nox MEDICAL

Clinical Application Paper

The Critical Role of Airflow in Sleep Diagnostics

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Introduction

Sleep-disordered breathing (SDB), particularly sleep apnea, remains one of the most prevalent yet underdiagnosed sleep conditions, significantly impacting health and quality of life. With advancements in home sleep apnea testing (HSAT), clinicians now have a range of diagnostic tools to better address this challenge. However, not all HSAT devices are created equal, and choosing the right technology can make a critical difference in diagnostic accuracy and patient outcomes.

This clinical application paper explores the importance of airflow measurement in sleep diagnostics and highlights the distinctions between different methods for identifying respiratory events. We examine how devices like the Nox T3s™ Home Sleep Test (HST) system, leveraging airflow and respiratory effort measurements, have demonstrated reliability across diverse patient groups, including those with complex chronic conditions. This analysis will inform clinicians on selecting an HSAT system that best meets their diagnostic needs, ultimately supporting effective, personalized care for patients with SDB.

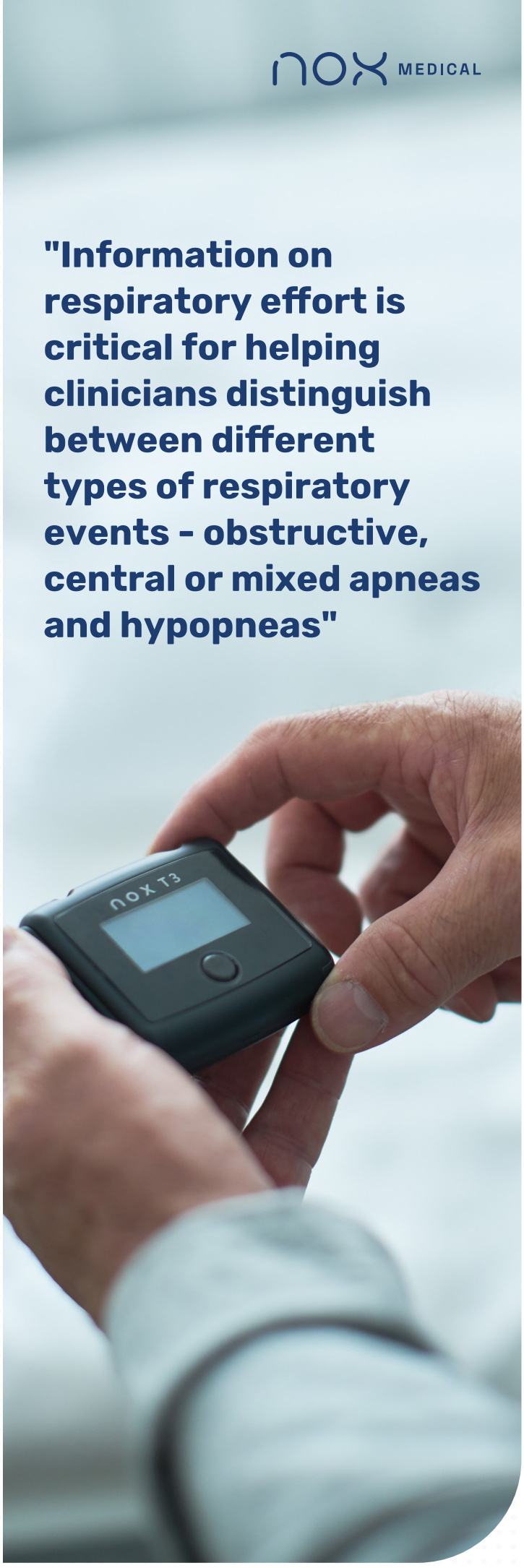
Classification of HSAT Device Capabilities

In diagnosing sleep apnea, HSAT devices are categorized by the American Academy of Sleep Medicine (AASM) into two distinct groups: those that utilize respiratory flow and/or effort parameters and those that rely on peripheral arterial tonometry (PAT) or surrogate signals. While both approaches provide insights into SDB, they differ in terms of diagnostic capabilities and data reporting requirements[1]. The Nox T3s (HST) system[2] manufactured by Nox Medical falls into the category of devices that utilize airflow measurement. It achieves this by directly measuring breathing through RIP (Respiratory Inductance Plethysmography) technology and a nasal cannula, providing detailed respiratory data.

The Role of Airflow and Respiratory Effort Measurement in Sleep Apnea Diagnosis

The AASM Manual for the Scoring of Sleep and Associated Events continues to emphasize the importance of airflow measurement in scoring respiratory events, particularly for home sleep apnea testing (HSAT). The manual recommends the use of an oronasal thermal sensor to identify respiratory events. Oronasal thermistors and thermocouples detect the presence of airflow due to a change in sensor temperature, as exhaled gas is warmed to body temperature. However, the signal from these thermal devices is not proportional to flow, and often overestimates flow as flow rates decrease[3]. Additionally, these sensors may be uncomfortable for some patients or at times unreliable. Therefore, nasal pressure transducers and/or dual RIP belts are recommended as alternatives, to monitor airflow and respiratory effort[1].

Dual RIP belt technology captures and measures abdominal and thoracic breathing movements during sleep, which can be used to infer breathing effort. This information on respiratory effort is critical for helping clinicians distinguish between different types of respiratory events, for example by allowing the clinician to see sustained or increased breathing efforts (obstructive apneas and hypopneas), the absence of breathing effort (central apneas and hypopneas) or both (mixed)[4]. Additionally, RIP belts can be calibrated to provide airflow estimates.



PAT Technology and its Limitations in Respiratory Event Detection

PAT-based devices monitor vascular changes associated with sleep and sleep apnea by measuring the arterial pulse wave volume in the finger. Although the AASM states that PAT, when combined with oximetry-derived oxygen desaturation and changes in heart rate, is acceptable for identifying respiratory events,[1] it is important to consider the inherent diagnostic limitations of the technology.

PAT devices indirectly identify respiratory events and rely on attenuation of the PAT signal[5,6]. Findings from a recent meta-analysis revealed clinically significant discrepancies between PAT and polysomnography (PSG, the currently recognized gold standard for sleep diagnostics) studies when determining apnea-hypopnea index (AHI), especially with regard to misclassifying mild-to-moderate OSA, with PAT performing poorly overall[7]. In another meta-analysis, the authors concluded that PSG is recommended in diagnosing sleep apnea and that PAT is not suitable as an alternative, as its sensitivity and specificity were found to be insufficient[8]. This can be understood as PAT devices do not directly measure total sleep time (TST); instead, they use actigraphy-based algorithms to estimate sleep/wake states. Additionally, they do not directly detect apnea or hypopnea events; instead, respiratory events are derived from attenuation of the PAT signal and oxygen desaturation at the end of each respiratory event[9].

Comprehensive use of Airflow and Respiratory Effort Measurement with the Nox T3s

The Nox T3's system sensors—including single-patient use Nox RIP belts, and a cannula-capture signals like respiratory flow and effort, which are used to derive events associated with SDB. The patented Nox RIP belts monitor thoracic and abdominal movements, providing both a high-fidelity measure of effort as well as a flow signal that is insensitive to mouth breathing. The combination of nasal cannula and RIP allows for a comprehensive assessment of airflow and respiratory effort[10].

The Nox RIP technology continuously and automatically calibrates the sum of the abdominal and thoracic signals providing accurate reflection on changes in lung volumes and airflow. Calibrating the belts during sleep is essential since the relationship between belt movement and lung volume can change depending on patients' body positions and following patient movements during sleep testing - a limiting factor for many RIP belts. Eliminating the need for constant manual calibration during sleep makes the Nox RIP dual belts ideal for home sleep testing.

Importantly, Nox RIP dual belts can act as an alternative flow signal in case a nasal cannula or nasal thermistor become dislodged or compromised by oral breathing. This feature helps avoid invalid test results. Data from validation studies has shown that RIP flow offered by Nox is a reliable surrogate for respiratory event scoring[11,12,13].

Nox Provides Advances in Dual RIP Belts Technology

In an effort to ensure that the Nox T3s HST and the Nox A1s PSG systems' dual RIP belts provide both accuracy and comfort, researchers at Nox Medical have consistently worked to advance the RIP belt design, resulting in both high quality and high reliability of respiratory signals during HSAT[14].

The Nox T3s system reflects these advances, including assurance that the Nox RIP belts are comfortable to wear over clothing and remain attached all night. Contacts have been seamlessly integrated into the no-fold, disposable dual belts, which have outperformed both cut-to-fit and semi-disposable RIP belts in a head-to-head comparison[15].

High Sensitivity and Specificity of Nox T3s: Validated Against PSG

Studies have been conducted to evaluate the performance of the Nox T3s sleep system compared to traditional PSG. Findings demonstrated that AHI manually scored using data from the Nox T3s shows close agreement with AHI from PSG, demonstrating high sensitivity and specificity for OSA severity classifications[11,13,16-21]. Sensitivity ranged from 91-100% for AHI≥ 5 and 69-93% for AHI≥15, reflecting the ability of data from the Nox T3s to be used to detect OSA severity. Specificity was also high, ranging from 69-95% for AHI≥5 and 85-98% for AHI≥15, which suggests that data from the Nox T3s can effectively support clinicians in identify patients with mild sleep apnea.

The Nox T3s sleep system has also been used as the reference test to validate many novel devices or methods for screening for OSA or sleep breathing disorders, reinforcing its status as a trusted device in the field[22-35].

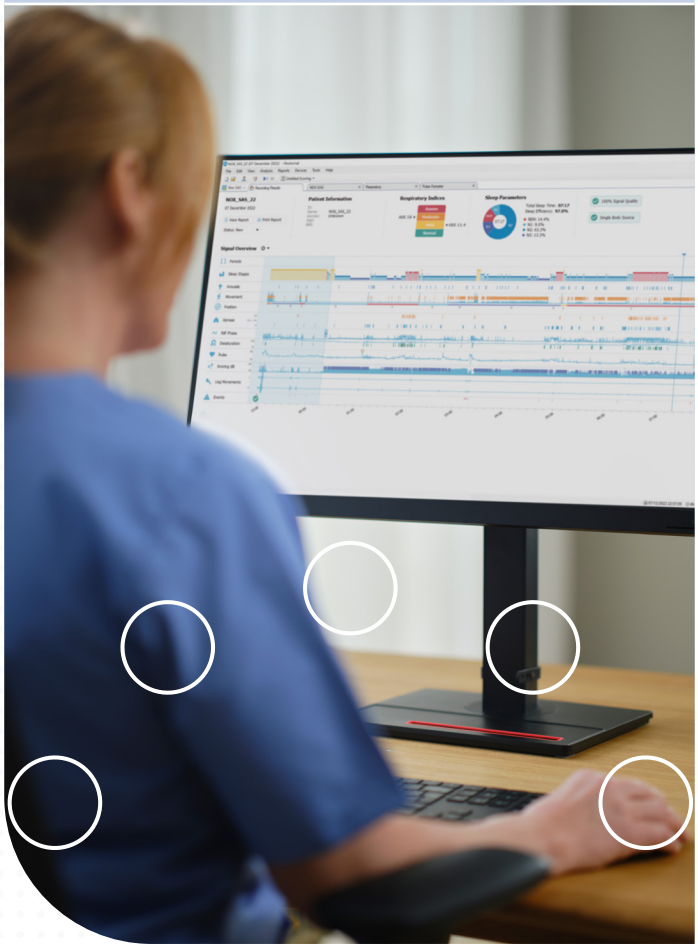
Prioritizing Patient Care Through Effective HSAT Solutions

Regardless of the HSAT system clinicians choose, the primary objective remains consistent: to optimize patient care. Accurate diagnosis of SDB is a critical step toward providing effective treatment, improving patient outcomes, and enhancing overall quality of life. Choosing a system that is backed by extensive research and inclusive of diverse patient populations is essential for achieving reliable and clinically meaningful results.

As advancements in HSAT technology continue, clinicians are encouraged to carefully evaluate the strengths and limitations of each system. The Nox T3s system[36] is designed for patients over two years old and has been widely used to support physicians in diagnosing sleep-disordered breathing across diverse patient groups, including both men and women with underlying chronic conditions, including cardiovascular diseases (e.g. atrial fibrillation[25,37-42], heart failure[43], acute coronary syndrome[44,45]), pulmonary diseases (e.g. COPD[11,18,46], pulmonary arterial hypertension[47-51],, pneumonia[52,53]), and neurological diseases (e.g. muscular dystrophy[54], multiple sclerosis[55], traumatic brain injury[17,56], stroke[57-60]).

"The Nox T3s has earned its place as a reference standard in sleep diagnostics, underscoring the trust it holds among both clinicians and researchers. This trust shows that, for those who need reliable and accurate respiratory data, the Nox T3s stands out as the preferred choice. Sleep professionals consistently turn to the Nox T3s because they know our technology provides the robust signals essential for meaningful analysis and diagnosis,"

- Sveinbjörn Höskuldsson, CTO at Nox Medical



Ultimately, the effectiveness of any HSAT system depends on its ability to deliver clear, accurate insights that assist the clinician in making informed decisions. The Nox T3s, with its comprehensive use of airflow and respiratory effort measurements, has demonstrated reliability for diverse patient groups, including those with complex chronic conditions. As sleep diagnostics continue to evolve, the Nox T3s stands ready to support clinicians in delivering high-quality and informed care.

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Nox Medical is a global leader in the sleep diagnostic technology space. The company provides sleep specialists with patient-friendly diagnostic devices and robust, reliable data collection. With easy-to-use medical device technology, Nox Medical eliminates common diagnostic pain points by prioritizing patient comfort and reliability of results, allowing providers to better assess, diagnose and treat the entire range of sleep health issues, including sleep apnea, circadian disorders and insomnia.

www.noxmedical.com
info@noxmedical.com

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