Positive Airway Pressure Units, Noninvasive

EXECUTIVE SUMMARY

This Product Comparison covers various types of noninvasive positive airway pressure devices, including single-level, continuous positive airway pressure (CPAP) and bi-level (BiPAP) units and their accessories. Noninvasive positive airway pressure devices are commonly used in hospitals, home settings, and long-term care facilities. Mechanical ventilators that provide all standard ventilator modes (A/C, SIMV, etc.), but also offer noninvasive ventilation, CPAP, or BiPAP modes, are not included in this report.

Noninvasive positive airway pressure units are specialized devices designed to apply continuous, bi-level, intermittent, or expiratory positive airway pressure to non-intubated adult, pediatric, or neonatal patients. They are commonly utilized on spontaneously-breathing patients who require short-term mechanical assistance; however, they are not designed to be life support devices and are not intended to replace basic or advanced mechanical ventilators.

CPAP units deliver air or a mixture of air and oxygen (O₂) at high flow rates through tubing to a nasal or oral-nasal mask which is affixed to the patient’s face. These devices use an airflow generator to deliver a continuous supply of gas to the patient at a set pressure, typically between 3 and 20 cm H₂O. CPAP units are commonly used to treat patients with obstructive sleep apnea (OSA) or sleep apnea/hypopnea syndrome (SAHS). OSA refers to the periodic cessation (apnea) or reduction (hypopnea) of breathing due to narrowing or closure of the upper airways during sleep. When CPAP is applied to these patients, the pressure acts as a pneumatic splint to prevent narrowing or closure of the upper airway. Optimal pressure levels are determined by a physician in a sleep laboratory and are set before the unit is used by the patient. Variable autoCPAP units, which can respond to changes in physiologic conditions to provide the lowest pressure required at a particular time, are also available. CPAP units are primarily used at home by patients with OSA; however, they are also used in hospitals and long-term care facilities to treat patients with this condition. CPAP units are also used in sleep labs to trial various levels of CPAP during sleep. By monitoring the number of apneas that occur at different CPAP pressures, an optimal pressure setting can be determined for each patient. Units used in sleep labs often have special functions or features to allow pressure adjustments and monitoring to be done remotely (e.g., from the sleep lab control room).

Specialized CPAP units with advanced functions and features are also used in hospitals to treat patients with other types of breathing problems, such as acute asthma, cardiogenic pulmonary edema, cystic fibrosis, or chronic lung disease. When exacerbations of these conditions make breathing more difficult and decrease blood oxygen levels, CPAP with supplemental oxygen may be utilized to facilitate the opening of small airways and improve oxygenation.

While CPAP units deliver pressure continuously at a single previously set level throughout the period of use, BiPAP units can deliver two different levels of pressure during the inspiratory and expiratory phases of a breath. BiPAP allows clinicians to adjust pressures more precisely for maximal benefit. It is sometimes prescribed for patients with OSA who are unable to tolerate CPAP. For most patients, a slightly lower pressure is set during the expiratory phase to reduce the effort required to exhale. By adjusting inspiratory and expiratory time variables, BiPAP units can also sync with the patient’s breathing. This can significantly reduce the work of breathing for patients who are struggling. BiPAP is primarily used in the hospital setting, but some patients use BiPAP at home or in long-term care facilities. In hospitals, BiPAP is commonly used as a first-line treatment for patients who need temporary ventilatory support. When effective, BiPAP can noninvasively improve both oxygenation (delivery of oxygen to the blood) and ventilation (removal of CO₂ from the blood). If treatment with BiPAP is not effective, intubation and mechanical ventilation is usually necessary.

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

- Positive Airway Pressure Units, Bi-Level [20-743]
- Positive Airway Pressure Units, Continuous [11-001]
- Positive Airway Pressure Units, Expiratory [20-744]
- Positive Airway Pressure Units, Intermittent [20-745]

These devices are also called: bi-level positive airway pressure units, BiPAP units, continuous positive airway pressure units, CPAP units, EPAP units, expiratory positive airway pressure units, intermittent positive air pressure units, intermittent positive pressure breathing units, IPPB units.
Scope of this Product Comparison

This Product Comparison covers various types of noninvasive positive airway pressure devices, including single-level, continuous positive airway pressure (CPAP) and bi-level (BiPAP) units and their accessories. High-flow nasal cannula (HFNC) systems are also covered. Noninvasive positive airway pressure devices are commonly used in hospitals, home settings, and long-term care facilities. Mechanical ventilators that provide all standard ventilator modes (A/C, SIMV, etc.), but also offer noninvasive ventilation, CPAP, or BiPAP modes, are not included in this report.

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Purpose

Noninvasive positive airway pressure units are specialized devices designed to apply continuous, bi-level, intermittent, or expiratory positive airway pressure to non-intubated adult, pediatric, or neonatal patients. They are commonly utilized on spontaneously-breathing patients who require short-term mechanical assistance; however, they are not designed to be life support devices and are not intended to replace basic or advanced mechanical ventilators.

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HFNC systems provide air or a mixture of air and oxygen to patients at flow rates that are much higher (up to about 40 LPM) than a nasal cannula connected to a standard flowmeter (up to about 15 LPM). These systems use an air/oxygen blender supplied by 50-psi air and oxygen gas lines to generate required flow rates. A specialized flowmeter and a heated humidifier are incorporated into the unit to deliver heated, humidified gases to the patient through a disposable nasal cannula. Unlike CPAP and BiPAP units, however, the cannula does not have to seal against the patient’s nares to be effective. Instead, the high flows generated from the system flood the patient’s nasal cavity with gases at a set FiO₂ (fraction of inspired oxygen) level, which increases the amount of oxygen delivered to the patient and reduces the likelihood of rebreathing expired CO₂. The high flow rates delivered to the patient may also generate a level of positive pressure at the patient’s airway, similar to CPAP. In addition, the heated, humidified gases delivered through the system may help to thin the patient’s secretions. High-flow nasal cannula systems are commonly utilized on infants, but can also be used on children and adults. Advantages of these systems include ease of use, quick setup, and a comfortable patient interface. As a result, HFNC systems are sometimes utilized in place of CPAP devices.

Principles of Operation

CPAP and BiPAP devices consist of a flow generator or “blower,” a length of tubing, and a patient interface (typically a tight-fitting mask). Masks come in three varieties: those that seal against the nares, those that cover the entire nose, and those that cover both the nose and mouth. Most masks are held in place by elastic bands that go around the patient’s head. Commercially available CPAP face masks are pre-formed and available in various sizes and contours. They are made of a hard plastic outer shell with a soft inner-flap seal of vinyl or silicone. Most CPAP and BiPAP units can be used with a variety of mask types as long as the mask allows for passive ventilation of exhaled CO₂ through some form of vent.

Non-invasive ventilation masks are not safe to use with CPAP or BiPAP since they do not allow for passive venting. Masks may be included with the equipment purchase or sold separately. The mask is attached to plastic tubing, which runs to the flow generator. High flow from the generator acts as a pneumatic airway splint by using gentle pressure, ranging from about 3 to 20 cm H₂O.

Power is supplied from either an electrical wall outlet or a battery. When equipped with a battery backup, switchover to battery operation (either internal or external) is usually automatic and is signaled by an alarm.

Most CPAP units are simple to operate and only have controls to set pressure levels. Some CPAP units offer a “pressure ramp” option that starts pressures at a low level (which is more comfortable for the patient), then slowly increases the pressure to the final prescribed level over a period of time (e.g., 15 to 30 minutes) as the patient falls asleep. For OSA patients, the pressure ramp feature can improve treatment compliance by making CPAP much more tolerable at night. CPAP units designed for use in sleep labs have additional features to facilitate patient testing and pressure adjustments. BiPAP units are more complex than CPAP units. Most have controls to set inspiratory time and pressure, expiratory time and pressure, cycle rate, and trigger sensitivity. These settings are specifically prescribed by a physician. Common accessories for CPAP and BiPAP units include humidifiers, O₂ analyzers, and tubing support arms or stands.
High-flow nasal cannula systems use an integrated air/oxygen blender to generate flow. The blender can deliver gases to the patient at any required FiO2 between 21% and 100%. The integrated flowmeter can be set to any required flow rate up to about 40 L/min. Initial FiO2 and flow rate settings are prescribed by a physician and are titrated as needed to optimize SpO2 readings or blood gas values.

Monitored Parameters and Alarms
Since most CPAP units are designed for and used by patients at home (and are not considered “life support” devices), most have no alarms and only basic monitoring capabilities (e.g., a pressure display). More advanced CPAP units may have additional monitoring capabilities and alarms. BiPAP units, which are primarily used in hospitals, are equipped with a variety of monitors and alarms to detect equipment-related problems and changes in patient status. They typically monitor respiratory rate, flow rate, the ratio of inspiratory to expiratory (I:E) time, inspiratory time and pressure, mean airway pressure (MAP), and air leaks.

Reported Problems
Noninvasive positive airway pressure devices are generally considered safe, and no serious problems with long-term use have been documented. Many of the reported problems involving CPAP and BiPAP units arise from air leakage that can cause a lack of pressure, discomfort or irritation related to the fit of the mask, nasal congestion or dryness, and loud noise coming from the unit.
Nasal obstruction, increased age, higher body mass index (BMI), central fat distribution and male sex are associated with increased risk of air leakage. Full-face masks are more likely to leak air than nasal masks due to the increased size of the seal. Air leaks are typically fixed by changing the mask type or size and adjusting it properly. Mouth breathers are generally prescribed full-face masks or nasal masks with chin strap to hold the mouth closed. Some patients complain of having a claustrophobic or smothering sensation while using the device. Changing the mask type and adding a humidifier may help to alleviate some of these problems.
For OSA patients, finding the appropriate pressure level(s) is important; if the pressure is set too low, OSA symptoms may persist. If the pressure is set too high, the patient may experience discomfort and remove the mask. Too much initial pressure on the face is a common complaint; this can often be alleviated by using the pressure ramp feature available on many CPAP units, which allows the pressure to increase gradually over a set period of time.
Patient compliance is a significant problem with CPAP units. Acceptance involves nightly use of the device to treat OSA. Education and adequate introduction to the therapy in a sleep lab or physician’s office may help increase patient compliance.
For infection control, CPAP units and masks require regular cleaning and microbiological monitoring. These units can accumulate bacteria and viruses from the patient’s face, hands, and environment, which can cause respiratory infections, especially in high-risk populations like low birth-weight infants. Proper cleaning includes cleaning the interface, humidifier, and tubing as well as changing water and filters.
Nasal trauma is a frequent complication of CPAP, especially in preterm infants. Nose injuries can range from skin irritation to septal necrosis. They are increasingly common with low gestational age, low birth weight, and longer CPAP use.

Purchase Considerations
ECRI Recommendations
Included in the accompanying comparison chart are ECRI’s recommendations for minimum performance requirements for CPAP, BiPAP, and HFNC systems.
Users should look for units that are easy to operate. The primary controls should be located on one side of the unit, and labels and displays should be clear and visible. The controls should be protected against accidental setting changes; this is especially important in homes in which young children are present.
Since OSA patients must use CPAP every night, the ease with which the CPAP unit can be carried or transported is also a major consideration. The unit should be small and lightweight enough to fit into a bag that can go in an overhead bin in an airplane and should resist tipping over.
For BiPAP and HFNC units, alarms should allow quick assessment and correction of the alarm condition. Devices that monitor use and alarms and automatically upload data to the cloud are advantageous. The priority of the alarm should be indicated by different audible tones and visual indicators. Audible alarms and visual indicators should activate when switching from line to battery power. The unit should also have low-internal-battery, power failure, overheat, fault, and mask alarms.
CPAP units should be able to operate in a variety of environments and should not be affected by electromagnetic interference and electrostatic discharge. Power-surge protectors are advisable, especially if the unit is used in an area that experiences frequent power surges or thunderstorms. Devices that can be easily modified to work with different plug configurations and electrical power delivery (e.g., voltage and frequency) are extremely convenient for users who frequently travel overseas. Servicing by a skilled technician should be easy; the operator’s manual should provide adequate information for clinicians, users, and caregivers.

Other Considerations
CPAP devices are typically priced between $300 and $5,500, depending on the configuration of the device. Some CPAP units can be combined with a monitor (diagnostic system), which is more expensive than the CPAP unit alone. Because CPAP is a long-term therapy, patients with OSA typically purchase the CPAP devices. CPAP, automatic positive airway pressure (APAP), and BiPAP are all reasonable options for patients with OSA. Comorbid medical problems, cost, portability, and access to online data management should be considered when selecting a device. BiPAP units with pressure ramp should be considered for patients who are noncompliant to therapy due to pressure intolerance.
Patient interface options include nasal, nasal pillow, and oronasal masks. These masks can break down after six to eight months and must be replaced in order to remain effective and prevent loss of pressure. Depending on the make and model, masks can cost between $100 and $200. Masks should fit the patient comfortably and seal well. Proper mask fitting requires testing the mask seal under the treatment pressure. Oronasal masks require greater pressures, are associated with greater likelihood of leaks, and may compromise CPAP effectiveness.
In the United States, the Centers for Medicare & Medicaid Services (CMS) provides coverage for CPAP devices to treat OSA. The diagnosis of OSA requires documentation of at least 30 episodes of apnea, each lasting a minimum of 10 seconds, during 6 to 7 hours of recorded sleep.
There is some concern that reprocessed CPAP units may not be adequately disinfected between patients; however, one study (Steinhauer, Goroncy-Bernes 2005) indicates that there is not a significant difference in the amount of microbial contamination between new and used devices. With careful disinfection, reusing CPAP devices and accessories is safe and cost-effective.
Stage of Development

Newer generations of CPAP units have built-in software that can monitor usage patterns and patient compliance. This information may help to determine what levels of usage are required to treat OSA effectively, and which patient interfaces work best. Some modern devices monitor the time the devices are used each night, any instances of apnea, leaks, and pressure changes (for devices that automatically adjust the pressure during the night) and transmit the data to the cloud.

Currently, patients using CPAP or BiPAP for treatment of chronic lung disease are confined to their beds or wheelchairs during therapy. More ambulatory models—units that are very lightweight and extremely compact—are becoming available to aid these patients. One new model, driven by compressed air, can pump air through tubing that is thinner, more lightweight, and much longer than traditional tubing sets. Although this model allows a patient to travel only a short distance, the mobility that is afforded to patients is significant. At least one manufacturer offers a CPAP device that is completely self-contained and will function without the need for an external power or water source.

Some manufacturers offer face masks constructed from either cloth or leather that are designed to be more comfortable. Additionally, at least one manufacturer offers a mask that allows the cushion and frame to move independently, to adapt to a user as they change position in sleep and avoid air leaks. Masks with quick release clips are becoming more available; these are designed to make it easier to remove the mask should the patient need to use the restroom or leave their bed during the night. Latex-free masks are now also readily available, as many potential users may be allergic to the material.

BIBLIOGRAPHY


