MANUAL

Nox A1

Nox A1 Manual

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Manufactured by:

Nox Medical ehf
Katrinartuni 2
IS - 105 Reykjavik
Iceland
Website: www.noxmedical.com

For distributor information go to:
www.noxmedical.com

CE 0086

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Introduction

Congratulations on choosing the Nox A1 PSG recorder. The A1 is an AASM (American Academy of Sleep Medicine) compliant PSG recorder and can be used for online and ambulatory sleep testing polysomnography (PSG). The device is compact, lightweight and easy to use. Simple sensor placement makes setup quick and easy.

Scope

This manual covers the A1 device and its components along with external sensors and devices that have been validated with the A1 system. It does not cover the software application needed for device configuration, data download, review and/or analysis.

This manual is only intended for professionals (healthcare professionals and service personnel) with relevant qualifications and skills.

Instructions for Operators

The A1 system 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 the Device”, “Patient Hookup” and “Maintenance” sections. The **ONLY** operation that patients might have to perform by themselves at home is to start recordings that have been configured to be manually started. In that case, the professional setting up the A1 device 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 representatives

- for assistance, if needed, in setting up and attaching the A1 device, its components and external sensors and devices that have been validated with the A1 system, operating or maintaining the device; or
- to report unexpected operation or events.

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

Warnings and Cautions for Use

- Warning: The A1 device 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: This device 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 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 this device and cause injuries to the operator/patient.
- Warning: The A1 device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the A1 device 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: This system may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements, causing possible patient harm.
- Caution: The A1 device is designed to be safe for use for pacemaker patients as long as the pacemakers comply with the EN 50061 standard of electrical safety of medical devices. Using non-compliant pacemakers may result in the operation of the pacemaker being affected by the use of A1 device and lead to possible recoverable patient harm. The operator should consult the accompanying documents of the pacemaker regarding its certifications and requirements of use or, if necessary, contact the producer.
- Warning: The A1 device 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 recoverable 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 A1 device is not intended to be used with high frequency (HF) equipment. Using the A1 device with high frequency (HF) equipment could cause potential serious harm to the patient.
- Warning: The Nox EEG Head Cable/Nox 5 Lead EEG Cables do not provide protection against the effect of the discharge of a cardiac defibrillator nor against high frequency burns. 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 recoverable patient harm.
- Warning: The A1 device is 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 A1 device to prevent harm to the operator/patient.
- Warning: The device 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 A1 System 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 A1 system, including patient cables and electrodes, in an MRI (Magnetic Resonance Imaging) environment. The energy absorption in conductive materials might lead to excessive heating and cause burns.
- Caution: The A1 device and RIP belts should be worn over clothing to prevent allergic

reaction to the equipment materials.

- Caution: The RIP belts should fit the patient snugly without being uncomfortably tight to avoid discomfort.
- Warning: The Nox disposable RIP belts are single use. Re-using the disposable RIP belts may affect the quality of recorded signals and lead to possible incorrect treatment.
- Warning: The Nox disposable RIP belts, Nox cannulas, Nox filter tube connectors and mask pressure tubes are 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, cannula, filter tube connector and mask pressure tube on more than one patient poses a risk of cross-infection.
- Warning: Do not use damaged equipment, sensors or accessories. This may result in bad performance of the device or patient/operator injury.
- Warning: The A1 device and its accessories should be removed from the patient before use of the USB connector to prevent electric 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 A1 device. The A1 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 A1 device is opened.
- Warning: No modification of this equipment is allowed. Un-authorized modifications could result in the device not performing as intended and cause serious harm to the patient.
- Warning: Remove batteries from the A1 device if the device 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 collateral standard IEC 60601-1-1 or the general standard IEC 60601-1, edition 3/3.1, 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 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 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: The Nox 5 Lead EEG 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 5 Lead EEG 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 device should always be transported in its accompanying carrying case to ensure adequate protection and prevent damage.

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

Device Description

The Nox A1 device is an AASM compliant PSG recorder.

The A1 input channels and built-in capabilities include the following:

- 13 unipolar channels; for recording of EEG, EOG and submental EMG
- 1 ground channel
- 4 bipolar channels; for recording of ECG, EMG – LM, bruxism or additional EMG
- 1 pressure/cannula channel; for recording of nasal or mask pressure
- 2 respiratory effort channels; for recording of abdomen and thorax effort
- 3-D built-in acceleration sensor; for recording of patient's position and activity
- Built-in microphone; for recording of audio and snoring
- Built-in Bluetooth® module; to support wireless connectivity allowing it to record signals from compatible auxiliary devices

The Bluetooth® function also allows wireless streaming of data for online review of signals.

The device is powered with one AA battery.

Intended Use

The Nox A1 device is intended for ambulatory and online recording of physiological signals during sleep. The recorded signals are either downloaded after the study or streamed wirelessly over Bluetooth® entry points/Nox C1 Access Point during the study to a PC where the signals can be viewed and analyzed by use of the Noxturnal application. The A1 recorder is also capable of communicating over Bluetooth® via the Nox C1 access point for the purpose of device control. The A1 recorder is finally capable of communicating over Bluetooth® with the Nox app running on a mobile platform for the purpose of device control and review of signals.

The A1 system is intended for patients greater than 2 years of age.

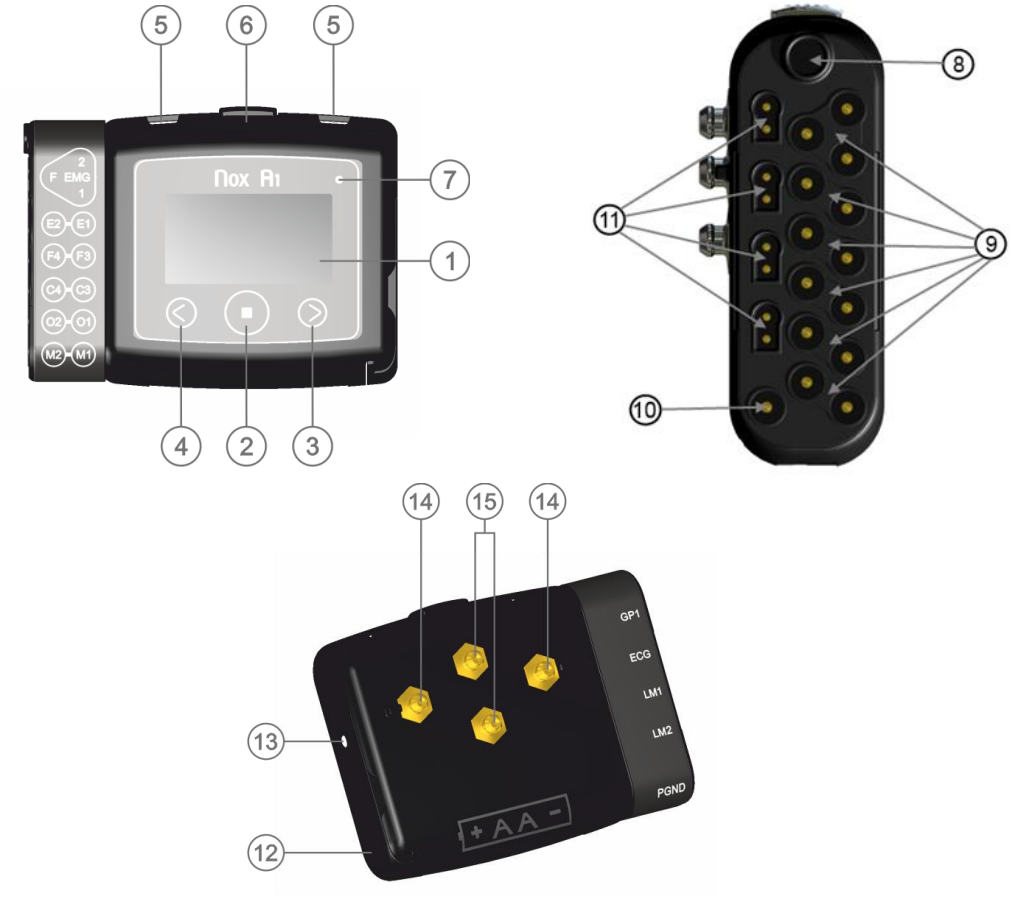
The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including patient's home.

Contraindications

The A1 device is **NOT** intended for any patient monitoring or automatic diagnosis.

A1 Interface

The A1 device interface consists of a display, buttons, sensor inputs/connections and a USB connector. The USB connector is placed under the battery lid and connects to a mini USB cable for device configuration and data download. See the figures and tables below for detailed description.



NUMBER	FUNCTION
1	Display
2	Push button – Middle
3	Push button – Forward
4	Push button – Backward
5	Clip strap loops
6	Microphone – For recording of respiratory sounds
7	Indicator light for device status
8	Pressure lock – Connects to nasal cannula/mask pressure tube
9	Unipolar touch proof inputs
10	Reference ground input
11	Bipolar touch proof inputs
12	Battery lid – Covers the battery and the USB connector

13	Battery lid pin
14	Metal snaps – Connects to thorax RIP belt
15	Metal snaps – Connects to abdomen cable

Operating the Device

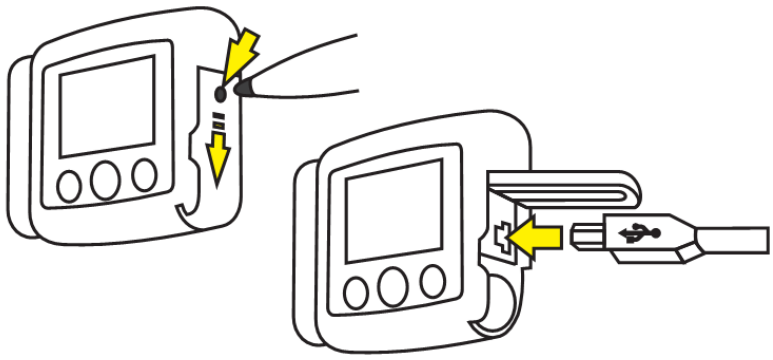
The A1 system is only intended to be operated by professionals (healthcare professionals and service personnel) with relevant qualifications and skills. The **ONLY** operation that patients might have to perform by themselves at home is to start recordings that have been configured to be manually started. In that case, the professional setting up the A1 device 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 A1 device is operated with three push buttons located on the front panel. Pressing the **Middle** button turns on the display. The display will automatically turn off in 3 minutes.

Connecting the A1 Device to a Computer

- Warning: The A1 device and its accessories should be removed from the patient before use of the USB connector to prevent electric shock. The USB connector shall only be used for the purposes of configuring the device and downloading data from the device.

To connect an A1 device 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 a pen or a similar tool, available from Nox Medical, on the battery lid pin and slide the battery lid down, towards the bottom of the device. The A1 device connects to the computer by using a mini USB cable. The battery does not have to be inserted while the device is connected to the computer.



When the A1 device is connected to the computer the device display lights up.

Configuring and Downloading from A1 Device

To download a recording or configure the A1 device you will need to start the Noxturnal software application and connect the device to the computer. Please refer to the applicable software user manual for more information on how to perform those tasks.

When you are done working with the device eject the device from the Noxturnal software and unplug the mini USB 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 a Recording

If the device has been configured to start the recording manually, you can use the **Middle** button to manually start a recording. Pressing the middle button turns on the display. The device will instruct you to “Hold middle button down to start recording”. Please do so until you see “Recording Duration” displayed. Note the **Middle** 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. After the display turns off, the light on the top right side of the display will blink intermittently indicating that 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 a Recording at a Scheduled Time

If the device has been configured to automatically start a recording at a scheduled time there are no actions required for the recording to start. Pressing the **Middle** 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.

Signal and Status Checks

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

- Battery low

Information about the recording and the device is shown on the display. If the display is turned off, pressing the **Middle** button turns it on. The display will turn itself off again after being inactive for 3 minutes.

1. On the top right corner is a battery indicator which shows the battery status. The battery indicator shows 100% when the device has fresh batteries.
2. Duration being displayed.

For detailed signal checks, please refer to the Noxturnal App, available on the Google Play® store.

Patient Hookup

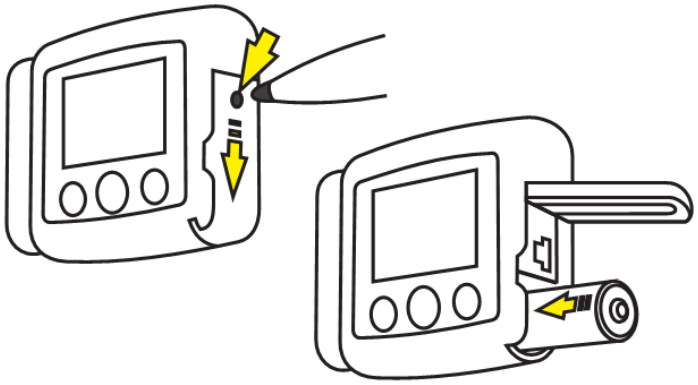
The A1 system is only intended to be hooked-up by professionals (healthcare professionals and service personnel) with relevant qualifications and skills.

- Warning: Do not use damaged equipment, sensors or accessories. This may result in bad performance of the device 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 device should always be transported in its accompanying carrying case to ensure adequate protection and prevent damage.

Inserting a Battery to the A1 Device

- Note: Always use fully charged **Powerex 2700 mAh Rechargeable Batteries** or fresh **lithium battery** for each sleep recording to prevent the need for the sleep study to be repeated.
- Note: All lithium batteries used with the A1 device shall be according to the standard IEC 60086-4 Primary batteries - Part 4: Safety of lithium batteries.

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



1. Open the battery compartment by pressing down the battery lid pin with the Nox Lid Key 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.

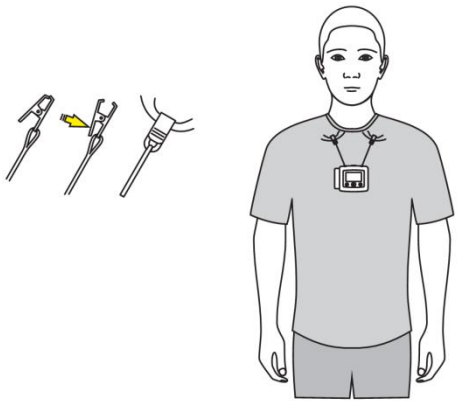
Attaching the A1 Device and the RIP Belts

- Caution: The A1 device and RIP belts should be worn over clothing to prevent allergic reaction to the equipment materials.
- Warning: The 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 device to the patient's shirt.

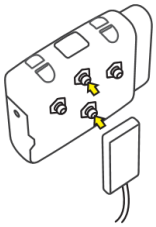
1



Step 2 to Step 4

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

2



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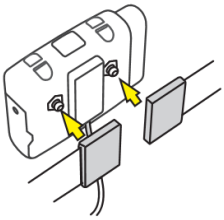

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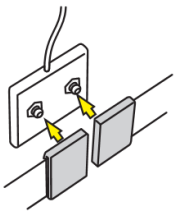
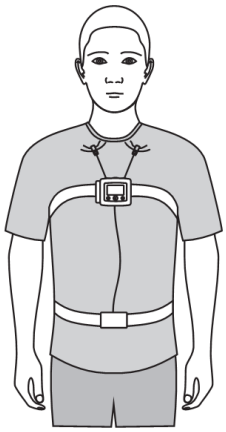


Step 5

Attaching the device and respiratory sensors is now completed.

5

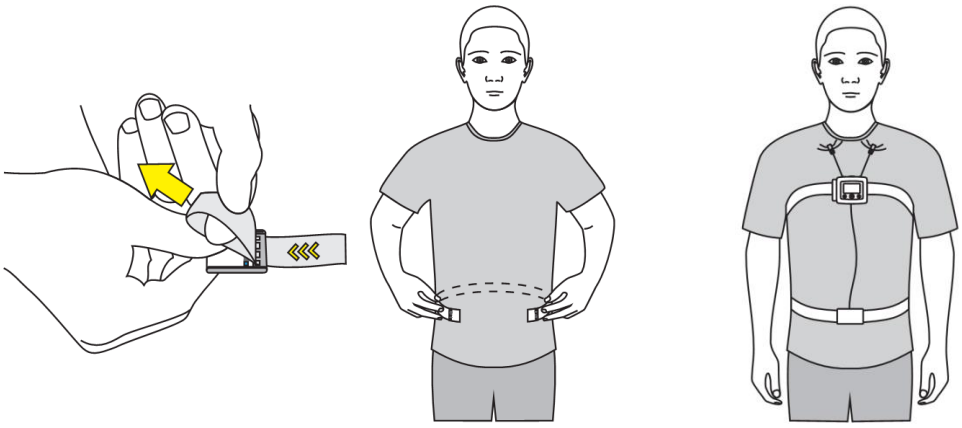


Adjusting the RIP Belts

- Caution: The RIP belts should fit the patient snugly without being uncomfortably tight to avoid discomfort.

Disposable RIP Belts

Fit the 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.



Refer to the "Compatible Sensors and Devices" section regarding the types of Nox RIP belts that have been validated with the A1 device.

NOTE: For most patients the 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 the product for more detailed instructions.

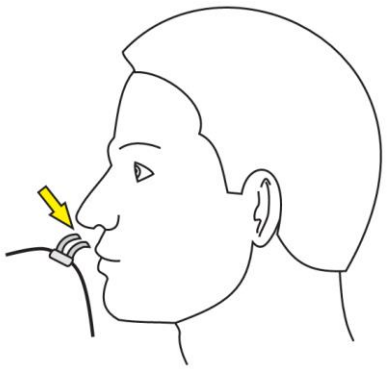
Attaching the Nasal Cannula

- Warning: The nasal cannula is 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.

Step 1

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

1



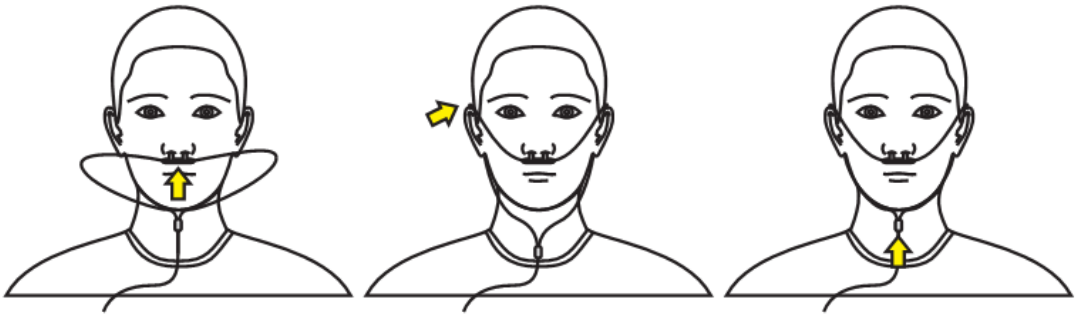
Step 2

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.

1 2 3



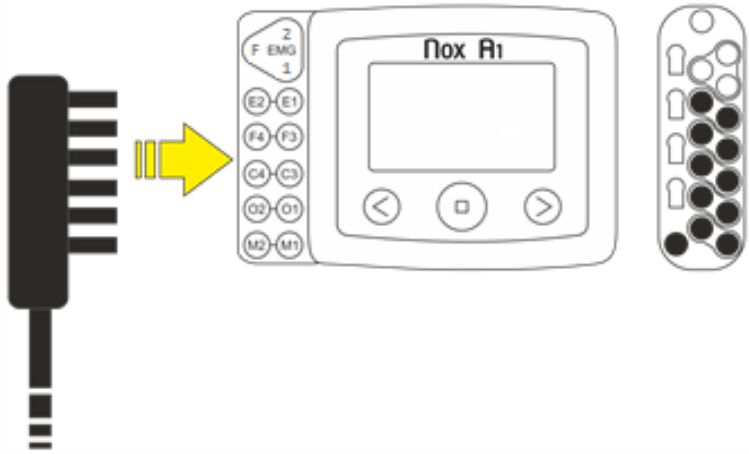
NOTE: The Nox nasal cannula with filter has a built-in hydrophobic filter and is the preferred way to measure nasal airflow and snoring as it is designed to maximize the signal quality and fits directly with the A1 device. If it is preferred to use a non-filtered Luer-lock cannula, it is necessary to use a filter tube connector from Nox Medical to interface with the A1 device.

Refer to the “Compatible Sensors and Devices” section regarding the types of nasal cannulas that have been validated with the A1 device.

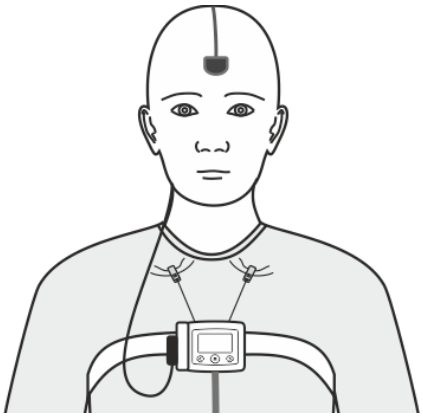
Measuring EEG Signals

- 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 5 Lead EEG 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 5 Lead EEG 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 EEG Head Cable/Nox 5 Lead EEG Cables do not provide protection against the effect of the discharge of a cardiac defibrillator nor against high frequency burns. 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 recoverable patient harm.
- Note: The Nox EEG Head Cable is available in both pediatric and adult lengths.

Connect the Nox EEG Head Cable to the E2-E1, F4-F3, C4-C3, O2-O1, M2-M1 unipolar and ground inputs of the A1 device.

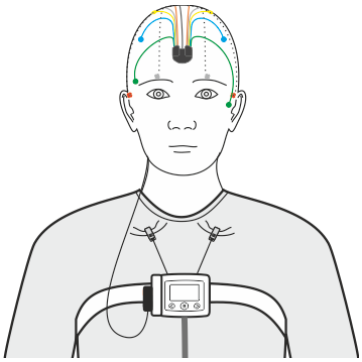


Place a snap-on electrode on the middle of the patient's forehead. Route the head cable behind the patients head and snap the cable to the electrode.

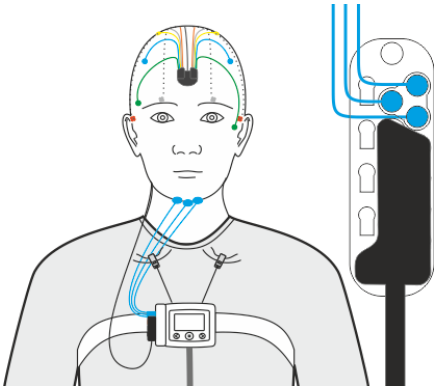


Connect two Nox 5 Lead EEG Electrode Cables to the head cable, one on each side.

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**.



For submental EMG, insert the electrode leads into the EMG channels of the device 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.

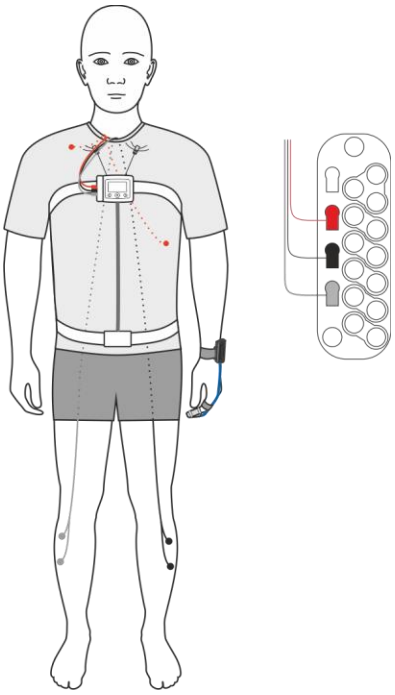


Measuring EMG/ECG Signals

- 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) 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.

The A1 device is equipped with 4 bipolar channels suitable for recording of ECG and EMG signals such as leg EMG or masseter EMG for bruxism detection. The device's bipolar channels are labeled with GP1, ECG, LM1, and LM2 and connect to bipolar electrode leads with keyhole connectors. However, during recording setup, those channels can be defined for any EMG/ECG signals. Please refer to the applicable software user manual for more information on how to configure the device.

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



Measuring Mask Pressure

- Warning: The Nox filter tube connectors and mask pressure tube are single patient use. Using the same filter tube connectors and mask pressure tube 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 A1 device by using the Nox filter tube connector.

A mask pressure tube is used for connection to CPAP masks for measuring mask pressure. The pressure tube connects to the pressure lock on the A1 device 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 A1 device.

Measuring Data from Auxiliary Devices

- Warning: The A1 device is **NOT certified to be used for continuous monitoring** where failure to operate can cause injuries or death of the 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 collateral standard IEC 60601-1-1 or the general standard IEC 60601-1, edition 3/3.1, 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.

The A1 device is able to communicate with auxiliary devices over a Bluetooth® link with the Nox W7 link. Refer to the user instructions accompanying the Nox W7 link package regarding the types of auxiliary devices that have been validated with the A1 device.

Measuring Pulse and Oxygen Saturation

The A1 device is able to communicate with an external 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 that have been validated with the A1 device.

- Warning: The A1 device is **NOT certified to be used for continuous monitoring** where failure to operate can cause injuries or death of the patient.
- 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 A1 device.
- Caution: The pulse oximetry system might misinterpret motion as good pulse quality. Minimize finger motion or change the type of sensor being used.
- Caution: Do not fasten the pulse oximeter too tightly around the wrist. Inaccurate readings and patient discomfort could result.
- Note: To prevent the sensor from falling off secure its cable with medical tape.
- Caution: Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.
- Caution: To prevent improper performance and/or patient injury, verify the sensor and pulse oximeter compatibility before use.
- Caution: Factors that may degrade pulse oximeter performance 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
- other cardiovascular dyes
- carboxyhemoglobin
- methemoglobin
- dysfunctional hemoglobin
- artificial nails or fingernail polish
- residue (e.g., dried blood, dirt, grease, oil) in the light path

▸ Refer to 3rd party instructions for use accompanying the pulse oximeter and/or oximeter sensor for maximum oximeter application time at a single site.
▸ Refer to 3rd party instructions for use accompanying the pulse oximeter and oximeter sensor for additional warnings and cautions.

Inserting Batteries into the Oximeter

Nonin 3150 Pulse Oximeter

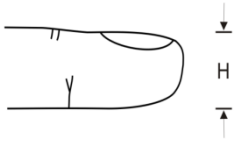
Refer to the 3rd party accompanying instructions regarding replacement of batteries when using the Nonin 3150 oximeter.

▸ 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

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.

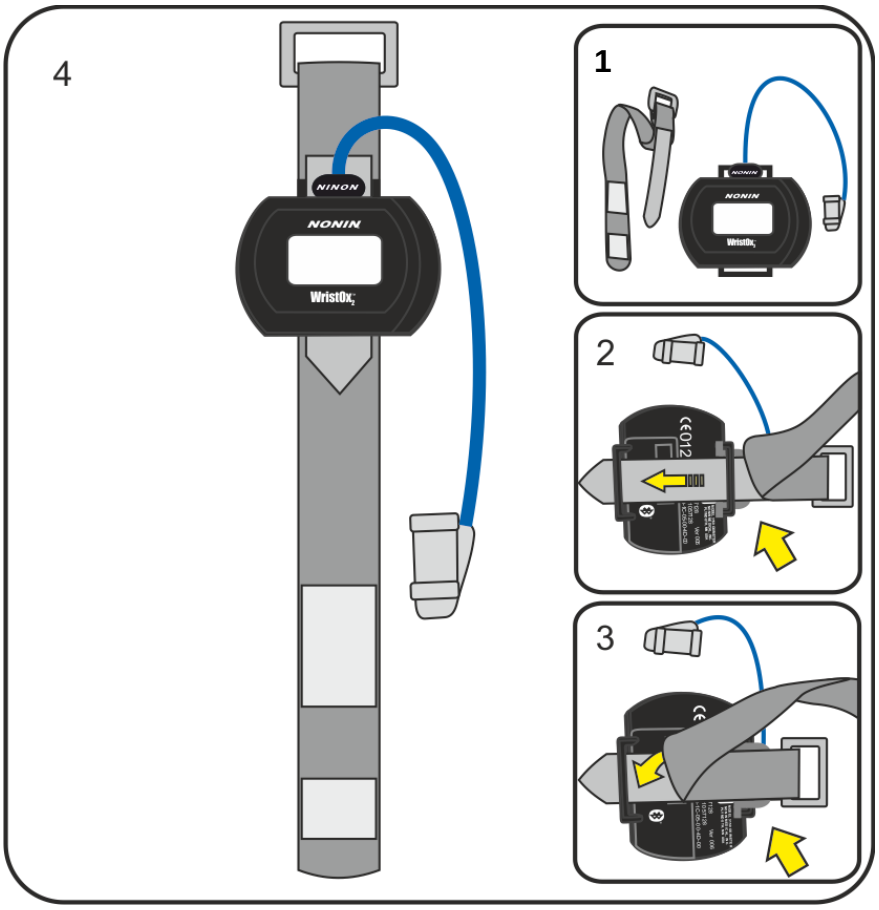
For digit height from 12.5 mm (0.5 in) to 25.5 mm (1.0 in), size large should be selected.

Attaching the Pulse Oximeter Module and Sensor

Nonin 3150 Pulse Oximeter

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.



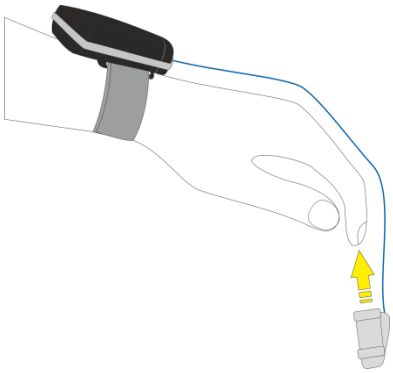
Step 5 to Step 6

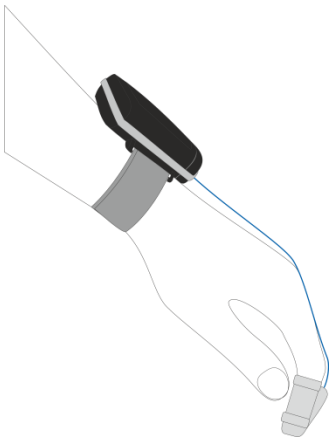
The preferred application site for patients over 20 kg is the index finger. However, other fingers or toes may be used where the tissue thickness is between 5 and 21 millimeters. Other sites may not give acceptable results because of inadequate light transmission or perfusion.

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

5

6





Configuring the Oximeter Setup

Establish Connection between the Nonin 3150 Oximeter and A1 Recorder

Use the Noxturnal software or Noxturnal App to establish the connection between the Nonin 3150 oximeter and A1 Recorder. The connection is established by entering the Bluetooth (BDA) address of the oximeter in the recording configuration.

Maintenance

The A1 system is only intended to be maintained by professionals (healthcare professionals and service personnel) with relevant qualifications and skills.

The A1 device and accessories should be stored in a clean, dry place.

Handle the A1 device with care and protect it against mechanical shocks, dirt and liquids. The device is not waterproof or splash proof.

To update the A1 device you will need the Noxturnal software running on the computer which the device is connected to. Please refer to the applicable software user manual for more information on how to perform this task.

No regular testing of the A1 device or accessories, including patient cables, is needed.

The service life of the A1 device is 5 years. The service life of reusable accessories is 1 year.

- Warning: Remove batteries from the A1 device if the device 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 A1 device. The A1 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 A1 device is opened.
- Warning: No modification of this equipment is allowed. Un-authorized modifications could result in the device not performing as intended and cause serious harm to the patient.
- Note: The A1 device has an internal battery which is automatically charged by regular use. It is recommended to charge the internal battery before the first use or if the device has not been in use for three months or more. The battery is charged by plugging the device to a computer with a USB cable for 6 hours or more.
- Note: It is never recommended to downgrade the firmware of the A1 device. 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.

Environmental Conditions

Temperature	Operation: +5°C to +50°C (+41°F to +122°F)
	Transport/Storage: -25°C to +70°C (-13°F to 158°F)
Relative Humidity	Operation: 10-95% (non-condensing)
	Transport/Storage: 10-95% (non-condensing)
Pressure	Withstands atmospheric pressures from 700 hPa to 1060 hPa

Calibration

The A1 device is factory calibrated. No further calibration is needed.

Cleaning

All reusable components should be cleaned between each patient use.

Clean the A1 device with a soft cloth dampened with hospital grade cleaner that is not corrosive to plastic or metal. Do not pour or spray any liquids onto the device, and do not allow any liquids to enter any openings on the device. Allow the unit to dry thoroughly before use.

All Nox cables used with the A1 device are reusable. Clean the cables with a moist cloth using hospital grade cleaner. Do not immerse the cables in liquid and avoid contact of the cleaning solution with the connectors.

For disinfection of the A1 device and Nox cables the following materials may be used:

- Sodium hypochlorite diluted with water at 1:500 (bleach)
- 70-90% isopropanol
- Super Sani-Cloth Plus disinfection wipes (from PDI)

Clean the carry case with a moist cloth using water or mild soap solution.

Gold cup electrodes and leads should be cleaned using a mild hospital-grade laundry detergent, wiped with soft towels and air dried. In addition, standard alcohol wipes can be used to clean leads (Super Sani-Cloth Plus disinfection wipes from PDI).

- Do not soak electrodes in alcohol
- Do not use bleach
- Do not use an abrasive-based cleaner on the electrodes, as it can damage the plating
- Only apply light force when cleaning gold plated surfaces. (Gold plating is soft and can easily be damaged or scratched when contacted).
- A dampened soft towel or dampened soft foam swab is recommended for use when cleaning gold plated surfaces.

Clean electrodes immediately after use.

The disposable RIP belts are single patient use ONLY.

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

- Warning: The A1 device 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 cleaning/disinfection of the A1 device to prevent harm to the operator/patient.
- Clean the device separately from its associated sensors.
- The Nox A1 components are NOT intended to be sterilized.
- Reusing single-use products on more than one patient poses a risk of cross-infection.
- Regarding cleaning/disinfection and re-use of 3rd party components and 3rd party sensors refer to the applicable 3rd party accompanying instructions.

Disposal

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

- According to the regulation in Europe on Waste of Electrical and Electronic Equipment (WEEE) the components labeled with this symbol may not be disposed of as unsorted municipal waste. The components shall be collected separately and returned to the appropriate collection system available.
- Please contact your distributor regarding take-back or recycling of the components.

Compatible Sensors and Devices

The following table includes information on accessories, sensors and devices that have been validated with the A1 device.

- Note: To ensure patient safety and effective use of the A1 device, only use accessories that have been validated for use by Nox Medical.

The items listed below are Nox products and have been validated for use with the A1 device:

NOX 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 CANNULAS/FILTER TUBE CONNECTORS

Type	Catalog Number
Nox Cannula with filter, 40 units	552010
Nox Cannula with Luer-lock, 50 units	552020
Nox Filter Tube Connector, 50 units	552110

A1 SYSTEM COMPONENTS

Type	Catalog Number
Nox Abdomen Cable	562010
Nox USB Cable	562011
Nox A1 EEG Head Cable, Adult 90 cm	562110
Nox A1 EEG Head Cable, Pediatric 70 cm	562111
Nox A1 Carry Case	568011
Nox Service Kit	569010
Nox Battery Lid	569011

Nox Clip Strap	569013
Nox Lid Key	569014

UNIPOLAR SNAP-ON LEADS

Type	Catalogue Number
Nox Snap-on Lead 50 cm, white, 1.5mm connector, 2 units	554020
Nox Snap On Lead 30 cm, beige-white, 1.5 mm connector, 2 units	554021
Nox Snap On Lead 100 cm, green, 1.5 mm connector, 1 unit	554022
Nox Snap On Lead 50 cm, beige-green, 1.5 mm connector, 1 unit	554023
Nox Snap On Lead 150 cm, grey, 1.5 mm connector, 2 units	554024
Nox Snap On Lead 100 cm, beige-grey, 1.5 mm connector, 2 units	554025
Nox Snap On Lead 150 cm, black, 1.5 mm connector, 2 units	554026
Nox Snap On Lead 100 cm, beige-black, 1.5 mm connector, 2 units	554027
Nox Snap On Lead 100 cm, orange, 1.5 mm connector, 2 units	554028

BIPOLAR SNAP-ON LEADS

Type	Catalogue Number
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

GOLD CUP ELECTRODES

Type	Catalogue Number
Nox Standard Gold Cup Electrode, 10 units	554410
Nox A1 EEG 5 Lead Electrode Cable	554411

BLUETOOTH® LINK

Type	Catalogue Number
Nox W7 Link Kit - S	544010
Nox W7 Link Kit - R	544011

ONLINE SETUP

Type	Catalogue Number
Blue Giga online module	544022
Nox C1 Access Point Kit	544020

MOBILE APP

Type	Catalogue Number
Noxturnal Mobile App, available from Google Play Store	536210

The items listed below are 3rd party products and have been validated for use with the A1 device:

PULSE OXIMETERS

Type	Catalogue Number
NONIN 3150	541010

PULSE OXIMETER ACCESSORIES

Type	Catalogue Number
WristOx$_2$ Soft Sensor – Small	553010
WristOx$_2$ Soft Sensor – Medium	553020
WristOx$_2$ Soft Sensor – Large	553030
WristOx$_2$ Wrist Band	564042

DIFFERENTIAL PRESSURE SENSOR

Type	Catalogue Number
Differential Pressure Sensor Kit	547010

FLOW SENSORS

Type	Catalogue Number
Thermal Flow Sensor - Adult	552230
Thermal Flow Sensor – Pediatric	552231

MASK PRESSURE TUBING

Type	Catalogue Number
Mask tubing 183cm (72in) Male x Male, 50 units	552310
Mask tubing 183cm (72in) Female x Male, 50 units	552320

ELECTRODES

Type	Catalogue Number
Lead with Attached Electrode 100 cm, 1.5 mm connector, 10 units	554109
Lead with Attached Electrode 152 cm, 1.5 mm connector, 10 units	554110
Lead with Attached Electrode 50 cm, 1,5 mm connector, 12 units	554111
Snap on Electrode Disposable, small 25 units	554209
Blue Sensor® Snap on Electrode, 50 units	554210

ELECTRODE APPLIANCES

Type	Catalogue Number
Nuprep ECG & EEG Abrasive Skin Prepping Gel, 4oz (114g), 3 units	555010
Ten20 Conductive EEG Paste, 4oz (114g), 3 units	555020
EC2 Electrode Cream, 3.5oz (100g), 1 unit	555030

CLEANING

Type	Catalogue Number
Super Sani-Cloth Plus Disinfection Wipes	559010

Specifications

A1 Device

DESCRIPTION	PROPERTIES
FUNCTION	
Storage Capacity	▸ 1GByte
Recording Time	▸ 8 hours
Internal Channels	▸ Two RIP Respiratory Effort ▸ Pressure ▸ Respiratory sound/snoring ▸ Four bipolar ▸ Thirteen unipolar ▸ Position ▸ Activity
External Channels	▸ Oximeter data via Bluetooth ▸ Capnography data via Bluetooth ▸ CPAP data via Bluetooth
PHYSICAL	
A1 Device Dimensions	▸ 82 mm (3.2”) W, 63 mm (2.5”) H, 21 mm(0.85”) D
A1 Weight	▸ 132 g (163 g with battery) (0.29 lbs (0.36 lbs with battery))
A1 Bipolar Inputs	▸ Touch proof 1 mm keyhole connector ▸ Input range ±8 mV AC ▸ Bandwidth 0.1 - 85 Hz ▸ Input impedance >5 MOhm ▸ Sampling Rate = 256 kHz ▸ Storage rate = 200 Hz
A1 Unipolar Inputs	▸ Touch proof DIN 42-802 ▸ Input range ±3.2 mV AC ▸ Bandwidth 0.1 - 85 Hz ▸ Input impedance >5 MOhm ▸ Sampling Rate = 256 kHz ▸ Storage rate = 200 Hz

EEG Head Cable	▸ Head-end connector: Black overmolded female snap and dual USB Micro receptacles ▸ Device-end connector: 11 pin touchproof connectors 1.5 mm (0.060") female
EEG 5 Lead Electrode Cables	▸ USB micro connector ▸ 10 mm diameter cup electrodes
Abdomen Cable Length	▸ 50 cm (19.7”)
Pressure Sensor	▸ Pressure input range: ±100 cmH_2O
Nox USB Cable	▸ Type of USB connector at device end: Mini-B ▸ Type of USB connector at PC end: Standard A
Filter Tube Connector	▸ Hydrophobic filter with female Luer-lock inlet - diameter of 13 mm (0.51”), with a 0.45 µm pore sized membrane

POWER

Power Source	▸ One 1.5 V AA battery ▸ Host PC (data configuration and download)
Battery Type	▸ Lithium ▸ Powerex 2700 mAh Rechargeable Batteries

DISPLAY

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

Transmitter

***Bluetooth®* Compliance**	▸ Version 2.0
Operating Frequency	▸ 2.402-2.480 GHz
Output Power	▸ < 1.62 mW
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	▸ 1 MHz

Material Information

COMPONENT	MATERIAL CONTENT
A1 Device	▸ Enclosure: 10% glass filled PC/ABS ▸ Proxy: PC/ABS ▸ Snaps: Gold plated stainless steel ▸ Display/Keypad: PET ▸ Clips: Nickel-plated steel clip , nylon rope, brass crimp
Abdomen Cable	▸ Cable Jacket: PVC ▸ Enclosure: PC/ABS ▸ Snaps: Gold-plated stainless steel ▸ Strain relief for device end: TPE ▸ Strain relief for belt end: PVC
USB Cable	▸ Cable Jacket: PVC ▸ Connector: PVC
Snap on electrode cables, Bipolar	▸ Cable Jacket: PVC ▸ Connector: Gold-plated spring socket contacts, Riteflex ▸ Snap: Nickel-plated brass socket, Riteflex
Snap on electrode cables, Unipolar	▸ Cable Jacket: PVC ▸ Connector: Gold-plated spring socket contacts, Riteflex ▸ Snap: Nickel-plated brass socket, Riteflex
EEG Head Cable	▸ Cable Jacket: PVC ▸ Head-end connector: Riteflex ▸ Device-end connectors: Gold-plated contacts, Riteflex
EEG 5 Lead Electrode Cables	▸ Cable Jacket: PVC ▸ USB Micro Connector: gold-plated contacts, Riteflex ▸ Electrode Cups: Gold-plated copper, Santoprene overmold
Carry Case	▸ External Part: Polypropylene ▸ Internal Part: PE foam
Disposable RIP Belts	▸ Belt Elastic: Polyester/Dorlastan ▸ Connector: ABS ▸ Belt Wire: Tin plated copper

- Note: The Nox A1 components and Nox sensors addressed in this manual are not made with natural rubber latex.

Battery Information

The list below is provided to assist the user in selecting the appropriate battery type for the A1 study:

- **Lithium batteries** and **Powerex 2700 mAh rechargeable batteries** should be used to record a minimum of 8 hours.

NOTE: The recording durations listed above depend on the quality of the batteries used.

- 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 A1 device shall be according to the standard IEC 60086-4 Primary batteries - Part 4: Safety of lithium batteries.

Regulatory Information

Performance Testing and Validation Summary

The Nox A1 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 EMC and patient safety as well as additional RF testing to assure compliance to R&TTE.

Nox Medical holds a CMDCAS ISO 13485:2003 certified Quality Management System which complies with the requirements of the Medical Device Directive (MDD), FDA Quality System Regulation (QSR) and Canada Medical Device Regulations (CMDR).

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 A1 device is classified IP20**, i.e. as defined by the standard IEC 60529 it is protected against solid foreign objects of 12.5 mm diameter and greater, but it is not protected against harmful ingress of liquids.
- 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**.

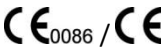
Description of Symbols and Abbreviations

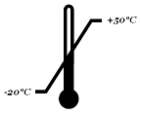
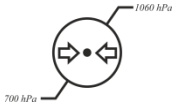
- Operating instructions / Consult instructions for use

- Manufacturer information

- Date of manufacture

- Do not re-use

SN	Serial number
LOT	Batch code / Lot number
REF	Catalogue number / Reference number
(01)1569431111XXXX(11)YYMMDD (21)WWWWWWWWW (01)1569431111XXXX(11)YYMMDD (10)ZZZZZZ	Unique Device Identifier (UDI); (01) represents the device identifier (DI) ("1569431111XXXX"), (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), (21) the serial number of the device ("WWWWWWWWW") if applicable, and (10)ZZZZZZ the lot number of the device ("ZZZZZZ") if applicable
	Type BF applied part (patient isolation from electrical shock)
	This product is not made with natural rubber latex
	In compliance with the European Directive on Waste of Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste
	Non ionizing radiation. Equipment includes RF transmitter: interference may occur in the vicinity of equipment marked with this symbol
	Federal Communications Commission (FCC) logo
	CE marking indicating conformance to EC directive 93/42/EEC and 2007/47/EC concerning medical devices
Nox A1	Brand name/Model name
APSG1EU, APSG1US	Technical name
Contains TX IC: 1520A-LMX9838	Industry Canada (IC) label
FCC ID: V5AASDB1	FCC ID label
REV	Revision of device
PGND	Patient ground
PRES	Pressure input connector

GP1	▸ General purpose bipolar input connector
E2-E1 **F4-F3** **C4-C3** **O2-O1** **M2-M1**	▸ Electroencephalography (EEG) and electrooculography (EOG) input connectors
ECG	▸ Electrocardiography (ECG) input connector
EMG: F, 1, 2	▸ Electromyography (EMG) input connectors
LM1 **LM2**	▸ Leg electromyography (EMG) for limb movement (LM) detection input connectors
	▸ 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

Bluetooth® Wireless Technology

The A1 device uses Bluetooth® 2.0 wireless technology to receive signals from 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 RF specifications for the A1 device.

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.

EMC Information

- Caution: Exposure to radio frequency radiation.
- Portable and mobile RF communications can affect the performance of the device.
- Warning: The A1 device should not be used adjacent to, or stacked with other equipment. If adjacent or stacked use is necessary, the A1 device 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 this device and cause injuries to the operator/patient.
- Warning: This system may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements, causing possible patient harm.
- Refer to the tables below in this section for specific information regarding the A1 device’s compliance to the standard IEC60601-1-2.

Declarations of Conformity with the US Federal Communications Commission (FCC) and Industry Canada Regulations

USA - FEDERAL COMMUNICATIONS COMMISSION (FCC)

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.

CANADA - INDUSTRY CANADA (IC)

This device complies with RSS 210 of Industry Canada.

Operation is subject to the following two conditions:

(1) this device may not cause interference, and

(2) this device must accept any interference, including interference that may cause undesired operation of this device.

Caution: Exposure to Radio Frequency Radiation.

The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population; consult Safety Code 6, obtainable from Health Canada's website: http://www.hc-sc.gc.ca/ewh-semt/pubs/radiation/radio_guide-lignes_direct/index-eng.php.

MODIFICATION STATEMENT

Any changes or modifications not expressly approved by Nox Medical could void the user's authority to operate the equipment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The A1 device is intended for use in the electromagnetic environment specified below. The customer or the user of the A1 device should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 2</td><td>The A1 device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The A1 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The A1 device is intended for use in the electromagnetic environment specified below. The customer or the user of the A1 device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV lines(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the A1 device requires continued operation during power mains interruptions, it is recommended that the A1 device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A /m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Continued)

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The A1 device is intended for use in the electromagnetic environment specified below. The customer or the user of the A1 Device should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 V_{rms}
150 kHz to 80 MHz

3 V/m
80 MHz to 2.5 GHz</td><td>3 V

3V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of A1 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

$d = 1.2 \sqrt{P}$

$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the A1 device is used exceeds the applicable RF compliance level above, the A1 device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the A1 device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended Separation Distance between Portable and Mobile RF Communications Equipment and the A1 Device

Recommended separation distance between portable and mobile RF communications equipment and the A1 device			
The A1 device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the A1 device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the A1 device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

About

This manual is provided in electronic format according to Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices.

This manual is provided as a pdf document. PDF readers are commonly available at no cost for users.

This manual is also available on Nox Medical's website: support.noxmedical.com/hc/en-us/articles/200478429-Nox-A1-Device-Manuals.

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