

*Sleep for All*



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# **User Instruction**

# **NOX T3**

## **Nox T3 - User Instruction**

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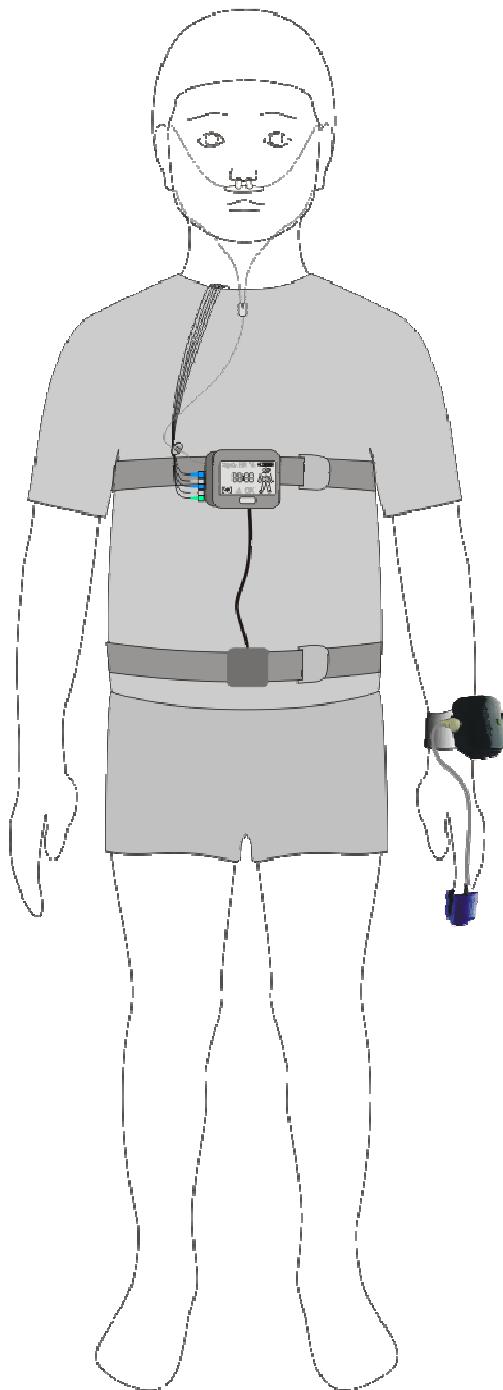
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## Introduction

The Nox T3 system consist of a compact digital recorder that is worn by the patient, along with two respiratory effort sensors, carry bag, clip straps, USB cable and the Nox T3 application (Noxturnal) used for analyzing and reviewing of data. The device is able of recording signals from two respiratory effort sensors, respiratory sound/snoring, nasal/mask pressure, pulse oximeter data, position/activity data, and two channels of EEG/EOG/EMG/ECG leads.



## Regulatory Information

### Intended Use

The Nox T3 device 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.

The Nox T3 system can be used with both children and adults.

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

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



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

### Warnings and Cautions for Use

- ▶ The device is **NOT CERTIFIED TO BE USED FOR CONTINUOUS MONITORING** where failure to operate can cause injuries or death of the patient. The term **CONTINUOUS MONITORING** is specified in the standard IEC60601-1.
- ▶ This system is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- ▶ Caution: U.S. Federal law restricts this device to sale by, or on the order of, a physician.
- ▶ This system complies with international standards IEC60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This 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 device’s performance. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to information detailed in the EMC Information section of this manual.
- ▶ The device is classified as ordinary equipment regarding ingress of liquids, that is, it is not drip-proof, splash-proof or watertight. During use of the device avoid all unnecessary contact with moisture.
- ▶ The device is not defibrillator proof.
- ▶ Do not use any part of the system in an MRI (Magnetic Resonance Imaging) environment.
- ▶ The device and its accessories should be removed from the patient before download of data.
- ▶ No user serviceable parts inside the device. Serviced by authorized parties only. Warranty void if opened.

### Guide to Symbols



▶ Consult instructions for use.



▶ Caution, consult accompanying documents.



▶ Manufacturer.



▶ Do not reuse



▶ Serial number.



▶ Batch code.



▶ Type BF applied part (patient isolation from electrical shock).



▶ 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 electromagnetic radiation. Equipment includes RF transmitter: interference may occur in the vicinity of equipment marked with this symbol.



▶ CE marking indicating conformance to EC directive No. 93/42/EEC concerning medical device

FCC ID:  
V5ANOX-T3-  
0100

▶ FCC ID label.

Contains TX  
IC: 1520A-  
LMX9838

▶ Industry Canada (IC) label.



▶ *Bluetooth*® wireless technology

### ***Bluetooth® Wireless Technology***

The Nox T3 uses Bluetooth® wireless technology to receive signals from the Nonin Pulse Oximeter.

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 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 Specification section for details on RF specifications for Nox T3 and Nonin Pulse Oximeter.

## System Components

### The Nox T3 Device

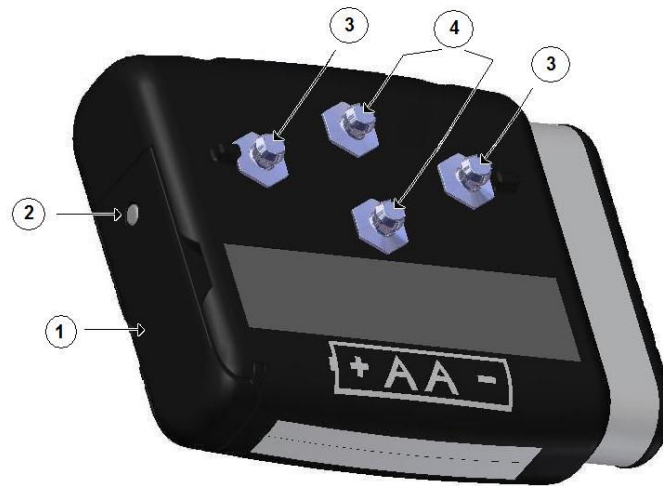
The Nox T3 device records signals from five external sensors and three built-in sensors. The external sensors that can be used with the device are abdominal and thoracic respiratory effort sensors, oximeter, and two leads of the following: ECG, EMG, EEG or EOG. The built-in sensors include a pressure transducer allowing either recording of nasal pressure or mask pressure, a three dimensional acceleration sensor for measure of patient’s position and activity, and a microphone for measuring of snoring and true audio recording capabilities. The arrangement of sensors will be determined by the type of study being performed. The device is worn on the patient’s chest by snapping it to the thoracic respiratory sensor and securing its position with the clip straps. The device is powered with one AA battery. The device has a display for status indication, signal integrity and preliminary results, and buttons for control and event marking.

### Interfaces

The Nox T3 device interface consists of a display, buttons, sensor inputs/connections and a USB connector. The USB connector is placed under the locked battery lid making it inaccessible and tamper prove for children, and connects to the USB cable for device configuration and data download. See the figures and tables below for detailed description.



Number	Function
1	Display
2	Push button – <i>Select</i> – used to start/stop recording and select display options
3	Push button – <i>Forward</i> button - navigate to the next page
4	Push button – <i>Backward</i> button - navigate to the previous page
5	Pressure lock - Connects to external nasal cannula
6	Bipolar touch proof input - Channel 1
7	Bipolar touch proof input - Channel 2
8	Reference ground input for bipolar channels
9	Microphone - For recording of respiratory sounds and snoring
10	Clip strap loops



Number	Function
1	Battery lid - Covers the battery and the USB connector
2	Battery compartment pin – Pressed down with a simple tool to open the battery compartment
3	Metal snaps - Used to connect to thorax respiratory effort sensor
4	Metal snaps - Used to connect to abdomen-thorax cable

### Starting/Stopping a Recording

The *Select button* located on the front panel of the device can be used to manually start and stop a recording.

**To manually start a recording:** Hold down the *Select button* for at least 3 seconds



- ▶ The configuration of the device must have been set to *Manually Start Recording*, refer to section *Configuring the Device*.
- ▶ The device must be disconnected from the PC (have a battery located in its battery compartment) to be able to start a recording.

**To stop the recording:** Hold down the *Select button* for at least 3 seconds

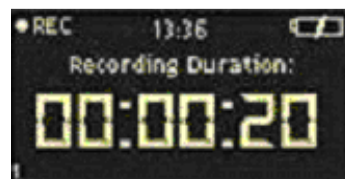
**To start the recording again:** Hold down the *Select button* again for at least 3 seconds

### Navigating the Nox T3 device

The device has three push buttons (*Select, Backward and Forward*) located on the front panel that are used to get information on the recording taking place. Pressing the *Forward* button will navigate to the next page and pressing the *Backward* button will navigate to the previous page.

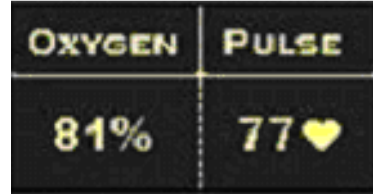
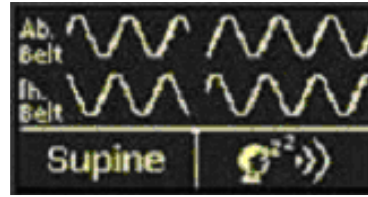
To navigate the information pages during a recording perform the following steps:

1. Press the *Select button* to get information on the duration of the recording, actual time and battery status.





2. Then press the *Forward* button to view the abdomen and thorax respiratory effort signals being recorded, as well as getting information of patient's position and whether a snoring signal is being recorded.
3. Press the *Forward* button again will show the actual oxygen saturation and pulse rate of the patient.

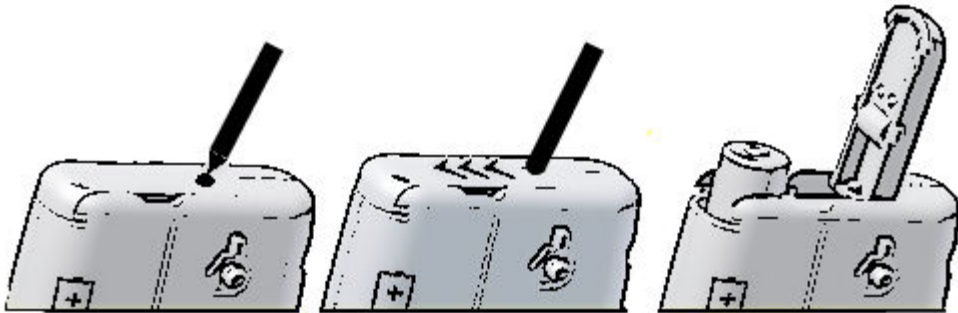


## Power


The Nox T3 device is powered by one AA battery. The battery lasts for a minimum of 3x 8 hours.

### Inserting the Battery:

1. To open the battery compartment press down the battery compartment pin with a pen 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.



### Checking the Battery:

The battery status indicator  positioned in the upper right hand corner of the device's display allows the user to check the battery status during recording.



- ▶ To avoid risk of leakage, battery should not be stored in the device for a prolonged period of time.
- ▶ Always use fully charged or fresh battery for each sleep study.

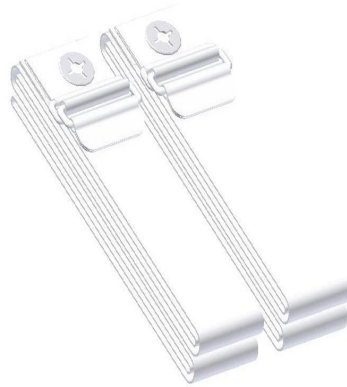
## The Nox T3 Application – Noxturnal

The Nox T3 application (Noxturnal) is used to configure the device for recording, and downloading, viewing and analyzing of recorded data. Refer to section **Nox Noxturnal** for detailed description.

## Respiratory Effort Sensor (Belt)

The device uses two identical respiratory effort sensors to measure the respiratory effort of the patient. One belt is placed around the patient's abdomen and the other around the patient's thorax. The belts are made out of knitted elastic with insulated wire conductor and have a plastic glider for adjustment of belt length. They are terminated with a metal snap at the ends that allows for the connection to the Nox T3 device.

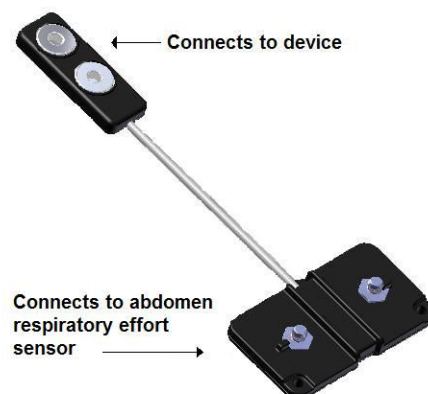
The belts are available in two versions and are adjustable to fit patient circumference from 40cm up to 205cm (Xin).



- ▶ The respiratory effort sensors should be worn over night-clothing or a T-shirt.
  - ▶ The respiratory effort sensors are single patient use.
- 

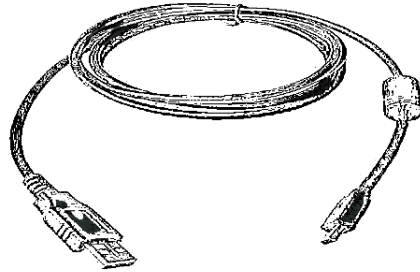
## Abdomen –Thorax Cable

The abdomen-thorax cable connects together the abdomen respiratory effort sensor and the device via metal snaps on each end of the cable. The cable is wrapped up around the abdomen end for adjustment of length.



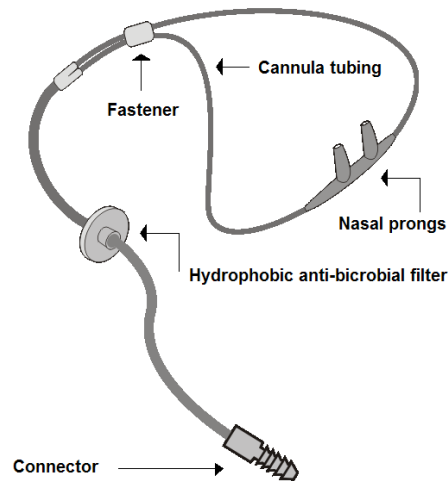
### USB Cable

After the recording the data is downloaded from the device over USB by use of the proprietary USB cable provided with the system.



### Nasal Cannula

The nasal cannula is optional and connects to the pressure lock on the Nox T3 device for measuring of airflow pressure. The nasal cannula is equipped with hydrophobic anti-microbial filter. The nasal cannula is available in two versions, adult and pediatric.



► The nasal cannula is single patient use.

### Clip Strap

The Nox T3 device is equipped with two clip straps, which are fastened to the night-clothing of the patient to secure the position of the device during night.



### Carry Bag

The carry bag is used to store the Nox T3 system and to carry around in.

### Pulse Oximeter

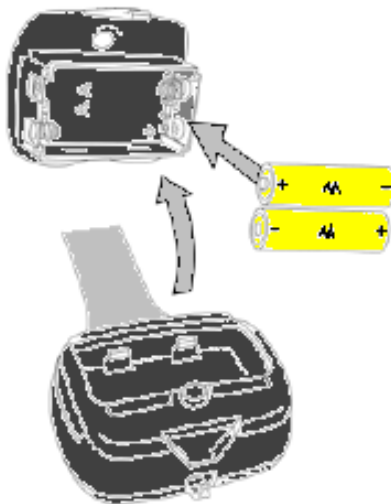
The Nonin pulse oximeter is an optional sensor which measures SpO<sub>2</sub>, pulse rate and plethysmographic data. It is worn on the patient’s wrist and sends data to the Nox T3 device via Bluetooth® wireless technology. The oximeter is battery powered.



### Inserting Batteries

The Nonin pulse oximeter requires two AA alkaline batteries.

1. Remove the battery cover of the pulse oximeter to open the battery compartment
2. Place two AA batteries in the compartment aligning the battery poles as illustrated on the bottom of the battery cover
3. Close the battery compartment. Make sure the cover is securely closed.



### Oximeter Sensors

The Nonin oximeter pulse oximetry module supports all Nonin PureLight™ pulse oximeter sensors:

Nonin’s Models	Soft Sensor - Reusable	Preferred Application Site
Model 8000SL/SL-WO (large)		Fingers, Toe
Model 8000SM/SM-WO (medium)		Fingers, Toe
Model 8000SS/SS-WO (small)		Fingers, Toe
Nonin’s Models	Finger Clip Sensor - Reusable	
Model 8000AA - Adult		Index, middle or ring fingers
Model 8000AP - Pediatric		Index, middle or ring fingers
Nonin’s Model s	Ear Clip Sensor - Reusable	
Model 8000Q		Ear lobe
Nonin’s Model s	Reflectance Sensor - Reusable	
Model 8000R		Middle forehead
Nonin’s Models	Flex Sensor - Reusable	
Model 8000J + 8000JW -Adult Flex Sensor and Wrap		Index, middle or ring fingers
Model 8008J + 8000JFW -Infant Flex Sensor and Wrap		Toe, thumb, medial aspect of hand

Nonin's Model 8000 Reusable Sensors are indicated for spot-checking and/or continuous monitoring of patients where little sensor motion is expected

***ExG Sensors***

The Nox T3 device is capable of recording any combination of two bipolar ExG channels, i.e. EMG, EEG, EOG or ECG. The use of electrodes is optional and they connect to the bipolar touch proof inputs on the device.

## **Nox Nocturnal**

The Nocturnal application interacts with the Nox T3 device. It allows the configuration of the device as well as navigating, analyzing and archiving recordings from the device.

### ***System Requirements***

The following tables show the minimum and recommended hardware requirements needed to operate the software effectively

#### **Desktop Minimum System Requirements**

	<b>Recommended</b>
Operating System	Windows® Vista (any version) Windows® XP Home or Professional with Service Pack 2 Windows® Server 2003 with Service Pack 1
Processor	X86 based Intel or AMD
Processor Clock Speed	1.7 GHz or faster
Memory	512 MB or more
Free Hard Drive Space	500 MB or more
Graphics Resolution	1024x768 or higher

#### **Laptop Minimum System Requirements**

	<b>Recommended</b>
Operating System	Windows® Vista (any version) Windows® XP Home or Professional with Service Pack 2
Processor	X86 based Intel or AMD
Processor Clock Speed	1.2 GHz or faster
Memory	512 MB or more
Free Hard Drive Space	500 MB or more
Graphics Resolution	1024x768 or higher

#### **Desktop Recommended System Requirements**

	<b>Recommended</b>
Operating System	Windows® Vista (any version) Windows® XP Home or Professional with Service Pack 2 Windows® Server 2003 with Service Pack 1
Processor	X86 based Intel or AMD
Processor Clock Speed	2.0 GHz or faster
Memory	1 GB or more
Free Hard Drive Space	500 MB or more
Graphics Resolution	1280x1024 or higher

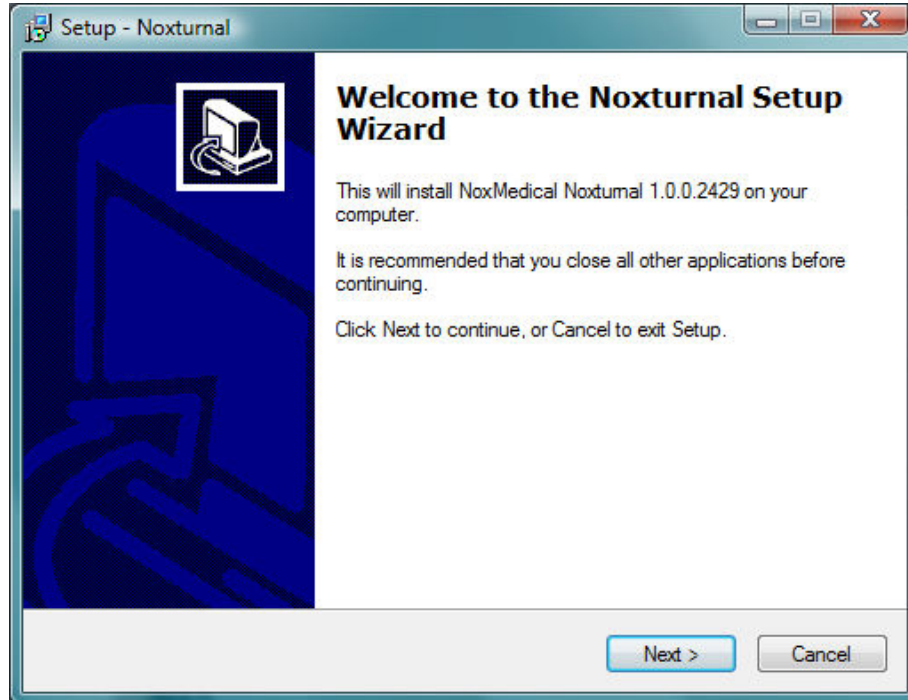
#### **Laptop Recommended System Requirements**

	<b>Recommended</b>
Operating System	Windows® Vista (any version) Windows® XP Home or Professional with Service Pack 2
Processor	X86 based Intel or AMD
Processor Clock Speed	1.5 GHz or faster
Memory	512 MB or more
Free Hard Drive Space	500 MB or more
Graphics Resolution	1280x1024 or higher

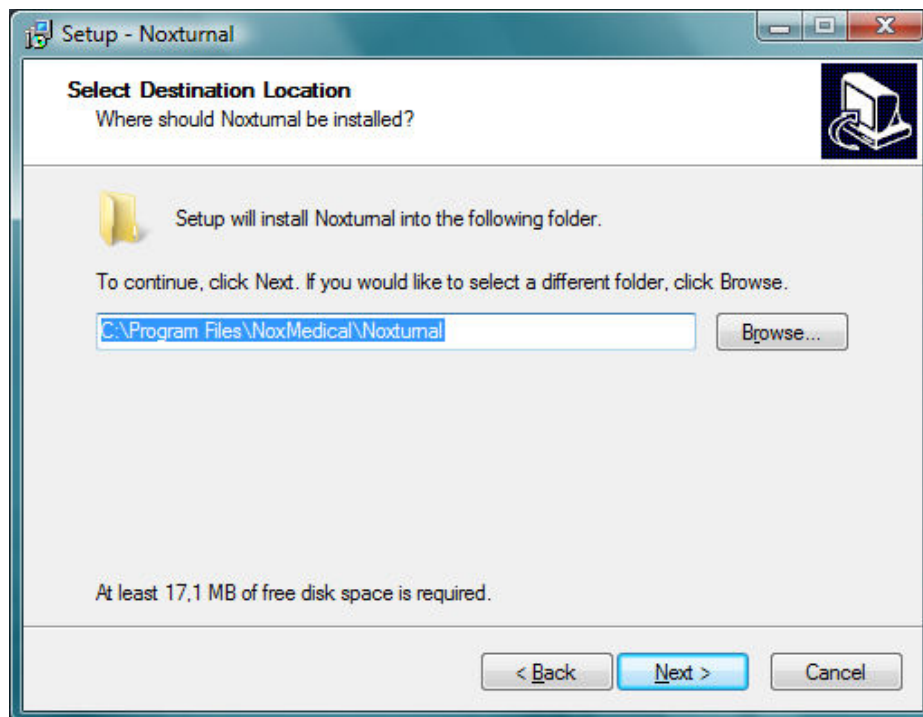
## Installation

Administrative privileges are needed to install Noxturnal. To install the application perform the following steps:

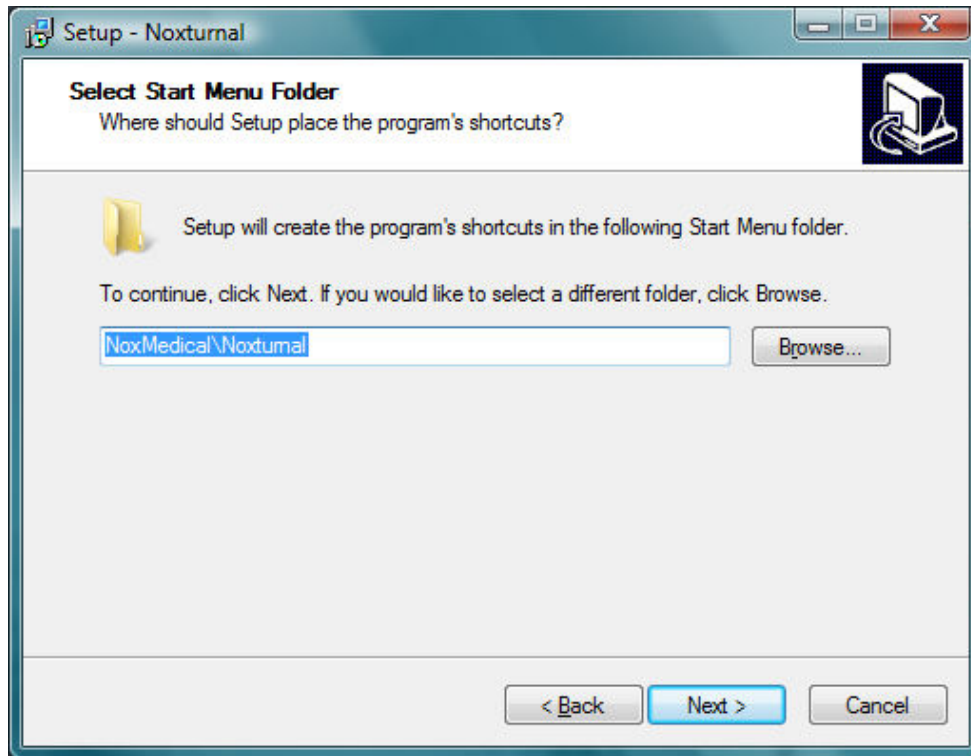
1. Run the setup.exe file on the installation DVD
2. An installation wizard will appear: Press **Next**



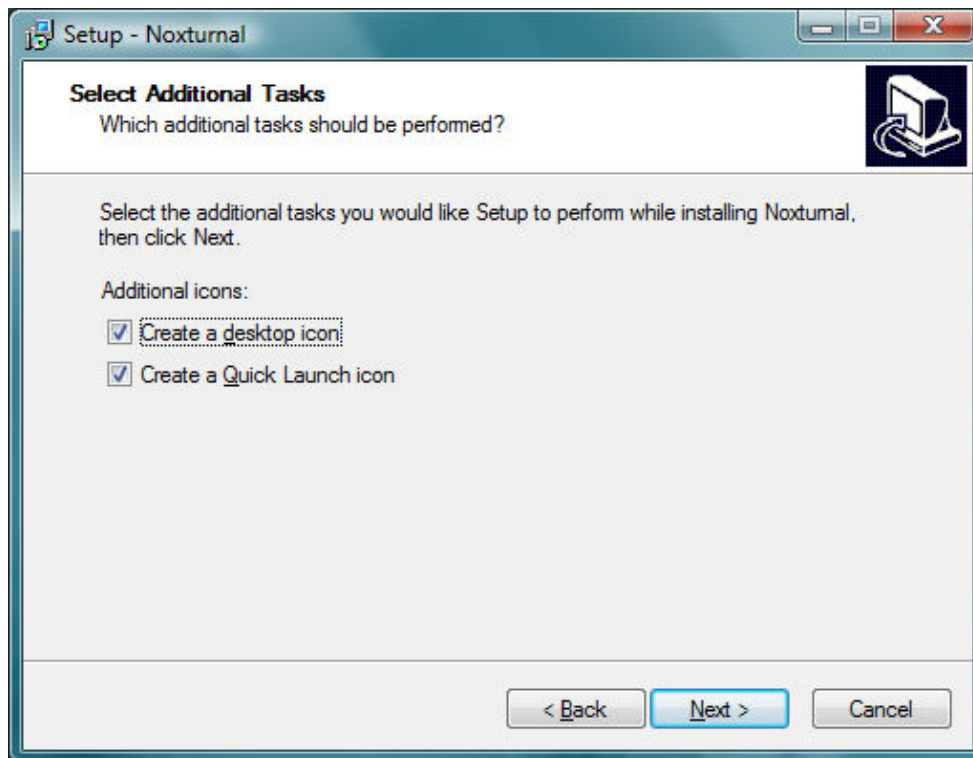
3. Select an installation location and then press **Next**



4. Type in the location for the shortcut for the application and then press **Next**

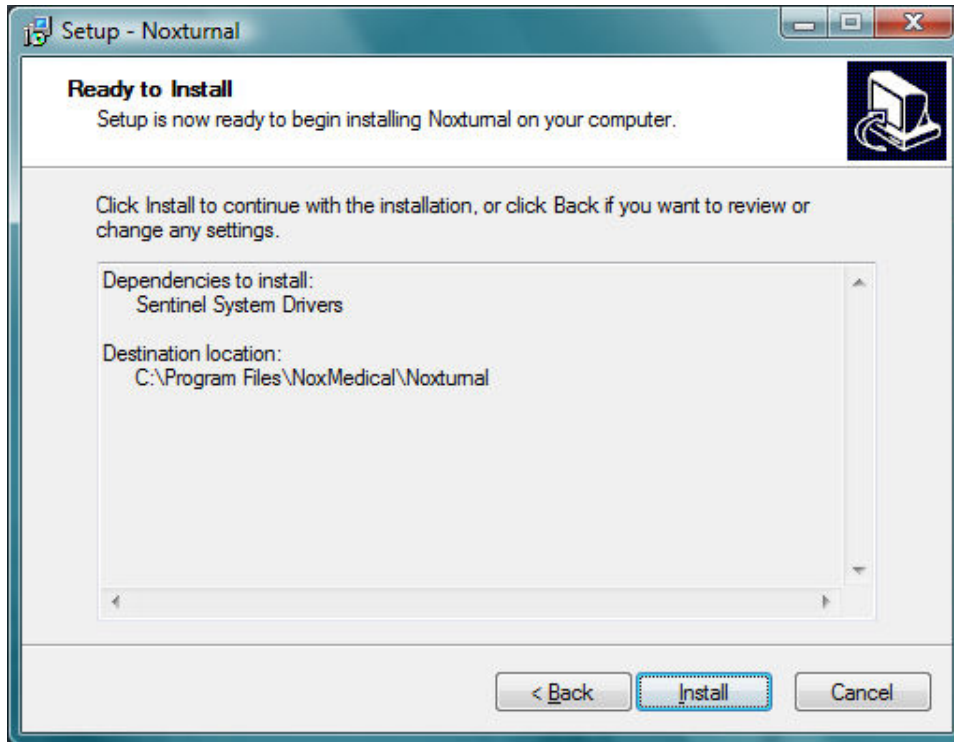


5. This page gives the option of creating a desktop and a quick launch icon for the application. Check the boxes as preferred and then press **Next**

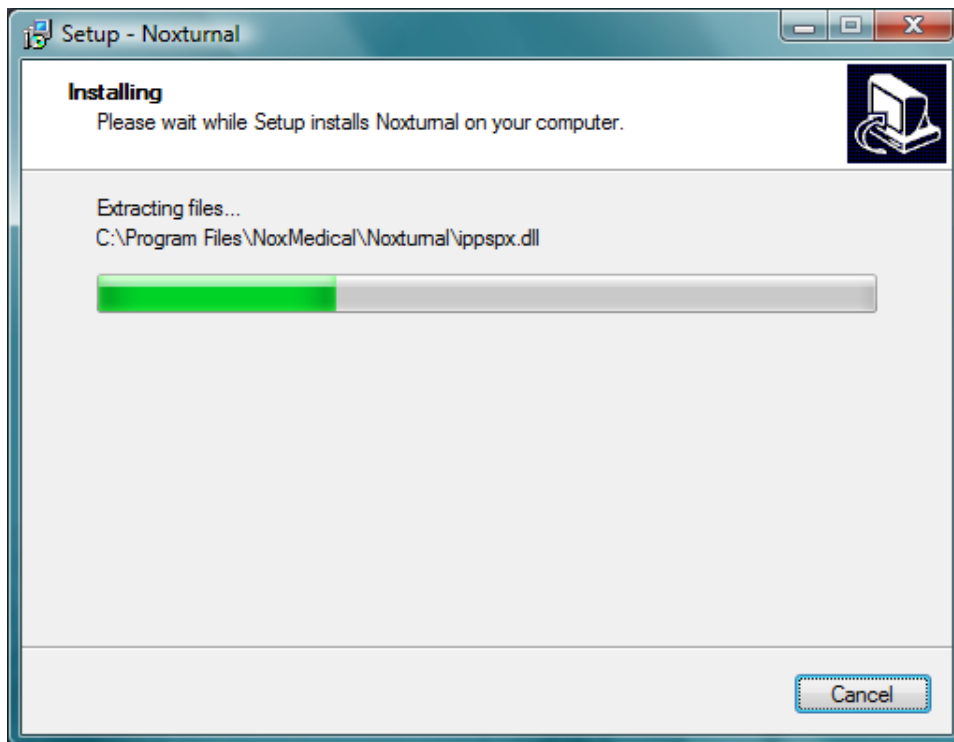




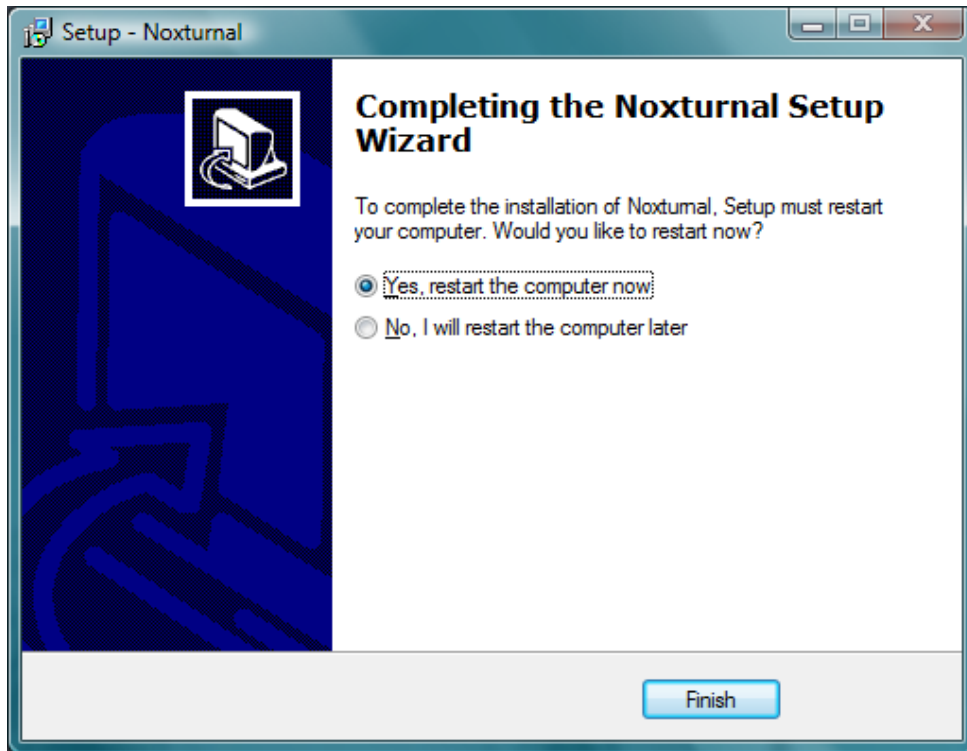
6. This screen gives overview of where the application will be installed and additional items that the application depends upon (dependencies). Press **Install** to accept otherwise press **Back** and change your settings



7. The application is now being installed on your computer. The progress bar gives an indication of the progress during installation

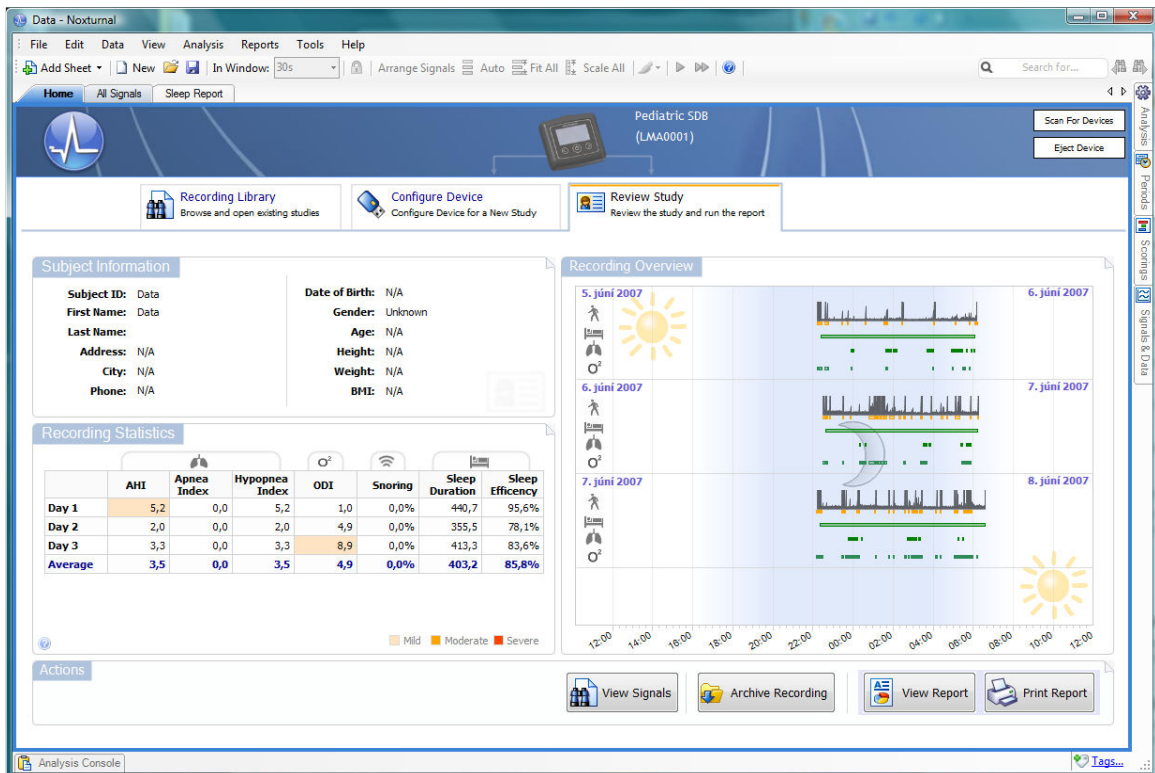


- After installation completes, you might be prompted to restart your computer, do so before running the application. Select your option and then press **Finish**.



### Running the software

When running the software, the first page that appears is the **Start Page** shown in the picture below.



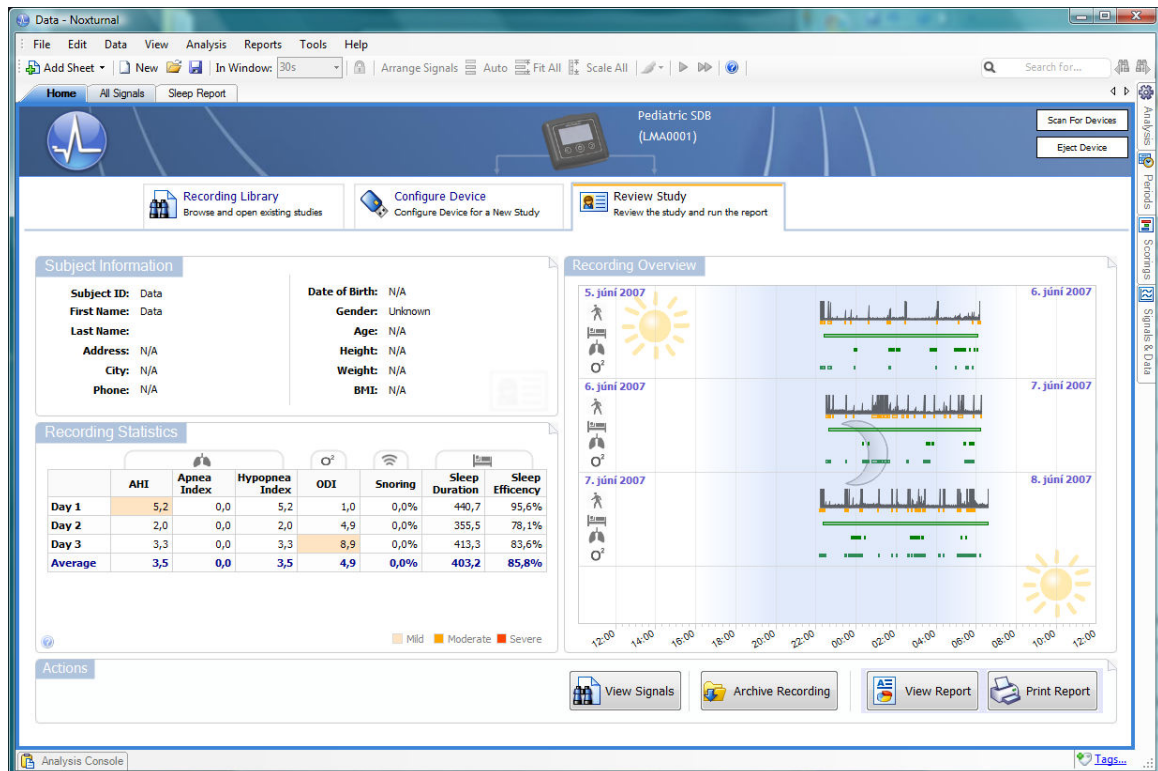
The **Start Page** has three tabs:

- **Recording Library:** The Recording Library sheet lists recorded studies and gives access to each one of those. By left clicking a recording on the Recording Library list, information pertaining to that study will be shown on the right side of the page. Double clicking on a recording in the Recording Library opens up that recording and shows it in the Review Study sheet.
- **Configure Device:** The Configure Device sheet let's you configure the device for a new recording.
- **Review Study:** The Review Study sheet shows summary statistics for the recorded data and gives an overview of that recording.

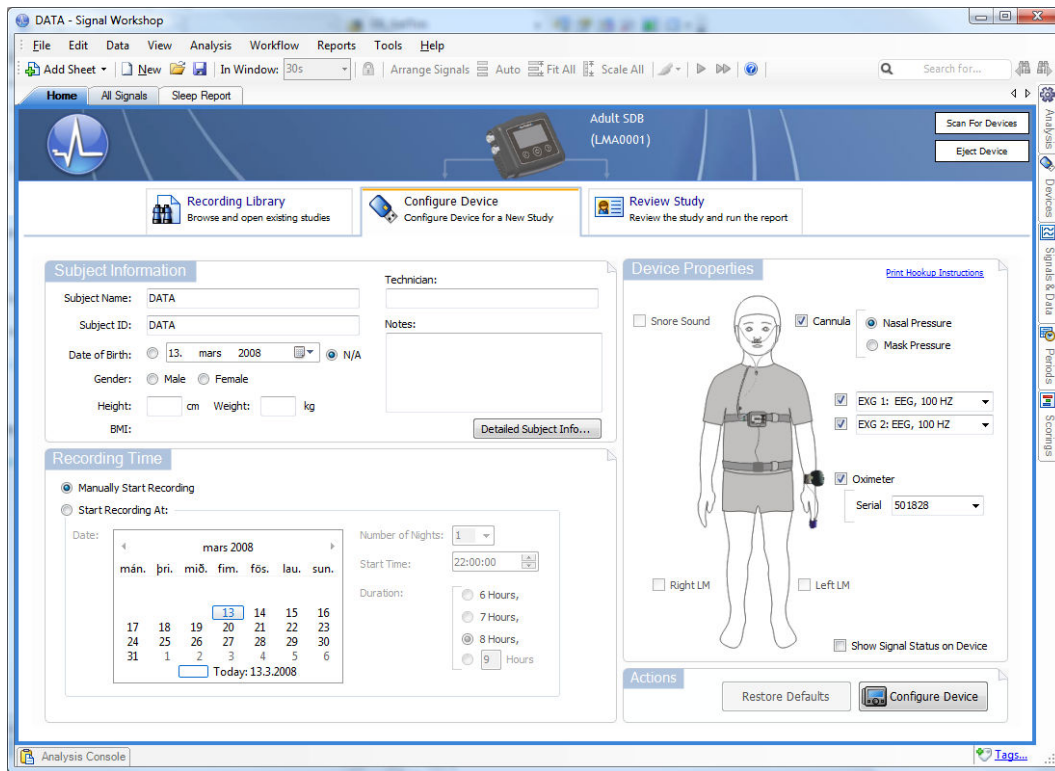
## Configuring the Device

To configure the Nox T3 device perform the following steps:

1. Run the Noxturnal application
2. Connect your device to a USB port on your PC using the USB cable delivered with the system.
3. The software automatically detects the device and switches to the *Review Study* tab. To manually scan for an already connected device you can press the *Scan for Devices* button in the upper right hand corner of the Start Page.



4. Once the device is detected, press the *Configure Device* tab and view the following sheet:

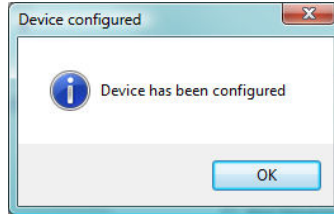


5. Type in information about the subject being recorded in the *Subject Info* section, e.g. name, age, address, gender, height and weight
6. Configure the conditions for starting the recording in the *Recording Time* section. The simplest option is to *Manually Start Recording*. If you select this option, once disconnected, the device will start its recording when you hold down its *start/stop/select* button for at least 3 seconds. See the picture below:



7. To start a recording at a given time and date, select the *Start Recording At* option, input the date, number of nights, start time and duration. When selecting more than one consecutive night of recordings each recording will start at the same time.
8. Select the applicable signals to be recorded in the *Device Properties*.

9. To be able to use the pulse oximeter module in the recording it needs to be paired to the Nox T3 device. Select the appropriate oximeter from the drop down list. In case the oximeter to be used is not shown in the drop down list type in the ID code for that pulse oximeter,.
10. Once the configuration is done press the *Configure Device* button. A *Device has been configured* button will be displayed.



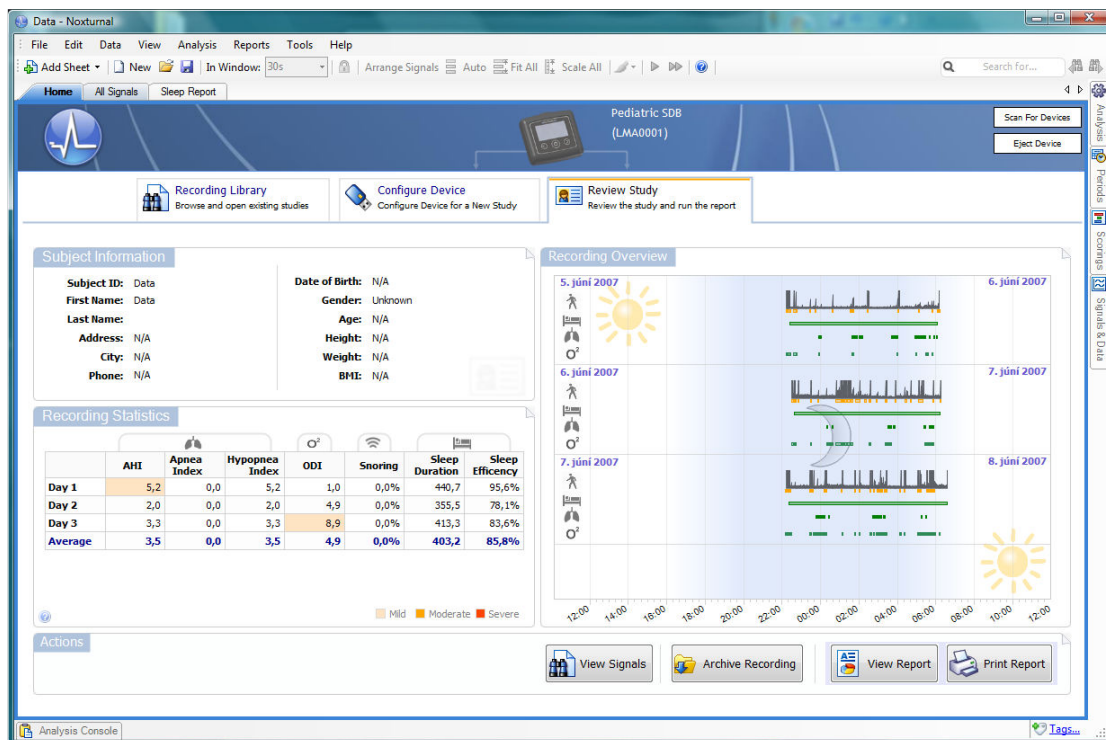
11. Press the *OK* button and then disconnect the device.

## Viewing Recorded Data

Before being able to view a recorded data in your PC you will need to upload the recording data to your PC. Perform the following steps:

1. Run the Noxturnal application
2. Connect your device to a USB port on your PC using the USB cable delivered with the system.
3. The software automatically detects the device and uploads and analysis the recording. During this task you can view various recording data in the *Review Study* sheet:
  - a. Recording overview – an overview of the recorded signals and marked events for each night recorded
  - b. Subject information - shows the subject information entered when preparing the study
  - c. Recording statistics - a table of key sleep parameters that help with diagnosing the recording data

See picture below:



**Recording statistics:** A table containing key parameters of statistics calculated from the raw underlying data and marked events for each night recorded:

- AHI (number of Apneas + Hypopneas per hour),
- Apnea Index (number of Apneas per hour),
- Hypopnea Index (number of Hypopneas per hour),
- ODI (number of desaturation events per hour),
- Snoring (percentage of breaths with snoring),
- Sleep Duration (number of minutes where the subject was treated as sleeping)
- Sleep Efficiency (Sleep Duration / Total Duration).

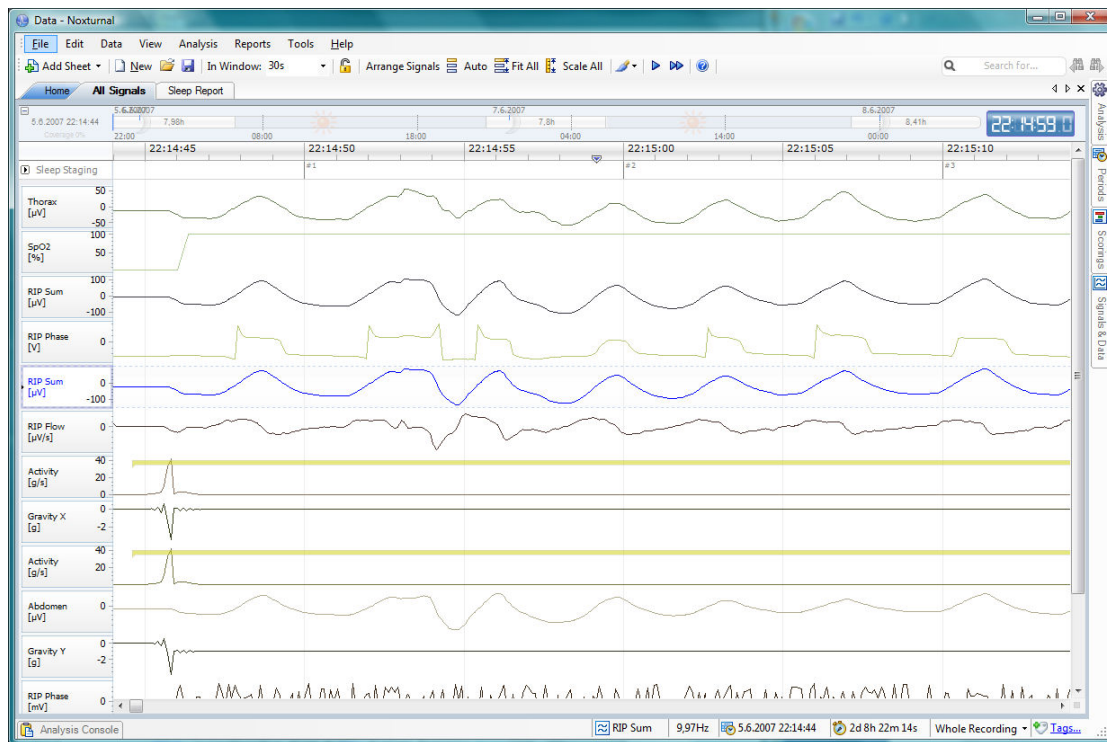
**Recording Overview:** Gives an overview for each night recorded, including:

- Activity
- Movement scored
- Estimated time in bed
- Apneas/Hypopneas scored
- Desaturation events.

The **Actions** section located at the bottom of *the Review Study* page shows options for working with the recorded data, including:

- *View Signals* - For browsing through the recorded signals and viewing the marked events
- *Archive Recording* - For archiving the recording to a different location
- *View Report* - Shows a report summarizing the recording parameters
- *Print Report* - Prints a report summarizing the recording parameters.

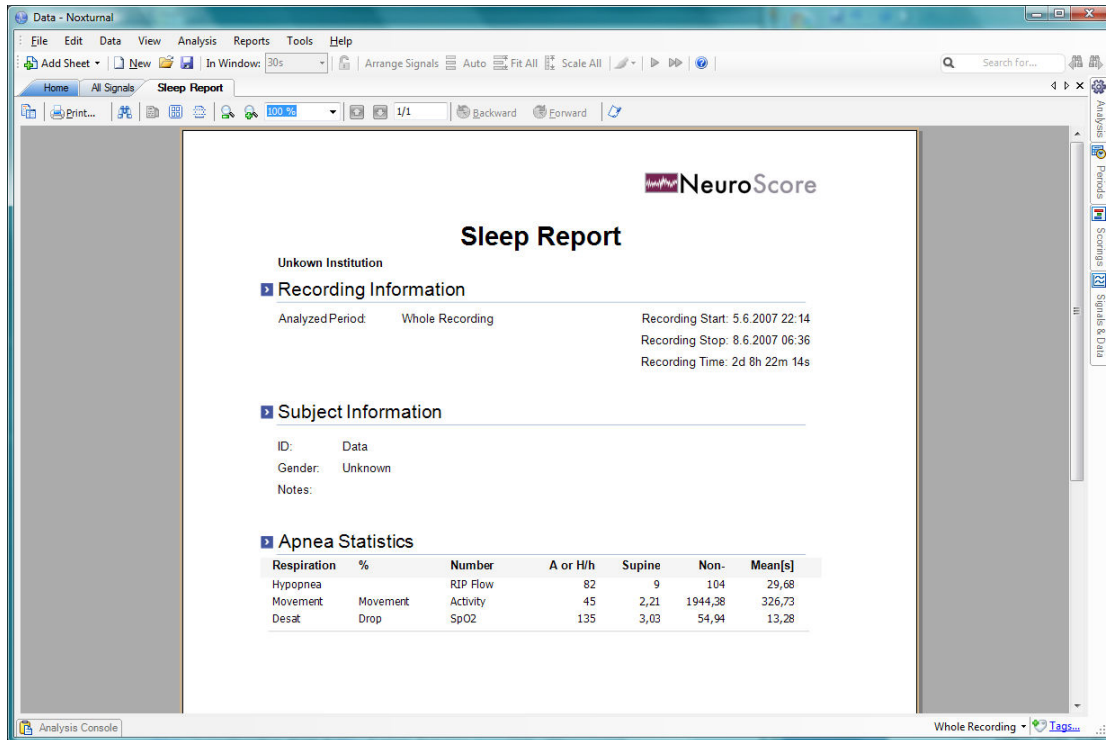
The *View Signals* action gives access to the recorded signals, see picture below:



When viewing the signals it is possible to navigate in time by pressing the left/right arrow keys, the Page-Up/Page-Down keys or by scrolling via a mouse-wheel or mouse-pad.

The *Archive Recording* action copies the recorded data to an archive location. The archive location can be set via the *Tools – Options – Data Locations* menu option.

The *View Report* action shows a printable report with key information helpful for the physician and the subject:



The *Print Report* action directly prints out the report above.

## Hook-Up

It is assumed that the clinician will demonstrate the use of the device and applicable sensors to the patient, or in the case of pediatrics to the parents, and the hook up then takes place at home by using a detailed instruction for hook up. In some cases the clinician may prepare the patient partly or completely.

### Go through the following points with the patient:

1. Applying of device and sensors
2. Testing of sensor connections
3. Status indications on the display including warnings
4. Replacement of battery

It is important to remind the patient to follow the instructions given prior to the study.

### Before sending the patient home:

1. Make sure the device has been configured correctly
2. Make sure the carry bag contains all equipment needed to finish the study, including batteries
3. Provide the patient with the Nox T3 Hook Up Card

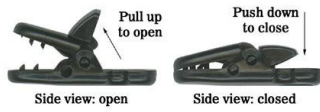


- ▶ Children should under no occasion hook up the system.
- ▶ Do not use damaged equipment like sensors or accessories.
- ▶ As with all medical equipment, carefully route cables and connections to reduce the possibility of entanglement or strangulation

## Attaching the Device and the Respiratory Effort Sensors

Step 1: Attach the device to the patient's

thorax by fasten the clip strap to the night-clothing of the patient



Step 2: Place the respiratory effort sensor around the patient's thorax by snapping its ends to the back panel of the device



Step 3: The belt length is adjusted using the sliders. The slider is fixed by the Velcro and secured by the attached tape.



Step 4: The abdomen - thorax cable is snapped to the back of the device and the cable length adjusted if needed by wrapping it up around the abdomen end



Step 5: The abdomen belt is snapped to the abdomen cable and the length adjusted if needed (see step 3)







- ▶ The device and respiratory effort sensors (belts) should be worn over night-clothing.
- ▶ The belt should fit the patient snugly without being uncomfortably tight.

## **Recording of Respiratory Sounds and Snoring**

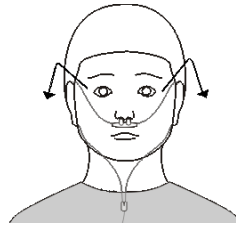
No applying of external sensor is needed for recording of respiratory sounds and snoring as the devices uses an inbuilt microphone.

## **Applying the Nasal Cannula**

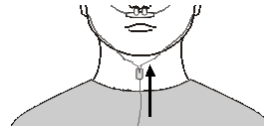
Step 1: Place the nasal prongs gently in the nostrils



Step 2: Drape 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.



Step 4: Connect the nasal cannula connector to the pressure lock on the device



- ▶ Medical tape can be used to hold the cannula against the cheeks to secure the cannula in place if necessary
- ▶ The nasal cannula is single patient use

## **Attaching Electrodes**

The electrodes are placed on applicable locations on the body depending on the type of study.



- ▶ Make sure the skin is clean before applying the electrode
- ▶ The ExG sensors are single use.

## **Pulse Oximeter Module**

### **Choosing the Appropriate Pulse Oximeter Sensor**

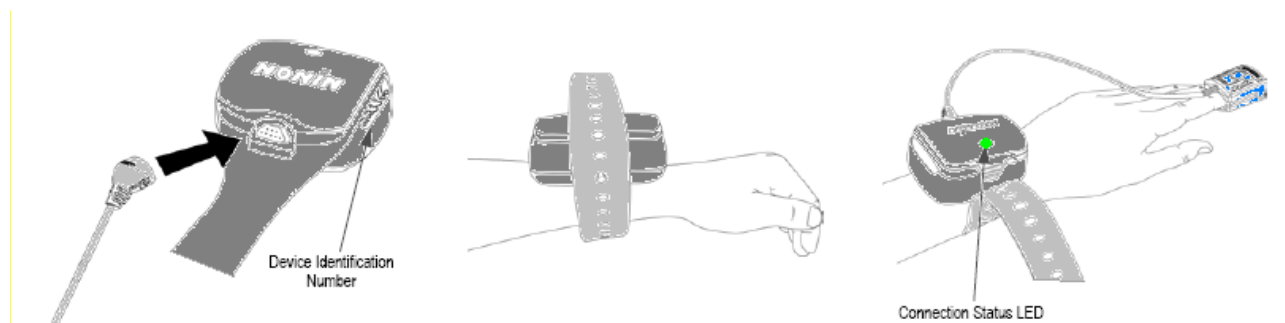
Use the measurements provided in the user instructions accompanying the sensor to determine which size of sensor should be used. Sensor size recommendations are based on digit height (thickness).



- ▶ Use only NONIN manufactured PureLight™ pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for NONIN pulse oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.
- ▶ To avoid the risk of confusing or misinterpreting patient data, verify that the patient module is paired with the correct Nox T3 device.
- ▶ This pulse oximetry system might misinterpret motion as good pulse quality. Minimize finger motion or change the type of sensor being used.

### **Attaching the Pulse Oximeter Module and Sensor**

1. Attach the sensor to the pulse oximeter module. Press firmly to make sure the sensor is securely connected. The pulse oximeter is automatically activated when an oximeter sensor is connected.
2. Secure the wristband to the patient's wrist
3. Insert the selected digit (refer to the sizing recommendations in the user instructions accompanying the sensor) into the sensor. The patient's digit must reach the end of the sensor.
4. Direct the cable along the patient's finger/toe, parallel to the arm/leg
5. Verify proper operation:
  - The connection status LED flashes green when a connection is established
  - It flashes amber if no connection is established.



The wristband can either be reused or discarded after each use, as desired. It may be cut to length to accommodate a variety of patient arm sizes.



- ▶ Proper sensor placement is critical for good performance. If the sensor is not positioned properly, light may bypass the tissue and result in SpO<sub>2</sub> inaccuracies.
- ▶ Do not fasten the pulse oximeter too tightly around the patient's wrist. Inaccurate readings and patient discomfort could result.
- ▶ Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.

## Precautions for Use of the Pulse Oximeter

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- ▶ Oximeter readings may be affected by the use of an electrosurgical unit (ESU)
  - ▶ This pulse oximetry system is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin, such as methemoglobin, might affect the accuracy of the measurement.
  - ▶ To prevent improper performance and/or patient injury, verify sensor and pulse oximeter compatibility before use.
  - ▶ A functional tester cannot be used to access the accuracy of a pulse oximeter monitor or probe.
  - ▶ Factors that may degrade pulse oximeter performance include the following
    - excessive ambient light
    - excessive motion
    - electrosurgical interference
    - arterial catheter, blood pressure cuffs, infusion lines, etc.
    - moisture in the sensor
    - improperly applied sensor
    - carboxyhemoglobin
    - methemoglobin
    - artificial nails
    - incorrect sensor type
    - poor pulse quality
    - venous pulsations
    - anemia or low hemoglobin concentrations
    - cardiovascular dyes
    - sensor not at heart level
    - dysfunctional hemoglobin
    - fingernail polish
  - ▶ Refer to instruction for use accompanying the pulse oximeter and oximeter sensor for additional warnings and cautions.
-

## System Maintenance

No special maintenance of the Nox T3 system is needed.



- ▶ Remove batteries if the system is not used within 30 days.

### **Calibration**

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

### **Cleaning**

No part of the Nox T3 system requires sterilization.

**Nox T3 Device:** Clean the 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 in the device. Allow the unit to dry thoroughly before use.

**Cables:** 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.

**Pulse Oximeter Module:** Clean the module with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids onto the device, and do not allow any liquids to enter any openings in the device. Allow the unit to dry thoroughly before use.

**Pulse Oximeter Sensor (Model 8000):** Unplug the sensor from the pulse oximeter module before cleaning or disinfecting. Clean the sensor by wiping all patient contact surfaces with a soft cloth dampened in water or a mild soap solution. To disinfect the sensor, wipe all patient contact surfaces with isopropyl alcohol (IPA).

For other types of pulse oximeter sensors refer to the sensor package inserts.

**Respiratory effort sensors:** The belts are one-time adjustable disposable belts and non washable.

**Nasal cannula:** The cannula is single patient use and shall not be sterilized.



- ▶ Clean the device separately from its associated sensors.
- ▶ Do not autoclave or immerse any device equipment or sensor in any kind of liquid.
- ▶ Do not use caustic or abrasive cleaning agents on the units.

### **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 equipment and its' accessories may not be disposed of as unsorted municipal waste. The equipment shall be collected separately and returned to the appropriate collection system available.
- ▶ Please contact your distributor regarding take-back or recycling of the equipment. If you are unsure how to reach your distributor, please call Nox Medical for your distributor's contact information.

## Specification

### Nox T3 Device

Description	Properties
<b>Function</b>	
Storage capacity	1GByte
Recording time	Nominal 24 hours with new or fully charged battery
Bipolar inputs	Touch proof DIN 42-802
<b>Physical</b>	
Device Dimension	79mm (3.11") W, 63mm (2.48")H, 21mm(0.83") D
Weight	65 gram (88 gram with battery)
<b>Power</b>	
Internal Power	One 1.5V AA battery
Type	- Alkaline primary or - Alkaline rechargeable) or - Nickel-metal hydride (NiMH)
<b>Display</b>	
Type	OLED
Display Dimension	19x35mm
Resolution	128x64 dots
<b>Environmental Condition</b>	
Temperature	Operation: +5°C to +50°C (40°F to 120° F) Storage: -20°C to +50°C (0°F to 120° F)
Rel. Humidity	Operation: 15-95% (non-condensing) Storage: 10-95% (non-condensing)
Pressure	Withstands atmospheric pressures from 0.5 to 2 bar
<b>Transmitter</b>	
Bluetooth® compliance	Version 2.0
Operating frequency	2.402-2.480 GHz
Output Power	< 2 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
<b>Material</b>	
Enclosure	ABS
Snaps	Stainless steel
Pressure port	Stainless steel

### Respiratory Effort Sensor

Description	Properties
<b>Physical</b>	
Size	Paediatric version adjustable from 40cm to 110cm Adult version adjustable from 70cm to 205cm
<b>Material</b>	
Belt	Polyester Latex free
Slider	Polypropylene (PP)
Snap wire	Spring steel


### Nasal Cannula

Description	Properties
<b>Physical</b>	
Filter	Hydrophilic Filter with Female Luer Lock Inlet
<b>Environmental</b>	
Storage	Store in a cool dry place
<b>Material</b>	
Cannula	PVC/Silicon
Filter	Acryl

### Pulse Oximeter Module


Description	Properties
<b>Range</b>	
Oxygen Saturation Range (%SpO2)	0-100%
Pulse Rate Range	18-300 pulse per minute
<b>Accuracy</b>	
Blood Oxygen Saturation (%SpO2) (± 1 S.D.)	70-100% ± 2 digits for adults using 8000AA-WO Finger clip sensor
Pulse Rate	± 3%
<b>Displays</b>	
Connection status LED	Amber or green
Recording time	Up to X hours
<b>Measurement Wavelengths and Output Power</b>	
Red	660 nanometers @ mW nominal
Infrared	910 nanometers @ mW nominal
<b>Internal Power</b>	
Battery	Two 1.5V AA batteries
Operating Life	Minimum 120 hours of continuous operation with new batteries
Storage Life	10 months
Weight	4.4 ounces with batteries (125g)
<b>Environmental Condition</b>	
Temperature	Operation: 0°C to +50°C (32°F to +122° F) Storage/Transportation: -30°C to +50°C (-22°F to +122° F)
Operating Altitude	Up to 40,000 feet
Humidity	Operation: 10-90% (relative humidity, non-condensing) Storage/Transportation: 10-95% (relative humidity, non-condensing) If transferred from a non-operating temperature and/or humidity condition, allow at least one hour of stabilization time before use.
Hyperbaric Pressure	Up to 4 atmospheres
Antenna Type	Inverted F type antenna
Antenna Gain	+ 2dB (typical), +3 dB (max)
<b>Transmitter</b>	
Bluetooth® compliance	Version 1.1
Operating frequency	2.4-2.4835 GHz
Output Power	< 1.1 mW
Operating Range	10 meter radius indoors
Network Topology	Point-to-Point
Operation	Slave: Model 4100
Antenna Type	Internal
Modulation Type	Frequency Shift Keying Frequency Hopping Spread Spectrum
Bandwidth	1 MHz

### Classifications

	▶ Degree of protection (applied part) against electric shock: The device is classified as of type BF.
▶ Powering of device: The device is internally powered	
▶ Mode of operation: The device is intended for <b>CONTINUOUS OPERATION</b> .	
▶ Degree of protection against ingress of liquids: The device is classified as an ordinary equipment regarding ingress of liquids, i.e. it is not drip-proof, splash-proof or watertight.	
▶ Use with Flammable Anesthetics: The device is not suitable for use in presence of a <b>FLAMMABLE ANAESTHETIC MIXTURE WITH AIR</b> or <b>WITH OXYGEN</b> or <b>NITROUS OXIDE</b> .	
▶ Installation/use of device: The device is classified as a portable device.	

### Certifications

The Nox T3 device complies with the following directives and standards:

	▶ Annex V of the <i>Medical Device Directive 93/42/EEC</i> and is certified by BSI to carry the CE label
▶ <i>IEC 60601-1</i> Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	
▶ <i>UL 60601-1</i> Medical Electrical Equipment, - Part 1: General Requirements for Safety (USA)	
▶ <i>CAN/CSA C22.2 NO. 601.1 - M90</i> Medical Electrical Equipment - Part 1: General Requirements for Safety (Canada)	
▶ <i>IEC 60601-1-2</i> Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and test	
▶ <i>IEC 60601-1-4</i> Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems	
▶ <i>IEC 60601- 2-25</i> Particular requirements for the safety of electrocardiographs	
▶ <i>IEC 60601- 2-26</i> Particular requirements for the safety of electroencephalographs	
▶ <i>IEC 60601- 2-40</i> Particular requirements for the safety of electromyographs and evoked response equipment	
▶ <i>ISO 14971</i> Medical devices - Application of risk management to medical devices	
▶ <i>ISO 13485</i> Medical devices – Quality Management systems – Requirements for regulatory purposes. The manufacturing site of the Nox T3 device is certified according to ISO 13485.	
▶ <i>EN 300 328</i> Electromagnetic compatibility and Radio Spectrum Matters (ERM); Wideband Transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using spread spectrum modulation techniques	
▶ <i>EN 301 489-17</i> Electromagnetic compatibility and radio spectrum matters (ERM); Electromagnetic compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for wideband data and HIPERLAN equipment	
▶ <i>EN 60950-1</i> Information technology equipment – Safety - General requirements	
▶ <i>EN 50371</i> Generic Standard to Demonstrate the Compliance of Low-Power Electronic and Electrical Apparatus with the Basic Restrictions Related to Human Exposure to Electromagnetic Fields (10 MHz–300 GHz) – General Public	
▶ <b>FCC Part 15</b> The device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of FCC Rules.	
▶ <b>RSS 210 of IC</b> The device complies with RSS 210 of Industry Canada (IC)	
▶ <b>RSS-GEN Issue 1</b> The device complies with RSS-GEN Issue 1 of Industry Canada (IC)	
▶ <b>Bluetooth®</b> compliance	

## **EMC – Information**

### **Declaration of Conformity with USA Federal Communications Commission (FCC) and Canadian Ministry of Health Rules for Electromagnetic Compatibility**

The Nox T3 device complies with Part 15 of the FCC Rules and RSS 210 of Industry Canada. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference, including interference that may cause undesired operation of this device.

For questions regarding your product or this FCC declaration, please contact:

Fusion Sleep Therapy Services LLC  
4265 Johns Creek Parkway, suite A  
Suwanee  
GA 30024  
USA  
Phone: 678 990 3262  
Fax: 678 990 3966  
Email: [reception@fusionsleep.com](mailto:reception@fusionsleep.com)

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 guarantee 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.

### **Modification Statement**

The FCC requires the user to be notified that any changes or modifications not expressly approved by Nox Medical could void the user's authority to operate the equipment.



## Specific Absorption Rate (SAR)

Ministry of Health (Canada), Safety Code 6: standards include substantial safety margin designed to ensure the safety of all persons, regardless of age and health. The Specific Absorption Rate or SAR is a measure of the rate at which electromagnetic energy is absorbed into the body. The SAR limit for the general public is 1.6W/kg for the trunk and 4W/kg for the limbs.




- ▶ This product emits radio frequency energy, but the radiated output power of this device is far below the FCC radio frequency exposure limits. Nevertheless, the device should be used in such a manner that the potential for human contact with the antenna during normal operation is minimized.
  - ▶ Caution: Exposure to radio frequency radiation.
  - ▶ Portable and mobile RF communications can affect the performance of the device.
  - ▶ The device should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
  - ▶ Electrostatic discharges (ESD) may cause artifacts in the signal from the device. Avoid conditions where electrostatic charge can build up because of low humidity and friction against carpets, clothing and sheets made from artificial fibers.
  - ▶ The use of accessories, sensors, and cables other than those listed in this manual may result in increased emission and/or decreased immunity of this device.
  - ▶ This system may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements.
  - ▶ Refer to the tables in this section for specific information regarding the device's compliance to the standard IEC60601-1-2
-

## Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

Guidance and manufacturer’s declaration – electromagnetic emissions		
The Nox T3 system 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 Nox T3 device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The Nox T3 system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

## Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

Guidance and manufacturer’s declaration – electromagnetic immunity			
The Nox T3 device is intended for use in the electromagnetic environment specified below. The customer or the user of the system 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	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
			Portable and mobile RF communications equipment should be used no closer to any part of Nox T3 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			<b>Recommended separation distance</b>
Conducted RF IEC 61000-4-6	$3V_{rms}$ 150kHz to 80MHz	$3V_{rms}$	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3V/m	$d = 1.2\sqrt{P}$ 80MHz to 800MHz
			$d = 2.3\sqrt{P}$ 800MHz to 2.5GHz 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, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80MHz and 800MHz, 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.

<sup>a</sup> 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 Nox T3 device is used exceeds the applicable RF compliance level above, the Nox T3 device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Nox T3 device.

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

### Recommended Separation Distance between Portable and Mobile RF Communications Equipment and the Nox T3 Device

#### Recommended separation distance between portable and mobile RF communications equipment and the Nox T3 device

The Nox T3 device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Nox T3 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		
	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
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 80MHz and 800MHz, 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.