Nox T3

Nox T3 Manual

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Introduction

Congratulations on choosing the new Nox T3® portable sleep recorder. The T3 device is designed for recording physiological signals of patients with suspected sleep disorders. The device is compact, lightweight and easy to use. Simple sensor placement and clear instructional diagram makes setup quick and easy.

Scope

This manual covers the T3 device and its components along with external sensors and devices that have been validated with the T3 system. It does not cover the software application needed for device configuration, data download, review and/or analysis.

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 IEC 60601-1.
- Caution: U.S. Federal law restricts this device to sale by, or on the order of, a physician.
- This device complies with the international standard IEC 60601-1-2 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 performance of the device. 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.
- External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. 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, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support. Any person who connects external equipment to signal input, signal output or other connectors has formed a system and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative.
- The T3 device does not increase the safety risk for pacemaker patients as long as the pacemakers comply with the EN 50061 standard of electrical safety of medical devices. Nevertheless, 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 producer.
- Warning/caution: Do not use the T3 System during radiography/X-ray studies.
- The T3 device is not intended to be used with high frequency (HF) equipment
- The device is not defibrillator proof.
- Do not use any part of the T3 system in an MRI (Magnetic Resonance Imaging) environment.
- The T3 device and RIP belts should be worn over clothing.
- WARNING: Avoid accidental contact between connected but unused APPLIED PARTS and other

conductive parts including those connected to protective earth.

▸ Do not use damaged equipment, sensors or accessories.

▸ The T3 device and its accessories should be removed from the patient before download of data.

▸ There are no user serviceable parts inside the T3 device. The T3 device should be serviced by authorized parties only. The warranty is void if the T3 device is opened.

▸ WARNING: No modification of this equipment is allowed.

▸ To avoid risk of battery leakage, the T3 device should not be stored with a battery inserted in the battery compartment.

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

Device Description

The Nox T3 device records signals from three built-in sensors and five external sensors. The built-in sensors include a pressure transducer allowing recording of nasal/mask pressure and snoring, a three dimensional acceleration sensor for measuring patient's position and activity and a microphone for true audio recording capabilities. The external sensors options are abdominal and thoracic RIP belts and two channels of ExG, i.e., ECG, EMG, EEG or EOG. The T3 device also supports wireless Bluetooth® connectivity allowing it to record signals from a compatible Bluetooth pulse oximeter, and capnography data via the Nox EtCO$_2$ Interface. The device is powered with one AA battery.

Intended Use

The Nox T3 device is intended for ambulatory recording of physiological signals during sleep. The T3 device 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 T3 device is **NOT** intended for any patient monitoring or automatic diagnosis.

T3 Interface

The T3 device interface consists of a display, buttons, sensor inputs/connections and a USB connector. The USB connector is placed under the battery lid and connects to a mini USB cable for device configuration and data download. The display allows for status indication where signals can be checked in real time. See the figures and tables below for detailed description.
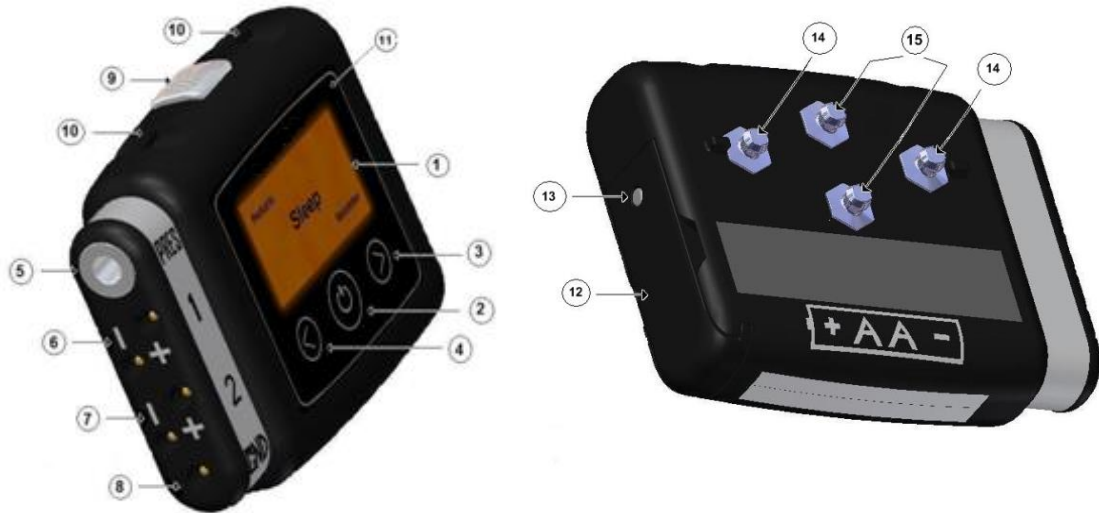
NUMBER	FUNCTION
1	Display
2	Push button – Middle
3	Push button – Forward
4	Push button – Backward
5	Pressure lock – Connects to external nasal cannula/mask pressure tube
6	Bipolar touch proof inputs – Channel 1
7	Bipolar touch proof inputs – Channel 2
8	Reference ground input for channels 1 and 2
9	Microphone – For recording of respiratory sounds
10	Clip strap loops
11	Indicator light for device status
12	Battery lid – Covers the battery and the USB connector
13	Battery lid pin
14	Metal snaps – Connect to thorax RIP belt
15	Metal snaps – Connect to abdomen cable

Operating the Device

The T3 device is operated with three push buttons located on the front panel. Pressing the **Middle** button turns on the display. The display will automatically turn off in 2 minutes.

Connecting the T3 Device to a Computer

To connect a T3 device to a computer you need to access the USB connector on the device. The USB connector is placed under the battery lid making it inaccessible and tamper proof for children. To open the battery lid, press with a pen or a similar tool on the battery lid pin and slide the battery lid down, towards the bottom of the device. The T3 device connects to the computer by using a mini USB cable. The battery does not have to be inserted while the device is connected to the computer.
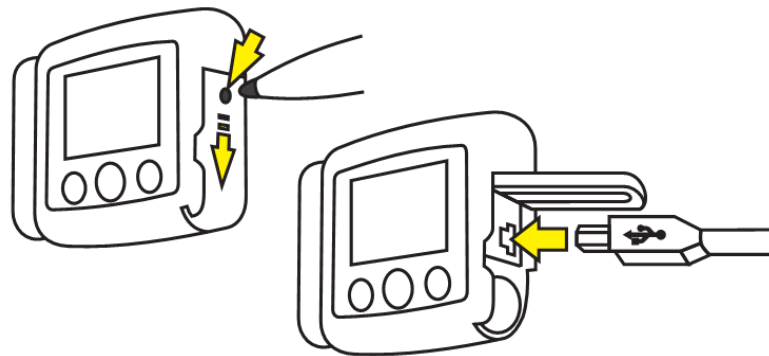
When the T3 device is connected to the computer the device display lights up and displays a message saying the device is connected to the computer.

Configuring and Downloading from a T3 Device

To download a recording or configure a T3 device you will need to start the applicable T3 software application after connecting the device to the computer. Please refer to the applicable software user manual for more information on how to perform those tasks.

When you are done working with the device unplug the mini USB cable, insert the battery and close the battery compartment by pressing the lid back towards the device without causing any strain, then slide it back into position, towards the top of the device.

Establishing a Connection between the Nonin 3150 Oximeter and a T3 Device

If you are using the Nonin SpO2 Oximeter, Model 3150 please follow the instructions below on how to establish a connection between the oximeter and the T3 device.

1. Configure the T3 device.
2. Insert fresh/fully charged batteries in the T3 and the 3150 oximeter.
3. Turn on the oximeter's display by connecting the Flex/Soft Sensor and pressing the oximeter's activation button for approximately 2 seconds and wait until the oximeter display is lit up
4. Turn on the display of the T3 device by pressing the middle button.

5. To program the oximeter follow the steps below:
   1. Wait until the letters "**CP**" appear on the oximeter's display.
   2. When you have seen the "**CP**" appear on the display the oximeter has been successfully programmed for the recording. The oximeter may display pulse/saturation information, when the finger is placed in the sensor or if you have scheduled a recording the intended start time for the recording will blink every 30s.
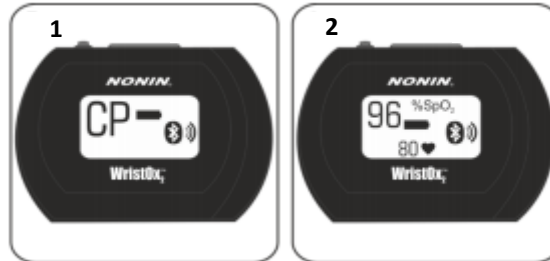
NOTE: If you are using a Flex Sensor it is strongly recommended to schedule the recording to start at a specific time.

NOTE: It is important NOT to remove the oximeter's batteries after the oximeter has been programmed as this will cause it to lose its configuration and making it necessary to repeat steps 3 – 5.

Manually Starting/Stopping a Recording

If the device has been configured to start the recording manually, you can use the **Middle** button to manually start a recording. Pressing the middle button turns on the display. The device will instruct you to "Hold middle button down to start recording". Please do so until you see "Recording Duration" displayed. Note the **Middle** button needs to be pressed down for approximately 4-5 s before "Recording Duration" displays. At this point the device has started to record data. After the display turns off, the light on the top right side of the display will blink intermittently indicating that recording is taking place. Use the same method to manually stop the recording.

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

Starting a Recording at a Scheduled Time

If the device has been configured to automatically, start a recording at a scheduled time there are no actions required for the recording to start. Pressing the **Middle** button before the recording has started will display a countdown to the specified start time of the recording. If the recording has begun, the display shows the current duration of the recording.

Signal and Status Checks

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

- Battery low

- 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 and signals status is shown on the device 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.

1. On the top right corner is a battery bar which shows the battery status. The battery bar is full when the device has fresh batteries.
2. In 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.

Signal Status

If the T3 device has been configured to *View Signal Status*, 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 T3 device. Note that if the *View Signal Status* option is not checked, the device is in simple operation mode and only the start page will be shown.

Respiratory Signals

Pressing **Forward** on the display shows information about the respiratory signals.

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

2. Audio, power gauge.

3. Patient's position (Left, Right, Supine, Prone and Upright).
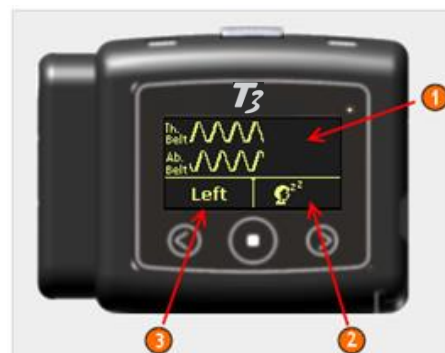
Oximeter Signals

Pressing the **Forward** button again will show the patient's actual oxygen saturation levels (SpO$_2$) and pulse rate in beats per minute (bpm).

If communication has not been established with the selected oximeter, a message is displayed indicating that the device is trying to communicate with an oximeter with a certain serial number.

Make sure that the serial number of the oximeter used matches the configured serial number. Also, be sure that the Bluetooth symbol is displayed on the screen of the oximeter. If the Bluetooth symbol is not displayed, the Bluetooth is inactive and the T3 device cannot connect to the oximeter.

If the Bluetooth symbol is not visible, press the small button at the top of the oximeter and hold it down for 3 seconds or until the Bluetooth symbol appears on the screen.

If the oximeter probe is not on the finger or the values received from the oximeter are outside normal range, a message comes up on the display saying *Probe not on finger*.

Capnography Signals

When the T3 device has been configured to record capnography data pressing the **Forward** button one more time will show the capnography display, including CO_2 waveform, end-tidal CO_2 (EtCO_2) value (mmHg) and respiratory rate/respiration per minute (rpm).

NOTE: If the T3 device has not succeeded in connecting with the capnography monitor, the display will indicate that it is still trying to connect and will display the serial number of the Nox EtCO_2 interface.

ExG and Pressure Signals

Pressing the **Forward** button one more time will show the ExG channels: channel 1, channel 2 and the values from the pressure transducer. Depending on the configuration, either the mask pressure or nasal pressure is shown. The mask pressure shows the average DC value in cmH$_2$0 ranging from 0-20 cmH$_2$0. The nasal pressure has its DC value removed and shows the pressure values as a signal plot that sweeps over the screen.

1. Mask pressure DC value

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

1. Nasal pressure signal

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

Patient Hookup

It is highly recommended that a trained clinician demonstrates the use of the T3 device to the patient, or in the case of pediatrics to the parents. In most cases the hookup takes place at home and the patient hooks up the device by using the T3 hookup instructions.

The technician should go through the following points with the patient:

1. Attaching T3 device and sensors.

2. Testing of sensors connections.

3. Status indications on the display.

4. Replacement of battery for multiple night recordings.

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

Before sending the patient home:

1. Make sure the device has been prepared correctly.

2. Make sure the carry case contains all the equipment needed to finish the recording, including batteries.

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

Inserting a Battery to the T3 Device

Before you start a recording you should make sure that the device has new or fully charged battery. To insert a new battery do the following:
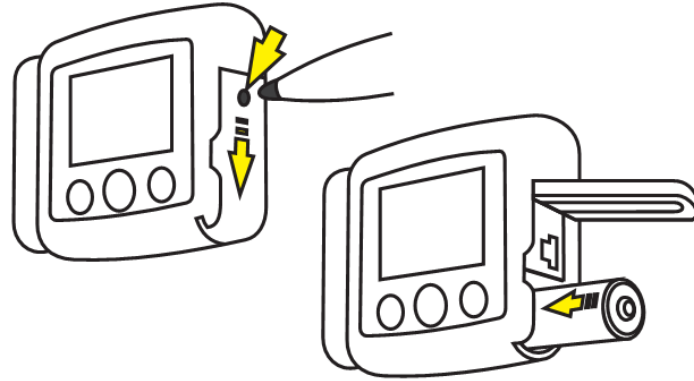
1. Open the battery compartment by pressing down the battery lid pin with a pen or similar tool and slide the lid towards the bottom of the device.

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.

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.

When recording multiple nights the patient might be required to change the battery after each night. Please refer to the section Battery Information regarding the types of batteries recommended for use with the T3 device.

> ▶ Always use fully charged or fresh battery for each sleep recording.
> ▶ All lithium batteries used with the T3 device shall be according to the standard IEC 60086-4 Primary batteries - Part 4: Safety of lithium batteries.

Attaching the T3 Device and the RIP Belts

Step 1

1. Snap the clips that are attached to the device to the patient's shirt.
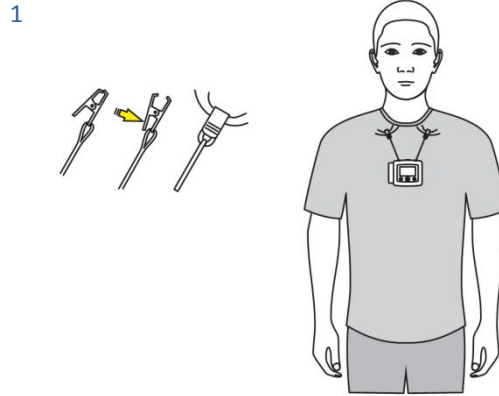
Step 2 to Step 4

2. Snap the abdomen cable to the back of the device.
3. Place a RIP belt around the thorax and snap its ends to the back panel of the device.
4. Adjust the cable length as needed by wrapping it around the abdomen connection unit. Place a RIP belt around the abdomen and snap in place.
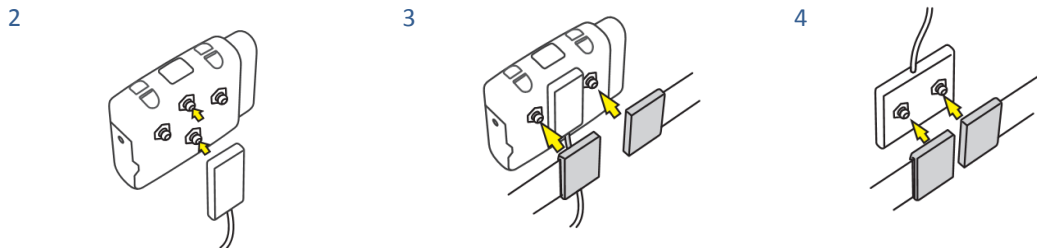
Step 5

5. Attaching the device and respiratory sensors is now completed.
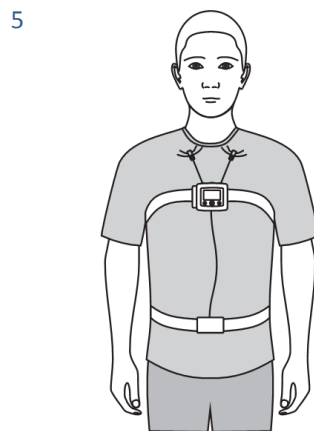
Adjusting the RIP Belts

Disposable RIP Belts

Fit the belts around the patient's waist and thorax and adjust the length using the loop on each end to adjust the belt length such that the belt covers about two thirds of the patient's circumference when the belt is unstretched. The length is fixed with hooks on the plastic connector of the belt.
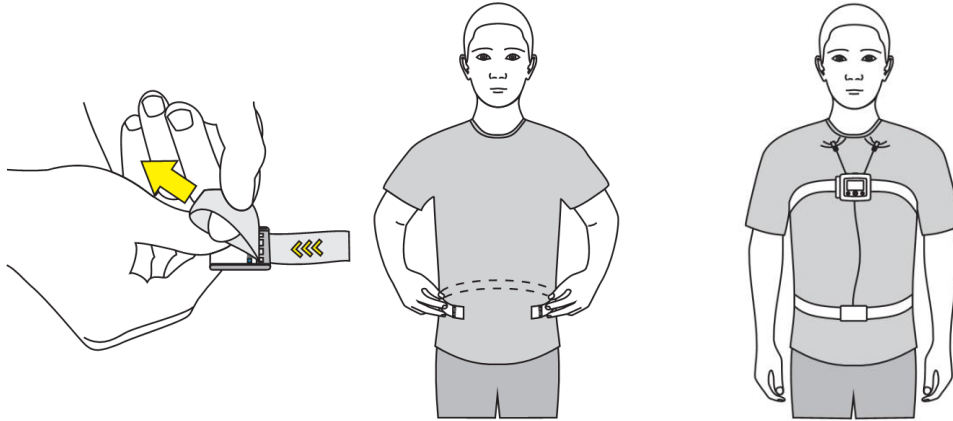
Refer to the section Compatible Sensors and Devices regarding the types of Nox RIP belts that have been validated with the T3 device.

NOTE: For most patients the disposable RIP belts do not need to be adjusted if the correct belt size is chosen based on the patient's abdomen circumference and/or body mass index (BMI). Belt size selection tables accompany the product for more detailed instruction.

> ▶ The T3 device and RIP belts should be worn over clothing.
> ▶ The RIP belts should fit the patient snugly without being uncomfortably tight.
> ▶ The disposable RIP belts are single use.
> ▶ The use of the same disposable RIP belt on more than one patient poses a risk of cross-infection.

Attaching the Nasal Cannula

Step 1

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

1

Step 2

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

Step 3

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

1   2   3

NOTE: The Nox nasal cannula with filter has a built-in hydrophobic filter and is the preferred way to measure nasal airflow and snoring as it is designed to maximize the signal quality and fits directly with the T3 device. If it is preferred to use a non-filtered Luer-lock cannula, it is necessary to use a filter tube connector from Nox Medical to interface with the T3 device.

Refer to the section Compatible Sensors and Devices regarding the types of nasal cannulas that have been validated with the T3 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.
> ▶ The use of the same nasal cannula on more than one patient poses a risk of cross-infection.

Measuring Mask Pressure

A mask pressure tube is used for connection to CPAP masks for measuring mask pressure. The pressure tube connects to the pressure lock on the T3 device 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 T3 device.

> - ▸ The mask pressure tube is single patient use.
> - ▸ The use of the same mask pressure tube on more than one patient poses a risk of cross-infection.
> - ▸ The mask pressure tube can only be connected to the pressure lock on the T3 device by using the Nox filter tube connector.
> - ▸ The filter tube connector is single patient use.

Measuring ExG Signals

The T3 device is capable of recording any combination of two ExG channels, that is, electromyograph (EMG), electrooculograph (EOG), electroencephalograph (EEG) or electrocardiograph (ECG). The electrodes connect to the bipolar touch proof inputs on the T3 device. 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 that have been validated with the T3 device.

> - ▸ Make sure the skin is clean before attaching the electrodes.

Measuring Capnography

The T3 device is able to communicate with a capnography monitor over a Bluetooth® link using Nox EtCO$_2$ Interface.

Refer to the section Compatible Sensors and Devices regarding the types of capnography monitors that have been validated with the T3 device.

> - ▸ The T3 device is **NOT CERTIFIED TO BE USED FOR CONTINUOUS MONITORING** where failure to operate can cause injuries or death of the patient.

Measuring Pulse and Oxygen Saturation

The T3 device is able to communicate with an external Bluetooth® pulse oximeter for recording of oxygen saturation levels (SpO$_2$), pulse rate, and plethysmography data.

Refer to the section Compatible Sensors and Devices regarding the types of pulse oximeters that have been validated with the T3 device.

> - ▸ The T3 device is **NOT CERTIFIED TO BE USED FOR CONTINUOUS MONITORING** where failure to operate can cause injuries or death of the patient.
> - ▸ To avoid the risk of confusing or misinterpreting patient data verify that the

patient module is paired with the correct T3 device.

▸ The pulse oximetry system might misinterpret motion as good pulse quality. Minimize finger motion or change the type of sensor being used.

▸ Do not fasten the pulse oximeter too tightly around the wrist. Inaccurate readings and patient discomfort could result.

▸ To prevent the sensor from falling off secure the wire to the digit with medical tape.

▸ Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.

▸ To prevent improper performance and/or patient injury, verify the sensor and pulse oximeter compatibility before use.

▸ Factors that may degrade pulse oximeter performance include the following:

- excessive ambient light

- excessive motion

- electrosurgical interference

- arterial catheter

- blood pressure cuffs

- infusion lines

- 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 3rd party instructions for use accompanying the pulse oximeter and/or oximeter sensor for maximum oximeter application time at a single site.

▸ Refer to 3rd party instructions for use accompanying the pulse oximeter and oximeter sensor for additional warnings and cautions.

Inserting Batteries into the Oximeter

Nonin 3150 Pulse Oximeter

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

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

Nonin 4100 Pulse Oximeter

Follow the instructions below whenever the batteries in the Nonin 4100 oximeter are changed to ensure effective use of the 4100 oximeter with the T3 device.
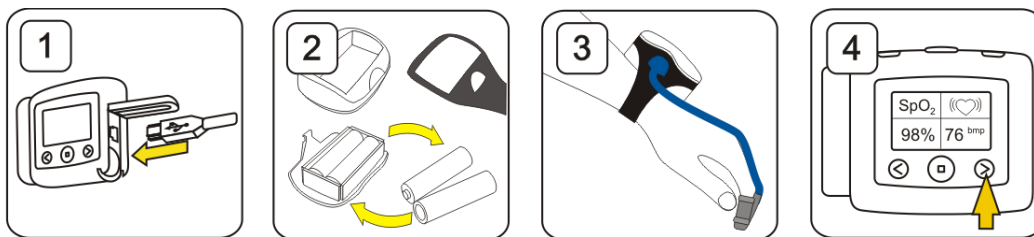
Step 1

Configure the T3 device.

Step 2

Change the batteries in the 4100 oximeter.

Steps 3 and 4

Put the probe of the oximeter on your finger and within 5 minutes use the buttons on the T3 device to check the connection of the oximeter and the oximeter signals (this action puts the oximeter in the correct mode).

NOTE: Now the oximeter is correctly configured. Do not open the battery compartment of the oximeter after checking the oximeter signals because that causes the oximeter to return to factory settings which can lead to an unsuccessful recording. If the battery compartment is opened, the steps above need to be redone.

> ▶ Single use batteries last up to 120 hours of use so it is important to track the number of measurements made with the Nonin 4100 pulse oximeter. It is recommended to change the batteries after 10 recordings.
> ▶ If you are using rechargeable batteries, it is recommended that you replace them at the beginning of each week.
> ▶ Refer to the 3rd party accompanying instruction for more detailed instruction on battery replacement for the Nonin 4100 Oximeter.

Selecting Oximeter Sensor Size

Soft Sensor

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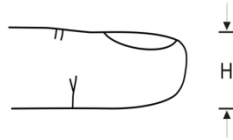
For digit height from 7.5 mm (0.3 in) to 12.5 mm (0.5 in), size small should be selected.

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

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

Flex Sensor

Flex sensor size is determined from the patient's weight.

For a patient who weighs 2-20 kg (4.4-44 lbs), size infant should be selected.

For a patient who weighs over 20 kg (44 lbs), size adult should be selected.

### Choosing the Sensor Application Site

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

Attaching the Pulse Oximeter Module and Sensor

### Nonin 3150 Pulse Oximeter

Step 1 to Step 4

1. Separate the short end of the wristband from the long end.
2. Insert the short end in the loops on the oximeter. Place the probe wire between the short and long end of the wristband.
3. 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
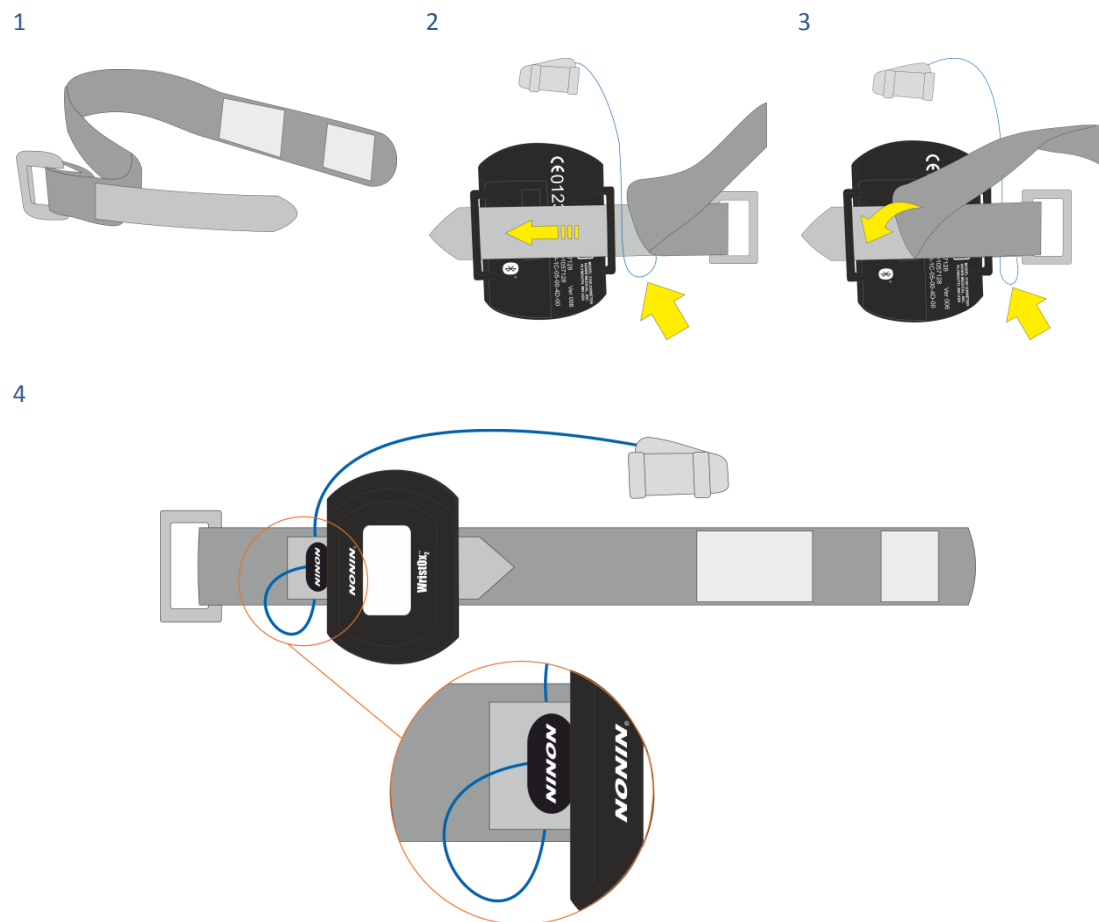
Step 5 to Step 6
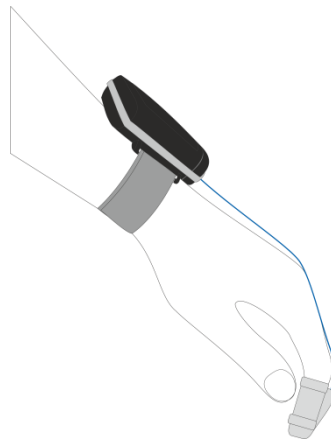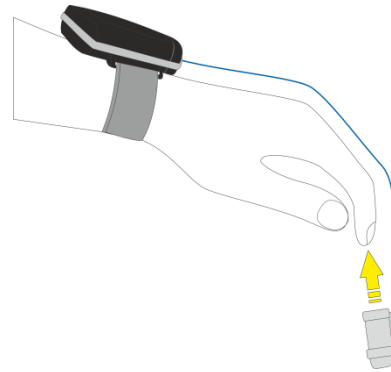
5. Place the wristband around the patient's wrist.
6. Put the probe on a finger.

5
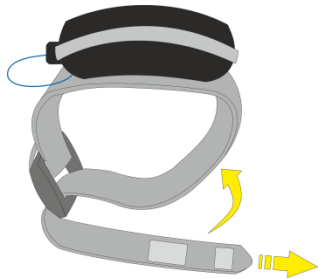
6

Step 7

7. Verify properly the connection status:

   a. The Bluetooth indicator displays with animated bars when the connection is established.

   b. The Bluetooth indicator displays without animated bars when the connection is not established.

7.a   7.b

Maintenance

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

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

To update the T3 device you will need the applicable T3 device software running on the computer which the device is connected to. Please refer to the applicable software user manual for more information on how to perform this task.

No regular testing of the T3 device or accessories, including patient cables, is needed.

> ▸ Remove batteries from the T3 device if the device is not used within 30 days.
> ▸ The T3 device has an internal battery which is automatically charged by regular use. It is recommended to charge the internal battery before the first use or if the device has not been in use for three months or more. The battery is charged by plugging the device to a computer with a USB cable for 6 hours or more.

Environmental Conditions

Temperature	Operation: +5 °C to +50 °C (41 °F to 122 ° F)
	Storage: -20 °C to +50 °C (-4°F to 122 ° F)
Relative Humidity	Operation: 15-95% (non-condensing)
	Storage: 10-95% (non-condensing)
Pressure	Withstands atmospheric pressures from 700 hPa to 1060 hPa

Calibration

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

Cleaning

All reusable components should be cleaned between patient uses.

Clean the T3 device with a soft cloth dampened with hospital grade cleaner that is not corrosive to plastic or metal. Do not pour or spray any liquids onto the device, and do not allow any liquids to enter any openings on the device. Allow the unit to dry thoroughly before use.

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

All Nox cables used with the T3 device are reusable. Clean the cables with a moist cloth using hospital grade cleaner. Do not immerse the cables in liquid and avoid contact of the cleaning solution with the connectors.

For disinfection of the T3 device, Nox cables and gold cup electrodes the following materials may be used:

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

The disposable RIP belts are single patient use ONLY.

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

> ▸ 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.
> ▸ The Nox T3 components are NOT intended to be sterilized.
> ▸ Reusing single-use products on more than one patient poses a risk of cross-infection.
> ▸ Regarding cleaning and re-use of 3rd party components and 3rd party sensors refer to the applicable 3rd party accompanying instructions.

Disposal

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

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

Compatible Sensors and Devices

The following table includes information on accessories, sensors and devices that have been validated with the T3 device. The items listed below are Nox products:

NOX 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 CANNULAS/FILTER TUBE CONNECTOR

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

T3 SYSTEM COMPONENTS

Type	Catalogue Number
Nox Abdomen Cable	562010
Nox USB Cable	562011
Nox T3® Carry Case	568010
Nox T3® Service Kit	569010
Nox Battery Lid	569011
Nox Clip Strap	569013

T3 SYSTEM EXTENSIONS

Type	Catalogue Number
Nox EtCO$_2$ Interface with RespSense ™	545010

The items listed below are 3rd party products:

PULSE OXIMETERS

Type	Catalogue Number
NONIN 3150	7704-001 (Nonin)/ 541010 (Nox Medical)
NONIN 4100	Model 4100

PULSE OXIMETER ACCESSORIES

Type	Catalogue Number
WristOx$_2$ Soft Sensor – Small	553010
WristOx$_2$ Soft Sensor – Medium	553020
WristOx$_2$ Soft Sensor – Large	553030
Flex Sensor with 25 Flexi Wraps, 1 m (39") cable – Neonatal	553110
Flex Sensor with 25 Flexi Wraps, 1 m (39") cable – Infant	553120
WristOx$_2$ Flex Sensor with 25 Flexi Wraps, 30 cm (12") cable – Adult	553130
WristOx$_2$ Wrist Band	564042

CAPNOGRAPHY MONITORS

Type	Catalogue Number
NONIN RespSense™	LS1R-9R (Nonin)/ 545009 (Nox Medical)

MASK PRESSURE TUBING

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

LEADS AND ELECTRODES

Type	Catalogue Number
Blue Sensor® Snap on Electrode, 50 units	554210
Snap on Electrode Disposable, small 25 units	554209
Lead with Attached Electrode 50 cm (20in), 1,5 connector, 12 units	554111
Lead with Attached Electrode 100 cm (40in), 1,5 connector, 10 units	554109
Lead with Attached Electrode 152 cm (60in), 1,5 connector, 10 units	554110

Specifications

T3 Device

DESCRIPTION	PROPERTIES
FUNCTION	
Storage Capacity	▶ 1GByte
Recording Time	▶ Nominal 24 hours with new lithium battery
Internal Channels	▶ Thorax Respiratory Effort
	▶ Abdomen Respiratory Effort
	▶ Pressure
	▶ Respiratory sound/snoring
	▶ Two bipolar (EXG)
	▶ Position
	▶ Activity
External Channels	▶ Oximeter data via Bluetooth
	▶ Capnography data via Bluetooth
PHYSICAL	
T3 Device Dimensions	▶ 79 mm (3.11") W, 63 mm (2.48") H, 21 mm(0.83") D
T3 Weight	▶ 65 g (88 g with battery) (0.14 lbs (0.19 lbs with battery))
T3 Bipolar Inputs	▶ Touch proof DIN 42-802; ±8mV input range AC
Abdomen Cable Length	▶ 57 mm (2.24")
Filter Tube Connector	▶ Hydrophobic Filter with Female Luer-lock inlet - diameter of 13 mm (0.51"), with a 0.2 μ filtering capability
POWER	
Power Source	▶ One 1.5 V AA battery
	▶ Host PC (data download)
Battery Type	▶ Alkaline primary
	▶ Lithium primary
	▶ Nickel-metal hydride battery rechargeable (NiMH)

<u>*DISPLAY*</u>

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

<u>*TRANSMITTER*</u>

***Bluetooth®* Compliance**	▶	Version 2.0
Operating Frequency	▶	2.402-2.480 GHz
Output Power	▶	< 1.62 mW
Network Topology	▶	Point-to-Point: Point-to-Multipoint
Operation	▶	Scatter-Net Master
Antenna Type	▶	Internal
Modulation Type	▶	Frequency Shift Keying/Frequency Hopping Spread Spectrum
Bandwidth	▶	1 MHz

Material Information

COMPONENT	MATERIAL CONTENT	
T3 Device	▶	Enclosure and Proxy: ABS/PC
	▶	Snaps/Pressure Port: Stainless steel
	▶	Display/Keypad: PET
	▶	Clips: Polyester/Steel
Abdomen Cable	▶	Cable Jacket: PVC
	▶	Connector: ABS/PC
	▶	Snaps: Stainless steel
USB Cable	▶	Cable Jacket: PVC
	▶	Connector: PVC/Steel
T3 Carry Case	▶	External Part: PVC/Polyester
	▶	Internal Part: PE foam

Disposable RIP Belts
- ▶ Belt Elastic: Polyester/Dorlastan
- ▶ Connector: ABS
- ▶ Belt Wire: Tin plated copper

> ▶ The Nox T3 components and Nox sensors addressed in this manual are not made with natural rubber latex.

Battery Information

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

- Alkaline batteries can be used to record from 8 to 16 hours.
- Lithium batteries can be used to record from 20 to 33 hours.
- 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 2000mAh battery can record from 10 to 15 hours.

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

> ▶ It is recommended to use fully charged or fresh battery for each sleep recording.
> ▶ All lithium batteries used with the T3 device shall be according to the standard IEC 60086-4 Primary batteries - Part 4: Safety of lithium batteries.

Regulatory Information

Performance Testing and Validation Summary

The Nox 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, including clinical evaluation, 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 EMC and patient safety as well as additional RF testing to assure compliance to FCC regulations and R&TTE.

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

Classifications

- ▶ Degree of protection (applied part) against electric shock: The device is classified as of type BF (see symbol to the left).
- ▶ Powering of the device: The device is internally powered.
- ▶ Mode of operation: The device is intended for **CONTINUOUS OPERATION**.
- ▶ 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 **FLAMMABLE ANAESTHETIC MIXTURE WITH AIR** or **WITH OXYGEN** or **NITROUS OXIDE**.
- ▶ Installation/use of the device: The device is classified as a portable device.

Description of Symbols

- ▶ Consult instructions for use

- ▶ Manufacturer information

- ▶ Date of manufacture
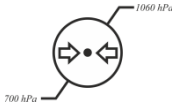
- ▶ Do not re-use

- ▶ Serial number

- ▶ Batch code

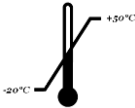|	
REF	▶ Catalogue number
	▶ Type BF applied part (patient isolation from electrical shock)
	▶ This product is not made with natural rubber latex
	▶ In compliance with the European Directive on Waste of Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste
	▶ Non ionizing electromagnetic radiation. Equipment includes RF transmitter: interference may occur in the vicinity of equipment marked with this symbol
	▶ Federal Communications Commission (FCC) logo
CE₀₀₈₆	▶ CE marking indicating conformance to EC directive 93/42/EEC and 2007/47/EC concerning medical devices
FCC ID: V5AASDB1	▶ FCC ID label
Contains TX IC: 1520A-LMX9838	▶ Industry Canada (IC) label
Nox T3	▶ Brand name/Model name
ASDB1 or ASDB1US	▶ Technical name
REV	▶ Revision of device
	▶ Bluetooth® wireless technology
	▶ Temperature limitation
	▶ Humidity limitation
	▶ Atmospheric pressure limitation
	▶ Keep away from rain

▶ Fragile, handle with care

Bluetooth® Wireless Technology

The T3 device uses Bluetooth® 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 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 the Specification section for details on RF specifications for the T3 device.

EMC Information

▶ 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 below in this section for specific information regarding the T3 device's compliance to the standard IEC60601-1-2.

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

The 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

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.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The T3 device 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 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 T3 device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	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 T3 device 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**	**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 T3 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
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,[a] should be less than the compliance level in each

			frequency range.[b]
			Interference may occur in the vicinity of equipment marked with the following symbol:

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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the T3 device is used exceeds the applicable RF compliance level above, the 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 T3 device.

[b] 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 T3 Device

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

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