

Up to 50% of continuous flow oxygen therapy patients experience clinically significant nocturnal desaturation.¹



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Continuous Flow Oxygen Delivery & Sleep

A number of theories and studies are published surrounding long term oxygen therapy (LTOT) during sleep. Many LTOT patients have been shown to experience clinically significant nocturnal desaturation. This holds true even for some LTOT users considered well managed on their prescribed LTOT setting while awake.

While continuous flow (CF) may have been traditionally seen as standard practice, it is not without flaws. Scientific data has revealed 30-50% of CF patients experience clinically significant desaturation during sleep¹; not a great track record for what some promote as the LTOT “gold standard”.

The clinical deficiencies associated with CF have been known for years, as evidenced by the American Thoracic Society recommendation to increase nighttime CF oxygen flows by 1 lpm. This recommendation is intended to compensate for nocturnal desaturation due to decreased minute ventilation resulting from slower respiratory rates and shallow breaths. Without increasing O₂ flows at night, the data suggests that HME providers may expect 30-50% of their patients will experience some level of clinically significant nocturnal desaturation.^{2,3,4}

CF Nocturnal O₂ Delivery

- **Awake: RR (20) X CF (3 lpm) = 660ml O₂ per minute**
- **Asleep: RR (10) X CF (3 lpm) = 330ml O₂ per minute**
(Assumes consistent inspiratory time of 1 second)

Most HMEs are unaware of these issues because it is not standard practice to perform overnight pulse oximetry on stable LTOT patients. This approach creates a false sense of clinical effectiveness in CF patients. This perception is based on healthcare dogma rather than evidenced-based research and outcomes.

¹ Plywaczewski R, et al. Incidence of nocturnal desaturation while breathing oxygen in COPD patients undergoing long-term oxygen therapy. CHEST 2000; 117(3): 679-83

² Tarrega J, et al. Are daytime arterial blood gases a good reflection of nighttime gas exchange in patients on long-term oxygen therapy? Respir Care 2002; 47(8): 882-6

³ Sliwinski P, et al. The adequacy of oxygenation in COPD patients undergoing long-term oxygen therapy assessed by pulse oximetry at home. Eur Respir J 1994;7(2): 274-278

⁴ Plywaczewski R, et al. Behavior of arterial blood gas saturation at night in patients with obstructive lung diseases qualifying for home oxygen therapy. Pneumonol Alergol Pol 1997;65(7-8): 494-499

Evolution of Oxygen Delivery

Pulse dose oxygen delivery (PDOD) is a logical extension and application of low flow oxygen delivery. Although prescriptions are typically written in liters per minute (1 lpm), all low flow oxygen devices actually deliver a volume of oxygen to the patient. The volume of oxygen delivered is simply a result of the fixed flow of the gas over time. As an example, a patient prescribed 2 lpm of oxygen via nasal cannula does not actually inspire 2 full liters of oxygen. The net volume of the inspired oxygen delivered to a patient over the course of a minute is a product of the oxygen flow rate, patient's respiratory rate, inspiratory time and the tidal volume minus anatomical deadspace.

Inogen One Nocturnal O₂ Delivery

- **Fixed minute volume of O₂ produced; bolus adjusted up or down based on RR. Adjusts for missed breaths, etc.**
 - **FMV* model of nocturnal O₂ delivery**
 - **May deliver more nocturnal net O₂ than CF**
- **Awake: (3) setting RR (20) = 450ml per min OR 22.5ml per breath**
- **Asleep: (3) setting RR (10) = 450ml per min OR 45ml per breath**

* FMV Fixed Minute Volume: Fixed amount of oxygen per minute. The bolus size varies based upon the patients breathing rate.

*(A lay explanation of this oxygen delivery concept is a water fountain):
If an individual stands in front of a water fountain flowing at 1 liter per minute, they don't actually drink one full liter of water. The amount of water a person drinks is a product of the number of sips and the size of the sip. The same applies to continuous flow oxygen; the net amount inspired is a combination of the flowrate, the number of breaths and the size of the breath (with some additional variables).*

The clinical basis of effective PDOD relies on the assumption that the oxygen participating in gas exchange in the lungs enters the airways quickly, during the first two-thirds of the inspiratory cycle. Oxygen flowing at the end of the inspiration, during exhalation and during the pause prior to the next inspiration is considered wasted, since it plays no role in gas exchange. Approximately one-third of a person's inspiration is gas that remains in the larger airways, sinuses, nose and mouth, anatomical deadspace.

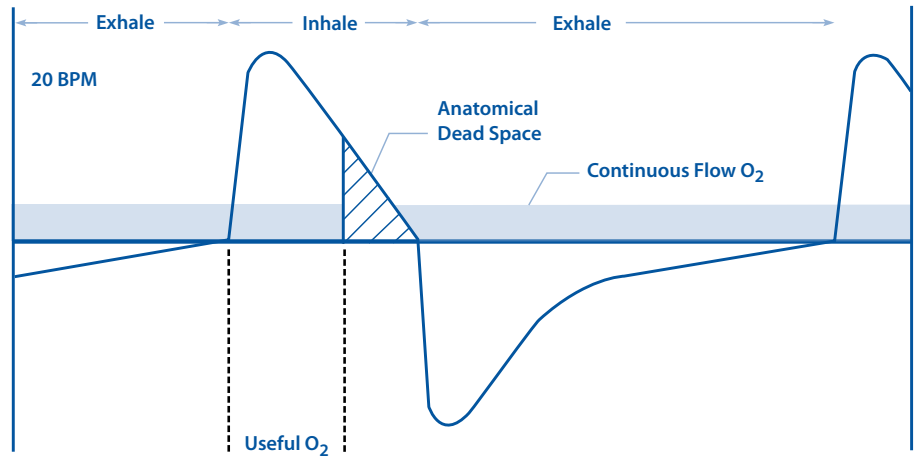
There are a few key elements associated with efficient PDOD technology, including bolus size, sensitivity, and bolus speed/delivery. PDOD promotes the theory that the earlier the oxygen bolus is delivered into the inspiratory cycle, the more efficient the oxygen delivery will be. Oxygen boluses delivered late in inspiration may be less effective in improving blood oxygen levels, as portions of the bolus may fall into the anatomical deadspace. Early work by Tiep and Lewis noted the efficiency of pulsed oxygen therapy can be improved by focusing the oxygen delivery to early inspiration.¹

¹ Tiep BL, Lewis MI. "Oxygen conservation and oxygen conserving devices in chronic lung disease: A review." Chest 1987 Aug;92(2):263-72

Inspiratory Cycle & Bolus Delivery

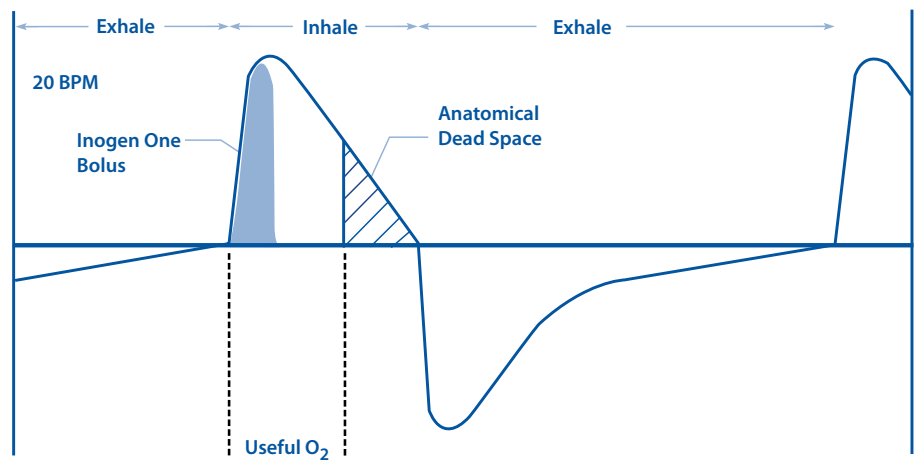
Continuous Flow Delivery

Oxygen delivered during the first 2/3 of the inspiratory effort typically has the most direct effect on lung gas exchange. Oxygen delivered after this point tends to remain in anatomical dead spaces, never reaching the lungs. More than 2/3 of continuous flow oxygen is delivered when patients are not inhaling. This oxygen contributes little to lung gas exchange.



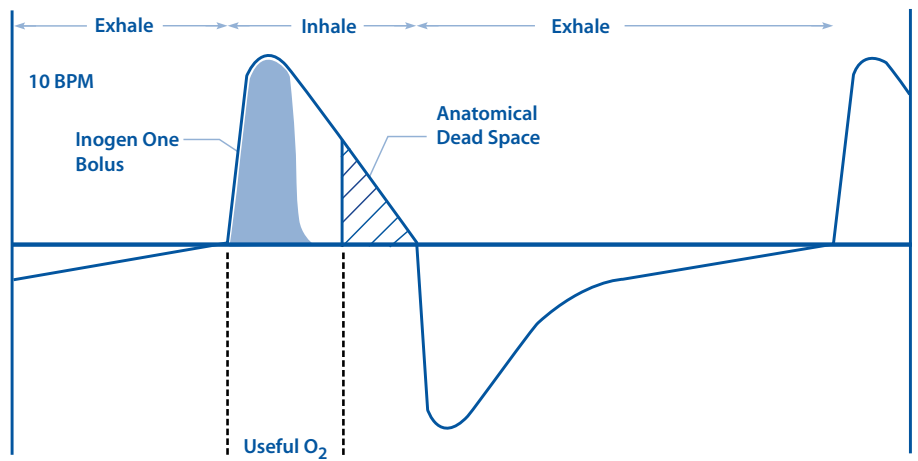
Inogen One Bolus Delivery

Patented conserver technology contained within the Inogen One ensures oxygen is delivered within the first 400 milliseconds of inspiration - where oxygen has the most effect on lung gas exchange. The Inogen One conserver utilizes unparalleled triggering sensitivity to quickly detect a breath and deliver oxygen within this critical period. Less sensitive conservers may create lags in the onset of the bolus, resulting in portions of the delivered bolus arriving too late, having less effect on lung gas exchange.



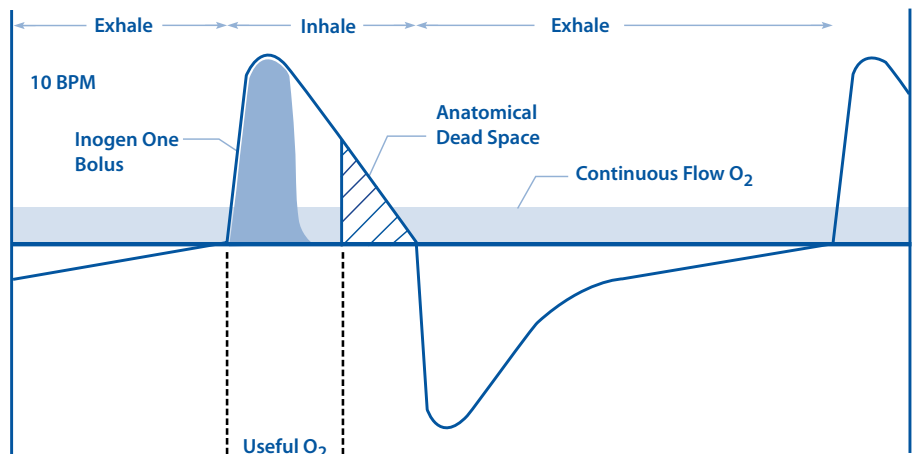
Inogen One Nocturnal Bolus Delivery

During periods of sleep, respiratory rates typically decrease. The Inogen One actively responds to this changing physiology through its use of patented technology to increase the bolus size. At 10 breaths per minute, the Inogen One delivers double the bolus size as it does when the breathing rate is 20 BPM.



Inogen One – Continuous Flow Comparison

Continuous flow oxygen delivery does not compensate for the amount of inspired oxygen during periods of decreased respiration (sleeping). The same volume is available, but at lower tidal volumes and in nocturnal breathing patterns, less oxygen is inspired. Inogen understood this deficit in continuous flow and designed the Inogen One to deliver more oxygen per breath as frequency and depth of respiration decreases.

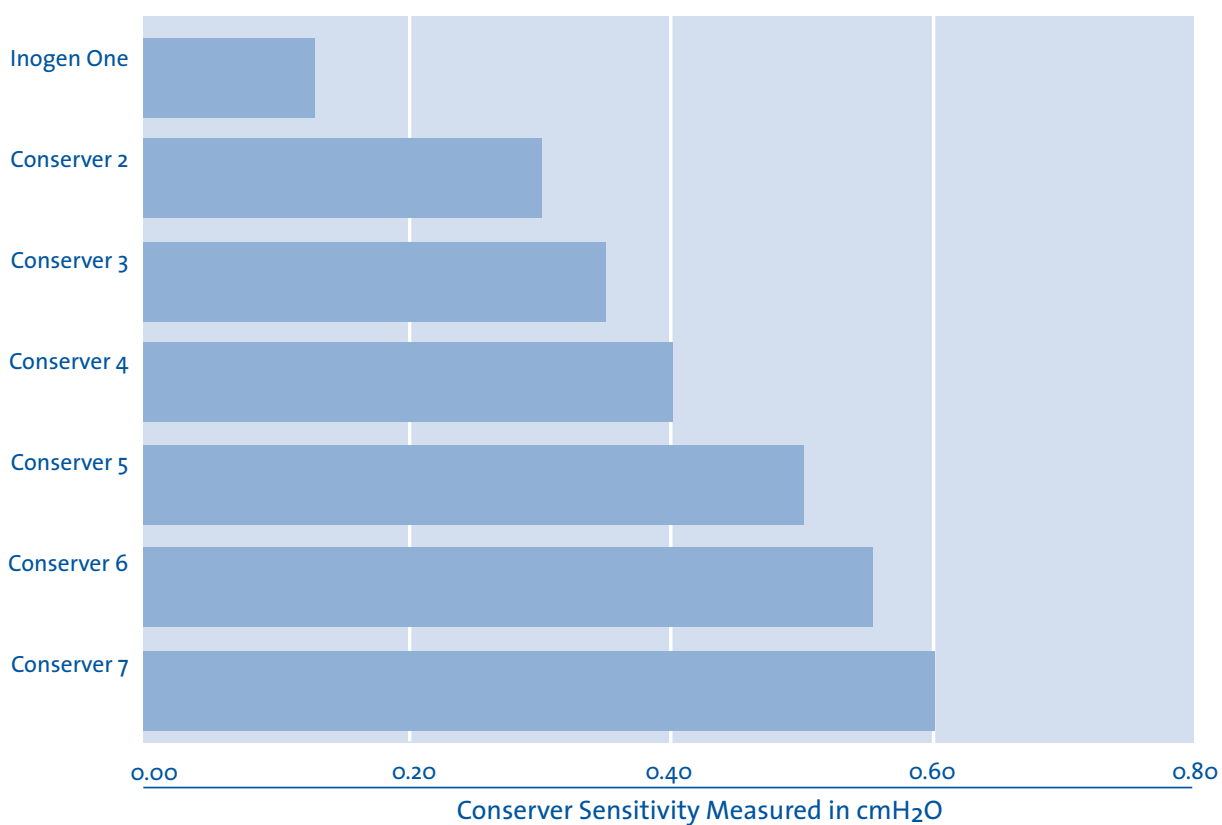


Designing an OCD for Sleeping Patients

Unlike other PDOD devices, the Inogen One was specifically designed to deliver oxygen to sleeping patients. The sensitivity of 0.12 cm H₂O makes the patented Inogen One conserver the most sensitive on the market and responsive to shallow breathing.

- The Inogen One Oxygen Conserving Device (OCD) is unique in that it is designed for use during all modes of activity, including sleep.
- Patented circuit electronics don't just produce an unprecedented level of sensitivity to a user's breathing, but also yields the ability to differentiate a breath from other variations in nasal cannula pressure.
- Patented OCD control software permits the device to be highly flexible to changing environments and meters oxygen delivery to promote increased oxygen delivery during sleep for most patients. As the patient's respiratory rate decreases, bolus volume increases to ensure the prescribed volume of oxygen is delivered.

The Inogen One Conserver: A New Level of Precision & Reliability



Conserver Trigger Precision Data Source: McCoy, R., "A Guide to Understanding Oxygen Conserving Devices" 2003 and 2004

"PDOD/DOD systems have been shown to be clinically effective in resting, exercising and sleeping patients."

-AARC Clinical Practice Guidelines; 2007 Revision

In contrast to the studies that identify deficiencies in traditional continuous flow oxygen use in sleeping patients, there are a series of favorable studies regarding the use of PDOD systems in sleeping LTOT patients.

- A number of scientific studies have examined the clinical efficacy of PDOD devices among LTOT users during sleep. One of the largest is a hospital based study by Kerby, O'Donahue, et al that evaluated a PDOD against continuous flow oxygen in 100 hospitalized, oxygen dependent patients. They concluded that a PDOD system produced clinically equivalent SaO_2 to that of continuous flow oxygen during all activities, including sleep.¹
- Cuvelier and associates used polysomnography to study the nocturnal sleep tolerance of a demand PDOD in COPD patients with hypoxemia and concluded that a demand PDOD device does not induce any significant alteration in nocturnal neurophysiologic and ventilatory profiles.²
- The American Association of Respiratory Care Clinical Practice Guidelines now recognize the clinical efficacy of PDOD systems in resting, exercising and sleeping patients.^{2,3}



¹ Kerby GR, O'Donahue WJ, et al. "Clinical efficacy and cost benefit of pulse flow oxygen in hospitalized patients." *Chest*. 1990 Feb;97(2):369-72

² Cuvelier A, et al. "Nocturnal efficacy and tolerance of a demand oxygen delivery system in COPD patients with nocturnal hypoxemia." *Chest*. 1999 July;116(7):22-29

³ AARC Clinical Practice Guide Oxygen Therapy in the Home or Alternate Site Health Care Facility - 2007 Revision & Update

Inogen has completed and published more clinical data surrounding the Inogen One than any other available oxygen therapy product.

Inogen Specific Research

1. Stegmaier JP, Chatburn RL, Lewarski JS. "Determination of an Appropriate Nocturnal Setting for a Portable Oxygen Concentrator with Pulsed-Dosed Delivery." Abstract. *Respir Care* November 2006;51(11): 1305.
Summary: The purpose of this study was to determine if a single titration of oxygen using a POC during ambulation/exercise would provide an appropriate setting for nocturnal use. The results suggested that an oxygen setting selection based on daytime ADL/ambulation appears to produce effective nocturnal oxygen therapy as evidenced by a mean sleeping SpO₂ of 92% and no clinically significant desaturation.
2. Chatburn, R, Lewarski J, McCoy R. "Nocturnal oxygenation using a pulsed dose oxygen conserving device compared to continuous flow oxygen." *Respir Care* March 2006;51(3): 252-256
Summary: The study compared nocturnal oxygenation with continuous flow versus the Inogen One among a group of established LTOT users with chronic lung disease. The results demonstrate that when appropriately titrated, the Inogen One is essentially clinically equivalent to continuous flow oxygen. The study also suggests that daytime pulse dose titrations may be effective in determining nocturnal oxygenation.
3. Case, R, Hausmann R. "Use of a portable oxygen concentrator with a fixed minute volume oxygen conserving device to deliver oxygen to exercising pulmonary rehabilitation patients." Abstract. *Respir Care* November 2005;50(11):1510.
Summary: The study concluded that the Inogen One was as clinically effective as continuous flow oxygen at maintaining target SpO₂ levels in high flow (4-5 lpm) oxygen users during intense exercise.
4. McCoy, R, Lewarski, J. "A test for clinical equivalency: A portable concentrator with integrated oxygen-conserving compared to continuous flow oxygen during nocturnal use." Abstract. *Respir Care* November 2005; 51 (11):
Summary: This study demonstrated the Inogen One™ POC was able to deliver adequate nocturnal oxygen therapy as evidenced by continuous SpO₂ monitoring in 9 of 10 (90%) of patients studied. The resting daytime oxygen titration and the resultant SpO₂ appears to be reasonably effective method for determining an appropriate nocturnal oxygen setting.

Why the Inogen One?

The Inogen One was specifically designed as a single-source oxygen system. It is Medicare coded for use 24 hours a day, 7 days a week.

The Inogen One is fully reimbursed by Medicare as both a stationary and portable system (E1390 for the stationary application and E1392 for the portable application).

The Inogen One is clinically proven to provide the necessary oxygen for most ambulatory patients during all phases of daily activity and during sleep.

- The Inogen One is the only POC with published scientific studies validating its clinical efficacy during multiple clinical applications, including sleep

The Inogen One simplifies your operations, patient set-ups, and patient use.

- One unit for inventory, deployment, and tracking
- No tracking or hydrostatic testing of cylinders - EVER!
- A single, simple titration at set-up - just like any other device utilizing an oxygen conserver

More than 30 commercial airlines permit the use of the Inogen One.

The Inogen One delivers the cost savings of transfilling systems PLUS eliminates travel cost & coordination.

- Transfilling systems do not remove the HME burden and expense of travel coordination
- Transfilling cylinders cannot be used during air travel or be refilled while in transit



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