noxturnal® - Web

Instructions for Use

English

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Intended Use

Noxturnal Web is intended as an aid in diagnosis of sleep disorders. Its main purpose is to allow for the display, and manual analysis/scoring, of the sleep study data recorded by Nox Medical devices. Additionally, it allows for the navigation, organization, reporting and interpretation of sleep study data/recordings.

Indications for Use

Noxturnal Web allows for review of physiological signals, which can aid healthcare professionals in the diagnosis of sleep disorders. Additionally, Noxturnal Web allows for analysis and interpretation of physiological signals recorded during sleep and wakefulness tests, which further aids healthcare professionals in diagnosing sleep disorders.

Patient Population

Patients over 2 years who are undergoing physiological measurements as part of a sleep or wakefulness test requested by a healthcare professional.

Intended Users

The 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 the Noxturnal Web is that it aids healthcare professionals in reviewing and interpreting sleep studies, which they can then use in the process of diagnosing sleep disorders. The device therefore provides an indirect benefit through a positive impact on patient management by facilitating the diagnostic process.

Information for Safety

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 and to your national authority.

Noxturnal Web Description

Noxturnal Web is a web-based software that can be utilized to screen various sleep and respiratory-related sleep disorders. The users of Noxturnal Web are medical professionals who have received training in the areas of hospital/clinical procedures, physiological monitoring of human subjects, or sleep disorder investigation. Users can input a sleep study recording stored on the cloud (electronic medical record repository) using their

established credentials. Once the sleep study data has been retrieved, the Noxturnal Web software can be used to display, manually analyze, generate reports and print the pre-recorded physiological signals.

Noxturnal Web is used to read sleep study data for the display, analysis, summarization, and retrieval of physiological parameters recorded during sleep and awake. Noxturnal Web facilitates a user to review or manually score a sleep study either before the initiation of treatment or during the treatment follow-up for various sleep and respiratory-related sleep disorders.

Noxturnal Web presents information from the input sleep study data in an organized layout. Multiple visualization layouts (e.g., Study Overview, Respiratory Signal Sheet, etc.) are available to allow the users to optimize the visualization of key data components. The reports generated by Noxturnal Web allow the inclusion of custom user comments, and these reports can then be viewed on the screen and/or printed.
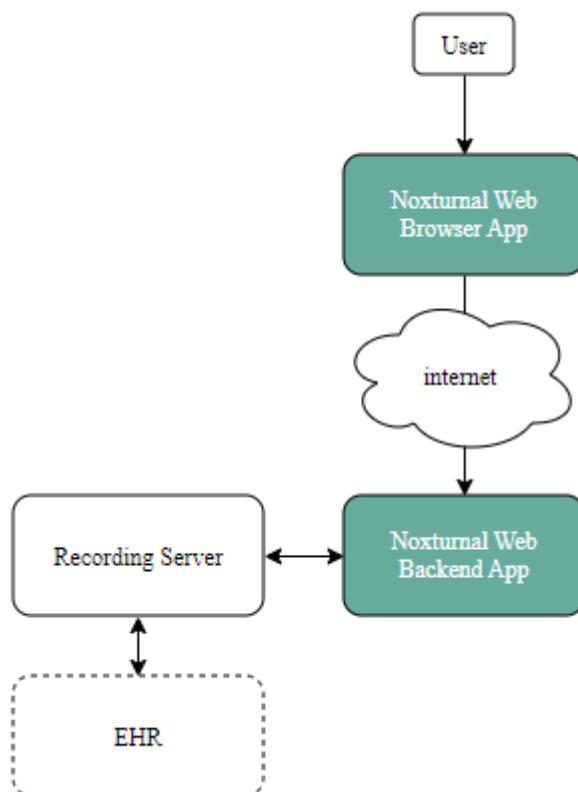
Noxturnal Web can utilize a link to access the selected sleep study via the cloud resident module entitled 'Recording Server'. The selected sleep study may have undergone analysis using external software. Additionally, it is possible to view sleep studies that have not undergone analysis prior to manual scoring in Noxturnal Web. Users can manually add/remove events or mark portions of the input signal as a signal artifact. When a sleep study is opened, Noxturnal Web displays the study details on the Study Overview page, summarizing different known information about the study on a single page.

Current Version

The current version of Noxturnal Web can be found by clicking the menu in the upper-right corner of the application window (refer to the green box in the image below):
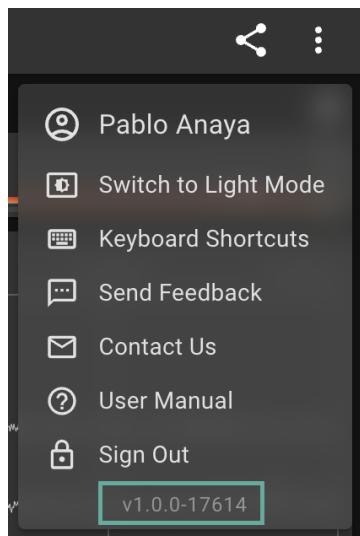
Supported Browsers

Noxturnal Web supports the following web browsers:

- Chrome version 134 and above
- Safari version 26.0 and above

No software installation is required for the use of Noxturnal Web.

Working with Recordings

Open a Recording

To open a recording, a valid link to an existing recording is required. The user needs valid credentials and permissions to access the recording.

Note: Be aware that multiple users may be permitted to access the same sleep study simultaneously.

Navigation Bar

On top of the page, the user can switch between the following sections:

- **Study Overview**
- **Respiratory Sheet**
  - Available if this section has been opened before for this recording during the current session.
- **PSG Sheet**
  - Available if this section has been opened before for this recording during the current session.
- **Custom Sheet**
  - Available if a Custom Sheet has been created during the current session.
- **Report**
 - Available if the scoring has been submitted.

Study Overview

For every recording, the recording parameters and signals are summarized on the Study Overview page.

A summary of the recording metadata such as Recording Start, Stop, and Duration is shown along with a summary of the patient information.

The density of events scored in a sleep study/combined density is displayed in the **Event Overview** as a single graph, resulting in a visual representation of the areas of potential interest within a recording/study. The event density is calculated by summing up events in each epoch. The summing is weighted to emphasize respiratory and arousal events. The possible weights with their values are high=5, medium=2, low=1, none=0. For more details on how the event types are weighted see the section **Event Types Supported**.
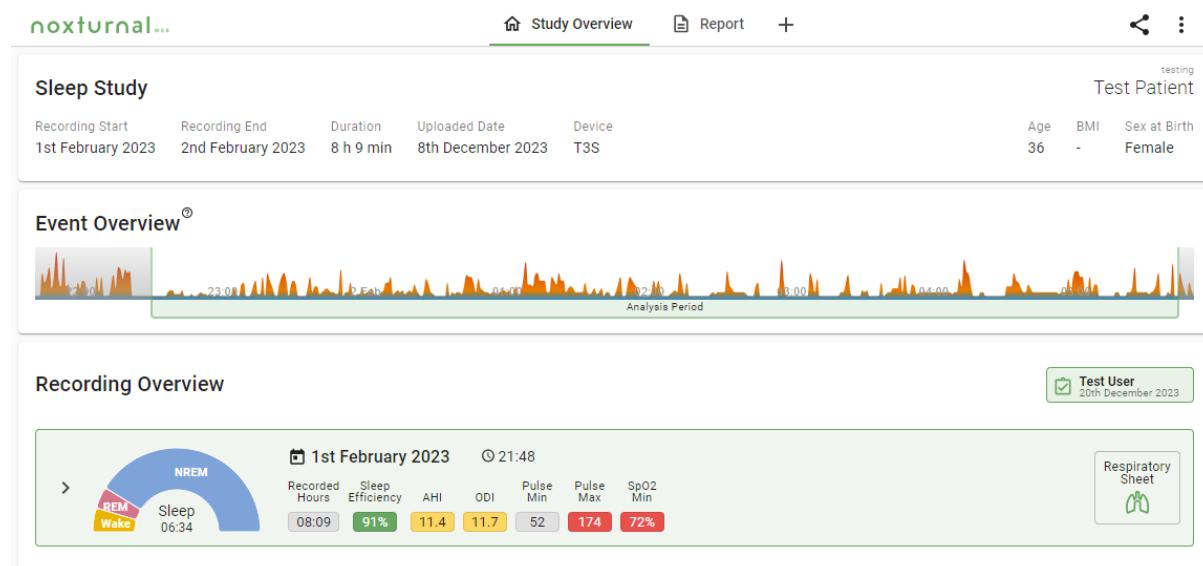
Recording Night Details

For each recording night, the start date, duration, and important parameters from the analysis are displayed. If the night contains Bio Calibration events, a BioCal indicator will be displayed. A Recording Overview can be expanded by clicking on the arrow on the left side of the row. This opens the Recording Night Detail. This detail can be collapsed by clicking the same arrow icon. When a Recording Overview is expanded, or when a recording only has one night, the Recording Night Detail is displayed by default.
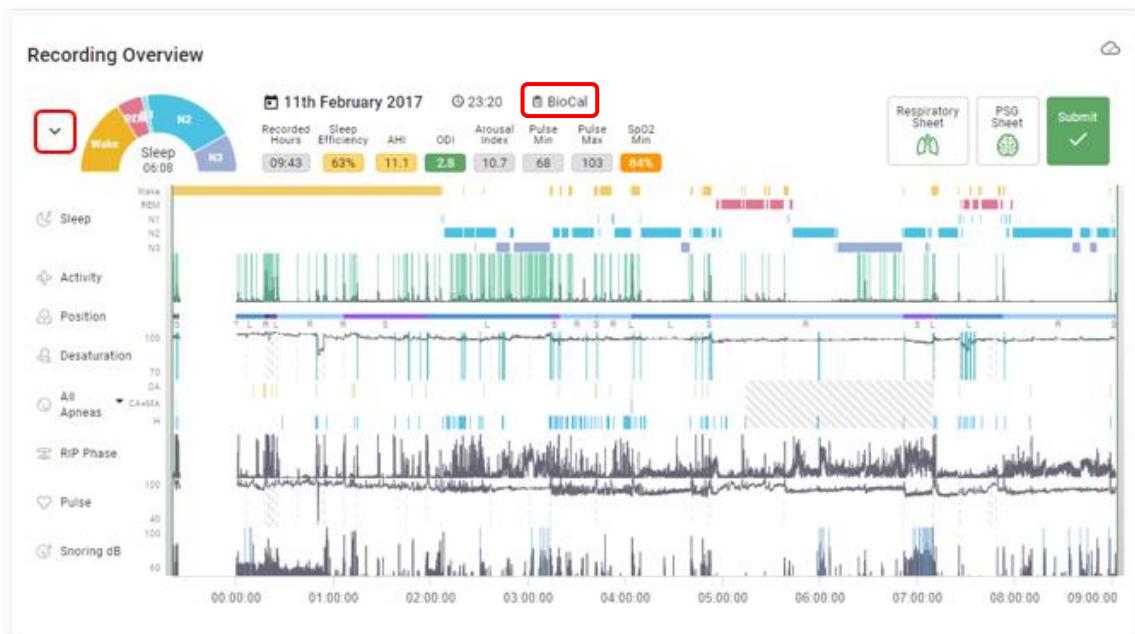
This view contains:

- **Overview Graphs:** a representation of either signals, events, or both to provide the user with a compact overview of the entire night and scoring.
    - Clicking any part of the graph allows the user to jump to the Signal Sheets to the exact clicked location in the recording.
- **Analysis Periods:** Vertical lines over the graphs represent the Analysis Start and Analysis Stop edges of the Analysis Period. These lines can be dragged to change the size of the Analysis Period. Changing the Analysis Start/Stop will trigger a recalculation of the stats values for the night, as applicable.

Recording Night Actions

Each recording night on the Study Overview page has buttons for the following actions:

- **Respiratory Sheet:** Open the Respiratory Sheet for the corresponding night.
- **PSG Sheet:** Open the PSG Sheet for the corresponding night (only displayed if the recording contains the required ExG signals)
- **Submit Night:** A night can be submitted for interpretation after the scoring has been completed. Once submitted, the report can be accessed from the Navigation Bar. After a recording has been submitted, the recording enters view-only mode and cannot be edited.
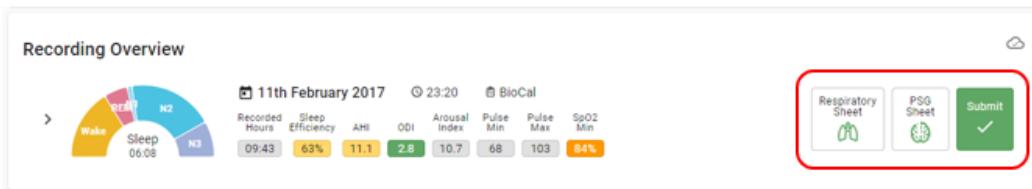

Sheet Workspace

The user workspace is comprised of a Signal Sheet showing the signals and any scored events where events can be edited, scored, or deleted along with tools available to the user to facilitate analysis and scoring.

All work in the Signal Sheet is automatically saved. This is indicated by a cloud icon in the top right corner of the workspace. In case of network drop out, the changes are temporally saved in the browser memory and will be uploaded automatically as soon as the connection is restored. Do not close the tab until the cloud icon confirms the changes have been saved successfully.

Split View

If more than one Signal Sheet tab is present in the Navigation Bar, a split view can be created to simultaneously display two of them. There are two possible layouts for Split Views: horizontal and vertical. To create a Split View, follow these instructions:

1. Open one of the signal sheets.
2. Once a signal sheet is open and visible on the screen, locate the button for the other signal sheet, which is intended to be displayed simultaneously, in the Navigation Bar.
3. Drag the button for the second signal sheet to the desired location; the left, right, bottom, or top of the opened signal sheet.
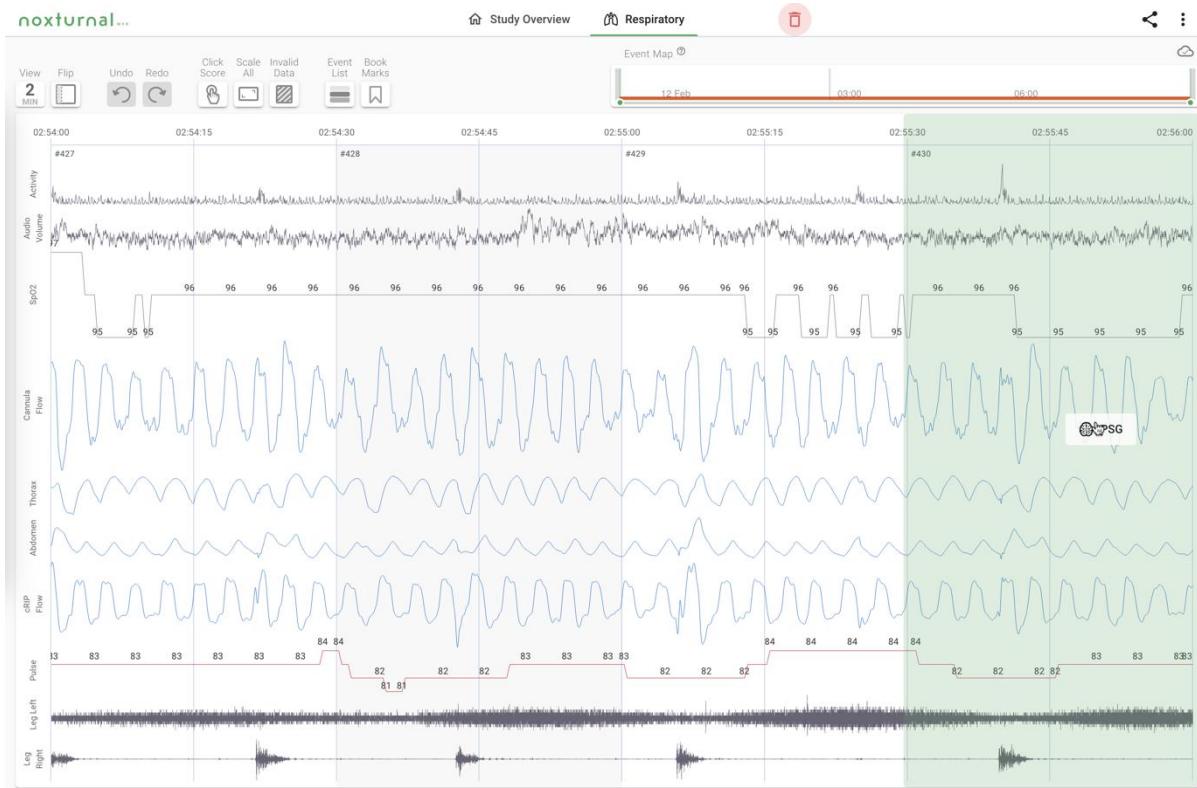
To separate the signal sheets that constitute the Split View, drag the split view button from the Navigation Bar to the side, over the scissor's icon. Upon releasing the button, the Split View will be separated and both signal sheets will be available again in the Navigation Bar for independent viewing.
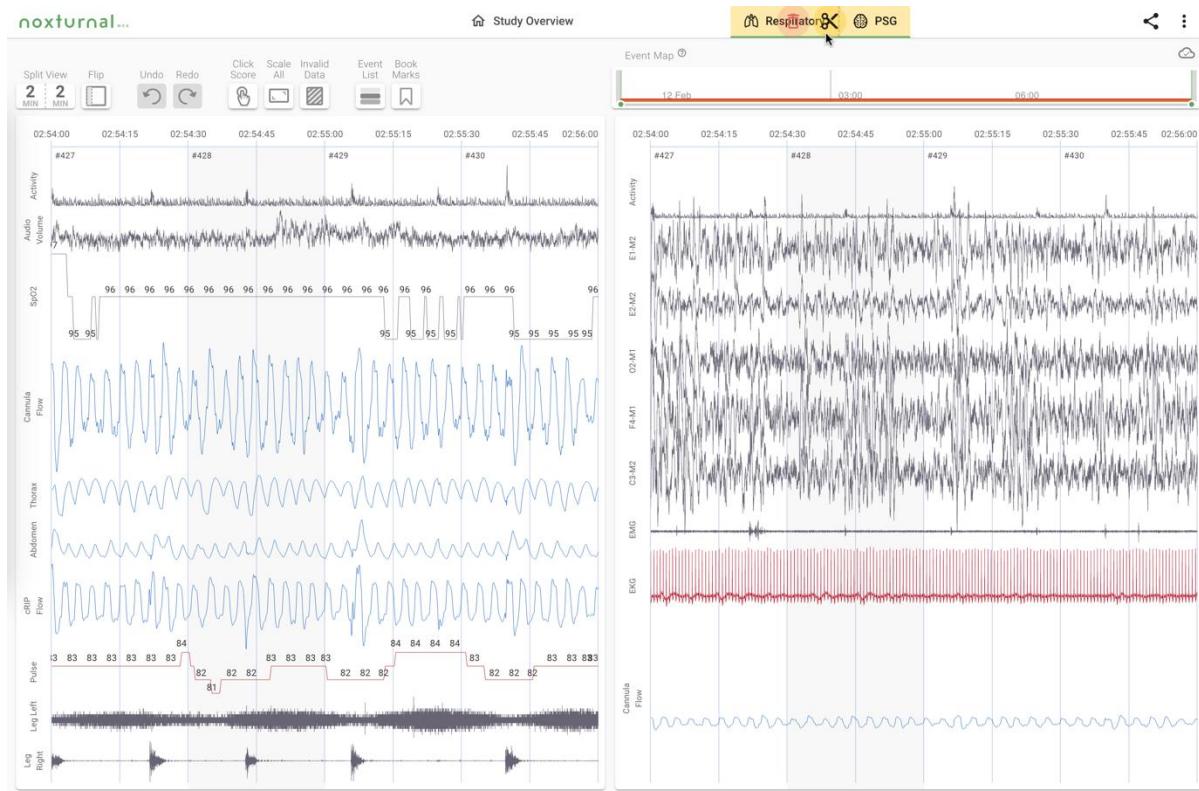
Toolbar

The toolbar on top of the signal sheets contains the following tools:

- **View:** sets the time-range displayed in the window. Available options are:
  - 30 seconds
  - 1 minute
  - 2 minutes (default option)
  - 5 minutes
  - 10 minutes
- **Page Flip Tool:** sets the page flip range when scrolling or navigating with arrow buttons:
  - Epoch (default option - flips one epoch at a time)
  - Half (flips half of the displayed time-range at a time)
  - Full (flips the entire displayed time-range at a time)
- **Undo/Redo Buttons:** used to undo or redo scoring actions performed on the Signal Sheet.
- **Single Click Scoring:** used to enable/disable Single Click Scoring on the Signal Sheet, scores an event of the same type and duration as the last scored event on the clicked signal.
- **Scale all:** scales all signals to fit the space allocated to them.
- **Invalid Data**: used to mark areas of the recording as "Invalid" and, therefore, exclude them from the final sleep parameter calculation.
- **Event List:** displays all events on the recording in a filterable list. Clicking on an event in the list jumps to that location in the recording.
- **Event Map:** displays the density of the events per epoch. The areas of potential interest within the map may be navigated by clicking the desired area.
  - **Navigator Timeline:** Below the Event Map, each dot indicates a point of interest in the recording.
    - Analysis Start (in green)

- ▪ Analysis Stop (in green)
- ▪ High Density area, high sum of weighted events
- ▪ Start of the night
- ▪ End of the night
- ▪ Longest Apnea
- ▪ Highest Desaturation drop
- ▪ Scoring Suggestions in review

Signal Sheet

*Respiratory Signal Sheet* contains the following signals in the default order of:

- ● **Activity** (Activity-Gravity)
- ● **Audio Volume** (Snore.Envelope-Audio.dB)
- ● **SpO2** (SpO2.Averaged-Probe)
- ● **Cannula Flow** (Resp.Flow-Cannula.Nasal)
  - ○ If the *Cannula Flow* signal is not available on the recording, it will attempt to display one of the following alternative signals:
    - ▪ Resp.Pressure-Raw.Mask
    - ▪ Resp.FlowTemp-Thermistor.NasalOral
    - ▪ Resp.FlowTemp-Thermocouple.NasalOral
    - ▪ Resp.Flow-RIP
- ● **Thorax** (Resp.Movement-Inductive.Thorax)
- ● **Abdomen** (Resp.Movement-Inductive.Abdomen)
- ● **cRIP** (Resp.FlowCal-RIP)
- ● **Pulse** (HeartRate-ECG)
  - ○ If the HeartRate-ECG signal is not available on the recording, it will attempt to display the following alternative signal:
    - ▪ Pulse.Averaged-Probe
- ● If leg signals are available, it will attempt to display:
  - ○ **Both Legs** (EMG.Tibialis-Leg)
  - ○ **Left Leg** (EMG.Tibialis-Leg.Left)
  - ○ **Right Leg** (EMG.Tibialis-Leg.Right)

PSG Sheet contains the following signals in the default order of:

- ● **Activity** (Activity-Gravity)
- ● **E1-M2** (EOG-E1-M2)
- ● **E2-M2** (EOG-E2-M2)
- ● **O2-M1** (EEG-O2-M1)
- ● **F4-M1** (EEG-F4-M1)
- ● **C3-M2** (EEG-C3-M2)
- ● **EMG** (EMG.Submental-1-2)
- ● **ECG** (ECG)
  - ○ If the *ECG* is not available on the recording, it will try to show an alternative signal:
    - ▪ EKG
- ● **Cannula Flow** (Resp.Flow-Cannula.Nasal)

- If the *Cannula Flow* signal is not available on the recording, it will attempt to display one of the following alternative signals:
  - Resp.Pressure-Raw.Mask
  - Resp.FlowTemp-Thermistor.NasalOral
  - Resp.FlowTemp-Thermocouple.NasalOral
  - Resp.Flow-RIP

A ***Custom Sheet*** can be created for the recording. From the Navigation Bar on top of the page, click on the "plus" button and navigate to Custom Sheet.
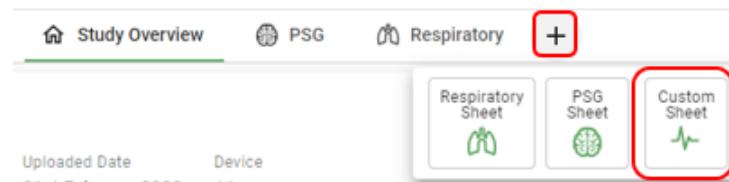

Select from the list of signals which signals to include in the desired order. Click "Create". A new Custom Sheet will then appear on the Navigation Bar, displaying the previously selected signals.

Signal Options

The ***Signal Options Menu*** is accessed by clicking the signal title in a Signal Sheet. The menu contains the following options:

- **Scale to fit (F9):** scales the signal to fit the allocated height
- **Lock/Unlock Scaling:** locks scaling for the selected signal
- **Enlarge:** allocates more height to signal in the Signal Sheet
- **Expand:** fits the selected signal into the entire height of the Signal Sheet
- **Compress:** reduces the allocated height of the signal
- For ExG signals**:** displays **signal filtering information**
  - **Bandpass Filter**
  - **ECG artifacts Filter:** allows turning on/off
  - **Powerline Filter**: allows adjusting and turning on/off
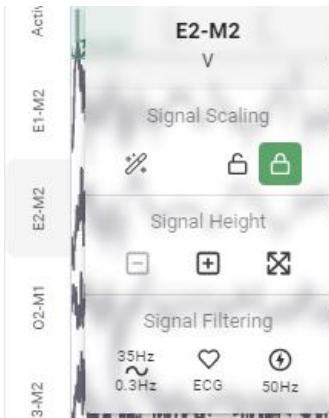
The **order of the signals** can be changed for the selected Signal Sheet in the Signal Options Menu. Click and drag the signal title button to the desired location.

The Signal Options Menu can also be opened by right-clicking the desired signal. From there, additional options can be accessed:

- Enable/Disable Single Click Scoring
- Add Scoring Note: add scoring notes to the selected locations. The notes can be edited and deleted by double-clicking the note
- Move Analysis Start/Stop to that location
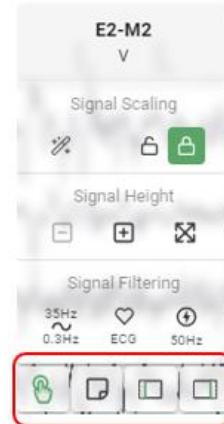
Navigation

- Zoom in: **+**
- Zoom out: **-**
- Move forwards: **→**
- Move backwards: **←**
- Move forward/backward: **Scroll mouse wheel**
- Move a full page back: **Ctrl + ⇧ + ← or PageUp**
- Move a full page forward: **Ctrl + ⇧ + → or PageDown**
- Select previous epoch: **⇧ + ←**
- Select next epoch: **⇧ + →**
- Jump to start: **Home**
- Jump to end: **End**

Other Keyboard Shortcuts

- Undo action: **Ctrl + Z**
- Redo action: **Ctrl + Y or Ctrl + ⇧ + Z**
- Delete event (while the event detail popup is open): **Delete** or **Backspace**
- Delete event: **Alt + Left-Click**
- Add Wake sleep stage (selected epoch): **0**
- Add N1 sleep stage (selected epoch): **1**
- Add N2 sleep stage (selected epoch): **2**
- Add N3 sleep stage (selected epoch): **3**
- Add REM sleep stage (selected epoch): **5**
- Add NREM sleep stage (selected epoch): **8**
- Score note (hovering the signal sheet): **F12**
- Scale to fit all signals: **Alt + F9**
- Scale to fit (hovering the signal): **F9**

Scoring

- **View the event details** by clicking on the event. This will open the Event Detail Popup.
- **To Delete a selected event:** press the keyboard Delete or Backspace button or click on the trash can icon on the Event Detail Popup after clicking the event.
- **Delete** an event by holding Alt and clicking on the event
- **Score** an event by holding down the left mouse button and dragging to the desired size and releasing
- **Change the type** of a scored event by clicking on it to open the Event Detail Popup and clicking the arrow up/down button, or by striking the shortcut key on the keyboard (see Events for a list of shortcuts)
- **Move** an event by dragging it using the left mouse button

Events

The following events can be scored using Noxturnal Web (where applicable, respective keyboard shortcuts are displayed in brackets):

- **Artifact (x)** on:
  - *all signals*

- **Movement (m)** on:
  - *Activity signal*
- **Single Snore** and **Snore Train (s)** on:
  - *Audio Volume signal*
- **Desaturation (d)** on:
  - *SpO2 signal*
- **Apnea (a), Obstructive Apnea (o), Mixed Apnea (m), Central Apnea (c)** and **Hypopnea (h)** on the following signals:
  - *Flow signals*
  - *Thorax*
  - *Abdomen*
  - *cRIP*
- **Bradycardia (b), Tachycardia (t)** on:
  - *Heart and Pulse signals*
- **Arousal (r), Limb Movement Arousal, PLM Arousal, Respiratory Arousal, Spontaneous Arousal** on:
  - *EEG signals*
  - *EOG signals*
- **Paradoxical Breathing** on**:**
  - *RIP Phase*
- **PLM, Limb Movement Twitch** on**:**
  - *Leg signals*
- **Invalid Signal** on**:**
  - *All signals*

If the recording contains Bio Calibration events, the BioCal events are displayed as Notes on the signal sheet at the timestamp they were created.

Event Detail Popup

Open the Event Detail Popup by clicking the event. The popup displays the following event details:

- Event **Time and duration**
- Event **Epoch location**
- Information about the source of the event
- **Time and date** when the event was scored
- If event has been **modified**, by who and when
- Suggested markers show **who approved** the suggestion
- Button for **deleting the event** *(trash can)*
- Button for **changing the event type** *(arrows up and down)*
- Button for **closing the Event Detail Popup** *(X)*

Scoring Suggestions

Scoring Suggestions are presented in Noxturnal Web after importing data when previously scored events are found on the RIP flow signal which are not present on the Cannula flow signal. Events on the RIP flow signal are presented as suggestions if they do not overlap events with the same type on the Cannula flow signal, i.e. are missing. This comparison feature can be useful in cases when the nasal pressure cannula has fallen off the patient during a study (i.e. resulting in a flat cannula signal). Suggestions are presented using an explanatory text in the Study Overview and in the signal sheets. Users verify whether the suggested events should be included in the scoring of the sleep study or not. Scoring suggestions are not considered for calculating any sleep parameters.
**Note:**

1) Sleep scoring suggestions are advisory and must be accepted to be integrated into the final scoring.
2) Scoring Suggestions are designed to assist clinicians in reviewing patient data.

In the *Study Overview*, different options can be chosen to handle the suggested scoring markers:
- Review: Marks all suggestions for review and prevents the scoring from being submitted until all suggestions have been either approved or rejected. Suggestions in Review also appear in the Event Map as blue dots.
- Accept All: Turns all scoring suggestions into scored markers and updates the sleep parameters.
- Reject All: Deletes all scoring suggestions and they will not be suggested again.
- Revert: Undo the last operation with the scoring suggestions.
- Jump to Next: When suggestions are in review mode, this button will navigate the user to the next suggestion in the Signal Sheets.
- Accept Remaining: When suggestions are in review mode, this action will mark all remaining suggestions as accepted.
- Reject Remaining: When suggestions are in review mode, using this button will delete all pending suggestions.
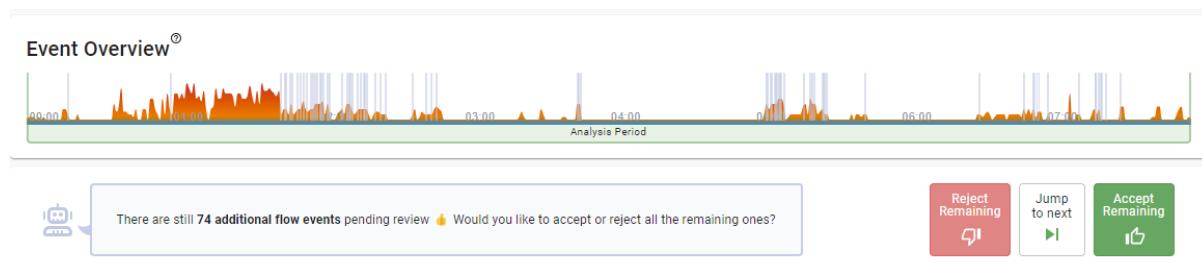
On the *Signal Sheets*, Scoring Suggestions are displayed in a distinctive style with a blueprint-like background.

Scoring Suggestion

Scored Marker
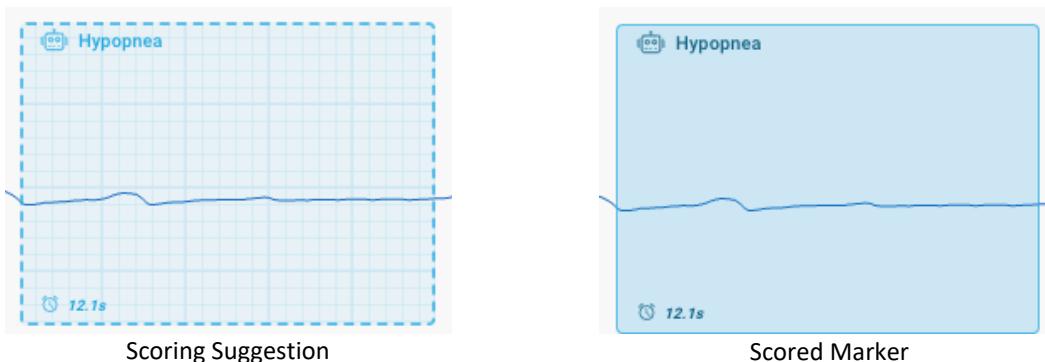
When reviewing scoring suggestions on the Signal Sheet there are two main options: Accept and Reject. To accept a suggestion, hover over the suggestion until a *"thumbs up"* icon appears and click on it.
To reject a suggestion, hover over the suggestion whilst keeping the ALT key pressed, until a *"thumbs down"* icon appears and click on it.

Accept Scoring Suggestion

Reject Scoring Suggestion
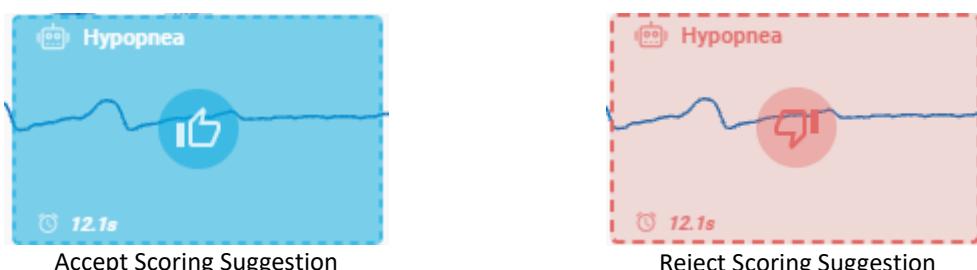
Right-clicking on a suggestion opens the **Marker Right Click Popup**. This menu offers several options:

- **Accept Suggestion:** Turns the suggestion into a scored marker.
- **Reject Suggestion:** Deletes the suggested marker.
- **Change marker type:** List of possible marker types that, when clicked, turns the suggestion into a scored marker of such type.
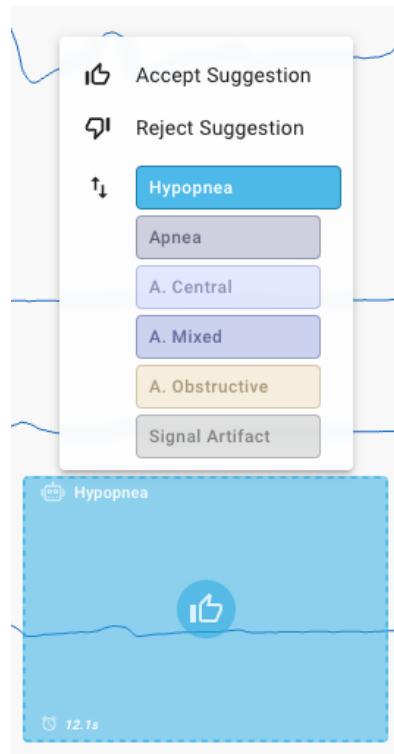

Analysis Start and Stop (Signal Sheets)

When a signal sheet is open, the Analysis Start and Stop of the recording can be moved. This can be done by dragging the edges to the new desired location.

To find the position of the edges on the recording, there are two main options:

- On the *Navigator Timeline*, click on the green dots. The first dot is the Analysis Start, and the second dot is the Analysis Stop.
- In the *Event Viewer*, filter by Analysis Periods. Clicking in either of them, the view will move the selected epoch to the position where the Analysis Period edge is located.

Share Study

A recording can be shared with a link or QR code. Click the "Share" button in the top right corner.

A specific section can be selected to direct the user to a desired location in the recording, e.g., to a specific Epoch on a signal sheet. Select the section, the Study Overview or other desired location, then choose how to share the study, either "Copy to Clipboard" or "See QR Code".

Study Report

Once a recording night has been submitted, a Study Report becomes available from the Navigation Bar.

The report includes different sections to summarize the recording and the scoring:

- Recording information
- Scoring information
- Subject information
- Scoring Stats (AHI, ODI, etc.)
- Sleep Stages information (if available)
- Overview Graphs
- Comments
  - View comments
  - Add comments
- Parameters list
  - Available metadata is presented in a list, such as the Patient Name, Patient Age, etc. (includes a search box to search by name and values)

The Study Report also contains a **Print** button. This will generate a report in a printable format that can be saved to the computer.

Closing the Recording

All changes made to the recording are automatically saved. The browser tab can be closed at any time and the user may resume by opening the same link used to access the recording.

Event Types Supported

The supported event types and Event Overview/Map weighting of event types is demonstrated in the table below. The possible weights with their values are high=5, medium=2, low=1, none=0.

Event Type	Density Weight	Description
sleep-wake	None	Sleep stage wake
sleep-rem	None	Sleep stage REM
sleep-nrem	None	Sleep stage Non-REM
sleep-n1	None	Sleep stage N1
sleep-n2	None	Sleep stage N2
sleep-n3	None	Sleep stage N3
position-upright	None	Position upright
position-supine	None	Position supine
position-left	None	Position left
position-right	None	Position right
position-prone	None	Position prone
position-unknown	None	Position unknown

apnea	None	Apnea event
apnea-obstructive	High	Obstructive apnea event
apnea-mixed	Low	Mixed apnea event
apnea-central	High	Central apnea event
technician-biocal	None	Biocalibration event
technician-note	None	Technicians note
hypopnea	Medium	Hypopnea
oxygensaturation-drop	Medium	Drop in SpO2
activity-movement	None	Movement event
snorebreath	None	Single snore event
snore-train	Low	Snore train event
arrhythmia-tachycardia	Medium	Tachycardia event
arrhythmia-bradycardia	High	Bradycardia event
signal-artifact	None	Signal artifact
breathing-paradoxical	Low	Paradoxical breathing event
limbmovement-twitch	None	Limb movement twitch
limbmovement-periodictwitch	None	Periodic limb movement twitch
Plm	None	Periodic limb movement
arousal	Medium	Generic arousal
arousal-limbmovement	Medium	Arousal caused by limb movement
arousal-plm	Medium	Arousal caused by PLM
arousal-respiratory	Medium	Arousal caused by a respiratory event
arousal-spontaneous	Medium	Generic arousal
signal-invalid	None	Invalid signal

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.

Security Information

- Please update your browser to the latest available version.
- 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

The device is a Web Application and operates on a Nox Medical proprietary cloud infrastructure (Nox Cloud). The operating environment has the following certifications:

- ISO-27001
- SOC2
- HITRUST

Data at Rest

All drives that store Nox Cloud platform data are encrypted, including database fields. The encryption used is an industry standard AES-256 data encryption.

Data in Transit

All data is transferred using encrypted endpoints (on port 443). No non-encrypted endpoints are provided for data communication. Users accessing port 80 are redirected automatically to port 443.

The endpoint encryption uses TLS 1.2 and only browsers supporting that level of encryption are supported. The connection is encrypted using 256-bit encryption. SHA1 is used for message authentication and DHE_RSA as the key exchange mechanism.

Backups

All data is backed up both fully and incrementally. Incremental backups are performed daily, weekly and monthly with full recovery at least annually. Backups are tested at regular intervals to ensure successful recovery of data.

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].

User Environment

The user accesses the medical device using a browser application, listed in the Supported Browser section. The following diagram explains the security ecosystem of the medical device from a user perspective:
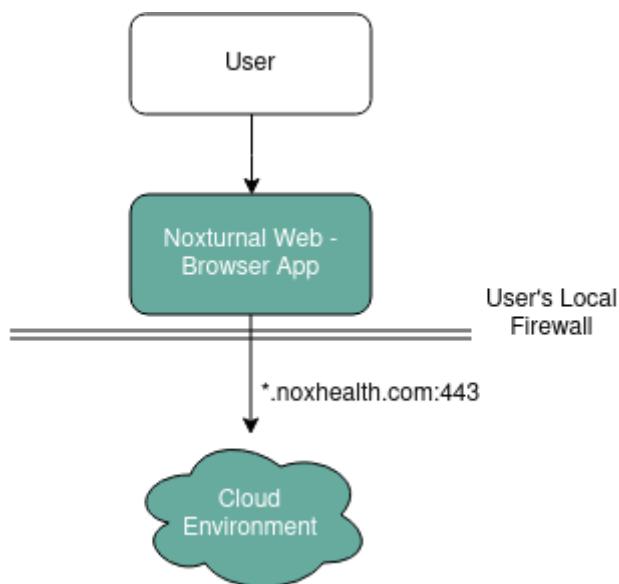
To ensure seamless operation of the Noxturnal Web, the following security measures shall be implemented by the user:

- 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.

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[1] Nox Medical operates an ISO 13485 Certified Quality Management System.

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 2 days.
- CVSS 4.0-6.9: Medium – Fix within 1 week.
- CVSS 0.1-3.9: Low – Fix within 4 weeks.
- 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 Noxturnal Web – Browser App as by design it is automatically downloaded as soon as it becomes available.

Vulnerabilities

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

The vulnerability process used complies with the ANSI/AAMI SW96:2023 Standard 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 Software Bill of Material for the product. The Software Bill of Material is updated with every product release / patch / vulnerability detection and is available both in a human readable and a machine-readable format.

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[2] The Common Vulnerability Scoring System (CVSS) is a method used to supply a qualitative measure of severity.

Description of Abbreviations and Symbols

PSG	Polysomnography
ExG	Term that refers to different types of measurements of the electrical activity of the body, such as the brain (EEG), the muscles (EMG), the heart (ECG or EKG), or the eyes (EOG)
EMG	Electromyography
ECG	Electrocardiogram
PLM	Periodic Limb Movement
AHI	Apnea Hypopnea Index
ODI	Oxygen Desaturation Index
EHR	Electronic Health Record
[symbol: operating instructions]	Operating instructions / Consult instructions for use
MD	Medical Device
CE 2797	CE marking indicating conformance to the applicable EU regulations.
(01)15694311112075 (8012)VVvvrr	Unique Device Identifier (UDI): the Application Identifier (01) indicates the device identifier (DI) (i.e. "15694311112075"), 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.