nox medical

NOX T3
MANUAL

nox medical

Nox T3 US Manual

Version 1.0
Latest Revision: January 2021
Copyright © 2021
Nox Medical – All rights reserved

Manufactured by:

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

nox medical

For distributor information go to:
www.noxmedical.com

Table of Contents

List of Abbreviations

ABS	-	Acrylonitrile Butadiene Styrene
BMI	-	Body Mass Index
CISPR	-	*Comité International Spécial des Perturbations Radioélectriques* (English: International Special Committee on Radio Interference)
ECG	-	Electrocardiography
EEG	-	Electroencephalography
EMG	-	Electromyography
EMC	-	Electromagnetic compatibility
EOG	-	Electrooculography
ESD	-	Electrostatic discharges
FCC	-	Federal Communications Commission
FDA	-	Food and Drug Administration
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
PVC	-	Polyvinyl Chloride
RF	-	Radio Frequency
RIP	-	Respiratory Inductance Plethysmography
SpO2	-	Oxygen Saturation Levels measured by pulse oximetry
TPE	-	Thermoplastic Elastomer

Introduction

Congratulations on choosing the Nox T3® recorder. The Nox T3 is an ambulatory body worn sleep recorder and is a part of the Nox T3 system. Its main function is to record physiological signals during sleep by use of built-in sensors and patient applied sensors. The Nox T3 recorder has a built-in Bluetooth® module also allowing it to record signals from compatible auxiliary devices. Placement of the recorder and connecting sensors is simple and makes the setup quick and easy. The Nox T3 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.

Intended Use

The Nox T3 recorder is intended for ambulatory recording of physiological signals during sleep. The recorded signals are then downloaded to a PC where the signals can be viewed and analyzed by use of the Nox T3 application (Noxturnal US). The Nox T3 recorder 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 the patient's home.

Contraindications

The Nox T3 recorder is **NOT** intended for any patient monitoring or automatic diagnosis.

Scope

This manual covers the use of the Nox T3 recorder and its components along with external sensors and auxiliary devices that have been validated with the Nox T3 system.

The use of Nox T3s Recorder and its components along with external sensors and auxiliary devices that have been validated with the Nox T3s System is covered in:

- Nox T3s US Manual

The picture below shows the different appearance of the Nox T3 Recorder and the Nox T3s Recorder. Please be sure you are following the correct manual for your recorder.
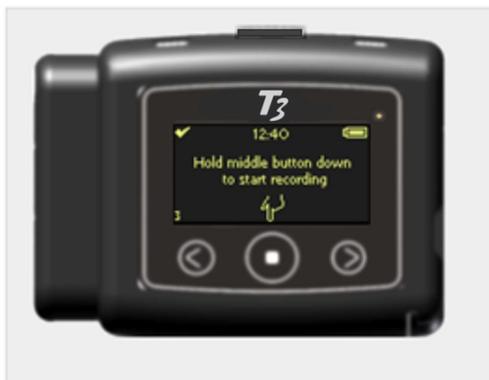
Nox T3 Recorder

Nox T3s Recorder

The use of the Noxturnal US software application that is needed for device configuration, data download, review, and analysis is covered in:

- Noxturnal US Manual

This manual is only intended for professionals (healthcare professionals and service personnel) with relevant qualifications and skills. Hookup instructions are available on the Nox Medical Support Site for self-application by the patient.

> ▶ Note: Additional material can be found on the Nox Medical Website, www.noxmedical.com

Instructions for Operators

Operators should contact Nox Medical or its sales representatives

- for assistance, if needed, in setting up, attaching, operating or maintaining the Nox T3 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.

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

Warnings and Cautions for Use

> ▶ Warning: The Nox T3 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 T3 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 detailed in the section "Electromagnetic Compatibility (EMC) Information" 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 T3 system and cause injuries to the operator/patient.
> ▶ Warning: The Nox T3 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 Nox T3 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.

▸ 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 the 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 a qualified medical technician or your local representative.

▸ Caution: The Nox T3 recorder is designed to be safe 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 the Nox T3 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: Do not use the Nox T3 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: The Nox T3 recorder and 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 T3 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: Do not use any part of the Nox T3 System, including patient cables and electrodes, in a Magnetic Resonance Imaging (MRI) environment. The energy absorption in conductive materials might lead to excessive heating and cause burns.

▸ Caution: The Nox T3 recorder and Nox RIP belts should be worn over clothing to prevent allergic reaction to the equipment materials.

▸ 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: Do not use damaged equipment, sensors or accessories. This may result in bad performance of the Nox T3 system or patient/operator injury.

▸ Warning: The Nox T3 recorder 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 Nox T3 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 T3 recorder is opened (except for opening of the battery compartment).

▸ Warning: No modification of the Nox T3 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 T3 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 T3 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: The Nox T3 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 of the Nox T3 recorder and accessories to prevent harm to the operator/patient.

▸ Warning: The Nox T3 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: As with all medical equipment, carefully route cables and connections to reduce the possibility of entanglement or strangulation.

▸ 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 cannulas, Nox filter tube connectors, mask pressure tubes and Nonin Wristband are single patient use. Using the same Nox disposable RIP belts, cannula, filter tube connector, mask tubing and wristband 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: 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: To prevent cross-contamination, make sure the Soft SpO2 sensor is properly cleaned after turning on the Nonin 3150 pulse oximeter by inserting a finger (other than the patient's) in the sensor. Refer to 3rd party instructions for use accompanying the pulse oximeter for cleaning instructions.

▸ Caution: The Nox T3 recorder and its accessories 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.

Nox T3 Description

The Nox T3 is a body worn ambulatory sleep recorder.

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

- 2 bipolar channels; for recording of electrocardiography (ECG), electromyography (EMG), electroencephalography (EEG) or electrooculography (EOG)
- 1 ground channel
- 1 pressure/cannula 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 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
- Built-in light sensor; for recording of ambient light

The Nox T3 recorder is powered with one AA battery.

Nox T3 Interface

The Nox T3 recorder 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. The display allows for status indication where signals can be checked in real time. See the figures and tables below for detailed description.
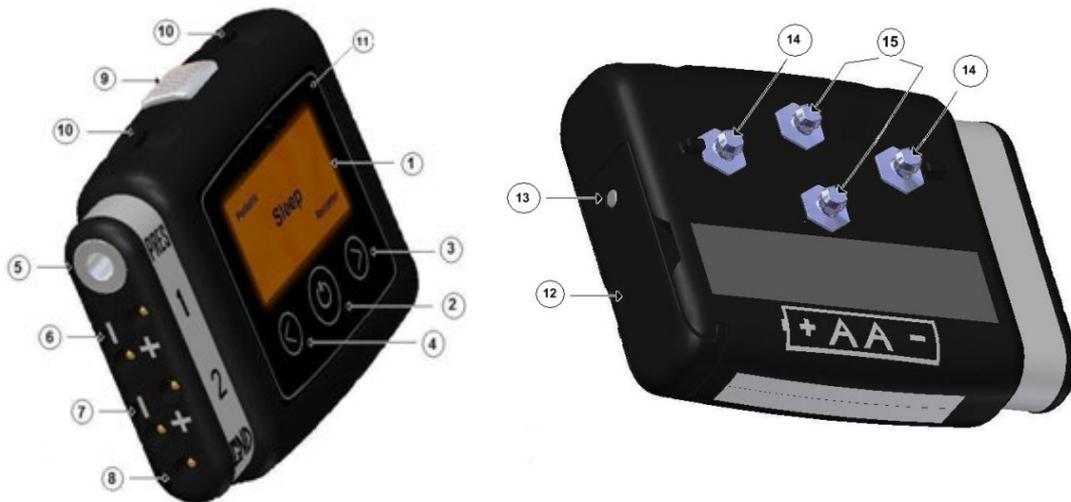
NUMBER	FUNCTION
1	Display
2	Push button – Middle

3	Push button – Forward
4	Push button – Backward
5	Pressure lock – Connects to external nasal cannula/mask pressure tube
6	Channel 1 – Bipolar touch proof inputs
7	Channel 2 – Bipolar touch proof inputs
8	Reference ground input for channels 1 and 2
9	Microphone – For recording of respiratory sounds Light sensor located under the shaded transparent microphone cover
10	2 Clip strap loops
11	Indicator light for device status
12	Battery lid – Covers the battery and the USB connector
13	Battery lid pin
14	2 Metal snaps – Connect to thorax RIP belt
15	2 Metal snaps – Connect to abdomen cable

Operating Nox T3

The Nox T3 recorder 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 2 minutes.

Connecting Nox T3 to a Computer

To connect Nox T3 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 T3 system kit, on the battery lid pin and slide the battery lid down, towards the bottom of the device. The Nox T3 connects to the computer by using Nox mini USB cable. The battery does not have to be inserted while the device is connected to the computer.
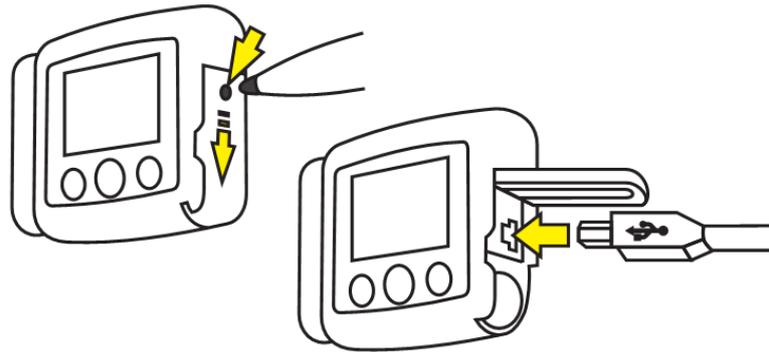
When the Nox T3 recorder is connected to the computer the device display lights up and displays a message saying the device is connected to the computer.

Configuring and Downloading from Nox T3

To download a recording or configure a Nox T3 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 the device from the Noxturnal US software and unplug the Nox 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 Nox T3

If the Nox T3 recorder 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 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 T3 at a Scheduled Time

If the Nox T3 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 **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 and the REC symbol appears on the top left corner.

Nox T3 Signal and Status Checks

Device Status

The indicator light on the Nox T3 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 orange. Warnings might include:

- Battery low

- Device not licensed. Note the license status is only shown for a short time on the display start page when turning on the device (a lock indicator in the bottom right corner).

Information about the recording duration 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 2 minutes. When Nox T3 is configured the clock is synchronized with the PC and is shown at the top of the display.

1. 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.
2. On the bottom left corner is a number indicating how many recordings are stored on the device. The device can contain as many recordings as the internal 1GB memory allows.
3. The device's clock

Signal Status

If the Nox T3 recorder has been configured to "Standard Device Display" in the Noxturnal US software, the signal status can be viewed by browsing through different device pages using the **Forward** and **Backward** buttons. The information presented will depend on the configuration of the Nox T3 recorder. Note that if the "Minimal Device Display" option has been selected in Noxturnal US instead of the "Standard Device Display", the device is in simple operation mode and only the start page and the Bluetooth® connection display screen is available.

Oximeter Signals

Pressing **Forward** on the display shows the Nonin 3150 pulse oximeter connection status. Refer to section "Establishing a Connection between the Nonin 3150 pulse oximeter and Nox T3" for further information on the oximeter connection status.

Respiratory Signals

Pressing **Forward** button on the display again shows information about the respiratory signals:

1. Abdomen and thorax respiratory effort movements. The signals sweep over the screen showing the breathing pattern.

2. Audio, power gauge.

3. Patient position ("Left", "Right", "Supine", "Prone" and "Upright").
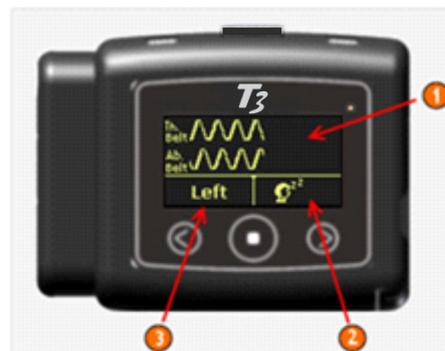
ExG and Pressure Signals

To enter the ExG channels, press the **Forward** button until the ExG channels appear: Channel 1, Channel 2, and values from the pressure channel. Depending on the configuration either the mask pressure or nasal pressure is shown. The mask pressure shows the average DC value ranging from 0-20 cmH$_2$0. The nasal pressure shows the pressure values as a signal plot that sweeps over the screen (no pressure value).

1. Mask pressure DC value.

2. ExG channels. The signals sweep across the screen showing the raw signals.

1. Nasal pressure signal.

2. ExG channels. The signals sweep across the screen showing the raw signals.

Nox T3 Patient Hookup

In most cases the hookup takes place at the patient's home and the patient hooks up the device by using the Nox T3 recorder hookup instructions. It is then recommended that a healthcare professional with relevant qualifications and skills demonstrates the steps needed to be conducted at the patient's home to the patient, or to caretakers in the case of pediatric patients. Hookup instructions are available on the Nox Medical Support Site for self-application by the patient.

The following points should be demonstrated to the patient or caretakers of pediatric patients:

1. Attaching Nox T3 recorder and sensors.

2. Testing of sensors connections.

3. Starting and stopping a recording (if manual recording mode is being used)

4. Status indications on the display.

It is important to remind the patient/caretaker to follow the instructions given, prior to the recording.

Before sending the patient home:

1. Make sure the Nox T3 recorder has been prepared correctly.

2. Make sure the carry case contains all the equipment needed to perform the recording in the patient's home, including batteries.

> ▸ Note: Children should under no circumstances hook up the Nox T3 by themselves.
> ▸ Warning: Do not use damaged equipment, sensors or accessories. This may result in bad performance of the Nox T3 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 T3 recorder and its accessories should always be transported in its accompanying carrying case to ensure adequate protection and prevent damage.
> ▸ Warning: No modification of the Nox T3 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 T3 system, only use accessories that have been validated for use by Nox Medical.
> ▸ NOTE: The compliance of the Nox T3 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 system.

Inserting a Battery to the Nox T3

The list below is provided to assist the user in selecting the appropriate battery type for a Nox T3 study:

- Alkaline batteries can be used to record from 8 to 16 hours depending on battery type.
- Lithium batteries can be used to record from 20 to 33 hours depending on study type and battery.
- Lithium batteries are optimal for multiple night recordings because it is possible to record 3 nights or more without having to change the batteries.
- 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 2000 mAh capacity** or fresh **lithium batteries** for each recording to prevent the need for the sleep study to be repeated.
> ▸ Note: All lithium batteries used with the Nox T3 recorder shall be per the standard IEC 60086-4 Primary batteries – Part 4: Safety of lithium batteries.
> ▸ Note: The recording durations listed above depend on the quality of the batteries used.
> ▸ Note: Further information on multiple night recordings can be found on the Nox Medical Support Site.

Before you start a recording, you should make sure that the Nox T3 recorder has a new or fully charged battery. To insert a new battery, do the following:
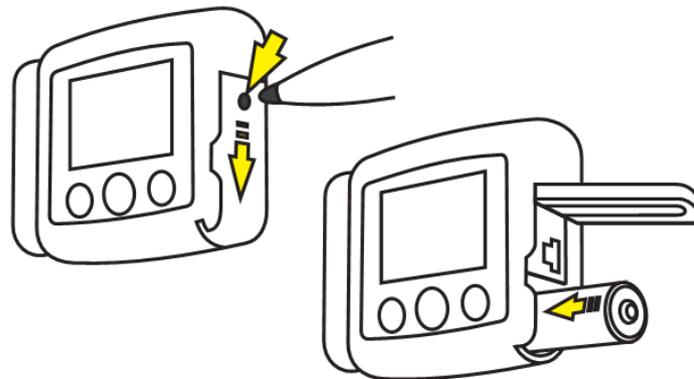
1. Open the battery compartment by pressing down the battery lid pin with the Nox Battery Lid Key accompanying the Nox T3 system kit or similar tool and slide the lid towards the bottom of the device.

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 T3 and the Nox RIP Belts

▶ Caution: The Nox T3 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 Nox disposable RIP belts may affect the quality of recorded signals and lead to possible incorrect treatment. Using the same Nox 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 T3 recorder to the patient's shirt.
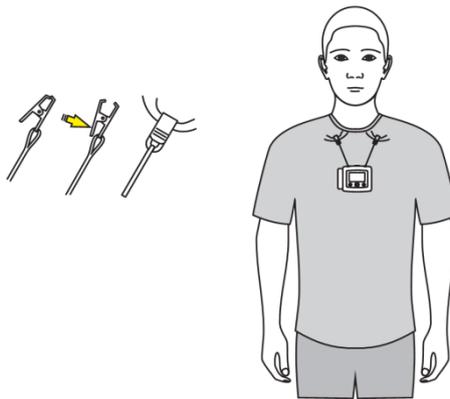
Step 2 to Step 4

- 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.
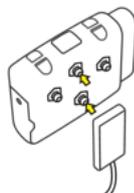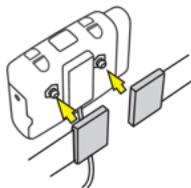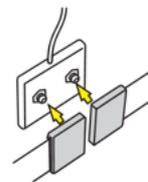
Step 5

Attaching the Nox T3 recorder and Nox disposable RIP belts is now completed.
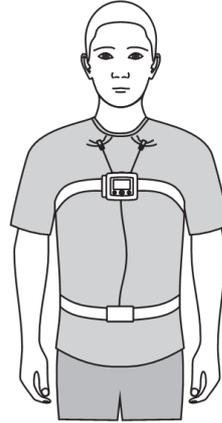
Adjusting the Nox RIP Belts

> ❗ ▸ 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.
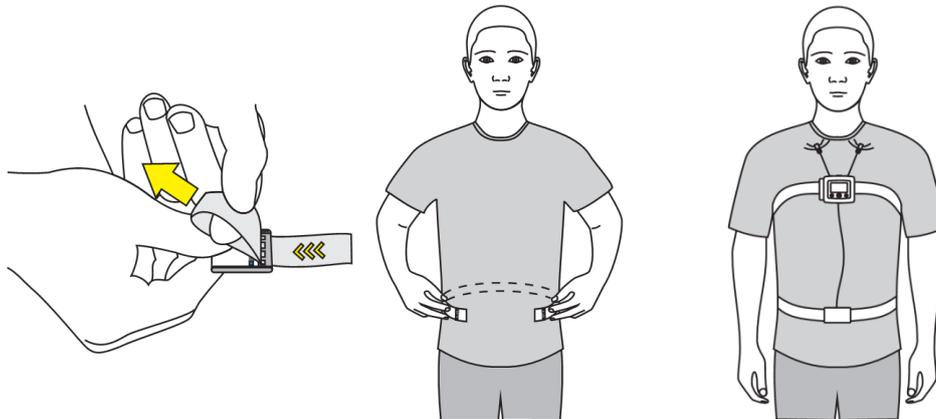
Attaching the Nox Nasal Cannula

> ❗ ▸ 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 T3 recorder. If you use a non-filtered Luer-lock cannula, it is necessary to use a filter tube connector from Nox Medical to interface with the Nox T3 recorder.

Step 1 Place the nasal prongs gently in the nostrils. The prongs should point downwards inside the nostrils.
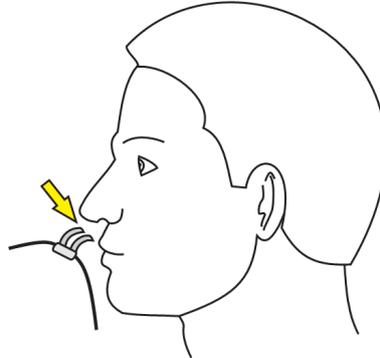
Step 2 Pull the cannula tubing over the ears and then position it under the chin.

Step 3 Slide the fastener snugly under the chin to hold the cannula tubing securely in place.
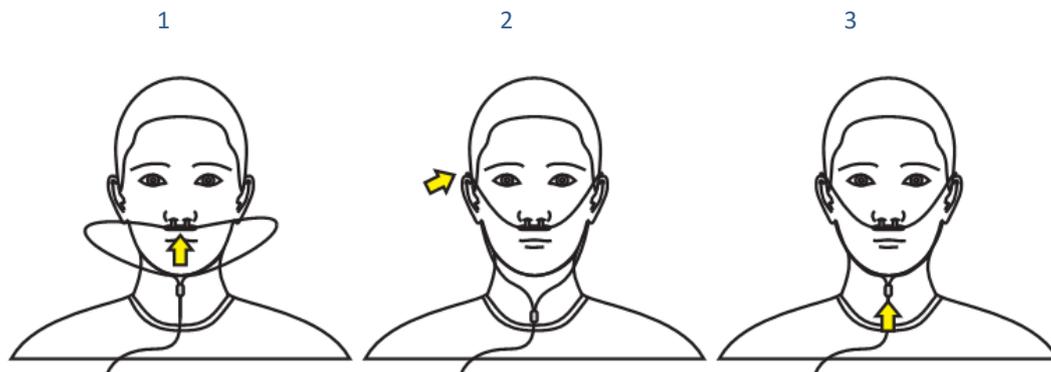
Refer to the section "Compatible Sensors and Devices" regarding the types of Nox nasal cannulas that have been validated with the Nox T3 device.

Measuring Mask Pressure

▶ Warning: 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 T3 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 T3 recorder via a filter tube connector from Nox Medical.

Refer to the section "Compatible Sensors and Devices" regarding the types of mask pressure tubes that have been validated with the Nox T3 system.

Measuring ExG 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 T3 recorder can record any combination of two ExG channels, that is, EMG, EOG, EEG or ECG. The electrode leads connect to the bipolar touch-proof inputs on the Nox T3 recorder. The electrodes are placed on applicable locations on the body depending on the type of recording.

Refer to the section "Compatible Sensors and Devices" regarding the types of electrodes and leads that have been validated with the Nox T3 system.

Measuring Data from Auxiliary Devices

> ▶ Warning: The Nox T3 system is **NOT certified to be used for continuous monitoring** where failure to operate can cause injuries or death of the patient.
>
> ▶ Warning: External equipment/sensors 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 a qualified medical technician or your local representative.

The Nox T3 recorder is able to communicate with supported auxiliary devices over a Bluetooth® link by use of the Nox W7 link; for more information refer to the user instructions accompanying the Nox W7 link kits and further information can also be found on the Nox Medical Support Site.

Measuring Pulse and Oxygen Saturation using Nonin 3150 Pulse Oximeter

> ▶ Warning: The Nox T3 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 T3 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 T3 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.

▸ Batteries may leak or explode if used or disposed of improperly. Remove batteries if the device will be stored for more than 30 days. Do not use different types of batteries at the same time. Do not mix fully charged and partially charged batteries at the same time. These actions may cause the batteries to leak.

The Nox T3 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 section "Compatible Sensors and Devices" regarding the types of pulse oximeters and sensors that are supported by the Nox T3 system.

Inserting Batteries into the Nonin 3150 Pulse Oximeter

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

Nonin Reusable Soft Pulse Oximeter Sensor

Soft sensor size recommendations are based on finger height (thickness). The finger height (H) is measured as shown in the figure below.
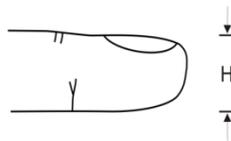
For finger height from 7.5 mm (0.3 in) to 12.5 mm (0.5 in), size small should be selected.

For finger height from 10.5 mm (0.4 in) to 19.0 mm (0.7 in), size medium should be selected.

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

Attaching the Nonin 3150 Pulse Oximeter and Soft Sensor

The Nonin 3150 WristOx$_2$ oximeter package accompanying the Nox T3 system kits includes:

- Model 3150, WristOx$_2$ pulse oximeter
- Model 8000SM-WO2, reusable 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 and the probe wire between the two ends.
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.

1   2   3

4
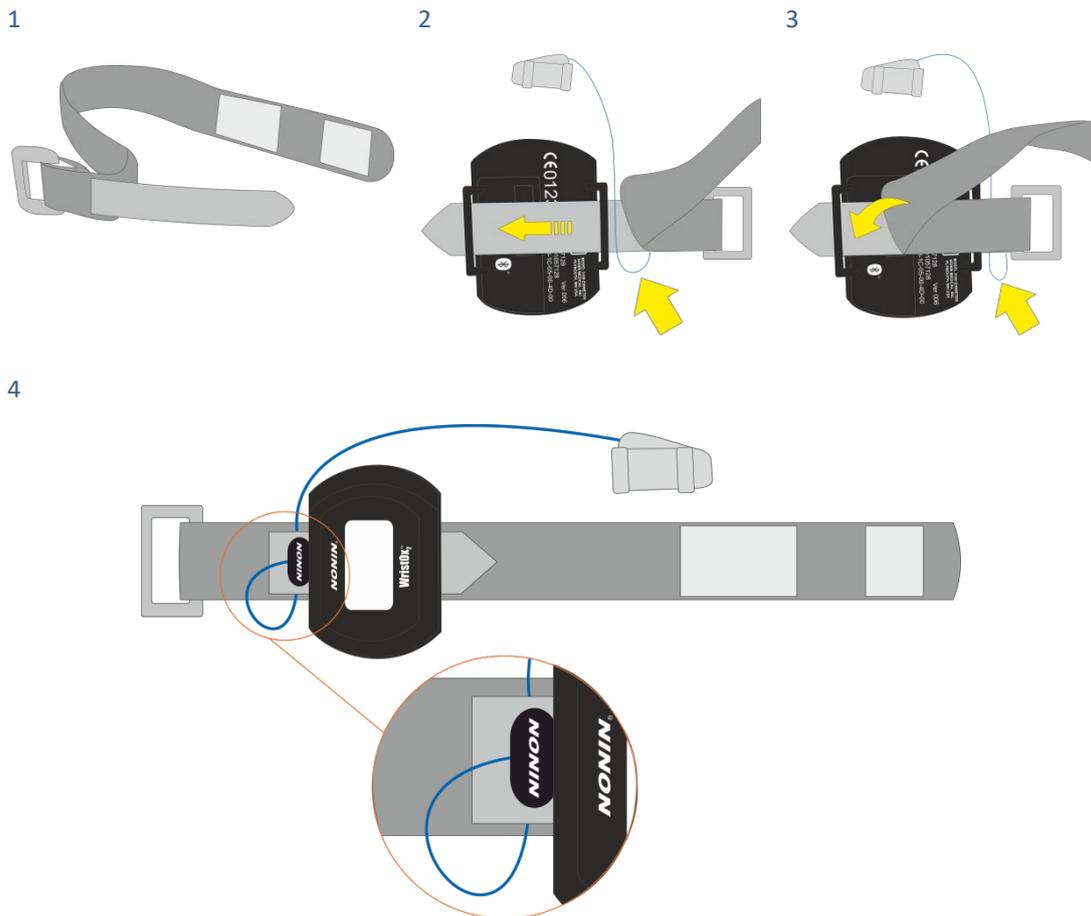
Step 5 to Step 6

> **!**   ▶ 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 a finger.
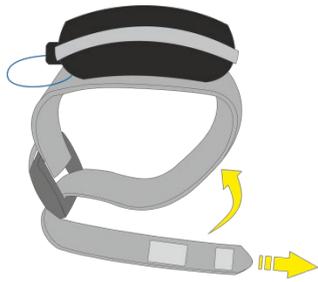
5   6
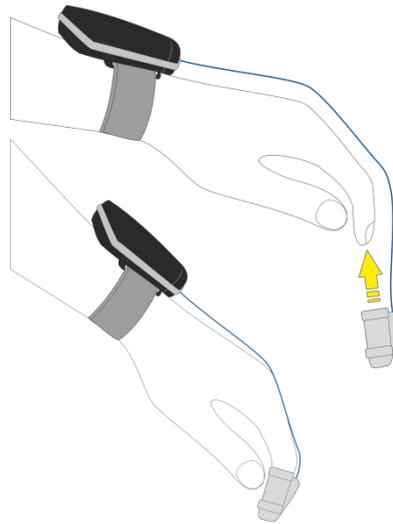
Step 7

7. Verify properly the connection status:

    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.

7.a   7.b

Establishing a Connection between the Nonin 3150 Pulse Oximeter and Nox T3

> ▶ Note: If you are using the Nonin 8000J series of Flex SpO2 sensors, it is strongly recommended to schedule the recording to start at a specific time.

Before you can send out the Nox T3 recorder and accessories for an ambulatory recording, you need to make sure that a connection has been established between the Nox T3 recorder and the oximeter. The pairing of the Nox T3 recorder and the oximeter is done after you have finished the configuration in Noxturnal US. If you are using the Nonin WristOx$_2$®, Model 3150 (oximeter), please follow the instructions below on how to establish a connection between the oximeter and the Nox T3 recorder. It is very important that the instructions for the pairing process are carefully followed in order to successfully pair the devices.

Pairing Process

Step 1. Inserting Batteries

Start by inserting fresh/fully charged batteries in the Nox T3 recorder and the Nonin 3150 pulse oximeter.

Step 2. Turning on the Nonin 3150 Pulse Oximeter

Inserting a finger in the probe automatically turns the device on:
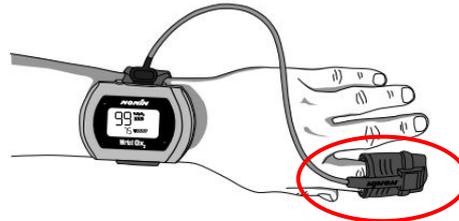
	▸ Warning: To prevent cross-contamination, make sure the Soft SpO2 sensor is properly cleaned after turning on the Nonin 3150 pulse oximeter by inserting a finger (other than the patient's) in the sensor. Refer to 3rd party instructions for use accompanying the pulse oximeter for cleaning instructions.

An alternative way to turn on the oximeter is to push the grey activation button (see red circle in the picture below). Hold button down for at least 3 seconds and you will see the display turn on. Be sure that you hold down the button long enough (minimum 3 seconds) and that the Bluetooth symbol is displayed on the oximeter (see yellow arrow in the picture below). If the Bluetooth symbol is not displayed, the Bluetooth radio is inactive and the Nox T3 recorder cannot connect to the oximeter.

	▸ Note: Be sure you hold down the button for at least 3 seconds. By doing this the oximeter will avoid a state where the oximeter won't allow a Bluetooth connection to occur. Oximeter units with serial numbers 501924607 and larger do not run the risk of entering this state.

Step 3. Turning on the Nox T3

Turn on the Nox T3 recorder by pressing the **Middle** button. Hold the **Middle** button until you see the screen turning on.

Then press the **Right** button once or until you see the message "Connecting to" and a PIN address displayed on the Nox T3 recorder.

Make sure that the displayed PIN address is the oximeter's one.

During the programming the Nox T3 will show the following display:

A checkmark on the Nox T3 signifies a successful and a correct pairing of the Nox T3 and the oximeter:

The Nox T3 system is now ready to be packed and sent along with the patient.

If you have configured for a **Scheduled Recording**, information on the start-up time will be displayed on the oximeter once the pairing is completed and the oximeter's display has powered off. If you have scheduled the recording time in Noxturnal US at 22:00 for example, the oximeter will display the time 21:59 every 30 seconds:

> ▸ Note: Make sure that batteries are not removed after the pairing has been completed. If for some reason the batteries are removed, resume the pairing process from Step 1.
> ▸ Note: If you experience problems in the pairing process, please try the troubleshooting tips addressed in the section below.

Troubleshooting Tips

1. If an X-mark appears instead of a checkmark:

This means that the pairing of the Nox T3 recorder and the oximeter has not been achieved and the programming of the oximeter failed. It is necessary to start the pairing process again. Before that can be done the oximeter needs to be restarted. That is done by removing the batteries and inserting batteries again to the oximeter. Then hold the grey activation button on the oximeter for at least three seconds. Resume the pairing process from Step 3 above.

> ▶ Note: If this happens repeatedly, it might be necessary to send the oximeter in for service.

2. If the Nox T3 recorder seems to be stuck in the "connecting to" display screen:

Verify that the PIN number of the oximeter used matches the number displayed on the Nox T3. Etched onto the oximeter is the word "PIN" followed by a 6-digit number. This number can be found on the back of the oximeter device.

Incorrect PIN number:

If the numbers do not match as is shown in the figure below the Nox T3 is unable to connect to the oximeter and is stuck in the "connecting to" display screen.

In the case of an incorrect PIN number it is necessary to re-configure the Nox T3 in Noxturnal US and insert there the correct PIN number:
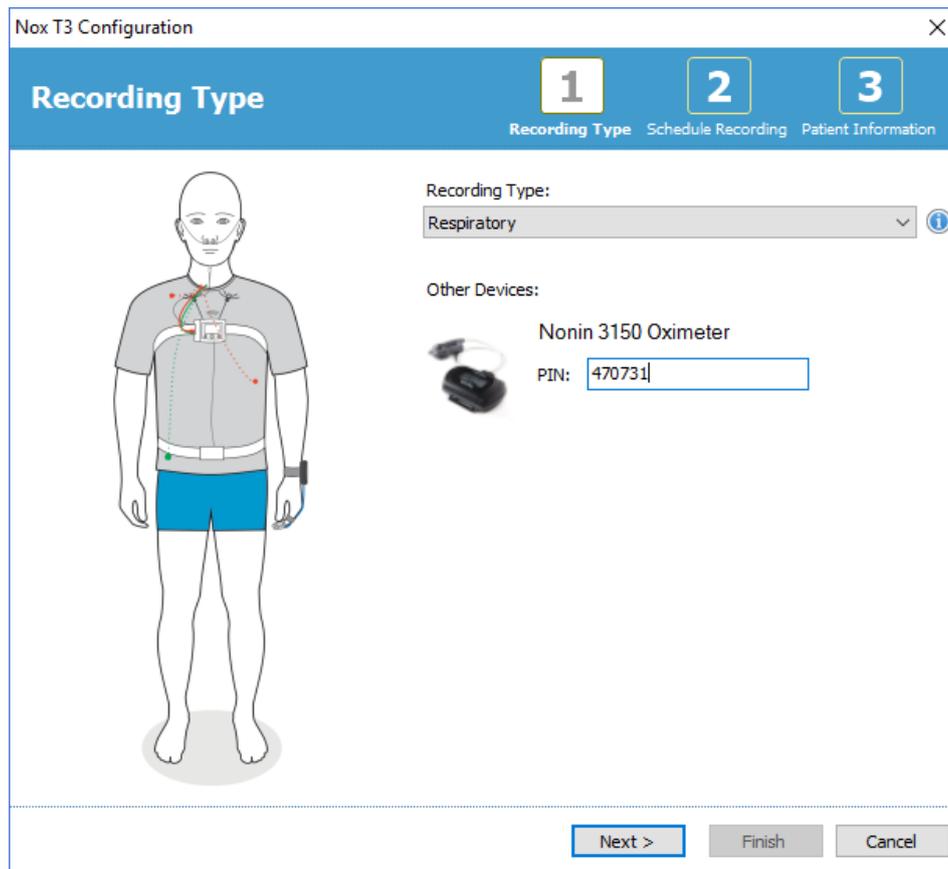
When you have completed the configuration with the correct PIN number in Noxturnal US, resume the pairing process from step 1 above.

Correct PIN number but still stuck in the "connecting to" display screen:

If you have verified that the PIN number is correct but the Nox T3 recorder is still stuck in the "connecting to" display screen, try to reboot the Nox T3 recorder. This is done by simply waiting for the Nox T3 to turn off (it turns off automatically in 2 minutes after it has been turned on) and then, turn on the Nox T3 again by pushing the middle button. Then, resume the pairing process from step 3 above.

For more troubleshooting tips, refer to the Nox Medical Support Site.

Maintenance

The Nox T3 recorder and accessories should be stored in a clean, dry place.

Handle the Nox T3 recorder with care and protect it against mechanical shocks, dirt, and liquids. The device is not waterproof or splash proof.

To update the Nox T3 recorder you will need the applicable 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 T3 recorder or accessories, including patient cables, is needed.

The service life of the Nox T3 recorder and Nox T3 carry case is 5 years.

> ▶ Warning: Remove batteries from the Nox T3 recorder 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 Nox T3 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 T3 recorder is opened (except for opening of the battery compartment).
> ▶ Warning: No modification of the Nox T3 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.
> ▶ Note: The Nox T3 recorder 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 Nox T3 recorder to a computer with a USB cable for 6 hours or more.
> ▶ Note: It is never recommended to downgrade the firmware of the Nox T3 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 T3 recorder with firmware files that come directly from Nox Medical.

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

Calibration

The Nox T3 recorder is factory calibrated. No further calibration is needed.

Cleaning of Nox T3 and its Accessories

> ▶ Warning: The Nox T3 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 cleaning of the Nox T3 recorder to prevent harm to the operator/patient.
> ▶ Note: Clean the Nox T3 recorder separately from its associated sensors.
> ▶ Note: The Nox T3 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 T3 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.

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

T3 System Cleaning Instructions

MATERIALS/EQUIPMENT:

- Endozime® AW Plus
- 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
   o Follow the instructions accompanying the hospital grade cleaner
2. Dampen a lint-free cloth with the solution
   o Do not pour or spray any liquids on the Nox T3 Recorder
   o Do not allow any liquids to enter any openings on the Nox T3 Recorder
   o Do not immerse the cables in liquid
   o 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
   o 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 T3 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.

* 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 T3 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 Nox 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 ~ 34 ~

> ▶ Warning: No modification of the Nox T3 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.
>
> ▶ Note: To ensure patient safety and effective use of the Nox T3 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 T3 recorder.

The items listed below are Nox products and have been validated for use with the Nox T3 recorder:

NOX DISPOSABLE RIP BELTS

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

NOX T3 SYSTEM COMPONENTS

Type	Catalogue Number
Nox Abdomen Cable	562010
Nox USB Cable	562011
Nox T3 Carry Case	568010
Nox Service Kit	569010
Nox Battery Lid	569011
Nox Clip Strap	569013
Nox Battery Lid Key	569014
Noxturnal US	NA
Noxturnal US CD	539012

NOX ELECTRODE LEADS

Type	Catalogue Number
Nox Snap On Lead 50 cm (20 in), White, 2 units	554020
Nox Snap On Lead 30 cm (12 in), Beige – White, 2 units	554021
Nox Snap On Lead 100 cm (40 in), Green, 1 unit	554022
Nox Snap On Lead 50 cm (20 in), Beige – Green, 1 unit	554023
Nox Snap On Lead 150 cm (60 in), Grey, 2 units	554024
Nox Snap On Lead 100 cm (40 in), Beige – Grey, 2 units	554025
Nox Snap On Lead 150 cm (60 in), Black, 2 units	554026
Nox Snap On Lead 100 cm (40 in), Beige – Black, 2 units	554027
Nox Snap On Lead 100 cm (40 in), Orange, 2 units	554028

NOX BLUETOOTH® LINK*

Type	Catalogue Number
Nox W7 Link Kit – A	544012
Nox W7 Link Kit – R	544011
Nox W7 Link Kit – S	544010

*This function needs Noxturnal US 1.0 to configure the Nox W7 links

The items listed below are 3rd party products and have been validated for use with the Nox T3 recorder:

LEADS AND ELECTRODES

Type	Catalogue Number
Blue Sensor® Snap on Electrode, 50 units	554210
Snap on Electrode Disposable, small 25 units	554209

PULSE OXIMETERS

Type	Catalogue Number
Nonin WristOx$_2$ Pulse Oximeter, Model 3150	541010

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	564050

MASK PRESSURE TUBING

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

CLEANING

Type	Catalogue Number
Super Sani-Cloth Plus Disinfection Wipes	559010
Sani-Cloth AF Universal - Alcohol free Disinfection Wipes	559011

Specifications

Nox T3 and Accessories

DESCRIPTION	PROPERTIES
FUNCTION	
Nox T3 Storage Capacity	▸ 1GByte
Nox T3 Recording Time	▸ Nominal 24 hours with new lithium battery
Nox T3 Internal Channels	▸ Two RIP Respiratory Effort
	▸ Pressure
	▸ Respiratory sound/snoring
	▸ Two bipolar (ExG)
	▸ Position
	▸ Activity
	▸ Light
Nox T3 External Channels	▸ Oximeter data via Bluetooth®
PHYSICAL	
Nox T3 Device Dimensions	▸ 79 mm (3.11 in) W, 63 mm (2.48 in) H, 21 mm (0.83 in) D
Nox T3 Weight	▸ 112 g with battery (0.25 lbs with battery)
Nox T3 Bipolar Inputs	▸ Touch-proof DIN 42-802;
	▸ Input range ±8 mV AC
	▸ Bandwidth: 0.1 – 85 Hz
	▸ Sampling frequency: 2KHz
	▸ Storage frequency: 200 Hz
Nox T3 Pressure Sensor	▸ Pressure input range: ±100 cmH$_2$O
	▸ Frequency: DC-85 Hz
	▸ Sampling frequency: 2KHz
	▸ Storage frequency: 200 Hz
Nox Abdomen Cable Length	▸ 50 cm (19.69 in)
Nox USB Cable	▸ Type of USB connector at device end: Mini-B

	▸	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 T3 Power Source	▸	One 1.5 V AA battery
	▸	Host PC (data configuration and download)
Nox T3 Battery Type	▸	Alkaline primary
	▸	Lithium primary
	▸	Rechargeable nickel-metal hydride battery (NiMH)

Nox T3 DISPLAY

Type	▸	OLED
Display Dimensions	▸	19 mm x 35 mm (0.75 in x 1.38 in)
Resolution	▸	128 dots x 64 dots

Nox T3 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

Nox T3 STORAGE FREQUENCY

Microphone	▸	8 kHz
SpO2	▸	3 Hz
Pleth	▸	75 Hz

Nox T3 SAMPLING FREQUENCY

Microphone	▶ 1 MHz	
SpO2	▶ 75 Hz	
BANDWIDTH		
Microphone	▶ Internal 3.8 kHz bandwidth, 16-bit ADC	

Material Information

COMPONENT	MATERIAL CONTENT
Nox T3 Recorder	▶ Enclosure: 10% glass filled polycarbonate (PC)/acrylonitrile butadiene styrene (ABS)
	▶ Proxy: ABS/PC
	▶ Snaps: Gold plated stainless steel
	▶ Pressure Port: Stainless steel
	▶ Display/Keypad: Polyethylene terephthalate (PET)
	▶ Clips: Nickel-plated steel clip, nylon rope, brass crimp
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 USB Cable	▶ Cable Jacket: PVC
	▶ Connector: PVC
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 T3 Carry Case	▶ External Part: BLK 600D POLYESTER
	▶ Internal Part: Polyethylene (PE) foam
Nox Disposable RIP Belts	▶ Belt Elastic: Polyester/Dorlastan
	▶ Connector: ABS
	▶ Belt Wire: Tin plated copper

Regulatory Information

Performance Testing and Validation Summary

The Nox T3 system has been tested and verified in various phases to include internal testing, verification, and validation as well as external testing to assure product safety, effectiveness, and reliability. The design was verified and validated throughout the design process, according to requirement specifications and intended use. An external accredited test house was used to conduct testing needed to comply with the applicable standards regarding Electromagnetic Compatibility (EMC) and patient safety as well as additional radio frequency (RF) testing to assure compliance with Federal Communications Commission (FCC).

The compliance of the Nox T3 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 T3 system.

Furthermore, use of other components than verified, validated or recommended by Nox Medical is considered to be a modification of the Nox T3 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 T3 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:
  o **The Nox T3 recorder 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 Labels

|	
	▸ 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); 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) 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 electric shock)
	▸ Non ionizing radiation. Equipment includes RF transmitter: interference may occur in the vicinity of equipment marked with this symbol
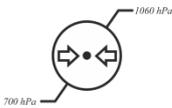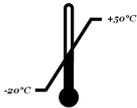
FC	▶ Federal Communications Commission (FCC) logo
CE 2797 / CE	▶ CE marking indicating conformance to the applicable EU regulations/directives
Nox T3	▶ Brand name/Model name
ASDB1US, ASDB1USD	▶ Technical name
FCC ID: V5AASDB1	▶ FCC ID label
REV	▶ Revision of the device
Bluetooth logo ®	▶ Bluetooth wireless technology
+50°C / -20°C	▶ Temperature limit
95% / 10%	▶ Humidity limitation
1060 hPa / 700 hPa	▶ Atmospheric pressure limitation
Umbrella symbol	▶ Keep dry
Glass symbol	▶ Fragile, handle with care
IPN₁N₂	▶ Degree of protection against harmful ingress of water or particulate matter as defined by the standard IEC 60529, where N1 defines the degree of protection against harmful ingress of particulate matter and N2 the degree of protection against harmful ingress of water
MD	▶ Medical Device

Bluetooth® Wireless Technology

The Nox T3 recorder 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 section "Specifications" for details on Radio Frequency (RF) specifications for the Nox T3 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.

- ▶ Portable and mobile Radio Frequency (RF) communications can affect the performance of the Nox T3 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 T3 System, 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 T3 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 T3 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 emission and/or decreased immunity of the Nox T3 recorder and cause injuries to the operator/patient.

- ▶ Warning: The Nox T3 system may be interfered with by other equipment, even if that equipment complies with CISPR (Special International Committee on Radio Interference) emission, causing possible patient harm.

- ▶ Refer to the tables below in this section for specific information regarding the Nox T3 recorder's 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.

Declarations of Conformity with the US 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.

MODIFICATION STATEMENT

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

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The Nox T3 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 A	The device, when connected via USB to a computer, is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	The device, when not connected via USB to a computer, is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage 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 Nox T3 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	± 1 kV for USB port 100 kHz repetition frequency
Surges 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 50 Hz and 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	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	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 Nox T3 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
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9	Yes
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28	Yes
1720 1845 1970	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
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 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9	Yes