Your 2007 Guide To Understanding

Oxygen Conserving Devices

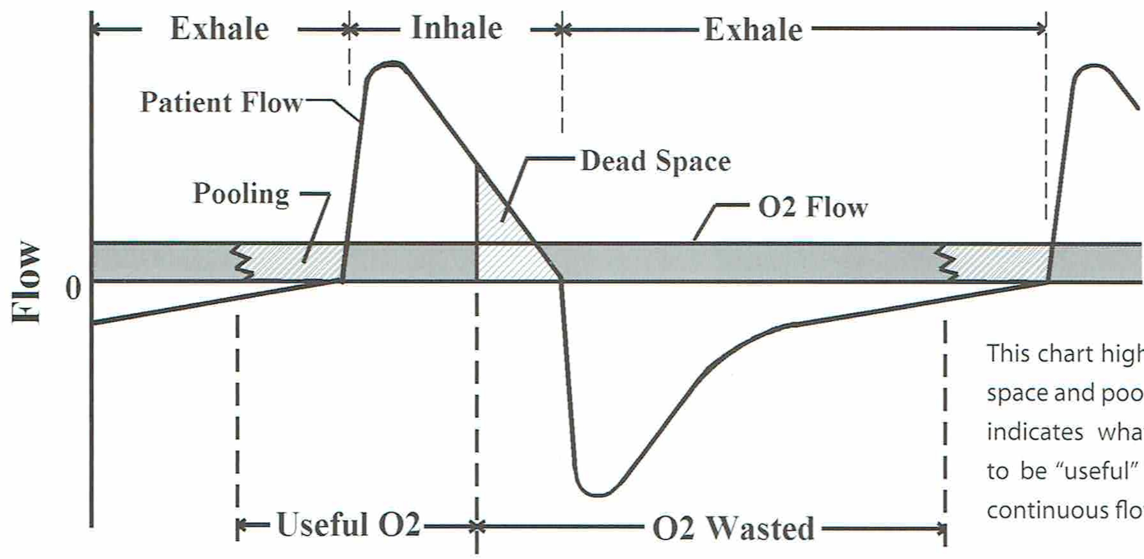
VALLEY INSPIRED PRODUCTS

Oxygen Delivery Fundamentals

To adequately understand OCDs, it is first beneficial to think about continuous flow oxygen (CFO) delivery, which for decades was considered the 'gold standard' of LTOT. As CFO is applied via nasal cannula, some of the oxygen delivered during inhalation is mixed with inspired air for a net Fraction of Inspired Oxygen (FIO2) in the lungs. Unfortunately, determining FIO2 isn't quite as simple as calculating the flow of oxygen and the flow of air. Several factors conspire to complicate the process.

Dilution

During CFO the flow rate is fixed, so as a patient breathes faster, creating a shorter inhalation time, the amount of oxygen inhaled per breath decreases. As a result, the net FIO2 drops.



This chart highlights the dead space and pooling factors, and indicates what is considered to be "useful" oxygen, during continuous flow therapy.

Dead Space

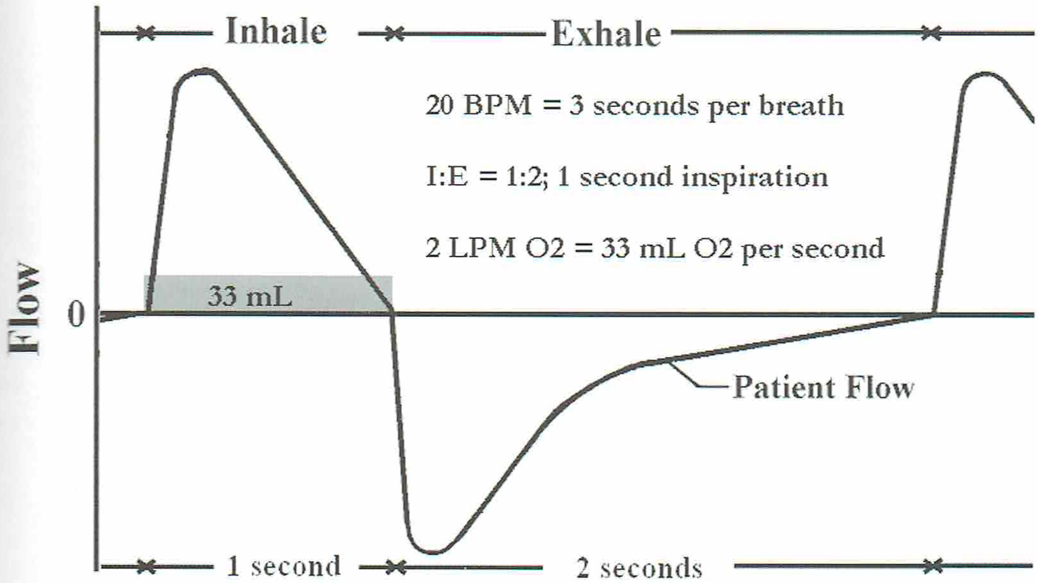
During the latter portion of inhalation, gas entering the airway never reaches the lungs. Instead, it remains in the air passages that lead to the alveoli, only to be exhaled before they reach these gas exchange units. This includes some of the oxygen volume delivered from CFO therapy, meaning that oxygen was wasted. The amount of oxygen wasted varies with the patient's anatomy and breathing pattern.

Pooling

Oxygen delivered from CFO therapy late in the exhalation phase, when the patient's expiratory flow rate is relatively low (or during the pause after total exhalation), may not be wasted. The oxygen exiting the small diameter cannula is traveling at a relatively high velocity and some amount of oxygen is 'pooled' in and around the nose, nasopharynx and upper airway. This oxygen volume is able to be inspired at the beginning of inhalation. Patient disease, anatomy and breathing pattern, as well as environmental conditions (like wind) can vary this effect.

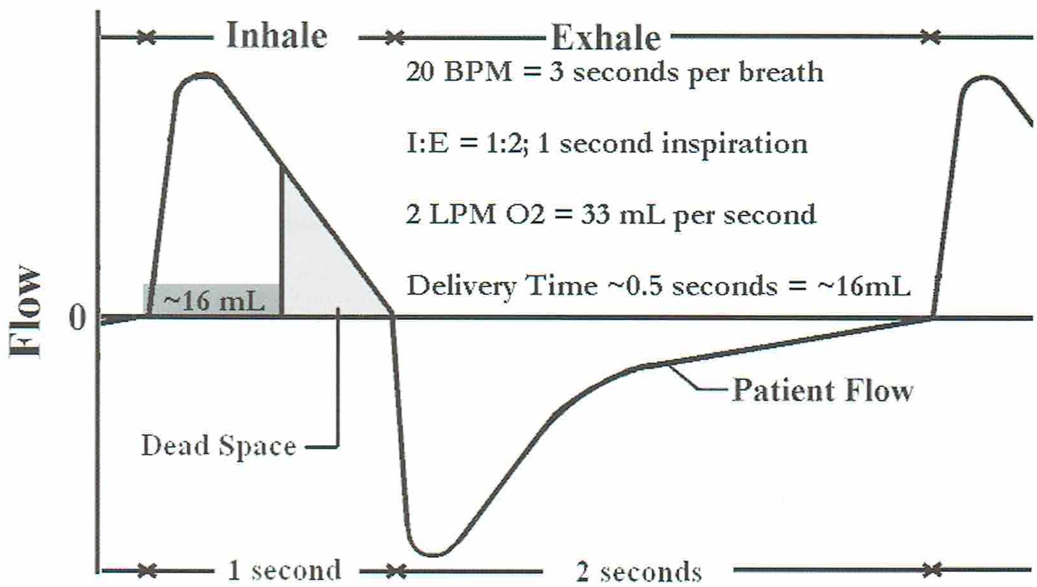
Early Conserving Concepts

Intermittent Oxygen Delivery with 2 LPM Flow Therapy



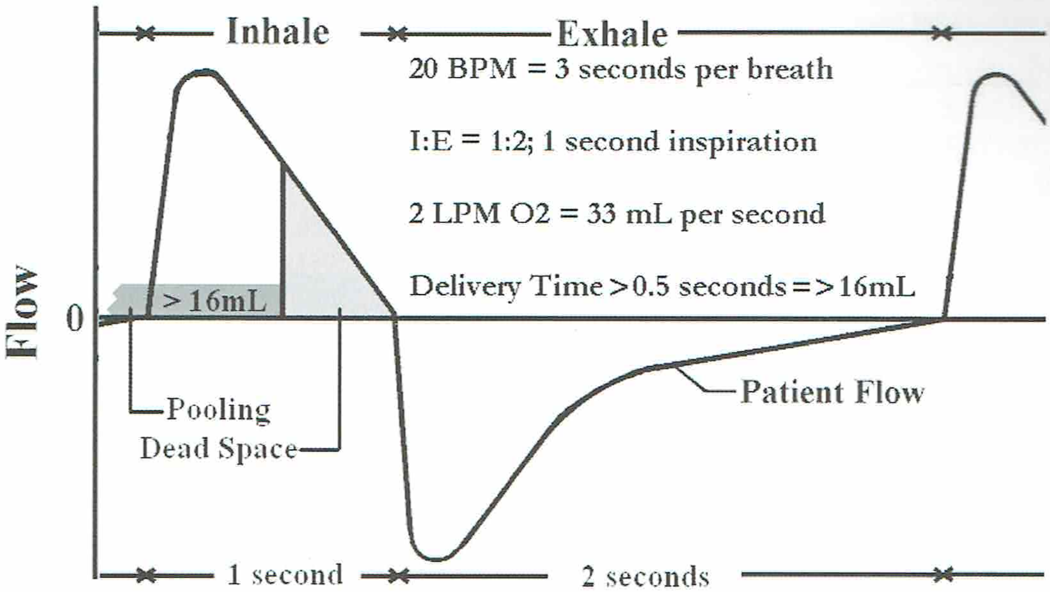
Early conserving pioneers estimated that only the oxygen delivered during inhalation was considered useful. Assuming a typical breath rate of 20 breaths per minute, and an Inspiratory:Expiratory (I:E) ratio of 1:2, that would mean that 1 second delivery was required. If a 2 LPM setting was used, this meant that on each breath, 33 mL of oxygen was "useful".

Intermittent Oxygen Delivery with Timed 2 LPM Flow Therapy



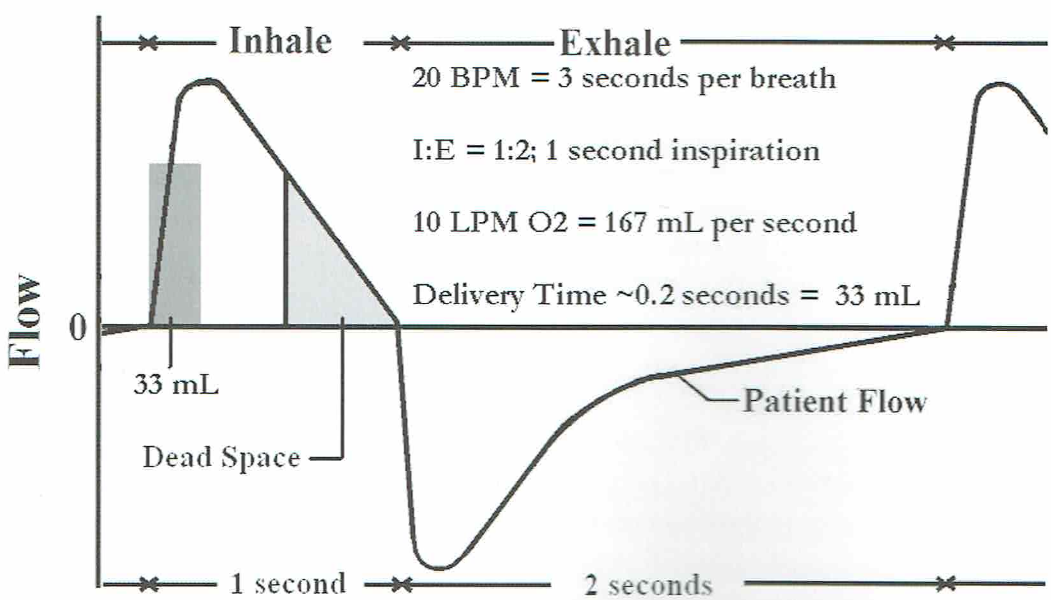
Others recognized that, while 1 second of inhalation time was spent breathing in air, the last portion of the delivered oxygen never reached the lungs; it remained in dead space, only to be exhaled. Product developers theorized that it was possible to cut the delivery time roughly in half while keeping the delivery flow rate the same. Since continuous flow oxygen could not be providing "useful" oxygen for the full inhalation time, reducing the delivery time from 1.0 seconds to approximately 0.5 seconds would reduce the delivered oxygen volume from 33 mL to ~16 mL, and, in theory, the patient should still get the same therapeutic benefit of CFO therapy. This theory led to the development of oxygen conserving devices that could claim a much higher savings ratio though they delivered oxygen in a very similar manner to other products.

Oxygen Delivery via Timed 2 LPM Flow Therapy with Pooling



To further complicate matters, with continuous flow therapy, there is oxygen flowing throughout exhalation also. While most of that is blown out into the atmosphere, the oxygen delivered at the very end of exhalation may pool in and around the nose, and then is inhaled when the patient starts their next breath. The amount of pooled oxygen will vary greatly (patients' breathing pattern, their anatomy, the oxygen flow rate, the wind, etc., all are factors), so it is very difficult to estimate how much oxygen is required to achieve an equivalent dose amount to a 2 LPM continuous flow rate of oxygen. But it was suspected that the oxygen dose would need to be more than 16 mL to maintain equivalent therapy to CFO delivery. This theory led to the idea of demand/hybrid delivery OCDs delivering a bolus volume early in inhalation to account for the lost volume from the lack of pooled oxygen around the nose at the start on the inspiratory phase.

Intermittent Oxygen Delivery via Pulse Delivery Device



Gerald Durkan, whose product development work led to the products and patents now marketed by Sunrise Medical, thought that it would be advantageous to deliver the same 33 mL dose resulting from 2 LPM continuous flow oxygen therapy early in inhalation, but at a higher flow rate and for a much shorter duration. With this method of delivery, the delivered pulse volume could easily be changed by varying the duration of the delivery. Most, but not all, pulse devices today operate in this manner, increasing the delivery time with an increase in the setting number.

Key Issues In Oxygen Therapy With Oxygen Conserving Devices

Proper Oxygen Saturation

One objective of an OCD is to ensure that the oxygen delivered to the patient reaches gas exchange units in the lung. Oxygen delivered anytime during the breathing cycle that does not reach a gas exchange unit is considered wasted.

The goal for efficient oxygen delivery using a conserving device is proper oxygen saturation or oxygen pressure in the blood for the patient requiring supplemental oxygen at all activity levels. It is important to note that oxygen savings is considered accomplished only after the patient is adequately oxygenated and is a secondary objective for device performance.

Ventilation and Perfusion Issues

A patient's respiratory physiology is a very dynamic process. Even if a conserving device is providing consistent oxygen delivery, results can vary for an individual patient from moment to moment, and also between groups of patients using similar devices. This issue, combined with the wide variety of performance differences in OCDs, often makes it a difficult challenge for patients to consistently maintain proper oxygenation across various portable oxygen systems.

Oxygen dependent patients should always be tested on their oxygen system at different activity levels — sleep, rest, and exercise, as well as at altitude, if possible — to ensure the device meets their oxygenation needs at all levels of activity.

Activity Levels

Several variables may affect a patient's oxygenation while using an oxygen delivery system. Increased respiratory rate will shorten inspiratory time and may reduce the amount of oxygen a patient will receive. In the past, an exercise prescription was written for patients whose increase in respiratory rate with exercise required more oxygen to maintain proper saturation levels. This increase in flow rate was to compensate for a shorter inspiratory time due to the faster respiratory rate. The general rule of thumb was to double the patient's flow rate (e.g. from 2 LPM to 4 LPM) during exercise.

Any change in respiratory rate or pattern may affect the patient's oxygenation. The lack of attention to this variable in the past has created the misperception that conserving devices do not oxygenate effectively. Oxygen dependent patients should be tested on their oxygen system at different activity levels reflecting real life conditions, including at rest, during exercise, while sleeping, and at altitude, where possible. This protocol has been recommended by respiratory clinicians for years, yet still has not hit the mainstream of patient care.

A titration test is the standard method of measuring patients' oxygen needs with exercise. It is a simple method that only requires an oximeter and a place to exercise. If a patient will be doing more strenuous activity, every attempt should be made to simulate that activity to see if the device properly oxygenates the user. Sleeping with an OCD is possible, yet an overnight oximetry test is strongly recommended to determine if the device is triggering with each breath and maintaining patient oxygen saturation.

Altitude

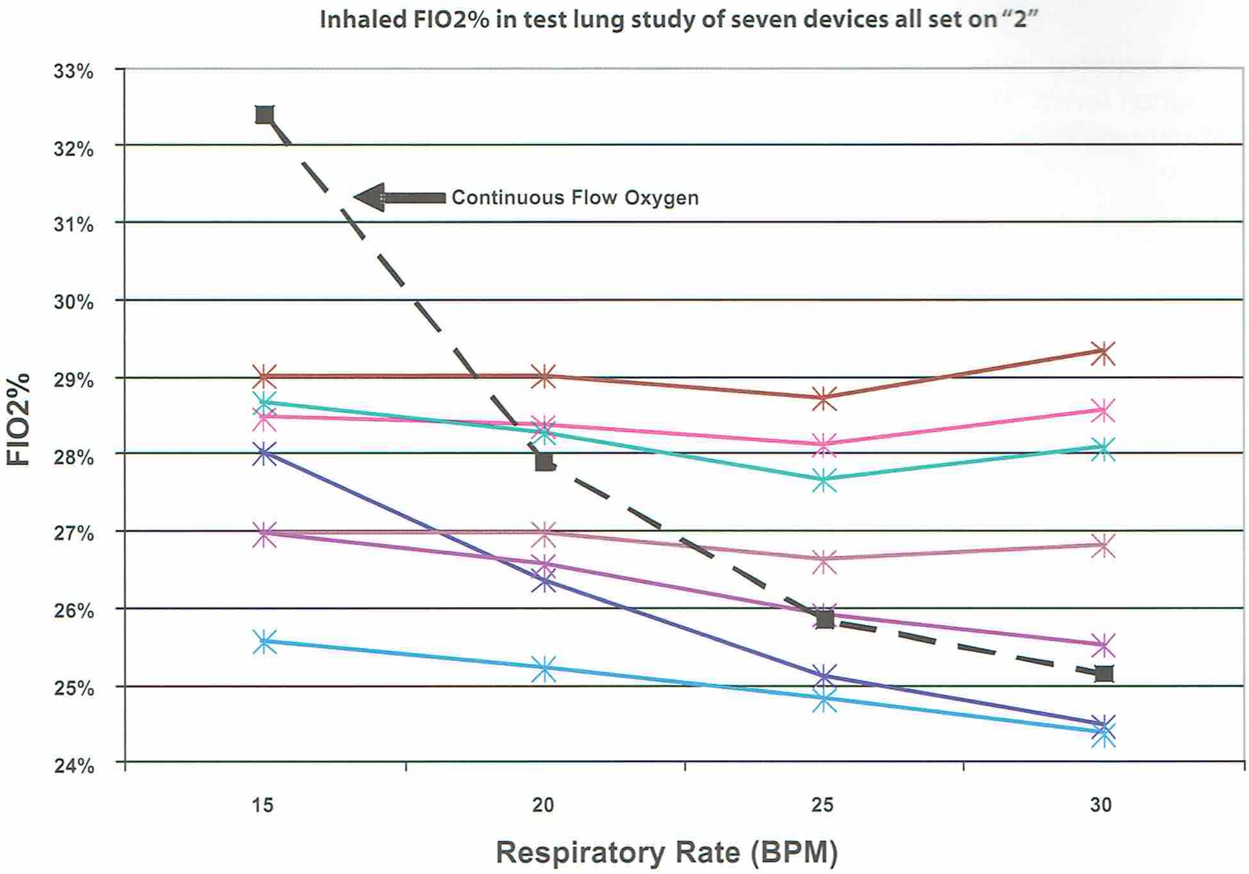
Altitude has an impact on the *pressure* of oxygen and not necessarily the *amount* of oxygen. Oxygen conserving devices will give approximately the same volume of oxygen at higher altitudes (or in an airplane), but the pressure differences at different altitudes may have an impact on oxygenation levels. It is important to understand that if an oxygen system is able to meet a patient's oxygen needs at a lower altitude, it is possible that that same system may not be able to meet the patient's needs at a higher altitude. Unfortunately, it is generally unfeasible to test patients on their oxygen systems at pressures that they would be experiencing at varying altitudes. In general, the common practice has been to double the device's delivery setting when the patient is at altitude. However, if the oxygen system the patient is using is already running at its top setting at a lower altitude, another system should be considered for use at higher altitudes.

Equivalency

When OCDs first entered the LTOT market, they were revolutionary, not evolutionary. A revolutionary product has no predecessor; therefore, there is nothing to compare the product with. For OCD manufacturers to be able to enter the market and sell their products, OCDs needed a reference point that could be understood by the persons using the device. Continuous Flow Oxygen (CFO) delivery was the gold standard in oxygen therapy up to this point, so an attempt was made to compare the effectiveness and delivery of the OCD to the CFO gold standard.

Intermittent flow devices such as OCDs deliver a certain volume of gas with each sensed patient breath. A patient breathing on a continuous flow device receives a variable volume of gas dependent on their breathing profile. By selecting *one* breathing pattern and *one* breath rate, a delivered dose volume of oxygen can be made equivalent to the volume taken in during continuous flow of oxygen. As a result, manufacturers selected a volume of oxygen for a given device setting that they felt would be equivalent to continuous flow and made that the flow setting on their device. However, this concept only works if the patient never changes their breathing pattern. Obviously that is not the case in real life.

Most OCDs have a number on the selector dial and, even though they may claim to deliver oxygen equivalently to continuous flow at that same setting, they typically are not equivalent to CFO, let alone any other conserving device at that setting.



The graph shown here displays the delivered FIO2 values for seven conserving devices, all of which are set at the device setting of 2. As can be seen, there is a wide range in delivered FIO2, and no device could be considered to have delivered therapy equivalent to CFO.

Standards for OCDs

There are few standards for the development of OCDs. This lack of standards has led to a wide variety in device performance and has fostered confusion in the market. Using the scenario outlined above as an example of this, the setting numbers on the dials do not relate to any manufacturing standard and were generally meant to be used only as a comparison to continuous flow. This is not a viable comparison. So this begs the question, "What does "2" really stand for?" With minimal standards regulating the manufacture of OCDs, the answer must be this: The 2 does not mean "liters per minute" or signify a specific volume of oxygen. In fact, it doesn't mean much of anything. It is only a reference point to be used to test the patient and to turn the selector, if necessary, to obtain the proper oxygen saturation in the patient. (An easy analogy for this situation would be if you just saw the number 50 on a speedometer. Is that kilometers per hour? Miles per minute? Furlongs per day? That kind of information would be nice to know if you found yourself in a speed trap!)

Savings Ratio

Oxygen saving is possible with conserving devices; therefore a ratio of oxygen use by an OCD compared to oxygen use by CFO therapy can be calculated. One can increase this savings ratio by decreasing the oxygen delivery by the device. This

> The numbers on the dial have been the culprit for misleading claims of high oxygen savings.

has been the basis for many manufacturers' claims of high oxygen savings.

Here is an example that illustrates how higher savings can easily be claimed: One "E" size cylinder having the same contents as another can last twice as long if the selector knob on the designated "efficient" cylinder is simply turned from "2" to "1". Now, if the flow selector's label on the efficient cylinder, which is currently showing "1", is simply changed to read "2", yet still giving flow at "1", you have an idea of how some OCDs can obtain the claim of high savings ratio.

Dose Volume

The dose volume from an OCD determines the fraction of inspired oxygen (FIO2) by the patient. A higher dose volume generally means a higher FIO2 at a constant, normal breathing volume (tidal volume). Dose volumes from various OCDs are different at the same numerical setting. Prior to using any OCD it should be determined what the dose volume per setting is. Some devices have limited maximum dose volumes and, as a result, are not suitable for patients requiring higher FIO2 at certain activity levels.

Triggering Sensitivity

The triggering sensitivity determines if and when a conserving device will deliver a volume of oxygen. All conserving devices need to sense a patient's inhalation to initiate the flow of oxygen. Some devices are more sensitive than others, meaning those devices will trigger their oxygen flow sooner than the others. The first half of inspiration is important in oxygen delivery—if a conserving device is slow to respond to an inspiratory signal, it may deliver oxygen late in the inspiratory cycle and the delivered oxygen may not go to gas exchange units in the lung. Additionally, if the device does not sense a breath at all, it will not deliver its dose, and the patient will not receive oxygen for that breath. At activity, most patients have a strong signal and most devices will trigger without issue. However, sleeping patients may not generate much of an inspiratory signal and oxygen delivery may be missed on weak breaths. It is recommended that a patient wishing to use their conserving device while sleeping undergo an overnight oximetry study with the device prior to using it in the home.

> If the device does not sense a breath, the patient will not receive oxygen for that breath.

Timing of Oxygen Delivery

There is an undefined "sweet spot" where oxygen delivery is most effective. Any oxygen delivery outside that sweet spot is wasted and does not provide oxygen to the patient's gas exchange units (alveoli). Typically, oxygen delivered in the first half of inspiration goes to the alveoli. Oxygen delivered after a certain point in the second half of inspiration remains in the conductive passages in the upper airway, where no gas exchange occurs, and is eventually exhaled.

Most pulse delivery style conserving devices attempt to deliver most of their entire oxygen dose within the first half of inspiration. Demand and hybrid conserving devices, by design, deliver oxygen all the way to the end of the inspiratory cycle, only turning off when the patient exhales. This means that the oxygen delivered near the end of inhalation is generally wasted, but the patient still receives the majority of the delivered volume.

Continuous Flow Back Up

Some devices provide an option for continuous flow operation in the event that the conserving device fails to operate. Typically this setting is a one-flow setting back up (e.g. 2 LPM continuous flow), though some devices do feature multiple CFO settings. Some OCDs have a fail open feature that allows the device to open to continuous flow if there is no inspiration sensed within a specific time frame. It is important for the user to note what CFO options are available to them on their device of choice.

Power Options

Pneumatic devices operate from the gas pressure in the supply system. These systems do not need an outside power source, therefore no power source needs to be checked or changed.

Electronic conserving devices, however, are battery operated and need to have the batteries changed as needed for continued operation. An advantage of using an electronic OCD is that it is able to provide a light to indicate that the device is operating normally. Be aware that an electronic light may flash, signifying the device acted on the breath signal, even if no oxygen is delivered. Additionally, the device may sound an alarm or change if the device does not sense a breath or cycle to oxygen delivery.

Portable oxygen concentrators require use of a power source to operate. All POCs use a rechargeable battery pack for portable operation. These devices also usually come equipped with a power pack that is able to be plugged into a wall outlet, which serves as both the power to the unit and the source for recharging the battery pack. Additional power source accessories are usually available, including car lighter adaptors.

Cannula: Single Lumen vs. Dual Lumen; Nasal Prong Style
Most pneumatic conserving devices require use of a dual lumen cannula—one lumen to sense the breath and the other lumen to deliver the oxygen. Some pneumatic devices use a single lumen and thus have a unique way of ending oxygen delivery. Electronic devices only need a single lumen cannula since a circuit times the end of the delivery.

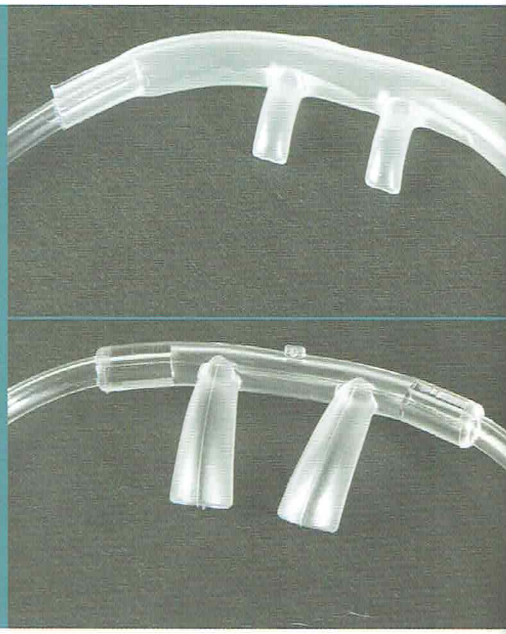
The size and shape of the cannula nasal prongs is also an issue to be aware of when using OCDs. Some cannula feature flared tips, some straight tips, and others tapered tips. These design differences can alter the resistance to flow inside the cannula, which can affect the amount of oxygen being delivered to the patient.

Pediatric or low flow cannulas are not recommended for most conserving devices as the resistance to flow can impact the triggering of the device and can cause the conserver to auto cycle.

Note that dual lumen cannula cannot be used with transtracheal oxygen delivery.

Cylinder Operating Pressure

Cannula Comparison: Straight-Tip (Top) vs. Flared-Tip Cannula (Bottom)



OCDs utilizing oxygen cylinders are usually rated for a specific cylinder operating pressure, often from 500psi to 2000psi. It is important that the OCD be switched to a compatible tank when the current tank pressure is outside of the specified pressure range for operation.

Also, many conserving regulators' delivery volumes change with a change in tank pressure. Some devices will deliver slightly lower dose volumes at 500psi than they will at 2000psi. These volumes are usually not significant, but should be noted. Devices with continuous flow capability will usually see delivered flow rates drop as the cylinder pressure drops.

Ease of Use
Extra features and benefits are often not utilized by patients using conserving devices. Adding clinical features are only an advantage if the patient's clinician sets the device up and knows how and why a special feature is a benefit to the patient. The "keep it simple" philosophy is an advantage for patients

and helps keep confusion using a device to a minimum. That said, there have been a few devices that have been released recently that have additional product features unique to that device.

Testing Operation of a Conserving Device

Since conserving devices have entered the market, it has been difficult for users questioning whether or not their device is operating correctly to see if that is indeed the case. Since conserving devices deliver a volume of gas as opposed to the "gold standard" of continuous flow oxygen, you cannot use a liter meter—the device used to spot check flow on a CFO system—to test OCD operation.
A device called a Pulse Volume Meter is available to test pulse type conserving devices. This unit is a volume-measuring device, and is used by connecting the OCD to the device and triggering oxygen delivery. The user is able to quickly spot check the amount of oxygen being delivered to the meter. Each OCD manufacturer should provide the volume of gas delivered per setting, so if the volume is incorrect, the device can be returned for repair. If the device appears to be delivering its O2 dose correctly, other reasons for the perception of an OCD malfunction would need to be investigated. Note that a pulse volume meter cannot be used to test a demand system.

Pulse Volume Meter
This device measures pulse volumes of single lumen, pulse delivery OCDs.

New Technology

Many manufacturers are developing new methods of using oxygen conservation concepts and techniques to improve the response of their systems in meeting the patient's constantly changing oxygen requirements due to their continually varying levels of activity. Methods utilized by an OCD of responding to a patient's changing oxygen needs include:

Movement: The device senses movement and changes the oxygen dose to a higher setting. When movement stops the OCD then switches back to the lower dose setting. There is already approved product featuring the ability to change dose setting as a result of device movement currently on the market.

Oximetery: The OCD device monitors the patient's oxygen saturation. An algorithm in the device changes the oxygen dose based on oxygen saturation. There is an FDA cleared product with this feature, but it is not currently on the market.

Respiratory Rate: The device monitors the patient's respiratory rate and has an algorithm that switches the dose setting to a higher dose with a higher respiratory rate. There are no currently approved devices with this feature on the market.

Other Application Issues

OCDs should never be used with in-line humidifiers as the OCD will not be properly triggered.

Long delivery tubing will slow the gas delivery and may affect device sensitivity. Refer to individual manufacturer recommendations before using non-standard lengths of tubing, and always test the patient's saturation when using longer delivery tubing.

OCDs should not be used with masks as the OCD will not sense an inspiratory signal and there is no oxygen delivery during exhalation to flush the dead space volume.

OCDs should not be used to bleed oxygen to a CPAP or Bi-Level device as the OCD will not properly trigger and oxygen flow/volume will not be adequate to change FIO2.