Advancing Sleep Diagnostics with Artificial Intelligence

AI-powered Analyses in Noxturnal

Advancing Sleep Diagnostics with Artificial Intelligence

AI-powered Analyses in Noxturnal

Artificial Intelligence (AI) is transforming sleep diagnostics by automating complex cognitive tasks, enabling sleep labs worldwide to operate more efficiently while unlocking deeper insights into sleep disorders.

At Nox Medical, we are committed to leveraging Artificial Intelligence to advance sleep diagnostics and improve patient care. Our AI analyses, available in Noxturnal software, automate routine tasks and provide greater insights to sleep study data, allowing sleep professionals to deliver care with greater ease and confidence.

Our AI offerings

AI Analyses in Noxturnal Software

Noxturnal Software is included with all Nox Medical diagnostic technology, including the Nox A1s polysomnography system and the Nox T3s home sleep apnea test. The software incorporates a wide range of AI analyses, including sleep staging, arousal scoring, and Nox BodySleep analysis, together with other rule-based automatic analyses for movement and respiratory events.

Overall, our hope is that each patient will reap the biggest benefits from Artificial Intelligence. AI-based tools offer a scoring aid and more automation, affording physicians and technologists the gift of time - meaning more quality face time with patients and allowing them to spend more time analyzing rare or difficult cases.

Autoscoring you Can Trust

Noxturnal Software offers autoscoring capabilities while ensuring that raw sleep study data is always accessible to sleep technologists. This allows them to review and correct the automated analysis, empowering clinical experts with our autoscoring features while maintaining their ability to ensure accurate scoring.

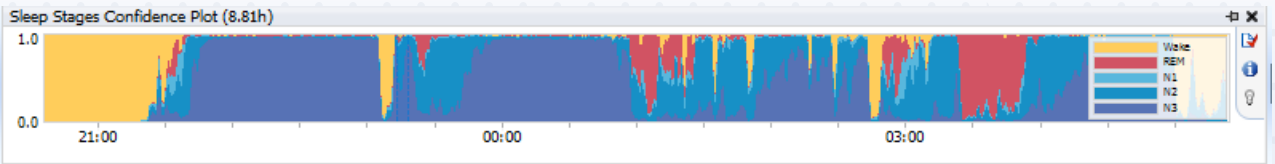
A confidence indicator feature is clearly displayed on the screen to tell clinicians how “confident” the automatic analysis is in its scoring of each epoch or event during a sleep study. This confidence level is shown on a scale of 0 to 1 (with 1 being certain), for the sleep stage pre-scored by the automatic analysis.

All Artificial Intelligence analysis results should always be reviewed by a certificated technologist or a physician prior to diagnosis.

Sleep Staging Analysis

The Noxturnal software incorporates an automatic sleep staging analysis designed to assist manual scorers in evaluating sleep stages. The AI algorithm used in this analysis processes key physiological signals, including EEG, EOG, and EMG. By leveraging these signals, the algorithm pre-scores sleep stages using the same physiological data as a sleep technologist would use when following the AASM manual.

To ensure the validity of this tool, the automatic sleep staging analysis was validated using clinical sleep recordings from adults with various sleep disorders. For sleep stage classification overall, the validation process demonstrated a Cohen’s Kappa of 0.76 indicating substantial agreement between the AI-estimated sleep stages and manual scoring, and showing performance similar to levels of agreement between multiple manual scorers. The AI algorithm's accuracy in estimating specific sleep stages was: N1 (54.4%), N2 (84.4%), N3 (84.8%), Wake (78.3%), and REM (88.2%)[2]. These results confirm that the Sleep Staging Analysis provided by Noxturnal is both safe and effective, offering a reliable aid in the diagnostic process.



The confidence level of the sleep staging analysis seen on the Sleep Stage Confidence Plot

[2] Additional data on file, reviewed by accredited notified body

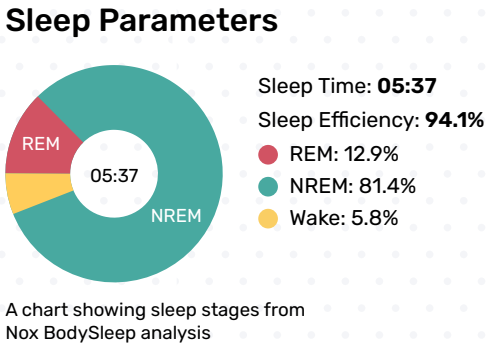
Arousal Analysis

The Noxturnal software's automatic arousal scoring feature is designed to detect arousal events, which may enhance the efficiency of hypopnea scoring in sleep studies. Using AI-driven algorithms that process EEG and EOG signals, the tool pre-scores arousals based on the same physiological data a sleep technologist would use when following the AASM manual.

Validated on clinical sleep recordings from a general adult population, the algorithm achieved a sensitivity of 67.67% and a specificity of 97.51% in detecting arousal events across 30,900 scored epochs, confirming its safety and effectiveness[2].

Nox BodySleep™ Analysis

The Nox BodySleep Analysis uses AI to classify epochs into sleep states: REM, NREM, and Wake, to provide a more precise estimate of sleep time during home sleep studies. This advanced analysis utilizes respiratory inductance plethysmography (RIP) signals and actigraphy to estimate sleep states, which can be used to refine the calculation of AHI. Notably, the Nox BodySleep achieves this without relying on traditional EEG, EOG, and EMG signals typically used in polysomnography (PSG), ensuring that the process remains simple and comfortable for patients in their home environment.



A chart showing sleep stages from Nox BodySleep analysis

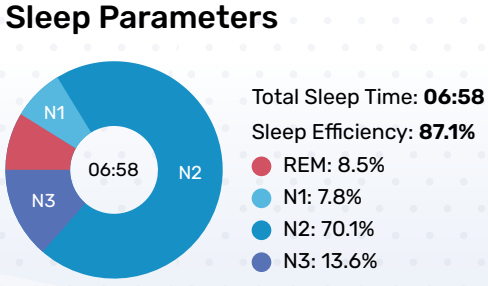
Validated against manually scored polysomnography (PSG) data, the Nox BodySleep has demonstrated high levels of agreement in sleep state classification, with wake classification agreement of 87% and overall classification accuracy of Cohen's kappa of 0.62[2]. When used in combination with automatic respiratory event scoring for estimation of AHI, articles have shown a Pearson correlation of 0.91[3] and intraclass correlation coefficients (ICC) ranging from 0.96 to 0.98[4] compared to manual scoring. Recent studies have therefore confirmed the Nox BodySleep algorithm's ability to estimate sleep states with high accuracy, making it a valuable tool for improving the diagnostic accuracy of home sleep tests. The algorithm has been tested across different BMI, sex, and AHI severity groups, showing consistent performance.

Nox SAS Sleep Staging Analysis

The SAS Sleep Staging Analysis in Noxturnal is designed to assist manual scorers in scoring sleep stages, to provide accurate estimates of total sleep time from sleep studies using the Nox SAS Solution. This AI algorithm uses electroencephalography (EEG) signals, electrooculogram (EOG) signals, and frontalis electromyography (EMG) signals to provide pre-scoring of sleep stages, using the same physiological data as a sleep technologist following AASM manual. Validated on clinical sleep recordings, the analysis achieved a Cohen's Kappa of 0.69 and high levels of agreement for individual sleep stage classifications, including 75.8% for wake and 86.1% for REM.

Nox SAS Arousal Analysis

The SAS Arousal Analysis in Noxturnal is designed to detect arousal events, which may enhance the efficiency of arousal scoring to improve hypopnea detection from sleep studies using the Nox SAS Solution. Using EEG, EOG, and frontalis EMG signals, the AI algorithm achieved a sensitivity of 68.10% and specificity of 94.48% when validated on clinical sleep recordings[2].



A chart showing sleep stages from Nox SAS sleep staging analysis

[2] Additional data on file, reviewed by accredited notified body

[3] Dietz-Terjung, S., Martin, A.R., Finnsson, E. et al. Proof of principle study: diagnostic accuracy of a novel algorithm for the estimation of sleep stages and disease severity in patients with sleep-disordered breathing based on actigraphy and respiratory inductance plethysmography. Sleep Breath 25, 1945–1952 (2021). https://doi.org/10.1007/s11325-021-02316-0

[4] Leger D, Elbaz M. Diagnosing OSA and Insomnia at Home Based Only on an Actigraphy Total Sleep Time and RIP Belts an Algorithm "Nox Body Sleep™". Nat Sci Sleep. 2024;16:833-845 https://doi.org/10.2147/NSS.S431650

Additional Autoscoring Tools

The following advanced analyses function independently of Artificial Intelligence (AI) and are designed to assist sleep professionals in assessing key sleep parameters.

Respiratory Flow Analysis (Calibrated RIP and cannula)

The Noxturnal software's Respiratory Flow Analysis is a rule-based algorithm that provides preliminary scoring of apneas, hypopneas, and desaturation events during sleep. By utilizing either the calibrated Respiratory Inductance Plethysmography (RIP) or cannula flow signals, together with other inputs from pulse oximetry and arousal scoring, the analysis detects respiratory events, such as apneas and hypopneas, based on the same physiological data that a sleep technologist would use when scoring according to the AASM manual. The analysis also distinguishes between central and mixed apneas by analyzing respiratory effort.

The performance of this analysis compared to manual scoring has been reported in various studies, with Pearson's correlations for AHI ranging from 0.91[5] to 0.98[6] and ICCs for AHI ranging from 0.96 to 0.97[7]. Furthermore, one recent article[8] reported that the accuracy of AHI classification when using the automated respiratory flow analysis was over 0.92 for all OSA severity levels. The validation of the analysis compared to manual scoring of clinical sleep recordings demonstrated an ICC of 0.91 for CAI and ICC of 0.95 for ODI[2]. These findings underscore the reliability of Noxturnal's automatic respiratory flow analysis.

PLM Analysis

The PLM Analysis in Noxturnal aids in the detection of periodic limb movements (PLMs) during sleep, to enhance the efficiency of scoring. Using EMG signals from both legs and activity data, this rule-based analysis identifies limb movements and determines if they are periodic, following the scoring rules in the AASM manual.

Validated on clinical recordings, the analysis achieved an Intraclass Correlation (ICC) of 0.98 and a Pearson correlation coefficient of 0.94[2].

Bruxism Analysis

The Bruxism Analysis in Noxturnal aids in the detection of masseter muscle activity, which may improve the efficiency of scoring potential bruxism-related events. This rule-based analysis identifies jaw contractions, classifying them as tonic (sustained clenching) or phasic (repetitive brief contractions) based on the scoring rules in the AASM manual.

While the analysis helps streamline the detection process, it is known to overestimate bruxism events, with an average of 42% of automatically scored events requiring manual removal. Validated on clinical recordings, the analysis showed a sensitivity of 95.7% and a specificity of 61.0%, confirming its ability to detect bruxism episodes[2].

---

[2] Additional data on file, reviewed by accredited notified body

[5] Cachada, Nuno & Thomas, Max & Wharton, Simon. (2017). Comparison of Manual and Automatic Scoring of limited channel sleep studies: Noxturnal Software correlates well with manual scoring in severe OSA. PA2301. 10.1183/1393003.congress-2017.PA2301.

[6] Olafsdottir, K., Sigurdardottir, S., Gislason, T., Johannesdottir, O., Hilmarsson, O., & Arnardottir, E. (2013). Difference between automatic and manual analysis of respiratory events in sleep studies. Sleep Medicine, 14(Supplement 1), e222-e223. https://doi.org/10.1016/j.sleep.2013.11.534

[7] Magalang UJ, Johns JN, Wood KA, Mindel JW, Lim DC, Bittencourt LR, Chen NH, Cistulli PA, Gíslason T, Arnardottir ES, Penzel T, Tufik S, Pack AI. Home sleep apnea testing: comparison of manual and automated scoring across international sleep centers. Sleep Breath. 2019 Mar;23(1):25-31. doi: 10.1007/s11325-018-1715-6. Epub 2018 Sep 10. PMID: 30203176; PMCID: PMC6615031.

[8] Kristiansen, S., Traaen, G. M., Øverland, B., Plagemann, T., Gullestad, L., Akre, H., Nikolaidis, K., Aakerøy, L., Hunt, T. E., Loennechen, J. P., Stein shamn, S., Bendz, C., Anfinsen, O.-G., & Goebel, V. (2020). Comparing manual and automatic scoring of sleep monitoring data from portable polyg raphy. Journal of Sleep Research. https://doi.org/10.1111/jsr.13036

Nox Medical is Leading the Way

At Nox, we have pioneered the development of AI medical software. Nox first released a deep learning neural network in the Noxturnal sleep software in 2016. Since then, the software has evolved, become more refined, and been backed by multiple research studies. Since 2015, a team of dedicated researchers and data scientists at Nox Medical has submitted to industry competition and collaborated on several research projects to validate its products to establish access to extensive data.

Nox Medical is actively and continuously performing clinical validation, working with regulatory bodies and consulting with industry stakeholders to ensure all Nox products are safe and effective for patients.

Warnings & Precautions

The Noxturnal Software does not provide any alarms and is not certified to be used for continuous monitoring where failure to operate can cause injuries or death of the patient.

The Noxturnal Software is intended as an aid in diagnosis of sleep disorders. The software must be used in conjunction with other methods of assessing clinical signs and symptoms.

Noxturnal automatic analysis may be less accurate than analysis conducted by trained physician. The result of the automatic analysis/scoring must always be manually verified by the trained physician prior to diagnosis.

Derived signals calculated by Noxturnal, especially heart rate and respiratory rate from the underlying electrocardiogram (ECG) and respiratory effort signals, are not validated for patients with diaphragm pacing/phrenic nerve stimulators.

Our Approach to AI

Building Trust Through Rigorous and Inclusive Validation

Our research and development process is driven by collaboration, innovation, and transparency. We rigorously validate our analyses on clinical data across all products. Additionally, our research team frequently shares new research findings in scientific journals and presents at conferences, ensuring that our methods and results contribute to the broader scientific community. We partner with leading scientists for both internal and independent research, and work with organizations like the American Association of Sleep Medicine (AASM), European Sleep Research Society (ESRS), European Society of Sleep Technologists (ESST) and European Respiratory Society (ERS) to advance education in sleep diagnostics.

Data diversity is central to our validation approach, with our AI analyses validated across diverse populations, considering factors like gender, age, and geography. We ensure rigorous validation of our AI algorithms during clinical validation by using data from independent clinical sources, separate from the development dataset. This ensures that patient, data acquisition, and site factors are fully independent and in line with FDA standards.[1]

> ***"We recognize the significant responsibility that comes with integrating AI and machine learning models into our medical products, as these technologies can greatly influence patient outcomes. That's why we are committed to upholding the highest safety standards and ensuring the effectiveness of our products. We take extra steps in our validation processes to ensure our validation results are representative of the performance in the real-world."***

Jón Skírnir Ágústsson, VP of Artificial Intelligence

[1] U.S. Food and Drug Administration. (2021, October). Good machine learning practice for medical device development: Guiding principles. U.S. Food and Drug Administration. https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles

nox MEDICAL

LBL-0516 REV01