nox MEDICAL

DeepRESP

INSTRUCTIONS FOR USE

English

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DeepRESP Version 2.x

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Intended Use

DeepRESP is intended as an aid in diagnosis of sleep disorders. Its main purpose is to retrieve and automatically analyse/score sleep study data recorded by Nox Medical devices. The results of the analysed data are transferred to another software for display, manual verification and scoring, and reporting.

Indications for Use

DeepRESP allows for automatic analysis/scoring of physiological signals recorded during sleep studies, which can aid healthcare professionals in the diagnosis of sleep disorders. All outputs generated by DeepRESP are subject to verification and interpretation by qualified healthcare professionals.

Patient Population

Patients 18 years and above who are undergoing physiological measurements as part of a sleep test requested by a healthcare professional.

Intended Users

The end users are healthcare professionals who have received training in the areas of hospital/clinical procedures, physiological monitoring of human subjects, or sleep disorder investigation.

Intended Environments

The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments.

Clinical Benefit

The main benefit of DeepRESP software is that it aids healthcare professionals in the process of diagnosing sleep disorders through automatic scoring of sleep study data. The device therefore provides an indirect benefit through a positive impact on patient management by facilitating the diagnostic process.

Information for Safety

- Medical professionals are responsible for checking the suitability of the data intended to be processed by the device. Any corrupted data, distorted data or signals lost may result in incorrect device outputs.

Potential Adverse Events

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer (support@noxmedical.com) and to your national authority.

Warnings and Disclaimers

- **Warning:** The output of DeepRESP is not the only source of information for diagnosis or treatment purposes. Medical professionals remain responsible for reviewing the device output and for the diagnosis or treatment decision.

DeepRESP Description

DeepRESP is a cloud-based software as a medical device (SaMD), designed to perform analysis of sleep study recordings, with and without EEG signals, providing data for the assessment and diagnosis of sleep-related disorders. Its algorithmic framework provides the derivation of sleep staging including arousals, scoring of respiratory events and key parameters such as the Apnea-Hypopnea Index (AHI) and Central Apnea-Hypopnea Index (CAHI).

DeepRESP is hosted on a serverless stack. It consists of:

- A web Application Programming Interface (API) intended to interface with a third-party client application, allowing medical professionals to access DeepRESP's analytical capabilities.
- Predefined sequences called Protocols that run data analyses, including artificial intelligence and rule-based models for the scoring of sleep studies, and a parameter calculation service.
- A Result storage using an object storage service to temporarily store outputs from the DeepRESP Protocols.

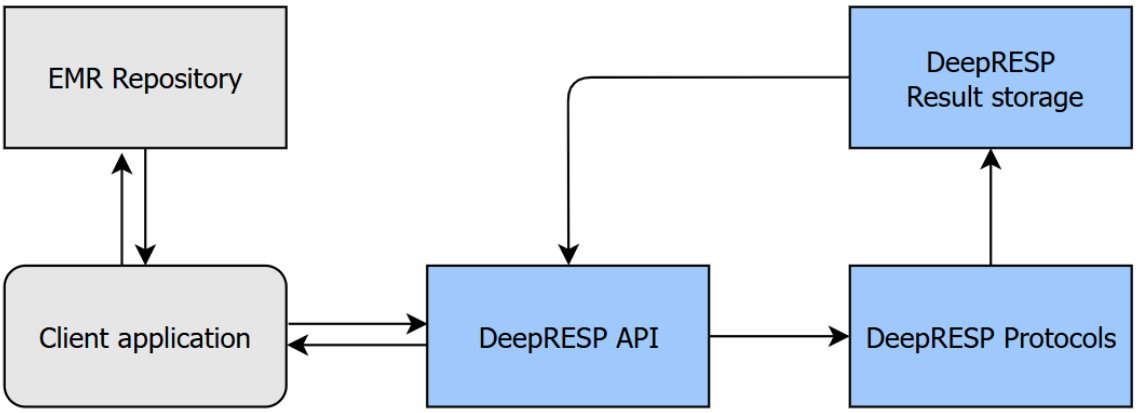


Figure 1 - DeepRESP dataflow

DeepRESP operates without a graphical user interface (GUI). The client application assumes the responsibility to provide the user interface to the end-user, manage sleep study and protocol selection, present the DeepRESP results to the end user and manage any exceptions encountered by DeepRESP (i.e., during accessing the sleep study or analyzing the study). The client application can call specific protocols but cannot customize any protocols or create its own protocols.

Signals and Parameters

The following Table 1 presents the input and output parameters of DeepRESP, for sleep studies with EEG signals (PSG studies) and without EEG signals (HSAT studies) in .ndf and .protobuf format uploaded by the user:

Table 1. Input and output parameters for DeepRESP

Study type	Physiological input signals	Output parameters
PSG	EEG signals EOG signals Chin EMG signals	Sleep stages: Wake, REM, N1, N2 and N3
	Abdomen and Thorax RIP Nasal Pressure Desaturation Events Arousal Events	Respiratory events: hypopneas

	Abdomen and Thorax RIP Nasal Pressure	Respiratory events: central apneas, obstructive apneas
	SpO2	Respiratory events: oxygen desaturations
	EEG signals EOG signals Chin EMG signals	Arousals events
	Respiratory events, sleep stages and arousal events	Parameters such as AHI.
HSAT	Abdomen and Thorax RIP	Sleep states: Wake, REM, NREM
	Abdomen and Thorax RIP Nasal Pressure (Optional) Desaturation Events Arousal Events	Respiratory events: hypopneas
	Abdomen and Thorax RIP Nasal Pressure (Optional)	Respiratory events: central apneas, obstructive apneas
	SpO2	Respiratory events: oxygen desaturations
	Abdomen and Thorax RIP	Arousals events
	Respiratory events, sleep states and arousal events	Parameters such as AHI.

Missing signals can affect DeepRESP's output parameters, as indicated in Table 1. A medical professional reviewing and interpreting the outputs should confirm that all required signals are present and of sufficient quality for them to verify that the outputs of DeepRESP are correct or not before relying on DeepRESP's results.

To provide the outputs, DeepRESP features a suite of automated protocols to analyze sleep data. The protocols orchestrate analyses according to a predefined sequence. To run a protocol, DeepRESP receives study data and a specification of which protocol to run. It then runs the corresponding protocol which will launch the corresponding analysis. The following provides the analysis outputs in more detail according to the type of study uploaded:

1. **For PSG studies:**
    - PSG Preprocessing Protocol

- Position Detection: Identifies patient positions (upright, prone, supine, left and right positions).
- Analysis Period Finder: Determines the likely period the patient attempted to sleep.
- Desaturation Detector: Identifies significant drops in blood oxygen saturation.
- Nox Respiratory Analysis: Detects various respiratory events, including apneas and hypopneas.
- PSG Sleep Staging: Categorizes sleep into distinct stages from EEG signals (Wake, REM, N1, N2 and N3)
- PSG Arousal Detection: Identifies arousal events.

    - PSG Postprocessing Protocol

- Parameter Engine: Computes sleep parameters such as AHI.
- Sleep Apnea Endotypes: Predicts the underlying causes of sleep apnea.
- Sleep Apnea Burden: Calculates the hypoxic and ventilatory impacts of sleep apnea.

2. **For HSAT studies:**
    - HSAT Preprocessing Protocol

- Position Detection: Identifies patient positions (upright, prone, supine, left and right positions).
- Analysis Period Finder: Determines the likely period the patient attempted to sleep.
- Desaturation Detector: Identifies significant drops in blood oxygen saturation.
- Nox BodySleep: Estimates sleep states (Wake, REM, NREM) and detects arousal events from respiratory signals.
- Nox Respiratory Analysis: Detects various respiratory events, including apneas and hypopneas.

    - HSAT Postprocessing Protocol

- Parameter Engine: Computes sleep parameters such as AHI.

- Sleep Apnea Endotypes: Predicts the underlying causes of sleep apnea.
- Sleep Apnea Burden: Calculates the hypoxic and ventilatory impacts of sleep apnea.

After a protocol is done, DeepRESP returns a structured human readable payload with all calculated parameters and provides a link (i.e., URL) to object artifacts such as scoring and new signals in the client application which incorporates and presents them to the end user for review.

Development

This device contains artificial intelligence/machine learning (AI/ML)-based analysis models as part of the Preprocessing protocols and that process signals to detect sleep events: Nox BodySleep, Nox Respiratory Analysis, PSG Sleep Staging, PSG Arousal Detection. The AI/ML-based analyses are based on artificial neural networks and rule-based models. The inputs to the AI/ML-based analyses are the recorded physiological signals from the Nox sleep recorders.

The training data for the models consisted of sleep recordings of healthy participants and patients diagnosed with sleep disorders acquired from different EU, US and Asian sites. The training data originates from a number of independent sites, a broad range of patients, recorded in ambulatory and in-lab settings, and performed as part of standard clinical practice and research studies. This ensures that the training data is highly diverse, including a diverse patient population, clinical practice, and environmental factors.

The validation data for the models consisted of sleep recordings from standard sleep clinical practice from 50 states of the United States. The validation data originates from sites that are distinct from the sites where the training data was collected. This ensures that the validation data is completely independent of the training data.

DeepRESP models are not adaptive continuous learning algorithms. The models are locked so that they do not change as a result of user input.

Supported File Format

DeepRESP accepts signals from sleep studies in .ndf and .prodobuf format.

Current Version

The current version of DeepRESP should be requested through the third-party client application which accesses the information by calling the "about" endpoint.

Standard Operation

DeepRESP is used through a third-party client application, which provides the user interface for DeepRESP's functionality. No installation is required for the use of DeepRESP.

The third–party client will run a DeepRESP preprocessing protocol to automatically score the uploaded sleep study. After the preprocessing sequence has been followed, the third-party client application can offer the end-user the opportunity to manually review, correct or adjust sleep scoring before requesting DeepRESP to initiate postprocessing to calculate the output parameters, such as the AHI. Please refer to the instructions of the third-party client application for further information.

Decommissioning and Disposal

If there are any questions or assistance is required regarding the decommissioning and/or disposal process, including the retrieval or deletion of user data, please contact support@noxmedical.com.

Performance Characteristics

DeepRESP has undergone clinical validation using retrospective, manually scored polysomnography (PSG) recordings from accredited sleep centers. The device has been evaluated for its ability to automatically score sleep stages, respiratory events, arousals, and derived respiratory parameters such as the AHI and CAHI.

The performance of DeepRESP was assessed by comparing its automated scoring to scoring performed by qualified and experienced sleep technologists following the American Academy of Sleep Medicine (AASM) guidelines. The validation dataset included recordings collected in routine clinical practice from a demographically and clinically diverse adult population.

DeepRESP demonstrated performance consistent with, or within the expected range of, human inter-scorer variability for manual sleep scoring. Across all validated outputs, DeepRESP showed agreement with manual scoring that was comparable to similar marketed devices previously cleared for clinical use. For classification of sleep stages, respiratory events, arousals, and sleep apnea severity thresholds, DeepRESP met predefined clinical performance criteria.

Security Information

- For operational support (e.g., clarification of system messages, website accessibility etc.), or in case of cybersecurity events, or other type of events, please contact support@noxmedical.com.

Cloud Environment

DeepRESP is an API-centric, cloud-based software system that automates the analysis of sleep study data using a serverless AWS infrastructure. The operating environment has the following certifications:

- ISO-27001
- SOC2
- HITRUST

Data at Rest

All API processing results are encrypted at rest. All processing results stored in Amazon S3 are encrypted using Server-Side Encryption with Amazon S3-managed keys.

Data in Transit

All data is transferred using encrypted endpoints (on port 443). No non-encrypted endpoints are provided for data communication.

The endpoint encryption uses TLS 1.2 and only clients supporting that level of encryption are supported.

Backups

No data is permanently stored in DeepRESP. Therefore, no backup strategy is needed or implemented in the operating environment.

System Monitoring

Best practices for system monitoring are employed to ensure the security and stability of the system. AWS Inspector, CloudWatch and CloudTrail are used to monitor the systems for vulnerabilities, unusual activities and performance issues. Wazuh is used to monitor the logs for unusual activities or unauthorized file system changes. All these systems can generate alerts and block potentially threatening IP addresses.

Intrusion Detection and Prevention

To ensure that unauthorized people and services do not gain access to the platform, a number of intrusion detection and prevention measures have been implemented.

Log files are monitored to detect and prevent brute force attacks. Log files are also monitored to detect multiple failed attempts to try to access the system and then block the IP of the calling system when this occurs.

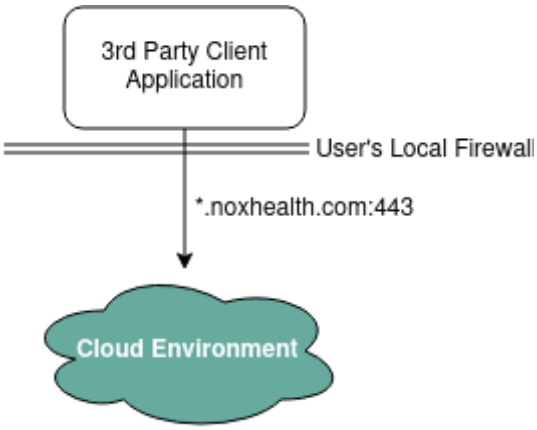
Reporting

In case of a security event is detected that has an impact on the security of the system or data, users are notified via Nox Medical's Customer Relationship Process (SOP-0004)[1].

Client Environment

DeepRESP is an API-centric, cloud-based software system that automates the analysis of sleep study data using a serverless AWS infrastructure. DeepRESP operates without a graphical user interface (GUI). It therefore integrates with third-party clients for data processing and result dissemination, relying on these systems for visualization and reporting.

The user accesses the medical device through a Client Application (third-party system). The following diagram illustrates the security ecosystem of the medical device from a user perspective:



To ensure seamless operation of the 3rd party client application access to DeepRESP, the following security measures shall be implemented by the user:

- Whitelisting of *.noxhealth.com (the asterisk means that subdomains shall be included) in the user's local firewall configuration
- Allowing outgoing traffic on port 443 to *.noxhealth.com in the user's local firewall configuration

No specific anti-malware software configuration is required for the application to operate securely and effectively.

Security Updates

All vulnerabilities notified / detected are assessed using the CVSS[2]. The score ranges between 0 and 10 and Security Updates are issued according to the following:

- CVSS 9.0-10.0: Critical – turn off service until the vulnerability has been patched.
- CVSS 7.0-8.9: High – Fix within 1 week.
- CVSS 4.0-6.9: Medium – Fix within 4 weeks.
- CVSS 0.1-3.9: Low – Fix within 8 weeks.

[1] Nox Medical operates an ISO 13485 Certified Quality Management System.
[2] The Common Vulnerability Scoring System (CVSS) is a method used to supply a qualitative measure of severity.

- CVSS 0: None – No action.

Security Updates are deployed to the Cloud Environment. This ensures that the end user is always using the latest version of the DeepRESP software.

Vulnerabilities

No vulnerabilities have been identified that can affect cybersecurity or safety of the device.

The vulnerability process used complies with the IEC 81001-5-1:2021 Health software and health IT systems safety, effectiveness, and security — Security. Activities in the product life cycle, ISO/IEC 29147:2018 Information technology — Security techniques — Vulnerability disclosure and ANSI/AAMI SW96:2023 Standards for medical device security using methods described in the AAMI TIR57:2016 guidance – Principles for medical device security.

Software Bill of Materials (SBOM)

The Software Bill of Material is provided as an IFU Addendum to this user manual. The SBOM may be maintained more regularly than the product under scope and it is therefore recommended to use the latest version when reviewing the content.

Please reach out to support@noxmedical.com for full disclosure **of the latest version** of the SBOM for the product. The SBOM is updated with every product release / patch / vulnerability detection and is available both in a human readable and a machine-readable format.

Description of Abbreviations and Symbols

AHI	Apnea-Hypopnea Index (AHI)
API	Application Programming Interface
AASM	American Academy of Sleep Medicine
CAHI	Central Apnea-Hypopnea Index
EEG	Electroencephalogram
EMG	Electromyogram
EOG	Electrooculogram
HSAT	Home Sleep Apnea Test
NREM	Non-Rapid Eye Movement sleep
PSG	Polysomnography
REM	Rapid Eye Movement sleep
SaMD	Software as a Medical Device
EMR	Electronic Medical Record
CE 2797	CE marking indicating conformance to the applicable EU regulations.
MD	Medical Device
(01) 15694311112129 (8012)VVvvrr	Unique Device Identifier (UDI): the Application Identifier (01) indicates the device identifier (DI) (i.e. “15694311112129”), the Application Identifier (8012) indicates the software version (i.e. “VVvvrr”)

About

The Instructions for Use and associated translations are available in electronic format on Nox Medical’s website: www.noxmedical.com/ifu. Note: A pdf reader is required to open the electronic file.

Hard copies can be requested at no additional cost by emailing support@noxmedical.com. The hard copy will be sent within 7 calendar days.