

Ventilators, Intensive Care

EXECUTIVE SUMMARY



This Product Comparison covers intensive care ventilators. Intensive care ventilators are defined as mechanical ventilators that can be configured to provide invasive ventilation (e.g., with an endotracheal tube or tracheostomy tube) or noninvasive ventilation (e.g., with a face mask). Intensive care ventilators should be capable of ventilating neonatal, pediatric, and/or adult patients.

Although some models listed in the chart may deliver high-frequency ventilation, units that provide only highfrequency ventilation are not included. Portable ventilators primarily used for patient transport, anesthesia ventilators, and ventilators designed exclusively for sub-acute and home care settings are also not included.

Mechanical ventilators are life support devices that move gas (e.g., air and/or oxygen) to and from a patient's lungs. These devices may provide temporary or permanent respiration for patients who cannot breathe on their own, or who require assistance maintaining adequate ventilation because of illness, trauma, congenital defects, or the effects of drugs (e.g., anesthetics). In most cases, mechanical ventilators are used for a short period of time (a few days to a few weeks) to deliver pressurized medical gases to the patient's lungs to support gas exchange and rest ventilatory muscles until the patient is able to breathe without mechanical assistance. Some patients, however, require permanent ventilatory support.

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

- Ventilators, Intensive Care [17-429]
- Ventilators, Intensive Care, Adult [18-792]
- Ventilators, Intensive Care, Neonatal/Pediatric [14-361]

These devices are also called: continuous ventilators, critical care ventilators, mechanical ventilators, neonatal ventilators, pediatric ventilators, positive-pressure ventilators.



Scope of this Product Comparison

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Purpose

Mechanical ventilators are life support devices that move gas (e.g., air and/or oxygen) to and from a patient's lungs. These devices may provide temporary or permanent respiration for patients who cannot breathe on their own, or who require assistance maintaining adequate ventilation because of illness, trauma, congenital defects, or the effects of drugs (e.g., anesthetics). In most cases, mechanical ventilators are used for a short period of time (a few days to a few weeks) to deliver pressurized medical gases to the patient's lungs to support gas exchange and rest ventilatory muscles until the patient is able to breathe without mechanical assistance. Some patients, however, require permanent ventilatory support.

Principles of Operation

For invasive ventilation, positive-pressure breaths are delivered through an endotracheal tube or a tracheostomy tube. During each breath, the lungs expand in proportion to the volume of gas delivered until a preset pressure, volume, or time limit is reached. Subsequently, a valve in the ventilator opens to allow the gas exchange to exit from the lungs, which causes the patient to passively exhale.

A critical care ventilator consists of a graphical user interface (GUI) and a breath delivery unit. Typically, these components are mounted on a cart and the breath delivery unit is connected to a gas supply, such as wall-mounted air and oxygen supplies and/or an air compressor. The GUI controls the breath delivery unit and provides users with measured data of the patient's inspiration and expiration (see Figure 1). Patients are connected to the ventilator using a breathing circuit. Accessory devices may include heating and humidification devices, nebulization devices and additional patient monitoring devices. Ventilators regulate the pressure, volume, and flow of the delivered positive-pressure breath, as well as the fraction of inspired oxygen (FiO₂), based on user settings. Communications interfaces transmit information on ventilator and alarm settings, measured patient data, and alarm history to a bedside monitor, an information system, or other interfaced device. Power is supplied by an electrical wall outlet with an internal battery backup; battery power is used for short-term ventilation during power failures, or for intrahospital patient transport. For more information on ventilator terminology, see [Ventilator Abbreviations](#).

Intensive care ventilators are designed to use medical gases (air and/or oxygen [O₂]) supplied from wall outlets that deliver gas at a pressure of approximately 50 pounds per square inch (psi). Air and/or O₂ cylinders that are outfitted with a 50 psi pressure regulating device can also be utilized (e.g., during patient transport). The flow of gas to the patient is regulated by flow-control valves in the ventilator. To obtain the desired FiO₂ for delivery to the patient, most ICU ventilators incorporate an air/oxygen mixing device (oxygen blender).

Gas is delivered to the patient through the flexible breathing circuit. Intensive care ventilators use a double-limb breathing circuit made of corrugated plastic tubing to transport the gas from the ventilator to the patient through one limb (the inspiratory limb) and return the exhaled gas to the ventilator through another limb (the expiratory limb). During gas delivery (the inspiratory phase), an exhalation valve inside the ventilator or on the breathing circuit is closed to force air into the tubing and the patient's lungs. After the inspiratory phase, the exhalation valve is opened, allowing the patient to passively exhale through the ventilator and out to ambient air (the exhalation phase). The breathing circuit may also provide sites where the delivered gas can be heated, humidified, monitored for proximal airway pressure, and mixed with aerosolized medications. Some breathing circuits also include reservoirs where condensation from inside the tubing can be collected. Many models have sensors within the ventilator or incorporated into the breathing circuit that can measure airway pressure or flow and provide feedback to the ventilator to automatically adjust its output.

Controls

Controls are used to select the breathing mode and ventilation parameters (e.g., tidal volume, breathing rate, FiO_2).

For the ventilator to produce a prescribed breathing pattern, various parameters can be independently set, such as length of the inspiratory or expiratory phase, rate of mechanical breaths, waveform shape, tidal volume, flow rate, peak pressure, and positive end-expiratory pressure (PEEP).

Ventilator controls for PEEP and continuous positive airway pressure (CPAP) work by restricting flow from the exhalation valve to maintain a set (user-defined) amount of positive pressure in the breathing circuit at the end of the expiratory phase. This increased baseline pressure helps keep small airways and alveoli in the lung inflated in order to increase lung volumes and improve oxygenation (i.e., the diffusion of oxygen across the alveolar capillary membrane).

The inspiratory to expiratory ratio (I:E ratio) is a measured indication of the partitioning of a breath into inspiration time and expiration time. In most cases, the expiratory time is set longer than the inspiratory time (e.g., I:E ratio 1:2 or 1:3) to allow full exhalation before the next breath. However, an equal or inverse ratio may also be used when required for specific types of patients (e.g., I:E ratio 1:1 or 1:0.5). Because inverse I:E ratio settings are not commonly used, some ventilators signal when an inverse I:E ratio has been set; others will not deliver inverse I:E ratio breaths.

Controls are also available for setting the flow waveform, which determines the delivery pattern of machine breaths. Volume-controlled ventilation flow patterns generally include square, accelerating, decelerating, or sinusoidal waveforms. Pressure ramp adjustments are also available in pressure-controlled ventilation modes. Such adjustments allow the user to maximize flow and pressure levels while maintaining a flow delivery that lowers the work of breathing and is more comfortable for the patient.

Operating Modes

Intensive care ventilators have numerous ventilation modes; a ventilation mode defines the algorithm that will be used to initiate (trigger) and end (cycle) a machine breath. Different modes can provide either full or partial ventilatory support, depending on the individual patient's condition and clinical requirements. Ventilator modes and the terminology used for these modes can vary greatly from one manufacturer to the next. For more information on the different ventilation modes available, as well as a taxonomy to compare ventilation modes from different manufacturers, see the Health Devices article cited in the bibliography.

Intensive care ventilators can deliver both volume-controlled (VC) and/or pressure-controlled (PC) breaths that can be used to provide either full or partial ventilatory support. With volume-controlled breaths, a control system is used to ensure that a set tidal volume is delivered during each inspiratory cycle. If the pressure generated during any breath

exceeds a user-set high-pressure limit or pressure-relief valve setting, the breath is cut off and the set volume may not be fully delivered. Volume-controlled modes are typically used for adult and pediatric patients. Pressure-controlled breaths regulate flow delivery to attain a user-set peak inspiratory pressure level during each breath. Because pressure-controlled breaths are affected by changes in airway resistance and lung compliance, the volume of air delivered during each breath may vary. Pressure-controlled modes are used with infants (because they are often intubated with an uncuffed endotracheal tube which makes regulating volume difficult) and there is some reason to believe that pressure-controlled breaths may be beneficial for patients with acute lung injury or acute respiratory distress syndrome (the theory being that pressure breaths encourage lung recruitment).

In addition to differing in terms of whether breaths are volume controlled or pressure controlled, modes of ventilation vary in terms of the sequence of breaths delivered. Breathes can be continuously delivered to the patient regardless of patient effort (continuous mandatory ventilation [CMV]), continuously delivered to the patient but allowing the patient to take spontaneous breaths (intermittent mandatory ventilation [IMV]) or completely patient-triggered (continuous spontaneous ventilation [CSV]).

Finally, in addition to the control variable (pressure or volume) and the breath sequence (CMV, IMV or CSV), modes will differ in terms of the triggering scheme that the device uses to initiate a breath. To trigger a breath delivery, modes may use a number of different methods. To facilitate comparing the different modes of ventilation, ECRI Institute has adopted a ventilator mode taxonomy that utilizes seven types of breath triggering methods or targeting schemes.

These are:

- Set-Point Targeting (s): All breathing parameters are preset by the operator.
- Adaptive Targeting (a): The ventilator automatically adjusts one parameter to achieve another target. This allows the ventilator to adjust the setting in response to varying patient conditions.
- Servo Targeting (r): The ventilator adjusts inspiratory pressure based on patient effort.
- Dual Targeting (d): The ventilator switches between volume control and pressure control during a single breath. This allows the ventilator to adjust settings based on patient conditions and ensures either a preset tidal volume or peak inspiratory pressure.
- Bio-variable Targeting (b): The ventilator randomly adjusts tidal volume (for volume controlled modes) or inspiratory pressure (for pressure controlled modes) within operator preset limits. This is done to mimic the variability of normal breathing.
- Optimal Targeting (o): An advanced form of adaptive targeting where the ventilator automatically adjusts targets to maximize or minimize some overall performance characteristic, such as work of breathing.
- Intelligent Targeting (i): The ventilator uses artificial intelligence tools such as fuzzy logic or rule-based expert systems and artificial neural networks.

Some ventilation modes may incorporate multiple targeting schemes, as in modes that provide intermittent mandatory ventilation. These modes can use one triggering method for mandatory breaths and another triggering method for the spontaneous (patient-initiated) breath.

Non-invasive ventilation (NIV) modes are also available on many intensive care ventilators. These modes are designed to facilitate short-term use of the ventilator on patients without an artificial airway (i.e., endotracheal tube or tracheostomy tube). By effectively compensating for air leaks and pressure changes, NIV mode utilizes a full or partial face mask to connect the patient to the ventilator. Although theoretically any mechanical ventilator can be used for non-invasive ventilation, large air leaks around the mask can make this type of patient interface extremely difficult to maintain. Because NIV mode is specifically designed to manage these problems, it can significantly improve the effectiveness of ventilation. NIV is often used for patients with acute severe respiratory problems (e.g., asthma,

congestive heart failure), who are likely to require ventilatory assistance for only a short period of time, and for patients who may be difficult to wean from the ventilator once they are intubated. Most modes of ventilation can be utilized during NIV.

Some mechanical ventilators can provide high-frequency ventilation (HFV). A high-frequency ventilator uses positive pressure to deliver extremely small breaths at frequencies much higher than the normal breathing rate (e.g., >100 breaths/min). High-frequency ventilators were developed in an effort to reduce barotrauma and some of the deleterious hemodynamic effects associated with the high tidal volumes and pressures used with conventional ventilators.

Monitors and Alarms

Intensive care ventilators are equipped with sensors to detect both equipment-related problems and changes in patient status. Monitored ventilation parameters include:

- Airway pressure
- Respiratory rates
- I:E ratio
- Oxygen concentrations
- Volumes of inhaled and exhaled gases

The GUI provides real-time information of measured pressure, volume, and flow over a set time periods (e.g., 15 seconds, 30 seconds). This information can be presented as measured data or in a graphical waveform or loop. To track patient progress, the GUI may include capabilities for performing respiratory maneuvers to assess pulmonary mechanics. Pressure-volume (PV) loops, which are graphs of pressure vs. volume during a single breath, and flow volume (FV) loops, which are graphs of flow vs. volume during a single breath, can help to identify subtle abnormalities and obstructive or restrictive changes in the lung. Because graphical displays allow clinicians to visually optimize ventilator settings and monitor trends more effectively, they have become an essential tool when caring for critically ill patients on ventilators.

Intensive care ventilators are equipped with audible and visual alarms to notify clinicians of changes in the patient's condition or of device problems. Alarms include those for apnea, high and low respiratory rate, high and low pressure, low exhaled volume, loss of power, loss of supply gases, system malfunction, and incorrect O₂ concentration. Some ventilators also have baseline-pressure alarms; the low-baseline-pressure alarm alerts clinicians to PEEP or CPAP pressure losses, which can affect the patient's O₂ saturation; the high-baseline-pressure alarm alerts clinicians to inadvertent increases in PEEP or CPAP levels, which can prevent complete exhalation and compromise the patient's hemodynamic status. An alarm should also be activated if disconnections occur in the breathing circuit or if flow resistance is encountered. A loss of power or of the gas supply, or other conditions affecting a ventilator's ability to operate, should produce an alarm and allow the patient to spontaneously breathe either room air or a user-specified gas mixture. All critical alarms should be easy to identify and impossible to disarm indefinitely.

To prevent injury to the patient until clinicians can respond to alarms, ICU ventilators incorporate a number of safety features such as the capability to release pressure in the breathing circuit if/when the high-pressure alarm setting is exceeded. Another feature is the capability to provide backup ventilation, in which the ventilator will initiate breaths at a predetermined volume and rate if/when it senses that the patient's breathing efforts have ceased, or the ventilator has malfunctioned.

Alarm-enhancement Systems

Ventilator alarms are crucial for safeguarding the health and lives of patients. Therefore, it is vital that they be readily detected in even the busiest, noisiest hospital departments. Alarm-enhancement systems, which communicate ventilator alarms to locations where they are more likely to be detected by caregivers, can be helpful.

There are four basic categories of ventilator alarm integration:

- Integration with physiologic monitors
- Inclusion in centralized monitoring systems
- Integration with nurse call systems
- Remote annunciators

The various options vary widely in complexity, cost, and the types of care settings for which they are likely to be suitable. For more information on alarm-enhancement systems and ventilator-physiologic monitoring system interfaces, see ECRI Institute's Health Devices citations in the bibliography of this report.

Communication Interfaces

Most intensive care ventilators have a standard or optional interface through which the ventilator can be connected to a bedside monitor or information system. Ventilator settings, monitored parameters, and information on alarms can be transmitted through this interface.

Reported Problems

There are many complications that can occur with intensive care ventilators. These include ventilator-induced lung injury caused by incorrectly setting ventilation parameters, and Ventilator-Associated Events (VAE). VAEs include ventilator-associated pneumonia (VAP), sepsis, Acute Respiratory Distress Syndrome (ARDS), pulmonary embolism, barotrauma, atelectasis and pulmonary edema. These complications can lead to longer durations of mechanical ventilation, increased length of stay in the ICU and hospital, increased time on antibiotics and higher patient mortality. These complications may be prevented with lung-protective ventilation strategies and VAE prevention programs.

Patient-ventilator asynchrony is a discrepancy between the patient and ventilator inspiratory and expiratory times, causing patient discomfort and increased work in breathing. These asynchronies occur frequently in all modes of invasive and noninvasive ventilation. A higher incidence of asynchronies is associated with extended duration of, and ineffective weaning from, mechanical ventilation.

Leaks in the breathing circuit or components may prevent the ventilator from delivering the intended tidal volume or accurately sensing flow and terminating a pressure-supported breath. Leaks can also affect the ventilator's ability to maintain required PEEP or CPAP levels, which can affect the patient's O₂ saturation and cause the ventilator to autcycle (i.e., rapid, repetitive cycling that prevents the ventilator from delivering effective breaths). The current generation of ICU ventilators have leak compensation algorithms to help alleviate these problems.

The friction-fit connector that attaches the ventilator circuit to a patient's artificial airway can become accidentally disconnected if it is not attached securely by the clinician. Ventilators should signal an audible and visual alarm whenever they detect a leak or disconnection; however, some low-pressure alarms can be inappropriately adjusted below the detection threshold.

Patient-ventilator dyssynchrony refers to the situation in which a mechanically ventilated patient fails to trigger the ventilator, or the ventilator erroneously senses a patient's effort and delivers breaths at an inappropriate time. The

result is a machine breath rate that does not match the rate of the patient's inspiratory efforts. This condition is often called desynchronization, or "fighting the ventilator."

Because in many cases the patient depends entirely on the ventilator for breathing, ensuring proper maintenance and avoiding operator errors or machine failures is critical. In addition, ventilators should be inspected at least semiannually, and proper operation should be verified before each use.

Serious cardiopulmonary and neurologic complications can occur when an infant is being ventilated. High PaO₂ levels in the blood can lead to retrolental fibroplasia and blindness. High FiO₂ levels in the gas delivered by the ventilator can lead to O₂ toxicity and exudative and necrotizing changes associated with bronchopulmonary dysplasia (BPD), which continues to be a leading cause of morbidity and mortality in prematurely born infants. O₂ levels must be constantly monitored.

The infant lung is fragile and easily damaged by high pressures, which can be a result of decreases in lung compliance, the patient not breathing in synchrony with the ventilator, obstruction of the exhalation portion of the circuit, or failure of the exhalation valve to open. Limiting the PIP and MAP can help prevent barotrauma, pulmonary interstitial emphysema, BPD, and reduced cardiac output. Many units have an adjustable high-pressure-relief valve, an immediate high-pressure alarm, and a means of automatically venting the patient circuit to reduce pressure.

The use of heated humidifier systems in neonates and infants intubated for mechanical ventilation has been associated with serious problems. Malfunction of these systems can result in severe tracheal or pulmonary damage, including burns. Common problems included excessive condensation (rain-out) in the ventilator circuit, overhydration, and nosocomial infections. Overhydration can lead to alveolar collapse, small-airway obstruction, atelectasis, and surfactant inhibition. To reduce problems with rain-out, most neonatal breathing circuits have water traps to capture condensation and/or internal heated wires to maintain gas temperatures and prevent cooling which causes moisture to form.

Purchase Considerations

ECRI Institute Recommendations

Included in the accompanying comparison chart are ECRI Institute's recommendations for minimum performance requirements for intensive care ventilators. The requirements are separated into two categories—universal ventilators (for adult, pediatric, and neonatal patients) and dedicated pediatric/neonatal ventilators. The differences between these two categories are based on performance criteria for operating modes and setting ranges.

Intensive care ventilators should be capable of basic ventilation modes including continuous mandatory ventilation (CMV, also called assist/control or A/C), synchronized intermittent mandatory ventilation (SIMV), and pressure support ventilation. In addition to ventilation mode requirements, intensive care ventilators should have capabilities for providing leak compensation and PEEP (positive-end expiratory pressure). Intensive care ventilators must also include a battery backup and should be transportable.

Other features recommended in intensive care ventilators include advanced modes for improving patient-ventilator synchrony and facilitating weaning, comprehensive graphical displays of ventilation waveforms and loops, and interoperability capabilities for data and alarms management

Advanced features and functions are becoming more important as differentiating factors for purchasers, especially given the emphasis placed on them by vendors during the selection process. If a feature under consideration is optional (as most of them are), facilities should carefully evaluate its clinical utility during the purchase process. Some advanced

features may not be worthwhile purchases for a facility's patient mix. In many cases, features can be added at a later date, as the budget allows.

ECRI Institute recommends that intensive care ventilators have patient-responsive features and patient-adaptive modes. For higher-end ventilators, modes should include those with either servo, dual, bio-variable, optimal or intelligent breath targeting. Ventilator graphical displays should include waveforms, trends, and loops. Loops should be able to be saved for comparisons and trending of monitored variables. Higher-end units should also provide respiratory maneuver measurements (e.g., static compliance, airway resistance, negative inspiratory pressure).

Patient alarms, both visual and audible, should be available for high and low FiO₂, high and low minute volume, high and low inspiratory pressure, loss of PEEP, apnea, continuous high pressure/occlusion, inverse IE ratio, high respiratory rate, high PEEP, and breathing circuit disconnect. Equipment alarms should be available for gas supply failure, power failure, ventilator inoperative, low battery, and self-diagnostics. All alarms should be distinct and easy to identify. Also, if the audible alarm volume is adjustable, it should not be possible to turn the volume down so low that the alarm is inaudible. The alarm silence feature must reactivate automatically within two minutes if the condition is not corrected. If an alarm is silenced, a visual display should remain on to clearly indicate which alarm is disabled.

Delivered oxygen concentrations should be continuously monitored with an O₂ analyzer that includes an alarm to warn users if the concentrations fall outside of the desired range (e.g., $\pm 5\%$ of the set FiO₂). Ideally, the O₂ analyzer should be incorporated into the ventilator; however, an add-on analyzer is also acceptable.

The controls (i.e., switches, knobs) should be clearly identifiable, and their functions should be self-evident. The design should prevent misinterpretation of displays and control settings. Controls should be protected against accidental setting changes (e.g., due to someone brushing against the panel) and be sealed to prevent fluid penetration. Patient and operator safety and system performance should not be adversely affected by fluid spills.

Other Considerations

Current ventilator designs offer a complicated variety of options, requiring a knowledgeable user. Staff shortages and frequent employee turnover in some hospitals can make effective training in the use of clinical equipment difficult. Therefore, ventilators with good human-factors design offer a significant advantage. In addition, standardizing equipment helps minimize retraining and confusion, and suppliers often give significant discounts when multiple units are purchased.

Reusable and disposable breathing circuits are typically offered separately by ventilator manufacturers and other suppliers. Breathing circuits should be thoroughly tested using the ventilators with which they are to be used to ensure compatibility.

Cost Containment

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. Purchasing a service contract 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.

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. For customized analyses and purchase decision support, readers should contact ECRI Institute's SELECTplus™ Group.

Two figures need to be considered when estimating the total cost of ownership for capital equipment. The first is the up-front, or capital, cost of the device. The second is the sum of the ongoing costs associated with the device over its lifetime, including the cost of consumables, regular maintenance, and unexpected repairs. For more information on estimating the cost of ownership for intensive care ventilators, refer to the Health Devices article cited in the bibliography.

Stage of Development

The mid-1980s witnessed the introduction of microprocessor-based ventilators that could be easily upgraded to perform additional operations by a simple software change. However, the use of microprocessors has given the operator a vast and sometimes confusing number of options to choose from. Graphical displays of patient status are widespread; new features and modes have been developed to better monitor and adjust to patient needs and facilitate more efficient and effective weaning from the ventilator.

Currently, information from medical devices can be collected, transferred, and stored electronically, which allows information to be displayed simultaneously on multiple monitors. Many ventilators are able to export data via bedside physiologic monitoring systems, but the type and utility of data transfer available vary widely depending on the model of ventilator and monitor and the implantation efforts of suppliers and facilities.

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