Introduction

The instructions below are specific to diagnostic testing for Obstructive Sleep Apnea (OSA) of subjects in Sleep SMART. The testing will utilize the Nox T3 Home Sleep Apnea Test (HSAT) device from Nox Medical (https://noxmedical.com/products/nox-t3-sleep-monitor/). In Sleep SMART, testing will take place in a hospital or rehabilitation facility rather than at home. These instructions assume that a research coordinator or other staff member, rather than the subject, will apply the sensors and equipment.
These instructions also assume that the Nox T3 device has already been configured and programmed in KOEO. Please refer to separate instructions to configure the Nox T3 device in KOEO.

Sleep Apnea Testing Kit Components

The following items are required for sleep apnea testing:

- Nox T3 Home Sleep Apnea Test (HSAT) device
- Abdomen cable attached to the Nox T3 HSAT device
- Nonin 3150 oximeter with disposable wristband
- Nonin 3150 oximeter probe
- Nasal Cannula, single use
- 2 Respiratory Inductive Plethysmography Belts (1 set). Size Medium*.
- 3 snap-on ECG leads, reusable
- 3 general purpose monitoring electrodes for ECG, single use
- Alcohol prep pads to clean the electrode placement sites
- Adhesive Tape
- One (1) fresh AA battery and two (2) fresh AAA batteries

If any items in the list above are missing or damaged, please contact the Sleep SMART Testing Hotline **404-480-5149 extension 4006** immediately.

* Large RIP belts are also available when needed outside of the kits.

Diagnostic Test Preparation and Instructions

Before the diagnostic test please do the following:

- Remove nail polish or artificial nails from the finger on which the oximeter probe will be placed. Typically, this is the index finger, although the ring finger may be used as well. The arm of preference to the subject or team should be used.
- The subject is to wear a hospital gown or a comfortable T-Shirt or night shirt to sleep in.
- Confirm all sleep testing kit components are accounted for.
- The study subject should be instructed to sleep in any position that is comfortable.

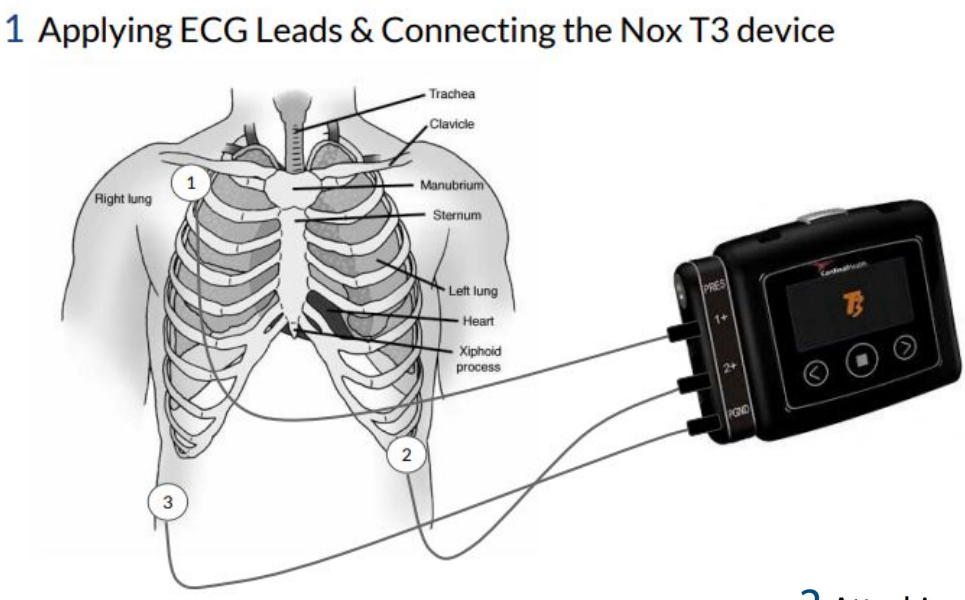
- The study subject is free to go to the restroom at any time during the study. The study does not need to be stopped.
- If any sensors come loose during the testing process, they should be reapplied as soon as possible. Hospital staff caring for the subject should know whom to contact, and how, if they observe loose sensors or other problems during the study.
- In the event of an emergency or if the subject needs to abort the study, stop the Nox T3 Device recording and remove all sensors and equipment as soon as possible.

Sleep SMART Testing Hotline **404-480-5149 extension 4006**

Attaching the Nox T3 Testing Device and the Sensors

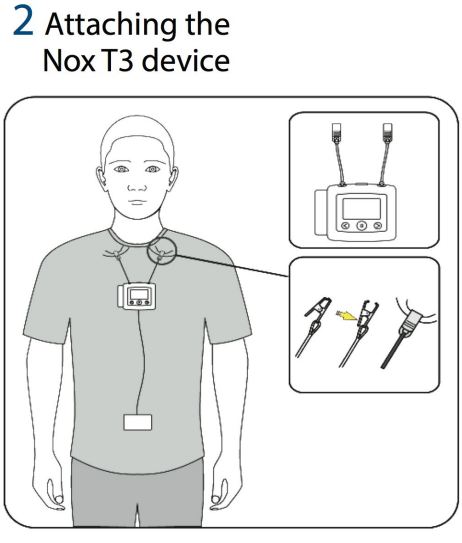
Step 1. Applying the ECG Electrodes and Connecting Snap-on Leads

- Clean the three electrode sites with alcohol swabs (see Figure 1)
- Apply first ECG electrode (1) below right collarbone
- Attach the first snap-on lead to the electrode
- Apply second ECG electrode (2) on lower left ribs
- Attach the second snap-on lead to the electrode
- Apply PGND, or patient ground, electrode (3) to the right hip bone
- Attach third snap-on lead to the electrode
- Ask the subject to assist in pulling the electrodes up through the subject's t-shirt or gown collar
- Connect the ECG electrodes (1) & (2) to the two side connectors near the top of the Nox T3 Device
- Connect PGND electrode (3) to side connector input PGND on Nox T3 Device



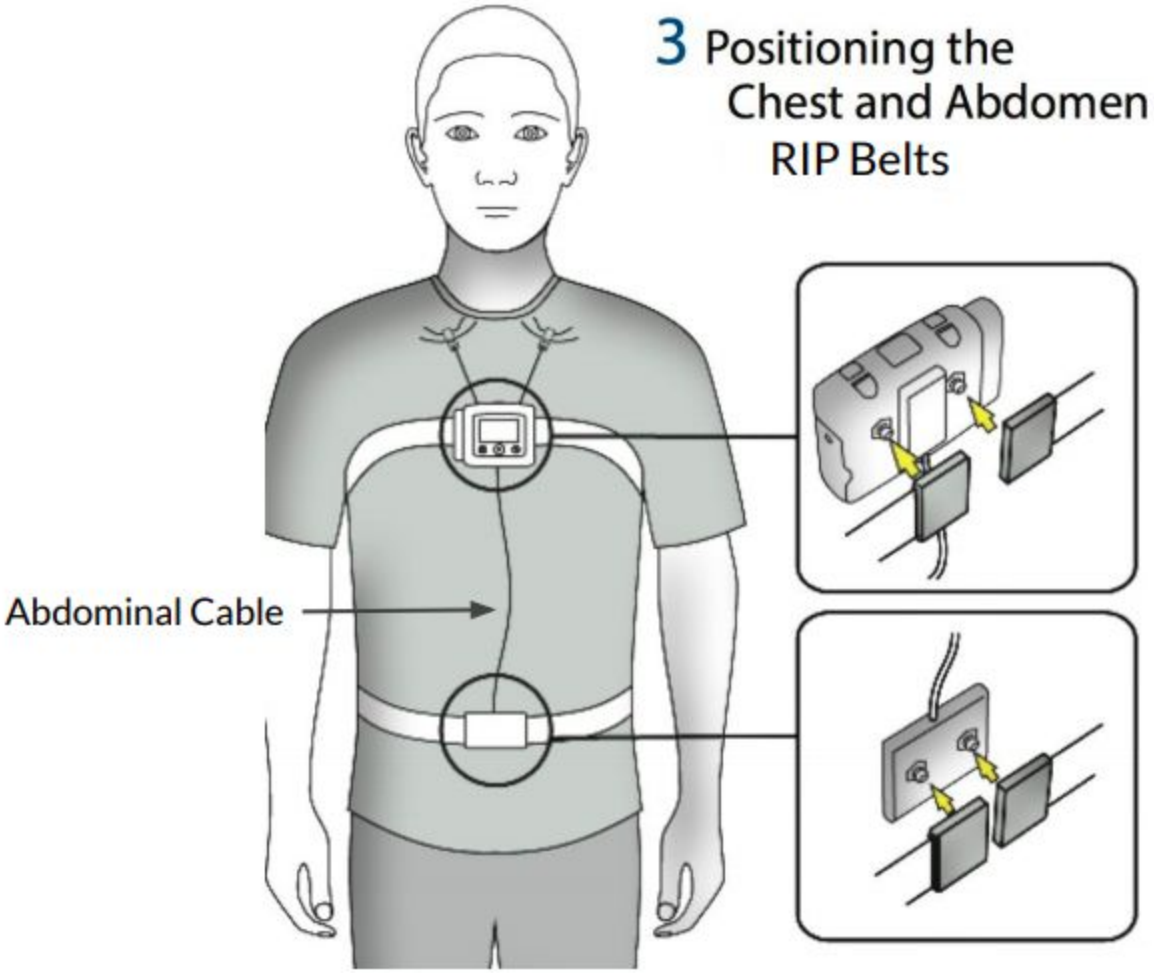
Step 2. Attaching the Nox T3 Device

The T3 device and remaining sensors should be worn over clothing. Snap the alligator clips of the Nox T3 device to the shirt/gown as shown in the image. Make sure the device display faces forward, as shown. The abdomen cable should fall down towards the abdomen.



Step 3. Attaching the Chest and Abdomen Sensors

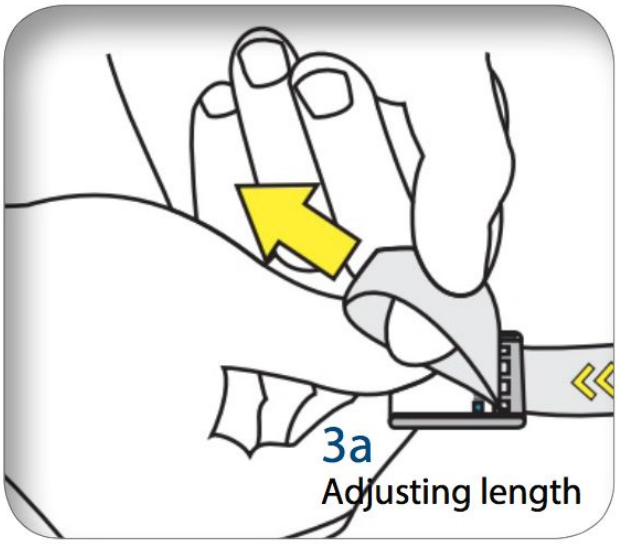
The respiratory inductance plethysmography (RIP) belts are soft bands that wrap around the chest and abdomen and record movements while the subject sleeps. The chest RIP belt snaps directly to the back of the Nox T3 Device. Place the first belt around the chest and snap the ends to the back panel as shown in Figure 3 below. The belt should be positioned roughly one inch below the armpits above the nipple line. In large or immobile subjects, you may need assistance rolling or moving the subject slightly to either side in order to place the RIP belt around the subject.



Step 3a. Adjusting the length of the Chest RIP Belt

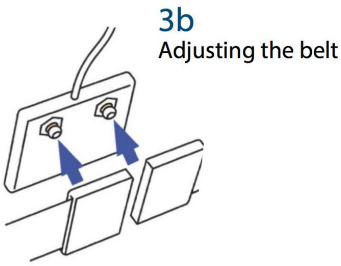
The RIP belts are fitted with loops that allow for adjusting the length until it is snug but comfortable. Length is adjusted by pulling the loop toward you as shown in Figure 3a.

Be careful not to overtighten.



Step 3b. Attaching and Adjusting the Abdomen RIP Belt

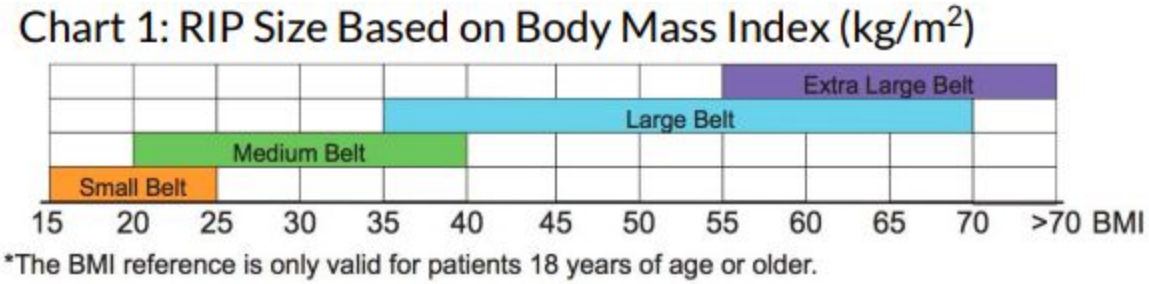
The abdomen RIP belt should be positioned just above the belly button. Adjust the distance between the T3 Device on the chest and the abdomen belt connector by wrapping excess cable around the abdomen belt connector. Once cable length has been adjusted, make sure that the flat side of the abdomen connector is facing away from the subject. Place the second belt around the abdomen and snap the ends to the back panel of the abdomen belt connector as shown in image 3b. As noted above, with large or immobile subjects, you may need assistance rolling or moving the subject slightly to either side in order to place the RIP belt around the subject.



As with the chest belt, the abdomen belt should fit snugly but comfortably and length can be adjusted by pulling the belt loop towards you as shown in Figure 3a.

Choosing the Appropriate Size Nox RIP Belts

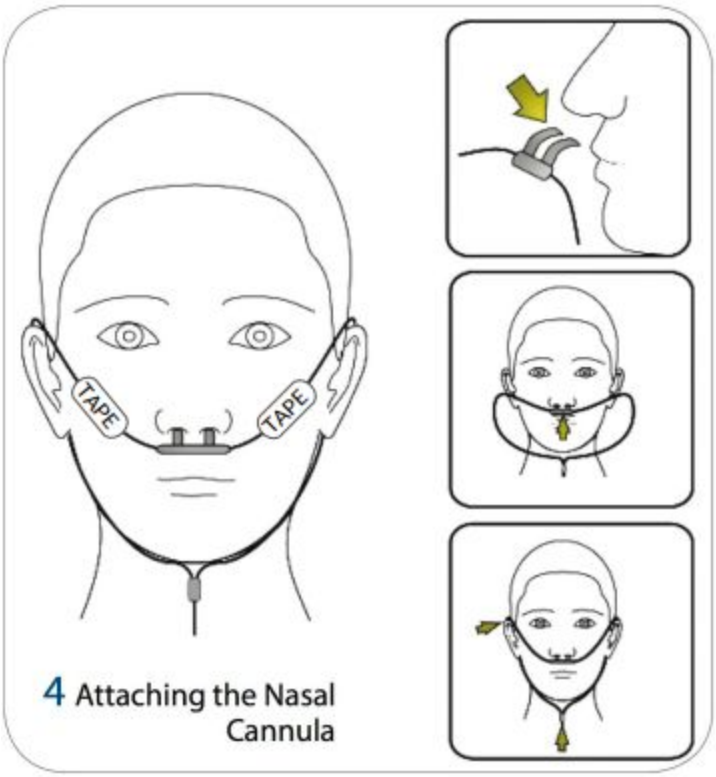
Using Chart 1 as a guide, determine the proper size RIP belt for each subject. Most subjects will require a Medium Size RIP belt (BMI 20 to 40); however, Large belts are available for individuals that fall outside of these measures. 1 set of Large Belts is included with each T3 Kit. Small and Extra Large belts are not included as part of the Sleep SMART Nox T3 device kit.

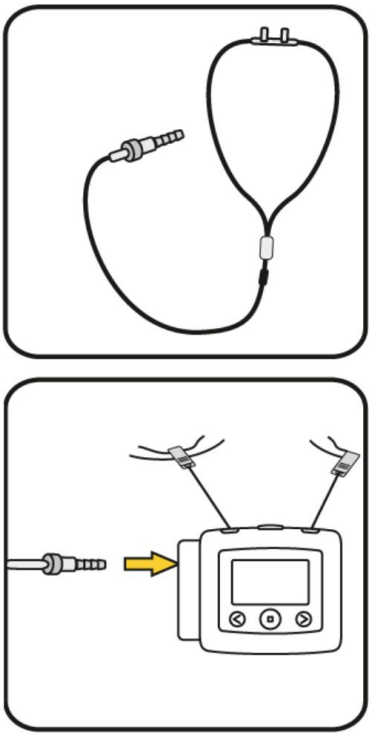


Step 4. Attaching the Nasal Cannula

The nasal cannula measures breathing. One end of the cannula is placed in the nostrils, the other connects directly to the Nox T3 device.
To attach the nasal cannula:

1. Remove the cannula from the sealed plastic bag.
2. Place the prongs gently into the nostrils.
3. The angle of the prongs should curve downward.
4. Pull the cannula tubing over the ears and then position it under the chin.
5. Slide the fastener snugly under the chin to hold the cannula tubing securely in place.
    - A small piece of tape found in the kit should be applied to each cheek in order to hold the nasal cannula in place during testing.
    - Connect the cannula to the silver input marked PRES (pressure port) on the side of the Nox T3 device.





Note: The Nox nasal cannula with filter has a built-in hydrophobic filter and is the preferred way to measure nasal airflow and snoring as it is designed to maximize the signal quality and fits directly with the Nox T3 Device.

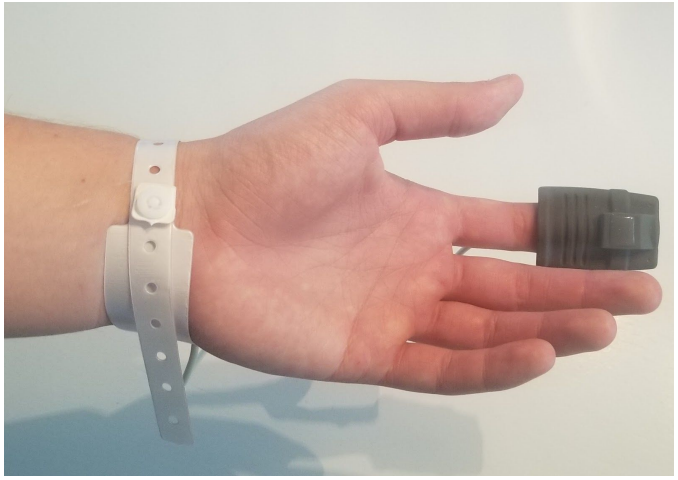
Step 5. Attaching the Pulse Oximeter and Probe

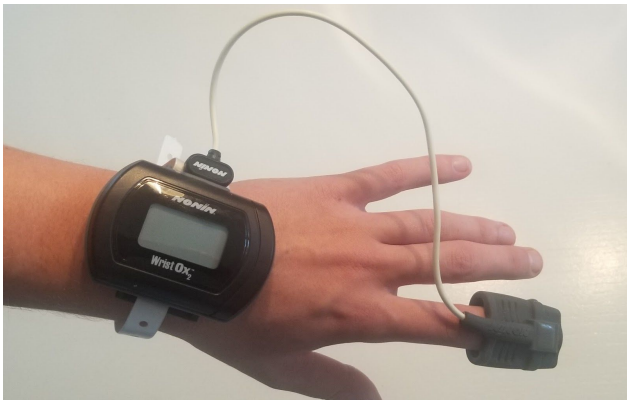
The pulse oximeter measures the oxygen level in the blood as well as heart rate.
The pulse oximeter is supplied with disposable wristbands. The wristbands are single-patient use.

The arm of preference to the subject or research team should be used.
The black velcro wristbands that were originally delivered with the oximeter and probe should be removed from the Nonin 3150 oximeter and should not be used on subjects.

The disposable wristband is run through the loops underneath the oximeter. The wider part of the wristband should be situated at the top of the oximeter where the oximeter probe is connected.

Place the wristband and oximeter around the wrist. Adjust the wristband to the desired hole. Insert the knob to the hole and close the snap to secure in place. Be careful not to make the wristband so tight that it will constrict circulation (especially if an IV line is distal to the wristband), prove uncomfortable, or fail to accommodate some swelling of the wrist as can sometimes occur in hospitalized patients.
It is possible to cut away any excess portion of the wristband with scissors. The wristband is single-patient use. The wristband cannot be readjusted once it is snapped in place. It will need to be cut off the subject with scissors and a new wristband applied.





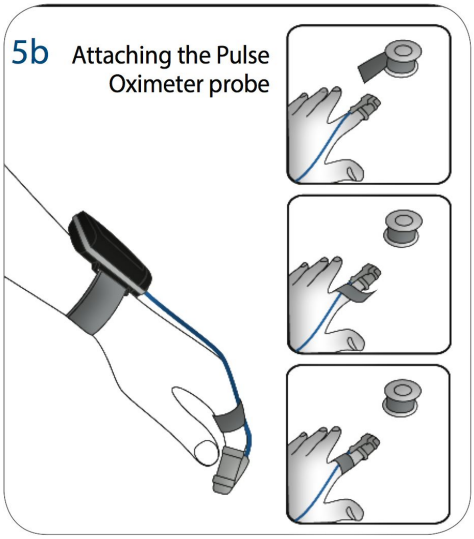
Step 5b. Place the probe on the index or ring finger, ensuring that the finger reaches the end of the probe. Do not push the finger all the way through the probe.

Direct the probe cable along the index or ring finger, as shown in Figure 5b below, and wrap tape (from kit) loosely around the base of the finger to secure the cable in place.

The Pulse Oximeter display will turn on automatically when the probe is placed on the finger. The display will show:

- Oxygen Saturation
- Pulse Rate
- Bluetooth Connection
- Battery Status

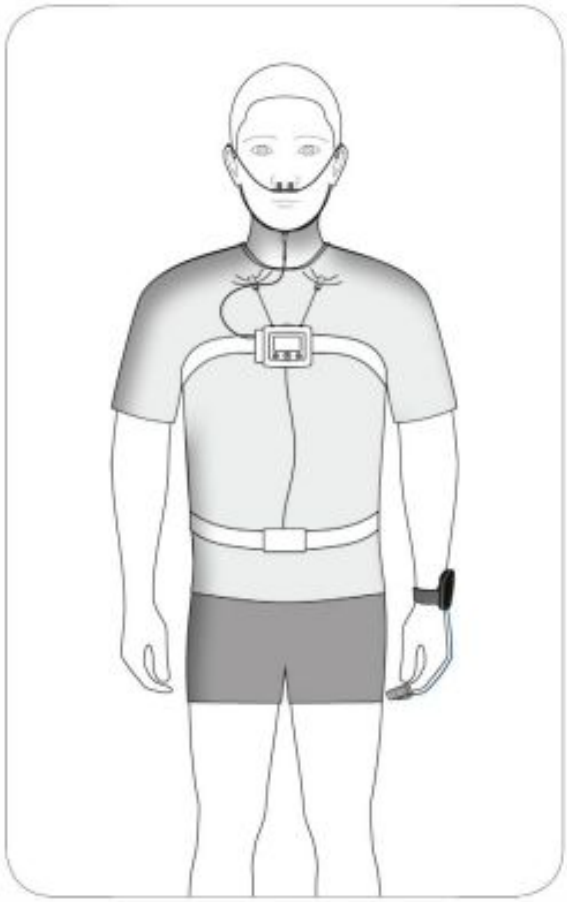
If the display remains blank, hold down the button on the oximeter for three (3) seconds to activate the sensor and probe.



Precautions and Additional Notes

- Ensure proper oximeter sensor placement at the tip of the finger as noted in the figures above
- Do not extend the finger beyond the end of the probe
- Do not overtighten the pulse oximeter around the wrist
- Do not use any component of the kit if it appears to be damaged
- Wrap tape around the probe cable at the base of the finger for stability as shown in Figure 5b above, but do not make this tape too tight
- Remove nail polish, artificial nails or any other artificial material from the finger as these will interfere with the accuracy of the probe
- If the index finger can not be used for any reason, use the ring finger
- When the Pulse Oximeter display turns on, verify that the battery signal is full, and if not, replace the batteries with two new AAA batteries

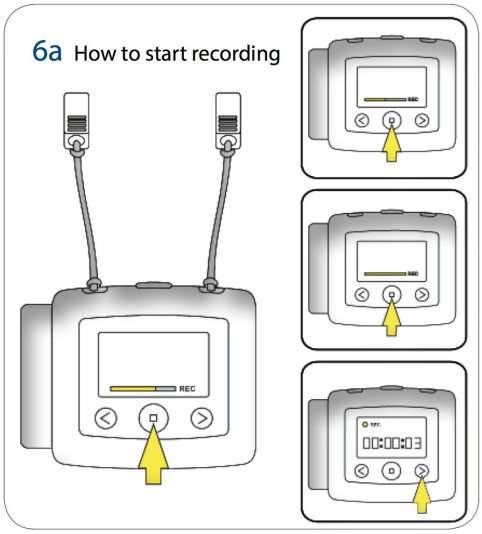
- Confirm all components have been secured as noted in Figure 5c before proceeding



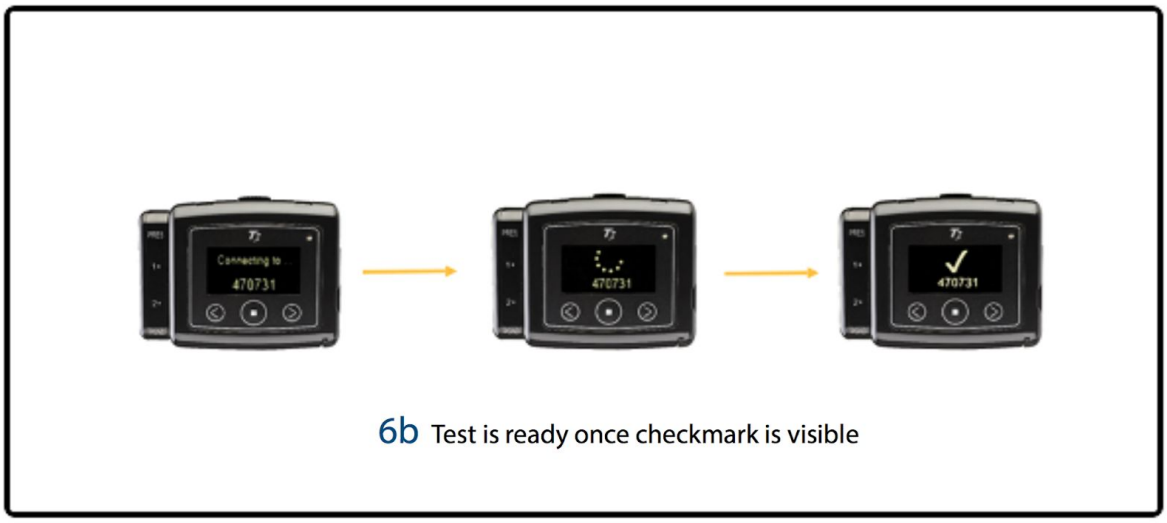
5c Proper placement of Nox T3 device and sensors

To Start the Recording

Before starting a recording, check the battery power symbol in the upper right hand corner of the display. If this does not appear completely full, replace with another new AA battery. To start the recording, press and release the middle button on the face of the Nox T3 Device as shown in Figure 6a. Text will appear on the display, reading “Hold Middle Button Down to Start Recording”. Now hold down the middle button for about three (3) seconds until the progress bar is replaced by a timer reading “00:00:01”.



Once the timer is visible, release the middle button and press the Right Arrow button once. You will see the first of the three (3) screens shown in Figure 6b.



As noted on the left image in Figure 6b, after pressing the Right Arrow button, you should see “Connecting To” on the display. The number shown indicates the serial number of the Pulse Oximeter that is pairing via Bluetooth with the Nox T3 device. Next, as noted on the middle image in Figure 6b, a “rotating spiral” indicates that the Bluetooth connection is in process. Finally, as seen on the right image in Figure 6b, once the connection is successful, a “check mark” appears on the display.

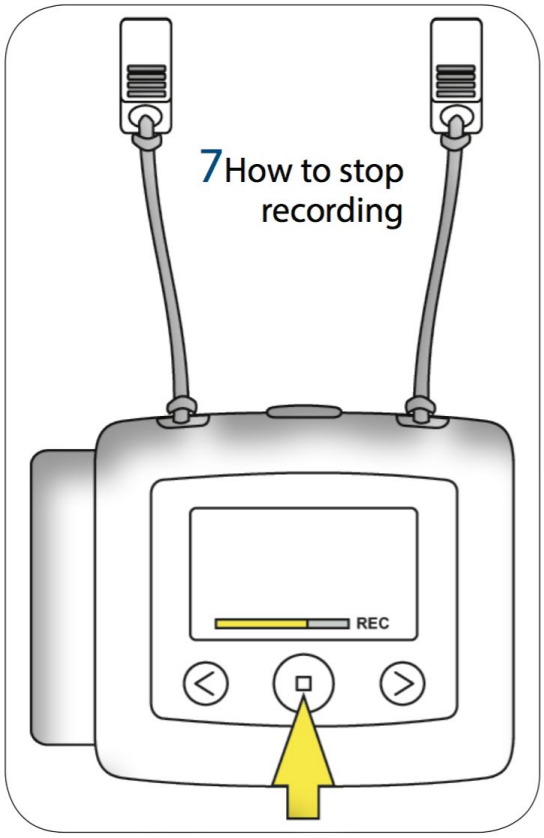
If an X appears instead of a checkmark, please call the Sleep SMART Testing Hotline **404-480-5149 extension 4006** immediately.

After The Testing Has Started

To conserve battery power, the display of the Nox T3 device will turn off after about 30 seconds. To turn on the display at any time, simply press the middle button on the face of the Nox T3 device once. The counter should come to view. The screen will turn off again after 30 seconds of inactivity. In addition, you may notice a green flashing light on the Nox T3 display. This simply indicates that the device is recording.

Let the subject and hospital staff caring for the subject know - verbally, through a note at the bedside, or by both means - what to do if the subject needs to get out of bed in the middle of the night, for example to use the restroom. In this event, do not remove anything or stop the recording. Take care not to get the pulse oximeter, oximeter probe, or other sensors wet. If the nasal cannula has become dislodged, simply re-adjust the cannula, if possible. If something has become fully disconnected during the night or if the pulse oximeter display is blank after the recording has started, please call the Sleep SMART Testing Hotline **404-480-5149 extension 4006**.

To Stop the Recording



To stop the recording, press the middle button on the face of the Nox T3 device once and release. The display will illuminate. You will see the counter showing the duration of the study in hours, minutes and seconds. As shown in Figure 7, hold down the middle button for about three (3) seconds until the progress bar is replaced by the stopped timer. This indicates the recording has been stopped. Release the middle button.

Remove the sensors from the subject.

Troubleshooting

If an “X” appears on the T3 display when pairing with an Oximeter

This means that the pairing of the Nox T3 device and the Pulse Oximeter was not achieved and the programming of the Oximeter failed. It will be necessary to start the pairing process again. Before that can be done, the Nox T3 study needs to be stopped and the Oximeter needs to be restarted. To restart the Oximeter, remove the batteries and re-insert the batteries into the Oximeter. Hold down the button on the oximeter for at least three (3) seconds. Now, restart the Nox T3 study.

Battery replacement

Before each Nox T3 study, replace the one (1) AA battery in the Nox T3 to ensure adequate battery power for the recording. If the AA battery in the Nox T3 device depletes before the study is over, you can replace the battery and restart the study. Prior to each study, replace the two (2) AAA batteries in the Pulse Oximeter. If the AAA batteries deplete in the Oximeter, you can replace them; however, it will not be necessary to stop and restart the Nox T3 Study.

The display turned off

After 30 seconds of inactivity, the screen of the Nox T3 device will turn off in order to save battery power. This is normal and does not impact the collection of sleep data. To check whether the device is still recording, press the middle button on the face of the Nox T3 device to turn on the display. If the Nox T3 device is recording, the timer will still be counting.

If the study needs to be stopped or aborted

If the Nox T3 study needs to be abruptly stopped or aborted, simply turn off the Nox T3 device and remove all the sensors. This may occur, for instance, if a subject requires an urgent test or procedure while the study is in progress. In this case, after stopping the study, you may restart the study again that same night by simply re-attaching the sensors and restarting the study as if it were a new Nox T3 study.

Cleaning Procedures

Per the manufacturer, no part of the Nox T3 system requires sterilization.

Any single-use items, such as the single-use oximeter wristband, nasal cannula, RIP belts, ECG monitoring leads and all batteries should be discarded at the end of each study.

Reusable items, such as the snap-on leads, Pulse Oximeter, oximeter finger probe (inside and outside), the Nox T3 device itself, and Nox Abdomen Cable should be wiped down with alcohol prep pads. Adhesive residue from tape on the oximeter probe wire can be removed with the alcohol prep pads.

The Nox T3 Device: Clean the device with an alcohol prep pad. 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 snap-on leads and Nox Abdomen Cable with alcohol prep pads. Do not immerse the leads in liquid and avoid contact of the cleaning solution with the connectors.

The Pulse Oximeter: Wipe down the oximeter and finger probe with an alcohol prep pad. 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.

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.