nox medical

noxturnal

US

MANUAL

Noxturnal US Manual

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Contents

Introduction

Congratulations on choosing the Noxturnal® US application software. The Noxturnal US software is a modern sleep diagnostics software platform designed for ease-of-use and operation efficiency. The Noxturnal US software is an essential part of the Nox Sleep System. Its main function is to work with physiological signals recorded/received using devices from Nox Medical (see Supported Devices chapter) and their linked devices and accessories. It takes the user through the workflow of configuring recordings, downloading data, analyzing and reporting.

Intended Use

The Nox Sleep System is used as an aid in the diagnosis of different sleep disorders and for the assessment of sleep.

The Nox Sleep System is used to measure, record, display, organize, analyze, summarize, and retrieve physiological parameters during sleep and wake.

The Nox Sleep System allows the user to decide on the complexity of the study by varying the number and types of physiological signals measured.

The Nox Sleep System allows for generation of user/pre-defined reports based on subject´s data.

The user of the Nox Sleep System are medical professionals who have received training in the areas of hospital/clinical procedures, physiological monitoring of human subjects, or sleep disorder investigation.

The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including patient's home.

Contraindications

The Nox Sleep System does not provide any alarms and is not intended to be used for continuous monitoring where failure to operate can cause injuries or death of the patient.

Scope

This manual covers the use of the Noxturnal US software. The use of the Nox devices and their accessories that are needed for the recording of physiological signals are covered in:

- Nox A1 US Manual
- Nox A1s US Manual
- Nox C1 US Manual
- Nox T3 US Manual
- Nox T3s US Manual

This manual also includes a short introduction about the Noxturnal App and its features.

Warnings and Cautions for Use

- Warning: The Nox Sleep System is **NOT CERTIFIED TO BE USED FOR CONTINUOUS MONITORING** where failure to operate can cause injuries or death of the patient.
- Warning: The Nox Sleep System is intended as an aid in diagnosis of sleep disorders. The system must be used in conjunction with other methods of assessing clinical signs and symptoms.
- Note: 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.
- Warning: Derived signals calculated by Noxturnal US, 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.
- Caution: U.S. federal law restricts this device to sale by, or on the order of, a physician.
- Warning: The Nox A1, Nox A1s, T3 and T3s Recorders shall under no circumstances be connected to the USB port on the PC while applied to the patient. This could result in electroshock to the patient and serious harm.

- Please read this manual carefully before use, especially sections marked with an exclamation mark.

Noxturnal US Description

The Noxturnal US software interacts with Nox Recording Devices and Nox Access Points. It allows the configuration of the devices as well as: displaying, navigating, organizing, analyzing, reporting, archiving and retrieving physiological signals recorded/received by use of the Nox devices. This section describes the main features of the application and installation instructions.

Noxturnal App Description

The Noxturnal App is an Android application that is used as a mobile interface to Nox A1 Recorders and Nox C1 Access Points. The app allows the user to perform certain tasks already known in the Noxturnal US software with more flexibility and proximity to the patient.
The App features include:

- Configure ambulatory recordings
- Connect to online rooms that have been configured in Noxturnal US
- Review signal quality
- Perform impedance check
- Perform bio calibration
- Start and stop recordings
- View status of online recordings (Recording, Standby, Not Prepared)

NOXTURNAL APP

Scan this **QR code** with your mobile device for easy access to the app. You can also search for "*Noxturnal*" in the **Google Play Store**.

To download the app, scan the QR code above or search for "*Noxturnal*" in the Google Play Store. The app runs on mobile devices running Android 8.0 or higher.

INTERFACES

The Noxturnal App uses wireless Bluetooth technology (Classic and/or BLE) for establishing communications with the following devices:

- Nox A1 Recorder
- Nox A1s Recorder
- Nox C1 Access Point
- Nox T3 Recorder
- Nox T3s Recorder

The devices support pin code configuration for authentication purposes. When enabled, the Noxturnal App will prompt the user to enter the pin code. Communication is established only if a correct pin code is entered.

Supported Devices

Noxturnal US supports the following Nox devices and their linked devices and accessories:

- Nox A1 Recorder
- Nox A1s Recorder
- Nox C1 Access Point

- Nox T3 Recorder
- Nox T3s Recorder

In this manual, a Nox Recorder is used as a collective name for Nox A1, Nox A1s, Nox T3 and Nox T3s recorder.

Throughout this manual, a Nox T3 recorder and Nox T3s recorder are collectively referred to as Nox T3 recorders. Likewise, a Nox A1 recorder and Nox A1s recorder are collectively referred to as Nox A1 recorders.

Installing Noxturnal US

Before installing the Noxturnal US software, review the system requirements for running the software application.

Noxturnal US System Requirements

- Note: The computer used must comply with the international standard IEC 60950-1 for the safety of information technology equipment.
- Note: It is recommended that a virus protection be installed on the computer running Noxturnal US.

The following table shows the minimum hardware requirements needed to install and operate the software effectively.

Minimum System Requirements

Hardware Type	Minimum Requirements
Operating System	Windows 10
Processor	x64 based Intel or AMD
Processor Clock Speed	1.7 GHz or faster
Memory	2 GB or more
Free Hard Drive Space	4 GB or more
Graphics Resolution	1024x768 or higher

For online system setup, the same minimum system requirements apply as listed above. It is highly recommended to use a separate computer for each online system. However, for expert users it is possible to run more than one system on a single computer.

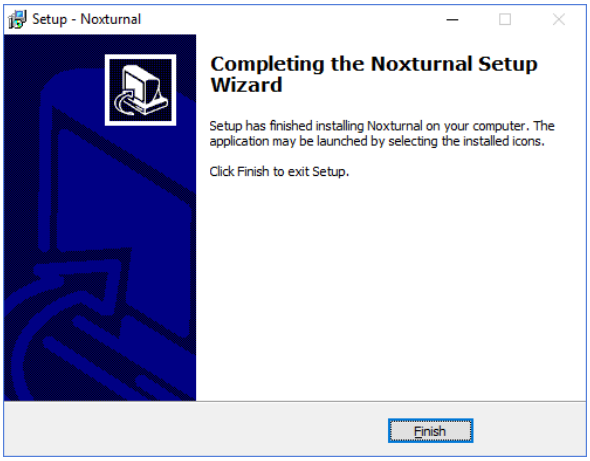
It is recommended to implement good IT practices such as:

- Control access to the PC running the system
- Enforce password policies
- Keep the PC operating system up to date
- Follow Microsoft Windows end of support dates
- Install an antivirus protection software
- Limit the usage of the PC for clinical use only
- Backup recording data location – Noxturnal US does not handle backups of data

Note: connections to external systems such as Nox Cloud, GDT, or HL7, Noxturnal US acts as a client relying on the existing system setup for security.

Installation Instructions

- Make sure to be logged onto the system with administrator privileges.
- Browse for a file on the installation CD or the installation web site called **Setup.exe** and run it.
- A wizard opens that guides the user through the installation. Follow the instructions to install the application. If upgrading from Noxturnal US 5.x, an upgrade process runs in the background. Upgrading the user application settings. A copy of the settings prior to the upgrade is stored in "[My Documents]\Noxturnal US Upgrade".



- For information about the latest software version and upgrade information, please contact your distributor. For distributor information go to: www.noxmedical.com.
- For operational support, in case of user errors, cybersecurity events or other type of events, please contact support@noxmedical.com

Standard Operation

To run the Noxturnal US Application, double-click on the desktop icon or click on the application icon in the Windows start menu. To close the application either click on the **X** in the top right corner, or on the **File** menu choose **Exit.**

When Noxturnal US starts up the workspace environment is displayed. If you have a device connected, you will see that in the picture, otherwise no device will be displayed. For the purposes of this document we have a Nox T3 Recorder connected as can be seen in the picture.

The **Recording** page is where the user works with Nox devices and the data recorded/received by use of those devices. This page guides the user through the most common tasks which are possible to perform in the application. These are:

- **Library**: In the top left corner, you will see this option. This option opens the recording library. The library stores a list of all recordings that have been recorded, downloaded or manually added to the recording library. For more information, refer to the section *The Recording Library*.
- **Configure Device**: To start a new ambulatory recording, select this option. A configuration wizard will guide the user through the configuration process. For more information, refer to the section *Starting a New Ambulatory* Recording.
- **Download Recording**: If a recording device is connected and it contains a recording, the user may download and review the recording. For more information, refer to the section *Downloading an Ambulatory Recording from a Nox Recording Device*.

To configure an online recording an online room needs to be pre-configured and it will appear in the Recording page and be selectable. For instructions on how to configure an online recording refer to the section *Setup of the Nox Sleep System for Online Recordings*.

Connecting a Nox Recording Device to Noxturnal US

- Note: Please note that although it is recommended to eject the recording device before unplugging it from the computer the device can be disconnected without ejecting.

Noxturnal US is used to configure and download recorded data from Nox recording devices. To work with a recording device, start by connecting it with a USB cable to the computer. Noxturnal US automatically detects the device and displays information about the device. Detection can take 2-4 seconds.

When Noxturnal US detects the connected device the following information about the device is displayed: **recording status, firmware version** and **device name**.

The tasks performed on the recording device depend on the device status which can be the following:

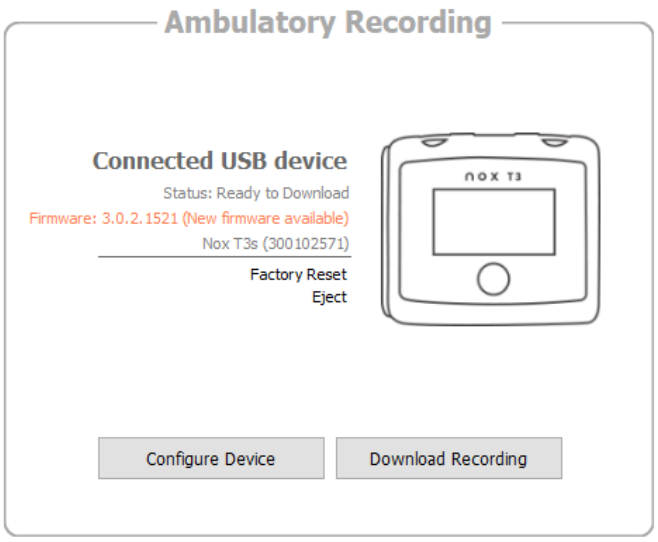
- **Empty** – The device has not been configured and does not contain any recordings. Click **Configure Device** to configure the device for a new recording. Please note that configuring the device will remove any existing recordings from the device.
- **Ready to Record** – The device has been configured but does not contain any recordings. At this point the user can disconnect the device and initiate the recording process.
- **Ready to Download** – The device contains a recording that has not been downloaded to the computer. Click on the **Download Recording** button to download the recording to the computer.
- **Download Complete** – The device contains a recording that has already been downloaded and has been added to the recording library. At this point the user can either click on **Configure Device** to configure the device for another recording or click on **Download Recording** to download the recording again.

When you are done working with the device click on the **Eject** link and unplug the device from the computer.

Upgrading the Recording Device Firmware

- Note: After clicking the upgrade firmware notification, you must disconnect the recording device from the computer and reconnect it again for a device firmware upgrade to take place.
- Note: It is always recommended to perform the device firmware upgrade to make sure the Nox recorder is running on the latest firmware version. New firmware versions can include important updates for the operation of the recorder.

If a new version of the device firmware is available for the connected device, Noxturnal US will notify the user. This behavior is device independent and you will see the type of device on this page, depending on which device you have connected. In this picture, we have a Nox T3 Recorder connected.



Choose either to ignore this message and continue working, or to upgrade the device firmware, which is always recommended. To upgrade click on the *New firmware available* and then follow the instructions presented.

Starting a New Ambulatory Recording

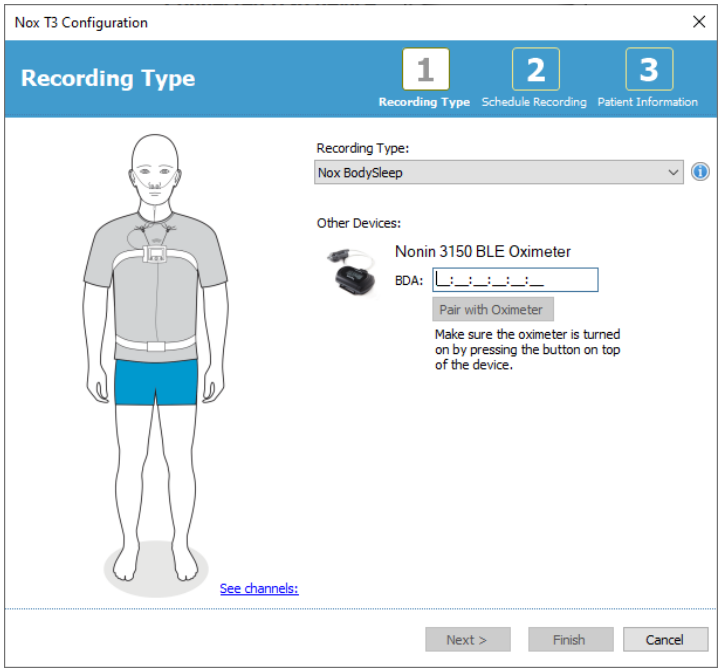
To prepare a recording device for a new recording, start the Noxturnal US Application and connect the device to the computer using a USB cable. Noxturnal US automatically detects the device and shows information about it on the **Recording** page. Click on the **Configure Device** button on the **Recording** page and a wizard opens which guides the user through the configuration process of the device.

The Configuration Wizard is device dependent. This means that the configuration wizard will vary depending on the type of Nox recording device being configured. However, the key steps are always the same:

1. **Configuration** of the device. Where you select the Recording Type to use (auxiliary devices that may be connected and channels to be recorded).
2. **Schedule Recording** where you can select the time and date for a recording to start or to have a patient start the recording themselves.
3. **Patient Information** where you add the necessary patient information to the recording.

This manual shows the configuration wizard for the Nox T3 Recorder. The first step is to define which Recording Type to use for the recording. The Recording Types have descriptive names to exhibit the recordings they are used for.

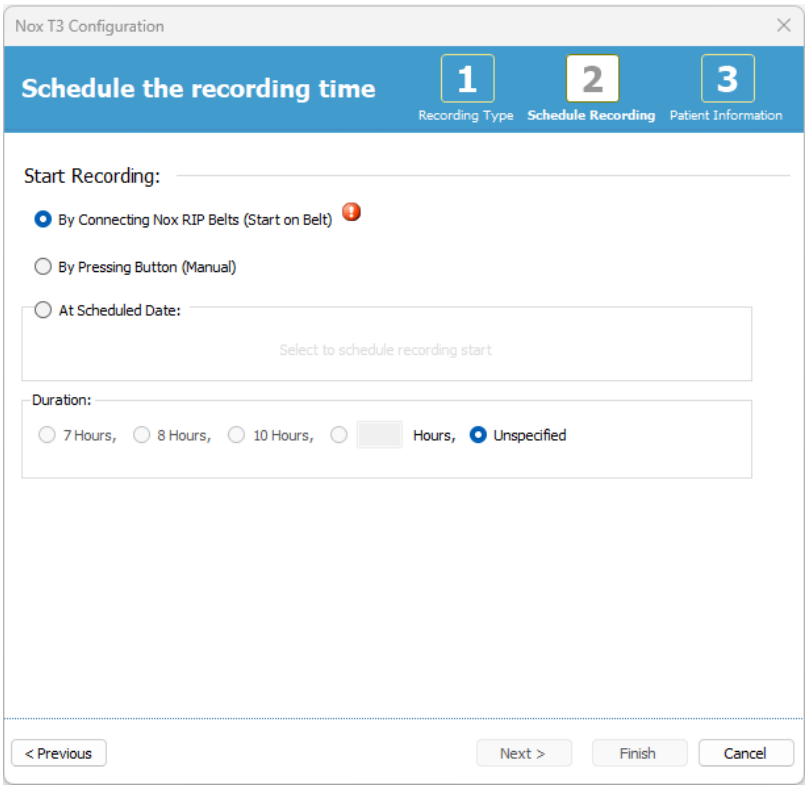
See the *Recording Types and Device Profiles* sections for more information on creating and editing recording types and device profiles.



If your Recording Type is set up to record data from an auxiliary Bluetooth device, e.g. pulse oximeter you will see that in the Configuration Wizard. To be able to use auxiliary Bluetooth device it needs to be paired to the Nox recording device. Enter the appropriate Bluetooth device Pin/BDA (Bluetooth Device Address) number in the relevant field in the Configuration Wizard.

For some devices, it is required to pair the device with the oximeter used. After entering the BDA address of the oximeter, click the **Pair with Oximeter** button and wait for the response. Note that the oximeter needs to be turned on by pressing the button of the oximeter when performing this step. Follow the instructions that appear on the screen.

Click **Next** to move on to step two where you schedule the recording time.



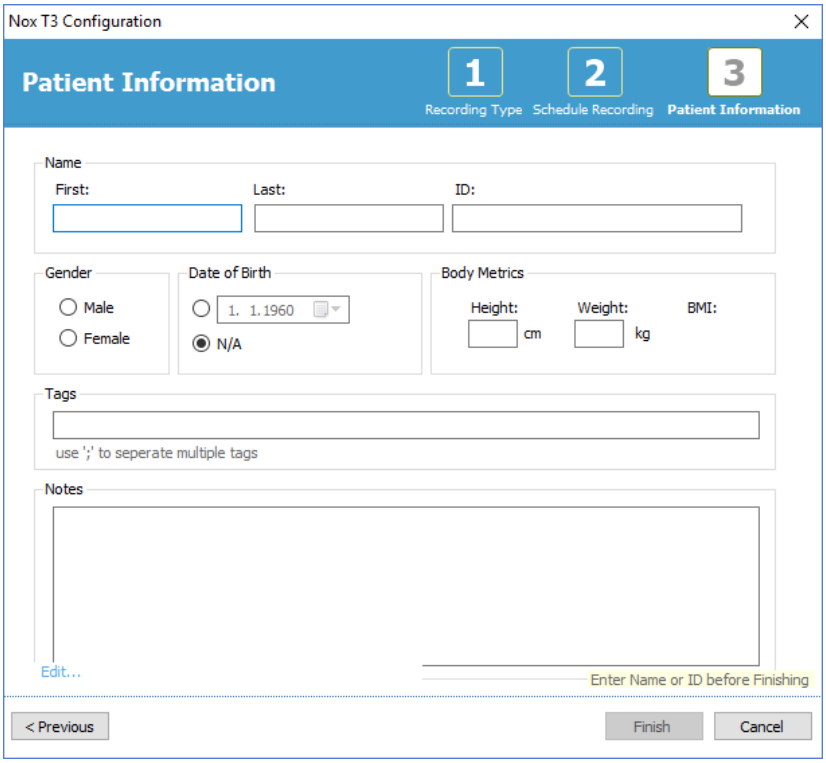
- If the **By Connecting Nox RIP Belts (Start on Belt)** option is checked, the recording will start when the user connects the Nox RIP belts to the Nox recording device. The duration for this option is *Unspecified* as the recording will stop by disconnecting the belt from the recorder. The feature is only available for Nox T3s and A1s devices with firmware 3.1.0 or newer.

- If the **By Pressing button (Manual)** option is checked, the user is responsible for starting/stopping the recording from the Nox recording device. This is done by pressing and holding the **Push** button on the device until the device display indicates that the recording has started.

- Check the *At Scheduled Date:* option to schedule a specific recording time. The device will turn itself on and automatically start recording at the specified time. If the user chooses to record for more than one night, each recording will start at the same time each night.

- To stop recording after a specific duration, specify the **Duration** to be either: **7 Hours**, **8 Hours**, **10 Hours** or enter a customized duration. If **Unspecified** is chosen, then the user is responsible for stopping the recording. This is done by pressing and holding the **Push** button on the device until the device display indicates that the recording has stopped.

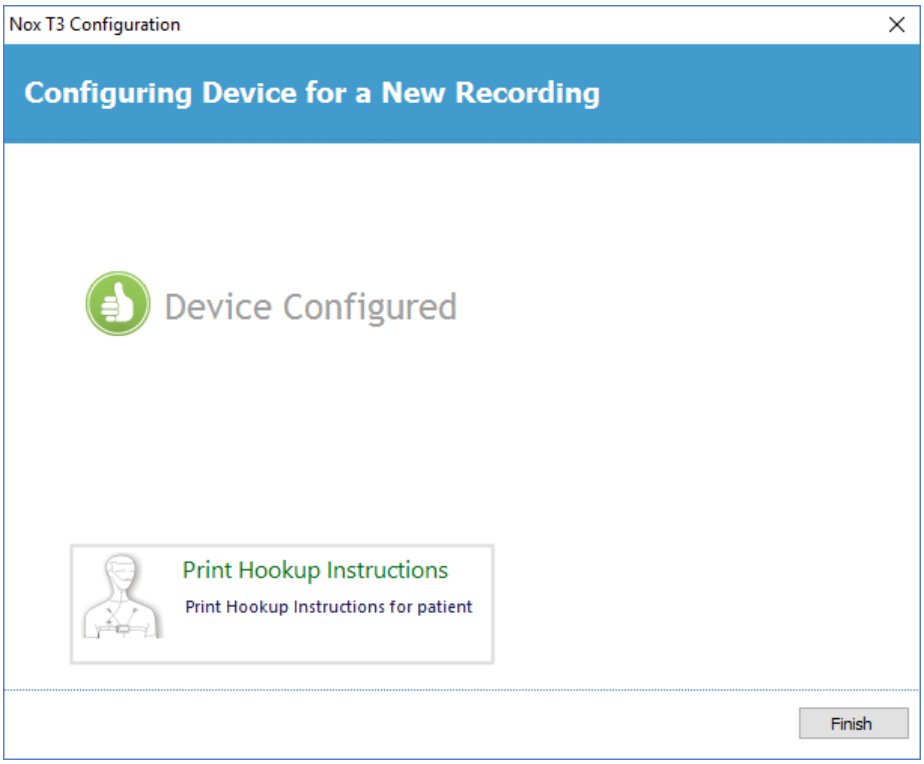
Click **Next** to continue to the third step, the patient information dialog. In this dialog, it is possible to enter detailed information about the patient. The only required field is the patient name or the patient ID.



After having entered the patient information click **Finish** to write the configuration to the device.

If there is a recording on the device, the user will be asked if he wants to erase the recording from the device.

Finally, a confirmation page appears confirming the device has been configured. For Nox T3 Recorders the hookup instructions can be printed by clicking the **Print Hookup Instructions** button. A PDF document containing the hookup diagram is launched and can be printed. If no hookup instructions are available, this option is not displayed.



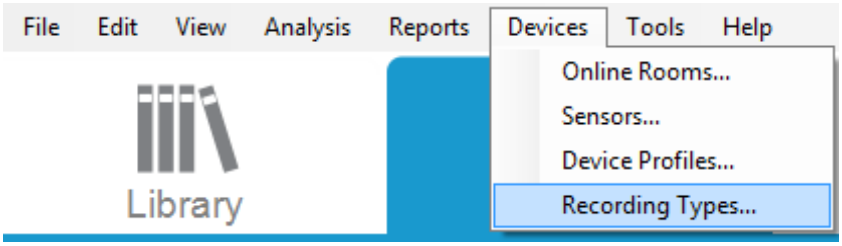
Recording Types

Noxturnal US offers a range of **Recording Types** available for configuration of both ambulatory and online recordings. The Recording Types encompass the device combination used for different types of sleep studies and the device settings. The Recording Types also define the automation for the different recordings, the relevant Workspace Layout, Analysis and Report that are used for the recording. In Noxturnal US you can easily create your own Recording Types to control devices and settings used for recordings. Follow these steps in order to create your own Recording Type.

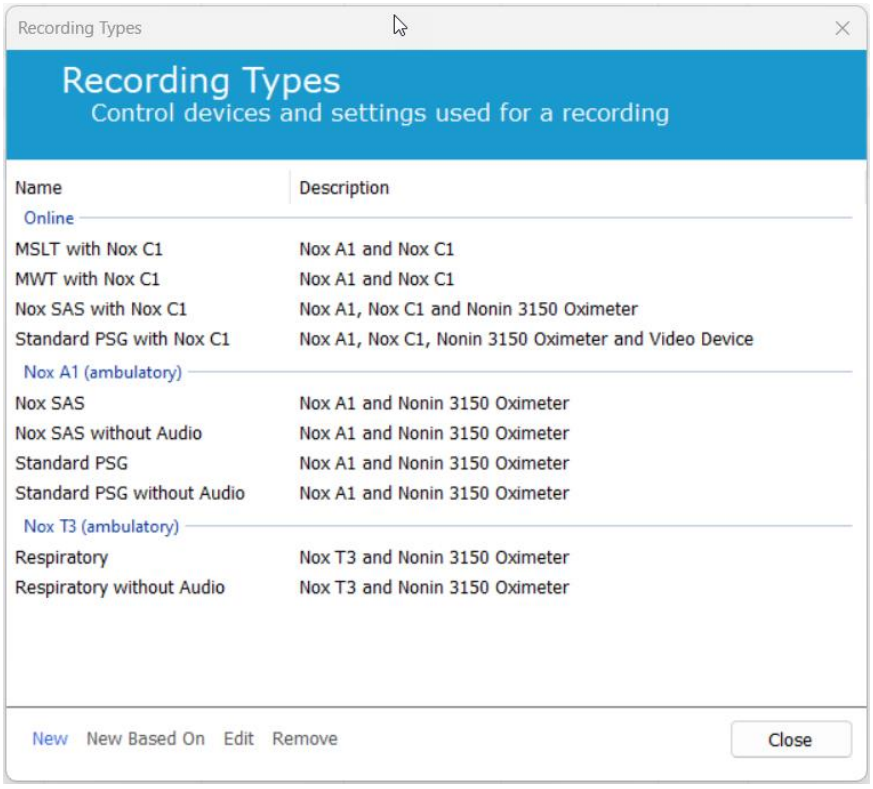
1. Select the Nox recording device you are creating the Recording Type for and if it is intended for ambulatory or online recordings.
2. Set up the Recording Type to include Workspace Layout, Analysis, Report and devices and device profiles to be used, as applicable.

The Recording Type Wizard is device dependent. This means that the wizard will vary depending on the type of Nox recording device being configured. However, the key steps are always the same:

From the Noxturnal US toolbar navigate to **Devices** > **Recording Types…**

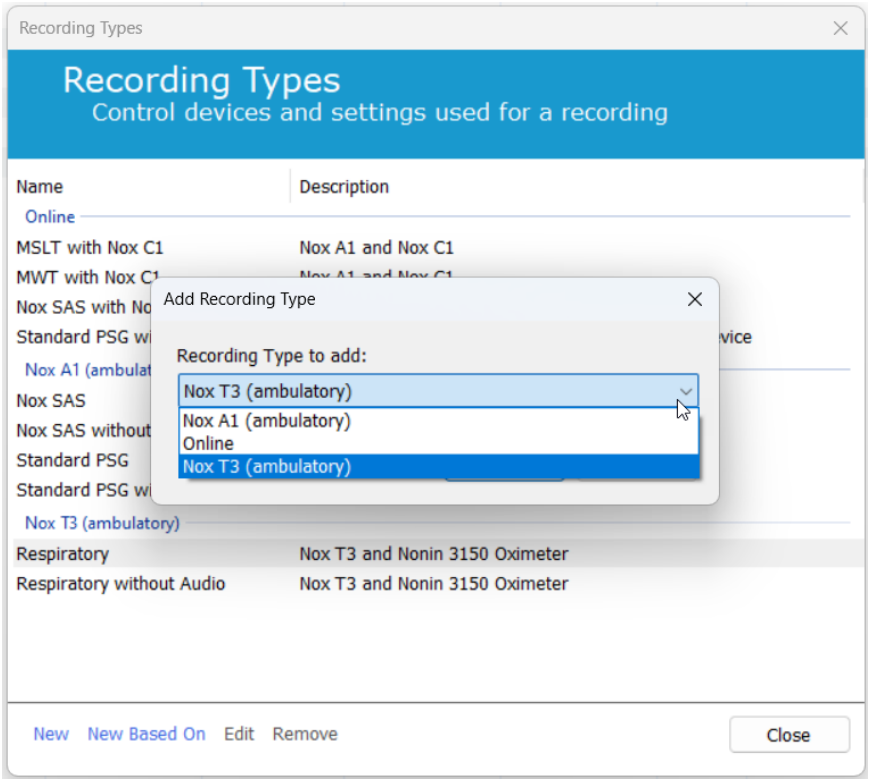


The Recording Types Wizard will open up.

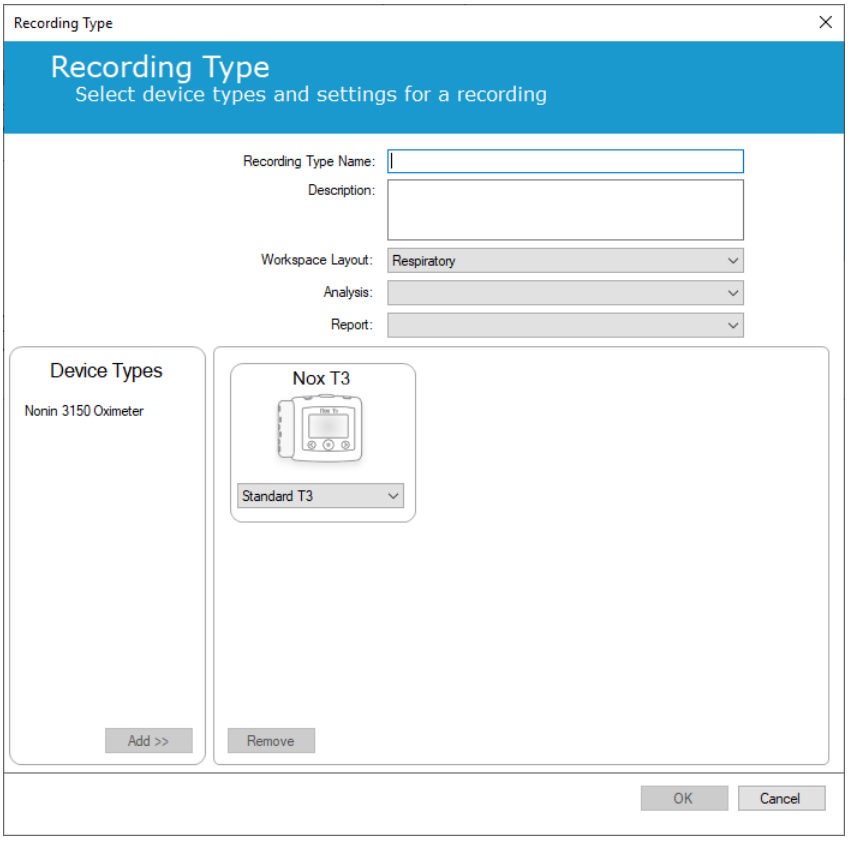


Here you can create a **New** Recording Type, a **New Based On** one of the available Recording Types and **Edit** or **Remove** custom Recording Types. For this example we will create a new Recording Type for the Nox T3 Recorder.

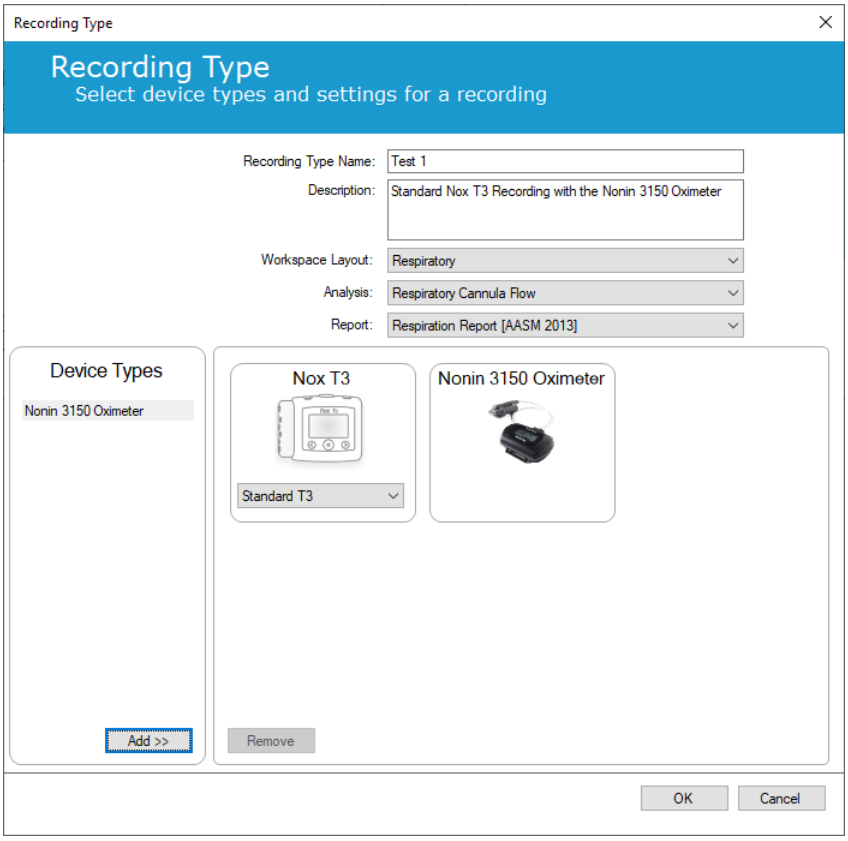
Select the **Nox T3 (ambulatory)** Recording Type from the dropdown list as shown below.



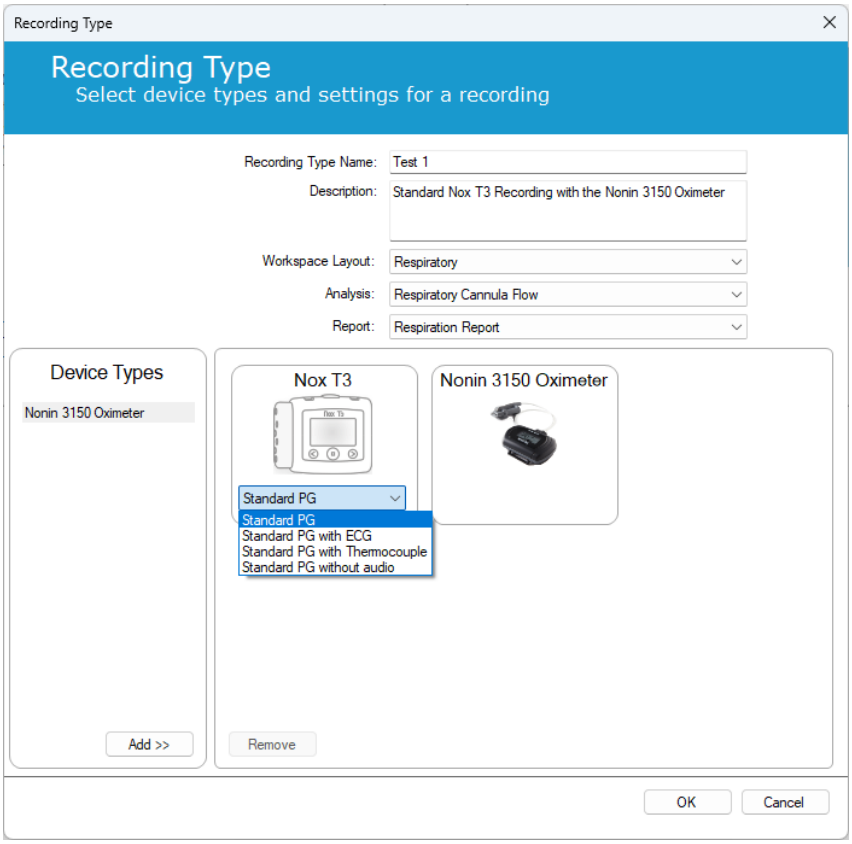
The next step is to set up the Recording Type as applicable. In the following wizard you can set up your Recording Type.



Type in the **Recording Type Name** and **Description** of the recording type. Choose the applicable **Workspace Layout**, **Analysis** and **Report**. You also have the availability to add auxiliary devices. Choose for example the Nonin 3150 *(under Device Types)* and click **Add>>**.



Note that it is also possible to choose the applicable Device Profile for this Recording Type directly in the Recording Type wizard, see below.



You can also create custom Device Profiles, please follow the instructions in the *Device Profiles* section for further instructions. Once you have created a new Device Profile it will appear in the dropdown list in the Recording Type wizard.

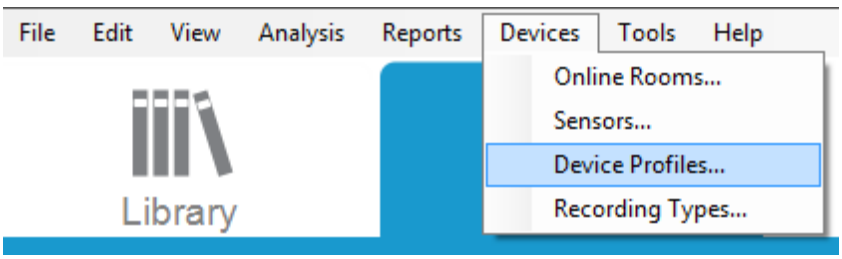
When you have set up your Recording Type click **OK** and your custom Recording Type will be available for configuration.

Device Profiles

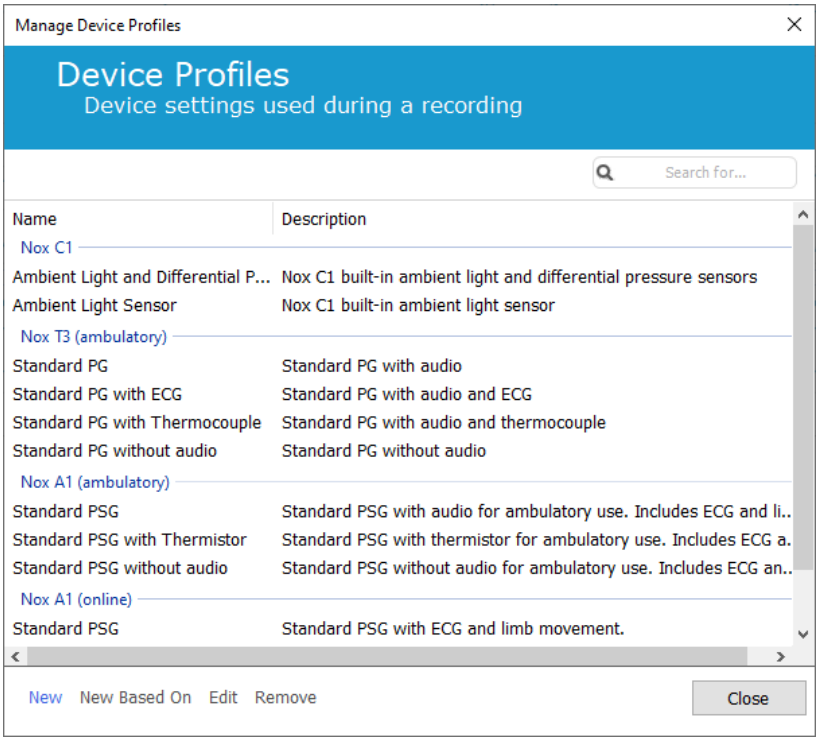
- Note: The Device Profiles wizards vary between Nox recording devices.

The Device Profiles are created for all standard recordings that you might perform with Nox devices. They allow for simple setup during the device configuration process.

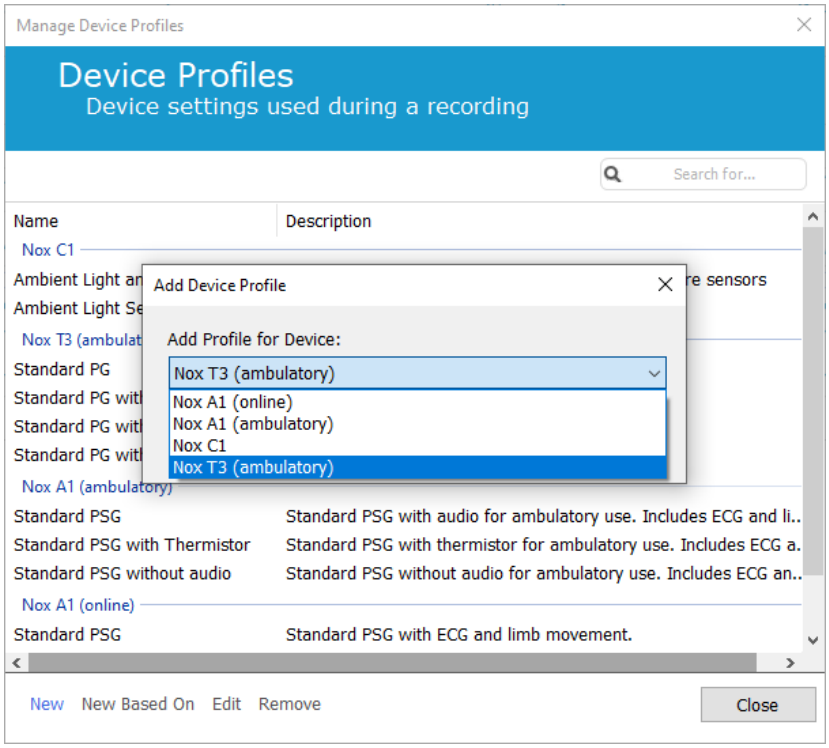
From Noxturnal US toolbar navigate to **Devices** > **Device Profiles…**



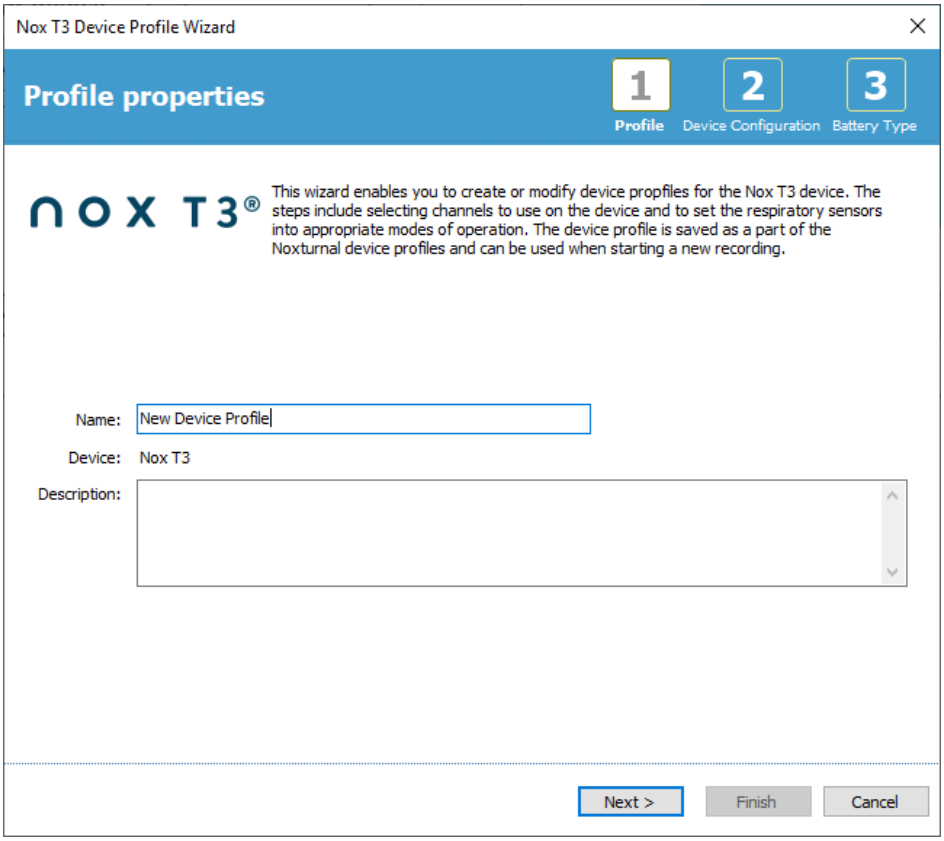
In the Device Profiles wizard, you can see list of the available Device Profiles for the Nox recording devices and the Nox access point.



To create a custom device profile, select New or New Based On. You will then need to select for which recording device the template is for or from which of the current device profiles you wish to base your new template on. For this example, we will create a new device profile for the Nox T3 Recorder.

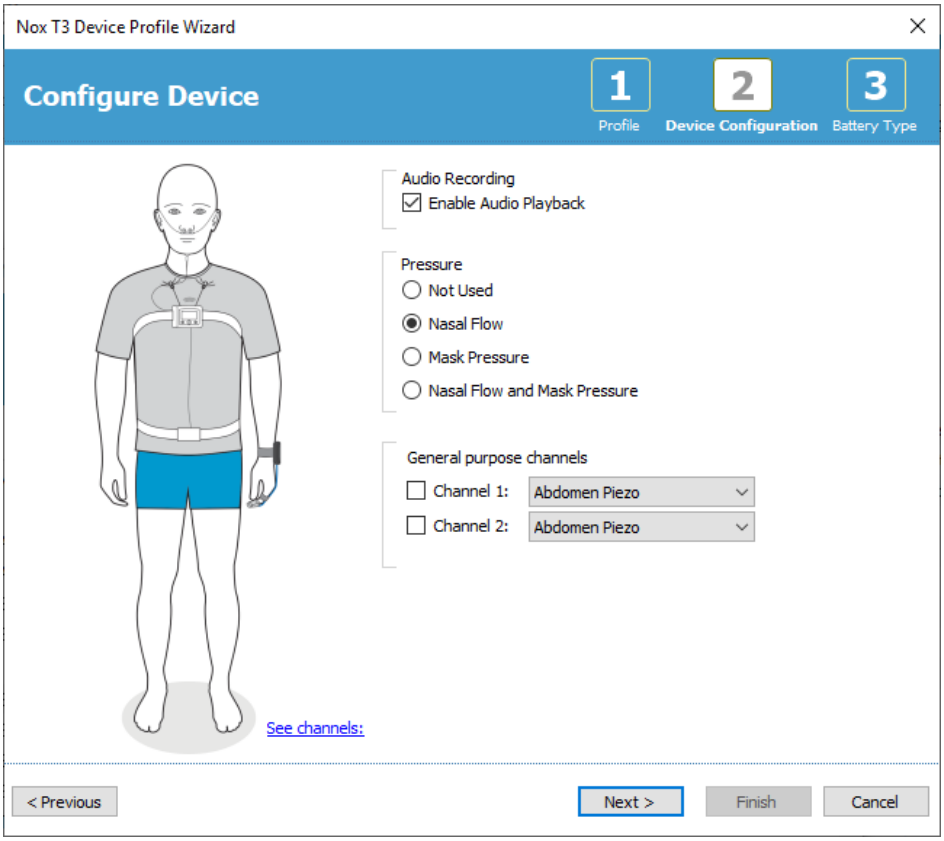


In the Profile Properties Wizard, you can setup the Device Profile. Type in the name (and description if you wish).

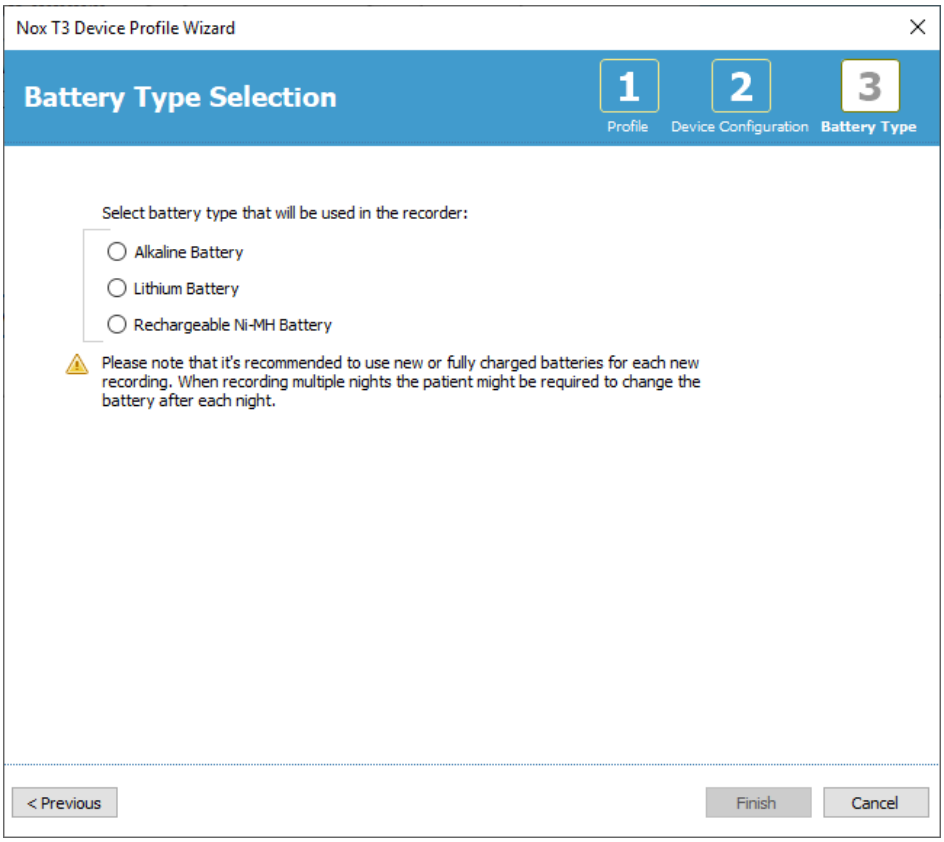


Click **Next** to proceed to the next step.

In the dialog below you can setup the channel configuration for the device. The Configure Device dialog is device dependent. This means that the wizard will vary depending on the type of Nox device being used. When you have setup the channel configuration, click **Next.**



The final step for configuring a Nox recording device is to define the battery type used. Select the applicable battery type and click **Finish**.



The Device Profile you created will be available from the list of Device Profiles and available for configuration.

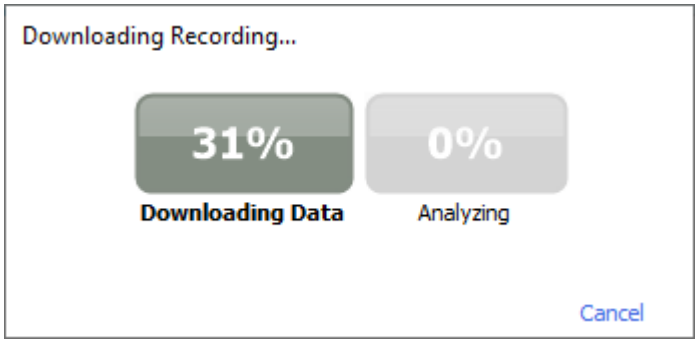
Downloading an Ambulatory Recording from a Nox Recording Device

- Note: If a download partially fails for any reason, it can lead to inconclusive recording results. The user will be warned when this happens and needs to decide whether the recorded data is complete or not. It is possible to download the data from the device again.
- Note: The downloaded recording is not deleted from the device until the device is configured for another recording.

To download recorded data from a Nox recording device to the computer, ensure that Noxturnal US is running and then connect a device to a USB port on the computer.

Noxturnal US automatically detects the device and shows information about it on the **Recording Page**. Detection can take 2-4 seconds.

Click on the **Download Recording** button on the **Recording Page** and Noxturnal US will start downloading the recording from the device to the computer. A download progress dialog will appear that displays the steps involved while downloading. The data is first downloaded then the default analysis protocol is run and, if the device was configured to record audio, the audio download starts.



After the download is completed the user is notified and can start working with the whole recording.

Recordings are always downloaded to the default data storage location. It is possible to change the default data storage location on the automation tab in the tools options dialog (**Tools** → **Settings…** → **General**). Downloaded recordings are automatically added to the recording library and can be reviewed any time by going to the recording library and opening it. For more information, refer to section *The Recording Library*.

Setup of the Nox Sleep System for Online Recordings

Online System Network Overview

To ensure steady operation of the online functionality for the Nox Sleep System please follow the recommended system setup below.

- It is recommended to use a separate computer for each online system setup. However, it is possible to run more than one online system on a single computer; refer to *Minimum System Requirements* section for details.
- Use a separate local area network (LAN) for each Nox C1 Access Point and a computer running the Noxturnal US software.
- Use a separate Nox C1 Access Point for each Nox A1 Recorders to be used.

The table below describes the setup of the control room where the computer with Noxturnal US installed is located.

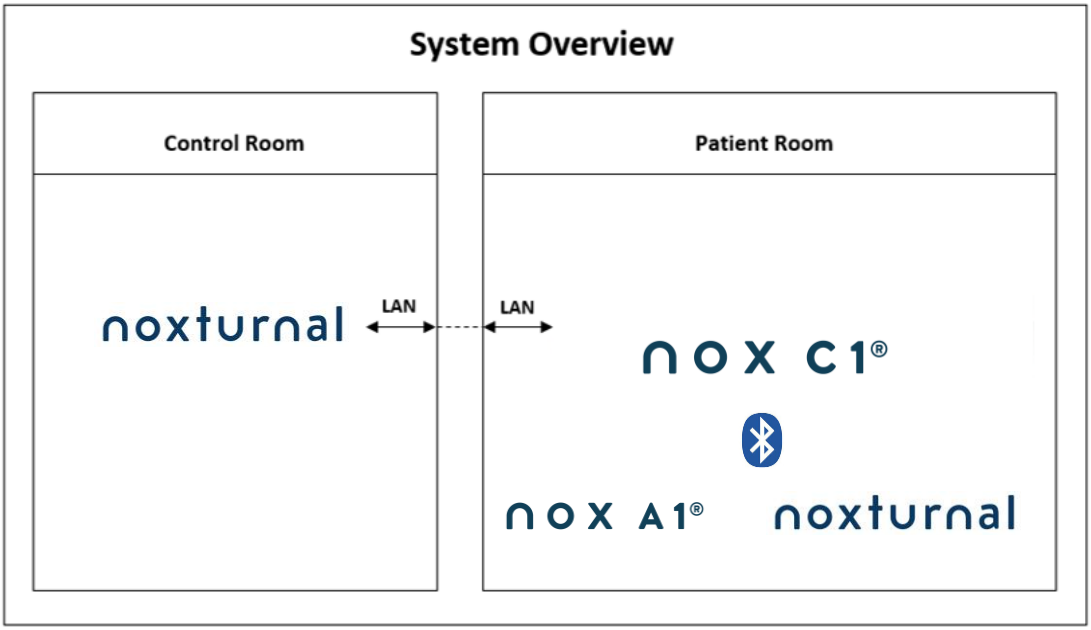
Control Room	
Item	**Connection**
PC	Connected to the same network as the Nox C1 Access Point with a network cable
Noxturnal US	Installed on PC

The table below describes the setup of the patient room where the patient is sleeping during a sleep study.

Patient Room			
Item Name	**Description**	**Function**	**Setup/Connection**
Nox C1 Access Point	Bluetooth access point with analog and serial inputs and built in light sensor and differential pressure sensor	• Data transfer received from Nox A1 over Bluetooth connection and forwarded to Noxturnal US via Ethernet • Commands received from Noxturnal US via Ethernet and forwarded to Nox A1 using Bluetooth connection • Data transfer received from auxiliary devices connected to analog and/or serial inputs and forwarded to Noxturnal US via Ethernet	Located in the patient room. Connected to the same LAN as the PC running the Noxturnal US software

Nox A1 Recorders and applicable sensors	Recording device that may be configured for different types of sleep studies	Records physiological signals from built-in and attached sensors	Attached to the patient in the patient room
Medical auxiliary devices	Any medical device that fits the input channel specifications of the Nox C1 Access Point. Medical devices supported by the system to be connected to Nox A1 Recorders via Bluetooth link	Depends on the auxiliary device being used	The applicable connection cable connected to the analog input/serial input on the Nox C1 access point. Via Bluetooth link to the Nox A1 Recorders
Noxturnal App	Android App	Can be used to connect to Online Rooms, review signal traces and perform bio calibration and impedance check. Can also be used to start and stop recordings	Set the App to Online Mode and connect to the applicable online room

Figure below shows the overview of the online setup for the Nox Sleep System.



The Nox C1 Access Point is operated by the Noxturnal US software.

For further instructions on the Nox C1 Access Point and the Nox A1 Recorders refer to the Nox C1 Manual and the Nox A1/A1s Manual.

Refer to the “Compatible Devices” section regarding the types of Ethernet supported devices and switches that have been validated with the Nox Sleep System.

Online System Configuration

This chapter describes how to setup the Nox Sleep System for online configuration. First make sure that you have setup all the devices and accessories needed, such as the Nox C1 Access Point, Ethernet cables and switch. Detailed information on how to setup your network, including the Nox C1 Access Point, is found in the Nox C1 Manual.

To set up the Nox Sleep System for online configuration you must perform the following steps in Noxturnal US, as applicable:

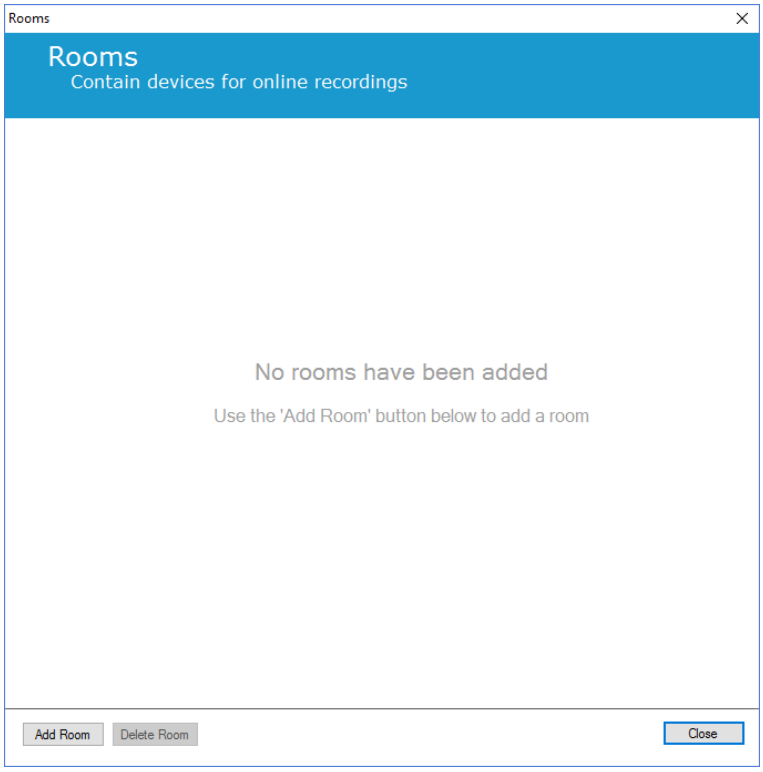
1. Set up **Online Rooms**
2. Configure new **Sensors**
3. Set up **Device Profiles**
4. Set up **Recording Types**

These steps are outlined below. Following these steps will allow you to start your online recording and then start working with the signals in Noxturnal US.

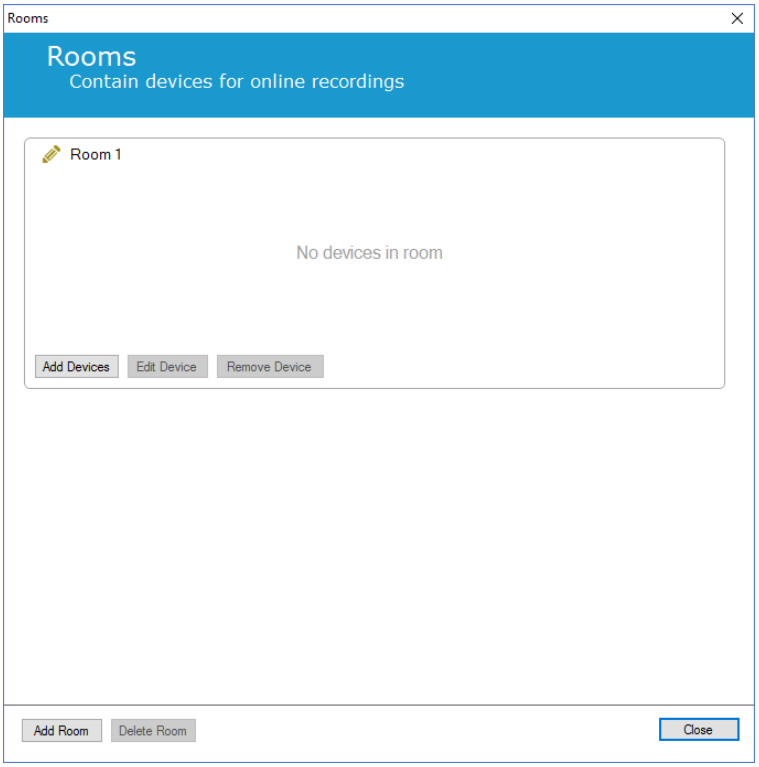
Online Room

Setting up an Online Room is part of setting up Noxturnal US for online recordings. The Online Room encompasses collection of devices which you normally keep together in a room. These may, for example, be all the devices that you keep in a particular hospital room dedicated for sleep studies.

To add a new room, select **Devices > Online Rooms…** from the Noxturnal US toolbar. This will bring up the **Rooms** dialog.



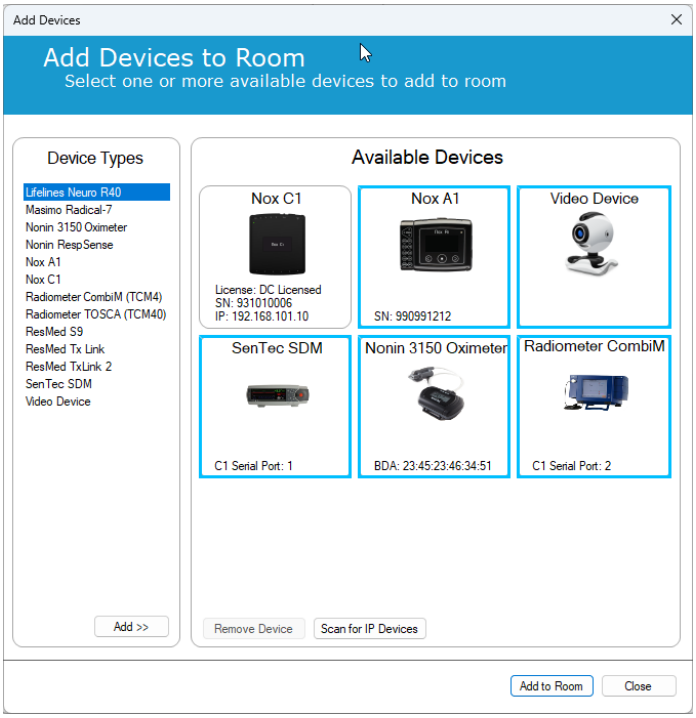
From here you can add a new room or edit an existing one. To add a new room click **Add Room** and in the dialog below you can give the new room a name, by clicking the pencil icon and add devices to your room by clicking **Add Devices**.



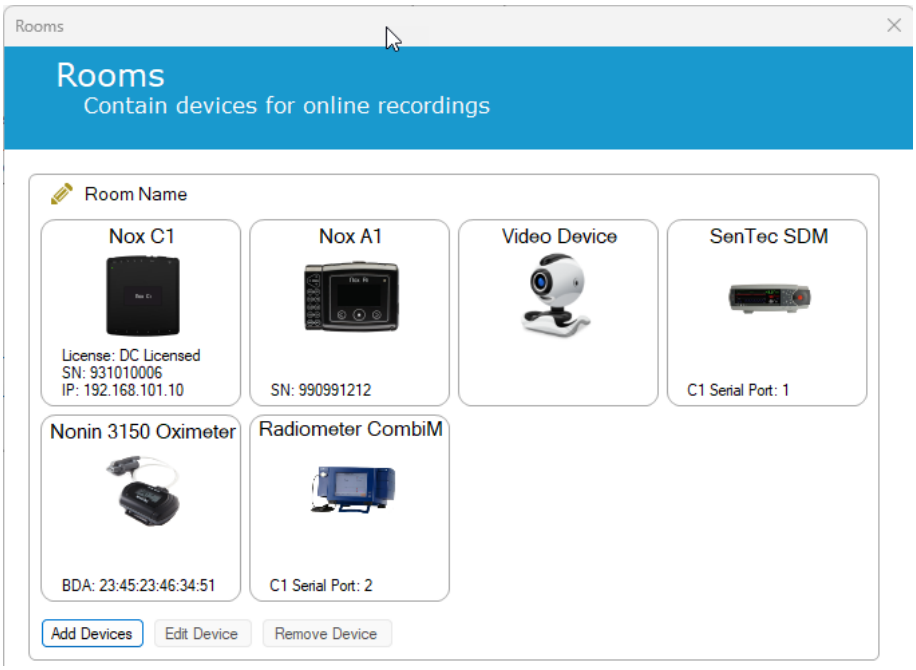
In the **Add Devices** Wizard you can add devices to your room. To add a device, select the applicable device from the **Device Types** list and click **Add >>** or double-click the device from the list. You can scan for connected IP devices on your network by clicking **Scan for IP Devices**.

When you add Nox A1 Recorders you will need to select the applicable Nox C1 Access Point being used in the room and click **Scan** for your Nox A1 Recorder or manually type in the A1 serial number. Remember to have your A1 Recorder turned on for this step. Select your recorder from the list and click **Next**.

When you have added a selection of devices to collection of available devices you can select the devices to add to your Online Room.



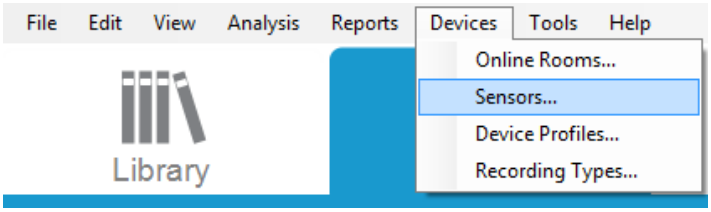
To select devices to add to your room click the device and a blue bold frame will appear around each selected device. When you have selected the devices to add to the room, click **Add to Room** and your room with this selection of devices will be added.



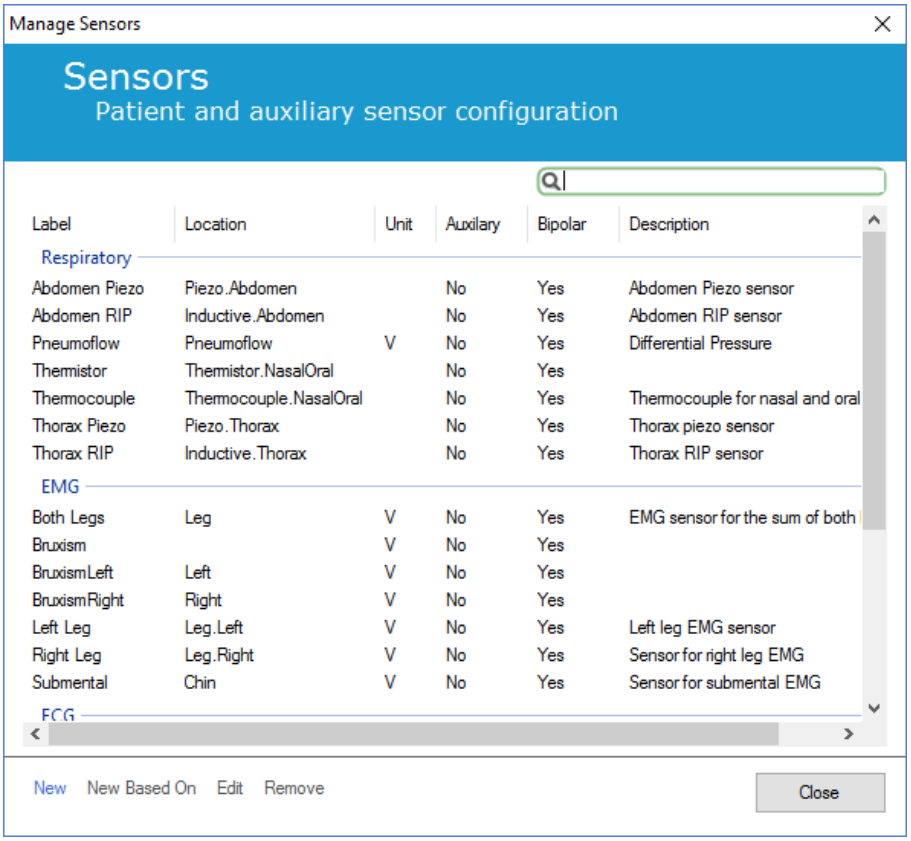
You have now completed the configuration of the online room. You can in the same way as described here above add additional rooms.

Configuration of New Sensors

If you want to create new sensor configurations, e.g. to use with the Nox C1 Access Point, you can do that by navigating to **Devices > Sensors…** from the Noxturnal US Toolbar.



From the **Manage Sensors** Wizard you can create a new sensor and edit/delete existing sensors. To create a new patient or auxiliary device sensor click **New**. Patient sensors are sensors connected to Nox A1, T3 or T3s Recorders and the patient. Auxiliary device sensors are connected to Nox C1 Access Point and an auxiliary device.



You can select whether a new patient sensor or an auxiliary device sensor is to be created. Fill in the applicable fields and click **OK** to save the sensor configuration.

Device Profiles for Online Devices

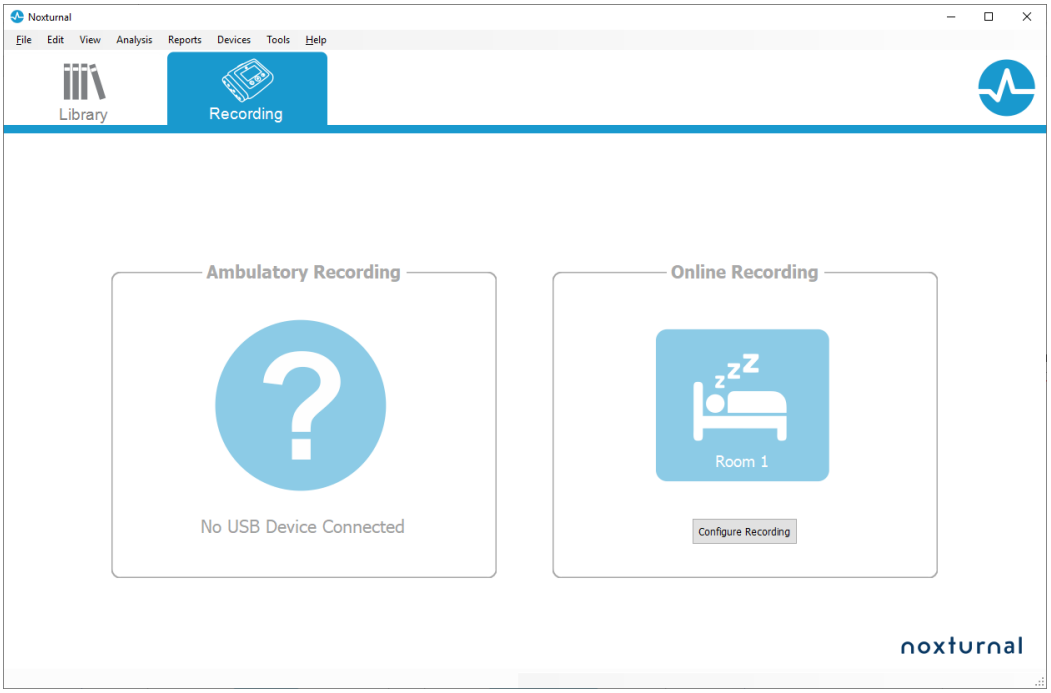
For the Nox devices used for online recordings you can set up **Device Profiles.** The Device Profiles encompass the device's channel configuration. Noxturnal US offers a range of default Device Profiles and you can also easily setup new Device Profiles. For instructions on how to customize Device Profiles refer to the *Device Profiles* section.

Recording Types for Online Devices

The final step is to set up **Recording Types**. This is a list of the types of recordings that you will record online in your clinic. Each **Recording Type** brings together a collection of available online device types which would be grouped together. Examples are: **Standard PSG with Nox C1**, would bring together a Nox C1 Access Point, Nox A1 Recorder, Nonin 3150 Oximeter and a Video Camera. For instructions on how to setup new Recording Types refer to the *Recording Types* section.

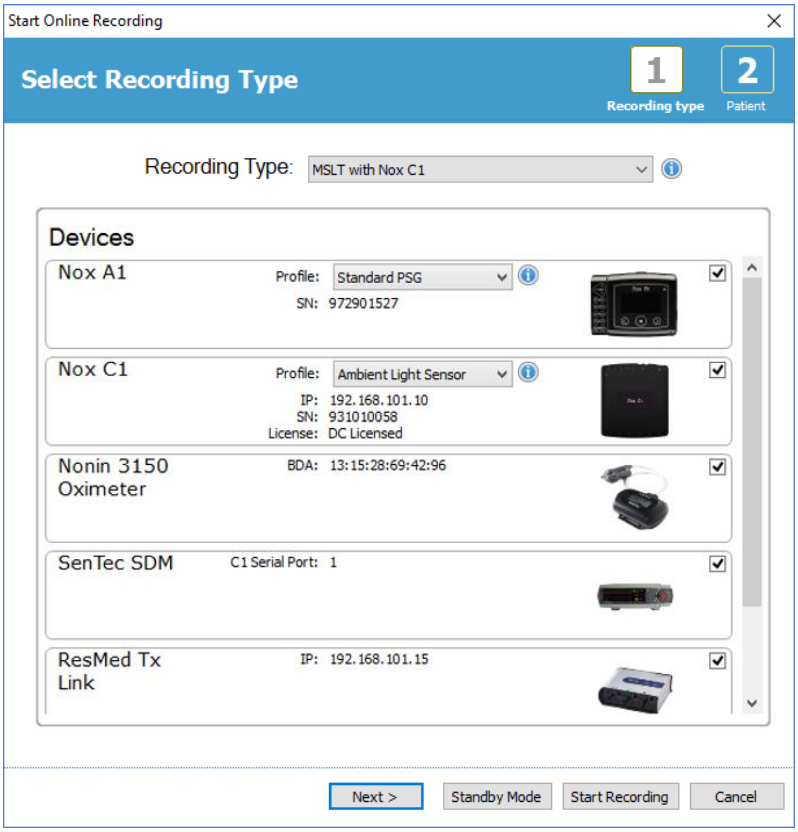
Starting an Online Recording

When you have completed the steps above to setup your online configuration an online recording can be started. From the **Recording** page you can start an online recording within the room you have set up. To start the recording either double-click the room icon or click **Configure Recording.**



This will bring up the **Start Online Recording** wizard. This wizard will allow you to:

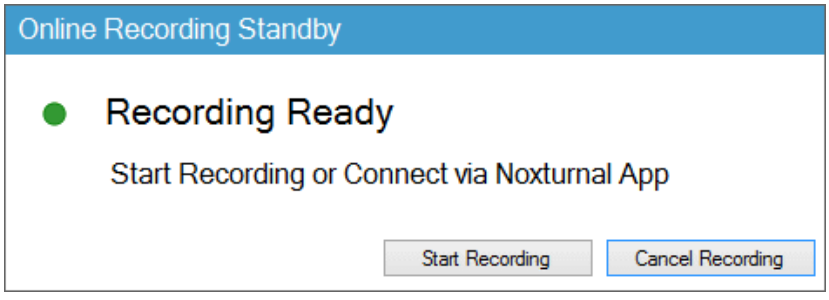
- Select the **Recording Type** which is about to be performed from the dropdown list.
- The selection of **Devices** is dependent on the **Recording Type** selected. All devices available in the online room are listed, however the devices not included in the recording type are greyed out. You can include the disabled devices for the recording by checking the appropriate boxes from the list of devices.
- Select **Device Profile** for some devices, such as the Nox A1 and the Nox C1.



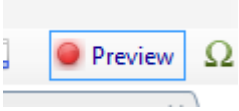
When you have selected your **Recording Type** and the applicable devices along with their **Device Profiles** you can click **Next** to enter the patient information. The final step is to start the recording and you do that by clicking **Start Recording** or clicking **Standby** within the **Patient Information** Wizard.

Start Recording:
You will then see your selected Workspace Layout appear with a status window showing the status of the recording which is starting. Finally, you will see the recorded signals appear in real time and you can start working with them.

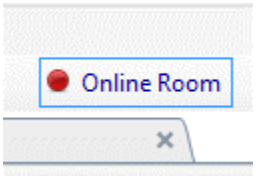
Standby Mode:
The **Standby Mode** will open your selected workspace with a status window showing you have entered **Standby Mode** that gives you the option to connect to the Online Room for preparing, evaluating, and assisting the patient hook-up and finally start the recording using the **Noxturnal App** or **Start Recording** as is described in the step above.



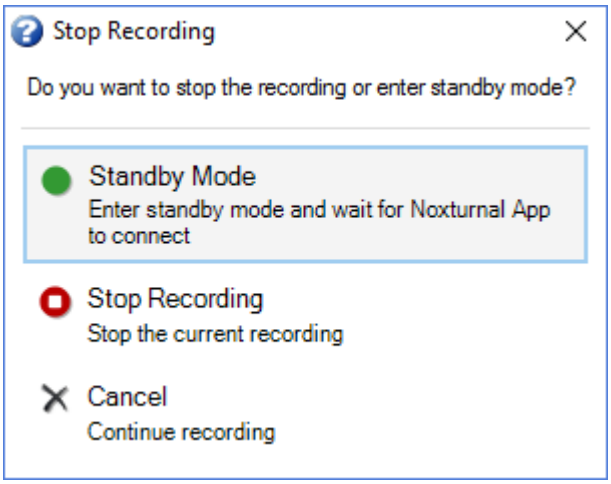
When the user has connected the Noxturnal App to the online room the live traces that start to appear are **NOT** being saved to the recording. It is only a preview as is indicated by the preview status. The signal will start to record as soon as the user hits **Start Recording** either in the Noxturnal App or in the Noxturnal US software.



The user can also enter the standby mode any time after the recording has been started if he wants to pause the recording for some period of time by clicking the red rec button on top of the screen.

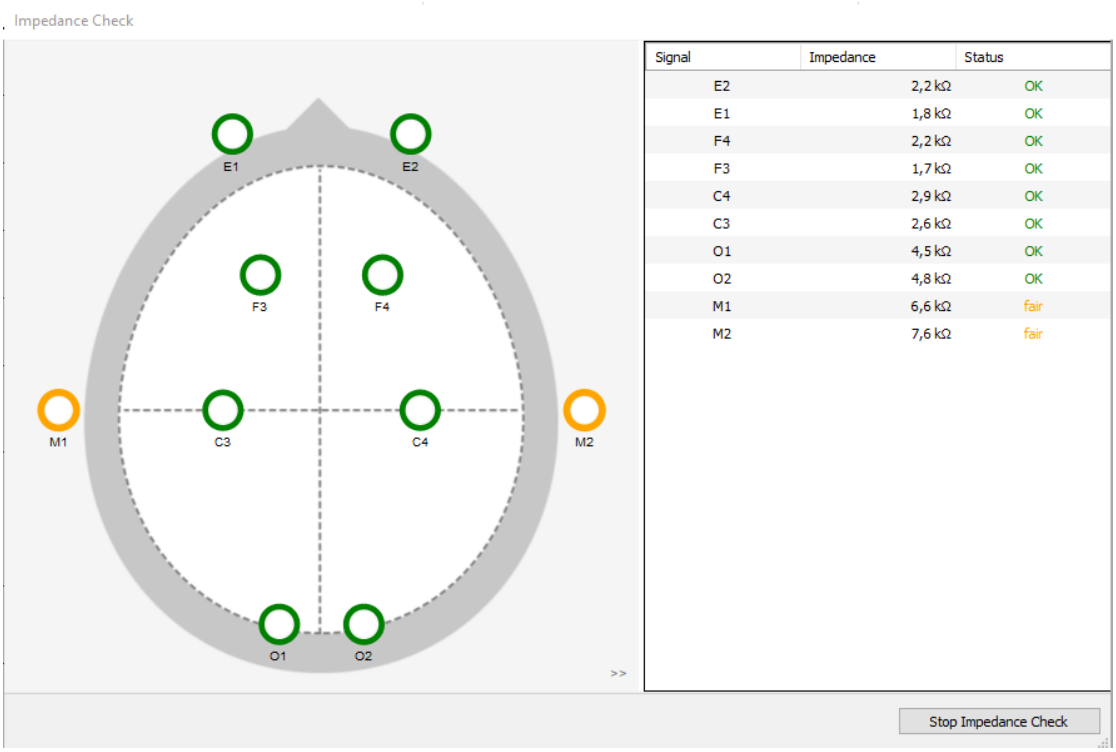


By clicking the rec button, it will give you the option to either enter standby mode, stop the recording or cancel and continue with the recording.



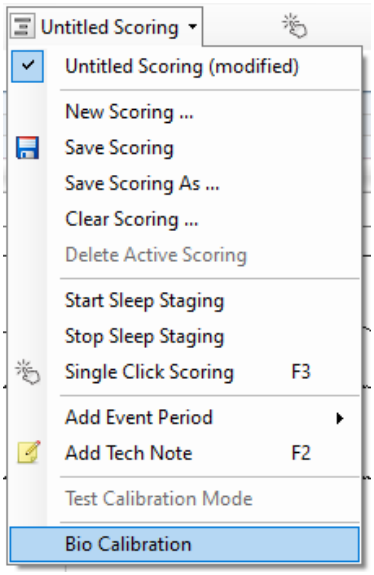
Performing Impedance Check and Bio Calibration

For a closer inspection of the electroencephalography (EEG) electrodes an Impedance Check can be performed. After a recording has been started click the "*Ohm*" button.

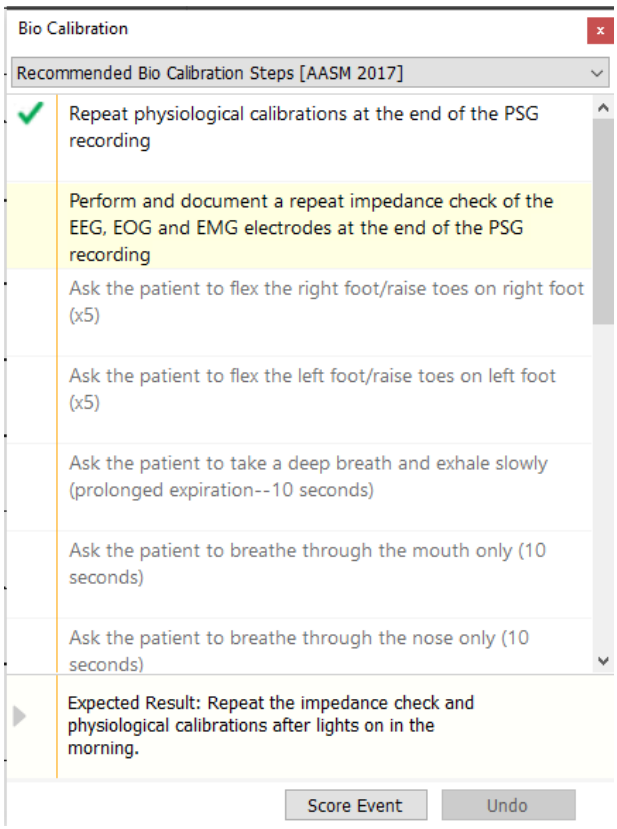


The colors of the circles indicate the quality of the connections. Green is Good (<5 kΩ), yellow is Fair (5 kΩ to 20 kΩ), and red is Bad (>20 kΩ).

The next step is to perform the Bio Calibration. Go to the *Scoring Button* and select *Bio Calibration*.



The selected task is highlighted, and the expected result listed on the bottom of the tab. When the event has been scored, the event will appear on the signal sheet.



Nox C1 Configuration

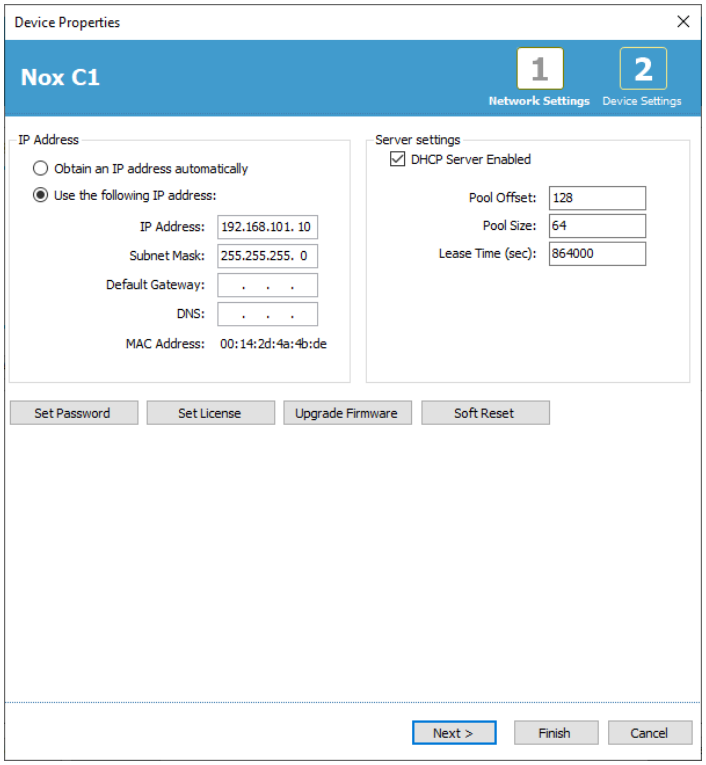
The Nox C1 Access Point is equipped with 12 analog channels suitable for collecting of DC signals from auxiliary devices. The channels are collected on 6 ports, labeled DC IN from 1 to 12 on the top of the device; each analog port yields 2 channels. Auxiliary devices can be connected to the Nox C1 analog inputs. The voltage range allows interfacing signals from -5V to +5V. For further information on the Nox C1 Access Point, refer to the Nox C1 Manual.

Nox C1 Access Point Network Configuration

The default factory configuration of the Nox C1 Access Point is listed in the table below. The Nox C1 network configuration can be managed through Noxturnal US.

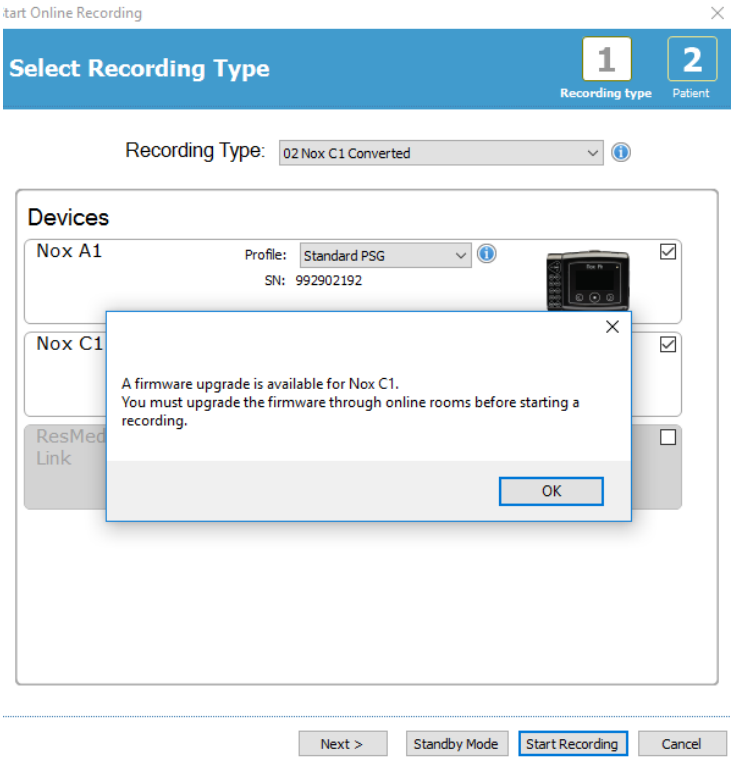
Nox C1 Network Configuration	**Details**
DHCP server	DHCP pool: 192.168.101.64-192.168.101.127
Static IP address	192.168.101.10
Universal Plug and Play (UPnP) discovery	Networking protocol that permits the Nox C1 to be discovered on a network

To manage the network configuration of the Nox C1 you can open an Online Room that has been configured (Devices > Online Rooms…) and select the Nox C1 within the room and click **Edit Device**. In the dialog below you can see how you can change the network configuration of the Nox C1.



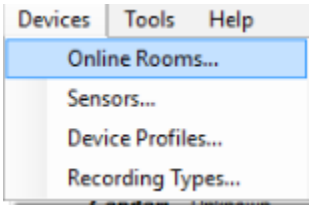
Upgrading Nox C1 Access Point firmware

If a new version of the Nox C1 Access Point firmware is available for the connected device, Noxturnal US will notify the user by displaying this message when the user starts an online recording.



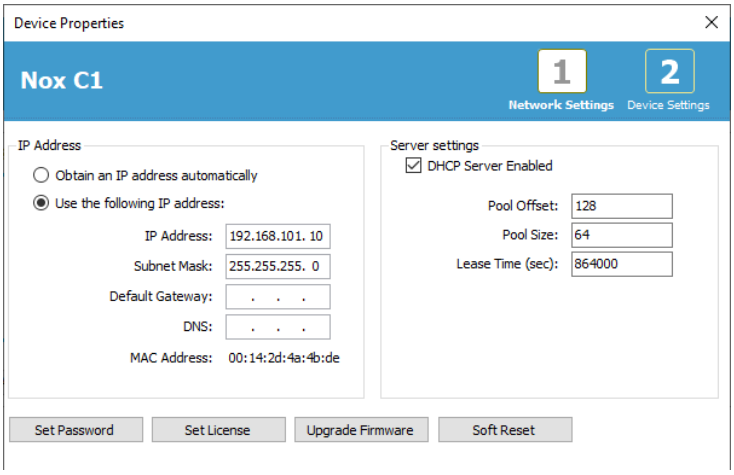
The user can access the firmware upgrade by navigating to the **Devices** tab in the menu bar.

Devices >> Online Rooms…

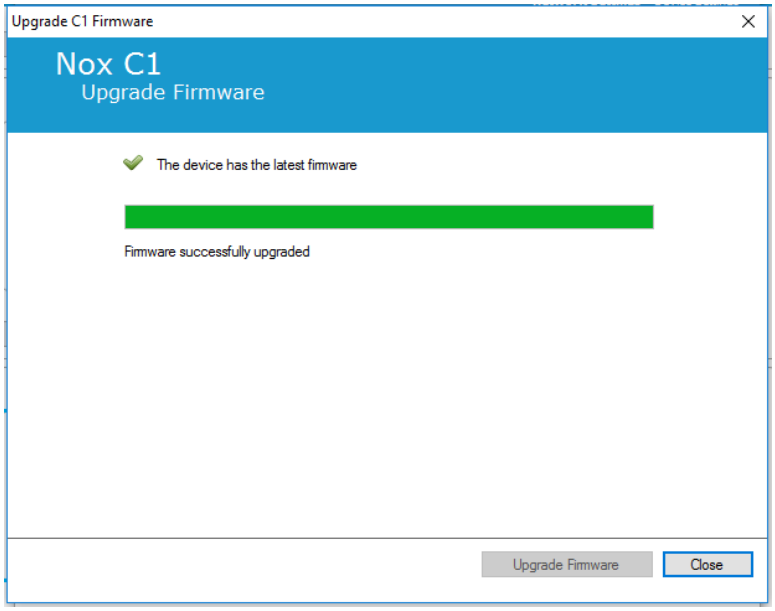


Select the Nox C1 access Point and click **Edit Device.**

In the device properties window select **Upgrade Firmware.**



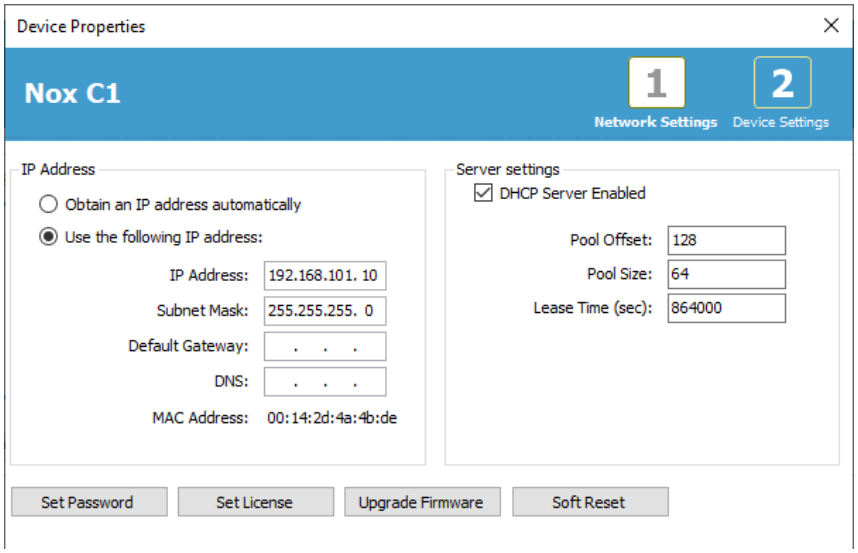
The firmware upgrade will be indicated with a status bar and when finished will display like this.



Activating Nox DC Channel License

The DC channels on the Nox C1 Access Point are locked by default. To be able to use the DC channels on the Nox C1 you will need to have a Nox DC Channel license activated. For further information on this, please consult with Nox Medical or their sales representatives.

The license is activated by clicking **Set License** in the **Device Properties** dialog that is shown below and following the instructions on the page.



Integration of Video Devices for Online Recordings

Noxturnal US supports online video recording. To use the digital video support provided by Noxturnal US in an online recording you need to configure your system to include a video device.

A video device can be added to your online system configuration and the setup saved for future use. To configure a video device with your system you must:

1. Ensure that you have **video codecs** installed on your computer
2. Ensure that the video device is connected to the same network as the Nox C1 Access Point and the computer running Noxturnal US
3. Setup an **Online Room** including the video device
4. Setup a **Recording Type** including the video device and define the video profile
5. Select the Online Room and start an online recording from the Noxturnal US **Recording** page

Setup an Online Room with a Video Device

VIDEO CODECS

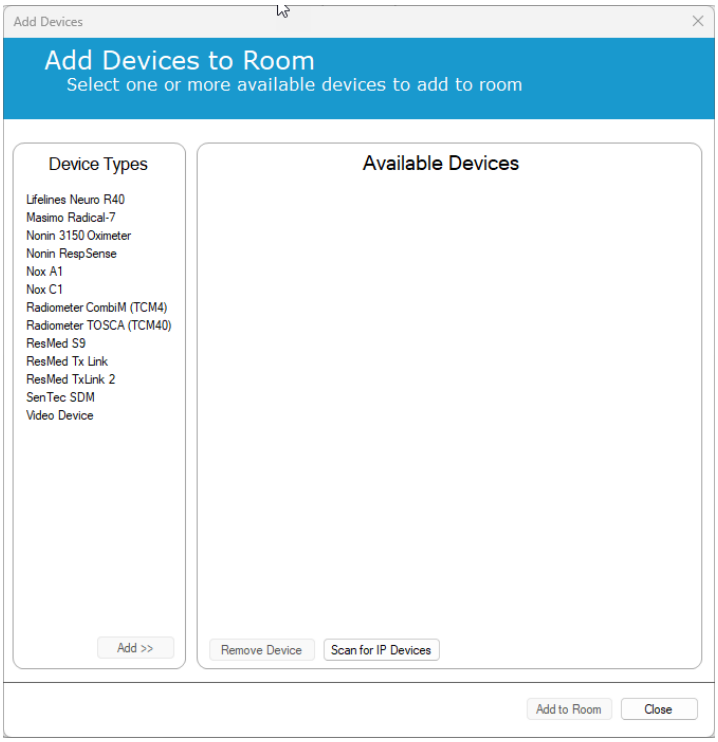
Noxturnal US's support for video is governed by the video codecs that are installed on your computer system. These video codecs are specialized software that enables the compression and decompression of digital video. Noxturnal US does not install any codecs but most computer systems have some types of codecs installed. You will require codecs to be installed on your computer system to use video with your Nox Sleep System. Noxturnal US will then provide you with access to the features supported by these codecs. You can download the **K-Lite Codec Pack** from the Nox Medical support site:

http://support.noxmedical.com/hc/en-us/articles/207882176

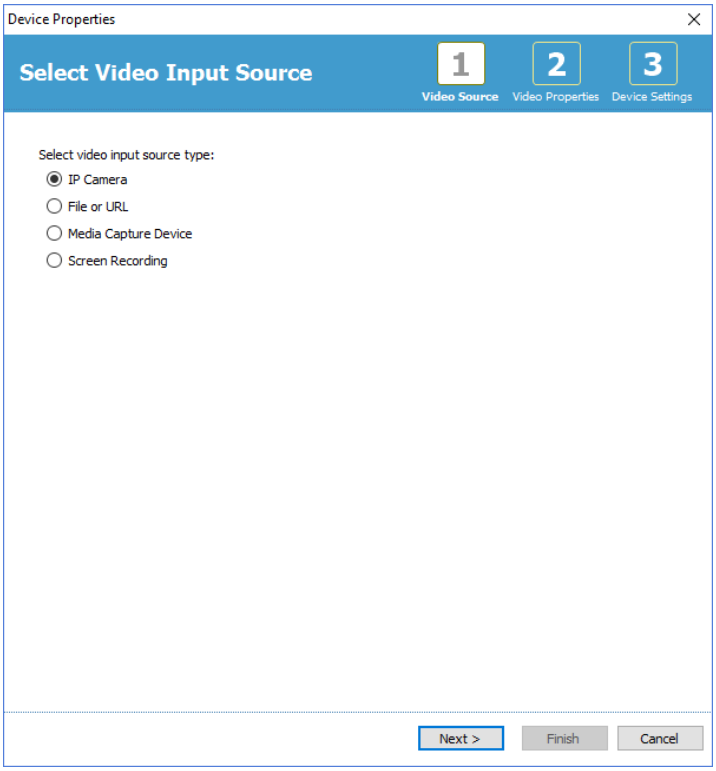
VIDEO CAMERA INTEGRATION

To setup an online recording including a video device follow the steps below.

1. Setup an Online Room in Noxturnal US as explained in *Online Room* section (Devices > Online Rooms… from the Noxturnal US toolbar).
2. Add a video device to your Online Room by clicking **Add Devices** and select **Video Device** from the **Device Types** list.

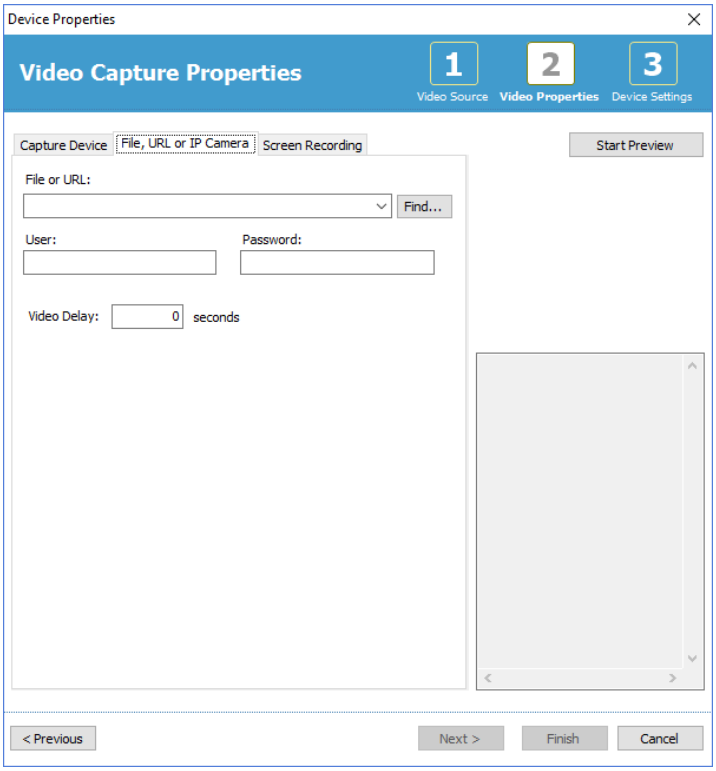


3. You will see the Device Properties dialog shown below. Check the applicable option, depending on the video device being used and click **Next**.



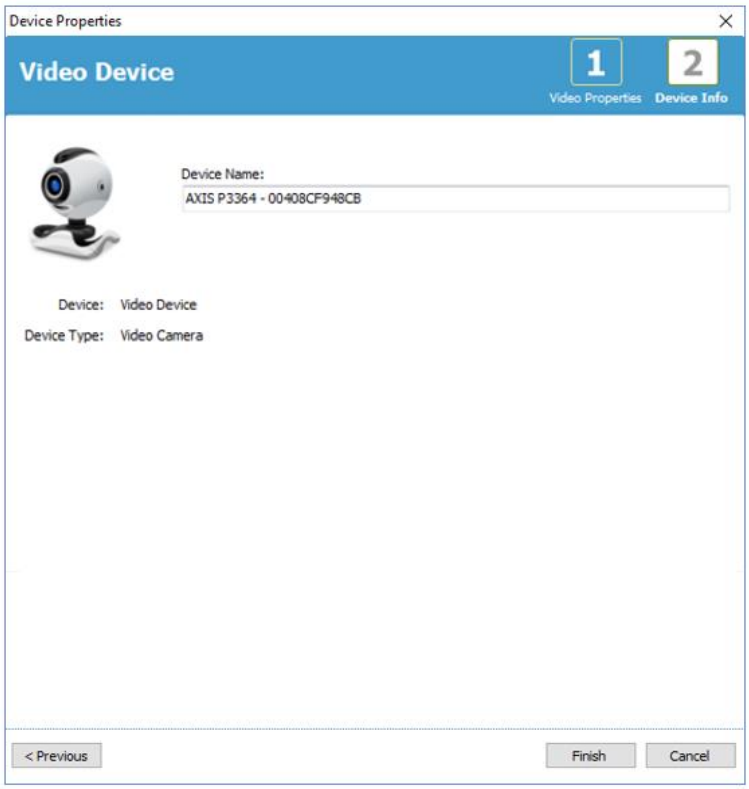
To setup your IP camera click **Find…** and Noxturnal US will scan your network and discover video cameras that are connected to your network if they have UPnP (networking protocol that permits IP camera to be discovered on a network) enabled. Noxturnal US offers default connection options for some IP cameras (Axis, D-Link cameras, Vivotek and Hikvision). Make sure that when choosing the connection string available in Noxturnal US to choose the connection string (URL) per the recording you are performing, if only video is to be recorded, or both video and audio are to be recorded.

If your camera is not automatically discovered by Noxturnal US when using the **Find…** action you can always manually add your camera by entering the relevant connection string (URL) and the camera IP address into the **File or URL** field.



If you have a video device that is not supported by the default connection options mentioned above you can always manually add new connection strings (URL) to have them accessible in Noxturnal US for future use. To do that browse to **Tools > Settings > Advanced** and select the **Default Settings**. Open the Video Profiles folder and open the *IPCameras* Excel sheet. You can add to the existing list of connection strings a new connection string for you video device and that will become available to use within Noxturnal US.

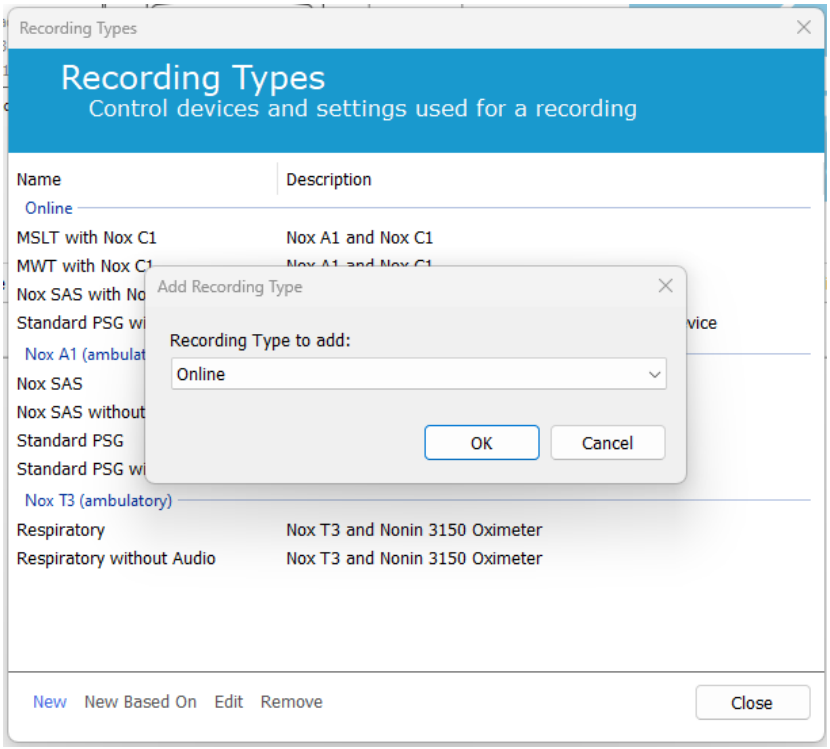
When you have entered the User and Password information for your camera you can click **Start Preview** to see if your camera is correctly set up and working with Noxturnal US. If a delay is observed during the preview a delay input can be added to correct the video replay during the analysis. Click **Next** and you can give the camera a unique name and then click **Finish**.



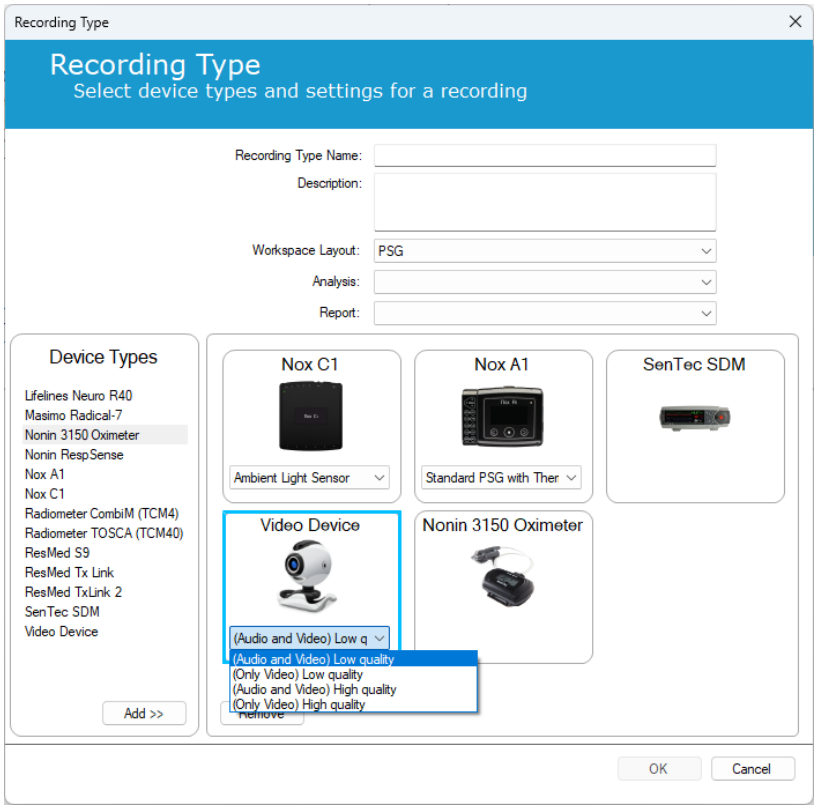
You have now added the video device to your online room.

Setup a Recording Type with a Video Device

Noxturnal US offers default Recording Types for online recordings that include video device. You can select one of the default Recording Types and start directly an online recording which includes a video device. You can also set up a custom Recording Type and define the Windows Media Profile to use with Noxturnal US when recording and compressing the online video. To do that navigate to **Devices > Recording Types…** from the Noxturnal US toolbar. In the Recording Types wizard select **New** and **Online** from the **Recording Type** dropdown list.

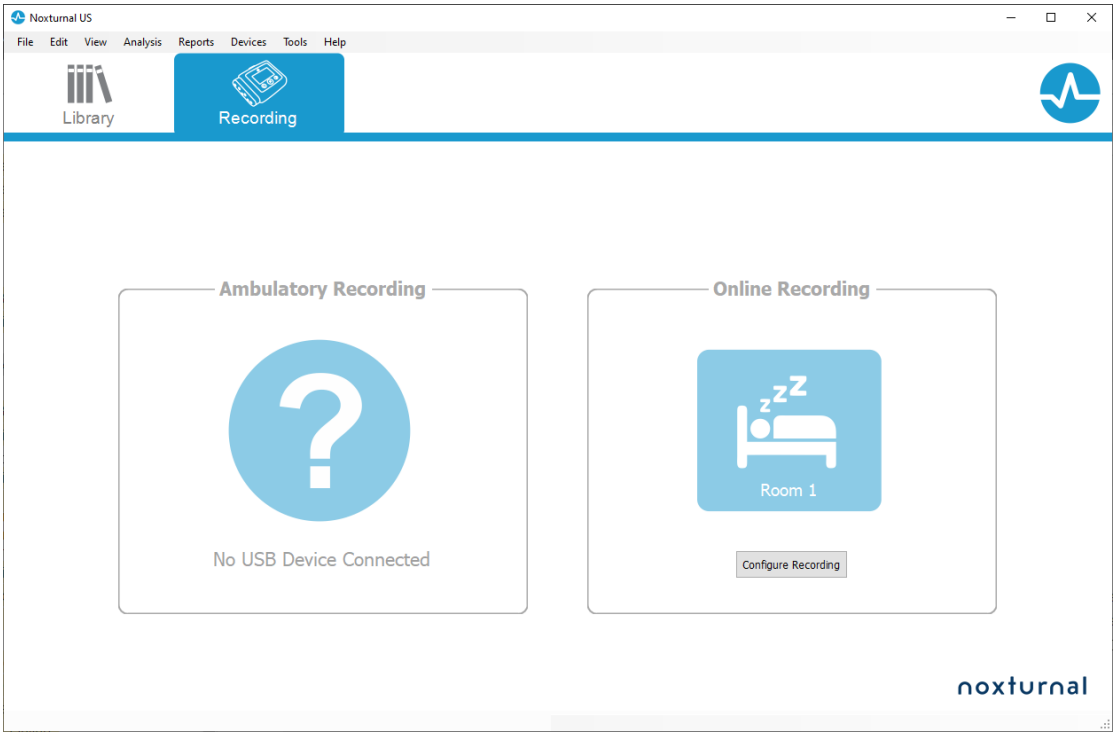


In the Online Recording Type wizard, you can add your video device as other devices. You can select the video profile to be used from the drop-down list, see image below.



Noxturnal US offers selection of default video profiles, however, you can create custom profiles and access them for use in Noxturnal US. For further information and instructions on how to do that refer to Nox Medical support site, Windows Media Profiles in Noxturnal US.

You have now configured your system to include a video device and you can start an online recording from the Noxturnal US **Recording** page by double-clicking the room or click **Configure Recording**.



Working with recordings in Noxturnal US

Recording Results Page

After downloading from a recording device or opening an existing recording in Noxturnal US the **Recording Results** page is shown. This page contains an overview of the most common analysis parameters and the recorded signals. The result page is automatically updated when changes are made to the existing scoring or if the automatic analysis is run. When sleep stages are available, such as for recordings done with the Nox A1 Recorders, you will see graphs and information with that information. For the Nox T3 Recorders, you will only see parameters available with those devices.

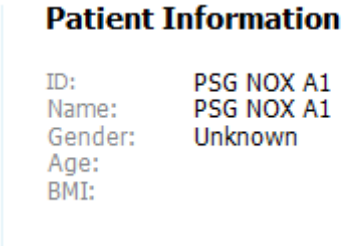
Result Page Commands

The **Recording Results** page has buttons for the following actions:

- **View Report**: This option creates the default report for the recording, the report defined within the Recording Type (for further information refer to the Recording Types section).
- **Print Report:** This option prints the default Report.
- **Recording Status**: This option allows to set the status of recordings. Downloaded recordings always have the status **New**. If a recording has failed for any reason, the status can be set to **Invalid**. If the recording has been diagnosed, the status can be set to **Scored**. If the recording and the scoring have been reviewed, the status can be set to **Reviewed**. If the recording has been interpreted, the status can be set to **Interpreted**. If a recording has been diagnosed and accepted, the status can be set to **Done**.

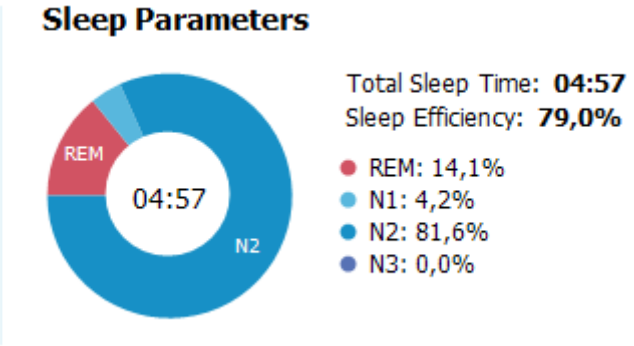
Patient Information

The **Information** panel shows information about the recorded patient. Edit the recording properties and patient information by clicking the patient icon or by pressing the **Ctrl+I** shortcut key.



Sleep Parameters

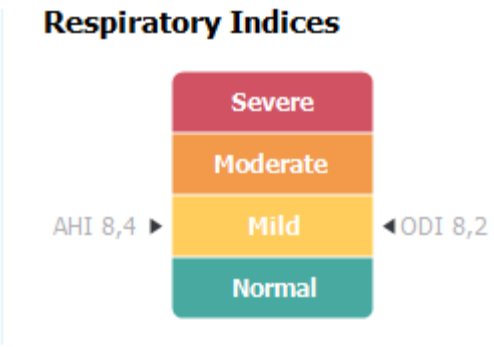
The **Sleep Parameters** panel shows a doughnut chart of different sleep stages **if** sleep stage events have been scored.



- **Total Sleep Time** is the time the patient spent asleep (based on Hypnogram).
- When **Total Sleep Time** is not available **Est. Total Sleep Time** (Same as AASM term Monitoring Time) is the parameter used. That is the time the patient is lying down during the recording.
- **Sleep Efficiency** ranges from 0-100% where 0% means that the patient was awake the entire night and 100% means that he slept throughout the night. When sleep scoring is not available the software uses movement periods to estimate this parameter.

Respiratory Indices

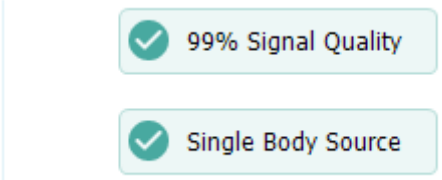
The **Respiratory Indices** panel shows the main analysis parameters and their relation to severity. AHI, the Apnea Hypopnea Index, is the number of apneas and hypopneas per hour of sleep and Oxygen Desaturation Index (ODI) is the number of scored oxygen saturation drops per hour of sleep (default automatic analysis scores all desaturations of 3% or higher but this can be customized by the user. The severity goes from *Normal* → *Mild* → *Moderate* → *Severe* and complies with the levels set forth by the AASM. If more than one night has been recorded, then these parameters will show the average values for all nights. Refer to the section *Analysis Protocols* for more information.



Overall Signal Quality and Single Body Source

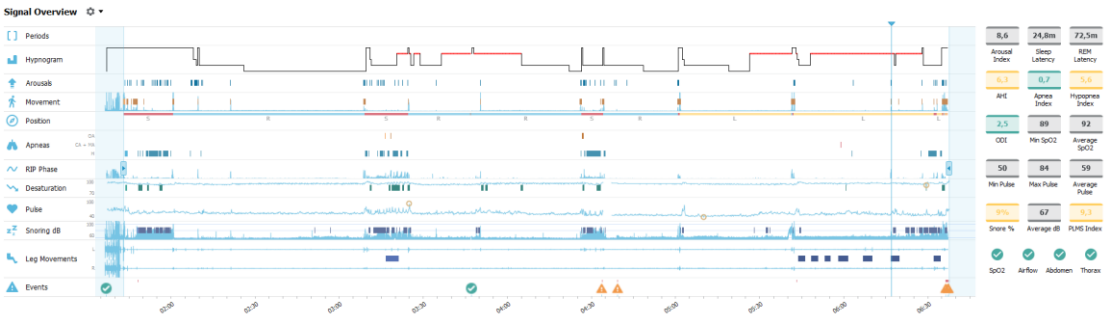
Overall **Signal Quality** is determined from the monitoring of signal quality of the following signals: oximeter, airflow, abdominal or thoracic respiratory effort signals. The lowest signal quality of those signals is displayed for the overall **Signal Quality** on the Recording Results Page and is represented from 0-100%.

The **Single Body Source** result indicates whether the oximeter and RIP belt signals are originated from the same subject. For further information about this result, refer to the section *Single Body Source*.



Signal Overview and Parameters

The **Signal Overview** panel is a top down reviewing tool where recording results can efficiently be reviewed and edited. The overview panel is split up into analysis parameters on the right and signal overview on the left.



The analysis parameters show a summary of the most common analysis parameters for a single night. If more than one night has been recorded, then each night is represented within its own panel. You can also select the period to view with the period menu located in the lower right corner of the application. Each parameter is color coded based on its severity ranging from green to red (*Normal → Mild → Moderate → Severe*).

- **Arousal Index** is the number of arousals per hour during sleep time.
- **Sleep Latency** is the duration in minutes from Lights out (Analysis Start Time) until the first epoch of scored sleep.
- **REM Latency** is the duration in minutes from the first occurrence of sleep until the first occurrence of REM.
- Respiration is represented by indices. Indices are a method to represent analysis parameters in a standardized way.
    - Apnea Hypopnea Index (**AHI**)
    - **Apnea Index** (AI)
    - **Hypopnea Index** (HI)
    - Oxygen Desaturation Index (**ODI**) represents a number of oxygen desaturation events per hour of **Total Sleep Time** or alternatively **Est. Total Sleep Time**.
    - **Snore Percentage** is the proportion of sleep time spent in snore episodes (marked as **Snore Trains**)
    - **Average dB** is the average dB levels during snore train periods.
- **Signal Quality** is determined from the monitoring of signal quality of the following signals: SpO2, airflow, abdominal or thoracic respiratory effort signals. The signal quality of those signals is and is represented from 0-100%.

Signals and Events

The signals and events plot in the signal overview panel give an overview of the whole night.

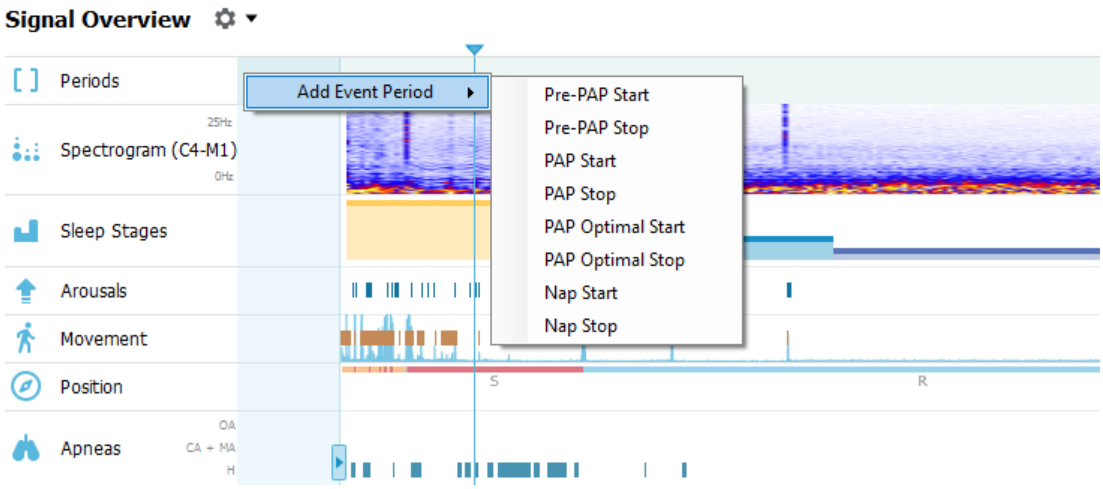
- Signals in the overview can include:
    - **Spectrogram** for the channel displayed on the screen (Right click the Spectrogram to change the channel)
    - **Sleep Stages/Hypnogram** shows the sleep stages throughout the night
    - **Arousals** shows the arousals throughout the night
    - **Movement**
    - **Position**
    - **Apneas/RIP Phase** (phase between abdomen and thoracic respiratory effort signals)
    - **Oxygen Desaturation** (SpO_2)
    - **Pulse**
    - Audio Volume (**Snoring dB**)
    - **Leg** Movements (optional)
- Events shown in the overview include apneas and hypopneas, oxygen saturation drops, snoring episodes and artifacts.

Changing the Analysis Periods

If a recording starts before all sensors have been attached or if the patient removes the sensors before the recording ends, it is possible to adjust the interval being analyzed by moving the Analysis Start[1] and Analysis Stop markers[3] to the appropriate location within the recording. All the analysis parameters are updated accordingly when these adjustments are made.

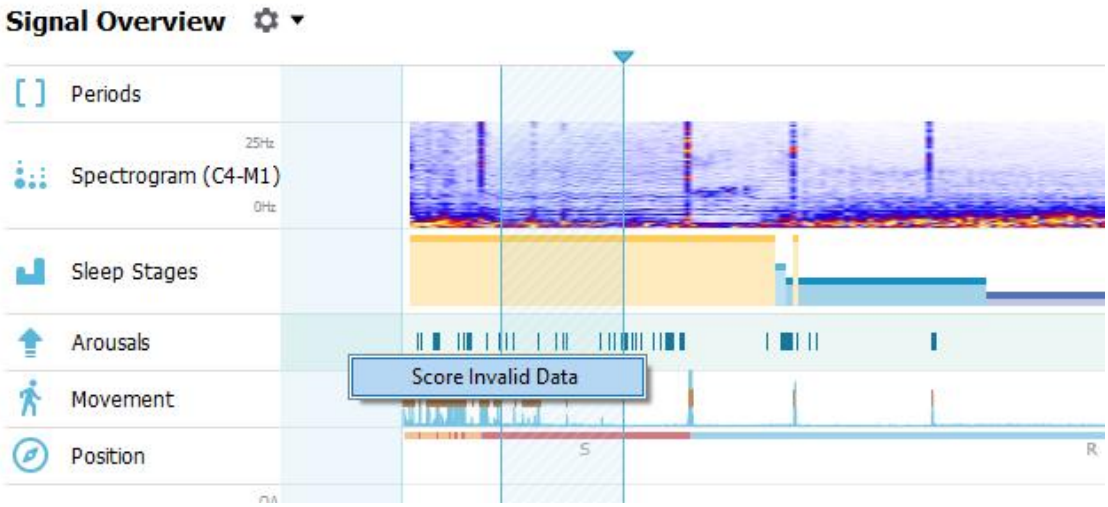
To navigate into the recording use the synchronization marker[2]. All signal sheets such as the **PSG**, **Respiratory** and **Pulse Oximeter** sheets are synchronized accordingly. If an interesting event is located in the overview, drag the synchronization marker over that area and browse into the relevant signal sheet to view the raw signals.

Event periods can be added directly from the **Signal Overview** panel. To add an event period, locate the mouse pointer to the **Periods** panel and mouse click. The **Event** period menu will be available as shown below.



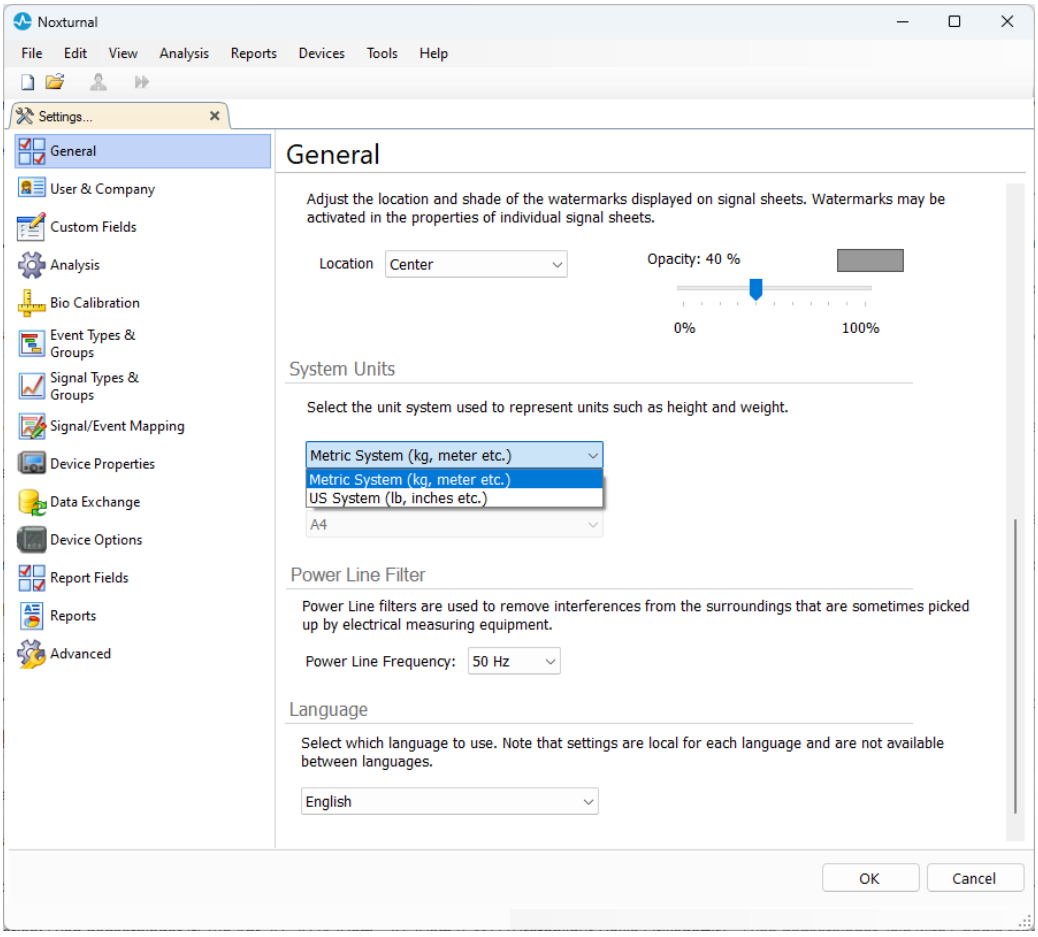
Exclusion of invalid data can be performed in Signal Overview panel. To exclude invalid data from the recording locate the mouse pointer on of the signals, left mouse click and select an area by dragging

left/right. Release the mouse button and the menu showed below will be available. The 'Invalid Data' events will be excluded from the report calculations.



Setting Units

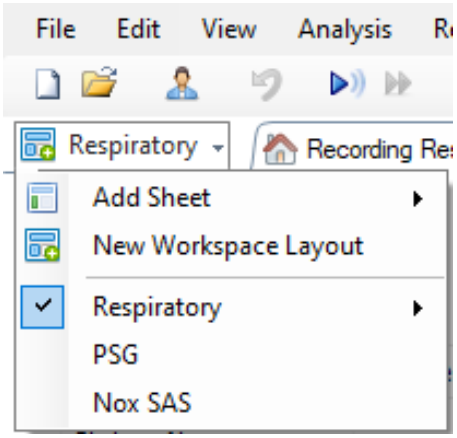
To change the unit system used to represent units such as height and weight navigate to **Tools** > **Settings…** from the Noxturnal US toolbar. On the **General** property page locate the **System Units** drop-down list and select the applicable field to be edited.



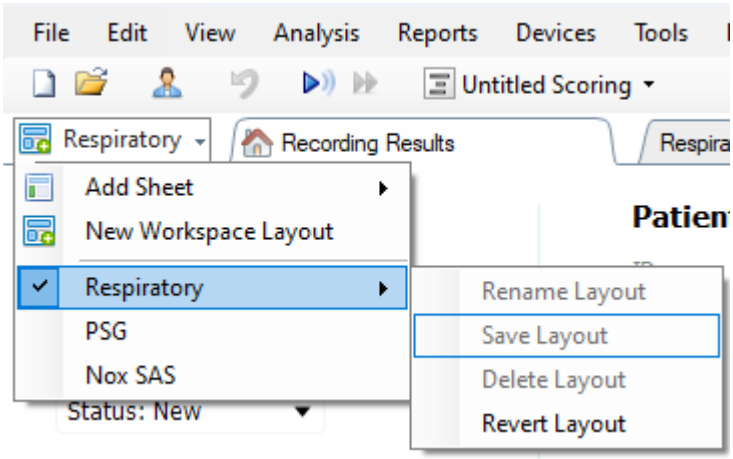
Viewing Signals

Workspace Menu Button

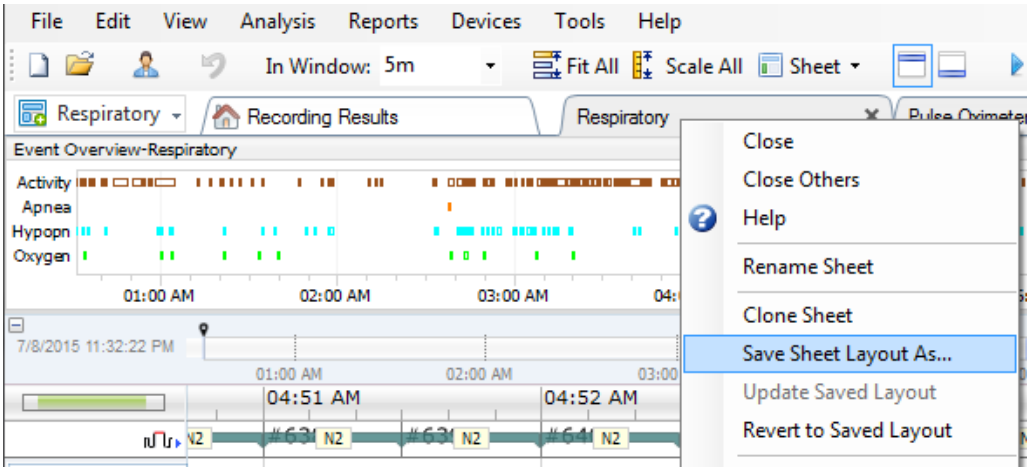
The **Workspace Menu Button** allows you to apply different Workspace Layouts and signal sheets to manage the way you want to see your recordings. The Workspace Layouts include a selection of signal sheets and signal sheet properties. Noxturnal US offers a range of default Workspace Layouts (Respiratory and PSG layouts) and signal sheets. You can also setup custom Workspace Layouts and Signal Sheets. You can save all changes to your workspace layout for future use. This means that you can change settings on traces and setup your work environment as you see fit.



You can use the Workspace Menu button to **Add Sheet**, create a **New Workspace Layout**, using a default layout to base it from or even **Revert Layout** after making changes.



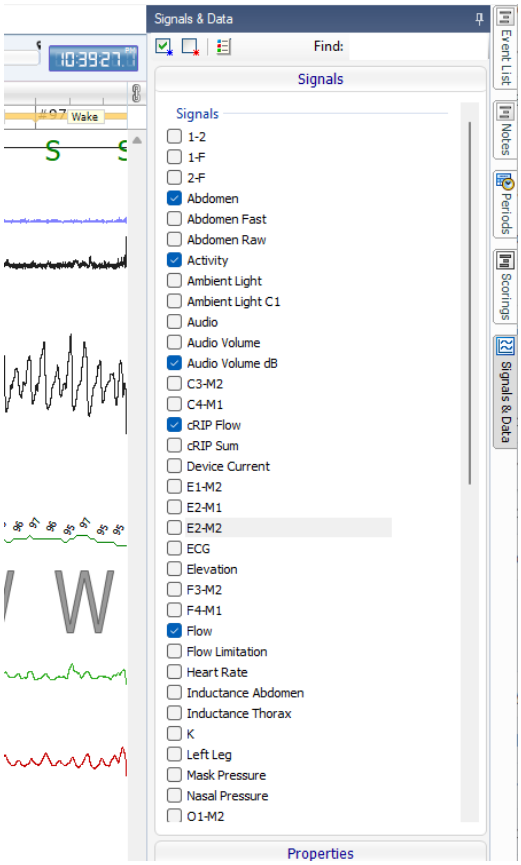
To save a customized signal sheet you right click on the signal sheet tab and select **Save Sheet Layout As...** When you have saved the customized signal sheet you can always **Update Saved Layout** if additional changes are made. For further information on signal sheets refer to the *Signal Sheets* section.



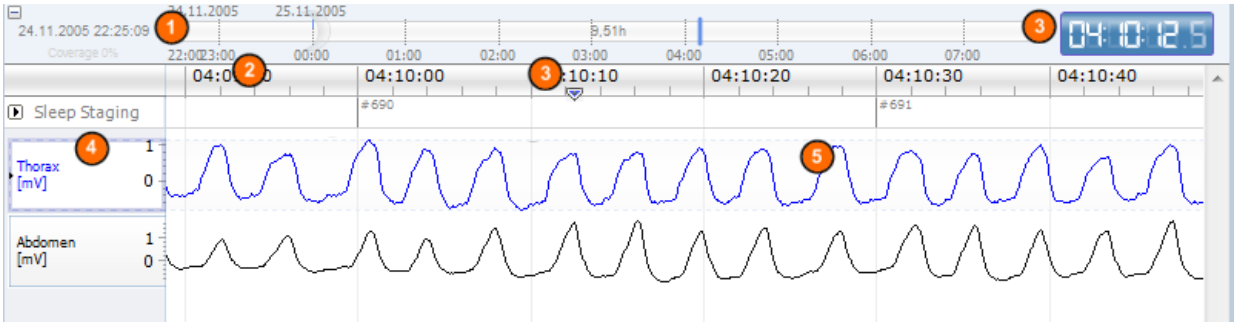
Signal Sheets

A signal sheet shows one or more signals in a tab window in the workspace. Noxturnal US comes with predefined signal sheets such as the **Respiratory** sheet, **PSG** sheet, and the **Pulse Oximeter** sheet.

To add or remove signals in a signal sheet navigate the mouse to the **Signals and Data** task window located to the right of the workspace. When the mouse cursor is over this tab the **Signals and Data** task window will slide out. A list of all signals available is listed in this task window. A checkbox next to the signal determines if the signal is displayed in the sheet or not. Check/Uncheck the box to add or remove the signal from the sheet. See the **Signals & Data** tab here below.



Working with Signals



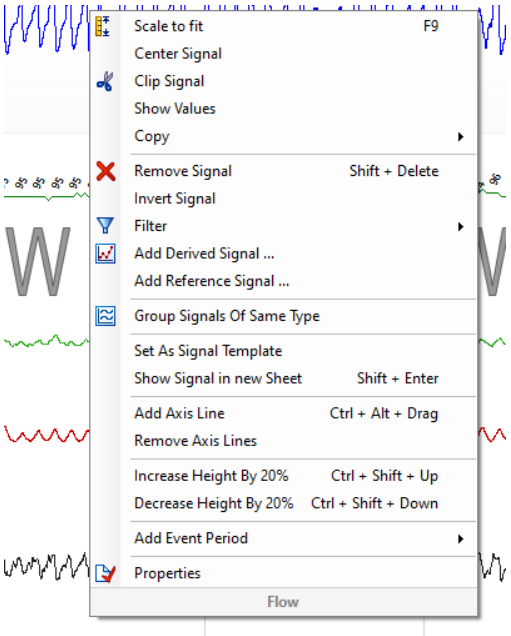
1. The navigation bar allows to quickly navigate to any time in the recording. The blue line indicates where the user is located in the recording. Click on any location in the bar to jump to that time.

2. Time axis displays the recording time and the time period in the window. Right-click on the time axis to change the interval in the window. Stretch/compress the time axis with the mouse to change time interval in the window.

3. The synchronization marker located on the time axis is used to synchronize with other signal sheets and views. The clock on the right side of the navigation bar shows the time of the marker position. The synchronization marker can be dragged and moved in time.

4. Signal value axis shows the name of the corresponding plotted signal and the value axis scale. The axis can be stretched/compressed with the mouse. To change the properties of the value axis, double-click on the axis and a dialog will appear where the properties can be changed.

5. Signal plot in a pane. Signals can be adjusted in many ways. Resize the signal pane or move the signal pane around by using the mouse. To change the properties of the signal, double-click on the signal and a dialog will appear where the signal properties can be changed. To access all actions for an individual signal trace right click the signal trace and the following menu will be available.



Keyboard Navigation

Navigate and manipulate the signal sheet by pressing the following shortcut keys:

Navigation:

- Right key = By default - Half page flip forward, user configurable
- Left key = By default - Half page flip backward, user configurable
- Ctrl + Right key = By default - Full page flip forward, user configurable
- Ctrl + Left key = By default - Full page flip backward, user configurable
- Page Down key = Page flip forward
- Page Up key = Page flip backward
- Home key = Start of recording
- End key = End of recording
- Shift + Right key = Increases time span in window
- Shift + Left key = Decreases Time span in window
- Shift + Ctrl + Left key = Jump to previous data session
- Shift + Ctrl + Right key = Jump to next data session
- - key = Zoom out of selection
- + key = Zoom into selection
- Mouse wheel = Scroll forward/backward
- Mouse wheel + Ctrl key = Scroll up and down

Active Signal:

- Shift + Up = Increase signal scaling
- Shift + Down = Decrease signal scaling
- Ctrl + Up = Shift signal up
- Ctrl + Down = Shift signal down
- Shift + Return = Show active signal in new sheet
- Shift + Delete = Remove active signal from sheet
- Up key = Select signal above
- Down key = Select signal below
- Ctrl + F = Find events
- F9 = Auto scale signal

Signal Sheet:

- Space = Play/Pause recording playback
- Ctrl + W = Auto scale signals
- Ctrl + A = Arrange signals

Events:

- Tab = Next event, if searching then next search result
- Shift + Tab = Previous event, if searching then previous search result
- Delete = Delete selected events, or delete events overlapping selection
- Return = Deselect all events
- Esc = Clear all selections

Default Derived Signals

Noxturnal US calculates default derived signals from the recorded source signals. Derived signals are statistical or direct transforms of any given signal and are described in detail in section Default Derived Signals.

Working with Events

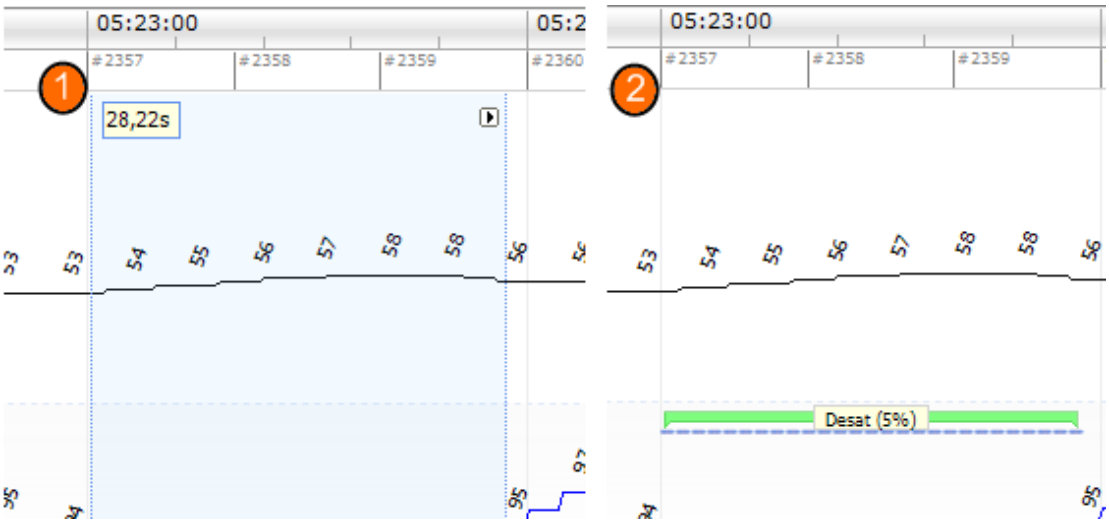
Events are used to identify areas of interest in a signal. An event has a start and stop time and a type used to classify it. Events can either be manually added to a signal or scored by the automatic analysis to flag areas of interest. Events can be modified or removed.

Scoring an Event

To score an event go to a sheet containing signals; locate an area on a signal of interest.

1. With the left mouse button, highlight an area to score the event on.

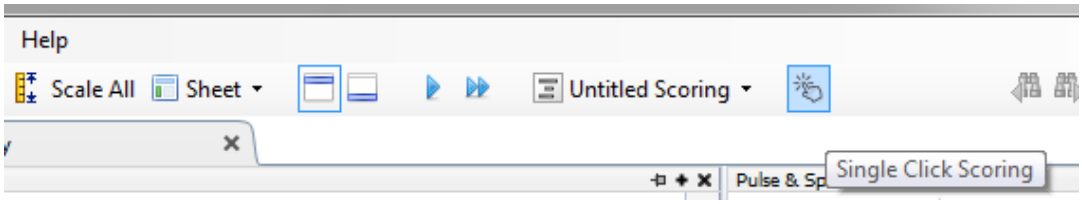
2. Press the shortcut key for that event. Shortcut key can be assigned to an event type from **Setting -> Event Types & Groups -> Edit -> Behavior.**



An alternative method for scoring an event is to highlight an area with the left mouse button, as before, but then right-click on the area and select an event from the list.

Single Click Scoring

Noxturnal US offers the option to use **Single Click Scoring**. To activate the single click scoring action click icon located in the Noxturnal US toolbar.



Within the applicable signal sheet manually score an event on the relevant signal trace, for instructions on how to manually score an event refer to the *Scoring an Event* section above. When you have scored the first event the single click scoring feature will enable you to continue scoring the same event type with only single mouse click as you browse through the recording.

Deleting an Event

There are several ways to delete existing events:

- Select an event by left-clicking it and then press the **Delete** key.
- Right-click on an event and select **Remove Event**.
- Select an area with the mouse that intersects with the events to delete and press the **Delete** key.

Moving an Event

To move an event to a different location, select the event by holding down the left mouse button and then drag the event to the desired location. Events can be dragged between signals as well as to a different time period.

Resizing an Event

To resize an event, move the mouse cursor over the left or right boundary of an event. The mouse cursor should change to an icon of an arrow pointing right and left. Once the icon has changed to an arrow, left-click and drag the event to the desired duration.

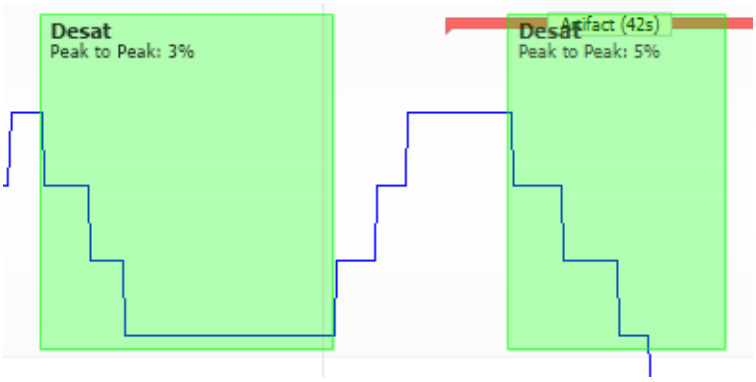
Navigating Events

There are several ways to navigate scored events in the recording:

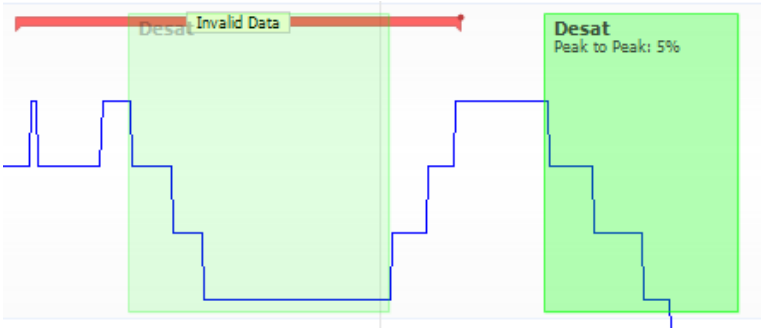
- Jump between the events that have been scored on a signal by clicking on the signal and pressing the **Tab** key which jumps to the next event in time. To jump to the previous event in time press the **Shift + Tab** key.
- In the top right corner of the workspace there is a search text box which allows you to search for any events that have been scored. Clicking on the textbox shows a dropdown list of all event types that have been scored. To search for events of some type click on the event type in the list. This shows the next event in time with that type. Click on the navigation buttons in the drop-down list to navigate the events.
- Select **View > Event Overview** from the Noxturnal US toolbar to bring up an overview window that shows all the events in a plot that have been scored in the recording. To navigate to a specific event, click on it in the overview plot.

Events overlapping Artifacts

Events that are overlapping Artifacts are counted. However, events overlapping Invalid Data are not counted and are drawn faded. See figures below:



Two Desats one with overlapping Artifact both drawn the same

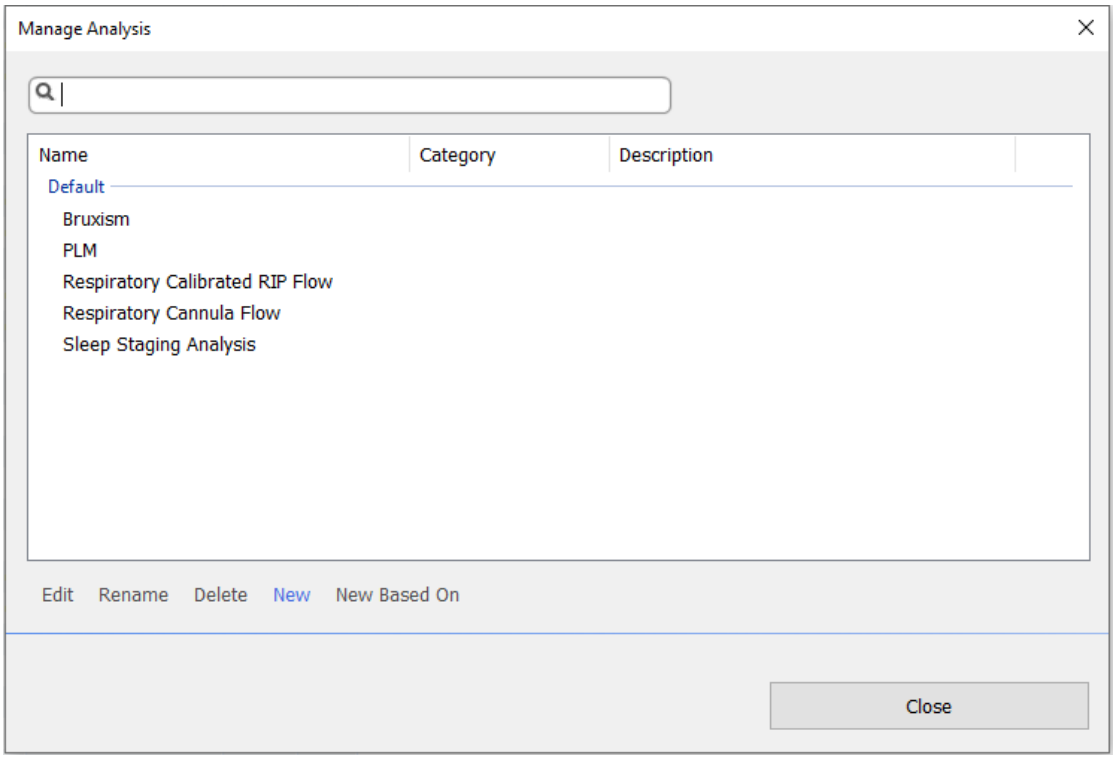


Two Desats, one is drawn faded as it will not be counted

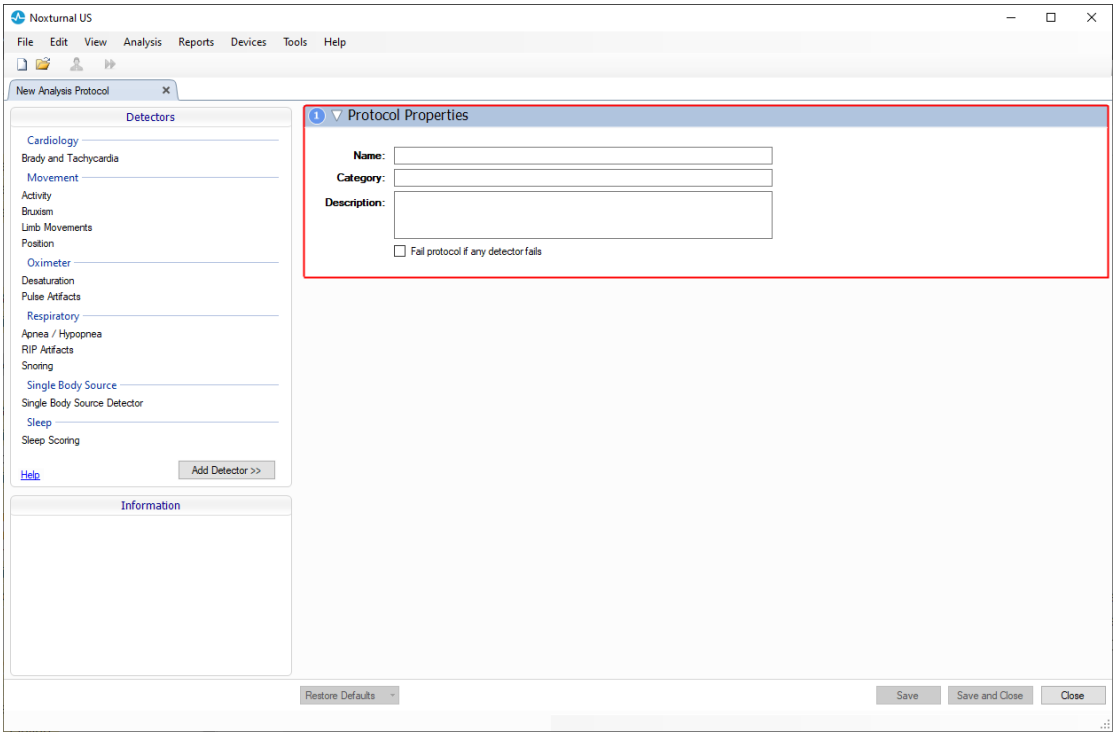
Analysis Protocols

An **Analysis Protocol** is a set of detectors that can be run on the recording to detect and mark various events within the recorded signals. The available analysis protocols, including the default protocols, are listed under the **Analysis** menu. To run an analysis protocol on the recording, select the applicable analysis from the **Analysis** menu and click on it.

Noxturnal US offers a range of default analysis protocols and you can also create a new analysis protocol which uses customized settings and/or detectors. To setup a customized analysis protocol go to **Analysis** > **Manage Protocols** from the Noxturnal US toolbar. You can **Edit** and **Rename** an existing protocol or create a **New based on** an existing protocol.



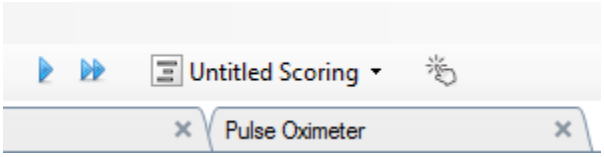
For this example, we will create a new analysis protocol. Select **New** in the **Manage Analysis dialog.** A new **Analysis Protocol** sheet will open up where the new protocol can be defined. A protocol is a collection of detectors and the function of a detector is to locate areas of interest within a signal and score the areas with events.



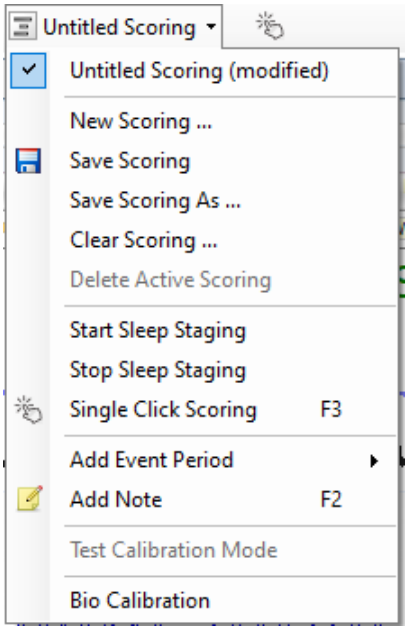
To add a detector to the protocol, choose detector from list of **Detectors** and select **Add Detector >>** **General Properties** and the **Input Signal** can be edited.
When you have setup your analysis protocol click **Save and Close** and the protocol will be added to the list of available analysis.

Working with Scorings

A scoring is a collection of events that are scored on signals in the recording. The actions for working with scorings are located in the **Scoring Button** in the Noxturnal US toolbar. The actions taken while working with scorings are listed in the sections below.



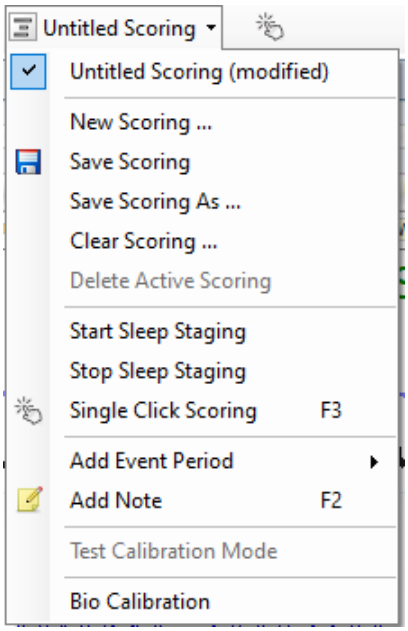
If you have included an **Analysis protocol** in the **Recording Type** configured for the recording then when downloading from a Nox recording device, Noxturnal US automatically uses the default analysis protocol to analyze the recording. For online studies you need to close down the recording when completed and when reopened from the recording library the defined default analysis will analyze the data. The automatic analyzing of the data creates a new scoring called **Untitled Scoring**, see screenshot above. In the **Scoring Button** you always see the **Selected Scoring** which is used for the reporting and recording overview features. You may easily create new scorings by using the features of the **Scoring Button**, for example if you make modifications to the automatic scoring, you can easily save that as a new scoring with the applicable name.



From the **Scoring Button** you can also **Add Event Period** or **Add Note** to the recording.

New Scoring

When using devices that record EEG, you can use the sleep staging features of Noxturnal US. Noxturnal US offers an automatic sleep stager with the system to assist the manual scorer. Also, a manual sleep staging without using the automatic sleep stager first, is possible.
To perform manual sleep staging click the **Scoring Button** and select a **New Scoring.**



After that, to start sleep staging you can select the **Start Sleep Staging** action from the menu in the **Scoring Button**. The number pad on your keyboard is used for the default sleep staging hotkeys. You can change the scoring hotkeys as explained below.

Select a Scoring

Multiple scorings can be associated with a single recording. All available scorings are listed in the scorings panel. Select the active scoring by clicking on it.

Save Scoring

Save the active scoring by clicking on the **Save Scoring** option. The user will be prompted for a name for the saved scoring. The saved scoring will be added to the list of scorings.

Clear Scoring

If a scoring is active, this action will clear it. If the active scoring has local modifications, the user will be prompted on whether he wants to save his local modifications.

Delete Selected Scoring

A saved scoring can be deleted by selecting it from the scoring list and clicking on the **Delete Selected Scoring** option. A prompt will come up, asking whether it is OK to delete the scoring.

Scoring Keyboard Shortcuts

A shortcut key is used to score events quickly. Shortcut key can be assigned to an event type from **Setting -> Event Types & Groups -> Edit -> Behavior.**

As a general rule events should only have a single keyboard character as a shortcut, but a combination of **Ctrl**, **Shift** and **Alt** plus a keyboard character is supported.

Noxturnal US Reports

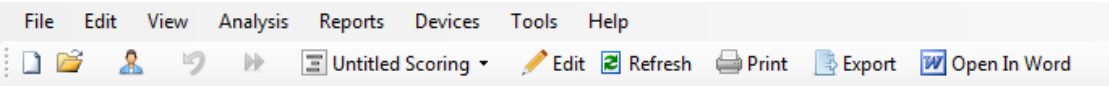
- Note: Report results are fixed and are not updated when the analysis of the recording changes.
- Note: If changes are made to the analysis another report can be generated or the existing report refreshed.

Noxturnal US offers a range of default reports that can be accessed by clicking the **Reports** menu from the Noxturnal US toolbar. For instructions on how to customize reports, refer to the Customizing Reports section below.

Generating Reports

Report can be generated by clicking the View Report button on the Recording Results page or choose a report from the Reports menu in Noxturnal US toolbar.

When you have generated a report in the report system, you can easily modify the report by using the **Edit** button which is visible in the toolbar when viewing reports.

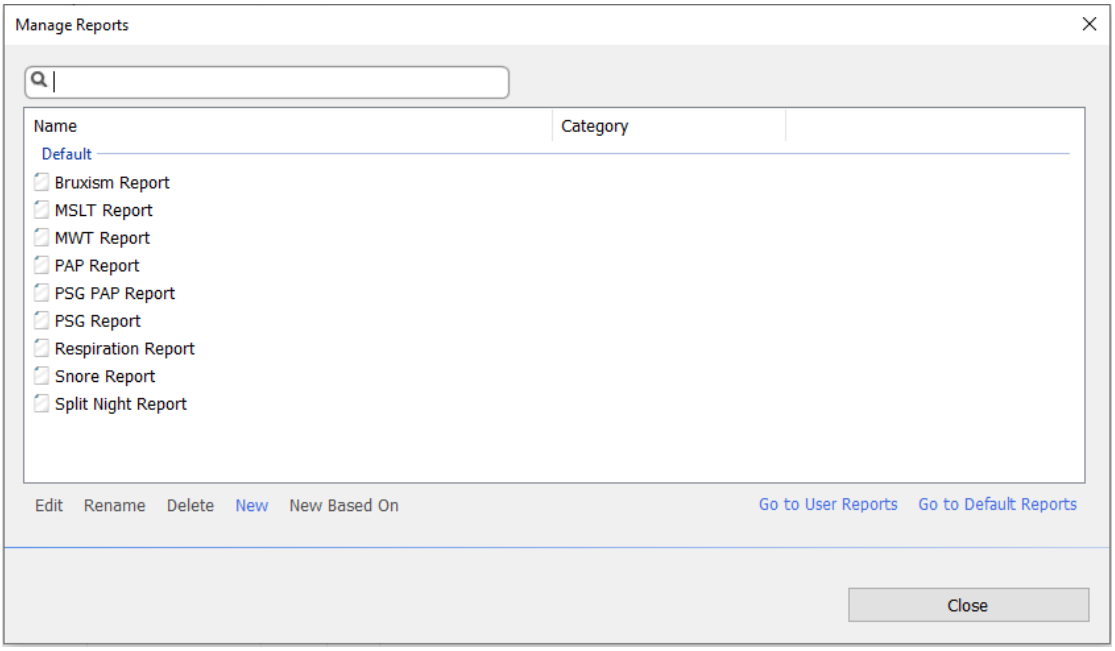


The Edit button launches the **Edit Mode** which allows you to edit the report in the same way as you would use Microsoft Word®. All changes that you make are immediately visible to you. You can also add new indices and even pre-defined report parts when interpreting a study. To stop **Edit Mode**, press the **Edit** button again. Changes that are made in the **Edit** mode are not saved as part of the report template.

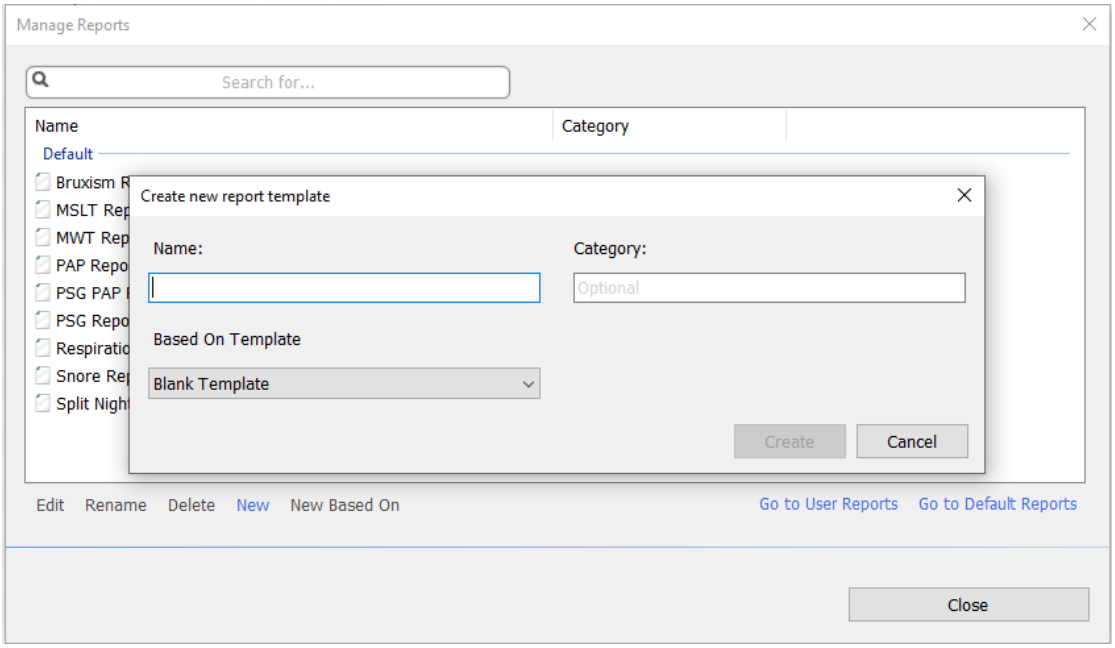
Customizing Reports

Noxturnal US offers a powerful custom report system that includes Microsoft Word® like editing capabilities. Reports in Noxturnal US can easily be customized. To create a custom report template, follow the steps below.

1. From the Noxturnal US Toolbar select **Reports -> Manage Reports…**
2. In the Manage Reports dialog select one of the options **Edit**, **New** or **New Based On** depending on your preferences.

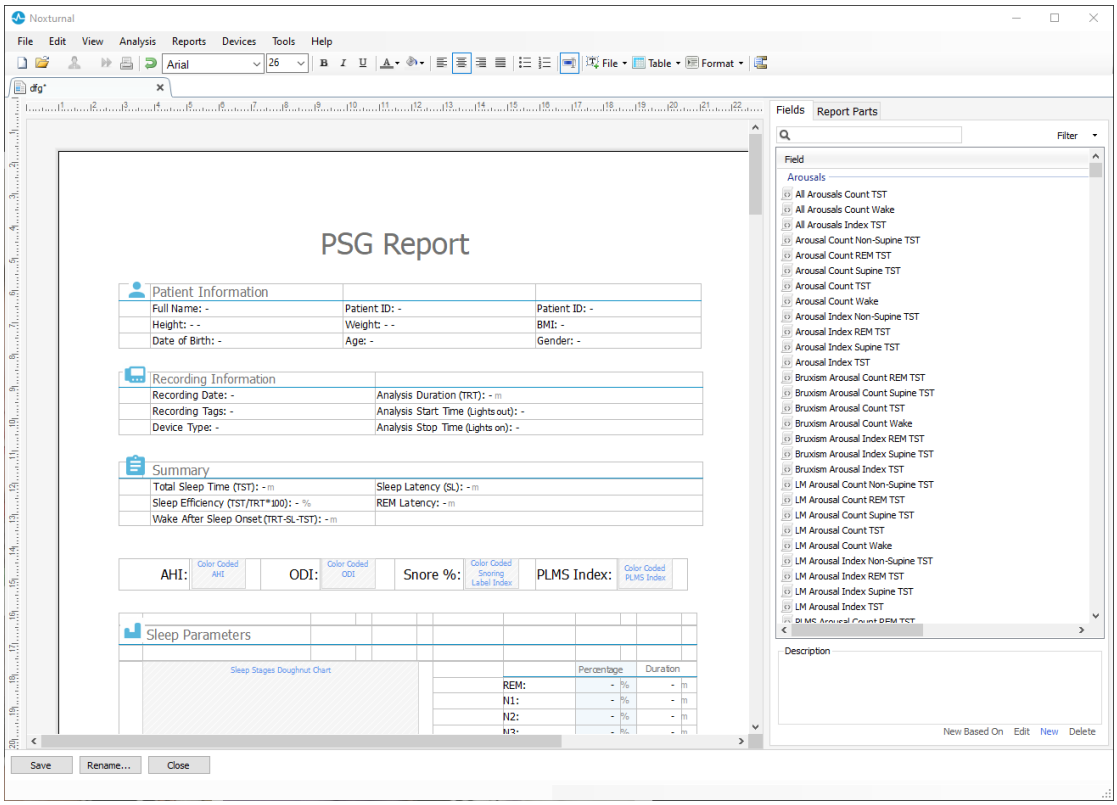


3. For this example, we will create a new custom report based on the default **PSG Report**. Select the **PSG Report** from the list of available reports and click **New Based On**.
4. You will see the following dialog where you can give the new report template a name and then select **Create**.

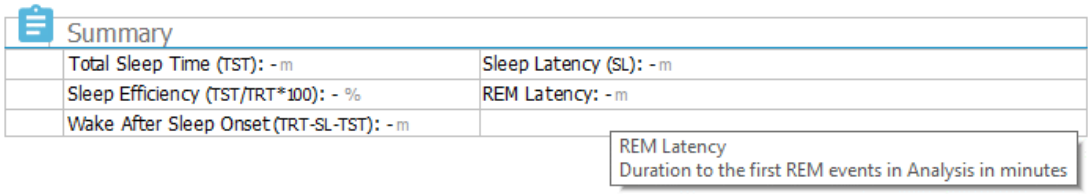


A new sheet opens up with the default chosen report and in this window you can edit it. On the right side of the screen you can find a collection of **Fields** and **Report Parts** that you can use for your report. For further information on Report Parts and Fields refer to the *Report*

Parts and Report Fields section below.



Note: In the report template you can hover over the fields (-) with the mouse to see the parameter's details. See figure below.



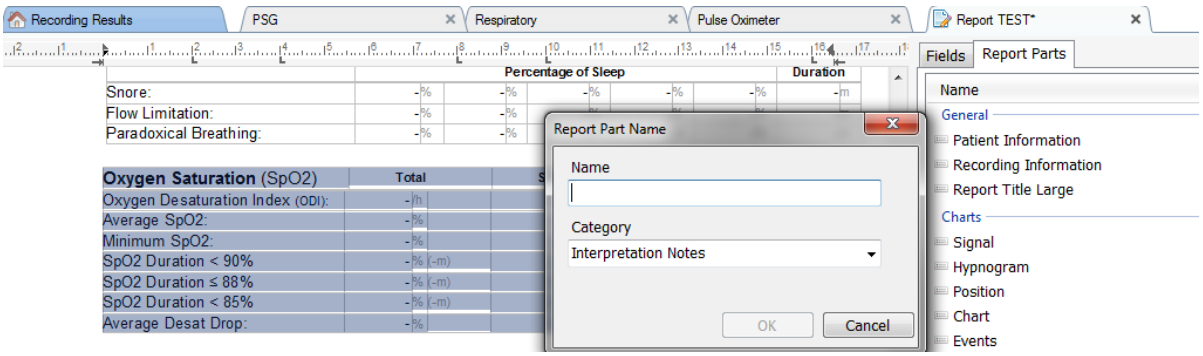
REPORT PARTS AND REPORT FIELDS

Each report part represents a section of your report such as Oximetry Saturation, PLM Details etc. Report parts and fields can be created in Noxturnal US and you can save report parts from default reports to have available when creating reports from scratch.

CREATE A NEW REPORT PARTS

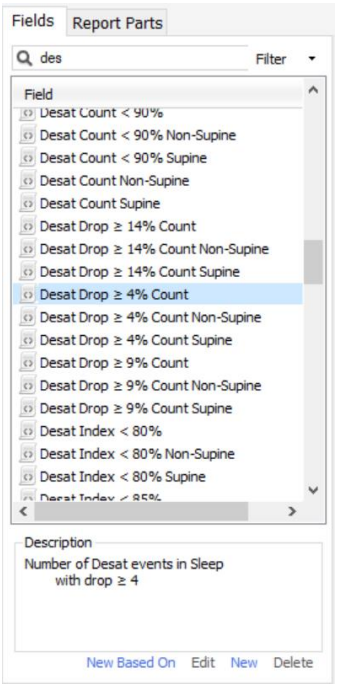
You can create new report parts and save for later use. To do that select the applicable report part in the report template (or any custom created text/table) and drag and drop it to the list of **Report**

Parts. Give the report part a name and select the category. The new report part you created will be added to the list of **Report Parts**.

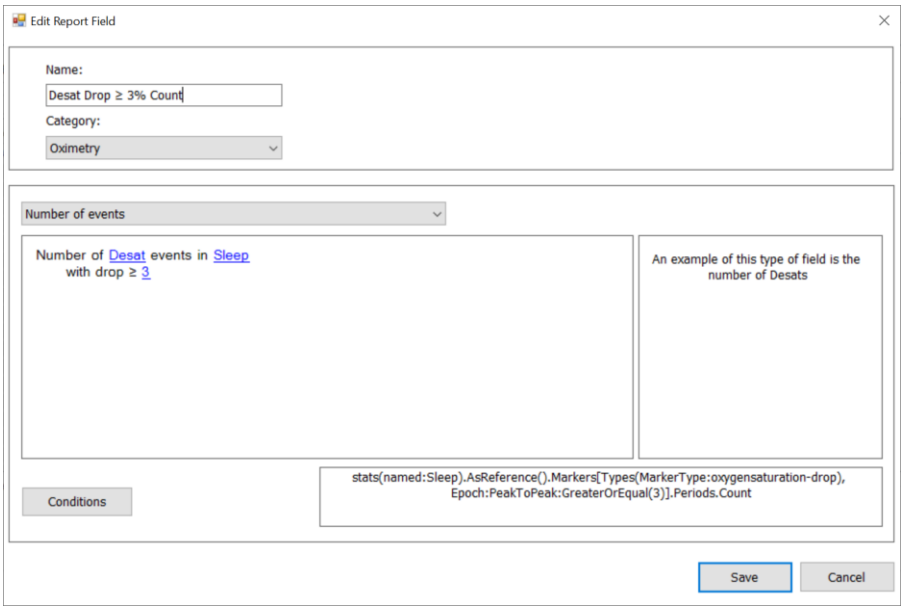


CREATE A NEW REPORT FIELD

You can create new report fields and save for later use. To do that follow the steps below.



1. For this example, we will select the default field available in Noxturnal US **Desat Drop ≥ 4% Count** as a base for our custom field. Select the **Desat Drop ≥ 4% Count** and **click New Based On**.
2. In the Edit Report Field dialog give the new field a name and edit the properties of the new field as required.



For this example, we will change the desaturation drop to ≥ 3 and give the new field a descriptive name **Desat Drop ≥ 3% Count**. If the conditions are to be changed click **Conditions** to see all available conditions.

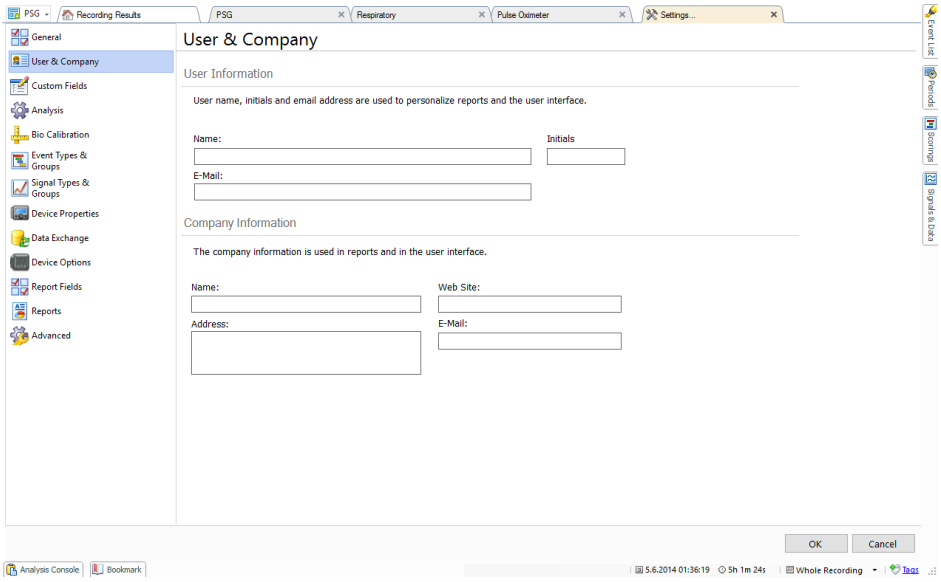
ADD REPORT PARTS AND FIELDS TO REPORTS

To add **Report Parts** and **Fields** to your report set the mouse point to the preferred location in the report and double-click the desired report part from the list on the right side. Another way to add a Report Part and Field to a report is to drag and drop the desired report part/field into your report.

REPORT HEADER AND FOOTER

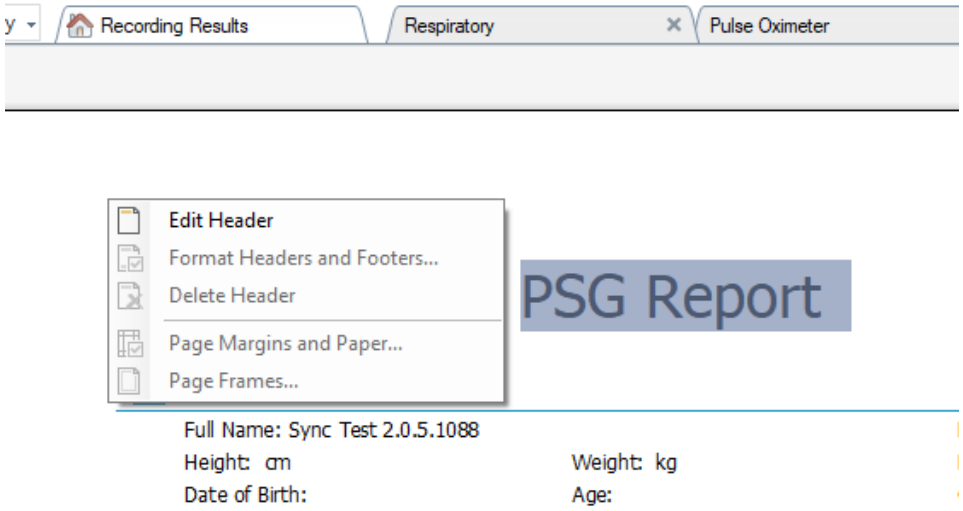
To customize the report header and footer follow the steps below.

1. From the Noxturnal US toolbar select **Tools -> Settings -> User & Company** and you will see the following wizard where you can enter user and company information.

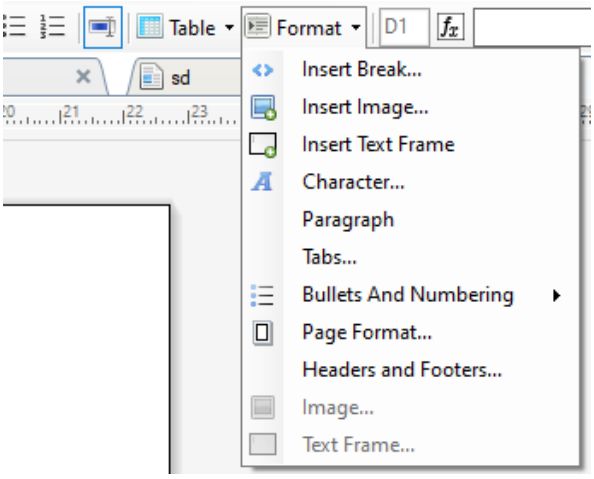


   Fill in the fields shown above the applicable information. You can insert the information entered into your report using the corresponding Report Fields.

2. To insert the information into the header/footer of your report place the mouse pointer within the upper part of the report, **right click** and select the option to **Edit Header/Footer**.



3. Add the applicable fields from the list of available fields into the header section.
4. To add logo to your report header, click **Format -> Insert Image…** as shown below.

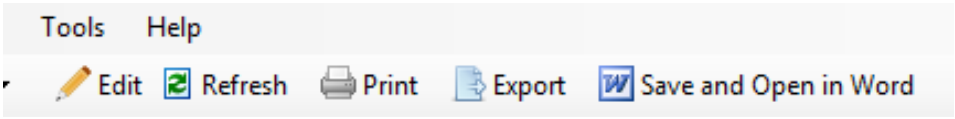


5. To add a page numbering to your report, go the bottom of the report page **right click** and select **Edit Footer**. **Right click** within the **footer** area and select **Insert > Page Number**.

When you have completed setting up your report template select **Save.** Your report will be added to the **Report** list available from the Noxturnal US toolbar.

Exporting Reports

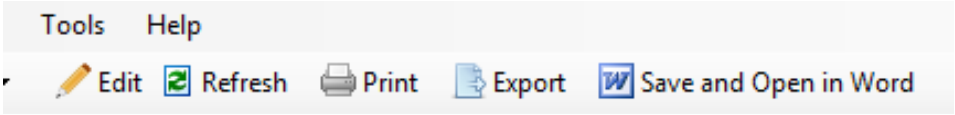
To export a report, click **Export** from the report toolbar.



This will open a new dialog to specify the file format and the file name. Click the **Save** button when done and the report will be saved to the disk in the specified file format.

Printing Reports

After a report has been generated the user can print the report. To print a report, select the **Print** option from the report toolbar.



A dialog will open where the printing options can be changed. Click the **Print** button to print.

The Recording Library

The recording library shows and manages all the recordings that have been downloaded from the Nox recording devices and online studies. When recordings are opened or downloaded in Noxturnal US they are automatically added to the recording library. It is also possible to acquire licenses to open EDF files, EDF+ files, Embla files and Somnostar files in Noxturnal US, and the corresponding recordings will be added automatically to the recording library.

To open a recording, select it from the recording library list and double-click.

Archiving Recordings

Recordings in the recording library can be archived to a different location or to a permanent storage. To archive a recording select one or more recordings in the library and click on the **Archive Recording…** button on the recording information panel. A dialog will appear guiding the user through the archiving process.

Single Body Source

The Single Body Source algorithm is a patent pending algorithm in Noxturnal US that determines if the same subject wore the recording device and the associated sensors during the recording period.

The algorithm can return one of three results. The results and their meanings are listed below.

- **Not analyzed:** The algorithm has not been run for the recording.
- **Approved:** A single body source can be verified for the recording.
- **Inconclusive:** A single body source cannot be verified for the recording.

A variety of factors can result in an **Inconclusive** result, including the following:

- The recording does not contain the necessary signals (a pulse waveform signal from the oximeter and at least one RIP signal)
- The necessary signals are noisy or include prominent artifacts
- The sensors were not placed on the subject
- The sensors were placed incorrectly on the patient or were displaced during sleep
- The oximeter and the RIP belts were worn by separate subjects
- The recording is too short (at least 15 minutes of concurrently recorded pulse waveform and RIP signals are necessary)

- The cardiac artifact in the RIP signals (caused by the emission of blood from the heart to the arteries and the resulting torso movement) is too small

The Single Body Source algorithm can be run either as a tool (by clicking **Tools -> Single Body Source**) or as an analysis detector, which can be included in a custom analysis protocol. The tool is run automatically after recordings are downloaded from a recording device.

The Single Body Source result is displayed on the **Recording Results** page under the **Signal Overview** section for each night and is also available as a report field for inclusion in custom reports. The result is indicated with one of the following symbols:

Not analyzed	**Approved**	**Inconclusive**
		
A grey circle	A white check mark on a green circle	A white question mark on a yellow circle

The automatic calculation of the Single Body Source algorithm for downloaded recordings and display of the Single Body Source result can be turned on and off in **Tools -> Settings… -> Advanced -> Single Body Source**.

Compatible Devices

The following table lists Ethernet supported devices and switches that have been validated with the Nox Sleep System. Noxturnal US can receive, synchronize, display, and store signals from Ethernet supported devices when they are connected to the same network.

SWITCHES, IP CAMERAS AND MICROPHONES

Type	Catalog Number
Trendnet PoE Switch	NA
Axis T8351, microphone 3.5 mm	NA
Axis P3374, internet protocol camera	NA

AUXILIARY DEVICES SUPPORTED

Type	Catalog Number
SenTec SDM	NA
Resmed TxLink	NA
Resmed Airsense™10	NA
Resmed S9™	NA
Resmed Aircurve	NA

Regulatory Information

Performance Testing and Validation Summary

The Nox Sleep System has been tested and verified in various phases to include internal testing, verification, and validation as well as external testing to assure product safety, effectiveness, and reliability. The design was verified and validated throughout the design process, according to requirement specifications and intended use.

Nox Medical holds an ISO 13485:2016 (MDSAP) certified Quality Management System which complies with the requirements of the Medical Device Directive (MDD - Council Directive 93/42/EEC as amended by Directive 2007/47/EC); Canada – Medical Devices Regulations – Part 1 – SOR 98/282; Australia – Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure; Japan – MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021); PMD Act and USA – 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D.

Description of Symbols and Abbreviations

PG	➢ Polygraphy
PSG	➢ Polysomnography
(01)15694311111368(8012)VVvvrr(11)YYMMDD(10)ZZZZZZ	➢ Unique Device Identifier (UDI): the Application Identifier (01) indicates the device identifier (DI) (i.e. “15694311111368”), the Application Identifier (8012) indicates the software version (i.e. “VVvvrr”), the Application Identifier (11) indicates the production date/date of manufacture (i.e. “YYMMDD”, with “YY” the last two digits of the production year, “MM” the production month and “DD” the production day), and the Application Identifier (10) indicates the lot number (i.e. “ZZZZZZ”)
	➢ Unique Device Identifier (UDI) presented in data matrix format on Noxturnal US CD
	➢ Manufacturer information
	➢ Date of manufacture
	➢ Batch code / Lot number
	➢ Catalogue number / Reference number

Security Information

The Noxturnal US software complies with the following security standards and guidelines:

- IEC 81001-5-1:2021 Health software and health IT systems safety, effectiveness and security – Security - Activities in the product life cycle
- IEC 82304-1:2016 Health Software – General requirements for product safety
- ANSI/AAMI SW96:2023 Standard for Medical Device Security – Security Risk Management for Device Manufacturers

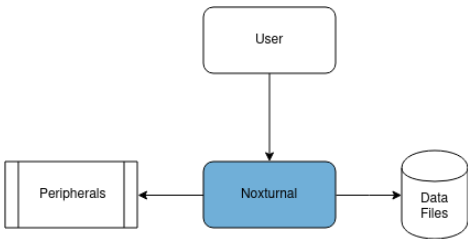
Cloud Setup: The Nox Cloud platform operating environment has the following certifications:

- ISO 27001
- SOC2
- HITRUST

Noxturnal Ecosystem

STANDARD SETUP

The standard setup contains local connections only to data files and peripherals.

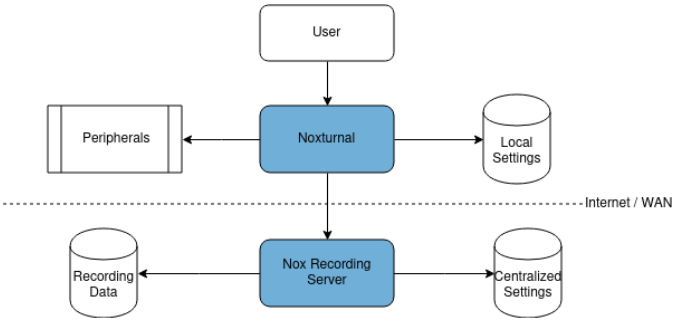


Data files are accessed directly (File I/O) while peripherals can be accessed using the following methods:

- Serial
- TCP/IP
- Bluetooth

CLOUD SETUP

The cloud setup contains local connections to Local Settings and Peripherals but Recording data and Centralized Settings are stored on the Nox Cloud platform storage.



Local Settings are accessed directly (File I/O) while peripherals can be accessed using the following methods:

- Serial
- TCP/IP
- Bluetooth

DATA AT REST

STANDARD SETUP

The Noxturnal US application stores data files containing the following settings:

- Centralized Settings
- Local Settings (overrides Centralized Settings when set)
- Recording Data

The software accesses the data files directly, and users can specify their location. It is recommended that local IT system policies are configured to allow access to the data files for relevant users only.

It is recommended to encrypt the file systems used to store the data files.

CLOUD SETUP

The following data is stored on the Nox Cloud when connected to the cloud:

- Centralized Settings
- Recording Data

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.

DATA IN TRANSIT (INTERNET / WAN)

All Internet/WAN 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. The connection is encrypted using 256-bit encryption. SHA1 is used for message authentication and DHE_RSA as the key exchange mechanism.

CLOUD 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.

CLOUD 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.

CLOUD 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.

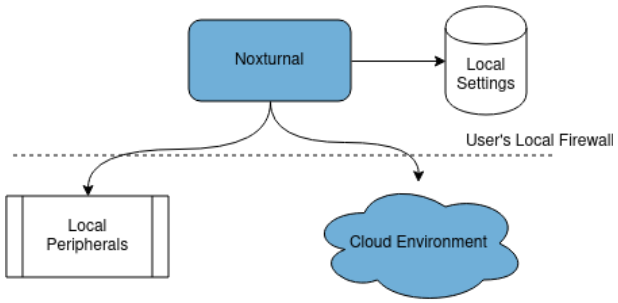
Log files are monitored to detect and prevent brute force attacks. Log files are monitored to detect multiple failed attempts to try to access the system and then block the IP of the calling system when this occurs.

CLOUD 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 following diagram explains the security ecosystem of the medical device from a user perspective:



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

To ensure seamless operation of the Noxturnal software when using Cloud Mode, 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

For seamless interoperability of Noxturnal and local peripherals the following security measures shall be implemented:

- Whitelisting of USB peripherals if applicable
- Whitelisting of IP addresses of ethernet connected peripherals

The application operates securely and effectively without requiring specific anti-malware software configurations. However, if anti-malware software is used, it is recommended to whitelist all data folders to ensure seamless operation of the Noxturnal software.

SECURITY MEASURES

It is strongly recommended to enable encryption and authentication on all peripherals that support such features. This applies to the following Nox Medical devices:

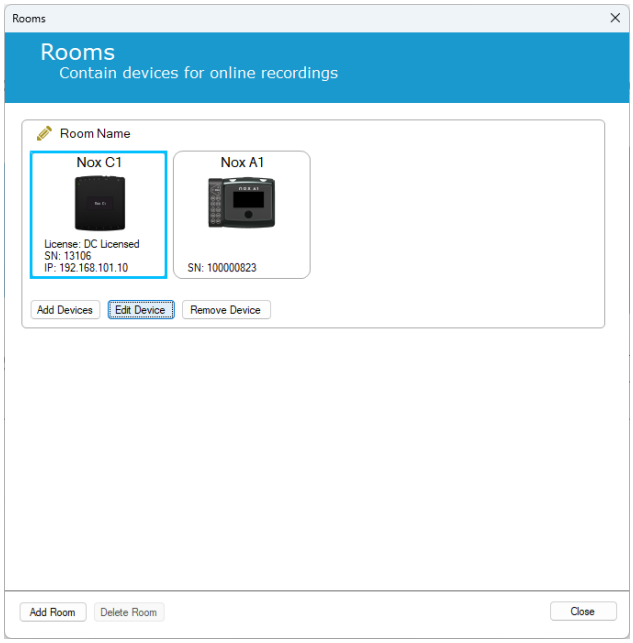
- Nox C1 Access Point – supports pin code authentication
- Nox A1 Recorder – supports pin code authentication
- Nox A1s Recorder – supports pin code authentication
- Noxturnal App – protect the mobile device running the Noxturnal App with built in mobile device security features.

NOX C1 ACCESS POINT – SETTING THE PIN CODE

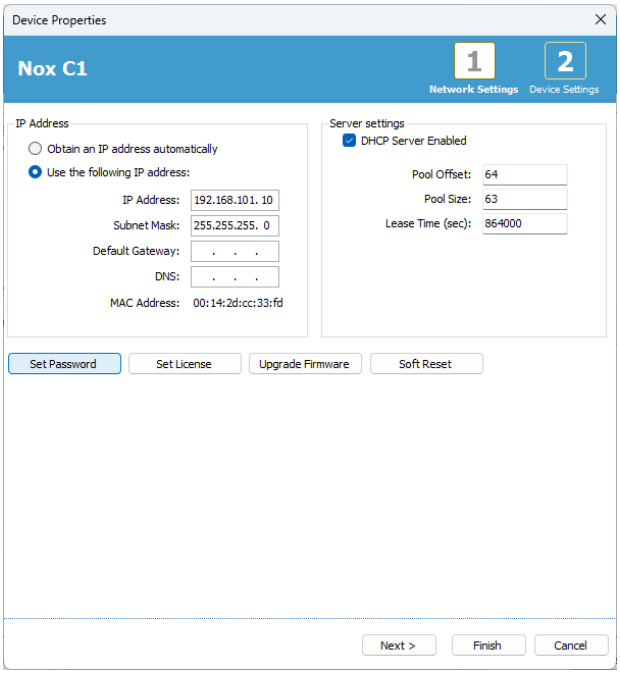
The Pin Code can be set either via Noxturnal or the Noxturnal App.

Noxturnal

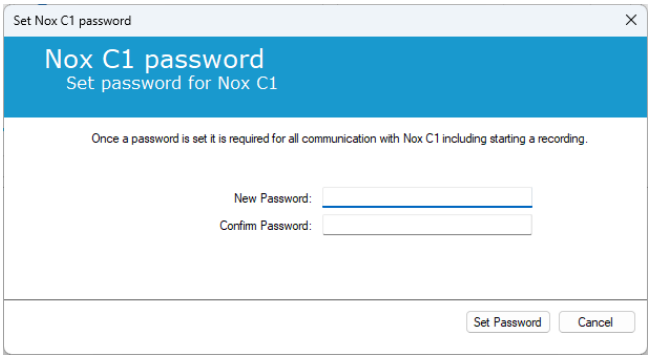
When C1 has been added to an Online Room in Noxturnal, the Pin Code can be set by navigating to Devices->Online Rooms->Edit Device (Select the relevant Nox C1 Access Point from the list of available Rooms):



Hit the Set Password button:

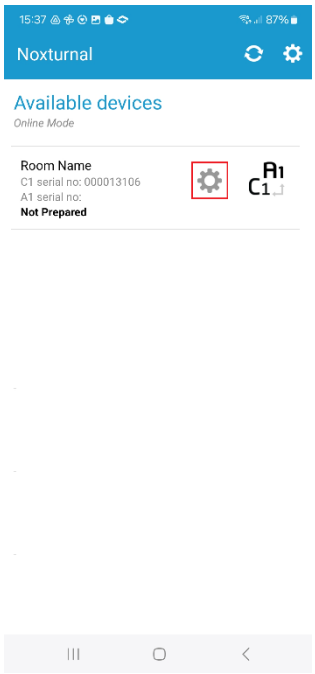


And enter a password and confirm it:

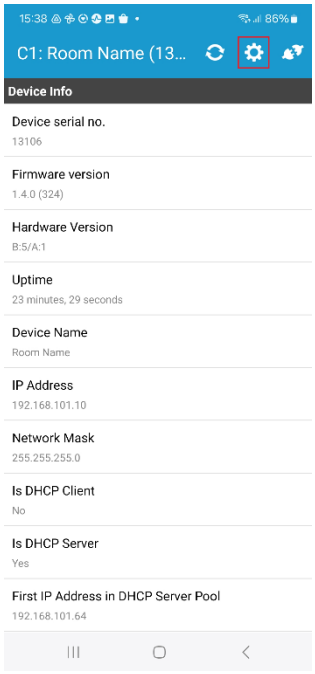


Noxturnal App

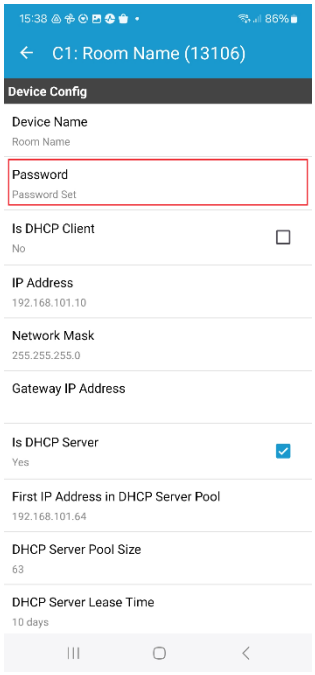
Open the Noxturnal App in Online Mode. Open the Configuration for the relevant device:



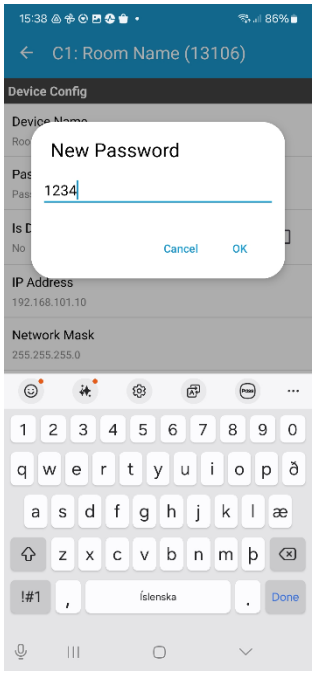
When connection has been established, select the Configuration again from the top banner:



Hit the Password field to set the password:



Enter the new password:



The password has now been set.

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 delivered via distributors as soon as they are released. All installation packets are digitally signed by Nox Medical for ensuring security and integrity of the installer content.

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)

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

The Software Bill of Material is provided as an IFU Addendum to this document. 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.

Appendix

Default Derived Signals

Noxturnal US calculates default derived signals from the recorded source signals. Derived signals are statistical or direct transforms of any given signal and are described in the table below.

Derived Signal	Source Signal	Description
Activity	Gravity X and Gravity Y	Indication on patient activity/movements. The Activity signal is calculated from raw gravity signals (X and Y axis) measured by 3-dimensional accelerometer in the Nox recorders. The measured gravity signal is differentiated with respect to time and scaled by the correct scaling factor to create the derived activity signal.
Audio Volume [dB]	Audio Volume	An Audio Volume signal in logarithmic scale (with units of decibels) is automatically calculated from the raw Audio Volume signal, which is in linear scale. The transform used to calculate the signal is ***V_dB = 20 log(x/P_0),*** where V_dB is the volume in decibels, P is the raw audio volume signal (which is a pressure signal with units of Pa) and P_0 is the reference sound pressure, which has a value of P_0 = 20 uPa in the Noxturnal US software.
Calibrated RIP Abdomen	RIP Abdomen	The Calibrated RIP Abdomen Signal is calculated by scaling each value of the RIP Abdomen signal with the corresponding RIP K signal (derived signal). The flow signal will be automatically created if both: RIP Abdomen and RIP K signal exist.
Calibrated RIP Flow	RIP Thorax	The calibrated RIP flow is calculated from a derivative of the sum of the RIP Thorax and calibrated RIP Abdomen signals (derived) and has the unit [V/s].
Calibrated RIP Sum	RIP Abdomen and RIP Thorax	The Calibrated RIP Sum signal is calculated by adding the RIP Thorax signal with the RIP Abdomen signal after the latter has been scaled with the RIP K signal.
Cannula Flow	Cannula Pressure	The Cannula Flow signal is a qualitative signal derived from the raw nasal Cannula Pressure signal and has the unit [cmH2O]. The nasal Cannula Pressure signal is low-pass filtered at 3 Hz and then the cannula flow signal is derived from a non-linear transformation.
Cannula Snore	Cannula Pressure	The snoring signal (Cannula Snore) is derived by high-pass filtering a raw nasal Cannula Pressure or airflow signal.

EMG Frontalis	E1-E3, and E2-E4	The EMG.Frontalis-Left signal corresponds to the rereferenced signal E1-E3 and the EMG.Frontalis-Right signal corresponds to the rereferenced signal E2-E4
Flow Limitation	Cannula Pressure	The Flow Limitation signal is derived by using a mathematical formula for calculating the flatness of an inhalation.
Heart Rate	ECG	An R wave detection algorithm is run to detect each heart beat in the ECG signal. The instantaneous heart rate is the reciprocal of the intervals between successive heart beats. The heart rate signal has the unit [bpm] (beats per minute).
Mask Pressure	Raw Pressure	The Mask Pressure signal is calculated on T3 and A1 devices, but in later versions of the devices the Mask Pressure signal is calculated in Noxturnal using the Raw Pressure signal, if the Mask Pressure channel is included in the device profile for the recording. The Mask Pressure should be identical to the Raw Pressure signal, but with a different signal type
Nasal Pressure	Raw Pressure	The Nasal Pressure signal is calculated on T3 and A1 devices, but in later versions of the devices the Nasal Pressure signal is calculated in Noxturnal using the Raw Pressure signal, if the Mask Pressure channel is included in the device profile for the recording. The Raw Pressure signal is filtered with a high-pass filter to create the Nasal Pressure signal.
Position	Gravity X and Gravity Y	Indication of patient posture to discriminate between upright, supine, prone, left, and right position. The Position signal is created from Gravity X and Gravity Y and is the angle of the rotation of the body. It ranges from -180° to 180° and is 0° if the patient is facing directly upwards.
Pulse Wave Amplitude	Plethysmograph	Pulse Waveform Amplitude (PWA) is a signal that shows the peak to peak value of a pulse waveform (the photoplethysmography signal from the oximeter) using a sample and hold method for the duration of the wave. The unit is [k].
RIP Sum	RIP Abdomen and RIP Thorax	The RIP Sum [V] is calculated as the sum of the RIP Abdomen and RIP Thorax signals.
RIP Flow	RIP Abdomen and RIP Thorax	The belt flow is calculated from a derivative of the sum of the RIP Abdomen and RIP Thorax signals and has the unit [V/s].
RIP K	RIP Abdomen and RIP Thorax	To get a more accurate estimate of the actual respiratory flow from the RIP Abdomen and Thorax signals, the RIP Abdomen signal needs to be scaled using a calibration factor. This calibration factor is stored as the derived signal K. The K is found by seeking the optimal value giving the best correlation between the derived RIP flow and a reference pneumoflow.

RIP Phase	RIP Abdomen and RIP Thorax	The phase difference between the RIP Abdomen and RIP Thorax belts. The phase signal ranges from 0-180°. The RIP Phase is shown as a signal synchronized with RIP Abdomen and RIP Thorax belts.
RIP Inductance and Fast RIP Inductance	Raw RIP counters	The RIP inductance signals are calculated on A1 devices, but in later versions of the devices the RIP inductance signals are calculated in Noxturnal using the Abdomen Raw and Thorax Raw signals. A transfer function is applied to the raw signals, which measure the resonant frequency of the RIP belts, to estimate the inductance of the belts. Two versions of each RIP inductance signal are available, one sampled at 25 Hz and the other at 200 Hz.
RIP and Fast RIP	Raw RIP counters	The RIP signals are calculated on A1 and T3 devices, but in later versions of the devices the RIP signals are calculated in Noxturnal using the Abdomen Raw and Thorax Raw signals. The raw RIP signals are filtered with a high-pass filter to create the RIP signals. Two versions of each RIP signal are available, one sampled at 25 Hz and the other at 200 Hz.
Reference EEG	EEG Signals	The reference EEG signal is an average of two or more EEG input signals.
Respiratory Rate	RIP Abdomen and RIP Thorax	The respiratory rate signal is derived from the RIP Sum signal (derived signal). The respiratory rate is displayed as respirations per minute or [rpm].
Set Pressure	Mask Pressure	The Set Pressure signal is created from the Mask Pressure signal. It shows the most common Mask Pressure over a 5 second interval.
TcCO2 [Pa]	TcCO2	The signal received from a transcutaneous CO2 device has the unit [torr]. The new TcCO2 signal which has the unit [Pa] is calculated, using the scaling factor 133.3 Pa/torr.

Automatic Analysis Overview

Clinical performance testing was conducted for the automatic analysis implemented in Nox Sleep System to demonstrate safety and effectiveness. The clinical performance testing consisted of retrospectively analyzing pre-existing clinical data from sleep studies that had already been collected and manually scored as part of routine clinical care. All scorers were qualified polysomnographic technologists and followed the American Academy of Sleep Medicine (AASM) scoring guidelines. The study protocol consisted of exporting the reported indices/events from the pre-existing manual scoring and then running the automatic analysis in Noxturnal US on the same clinical data. The results of the automatic scoring were exported and compared to the results of the manually scored data. The overall conclusion of the clinical performance testing is that the Noxturnal US's automatic analysis tools are found to be acceptable as a scoring aid in the clinical routine for the clinical purpose as specified for each analysis in the table below.

The table below lists the automatic analysis implemented in Noxturnal US, gives a short overview how the algorithm works, what signals are analyzed, describes the criteria used for scoring, and what indices/event/parameters are calculated/scored.

Furthermore, the table includes information on the clinical purposes and limitations, the clinical conditions being analyzed, safety endpoints specified for each analysis and the type of clinical data sets used for validation.

Name, Purpose, Indices, Events	**Clinical Condition**	**Overview**
Bruxism Analysis The clinical purpose is to improve the efficiency of scoring EMG data that is consistent with potential bruxism-related events by labeling mandibular movements as measured by masseter EMG for review and confirmation by a trained healthcare professional. Limitations: The analysis is known to overestimate the number of bruxism events and on average 42% of automatically scored events may have to be removed manually. The automatic analysis results should always be reviewed by a certified technician or a physician prior to diagnosis. Index scored: Bruxism Episode Index (BEI) - number of bruxism episodes per hour of sleep	Jaw contractions during sleep. Jaw contractions (possible bruxism-related events) are classified either as tonic (sustained clenching contractions) or phasic (repetitive brief contractions).	The algorithm uses a masseter EMG signal and the activity signal. Periods of temporarily increased masseter muscle activity are found and scored as bursts. If the scored bursts fit the pattern of tonic or phasic bruxism episodes they are scored as such as defined by the AASM guidelines. By default, bruxism episodes are disregarded if they occur concurrently with patient movement, which is characterized by an increase in the activity signal. Clinical data set: The automatic analysis was validated on clinical sleep recordings from an adult general population seeking medical attention with regards to their sleep disorders. The sleep recordings were scored by a certified technician as a part of standard clinical routine. Primary safety endpoint: The analysis was considered to be safe if it detects at least 90% of oromandibular movements considered by a human expert to be bruxism events with 95% confidence. Result: The sensitivity of the analysis was 95.7% (95% CI 93.2% - 97.4%), specificity was 61.0% (95% CI 58.9% - 63.0%), PPV was 34.6% (95% CI 32.0% - 37.3%), NPV was 98.5% (95% CI 97.7% - 99.1%).

		The Bruxism Analysis is therefore considered safe and effective.
PLM Analysis The clinical purpose is to improve the efficiency of scoring periodic limb movement events. Limitations: The automatic analysis results should always be reviewed by a certified technician or a physician prior to diagnosis. Indices scored: Limb Movement Index (LMI) - number of limb movements per hour of sleep Periodic Limb Movement Index (PLMS) - number of periodic limb movements per hour of sleep	Limb Movements during sleep: Periods, during sleep, lasting 0.5-10 seconds where the muscle tone in a limb, typically measured on the tibialis muscle, is increased from baseline. Periodic Limb Movements during sleep: Period, during sleep, containing at least 4 limb movement events separated by 5-90 seconds.	The Limb Movement algorithm uses left leg and right leg EMG signals to identify periods where muscle tone is increased. Additionally, the activity signal is used to detect patient activity. The PLM analysis locates events of high muscular activity or kinetic activity and identifies as LM (limb movement) events. These are subsequently used to determine if any PLM (periodic limb movement) events are present. The analysis follows the guidelines set forth by the AASM. Clinical data set: The automatic analysis was validated on clinical sleep recordings from an adult general population seeking medical attention with regards to their sleep disorders. The sleep recordings were scored by a certified technician as a part of standard clinical routine. Primary safety endpoint: The analysis was determined to be safe based on the safety hypothesis of having all criteria below met for the PLMI index. • Interclass correlation (ICC) must exceed 0.61 • Pearson correlation coefficient (PCC) must match or exceed r = 0.65 • The absolute bias must not exceed 5.7 Result: ICC is 0.98, Pearson correlation coefficient is 0.94 and absolute bias is 0.29 for the Periodic Limb Movement Index The PLM Analysis is therefore considered safe and effective.

Respiratory Flow Analysis (calibrated RIP, Cannula)[3] 1) The clinical purpose is to improve the efficiency of scoring Apneas, Hypopneas (using calibrated RIP, cannula) and desaturation events from oximeter. Limitations: The results should always be reviewed by a certified technician or a physician prior to diagnosis. Indices scored: Apnea Hypopnea Index (AHI) - number of apneas and hypopneas per hour of sleep Apnea Index (AI) - number of apneas per hour of sleep Hypopnea Index (HI) - number of hypopneas per hour of sleep Oxygen Desaturation Index (ODI) - number of oxygen desaturation events per hour of sleep. 2) The clinical purpose is to improve the efficiency of classifying apneas into central apneas, mixed apneas or neither. Limitations: The results should always be reviewed	Apneas during sleep: Periods lasting 10 seconds or longer where a patient stops breathing. Hypopneas during sleep: Periods lasting 10 seconds or longer where a patient's breathing is severely reduced. Oxygen desaturation during sleep: Periods where the oxygen saturation of a patient's arterial blood falls below the baseline by 3% or more. Central Apneas during sleep: Periods lasting 10 seconds or longer where a patient stops breathing and respiratory effort is absent. Mixed Apneas during sleep: Periods lasting 10 seconds or longer where a patient stops breathing. Respiratory effort is absent at the start of the period but present at the end.	1) The Apnea / Hypopnea (AHI) algorithm uses as applicable the respiratory cannula flow or respiratory calibrated RIP flow signal depending on the analysis run and can utilize scored events in the EEG to score hypopneas. The scored EEG events are arousals during sleep scored manually. The algorithm also uses an SpO2 signal measured by an oximeter to find desaturation events which are used to score hypopneas, but the algorithm does not score the desaturation events. The AHI algorithm determines if a patient is breathing normally, if breathing is severely reduced resulting in a hypopnea, or if a patient is not breathing resulting in an apnea. If breathing is severely reduced the algorithm looks if there is an arousal or a drop-in blood oxygen saturation associated with the reduction in breathing to score an hypopnea. The Desaturation (ODI) algorithm uses an SpO2 signal measured by an oximeter to determine if there is a drop of 3% or more in blood oxygen saturation. The analyses follows the guidelines set forth by the AASM. 2) The Apnea Classification algorithm uses a respiratory flow signal, with the addition of the abdomen and thoracic respiratory Inductance plethysmography (RIP) signals.

[3] Includes AHI and ODI Algorithm and Apnea Classification Algorithm

by a certified technician or a physician prior to diagnosis. Indices scored: Central Apnea Index (CAI) number of central apneas and hypopneas per hour of sleep Mixed Apnea Index (MAI) - number of mixed apneas per hour of sleep Central Mixed Apnea Index (CMAI) - number of central and mixed apneas per hour of sleep		The Apnea Classification algorithm classifies scored apneas as central or mixed if respiratory effort is absent during the apnea, or neither. The analysis follows the guidelines set forth by the AASM. Clinical data set: The automatic analyses were validated on clinical sleep recordings from an adult general population seeking medical attention with regards to their sleep disorders. The sleep recordings were scored by a certified technician as part of standard clinical routine. Primary safety endpoints: 1) The automatic respiratory flow analysis was determined to be safe if it met the safety endpoint of having a 95% confidence in not classifying patients with an AHI below 5 as having an AHI greater than or equal to 15 or having a 95% confidence in not classifying patients with an AHI greater than or equal to 15 as having an AHI below 5. Two co-primary endpoints are used for AHI. a) Cohen's Kappa to match or exceed 0.66 and Pearson correlation matches or exceeds r = 0.96 for the cannula. b) Cohen's Kappa of 0.66 to be within the 95% confidence interval and Pearson correlation matches or exceeds r = 0.72 for the cRIP. The criteria for ODI is that Intra-Class Correlation (ICC) matches or exceeds 0.93 2) The automatic apnea classification analysis was deemed to be safe if it met the acceptance criteria of an ICC comparable with what has been

		reported in scientific literature of Central Apnea Index (CAI 0.46). Result: 1) The analysis is safe since the odds of misclassifying between severity groups is less than the acceptable 5%. a) Cohens Kappa is 0.78 and Pearson's r = 0.96 for the cannula. b) Cohen's Kappa is 0.62 (95% CI 0.56 – 0.66) and Pearson's r = 0.79 for the cRIP. The ICC for ODI was 0.95. The ICC was 0.91 for the Central Apnea Index. The Respiratory Flow Analysis is therefore considered safe and effective.
Sleep Staging Analysis The clinical purpose is to improve the efficiency of scoring sleep stages with the intent of estimating total sleep time. Limitations: The automatic analysis results should always be reviewed by a certified technician or a physician prior to diagnosis. The following events are scored: Sleep stage W (Wake), Stage N1, Stage N2, Stage N3 and Stage R (REM)	The pattern of sleep stages is used to analyze how the individual sleeps and determine any abnormalities in the sleep profile that might indicate sleep disorders.	The algorithm uses electroencephalography (EEG) signals, electrooculogram (EOG) signals, activity signal and submental electromyography (EMG) signal to provide pre-scoring of sleep stages according to the AASM manual. The algorithm is implemented with an artificial neural network. Various features are calculated from the EEG, the EOG, the activity signal and the submental EMG and fed into the neural network, which returns sleep stages for 30 second epochs, to simulate the way sleep stages are scored by human scorers. Clinical data set: The automatic analysis was validated on clinical sleep recordings from an adult general population seeking medical attention with regards to their sleep disorders.

		The sleep recordings were scored by a certified technician as a part of standard clinical routine. Primary Safety endpoint: The analysis was determined to be safe if it met the safety endpoint of having an average agreement of at least 60% when scoring wake epochs. Co-primary endpoint is that Cohen's kappa statistics matches or exceeds 0.63 Results: The Cohen's Kappa was calculated resulting in κ=0.68. The accuracy of predicting the sleep stages resulted in N1 (9.7%), N2 (86.7%), N3 (84.7%), Wake (66.7%), and REM (84.1%). The Sleep Staging Analysis is therefore considered safe and effective.