nox medical

nox A1s

MANUAL

US Manual

Nox A1s US Manual

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nox medical

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List of Abbreviations

AASM	-	American Academy of Sleep Medicine
ABS	-	Acrylonitrile Butadiene Styrene
BMI	-	Body Mass Index
CISPR	-	*Comité International Spécial des Perturbations Radioélectriques* (English: International Special Committee on Radio Interference)
CPAP	-	Continuous positive airway pressure
ECG	-	Electrocardiography
EEG	-	Electroencephalography
EMG	-	Electromyography
EMC	-	Electromagnetic compatibility
EPA	-	Environmental Protection Agency
EOG	-	Electrooculography
ESD	-	Electrostatic discharges
HF	-	High Frequency
IEC	-	International Electrotechnical Commission
ISM	-	Industrial, Scientific and Medical
MRI	-	Magnetic Resonance Imaging
NiMH	-	Nickel-metal hydride battery rechargeable
PAP	-	Positive Airway Pressure
PC	-	Polycarbonate
PET	-	Polyethylene Terephthalate
PE	-	Polyethylene
PG	-	Polygraphy
PID	-	Product Identification
PSG	-	Polysomnography
PVC	-	Polyvinyl Chloride
	-	

RF	-	Radio Frequency
RIP	-	Respiratory Inductance Plethysmography
SpO2	-	Oxygen Saturation Levels measured by pulse oximetry
TPE	-	Thermoplastic Elastomer
VID	-	Vendor Identification

Introduction

Congratulations on choosing the Nox A1s recorder. The Nox A1s recorder is a body worn sleep recorder intended to be worn over clothing or pajama. The Nox A1s recorder is a part of the Nox Sleep System. Its main function is to record physiological signals by use of built-in sensors and patient applied sensors. The Nox A1s recorder has a built-in Bluetooth® module also allowing it to communicate with other Nox Sleep System devices and to record signals from compatible auxiliary devices. The Nox A1s recorder is configured by the Noxturnal US software from Nox Medical, running on a PC, that also allows for the review, organization, analyzing, and summarizing of all signals recorded by the device. The complexity of the study is defined by varying the number and types of physiological signals measured, supporting both ambulatory and online sleep testing. During online configuration of the Nox Sleep System, commands and data are sent between the Nox A1s recorder and the Noxturnal US software by use of the Nox C1 Access Point from Nox Medical. The Nox A1s recorder can communicate over Bluetooth link, either direct or via the Nox C1 Access Point (depending on the system configuration), with Noxturnal App from Nox Medical running on a mobile platform for device control and online review of signals being recorded.

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 users 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 Nox A1s recorder and its components along with external sensors and auxiliary devices that have been validated with the Nox Sleep System.

The use of Nox A1 Recorder and its components along with external sensors and auxiliary devices that have been validated with the Nox Sleep System is covered in

- Nox A1 US Manual

The pictures below show the different appearance of the Nox A1s Recorder and the Nox A1 Recorder. Please be sure you are following the correct manual for your recorder.

Nox A1 Recorder

Nox A1s Recorder

The use of the Noxturnal US software application that is needed for device configuration, data download, review, and analysis as well as the use of the Nox C1 Access Point that is needed for the online setup of the Nox Sleep System are covered in:

- Noxturnal US Manual
- Nox C1 US Manual

This manual is only intended for professionals (healthcare professionals and service personnel) with relevant qualifications and skills. Additional material can be found on the Nox Medical Website.

Instructions for Operators

The Nox A1s recorder is only intended to be set-up and maintained by professionals (healthcare professionals and service personnel) with relevant qualifications and skills according to the instructions given in the "Operating Nox A1s", "Nox A1s Patient Hookup" and "Maintenance" sections. The **ONLY** operation that patients might have to perform by themselves at home during a PSG study is to start recordings that have been configured to be manually started[1]. In that case, the professional setting up the Nox A1s recorder and hooking up the patient shall demonstrate how to start the recording manually and train the patient to do so according to the "Manually Starting/Stopping a Recording" section.

Operators should contact Nox Medical or its sales representatives

- for assistance, if needed, in setting up, attaching, operating or maintaining the Nox Sleep System, its accessories, and as applicable external sensors and auxiliary devices that have been validated with the system; or
- to report unexpected operation or events.

[1] The patient might perform the hook-up on him/herself or with the assistance of a family member when conducting a simple PG study in the home environment (similar as with the Nox T3/Nox T3s recorder). In this case the patient is either instructed how to perform the hookup by a qualified healthcare professional before he/she is sent home with the system or directed to a video file that demonstrates the hook-up process.

Support information and information about Nox Medical's sales representative can be found on Nox Medical's website: www.noxmedical.com/distributors.

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.
- Caution: U.S. Federal law restricts this device to sale by, or on the order of, a licensed medical practitioner.
- Caution: The Nox A1s recorder complies with the international standard IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. That standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of interference due to close proximity or strength of source might disrupt the performance of the device, affecting recorded signals and therefore data analysis and resulting in possible incorrect treatment. Medical electrical equipment needs special precautions regarding Electromagnetic Compatibility (EMC), and needs to be installed and put into service according to the EMC information provided in the "EMC Information" section of this manual.
- Warning: The use of accessories, transducers, sensors, and cables other than those listed in this manual may result in increased emissions and/or decreased immunity of the Nox Sleep System and cause injuries to the operator/patient.
- Warning: The Nox A1s recorder(s) should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device(s) should be observed to verify normal operation in the configuration in which it/they will be used and prevent abnormal operation which might cause injuries to the operator/patient.
- Warning: The Nox Sleep System may be interfered with by other equipment, even if that equipment complies with International Special Committee on Radio Interference (CISPR) emission requirements, causing possible patient harm.
- Caution: Exposure to radio frequency radiation.
- Caution: The Nox A1s recorder is designed to be safe for use for pacemaker patients if the pacemakers comply with the standard: EN 45502-2-1 Active implantable medical devices. Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers) and/or EN 45502-2-2 Active implantable medical devices. Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators). Using non-compliant pacemakers may result in the operation of the pacemaker being affected by the use of Nox A1s recorder and lead to possible patient harm. Prior to using the device with pacemaker patients, the operator should consult the accompanying documents of the pacemaker regarding its certifications and requirements of use or, if necessary, contact the manufacturer.
- Warning: The Nox A1s recorder is not defibrillator proof. Not removing the device from a patient before defibrillation may lead to the creation of high current density at the electrode sites, causing burns and leading to possible patient harm. Not removing the device from a patient before defibrillation may also alter the intended flow of the current, affecting the defibrillation efficiency and causing injuries or death of the patient.
- Warning: The Nox A1s recorder and its accessories are not intended to be used with high frequency (HF) equipment. Using the device with high frequency (HF) equipment could cause potential serious harm to the patient.

- Warning: The Nox A1s EEG Head Cable/ Nox EEG 5 Lead Gold Electrode Cable do not provide protection against the effect of the discharge of a cardiac defibrillator nor against high frequency burns. Not removing the equipment from a patient before defibrillation may lead to the creation of high current density at the electrode sites, causing burns and leading to possible patient harm.
- Warning: The Nox A1s recorder and accessories are not designed to give a specified degree of protection against harmful ingress of liquids. Do not autoclave or immerse the device in any kind of liquids. Ingress of liquids may result in electric shock.
- Warning: Only use United States Environmental Protection Agency (EPA) registered products for cleaning/disinfection of the Nox A1 recorder and accessories to prevent harm to the operator/patient.
- Warning: The Nox A1s recorder is NOT suitable for use in presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. That could lead to the creation of electrostatic charges or temperature exceeding limits resulting in sparks or ignition, causing burns or explosions.
- Warning: Do not use the Nox A1s recorder and accessories during radiography/X-ray studies. The energy absorption in the device, cables or electrodes might lead to excessive heating and cause burns.
- Warning: As with all medical equipment, carefully route cables and connections to reduce the possibility of entanglement or strangulation.
- Warning: Do not use any part of the Nox Sleep System, including patient cables and electrodes, in a MRI (Magnetic Resonance Imaging) environment. The energy absorption in conductive materials might lead to excessive heating and cause burns.
- Caution: The Nox A1s recorder and Nox RIP belts should be worn over clothing to prevent allergic reaction to the equipment materials.
- Caution: The Nox RIP belts should fit the patient snugly without being uncomfortably tight to avoid discomfort.
- Warning: The Nox disposable RIP belts, Nox nasal cannula, Nox filter tube connector, Pro Tech Airflow Thermocouple, Ambu Leads with attached electrode, Ambu Snap-on electrodes, Nonin Wristband, and Westmed Mask tubing are single patient use. Using the same disposable RIP belts, cannula, filter tube connector, thermocouple, leads, snap-on electrodes, wristband, and mask tubing on more than one patient poses a risk of cross-infection.
- Warning: The disposable RIP belts are single use. Reusing the belts may affect the quality of recorded signals and lead to possible incorrect treatment.
- Warning: Do not use damaged equipment, sensors, or accessories. This may result in bad performance of the Nox Sleep System or patient/operator injury.
- Warning: The Nox A1s recorder and its accessories should be removed from the patient before use of the USB connector to prevent electrical shock. The USB connector shall only be used for the purposes of configuring the device and downloading data from the device.
- Warning: There are no user serviceable parts inside the Nox A1s recorder. The device should be serviced by authorized parties only. Service performed by non-authorized parties may affect data analysis and result in possible incorrect treatment. The warranty is void if the Nox A1s recorder is opened (except for opening of the battery compartment).
- Warning: No modification of the Nox A1s recorder and its accessories is allowed. Un-authorized modifications could result in the device not performing as intended and cause serious harm to the patient. To ensure patient safety and effective use of the Nox Sleep System, only use accessories that have been validated for use by Nox Medical. Refer to section “Compatible Sensors and Devices”.
- Warning: Remove batteries from the Nox A1s recorder if it is not used within 30 days to prevent damage from possible battery leakage and prevent possible minor burns to the operator/patient.

- Warning: External equipment and all auxiliary devices intended for connection to signal input, signal output or other connectors shall comply with the relevant product safety standards, e.g. IEC 60950-1 for IT equipment and the IEC 60601 series for medical electrical equipment, to prevent electric shocks. In addition, all such combinations – *systems* – shall comply with the safety requirements stated in the general standard IEC 60601-1, edition 3/3.1/3.2, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support. Any person who connects external equipment to signal input, signal output or other connectors has formed a system and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative.
- Warning: Avoid accidental contact between connected but unused patient applied parts and other conductive parts including those connected to protective earth to prevent potential serious harm to the operator/patient.
- Warning: Make sure the conductive parts of electrodes and associated connectors, including the neutral electrode, do not contact other conductive parts including earth to prevent potential serious harm to the operator/patient.
- Warning: Electrodes should only be used by or in consultation with a healthcare provider familiar with their proper placement and use. Not using and placing the electrodes correctly may affect recording of data, and therefore interpretation and diagnostics.
- Warning: The electrodes should be applied only to intact, clean skin (e.g. not over open wounds, lesions, infected or inflamed areas) to prevent infections.
- Warning: The Nox EEG 5 Lead Gold Electrode Cables should be properly disposed of if they cannot be fully cleaned between uses to prevent the risk of cross-infection between patients.
- Warning: The Nox EEG 5 Lead Gold Electrode Cables are not certified to be used for electrical stimulation purposes. Using the product for electrical stimulation purposes might create burns and cause injuries to the patient.
- Caution: The Nox A1s recorder and its accessories should always be transported in the accompanying carrying case to ensure adequate protection and prevent damage.

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

Nox A1s Description

The Nox A1s is a body worn sleep recorder. The input channels and built-in capabilities of the device include the following:

- 13 unipolar channels; for recording of electroencephalography (EEG), electrooculography (EOG) and submental electromyography (EMG)
- 1 ground channel
- 4 bipolar channels; for recording of electrocardiogram (ECG), periodic limb movements (PLM), masseter EMG, or other such as additional EMG or airflow
- 1 pressure channel; for recording of nasal or mask pressure
- 2 respiratory effort channels; for recording of abdomen and thorax ventilatory effort signals
- 3-D built-in acceleration sensor; for recording of patient's position and activity
- Built-in light sensor; for recording of ambient light
- Built-in microphone; for recording of audio and snoring
- Built-in Bluetooth® module; to support wireless connectivity allowing the device to record signals from compatible auxiliary devices

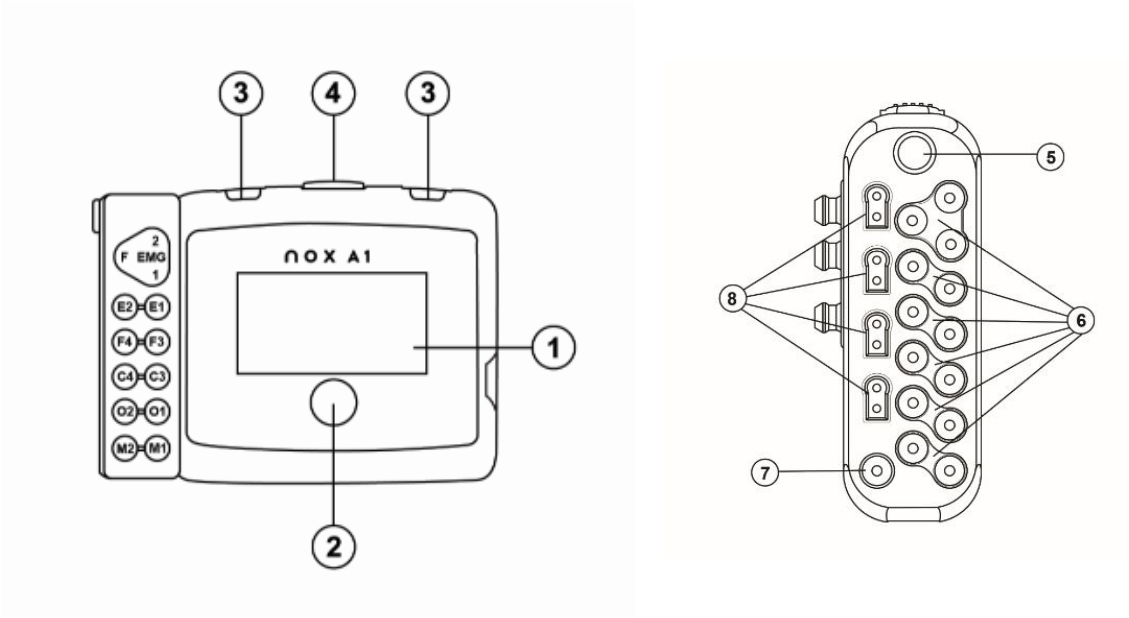
During online configuration of the Nox Sleep System the Bluetooth function enables the Nox A1s recorder to communicate with the Noxturnal US software and the Noxturnal App via the Nox C1 Access Point for device control and online review of recorded signals.

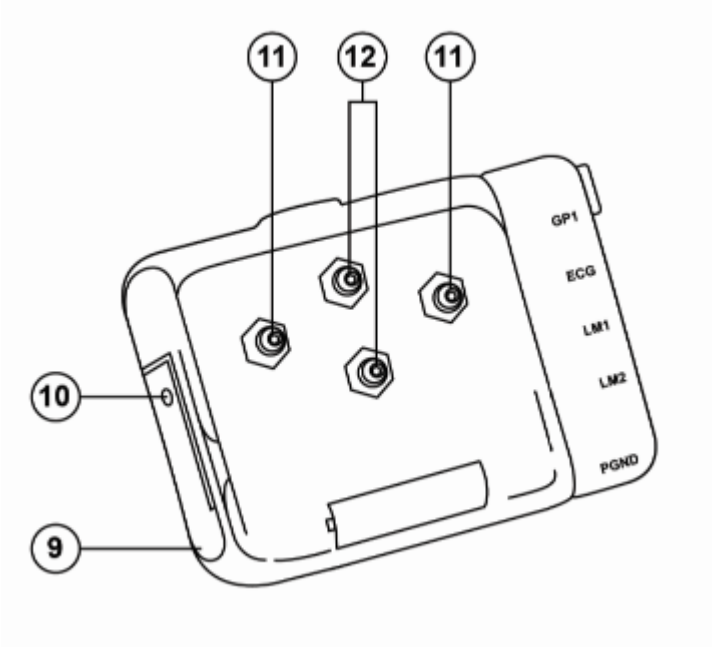
During ambulatory configuration of the Nox Sleep System, the Bluetooth function enables the Nox A1s recorder to communicate with Noxturnal App for device control and online review of recorded signals.

The Nox A1s recorder is powered with one AA battery.

Nox A1s Interface

The Nox A1s recorder interface consists of a display, button, sensor inputs/connections, indicator light and a USB connector. The USB connector is placed under the battery lid and connects to Nox USBc cable for device configuration and data download. See the figures and tables below for detailed description.





NUMBER	FUNCTION	INPUT/SENSOR LABEL
1	Display	NA
2	Push button Light sensor located under the push button Indicator light for device status in the push button	NA
3	2 Clip strap loops	NA
4	Microphone – For recording of respiratory sounds	NA
5	1 Pressure lock – Connects to nasal cannula/mask pressure tube	PRES: Pressure input connector
6	13 Unipolar touch proof inputs (10 EEG/EOG, 3 chin EMG)	• EMG: 1,2, F – Electromyography (EMG) input connectors • E2-E1, F4-F3, C4-C3, O2-O1, M2-M1: Electroencephalography (EEG) and electrooculography (EOG) input connectors
7	1 Reference ground input	• PGND: Patient ground
8	4 Bipolar touch proof inputs	• GP1: General purpose bipolar input connector • ECG: Electrocardiography (ECG) input connectors • LM1, LM2: Electromyography (EMG) input connectors
9	Battery lid – Covers the battery and the USB connector	NA
10	Battery lid pin	NA
11	2 Metal snaps – Connects to thorax RIP belt	NA
12	2 Metal snaps – Connects to abdomen cable	NA

Operating Nox A1s

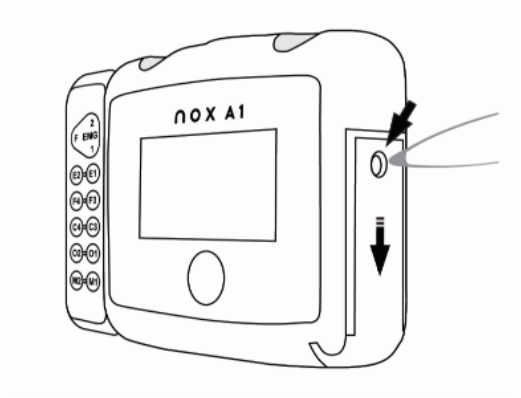
The Nox A1s recorder is only intended to be operated by professionals (healthcare professionals and service personnel) with relevant qualifications and skills. The **ONLY** operation that patients might have to perform by themselves at home[2] is to start recordings that have been configured to be manually started. In that case, the professional setting up the Nox A1s recorder and hooking up the patient shall demonstrate how to start the recording manually and train the patient to do so according to the "Manually Starting/Stopping a Recording" section.

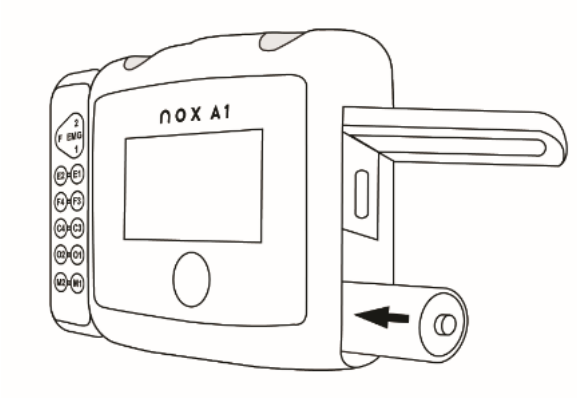
The Nox A1s recorder is operated with one push button located on the front panel. Pressing the button turns on the display. The display will automatically turn off in 3 minutes.

Connecting Nox A1s to a Computer

- Warning: The Nox A1s recorder and its accessories should be removed from the patient before use of the USB connector to prevent electrical shock. The USB connector shall only be used for the purposes of configuring the device and downloading data from the device.

To connect Nox A1s recorder to a computer you need to access the USB connector on the device. The USB connector is placed under the battery lid making it inaccessible and tamper proof for children. To open the battery lid, press with the Nox battery Lid Key, accompanying the Nox A1s System Kit, on the battery lid pin and slide the battery lid down, towards the bottom of the device. The Nox A1s recorder connects to the computer by using Nox USBc cable. The battery does not have to be inserted while the device is connected to the computer.





When the Nox A1s recorder is connected to the computer the device display lights up and a message saying the device is connected to the computer.

[2] The patient might perform the hook-up on him/herself or with the assistance of a family member when conducting a simple PG study in the home environment (similar as with the Nox T3/Nox T3s recorder). In this case the patient is either instructed how to perform the hookup by a qualified healthcare professional before he/she is sent home with the system or directed to a video file that demonstrates the hook-up process.

For IT environments that restrict USB port access to USB peripherals, the following vendor id (VID) and product id (PID) shall be allowed on the network for communicating with Nox recorder devices: VID=0x1E0A, PID=0x1002.

Configuring and Downloading from Nox A1s

To download a recording or configure the Nox A1s recorder you will need to start the Noxturnal US software application and connect the device to the computer. Please refer to the Noxturnal US manual for more information on how to perform those tasks.

When you are done working with the device eject it from the Noxturnal US software and unplug the Nox USBc cable. Insert the battery and close the battery compartment by pressing the lid back towards the device without causing any strain, then slide it back into position, towards the top of the device.

Manually Starting/Stopping Nox A1s

If the Nox A1s recorder has been configured to start the recording manually, you can use the button to manually start a recording. Pressing the button turns on the display. The device will instruct you to “Hold button to record". Please do so until you see “Recording Duration” displayed. Note the button needs to be pressed down for approximately 4-5 s before “Recording Duration” displays. At this point the device has started to record data and the REC symbol appears at the top of the screen. After the display turns off, the light under the button will blink green intermittently indicating that a recording is taking place. Use the same method to manually stop the recording.

If the duration of the recording has been specified during configuration, the recording will automatically stop after the specified duration.

Starting Nox A1s at a Scheduled Time

If the Nox A1s recorder has been configured to automatically start a recording at a scheduled time, there are no actions required for the recording to start. Pressing the button before the recording has started will display a countdown to the specified start time of the recording. If the recording has begun, the display shows the current duration of the recording and the REC symbol appears on the top of the screen.

Nox A1s Status

Indicator Light

The indicator light on the Nox A1s recorder blinks green when a recording is in progress and the device is functioning normally. When there are any device warnings the indicator light blinks amber. Warnings might include:

- Battery low
- Device not licensed.

Displays

Information about the recording duration, recording status and device connections is shown on the display. If the display is turned off, pressing the button turns it on. By pressing the button again, you will loop through the available displays. The display will turn itself off again after being inactive for 2 minutes.

The display includes information about device connection, time and battery status.

1. A Bluetooth symbol and an "X" or a checkmark "✓" are visible on all displays. This symbol shows the status of the Bluetooth connection with the oximeter. An "X" means there is not Bluetooth connection, a "✓" means there is a Bluetooth connection.
2. The device's clock. When Nox A1s is configured, the clock is synchronized with the PC and is shown at the top of the display.
3. On the top right corner is a battery indicator which shows the battery status. The battery indicator is full when the device has fresh batteries.

The first display that shows up after the device is turned on shows information about the recording planned or ongoing as explained in previous sections. The second display shows the status of the oximeter connection.

1. An "X" next to SpO_2 indicates that the oximeter is not connected to the device. Once an oximeter has been connected, a checkmark "✓" will appear.
2. The Bluetooth device address (BDA) of the oximeter that the device is trying to connect to or is connected to.

The third display shows the status of scheduled recordings. It only appears if the device is configured for 2 or 3 scheduled recordings.

1. Status of scheduled recordings. The number of squares represent the number of recordings scheduled. A full square represents a recording that has already been recorded successful. An empty square represents a recording yet to be performed.

Examples of the multiple night status indicator and their meanings can be seen below:

 **Three empty squares:** The device has been configured to record three nights, but no recording has been performed.

 **Three squares, the first one full:** The device has been configured to record three nights, and one night has been recorded successfully.

Nox A1s Patient Hookup

- Warning: Do not use damaged equipment, sensors, or accessories. This may result in bad performance of the Nox Sleep System or patient/operator injury.
- Warning: As with all medical equipment, carefully route cables and connections to reduce the possibility of entanglement or strangulation.
- Caution: The Nox A1s recorder and its accessories should always be transported in its accompanying carrying case to ensure adequate protection and prevent damage.

The Nox A1s recorder is only intended to be hooked-up by professionals (healthcare professionals and service personnel) with relevant qualifications and skills[3].

Inserting a Battery to the Nox A1s

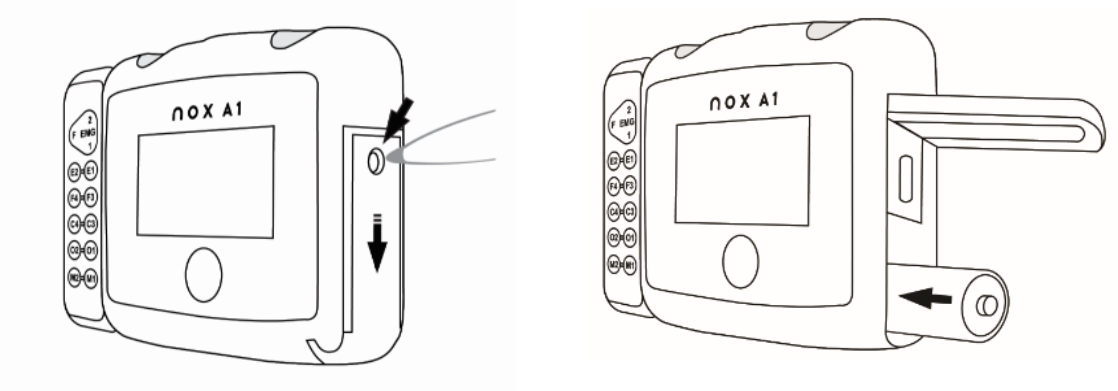
The list below is provided to assist the user in selecting the appropriate battery type for a Nox A1s study:

- Alkaline batteries can be used to record from 10 to 12 hours depending on battery type.
- Lithium batteries can be used to record from 20 to 30 hours depending on study type and battery.
- Rechargeable NiMH batteries can be used to record for 1 hour to 1.5 hours per 200 mAh capacity. Thus, a standard 2000 mAh battery can record from 10 to 15 hours.

- Note: Always use fully charged **Powerex 2700 mAh Rechargeable Batteries, high quality alkaline batteries of at least 2000mAh capactiy** or fresh **lithium battery** for each recording to prevent the need for the sleep study to be repeated.
- Note: All lithium batteries used with the Nox A1s recorder shall be per the standard IEC 60086-4 Primary batteries - Part 4: Safety of lithium batteries.

Before you start a recording, you should make sure that the Nox A1s recorder has a new or fully charged battery. To insert a new battery, do the following:

[3] The patient might perform the hook-up on him/herself or with the assistance of a family member when conducting a simple PG study in the home environment (similar as with the Nox T3/Nox T3s recorder). In this case the patient is either instructed how to perform the hookup by a qualified healthcare professional before he/she is sent home with the system or directed to a video file that demonstrates the hook-up process.



1. Open the battery compartment by pressing down the battery lid pin with the Nox Battery Lid Key accompanying the Nox A1s System Kit or similar tool and slide the lid towards the bottom of the device.
2. Place one AA battery in the compartment aligning the battery poles as illustrated on the back of the device (the positive (+) pole is towards the battery lid).
3. Close the battery compartment by pressing the lid back towards the device without causing any strain, then slide it back into position, towards the top of the device. Make sure the lid is securely closed.

The status of the battery can be checked by turning on the device. The battery status indicator positioned in the upper right-hand corner of the device display allows you to check the battery status. When the battery is running low during a recording the device will automatically stop the recording.

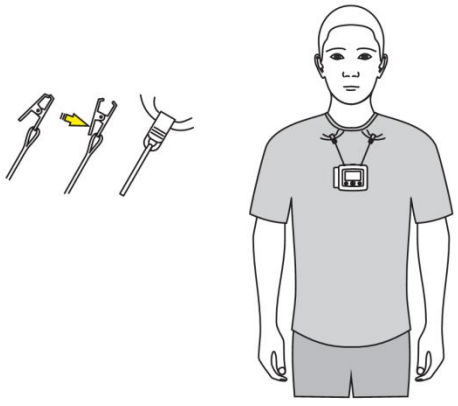
Attaching the Nox A1s and the Nox RIP Belts

- Caution: The Nox A1s recorder and Nox disposable RIP belts should be worn over clothing to prevent allergic reaction to the equipment materials.
- Warning: The Nox disposable RIP belts are single use and single patient use. Re-using the disposable RIP belts may affect the quality of recorded signals and lead to possible incorrect treatment. Using the same disposable RIP belt on more than one patient poses a risk of cross-infection.

Step 1

Snap the clips that are attached to the Nox A1s recorder to the patient's shirt.

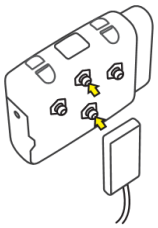
1



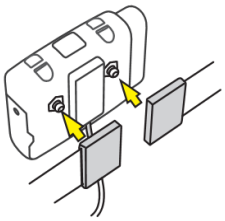
Step 2 to Step 4

- Snap the Nox abdomen cable to the back of the device.
- Place a Nox disposable RIP belt around the thorax and snap its ends to the back panel of the device.
- Adjust the Nox abdomen cable length as needed by wrapping it around the abdomen connection unit. Place a Nox disposable RIP belt around the abdomen and snap it in place.

2



3



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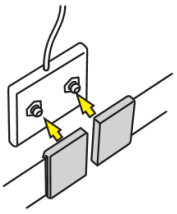
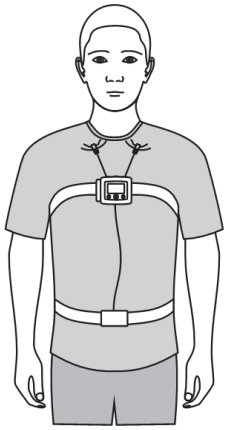


Step 5

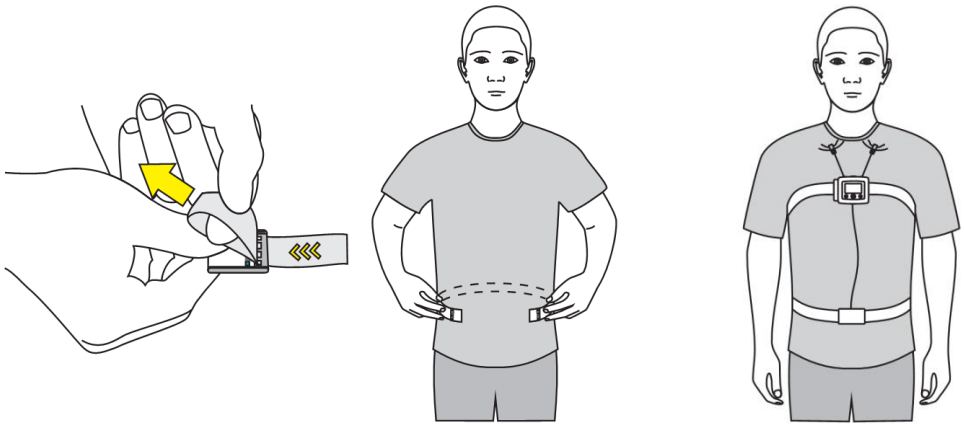
Attaching the Nox A1s recorder and Nox disposable RIP belts is now completed.



Adjusting the Nox RIP Belts

- Caution: The Nox disposable RIP belts should fit the patient snugly without being uncomfortably tight to avoid discomfort.
- Note: For most patients, the Nox disposable RIP belts do not need to be adjusted if the correct belt size is chosen based on the patient's abdomen circumference and/or body mass index (BMI). Belt size selection tables accompany Nox disposable RIP belts packages for more detailed instruction.

Fit the Nox disposable RIP belts around the patient's waist and thorax and adjust the length using the loop on each end to adjust the belt length such that the belt covers about two thirds of the patient's circumference when the belt is unstretched. The length is fixed with hooks on the plastic connector of the belt.

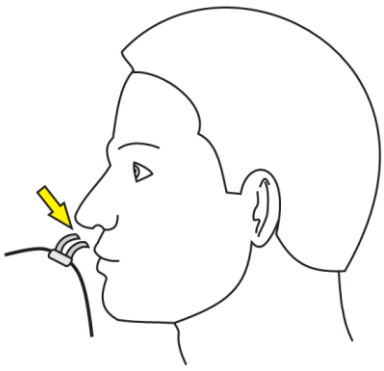


Attaching the Nox Nasal Cannula

- Warning: The Nox nasal cannulas are single patient use. Using the same nasal cannula on more than one patient poses a risk of cross-infection.
- Note: Medical tape can be used to hold the cannula against the cheeks to secure the cannula in place if necessary.
- Note: The Nox nasal cannula with filter has a built-in hydrophobic filter and is the preferred way to measure nasal airflow and snoring as it is designed to maximize the signal quality and fits directly with the Nox A1s recorder.

Step 1

Place the nasal prongs gently in the nostrils. The prongs should point downwards inside the nostrils.

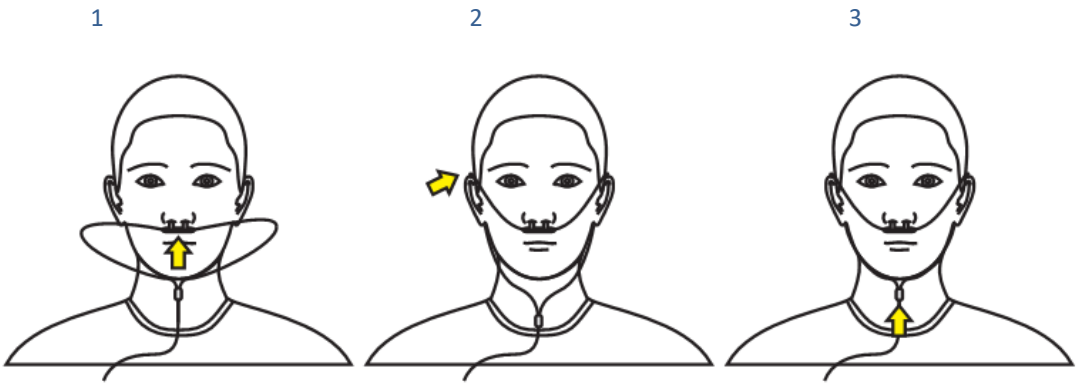


Step 2

Pull the cannula tubing over the ears and then position it under the chin.

Step 3

Slide the fastener snugly under the chin to hold the cannula tubing securely in place.



Measuring Mask Pressure

- Warning: The mask pressure tubes and Nox filter tube connectors are single patient use. Using the same mask pressure tube and filter tube connector on more than one patient poses a risk of cross-infection.
- Note: The mask pressure tube can only be connected to the pressure lock on the Nox A1s recorder by using the Nox filter tube connector.

A mask pressure tube is used for connection to positive airway pressure (PAP) masks for measuring mask pressure. The pressure tube connects to the pressure lock on the Nox A1s recorder via a filter tube connector from Nox Medical.

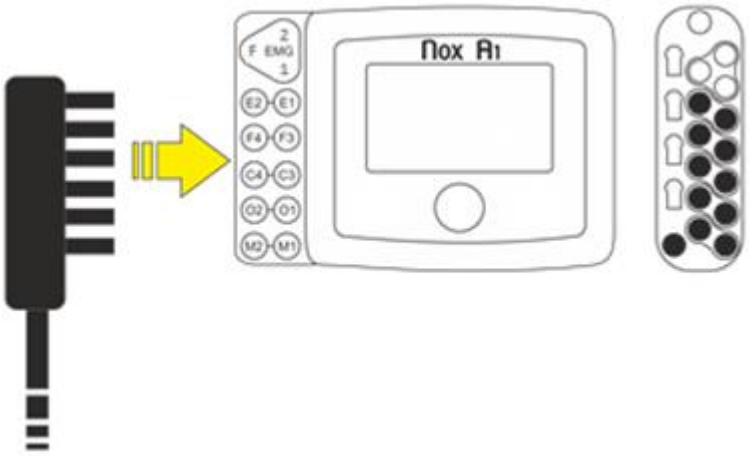
Refer to the “Compatible Sensors and Devices” section regarding the types of mask pressure tubes that have been validated with the Nox A1s recorder.

Measuring EEG Signals

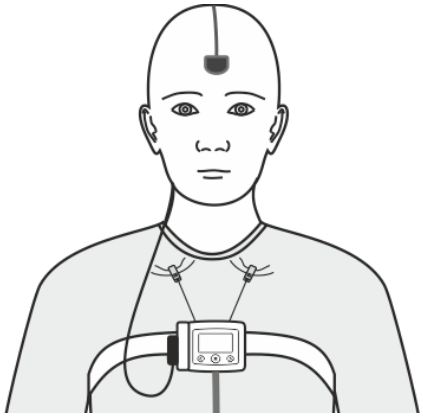
- Warning: Electrodes should only be used by or in consultation with a healthcare provider familiar with their proper placement and use. Not using and placing the electrodes correctly may affect recording of data, and therefore interpretation and diagnostic.
- Warning: The electrodes should be applied only to intact, clean skin (e.g. not over open wounds, lesions, infected or inflamed areas) in order to prevent infections.
- Warning: Make sure the conductive parts of electrodes and associated connectors, including the neutral electrode, do not contact other conductive parts including earth to prevent potential serious harm to the operator/patient.
- Warning: The Nox EEG 5 Lead Gold Electrode Cables should be properly disposed of if they cannot be fully cleaned between uses in order to prevent the risk of cross-infection between patients.
- Warning: The Nox EEG 5 Lead Gold Electrode Cables are not certified to be used for electrical stimulation purposes. Using the product for electrical stimulation purposes might create burns and cause injuries to the patient.
- Warning: The Nox A1s EEG Head Cable/ Nox EEG 5 Lead Gold Electrode Cables do not provide protection against the effect of the discharge of a cardiac defibrillator nor against high frequency burns. Not removing the equipment from a patient before

defibrillation may lead to the creation of high current density at the electrode sites, causing burns and leading to possible patient harm.

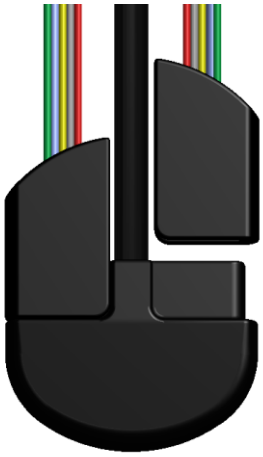
Connect the Nox A1s EEG Head Cable to the E2-E1, F4-F3, C4-C3, O2-O1, M2-M1 unipolar and ground inputs of the Nox A1s recorder.



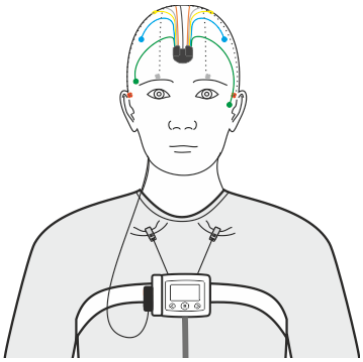
Place a snap-on electrode on the middle of the patient's forehead. Route the Nox A1 EEG Head Cable behind the patient's head and snap the cable to the electrode.



Connect two Nox EEG 5 Lead Gold Electrode Cables to the head cable, one on each side.



Attach the gold cup electrodes to the patient's head. The **green** wire is for **E1/E2**, the **blue** wire is for **F3/F4**, the **yellow** wire is for **C3/C4**, the **grey** wire is for **O1/O2** and the **red** wire is for **M1/M2**. Optionally instead of using the customized Nox A1s EEG 5 Lead Gold Electrode Cables and Nox A1 EEG Head Cable, eleven standard gold cup electrode leads may be used that connect to the unipolar inputs on the Nox A1s Recorder.



Before electrodes are placed it is important to inspect the skin locations and make sure the electrodes are placed on a dry and clean location that has no abrasions or wounds. To prepare the skin, it is recommended to clean the skin with water and abrasive skin prepping gel. In some cases, if the skin is very oily it can be necessary to use wipes with alcohol. The electrodes are then applied to the skin by use of suitable gel or paste) ensuring biocompatibility and electrical contact. To ensure the proper resistive, cohesive, and adhesive characteristics necessary for accurate recording electrode cream is applied over the surface cup electrodes.

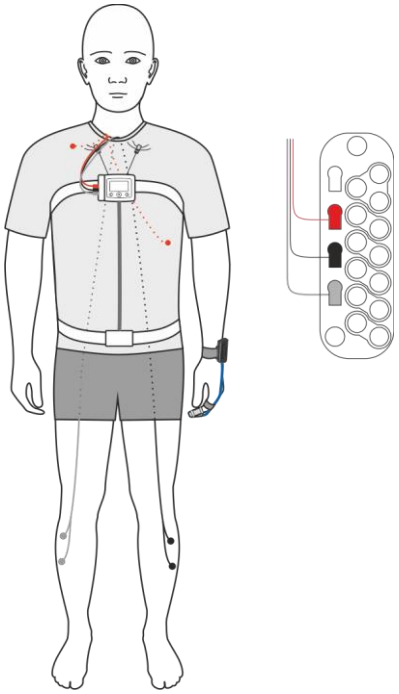
Measuring EMG/ECG Signals

- Warning: Electrodes should only be used by or in consultation with a healthcare provider familiar with their proper placement and use. Not using and placing the electrodes correctly may affect recording of data, and therefore interpretation and diagnostic.
- Warning: The electrodes should be applied only to intact, clean skin (e.g. not over open wounds, lesions, infected or inflamed areas) to prevent infections.
- Warning: Make sure the conductive parts of electrodes and associated connectors, including the neutral electrode, do not contact other conductive parts including earth to prevent potential serious harm to the operator/patient.

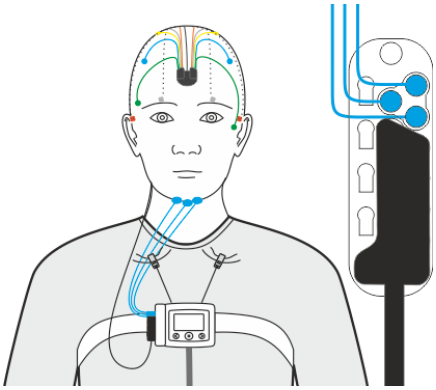
The Nox A1s recorder is equipped with 4 bipolar channels suitable for recording of ECG and EMG signals such as leg EMG or masseter EMG for possible bruxism-related event detection. The bipolar channels are labeled

with GP1, ECG, LM1, and LM2 and connect to bipolar electrode leads with keyhole connectors (Nox Snap On Double Leads) that snap on to surface electrodes. However, during recording setup, those channels can be defined for any EMG/ECG signals or for supported respiratory flow/pneumoflow sensor. Please refer to the Noxturnal US manual for more information on how to configure the Nox A1s recorder.

The figure below shows connections for ECG, EMG on right leg and EMG on left leg. When not using the Nox A1s EEG head cable you can connect your ground electrode to the PGND input on the device.



For submental EMG, insert the electrode leads into the EMG channels of the Nox A1s recorder and attach the electrodes to the patient's chin. The front chin electrode goes into the **F** input, the left chin electrode goes into the **1** input, and the right chin electrode goes into the **2** input.



Before electrodes are placed it is important to inspect the skin locations and make sure the electrodes are placed on a dry and clean location that has no small abrasions and wounds. To prepare the skin, it is recommended to clean the skin with water and abrasive skin prepping gel. In some cases, if the skin is very oily

it can be necessary to use wipes with alcohol. The electrodes are then applied to the skin by use of suitable gel or paste ensuring biocompatibility and electrical contact.

Measuring Pulse and Oxygen Saturation using Nonin WristOx2 Pulse Oximeter, Model 3150 BLE

- 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: Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
- Warning: To prevent improper performance and/or patient injury, verify compatibility of the Nox A1s recorder, oximeter, sensor(s), and accessories before use.
- Warning: Before changing the batteries, make sure the oximeter is off and the sensor is not applied to a digit.
- Caution: The oximeter has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. In some circumstances, however, the device may still interpret motion as good pulse quality.
- Caution: To avoid the risk of confusing or misinterpreting patient data when transmitting data via Bluetooth, verify that the oximeter is paired with the correct Nox A1s recorder.
- Caution: Do not fasten the pulse oximeter too tightly around the patient's wrist. Inaccurate readings and patient discomfort could result.
- Caution: Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.
- Caution: The oximeter is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:
    - excessive ambient light
    - excessive motion
    - electrosurgical interference
    - blood flow restrictors (arterial catheter, blood pressure cuffs, infusion lines, etc.)
    - moisture in the sensor
    - improperly applied sensor
    - incorrect sensor type
    - poor pulse quality
    - venous pulsations
    - anemia or low hemoglobin concentrations
    - cardiogreen and other cardiovascular dyes
    - carboxyhemoglobin
    - methemoglobin
    - dysfunctional hemoglobin
    - artificial nails or fingernail polish
    - residue (e.g., dried blood, dirt, grease, oil) in the light path
- Caution: When using the oximeter in the home, avoid exposing it to lint and dust.

- Caution: The pulse oximeter may not work when circulation is reduced. Warm or rub the finger or reposition the sensor.
- Note: Refer to 3rd party instructions for use accompanying the pulse oximeter and/or oximeter sensor for maximum oximeter application time at a single site.
- Note: Refer to 3rd party instructions for use accompanying the pulse oximeter and oximeter sensor for additional warnings and cautions.
- Warning: The Nonin wrist band is single patient use only. The wrist band may be cleaned, refer to 3rd party instructions for use accompanying the pulse oximeter for cleaning instructions, but after cleaning the wrist band should only be applied to the same patient, not to a different patient.

The Nox A1s recorder can communicate with an auxiliary Bluetooth® pulse oximeter for recording of oxygen saturation levels (SpO_2), pulse rate, and plethysmography data.

Refer to the "Compatible Sensors and Devices" section regarding the types of pulse oximeters and sensors that are supported by the Nox Sleep System.

Inserting Batteries into the Nonin WristOx2 Pulse Oximeter, Model 3150 BLE

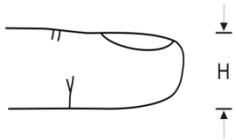
Refer to the 3rd party accompanying instructions regarding replacement of batteries when using the Nonin WristOx2 Pulse Oximeter, Model 3150.

- Note: Single use batteries last up to 48 hours of use, so it is important to track the number of measurements made with the Nonin 3150 pulse oximeter. It is recommended to change the batteries after 2-3 recordings depending on the quality of the batteries being used.
- Note: If you are using rechargeable batteries, it is recommended that you replace them before every recording.

Selecting Oximeter Sensor Size

Reusable Nonin WristOx2 Soft Sensor

Soft sensor size recommendations are based on digit height (thickness). The digit height (H) is measured as shown in the figure below.



For digit height from 7.5 mm (0.3 in) to 12.5 mm (0.5 in), size small should be selected.

For digit height from 10.5 mm (0.4 in) to 19.0 mm (0.75 in), size medium should be selected.

For digit height from 12.5 mm (0.5 in) to 25.5 mm (1.0 in), size large should be selected.

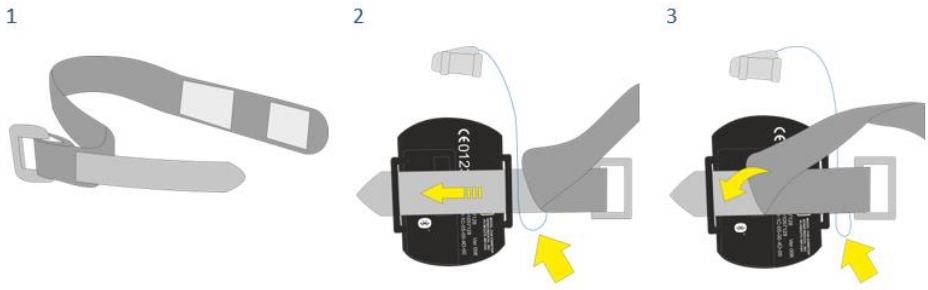
Attaching the Nonin WristOx2 Pulse Oximeter, Model 3150 BLE and Nonin WristOx2 Soft Sensor

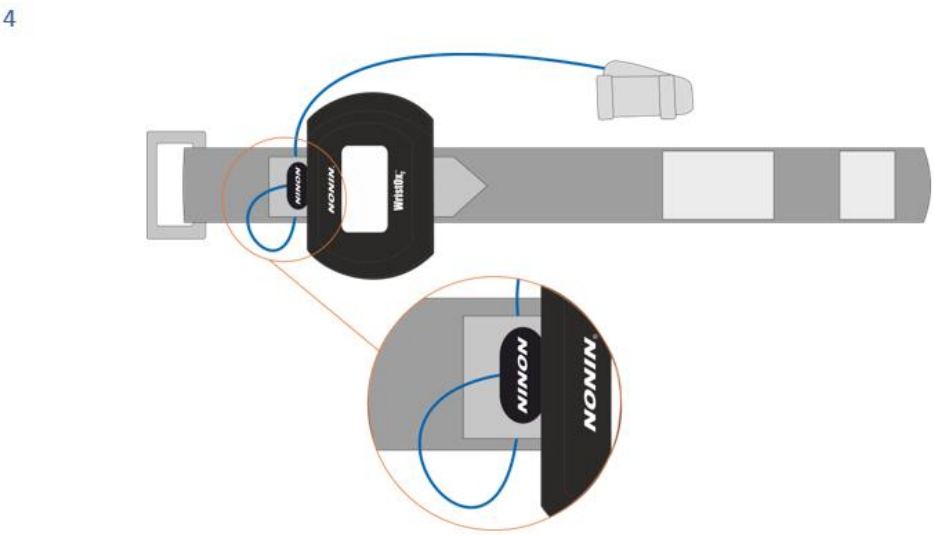
The Nonin 3150 WristOx$_2$ Oximeter package accompanying the Nox A1s system kits includes:

- WristOx$_2$® Model 3150 BLE pulse oximeter
- Model 8000SM-WO2, Nonin WristOx2 Soft Sensor
- 1 wrist band
- CD – ROM of the Operator's manual

Step 1 to Step 4

1. Separate the short end of the wristband from the long end.
2. Insert the short end in the loops on the oximeter.
3. Place the probe wire between the short and long end of the wristband. Attach the long end to the short end to secure the wristband on the oximeter.
4. The oximeter is now securely placed on the wristband and the probe wiring is secured between the two ends, forming a loop that prevents direct pulling of the connector.





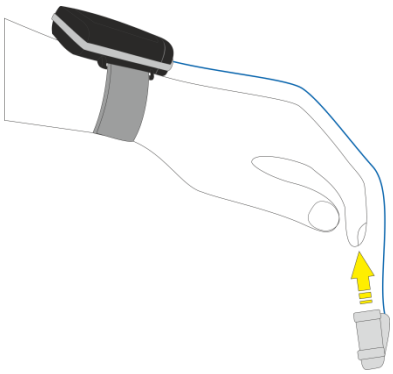
Step 5 to Step 6

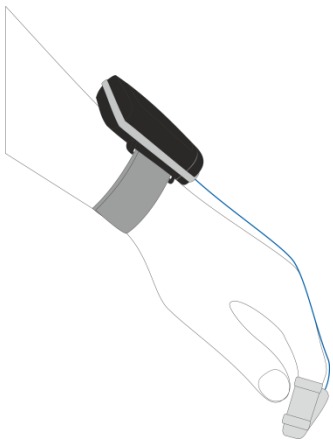
- Note: To prevent the oximeter sensor from falling off, secure its cable with medical tape.

5. Place the wristband around the patient's wrist.
6. Put the probe on the finger.

5

6





Establishing a Connection between the Nonin 3150 BLE Pulse Oximeter and Nox A1s

Ambulatory studies

Before you can send out the Nox A1s recorder and accessories for an ambulatory recording, you need to make sure that a connection has been established between the Nox A1s recorder and the oximeter. The pairing of the Nox A1s recorder and the oximeter is done during the configuration of the device in the Noxturnal US software. Follow the instructions below in order to establish a successful connection between the Nox A1s recorder and the Nonin 3150 BLE oximeter.

Note: The Nox A1s recorder will only connect to Nonin 3150 BLE oximeters and does not support connecting to the Nonin 3150 Classic oximeters. Refer to the Nox Medical support page for further information.

Pairing Process

Step 1. Inserting Batteries

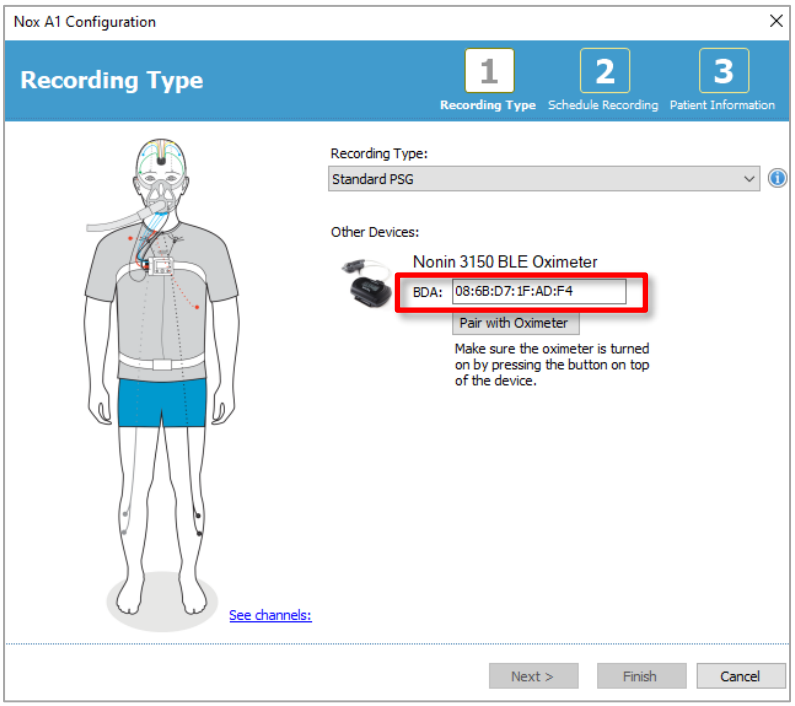
Start by inserting fresh/fully charged batteries in the Nonin 3150 BLE pulse oximeter.

Step 2. Turning on the Nonin 3150 BLE Pulse Oximeter

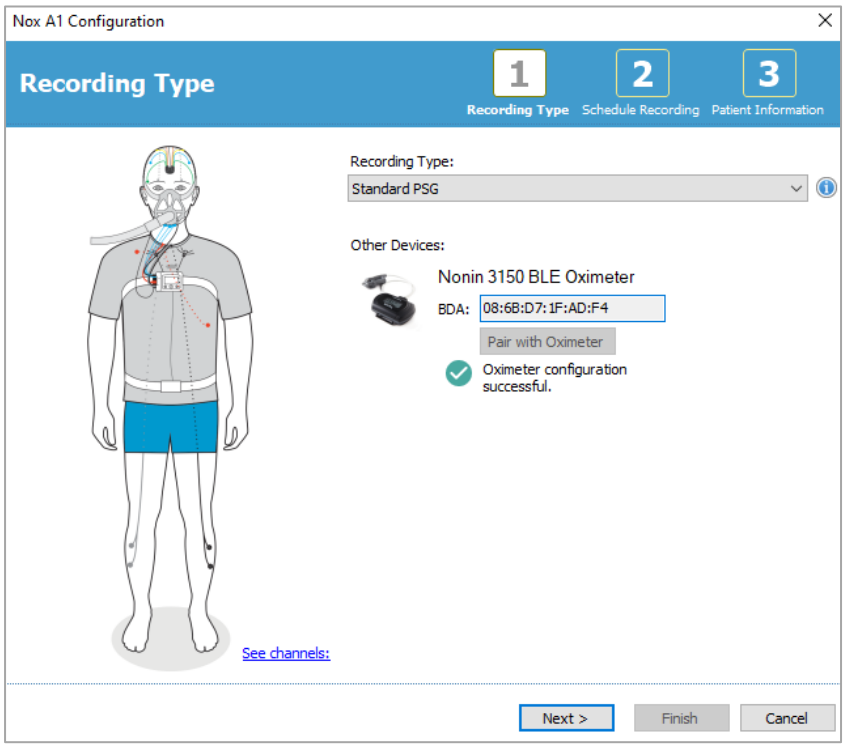
Turn on the Nonin 3150 BLE pulse oximeter by pressing the gray activation button (red circle on the picturee below) on tope of the device and you will see the display turn on.

Step 3. Connect the Nox A1s recorder with a USB cable and follow the configuration in Noxturnal

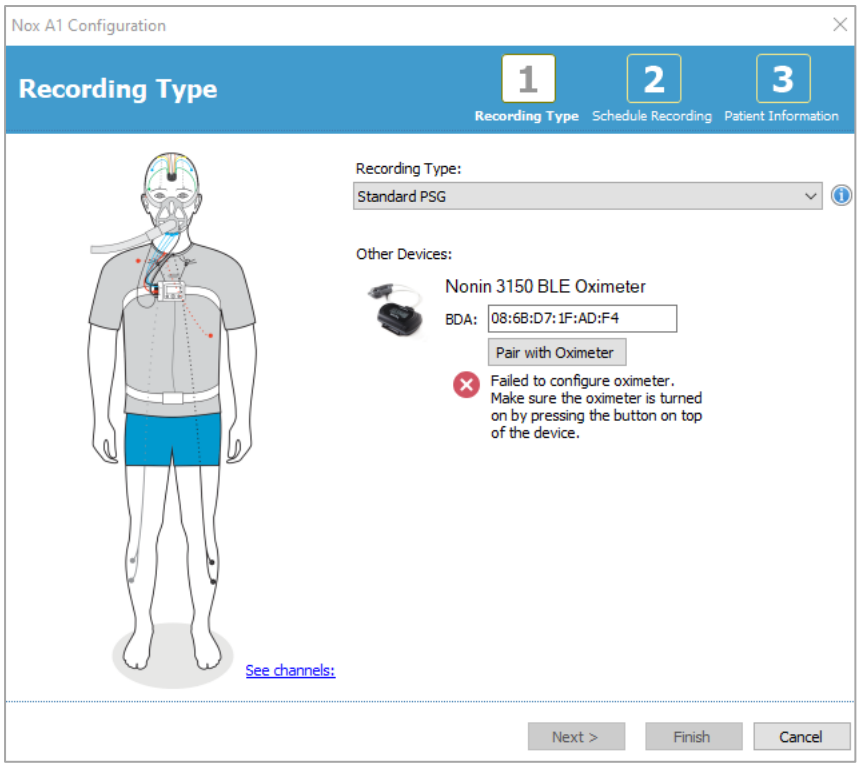
Fill in the BDA number of the pulse oximeter found on the back of the Nonin 3150 BLE oximeter



Click Pair with Oximeter and the pairing will be performed either result in a successful pairing



Or an unsuccessful paring



If not successful follow the troubleshooting tip in the software or see the troubleshooting tips below

Step 4. Bluetooth Wake up mode.

If the pairing was successful during the configuration step in Noxturnal US the Nonin 3150 BLE has been put into Bluetooth Wake up Mode. That is indicated by the Bluetooth symbol blinking on regular time interval of the study.

The Nonin 3150 BLE will then turn on when the Nox A1s recorder starts a study (either manual start or scheduled start)

Now the Nox A1s is ready to be packed and handed over/shipped to customer for an ambulatory study

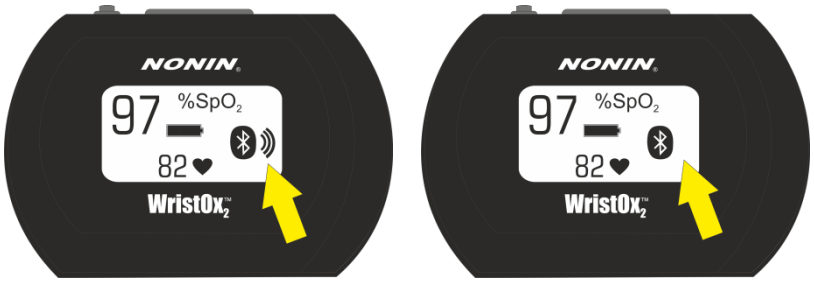
Online Studies

Verify the connection status by:

- Seeing the checkmark on the Nox A1s recorder screen indicating a successful connection to the Nonin 3150 BLE pulse oximeter.

- And/or look at the Nonin 3150 Pulse oximeter and check the following
  a. The Bluetooth® indicator displays with animated bars when the Bluetooth connection is established.
  b. The Bluetooth indicator displays without animated bars when the connection is NOT established.

a b



Troubleshooting Tips

Troubleshooting during oximeter pairing in Noxturnal US for ambulatory studies

Incorrect BDA number:

If failing, check the BDA number of the device and make sure it matches the number on the Nonin 3150 BLE oximeter.

Correct BDA number but devices not pairing

a) Restart the oximeter by removing the batteries and inserting batteries again to the oximeter. Then hold the grey activation button to turn on the device. Resume the pairing process from Step 3 above or
b) Restart the Nox A1s by unplugging the Nox A1s from the computer and plugging it back in again. Resume the pairing process from Step 3 above.

Note: This pairing only works for Nonin 3150 BLE oximeters and is not supported with Nonin 3150 Classic oximeters. Refer to the Nox Medical support page for further information.
Note: If this happens repeatedly, it might be necessary to send the oximeter in for service.

Troubleshooting of oximeter connection during hook-up (after successful pairing in Noxturnal US) or during online studies

Verify that the BDA number of the oximeter used matches the number used to configure the Nox A1s Recorder. The BDA number used in configuration of the Nox A1s can be found on in the display of the device that shows the status of the oximeter connection. The oximeter BDA number is displayed on the back of the oximeter.

In the case of the number on the device does not match the number of the oximeter it is necessary to re-configure the Nox A1s in Noxturnal US and insert there the correct BDA number as in step 3 of the pairing

Correct BDA number but oximeter still marked with "x" on status display:

This means that the Nox A1s recorder and the oximeter are not pairing as expected. To resolve try the following:

c) Restart the oximeter by removing the batteries and inserting batteries again to the oximeter. Then hold the grey activation button to turn on the oximeter.

d) Reboot the Nox A1s recorder by simply waiting for the Nox A1s to turn off (it turns off automatically in 2 minutes after it has been turned on) and then, turn on the Nox A1s again by pushing the button or removing and re-inserting the battery.

Note: If this does not solve the issue and this happens repeatedly, it might be necessary to send either A1s or the oximeter in for service.

For further information on troubleshooting refer to the Nox Medical Support Site.

Maintenance

The Nox Sleep System is only intended to be maintained by professionals (healthcare professionals and service personnel) with relevant qualifications and skills.

The Nox A1s recorder and accessories should be stored in a clean, dry place.

Handle the Nox A1s recorder with care and protect it against mechanical shocks, dirt, and liquids. The device is not waterproof or splash proof.

To update the Nox A1s recorder you will need the Noxturnal US software running on the computer which the device is connected to. Please refer to the Noxturnal US manual for more information on how to perform this task.

No regular testing of the Nox A1s recorder or accessories, including patient cables, is needed.

The service life of the Nox A1s recorder and Nox A1s carry case is 5 years or the equivalent of 1000 studies in total, given that 200 studies are performed in a year. The service life of Nox A1 EEG Head Cable is 1 year, or 200 studies, and the service life of Nox EEG 5 Lead Gold Electrode Cable is 6 months or 100 studies.

The service life is dependent on full compliance with the direction for use given in this manual.

- Warning: Remove batteries from the Nox A1s recorder if it is not used within 30 days to prevent damage from possible battery leakage and prevent possible minor burns to the operator/patient.
- Warning: There are no user serviceable parts inside the Nox A1s recorder. The device should be serviced by authorized parties only. Service performed by non-authorized parties may affect data analysis and result in possible incorrect treatment. The warranty is void if the Nox A1s recorder is opened (except for opening of the battery compartment).
- Warning: No modification of the Nox A1s recorder and it´s accessories is allowed. Un-authorized modifications could result in the device not performing as intended and cause serious harm to the patient.
- Note: It is never recommended to downgrade the firmware of the Nox A1s recorder. Downgrading the firmware will result in losing the calibration for the device: calibration values will be replaced with default values that might affect the pressure and impedance signals being recorded. Only upgrade the firmware of the Nox A1s recorder with firmware files that come directly from Nox Medical

Environmental Conditions

Temperature	Operation: +5°C to +40°C (+41°F to +104°F)
	Transport/Storage: -25°C to +70°C (-13°F to 158°F)

Relative Humidity	Operation: 15-90% (non-condensing) Transport/Storage: 10-95% (non-condensing)
Pressure	Withstands atmospheric pressures from 700 hPa to 1060 hPa

Calibration

The Nox A1s recorder is factory calibrated. No further calibration is needed.

Cleaning of Nox A1s Recorder and its Accessories

- Warning: The Nox A1s recorder is not designed to give a specified degree of protection against harmful ingress of liquids. Do not autoclave or immerse the device, nor any sensor, in any kind of liquids. Ingress of liquids may result in electric shock.
- Warning: Only use United States Environmental Protection Agency (EPA) registered products for disinfection of the Nox Sleep System to prevent harm to the operator/patient.
- Note: Clean the Nox A1s recorder separately from its associated sensors.
- Note: The Nox A1s recorder components are NOT intended to be sterilized.
- Note: Reusing single-use products on more than one patient poses a risk of cross-infection.
- Note: Regarding cleaning/disinfection and re-use of 3rd party components and 3rd party sensors refer to the applicable 3rd party accompanying instructions.
- Note: Incorrect cleaning of the Nox Sleep System's reusable components can result in contamination and/or biologic risk to patient or clinician.
- Note: Soiled towelettes/cloths should be disposed of as biohazard material in accordance with federal, state, and local regulations.
- Note: Do not soak gold cup electrodes in bleach or alcohol
- Note: Do not use an abrasive-based cleaner on the electrodes, as it can damage the gold plating
- Note: Only apply light force when cleaning gold plated surfaces. Gold plating is soft and can easily be damaged or scratched when contacted.
- Note: Do not rub the gold-plated electrodes with the disinfection wipes
- Note: Do not disinfect the gold-plated electrodes with bleach

All reusable components should be cleaned immediately after use to prevent accumulation of residual soil and minimize soil transfer between patients.

Nox A1s Recorder, Nox Snap On Double Leads, Nox USBc Cable, Nox Abdomen Cable, Nox A1 EEG Head Cable, Nox A1s Carry Case:

MATERIALS/EQUIPMENT:

- Endozime® AW Plus hospital grade cleaner
- Lint-free cloths
- Gloves
- Soft bristle nylon brush (i.e. electrode brush, toothbrush, or nail brush)
- PDI Sani-Cloth Plus Germicidal Disposable Cloth or equivalent validated disinfectant*

CLEANING/DISINFECTING PROCEDURE:

1. Prepare a solution with the Endozime® AW Plus hospital grade cleaner
    - Follow the instructions accompanying the hospital grade cleaner
2. Dampen a lint-free cloth with the solution
    - Do not pour or spray any liquids on the Nox A1s Recorder
    - Do not allow any liquids to enter any openings on the Nox A1s Recorder
    - Do not immerse the cables in liquid
    - Avoid contact of the cleaning solution to cable/electrode connectors
3. Wipe all surface areas thoroughly to remove all visible soil and contaminants. Wipe the component for at least 2 minutes. Use a soft bristle nylon brush if necessary.
4. Visually inspect the cleaned components to ensure no soil remains. Pay good attention to all junctions and details. Repeat steps 2 and 3 if necessary.
5. Allow components to air dry completely before disinfection (minimum of 3 minutes)
6. For disinfection, take a new wipe of PDI Sani-Cloth Plus Germicidal Disposable Cloth or equivalent validated disinfectant*
7. Wipe all surface areas of the component with the disinfectant for at least three minutes
    - If other disinfection materials are used than PDI Sani-Cloth Plus Germicidal Disposable Cloth make sure:
        - they are safe to use on metals and plastics
        - to read the instructions from the manufacturer regarding required contact time of the solution to provide sufficient disinfection
8. Allow components to air dry completely before next use (minimum 1 minute)
9. Visually inspect the components under adequate lighting conditions (and magnification if needed) to confirm that the cleaning/disinfection process has not damaged components. Inspect for surface wear, discoloration, corrosion, or cracking. **

If necessary, the clips on the Nox A1s recorder can be removed before cleaning. The cleaning process described above also applies for the clips. If the clips are visibly contaminated, they should be replaced.

Nox Gold Cup Electrodes and leads

Clean the gold cup electrodes immediately after use.

MATERIALS/EQUIPMENT:

- Lint-free cloths
- Gloves
- Soft bristle brush (i.e. electrode brush, toothbrush, or nailbrush)
- Q-Tip
- Bowl or a cup
- PDI Sani-Cloth Plus Germicidal Disposable Cloth or equivalent validated disinfectant*
- Warm water

CLEANING PROCESS:

1. Soak the electrodes (not the connectors) in warm water (55-65°C/131-149°F) for minimum 5 minutes to soften dried electrode paste
    - Do not soak the electrodes in alcohol or bleach
    - Do not use an abrasive-based cleaner on the electrodes, as it can damage the gold plating
2. Use a lint- free cloth, soft bristle brush or a Q-tip to remove all traces of electrode paste from the electrodes
    - Only apply light force when cleaning gold plated surfaces. Gold plating is soft and can easily be damaged or scratched when contacted.
3. Allow the Gold Cup Electrodes to air dry completely (minimum 3 minutes)
4. For disinfection use a fresh wipe of PDI Sani-Cloth Plus Germicidal Disposable Cloth or equivalent validated disinfectant*. Wipe the electrodes and leads gently for 3 minutes
    - Do not rub the electrodes with the disinfection wipes
    - Do not disinfect the electrodes with bleach
    - If other disinfection wipes are used make sure:
        - they are safe to use on gold plating, metals, and plastics
        - to read the instructions from the manufacturer regarding required contact time of the solution to provide sufficient disinfection
5. Allow the Gold Cup Electrodes to air dry completely (minimum 1 minute)
6. Visually inspect the Gold Cup Electrodes under adequate lighting conditions (and magnification if needed) to confirm that the cleaning/disinfection process has not damaged components. Inspect for surface wear, discoloration, corrosion, or cracking. **

* PDI Sani-Cloth Plus Germicidal Disposable Cloth are Environmental Protection Agency (EPA) registered product for disinfection of medical devices in the United States of America.

** If any component damage occurs during cleaning process, contact Nox Medical immediately at support@noxmedical.com. Do not attempt to use the Nox Sleep System until the device has been inspected and repaired by authorized Nox Medical personnel.

The Nox disposable RIP belts are single patient use ONLY.

The Nox nasal cannulas and filter tube connectors are single patient use ONLY.

Disposal

Follow local governing ordinances and recycling instructions regarding disposal or recycling of this device and accessories, including batteries.

Compatible Sensors and Devices

- Warning: No modification of the Nox A1s recorder and it´s accessories is allowed. Unauthorized modifications could result in the device not performing as intended and cause serious harm to the patient. To ensure patient safety and effective use of the Nox Sleep System, only use accessories that have been validated for use by Nox Medical.

The following table includes information on accessories, sensors and devices that have been validated with the Nox A1s recorder.

The items listed below are Nox products and have been validated for use with the Nox A1s recorder:

NOX DISPOSABLE RIP BELTS

Type	Catalog Number
Nox RIP Belts Disposable, Extra Large 14 sets	551050
Nox RIP Belts Disposable, Large 20 sets	551040
Nox RIP Belts Disposable, Medium 20 sets	551030
Nox RIP Belts Disposable, Small 20 sets	551020
Nox RIP Belts Disposable, Pediatric 20 sets	551010

NOX NASAL CANNULAS/FILTER TUBE CONNECTORS

Type	Catalog Number
Nox Cannula with filter, 40 units	552010
Nox Filter Tube Connector, 50 units	552110

NOX SLEEP SYSTEM COMPONENTS

Type	Catalog Number
Nox Abdomen Cable, s	561212
Nox A1 EEG Head Cable, Adult 90 cm	562110
Nox A1 EEG 5 Lead Electrode Cable	554411
Nox Carry Case, s	568012
Nox Service Kit, s	569015
Nox Battery Lid, s	569020
Nox Clip Strap, s	569021

Nox Battery Lid Key	569014
Nox C1 Access Point	544020
Noxturnal US	NA
Noxturnal App	536210
Noxturnal US CD	539012

NOX SNAP-ON LEADS

Type	Catalogue Number
Nox Snap on Lead 50 cm, White, 1 unit	554020
Nox Snap on Lead 30 cm, Beige-White, 1 unit	554021
Nox Snap on Lead, 100cm, Green, 1 unit	554022
Nox Snap on Lead 50 cm, Beige – Green, 1 unit	550423
Nox Snap on Lead 150 cm, Grey, 1 unit	554024
Nox Snap on Lead 100 cm, Beige-Grey, 1 unit	554025
Nox Snap on Lead 150 cm, Black, 1 unit	554026
Nox Snap on Lead 100 cm, Beige-Black, 1 unit	554027
Nox Snap on Lead 100 cm, Orange, 1 unit	554028
Nox Snap On Double-Lead 50/100 cm, orange, keyhole connector, 1 unit	554310
Nox Snap On Double-Lead 30/50 cm, beige-orange, keyhole connector, 1 unit	554311
Nox Snap On Double-Lead 148/150 cm, grey, keyhole connector, 1 unit	554312
Nox Snap On Double-Lead 98/100 cm, beige-grey, keyhole connector, 1 unit	554313
Nox Snap On Double-Lead 148/150 cm, black, keyhole connector, 1 unit	554314
Nox Snap On Double-Lead 98/100 cm, beige-black, keyhole connector, 1 unit	554315
Nox Snap On Double-Lead 50/52 cm, white, keyhole connector, 1 unit	554316
Nox Snap On Double-Lead 30/32 cm, beige-white, keyhole connector, 1 unit	554317

The items listed below are 3rd party products and have been validated for use with the Nox A1s recorder:

PULSE OXIMETERS

Type	Catalogue Number
Nonin WristOx$_2$ Pulse Oximeter, Model 3150 BLE	541012

PULSE OXIMETER ACCESSORIES

Type	Catalogue Number
NONIN WristOx$_2$ Soft Sensor – Small	553010
NONIN WristOx$_2$ Soft Sensor – Medium	553020
NONIN WristOx$_2$ Soft Sensor – Large	553030
NONIN WristOx$_2$ Flex Sensor with 25 Flexi Wraps, 30 cm (12 in) cable – Adult	553130
NONIN WristOx$_2$ Wrist Band	564042
WristOx$_2$ Wrist Band, Disposable	560450

THERMAL FLOW SENSORS

Type	Catalogue Number
Thermal Flow Sensor – Adult (S.L.P. Limited)	552230

MASK PRESSURE TUBING

Type	Catalogue Number
Mask tubing (Westmed) 183cm (72in) Male x Female, 50 units	552320

ELECTRODES

Type	Catalogue Number
Lead with Attached Electrode (Ambu) 50 cm, 1,5 mm connector, 12 units	554111
Snap on Electrode Disposable (Ambu), small 25 units	554209
Blue Sensor® Snap on Electrode (Ambu), 50 units	554210
Neuroline Cup Disposable EEG Electrodes, 10 per pack	554220

ELECTRODE APPLIANCES

Type	Catalogue Number

Nuprep ECG & EEG Abrasive Skin Prepping Gel (Weaver and Company), 4oz (114g), 3 units	555010
Ten20 Conductive EEG Paste (Weaver and Company), 4oz (114g), 3 units	555020
Tensive Conductive Adhesive Gel, 12 units	555031

USB CABLE

Type	Catalogue Number
USB Type-C Cable	562016

CLEANING

Type	Catalogue Number
PDI Sani-Cloth Plus Germicidal Disposable Cloth	NA
Endozime® AW Plus	NA

Specifications

Nox A1s and Accessories

DESCRIPTION	PROPERTIES
FUNCTION	
Nox A1s Storage Capacity	▸ 4GByte
Nox A1s Recording Time	▸ 10 hours
Nox A1s Internal Channels	▸ Two RIP Respiratory Effort ▸ Pressure ▸ Respiratory sound/snoring ▸ Four bipolar ▸ Thirteen unipolar ▸ Position ▸ Activity ▸ Light
Nox A1s External Channels	▸ Oximeter data via Bluetooth®
PHYSICAL	
Nox A1s Dimensions	▸ 82 mm W, 63 mm H, 26 mm D +/- 4 mm
Nox A1s Weight	▸ 92 ± 3 g without battery
Nox A1s Bipolar Inputs	▸ Touch proof 1 mm keyhole connector ▸ Input range ≥ ±1024 mV ▸ Bandwidth: 0-80 Hz (6dB) ▸ Input impedance >5 MΩ ▸ Sampling Rate = 200 Hz
Nox A1s Unipolar Inputs	▸ Touch proof 1.5 mm unipolar electrode connector ▸ Input range ≥ ±3.2 mV ▸ Bandwidth > 0.2 - 80 Hz ▸ Input impedance >5 MΩ ▸ Sampling Rate = 200 Hz
Nox A1s Pressure Sensor	▸ Pressure input range: -5 cmH2O - +50 cmH2O ▸ Bandwidth: DC -90 Hz (6dB) ▸ Sampling Rate: 200 Hz

	▸ Connector fitting with Nox Cannula or Nox Filter Tube Connector
Nox A1 EEG Head Cable	▸ Head-end connector: Proprietary Nox Connector ▸ Device-end connector: Proprietary Nox Connector ▸ Lengths: Adults – 90 cm (35.4”), Pediatric – 70 cm (27.6”)
Nox A1 EEG 5 Lead Electrode Cables	▸ Proprietary Nox Connector ▸ 10 mm (0.39”) diameter cup electrodes
Nox Abdomen Cable	▸ 50 cm (19.7”) length of cable
USB-C Cable	▸ Type of USB connector at device end: Type-C ▸ Type of USB connector at PC end: Standard A
Nox Filter Tube Connector	▸ Hydrophobic filter with female Luer-lock inlet - diameter of 13 mm (0.51 in), with a 0.45 µm filtering capability

POWER

Nox A1s Power Source	▸ One AA battery ▸ Host PC (data configuration and download)
Nox A1s Battery Type	▸ Alkaline ▸ Lithium ▸ Rechargeable NiMH Batteries

Nox A1s DISPLAY

Type	▸ OLED
Display Dimensions	▸ 19 mm x 35 mm
Resolution	▸ 128 x 64

Nox A1s Transmitter

***Bluetooth®* Compliance**	▸ Version 5.0
Operating Frequency	▸ 2.402-2.480 GHz
Output Power	▸ < 4 dBm (± 3dB)
Network Topology	▸ Point-to-Point: Point-to-Multipoint
Operation	▸ Scatter-Net Master
Antenna Type	▸ Internal
Modulation Type	▸ Frequency Shift Keying/Frequency Hopping Spread Spectrum
Bandwidth	▸ 2 Mbps

Nox A1s SAMPLING RATE

Thorax and Abdomen RIP	200 Hz
Microphone	8 kHz
Oximeter - Pleth	75 Hz

BANDWIDTH

Microphone	Internal 3.5 kHz bandwidth

Material Information

COMPONENT	MATERIAL CONTENT
Nox A1s Recorder	Enclosure: 10% glass filled acrylonitrile butadiene styrene (ABS)/ polycarbonate (PC) Screen: Polycarbonate (PC) Proxy: PC/ABS Snaps: Gold plated stainless steel Clips: TPU/TPE and nickel-plated steel
Nox Abdomen Cable	Cable wire: Tinsel Cable jacket: PVC Abdomen and thorax plastic enclosures: PC/ABS Snaps: Gold-plated stainless steel Strain relief for device end: TPE Strain relief for belt end: PVC Contact springs in the device end: spring steel
Nox Snap on electrode cables, Bipolar	Cable Jacket: PVC Cable wire: Tinsel Connector: Gold-plated spring socket contacts, Riteflex® Snap: Nickel-plated brass socket, Riteflex®
Nox Snap on electrode cables, Unipolar	Cable Jacket: PVC Cable wire: Tinsel Connector: Gold-plated spring socket contacts, Riteflex® Snap: Nickel-plated brass socket, Riteflex®
Nox A1 EEG Head Cable	Cable Jacket: PVC

	▸ Head-end connector: TPE ▸ Device-end connectors: Gold-plated contacts, TPE ▸ USB Micro Connector: gold-plated contacts ▸ Connector Pins at Device End: gold-plated contacts
Nox A1 EEG 5 Lead Electrode Cables	▸ Cable Jacket: PVC ▸ USB Micro Connector: gold-plated contacts, TPE ▸ Electrode Cups: Gold-plated silver, TPE overmold
Nox A1s Carry Case	▸ External Part: BLK 600D Polyester ▸ Internal Part: PU ▸ Insert: ABS
Nox Disposable RIP Belts	▸ Belt Elastic: Polyester/Spandex ▸ Connector: ABS ▸ Belt Wire: Tin plated copper

Nox A1s Battery Information

- Note: Always use fully charged or fresh batteries for each sleep study to prevent the need for the sleep study to be repeated.
- Note: All lithium batteries used with the Nox A1s recorder shall be according to the standard IEC 60086-4 Primary batteries - Part 4: Safety of lithium batteries.
- Note: The recording durations listed below depend on the quality of the batteries used.

The list below is provided to assist the user in selecting the appropriate battery type for the Nox A1s study:

- **Lithium batteries** and **Powerex 2700 mAh rechargeable batteries** should be used to record a minimum of 10 hours.

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, including clinical evaluation, throughout the design process, according to requirement specifications and intended use. External accredited test houses were used to conduct testing needed to comply with the applicable standards regarding Electromagnetic Compatibility (EMC) and patient safety as well as additional RF testing to assure compliance with Federal Communications Commission (FCC).

The compliance of the Nox Sleep System towards patient safety and medical device standards has ONLY been verified and validated with the sensors and accessories listed in this manual. This includes all signal characteristics and automatic analysis provided by the Nox Sleep System.

Furthermore, use of other components than verified, validated or recommended by Nox Medical with the Nox A1s recorder is considered to be a modification of the Nox Sleep System. Such modifications could result in the system not performing as intended and cause serious harm to the patient.

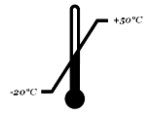
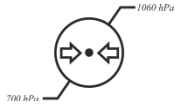
Nox Medical holds an ISO 13485:2016 (MDSAP) certified Quality Management System which complies with the requirements of the Medical Device Directive (MDD - Council Directive 93/42/EEC as amended by Directive 2007/47/EC); Canada – Medical Devices Regulations – Part 1 – SOR 98/282; Australia – Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure; Japan – MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act and USA – 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D.

Nox A1s Classifications

- Degree of protection (applied part) against electric shock: The entire device is an applied part and is classified as of **type BF** (see symbol to the left).
- Powering of the device: The device is **internally powered**.
- Degree of protection against harmful ingress of liquids and particulate matter:
    - **The Nox A1s recorder is classified IP22**, i.e. as defined by the standard IEC 60529 it is protected against solid foreign objects of 12.5 mm diameter and greater and vertically falling water drops when enclosure tilted up to 15°. It is not protected against spraying or splashing of water.
- Method of sterilization: The device is **NOT delivered sterile or intended to be sterilized**.
- Suitability for use in an oxygen rich environment: The device is **NOT intended for use in an oxygen rich environment**.
- Suitability for use with flammable agents and anesthetics: The device is **NOT intended for use in conjunction with flammable agents or with flammable anesthetic mixture with air or with oxygen or nitrous oxide**.
- Mode of operation: The device is intended for **continuous operation**.

Description of Symbols and Labels

	Operating instructions / Consult instructions for use
	Manufacturer information
	Date of manufacture
	Do not re-use
	Serial number
	Batch code / Lot number
	Catalogue number / Reference number
(01)1569431111XXXX(11)YYMMDD(21)WWWWWWWWW (01)1569431111XXXX(11)YYMMDD(10)ZZZZZZ	Unique Device Identifier (UDI); the Application Identifier (01) represents the device identifier (DI) (“1569431111XXXX”), the Application Identifier (11) the production date/date of manufacture (“YYMMDD”, with “YY” the last two digits of the production year, “MM” the production month and “DD” the production day), the Application Identifier (21) the serial number of the device (“WWWWWWWWW”) if applicable, and the Application Identifier (10)ZZZZZZ the lot number of the device (“ZZZZZZ”) if applicable
	Unique Device Identifier (UDI) presented in data matrix format
	RfID containing UDI information
	Type BF applied part (patient isolation from electrical shock)
	Non-ionizing radiation. Equipment includes RF transmitter: interference may occur in the vicinity of equipment marked with this symbol

CE 2797 / CE	CE marking indicating conformance to the applicable EU regulations/directives
Nox A1s	Brand name/Model name
APSG1SUS	Technical name
Contains FCC ID: V5A-NOXBLEMOD	FCC ID label
REV	Revision of device
	Bluetooth® wireless technology
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Keep dry
	Fragile, handle with care
IPN$_1$N$_2$	Degree of protection against harmful ingress of water or particulate matter as defined by the standard IEC 60529, where N_1 defines the degree of protection against harmful ingress of particulate matter and N_2 the degree of protection against harmful ingress of water
	Unsafe for MR (Magnetic Resonance) Environment.
	Medical Device

Bluetooth® Wireless Technology

The Nox A1s recorder uses Bluetooth® 5.0 wireless technology to communicate with external Bluetooth modules.

The Bluetooth wireless technology is based on a radio link that offers fast and reliable transmission of data. Bluetooth radio uses globally available frequency range in the industrial, scientific and medical (ISM) band, intended to ensure communication compatibility worldwide and a fast acknowledgement and frequency-hopping scheme to make the link robust, even in noisy radio environments. Please refer to the "Specifications" section for details on Radio Frequency (RF) specifications for the Nox A1s recorder.

The *Bluetooth*® word mark and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by Nox Medical is under license. Other trademarks and trade names are those of their respective owners.

Electromagnetic Compatibility (EMC) Information

- Caution: Exposure to radio frequency radiation.
- Note: Portable and mobile Radio Frequency (RF) communications can affect the performance of the Nox A1s recorder.
- Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Nox Sleep System BLE, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Warning: Electromagnetic interference (EMI) can be picked up by the Nox A1s recorder, causing disturbed or altered signals to appear in the Noxturnal US software. This may affect data analysis and result in incorrect interpretation of data.
- Warning: The Nox A1s recorder(s) should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device(s) should be observed to verify normal operation in the configuration in which it will be used and prevent abnormal operation which might cause injuries to the operator/patient.
- Warning: The use of accessories, transducers, sensors, and cables other than those listed in this manual may result in increased emissions and/or decreased immunity of the Nox A1s recorder and cause injuries to the operator/patient.
- Warning: The Nox Sleep System BLE may be interfered with by other equipment, even if that equipment complies with CISPR (Special International Committee on Radio Interference) emission requirements, causing possible patient harm
- Refer to the tables below in this section for specific information regarding the Nox A1s recorder's compliance to the standard IEC60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Declarations of Conformity with the US Federal Communications Commission (FSS)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not

installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no ensured specification that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by tuning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Caution: Exposure to Radio Frequency Radiation.

This device must not be co-located or operating in conjunction with any other antenna or transmitter.

Compliance to the standard IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and Tests.

ELECTROMAGNETIC EMISSIONS

The Nox A1s recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 2	The device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

ELECTROMAGNETIC IMMUNITY

The A1s recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Immunity test	**IEC 60601 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV and ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV and ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output parts port 100 kHz repetition frequency	Not applicable
Surge IEC 61000-4-5	±0,5 kV, ±1 kV line-to-line ±0,5 kV, ±1 kV, ±2 kV lines-to-ground	Not applicable
Voltage dips IEC 61000-4-11	0 % U_T for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315°. 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles	Not applicable
Voltage Interruptions IEC 61000-4-11	0 % U_T for 250/300 cycles	Not applicable
Rated power frequency magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 60 Hz
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0,15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz
Radiated RF EM fields IEC 61000-4-3	3 V/m and 10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m and 10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Refer to Immunity to proximity fields from RF wireless communications equipment	Refer to Immunity to proximity fields from RF wireless communications equipment
NOTE U_T is the a.c. mains voltage prior to application of the test level.		

IMMUNITY TO PROXIMITY FIELDS FROM RF WIRELESS COMMUNICATIONS EQUIPMENT

The A1s recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance (Yes/No)
385	380-390	TETRA 400	Pulse modulation 18Hz	1,8	0,3	27	Yes
450	430-470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0,3	28	Yes
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9	Yes
745							
780							
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28	Yes
870							
930							
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28	Yes
1845							
1970							
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28	Yes
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9	Yes
5500							
5785							