetic, and, if necessary, N₂O and other gases. Because normal breathing is routinely depressed by anesthetic agents and by muscle relaxants administered in conjunction with them, respiratory assistance is also provided via either an automatic ventilator or by manual compression of the reservoir bag.

The following device terms and product codes listed in ECRI Institute's Universal Medical Device Nomenclature System™ (UMDNS™) are covered:

- Anesthesia Systems [35-373] Anesthesia
- Units [10-134]

These units are also called: anesthesia machines.



Scope of this Product Comparison

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Purpose

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Principles of Operation

An anesthesia unit comprises two basic subsystems: a gas delivery platform, which creates and delivers gas mixtures and monitors the patient's respiration (e.g., rate, airway pressure) and a data analysis and distribution system. Many units also include integrated multigas monitors, which measure and display gas and agent concentrations, including end-tidal carbon dioxide (ETCO₂), in breathed-gas mixtures. Manufacturers also typically offer a minimum combination of monitors, alarms, and other features that customers must purchase to meet local standards and ensure patient safety. To meet the minimum standard of care in the United States, the American Society of Anesthesiologists (ASA) states that anesthesia units must continually monitor the patient's oxygenation, ventilation, circulation, expired carbon dioxide (CO₂) levels, and temperature. Integrated or stand-alone monitors may be used.

Gas Supply and Control

Because air, O₂, and N₂O are used in large quantities, they are usually drawn from the hospital's central gas supplies. Compressed gas cylinders mounted on yokes attached to the anesthesia unit serve as an emergency gas supply in case central supplies fail. Cylinder connections should include indexing systems (e.g., specific pattern of pins), which are intended to prevent accidental mounting of a gas cylinder on the incorrect yoke. Each gas entering the system from a cylinder flows through a filter, a one-way check valve, and a regulator that lowers the pressure to approximately 45 pounds per square inch (psi). There is no need for a separate regulator when the central gas supply is used because the pressure is already at about 50 psi.

Anesthesia units have several safety features that prevent the delivery of a hypoxic mixture of gases to the patient. One is an oxygen proportioner that maintains a minimal O₂ concentration when N₂O is used. Another is an O₂ supply-failure device that decreases or shuts off the flow of the other gases and activates an alarm if the O₂ supply pressure drops below an acceptable psi level.

Fresh gas flow is controlled by a valve and indicated by a flowmeter. Mechanical flowmeters indicate the flow with a bobbin which moves up and down depending on the flow. Electronic flowmeters use sensors and an LCD or digital display. After the gases pass through the control valve and flowmeter, enter the low-pressure system, and, if required, pass through a vaporizer, they are administered to the patient. An O₂ monitor on the inspiratory side of the breathing circuit analyzes gas sampled from the patient's breathing circuit, displays the percent by volume of O₂ concentration, and generates an alarm if the O₂ level falls below a preset limit.

If the flow of anesthetic gases to the patient must be interrupted for any reason, an O₂ flush valve can be activated to provide a large flow of central-source O₂ to purge the breathing circuit of anesthetic vapors. The O₂ flush flow bypasses the flowmeters and vaporizers.

Vaporizers

Because the inhaled anesthetic agents exist as liquids at room temperature and sea-level ambient pressure, they must be evaporated by a vaporizer. Vaporizers add a controlled amount of anesthetic vapor to the gas mixture. Most vaporizers are either variable bypass (conventional) or heated blender. These vaporizers are manually controlled by the clinician, generally by turning a dial that controls how much agent is picked up by the fresh gas as it passes through the vaporizer. A few anesthesia units now have a liquid-injector type of vaporizer. This vaporizer is electronically controlled and injects the liquid anesthetic agent directly into the stream of gases. Manufacturers may provide multiple in-line vaporizers, which is useful for anesthesiologists to switch agents during a procedure. Some units may have up to three vaporizers; units with multiple vaporizers should have an interlock that prevents the use of more than one vaporizer at once.

Variable bypass and heated blender vaporizers are concentration calibrated and thus can deliver a preselected concentration of vapor under varying conditions. In a variable bypass vaporizer, such as one used for enflurane, isoflurane, halothane, or sevoflurane, a shunt valve divides the gas mixture entering the vaporizer into two streams; the larger stream passes directly to the outlet of the vaporizer, while the smaller stream is diverted through an internal chamber in which vapor fills the space over the relatively volatile liquid anesthetic. The vapor mixes with the gas of the smaller stream, which then rejoins the larger stream as it exits the vaporizer. In a mechanically controlled variable-bypass vaporizer, a bimetallic thermal sensor that regulates the shunt valve to divert more or less gas through the chamber compensates for temperature changes that affect the equilibrium vapor pressure above the liquid. Each variable bypass vaporizer is specifically designed and calibrated for a particular liquid anesthetic.

The heated blender vaporizer was introduced for use with the anesthetic agent desflurane. In this type of vaporizer, desflurane is heated in a sump chamber. A stream of vapor under pressure flows out of the sump and blends with the background gas stream flowing through the vaporizer. Desflurane concentration is controlled by an adjustable, feedback-controlled metering valve in the vapor stream.

Measured-flow vaporizers (also known as copper kettle or flowmeter-controlled) are considered largely obsolete but may still be in limited use in some developing countries. These vaporizers are not concentration calibrated; instead, a measured flow of carrier gas is used to pick up anesthetic gas.

Draw-over vaporizers are sometimes used by the military in the field, as well as in situations or countries in which pressurized gas sources are unavailable. Such units offer low resistance to gas flow and are relatively simple.

Ventilation

An automatic ventilator included on the unit is generally used to mechanically deliver and control breaths. These ventilators use a bellows or some other reservoir in place of the manually compressed reservoir bag. The ventilator forces the anesthesia gas mixture into the patient's breathing circuit and lungs and, in a circle breathing system, receives exhaled breath from the patient as well as fresh gas. The anesthetist can vary the volume of a single breath (tidal volume) and the ventilation rate, either directly by setting them on the ventilator or indirectly by adjusting parameters such as the duration of inspiration, the inspiratory flow, and the ratio of inspiratory to expiratory time. The ventilatory pattern is adjusted to the varying needs of the patient.

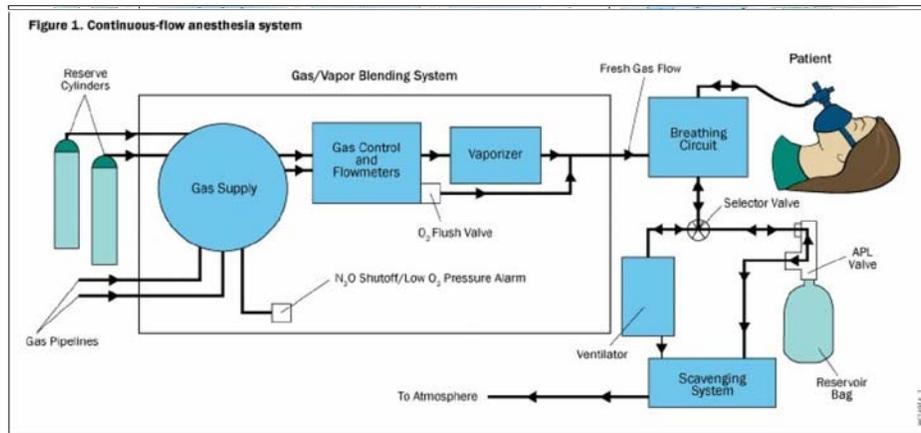
Modern anesthesia ventilators have some method of isolating the fresh gas flow from the tidal volume such that the set tidal volume is delivered regardless of changes in the fresh gas flow. Devices with fresh gas compensation use calculations from the inspiratory flow sensor to know when the set tidal volume has been delivered (from a combination of fresh gas and exhaled gas) and stop the displacement of the bellows. Other devices have a fresh gas decoupling valve that diverts fresh gas into the reservoir bag where it mixes with exhaled gas before being delivered to the patient.

Minute ventilation, the total volume inspired or expired during one minute, can be evaluated as the product of the expired tidal volume and the ventilation rate. It requires careful monitoring, not only because it is physiologically important to the patient, but also because it can indicate malfunctions of the ventilation delivery system (e.g., leaks in the breathing circuit). The expired tidal volume can be measured with a flowmeter, with a spirometer, or (most commonly) with a sensor placed in the expiratory circuit. Most ventilators are capable of providing controlled ventilation and can maintain a positive airway pressure during the expiratory phase of the breath (positive endexpiratory pressure [PEEP]). Many ventilators can be equipped with modes that permit spontaneous breathing during mechanical ventilation. The newest and most advanced anesthesia ventilators have modes and features comparable to advanced ICU ventilators. These advanced modes (e.g., modes that are volume-targeted and pressure-controlled) and features (e.g., inspiratory hold maneuvers and pressure-volume loops) allow the anesthesia provider to match the ventilation settings during surgery to those used in the ICU for patients with diseased or damaged lungs. The advanced modes can also be useful for trauma patients with severely injured lungs (e.g., a crushing chest wound).

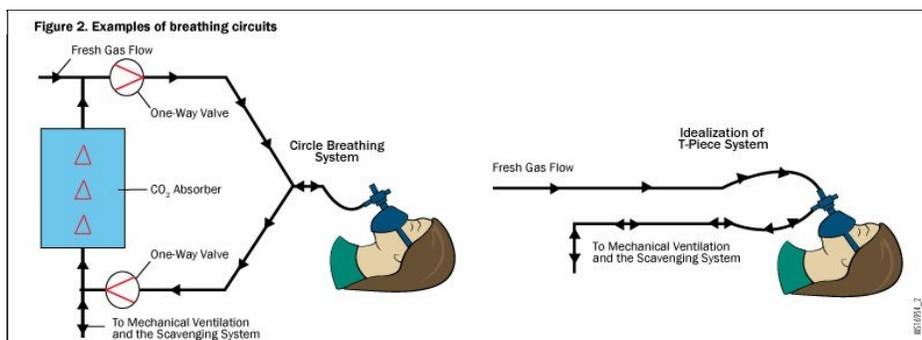
Units also have a breathing bag for manual ventilation. The operator squeezes the bag to deliver a breath to the patient. This manual bag is typically used at the beginning and end of the procedure and is critical if the automatic ventilator fails during a procedure.

Breathing Circuits

Most anesthesia units are continuous-flow systems (see Figure 1), that provide a continuous supply of O₂ and anesthetic gases. There are two basic types of breathing circuits used in modern systems: the circle system and the T-piece system (see Figure 2).



In the circle system, the breathing system receives exhaled breaths from the patient, removes expired CO₂, and then recirculates a high proportion of anesthetic gases combined with fresh gas to the patient. Fresh gas from the anesthesia machine enters the inspiratory limb of the breathing circuit and mixes with gas in the system before the resulting mixture flows through a one-way valve to the patient. Expired gas flows from the patient through a second (expiratory) limb of the circuit, passing another one-way valve, into either a reservoir bag or a ventilator. When positive pressure is generated in the system, either by a manual squeeze of the reservoir bag or by compression of the bellows or piston by a mechanical ventilator, collected gas that does not escape via an adjustable pressure-limiting (APL) valve to the scavenging system is driven through a CO₂ absorption canister where CO₂ is removed from the gas before it is returned to the patient. In circle breathing systems, a fresh-gas flow of 1 L/min or less is typically considered low-flow anesthesia (2 to 6 L/min is typically considered a high fresh-gas flow rate). A fresh-gas flow of 0.5 L/min is generally considered minimal-flow anesthesia. In situations in which the cost of anesthetic agents is high, low-flow anesthesia may be the preferred option.



T-piece systems vent most of the exhaled gas from the system, with the precise portion of rebreathed gas depending on the fresh gas flow rate. Machines with a T-piece design have corrugated tubing in which fresh gas and some expired gas mix before entering the patient at each inhalation. Partial rebreathing is controlled by the supply rate of fresh gas, and the exhaled anesthetic mixture leaves the circuit through an APL valve. Elimination of rebreathed CO₂ depends on fresh-gas flow and occurs in direct proportion to that flow. This system, although adaptable to a variety of anesthetic procedures, is used most often in pediatric anesthesia.

Circle systems offer advantages over T-piece systems in that they conserve a greater proportion of the anesthetic gases and conserve body heat and moisture from the patient. The advantages of T-piece systems include a lower circuit compliance, and a less complex design requiring fewer valves and no CO₂ absorber (although one can be used with it).

Because excess pressure imposed on the patient's lungs can cause serious lung damage, either an APL valve (during manual ventilation) or a valve in the ventilator (during automatic ventilation) allows excess gas to escape when a preset

pressure is exceeded. Circle systems and T-piece systems also include a pressure gauge for monitoring circuit pressure and setting the APL valve. An electronically controlled, settable, and calibrated APL valve is available on most modern anesthesia machines.

Scavenging System

A scavenging system captures and exhausts waste gases to minimize the exposure of the operating room staff to harmful anesthetic agents. Scavenging systems remove gas by a vacuum, a passive exhaust system, or both. Vacuum scavengers use the suction from an operating room vacuum wall outlet or a dedicated vacuum system, though some units may have an integrated suction system. To prevent the vacuum system from affecting the pressure in the patient circuit, manifold-type vacuum scavengers use one or more positive or negative pressure relief valves in an interface with the anesthesia system. In contrast, open-type vacuum scavengers have vacuum ports that are open to the atmosphere through some type of reservoir; such units do not require valves for pressure relief.

Passive-exhaust scavengers can vent into a hospital ventilation system (if the system is the nonrecirculating type) or, preferably, into a dedicated exhaust system. The slight pressure of the waste-gas discharge from the anesthesia machine forces gas through large-bore tubing and into the disposal system or directly into the atmosphere.

Monitors and Alarms

Anesthesia units monitor airway pressure, expiratory volume, inspired O₂ concentration, inspired and end-tidal CO₂ concentration, exhaled N₂O concentration, anesthetic agent concentration, and apnea.

While this report covers preconfigured units, anesthesia machines may be placed in a modular system, with the addition of other physiologic monitors. Some of these specially configured models exist to predict the level of wakefulness in anesthetized patients, such as the Ramsay Scale and the Modified Observer's Assessment of Alertness/Sedation Scale. However, in lieu of a direct method of monitoring brain activity during surgery, users may rely on indirect means of assessing consciousness, such as blood pressure and vital signs. According to proponents, one indirect method, level-of-consciousness monitoring (e.g., Bispectral Index [BIS], Physiometrix's Patient State Index), measures the effectiveness of painkilling agents while ignoring the sedative and paralytic elements that constitute a significant portion of anesthetic agents. Some anesthesia units may incorporate this technology as an additional tool to monitor the patient. Level-of-consciousness monitors use a metered scale (0 to 100) to indicate the degree of patient wakefulness based on collected and processed data. A digital meter indicates the number on the scale that corresponds to the patient's degree of wakefulness, with a higher number representing a higher degree of consciousness and awareness of sensation despite the presence of anesthetic agents. One supplier offers an entropy module that provides information on the central nervous system during general anesthesia. The information is acquired based on the acquisition and processing of raw electroencephalogram (EEG) and frontalis electromyography (FEMG) signals using a proprietary algorithm. The entropy module is designed to assist clinicians in delivering the appropriate amount of anesthetic agents. ASA states that there is not enough evidence to warrant mandatory use of these technologies for patients under general anesthesia. However, ASA states that it may be useful for at-risk patients to be monitored for intraoperative awareness. For additional information, visit ASA's website at <http://www.asahq.org/>.

Physiologic monitors can be electronically integrated into an anesthesia unit to monitor patient parameters, such as ECG, blood pressure, oxygen saturation (SpO₂), and others. Physiologic monitors are typically physically located adjacent to or on the anesthesia unit (via rails and mounts).

Most newer systems include an integrated gas analyzer, which displays all parameters measured by the gas analyzer on the same display as the respiratory parameters monitored by the anesthesia unit. Advanced systems automatically

identify the anesthetic agent(s), and can trigger an alarm if multiple agents are detected or an agent level is too low. These systems can also measure and record the amount of agent used in a procedure if fresh gas flow is electronically measured.

Connectivity

Anesthesia systems capture patient parameters at regular intervals, and this data is often sent to external systems for automated record keeping. Parameters that are captured in this way include airway pressure, respiratory rate, tidal volume, minute volume, inspired and end-tidal CO₂ concentration, and inspired oxygen concentration. Certain system information, such as agent usage, fresh gas delivery, and ventilation settings, is also captured by some systems or can be manually added to the log by the clinician. Other key information like drugs administered, lab data, and intraoperative events can only be added manually. The archiving of this case data can be handled by a dedicated automated anesthesia record keeper (AARK), but increasingly, data is being added to the patient's existing electronic medical record. Gathering and storing such data can expedite individual patient management and billing, quality assurance, and critical incident analysis.

An anesthesia information management system (AIMS) can receive, analyze, store, and distribute information relating to the clinical and administrative management of anesthesia. Information can be collected from numerous sources associated both directly with anesthesia administration (e.g., an AARK system) and indirectly with the surgical procedure (e.g., preoperative evaluation, laboratory, and pharmacy records). Some systems may also incorporate administrative management tools such as room scheduling and patient billing. In some instances, the anesthesia unit may be able to accept incoming perioperative data from an AIMS or directly from other systems.

Reported Problems

Problems have been reported in all areas of anesthesia systems. Because patients under general anesthesia depend entirely on others for life support, errors caused by machine failure, faulty adjustments, or the operator can be critical. Pre-use checklists, regular inspections, and preventive maintenance are critical to minimizing anesthesia unit hazards. One of the greatest dangers of general anesthesia is a lack of O₂ delivered to the patient (hypoxia), which can result in brain damage or death. Conversely, the administration of O₂ in a concentration of 100%, even for a short duration, may be toxic. Inhalation of 100% O₂ may cause resorption atelectasis. The danger of inhaling 100% O₂, even for a short duration, is particularly acute in neonatal anesthesia, potentially causing retrolental fibroplasia and bronchopulmonary dysplasia. Inadequate O₂ delivery can be caused by any number of conditions, including disconnection of the patient from the breathing circuit; accidental movement of the O₂, N₂O, or other gas flow control setting knobs; changes in the patient's lung compliance; and gas leaks. One common safety measure is the inclusion of an O₂ monitor and a CO₂ monitor or an expired volume alarm (in an anesthesia unit with an ascending bellows) in the anesthesia system. An O₂ monitor warns of inadequate O₂ concentration in the inspiratory limb. A CO₂ monitor or a spirometer alarm (in an anesthesia unit with an ascending bellows) in the breathing circuit can alert the anesthetist to inadequate ventilation such as that caused by a disconnection.

Some anesthesia system malfunctions can cause delivery of gas with excessive CO₂ concentration, an inadequate or excessive amount of anesthetic agent, or dangerously high pressure. Hypoventilation, compromised cardiac output, air in the pleural cavity (pneumothorax), and asphyxiation are possible consequences of such problems.

Improperly calibrated vaporizers can result in the delivery of the wrong concentration of anesthetic agent to the patient. Removing some vaporizers from the anesthesia machine and transporting them can disturb their calibration and could eventually cause delivery of too much or too little anesthetic. However, many "tip-proof" vaporizers have been released to reduce calibration errors. The output of an anesthesia vaporizer should be tested each time the vaporizer is removed from a system and each time it is returned to service. Each vaporizer should be inspected and the calibration verified at least twice a year.

Contamination of any part of the anesthesia breathing circuit, including the breathing tubes, Y-connector, face mask, and reservoir bag, may lead to nosocomial infections. Reported cases include infections of the upper respiratory tract or the lungs and, in one instance in Australia, transmission of hepatitis C. The Centers for Disease Control and Prevention (CDC) and the American Association of Nurse Anesthetists recommend single use of disposables or high-level disinfection of reusables or disposables between patients to prevent cross-contamination. There has been some controversy concerning the use of disposable bacteria filters to prevent patient crossinfections (Dorsch and Dorsch). CDC has not made a definitive recommendation concerning the use of bacterial filters with anesthesia machines. Possible hazards, such as the increased impedance to gas flows and obstruction of the circuit, are associated with these filters. Because many viruses are difficult to culture, the efficacy of viral filters that attempt to reduce viral contamination of breathing systems is not established. Frequent replacement of disposable filters can prevent inadequate gas delivery due to clogging. Some filters can be sterilized and reused. Manufacturers' instructions should be followed when disinfecting anesthesia equipment.

The piping connections for O₂ and N₂O within the hospital walls can be accidentally interchanged during installation or repair of medical gas systems, potentially causing patient injury or death. After any such work, careful inspection and testing with an O₂ analyzer are vital. Gas lines should also be checked for liquid, gaseous, solid particulate, and microorganism contamination after installation or repair and periodically thereafter.

In many countries, a diameter index safety system (DISS) is used to prevent the connection of gas hoses from the machine to the wrong wall outlet, and a pin index safety system is used to prevent the connection of the wrong cylinders to the yokes in the anesthesia machine. The pin index safety system employs pins protruding from the yoke that correspond to holes in a specific type of gas cylinder post. Only a cylinder post with the corresponding holes can fit properly onto the yoke. ECRI Institute has seen instances of improper connections in which damaged pins allowed users to force the wrong cylinder into place. ECRI Institute recommends that damaged indexing components should never be used.

Faulty or inoperative scavenging systems are responsible for most anesthetic gas pollution in the operating room; other causes include improper anesthesia administration technique and leaks in anesthesia equipment. Common sources of leaks include hose connectors, the CO₂ absorber, the APL valve, and the endotracheal tube or mask.

Current scientific and epidemiologic studies have shown that exposure to trace levels of anesthetic gases continually present in the operating room can cause adverse health effects in operating room personnel, such as an increased incidence of spontaneous abortion and congenital anomalies in offspring. In addition, trace gas levels in the air may have a slight anesthetizing effect on the anesthetist and surgeon.

Inadequate evacuation of some scavenging systems can cause pressure to build up in the breathing circuit, with the potential for pneumothorax.

Another common problem is circuit obstruction due to the presence of a foreign object (e.g., needle caps) or a manufacturing defect. This problem occurs most often when a pre-use check is omitted.

Anesthesia units that lack integrated monitors and alarms can cause confusion by sounding numerous alarms simultaneously. While integrated monitors and alarms are becoming more widespread, both modular and integrated

systems are subject to the confusion caused by false alarms. A false alarm, caused by accidental patient movement or other nonphysiologic reasons, can confuse operating room staff and possibly draw attention away from other alarms that may truly indicate a change in the patient's physiologic condition. Ensuring that the alarm limits are properly set and positioning sensors and electrodes in such a way as to minimize artifacts can reduce the incidence of false alarms. ECRI Institute recommends that users do not set physiologic alarm limits below normal values in order to reduce nuisance alarms.

The magnetic fields created by magnetic resonance imaging (MRI) equipment may interfere with the function of conventional anesthesia units and electronic monitoring equipment when used in proximity to such equipment. Conversely, magnetic materials and electronic monitors may interfere with MRI scanner function and degrade image quality. Many MRI-conditional anesthesia machines have restrictions or limitations to their use in the MRI environment. If they are not used in accordance with these restrictions/limitations, MRI-conditional devices can pose the same types of hazards in the MRI environment as devices that are not MRI-conditional. For instance, if some MRI-conditional devices are positioned closer to the MRI unit than is specified by the device supplier, they may not function properly or be attracted to the magnet. Some MRI-conditional devices that come into physical contact with a patient, if used inappropriately, can cause burns (or the sensation of heat) to a patient. The hazards posed by the inappropriate use of MRI-conditional devices in the MRI environment can cause injury to the patient or staff and/or damage to equipment (e.g., the MRI-conditional device, the MRI unit itself). A few suppliers offer MRI-compatible anesthesia machines, and a line of MRI-conditional monitors is available.

Purchase Considerations

ECRI Institute Recommendations

Included in the accompanying comparison chart are ECRI Institute's recommendations for minimum performance requirements for anesthesia units. The recommendations are listed in two categories: basic and high-performance. Basic units are suitable for patients with healthy lungs, whereas high-performance systems use advanced ventilation modes and features more appropriate for patients with less healthy lungs. High-performance units match the capabilities of ICU ventilators and allow the patient to undergo surgery in a matched ventilation environment.

ECRI Institute considers certain minimum safety measures necessary for all anesthesia units. Among these measures are O₂ fail-safe and hypoxic mixture fail-safe systems, gas cylinder yokes for O₂ if central supplies fail, and an internal battery (for units with automatic ventilators) capable of powering the unit for at least 30 minutes.

The unit must be able to measure O₂ concentration, airway pressure, and either the volume of expired gas or the concentration of expired CO₂ (ETCO₂). (Note: ASA recommends monitoring of ETCO₂ in all intubated patients; this can be accomplished by the anesthesia unit or by a separate device [e.g., capnograph, multigas monitor].)

Gas cylinders should be attached through hanger yokes with the proper pin index safety system and check valves. Each pipeline gas cylinder supply should have a pressure gauge with scale numbers large enough to be easily read. Gas hoses and machine receptacles should use DISS fittings to prevent misconnection.

All units should have the ability to adjust each ventilator mode to fit the needs of each patient. Tidal volume should range between 50-1,200 cc.

It is advantageous if the anesthesia unit accepts medical-air input to allow delivery of either air and/or N₂O as the gas carrier. In the event of a partial or complete loss of O₂ supply, an undefeatable audible alarm should activate and the flow of N₂O gases should automatically shut off or decrease proportionately to the flow of O₂ to prevent a hypoxic condition. Also, flows and the mixture ratios determined from flowmeter settings should be accurate to within 10% of

set values. Anesthetic vapor concentration delivered to the common gas outlet should be accurate to within 0.2% vapor concentration of agent or 10% of the set value (whichever is greater) at any gas flow. It is preferable that ventilation rate and PEEP values be monitored. It should not be possible to silence or disable a ventilator monitor alarm for longer than two minutes.

Units should have a power-loss alarm, and the battery backup should have an automatic low-battery alarm. All units should include a backup battery to guard against power loss. The anesthesia unit should automatically switch to the internal battery if line power is interrupted; also, the loss of line power should be accompanied by an alarm. The battery should also operate the anesthesia unit and integral monitors for at least 30 minutes. A low-battery alarm should visually and audibly indicate when the battery voltage falls to a level below which the unit may fail to perform satisfactorily. The battery should not require more than 16 hours to recharge completely after depletion.

High-performance systems are distinguished largely by their ability to serve a wide range of patients and to operate with little or no supplemental equipment. Features that make this possible include pressure-controlled ventilator modes and tidal volume ranges suitable for neonates and adults, as well as integrated gas and sometimes physiologic monitoring. (Although most models tend to include only a small number of standard ventilation modes, additional modes can typically be added via software upgrades following purchase.) High-performance systems generally include more automated features, including storage of trends and self-tests at the beginning of each procedure.

Basic units include only the most vital monitoring capabilities (i.e., O₂ and CO₂ volumes or pressures) and have only one or two automatic ventilator modes. When equipped with appropriate stand-alone monitors, these units are adequate for treatment of most patients but may remain ill-suited for use on neonates and very sick patients, as well as for monitoring-intensive procedures (e.g., certain types of cardiac surgery). These fundamental systems may also include units designed for military or field use, which often lack ventilators and pipeline gas inlets.

Other Considerations

Some anesthesia units require stand-alone physiologic monitors (modular approach) and/or anesthetic agent monitors, while others have integrated monitors (preconfigured approach). The advantages of preconfigured monitoring include convenience and electronically integrated displays and prioritized alarms. Modular systems can be less expensive than preconfigured systems, especially if the facility already owns the monitors.

Hospitals can purchase customized modular systems assembled from standard components, or they can assemble their own modular systems. These systems must meet all national and regional safety standards. Advantages of the modular approach include flexibility in choosing and upgrading monitors and ease of service; drawbacks include assembling a system that may not be successfully integrated and thus has multiple alarms and/or displays.

Anesthesia units and patient monitoring systems should be carefully chosen to ensure that all essential monitoring functions recommended by the ASA are obtained and to ensure optimal integration and an adequate standard of care. For legal reasons, the level-of-monitoring and anesthesia-delivery capabilities for each anesthesia station should be uniform so that all patients receive the same standard of care for the same surgical procedures.

Integrated anesthesia workstations, along with the gas/vapor dispensing subsystem and individual physiologic and equipment monitors, may also include a device for automatically dispensing injectable drugs. Consequently, the anesthesia workstation can be viewed as an integrated monitoring system that dispenses anesthetic drugs.

Hospitals should also consider the standardization of anesthesia equipment; that is, purchasing systems that are compatible with equipment already in operating rooms or other areas of the hospital (e.g., intensive care units). The

purpose of standardization is to allow a reduced parts inventory, minimize the number of suppliers and service personnel, and reduce confusion among the staff.

Pulse oximetry is considered a standard of care for monitoring arterial O₂ saturation in the operating room during procedures requiring anesthesia and in intensive care units and recovery.

Pulse oximeters noninvasively measure SpO₂ and, along with O₂ monitors and CO₂ monitors, are increasingly being required for anesthesia units by state law. Some U.S. states have specified their own requirements for anesthesia units. Hospitals should check with their state's department of health for any regulations that may apply to their area. Pulse oximeters provide a spectrophotometric assessment of hemoglobin oxygenation by measuring light transmitted through a capillary bed, synchronized with the pulse. The detection system consists of singlewavelength LEDs (light-emitting diodes) and microprocessors located within a sensor.

CO₂ monitors measure end-tidal CO₂ and can help identify leaks and misconnections as well as indicate when the trachea has not been properly intubated.

Many features of anesthesia systems are optional, allowing hospitals to choose those that best fit their needs. Among anesthesia units with essentially equivalent mechanical gas/vapor dispensing subsystems, the monitors included in the system and the ways in which information is integrated and displayed are often the primary distinguishing features.

Cost Containment

Because anesthesia systems entail ongoing maintenance and operational costs, the initial acquisition cost does not accurately reflect the total cost of ownership. The anesthetic agents are the biggest ongoing expense associated with anesthesia units. Therefore, a purchase decision should be based on issues such as life-cycle cost (LCC), local service support, discount rates, and non-price-related benefits offered by the supplier.

An LCC analysis should be conducted to determine the cost-effectiveness of all units that meet users' needs.

Although costs associated with many of the following may be similar for a number of anesthesia units, they should still be carefully considered to determine the total LCC for budget purposes:

- Maintenance, service, and inspection
- Accessories, such as monitoring equipment, necessary to comply with standards
- Optional accessories
- Vaporizers (some have been offered at discounted prices or at no cost upon the introduction of a new anesthetic agent)
- Gases, including O₂, N₂O, and anesthetic agents
- Features that help clinicians safely deliver low-flow anesthesia which can reduce the use of costly inhaled agents
- Anesthesia circuits
- Recording and storage of anesthesia-related data
- Disposables
- Utilities

Hospitals can purchase service contracts or service on a time-and-materials basis from the supplier. Service may also be available from a third-party organization. The decision to purchase a service contract should be carefully considered. Most suppliers should provide routine software updates, which enhance the system's performance, at no charge to service contract customers. Purchasing a service contract also ensures that preventive maintenance will be performed at regular intervals, thereby eliminating the possibility of unexpected maintenance costs. Also, many suppliers do not

extend system performance and uptime guarantees beyond the length of the warranty unless the system is covered by a service contract. Hospitals that plan to service their anesthesia units in-house should inquire about the availability and cost of service training and the availability and cost of replacement parts.

ECRI Institute recommends that, to maximize bargaining leverage, hospitals negotiate pricing for service contracts before the system is purchased. Additional service contract discounts may be negotiable for multiple-year agreements or for service contracts that are bundled with contracts on other similar equipment in the department or hospital. Discounts will depend on the hospital's negotiating skills and knowledge of discounts offered to other customers, the system configuration and model to be purchased, previous experience with the supplier, and the extent of concessions granted by the supplier, such as extended warranties, fixed prices for annual service contracts, and guaranteed on-site service response. Buyers should make sure that applications training and service manuals are included in the purchase price of the system. Some suppliers offer more extensive on- or off-site training programs for an additional cost. For customized analyses and purchase decision support, readers should contact ECRI Institute's SELECTplus™ Group.

Stage of Development

Efforts to improve the design of anesthesia units center on gas supply and proportioning systems, gas monitors, ventilators, vaporizers, and data-handling (display, processing, and reporting) software. There is also an effort to decrease the overall size of anesthesia units.

Although anesthesia systems are fundamentally unchanged, manufacturers have made a handful of improvements, including:

- The introduction of low-volume breathing circuits
- The increasing availability of ventilation modes
- Increasing automation of pre-use checks
- The introduction of low-flow decision support tools that help with the adoption of low-flow anesthesia.

BIBLIOGRAPHY

Dorsch JA, Dorsch SE. Understanding anesthesia equipment. 5th ed. Baltimore: Lippincott, Williams & Wilkins; 2007.

ECRI Institute. A look at low-flow anesthesia decision-support tools. Health Devices 2016 Mar.

Anesthesia units [inspection and preventive maintenance procedure]. BiomedicalBenchmark. Procedure no. 400-20081015.

Anesthesia units: the essentials [update evaluation]. Health Devices 2016 Nov.

Anesthesia vaporizers [inspection and preventive maintenance procedure]. BiomedicalBenchmark. Procedure no. 436-20081015.

Dangerous misconnection goes undetected by Datex-Ohmeda ADU's pre-use check [hazard report]. Health Devices 2009 Feb;38(2):58-60.

Evaluation background: general-purpose anesthesia units. Health Devices 2016 Nov.

Waste anesthetic gases. Healthcare Risk Control 2016 May.

Hoeneemann C, Hagemann O, Doll D. Inhalational anaesthesia with low fresh gas flow. Indian J Anaesth 2013 JulAug;57(4):345-50.

Levy RJ. Anesthesia-related carbon monoxide exposure: toxic and potential therapy. *Anesth Analg* 2016 Sep; 123(3):670-81.

Springer R. Cleaning and disinfection of anesthesia equipment. *Plast Surg Nurs* 2010 Oct-Dec;30(4):254-5.

Tablan OC, Anderson LJ, Besser R, et al. Guidelines for preventing health-care-associated pneumonia, 2003: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. *MMWR Recomm Rep* 2004 Mar 26;53(RR-3):1-36.
