

# DETERMINATION OF AN APPROPRIATE NOCTURNAL SETTING FOR A PORTABLE OXYGEN CONCENTRATOR WITH PULSE-DOSED DELIVERY

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**Introduction:** Expert recommendations suggest titration of long-term oxygen therapy (LTOT) settings to the patient's activity level. However, clinicians in the US routinely specify a continuous flow (CF) oxygen prescription (i.e., 2 L/min) and employ this prescription during all activities of daily living (ADL), including sleep. New portable oxygen concentrators (POC) that operate using an integrated and real-time pulse-dosed oxygen delivery (PDOD) device are now readily available. There are published data supporting the safe and effective use of appropriately titrated oxygen using a PDOD at all activity levels, including sleep. The purpose of this study was to determine if a single titration of oxygen using a POC during exercise would provide an appropriate setting for nocturnal use.

**Methods:** We selected the Inogen One™ POC (Inogen, Inc., Goleta, CA) because: (1) it is FDA 510(k) cleared for use as described, (2) it is the only POC currently recognized by Medicare as both a stationary and portable O<sub>2</sub> device and (3) it incorporates modern PDOD technology specifically designed for use at night. Eleven (11) oxygen patients were randomly selected from a mix of newly referred and existing home LTOT patients. Additional selection criteria included a CF prescription of ≤ 4 L/min, a diagnosis of COPD, age range 55-80 years and no known evidence of obstructive sleep apnea. All patients signed an informed consent prior to enrollment in the study and all had valid prescriptions for O<sub>2</sub>, PDOD and clinical assessment/oximetry. Patients were titrated by a respiratory therapist to a POC setting that produced a SpO<sub>2</sub> of > 90% during a 3-minute walk/ADL challenge. For sleep, patients were instructed to select the "sensitive" PDOD setting and the highest oxygen setting used during the walk/ADL assessment. All patients underwent a single overnight pulse oximetry study while using the POC. Clinically significant nocturnal oxygen desaturation (NOD) was defined as ≥ 20 cumulative minutes below a SpO<sub>2</sub> of 88% or ≥ 5% of their total sleep time below 88%. Patients were returned to their original oxygen device upon completion of the study.

**Results:** No patients experience clinically significant oxygen desaturation during sleep. Mean (standard deviation) clinical evaluation results are reported:

POC Setting	Nocturnal SpO <sub>2</sub>	Cumulative minutes NOD	% Sleep time NOD
2.6 (0.5)	92% (1%)	3.3 (2.6)	1.3% (0.8%)

**Conclusion:** Nocturnal POC oxygen setting selection based on daytime ADL/ambulation appears to produce effective nocturnal oxygen therapy as evidenced by a mean sleeping SpO<sub>2</sub> of 92% and no clinically significant NOD. These results suggest that a single, one-step clinical evaluation and titration of oxygen setting with one brand of POC/PDOD device can produce effective oxygenation at rest, with ADL/ambulation and during sleep. Because of differences in design, signal sensitivity, and pulse volume, these results cannot be generalized to all POC and PDOD devices.

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