

Chapter 241 L-PVDOMICS

Clinical Center Sleep Study Monitoring MOP

41.1 Purpose and Background:

Sleep apnea occurs when the airway is blocked for 10 seconds or greater, reducing or preventing airflow repeatedly during sleep. Other conditions can exacerbate sleep apnea and related hypoxemia resulting in inflammation among many other side effects and can cause serious complications such as diabetes and cardiovascular disorders. Typical treatment of sleep apnea is positive airway pressure (PAP) which gently opens the airway to prevent collapse and often improves oxygen levels.

A nocturnal sleep or oximetry study allows an opportunity to understand how changes in the degree of sleep apnea and low oxygen during sleep may be associated with negative clinical outcomes in PH, or worsening in other parameters, such as heart function, from the parent study to now. The collection of rich phenotypic data in the setting of pulmonary hypertension as proposed provides a unique opportunity to examine the sleep-pulmonary hypertension inter- relationships on a more granular level.

What is sleep apnea?

Sleep apnea occurs when the airway is blocked for 10 seconds or greater, reducing or preventing airflow repeatedly during the night. Inflammation from the apnea and low oxygen, as well as other side effects, can cause serious complications such as metabolic and cardiovascular alterations and cardiac arrhythmias.

What does sleep apnea have to do with pulmonary hypertension?

Sleep apnea places direct stress on the heart because it changes the pressure in the chest when the airway is obstructed. This, along with intermittent lowering of oxygen levels, changes in blood pressure and heart rate regulation, inflammation, etc. can worsen pulmonary hypertension and cause higher pressures in the lungs.

Why do I need another sleep test? I did one in the last research study.

Sleep apnea can change over time and vary from night to night. We understand sleeping with the device is uncomfortable but often patients sleep better the second time they are tested, resulting in a better test. We are collecting detailed information on your breathing and oxygen patterns and reviewing any changes over time, as well as comparing data from your last study, to investigate whether these changes on oxygen levels and sleep apnea severity worsen pulmonary hypertension.

What is the benefit of a sleep test when I am sleeping with a CPAP machine already?

A sleep test can show if you are receiving proper ventilation during the night. Sleep apnea can change over time and vary from night to night. If your sleep apnea is well-treated, then it would be helpful to see if your pulmonary hypertension measures also improve.

I had a clinical sleep study after my results came back last time. Do I need another test?

No, we can use the results from your test done in the clinic instead if conducted within the last year.

41.2 Logistics for Sleep Core Reading

The Sleep Reading Core under the direction of Dr. Reena Mehra (email: mehrar@ccf.org), is part of the Data Coordinating Center at the Cleveland Clinic, Cleveland, Ohio. Additional contact information can be found in the L-PVDOMICS Address Directory. All sleep study files will be transmitted to the DCC Sleep Core for scoring of the data and assessment of quality grade.

41.3 Participation Overview

This manual provides standard operating procedures for the management of Overnight Sleep Study Monitoring for the L-PVDOMICS Study. This manual will address the acquisition, processing, scoring, archiving, and transfer of data; as well as the certification of Clinical Centers. If the participant has had a

sleep study within the last year of study enrollment, then it is at the discretion of the Clinical Center as to whether a research sleep study should be performed.

41.3.1 Sleep Study for L-PVDOMICS Study

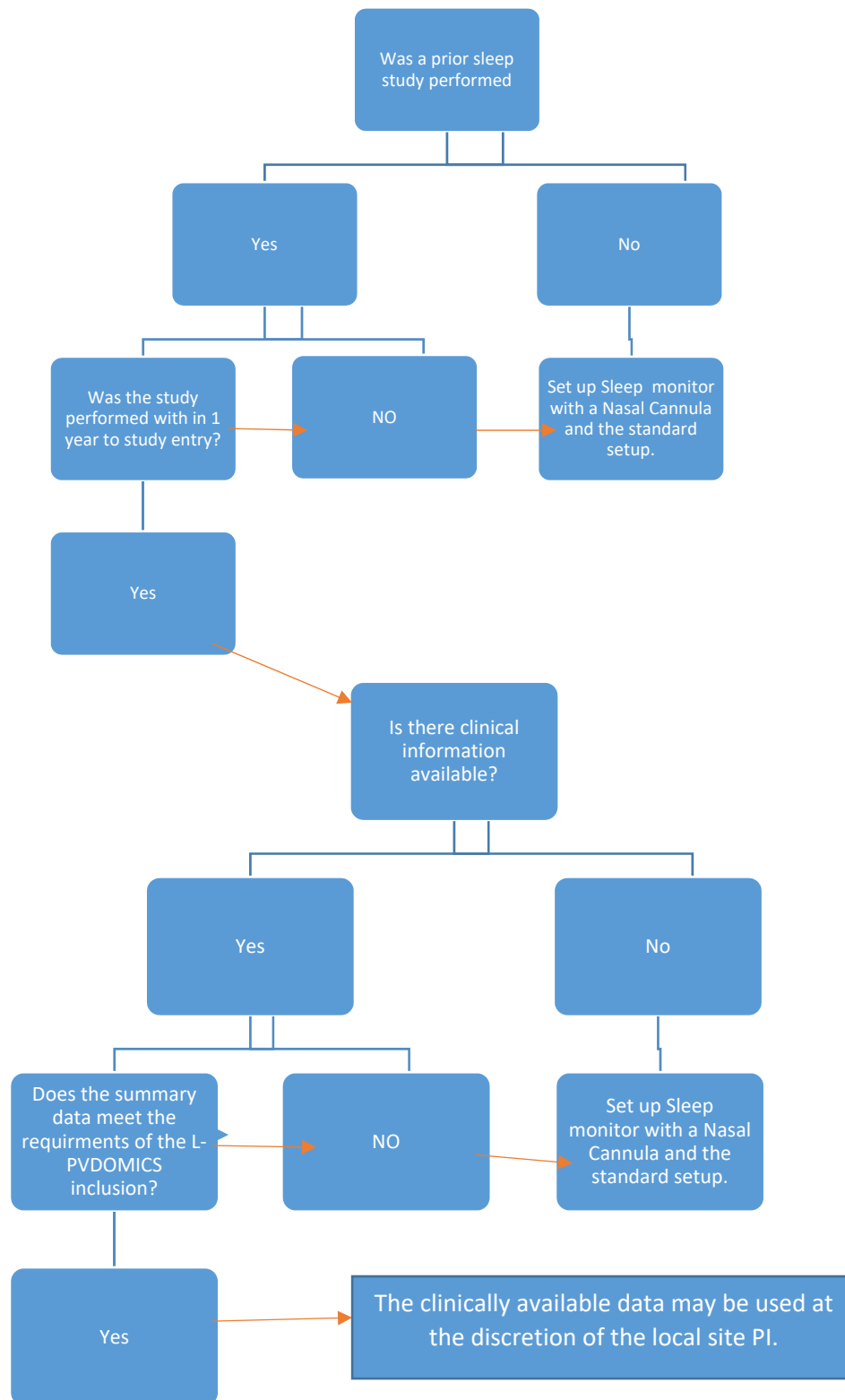
Overnight sleep monitoring is encouraged for all enrollees, using a portable home monitoring system (Nox T3, Carefusion) with either oximetry-only, or full respiratory recording of nasal airflow, chest wall and abdominal motion, pulse oximetry, heart rate, and position for quantifying overnight oxygen saturation patterns. Participants already receiving oxygen supplementation and/or positive airway pressure therapy on a regular, nightly basis will be studied during use of their equipment. Each center will purchase the equipment necessary to perform these studies, and study personnel will be trained in the proper application of the devices.

41.3.2 Clinically Performed Sleep Study

If a level 1 participant has had a clinical sleep study since their PVD study enrollment, or is scheduled for a future clinical sleep study, then it is at the discretion of the Center PI as to whether a research sleep study should be performed. Results of clinical sleep studies will be recorded for patients in all enrollment levels, as well as any additional testing or interventions obtained as a consequence of the portable monitoring. The sleep study report is electronically transmitted to the DCC for integration into the database and for statistical analysis. When available, the Sleep Core will request transmittal of the raw data of the clinically performed sleep study (if conducted at the clinical lab of the site) in an EDF format for central review quality assessment and scoring. Sleep studies will be scored using standardized methods for home sleep apnea testing and will conform to American Academy of Sleep Medicine guidelines.

<u>PVDomics Historical Sleep Data Summary</u>		
<u>Recording Information</u>	<u>Respiration Overview</u>	<u>Saturation</u>
Recording Date	AHI	Desaturation Index
Recording Duration	ODI	Lowest SpO2
Bed time Start	<u>Respiratory Indices</u>	Average SpO2
Bed time Ends	Apnea Index	Desaturation < 90%
Total Time in bed	Hypopnea Index	Desaturation <85%
		SpO2 time <90%
		SpO2 time <85 %
<u>Pulse</u>	<u>Respiratory Count</u>	
Average Pulse	Obstructive Apnea	
Highest Pulse	Central	
Lowest Pulse	Hypopneas	

*See L-PVDOMICS Historical Sleep Data Form (Form 555)



41.4 Sleep Study Overview

All sleep monitoring devices and kits should be labeled with the site's contact information.

* All equipment must be tested and labeled before given to a participant for home use.



Each unit should be labeled with the Center ID and a chronological number. Each unit and unit packaging container should be labeled with the Center address and a contact phone number.

Each participant will be taught how to self-apply the sensors for the portable sleep testing to take place in their own homes. Application of sensors will be demonstrated by L-PVDOMICS Study-trained certified staff. Staff must be able to follow procedures in this manual in order to produce technically acceptable overnight sleep recordings.

- Participants will be asked to demonstrate their understanding of sensor placement and will be provided with simple pictorial and written instructions.
- Participants will be asked to apply the sensors before bedtime and remove them upon awakening.
- Participants will be asked to bring with them their Positive Airway Pressure device with them to the visit if it's known that they are currently on treatment.
- Participants are to return monitor and kit to the clinical center using local site funds (by mail, courier or direct drop-off)

At the Clinical Center:

- Units are cleaned prior to data processing.
- Data are downloaded to local computers.
- Downloaded study data are reviewed by the local center coordinator to ensure data integrity
- Data file is transmitted electronically to the Sleep Study Core via secure file transfer protocol.

At the Sleep Study Core:

- Sleep Core staff will review data file to determine study quality.
- Each sleep study is scored using approaches that comply with AASM guidelines for standard hypopnea and apnea definitions.

- If Sleep Core staff determines that a study that does not meet minimal quality grades (3 hours of score-able data) the center will be informed and coached, as needed, to help future participants collect quality sleep data.
- Note: a repeat sleep test for the L-PVDOMICS Study will **NOT** be completed for research purposes.

Certification is essential to ensure that the equipment, software, and recording used in this study are standardized and consistent. All L-PVDOMICS clinical centers will convert the data file to EDF and transfer the file into the SSH home directory for L-PVDOMICS on the DCC server.

41.5 Center and Technician L-PVDOMICS Study Certification

The Sleep Core requires at least one (1) Staff member at each collection Center to be certified to collect for the L-PVDOMICS study. This certified research staff will be responsible for protocol adherence by any study personnel performing data collection at that Center. Certification must be accomplished prior to the Center performing actual data collection.

Sleep monitoring data collection certification is provided upon demonstration that the staff member has:

- Basic understanding of sleep-specific study objectives and protocol for L-PVDOMICS.
- Understanding of equipment and application of specific sensors to be used for the sleep monitoring data acquisition.
- Demonstrated compliance with the study protocol for sleep monitoring data collection and data transmittal to the Sleep Core including removal of identifier information and correct re-identification with participant ID and study date.
- Submission of two acceptable overnight pilot studies (non-participant) recordings. Pilot studies on non-participant are conducted to assure that all staff are familiar with the equipment and protocol.

These data file submissions must be correctly de-identified, re-identified with a standard convention, successfully converted to EDF format and placed on DCC server using SSH. This serves both as part of the research staff certification process and as practical experience in using the equipment in the study environment. Certification studies also allow for verification that all sensors and equipment are functioning properly before being used on a study participant, and that post-acquisition treatment and transfer of data is consistent with study protocol. The certifying research staff does need not to actually perform every required task, but will be responsible for the acceptable completion of each task.

To be considered acceptable, the recordings submitted for certification must:

- Have adequate quality signal on each channel (i.e. all electrodes must work) and signals must be relatively free from artifact.
- Reflect sleep monitoring protocol and procedure including placement of electrodes and sensors.
- Have correct study identification as a certification recording using the following format when naming (or re-naming) the recording: {LSleep}_[CR][staffusername]_[complete date of study].

An example of this format would be:

LSleep_CRsmiths_10292016

- The electronic recording file must be accompanied with paperwork that matches this naming convention and additionally includes the technician identification and equipment ID.
- Include Form 552-Download and File Transmission.

41.6 Equipment and Supplies

After written informed consent is obtained, participants will be instructed in the use of the Nox T3 portable monitor. This battery-operated device can store data at 200 Hz, with 1 GB of storage capacity allowing storage of data from up to 1-24 hours of recording. The local center should contact their Research Administrator for information on insurance coverage for the Nox T3 device to cover any loss, stolen, or damaged devices. Any device insurance policy must be covered using local Center funds. The sleep monitor service agreement will need to be in good standing, if expired the agreement will need to be renewed using local Center funding.

The following supplies need to be purchased using local Center funds:

Nox-T3 portable sleep monitor- The sleep monitoring device and accessories should be stored in a clean, dry space. The device is not waterproof. Each device will be tested for a minimum of 4 hours during normal work hours to assure all signals are working accurately before sleep data collection begins.

- **Nox Cannulas/ Filter Tube connectors-** for measurement of flow for apnea detections. If a filter is not directly attached to the cannula then the connector will need to be purchased. The cannula will be disposed of after each single participant use. A new cannula will be sent home with each participant.

Part Number: 69594 40 Nox Cannula with Filter – Adult

- **ECG leads and electrodes-** Single use electrodes will be snapped on three wire leads to allow the recording of ECG activity on two channels. One electrode shall be placed approximately 3 – 5 cm. (2 finger breadths) below the midpoint of the right clavicle and one below the midpoint of the left clavicle. One electrode shall be placed approximately on the lower left abdomen within the rib cage frame (intercostalspace) 3 – 5 cm. The ECG data are collected at a sampling rate of 200Hz. (.ie Kendall™ Foam electrodes). The snap leads may be purchased at any medical supply chain (ie. MVAP).



- **NOX RIP belts** = Respiratory Efforts are monitored utilizing respiratory inductance plethysmography (RIP), secured around the thorax and abdomen. The sensors are snapped into the designated areas on the portable sleep monitor. Measure the circumference around the participant

chest (belt circumference will be centered under the armpit) and abdomen (belt circumference will be centered over the belly button) to determine what size belt is needed.

Part Number: 69590 Nox RIP Belts, Disposable - Small (belt size 50-85 cm (20-34 in))

Part Number: 69591 Nox RIP Belts, Disposable - Medium (belt size 75-125 cm (30-49 in))

Part Number: 69592 Nox RIP Belts, Disposable - Large (belt size 100-170 cm (39-67 in))

Part Number: 27641-001 14 Nox RIP Belts, Disposable - Extra Large (belt size 125- 210 cm (49-82 in))

- **Nonin and Wrist Ox**= Pulse oximetry is measured through a DC channel and is designated SaO₂ on the montage via a reusable fingertip probe. The sensor is placed on the index finger (preferably on the non-dominant hand). The sensor is plugged into the designated area on the wrist device.

Part Number: 69466 1 WristOx2TM, Model 3150

- **Mask pressure tubing and a CPAP adapter** = For participants using **Positive Airway Pressure (PAP) Flow** in the study, flow should be measured from the output signal from the PAP device, which interfaces with a port on the PAP mask and tubing that connects to the Nox T3 device.

Part Number: 22990-001 50 CPAP Mask Tubing and TRP-740 adapter

- **Batteries**= AA (Nox sleep monitor) and AAA (Nonin pulse oximeter) batteries (alkaline and Lithium)
- **Scanpor** = Paper tape that will be used to help secure leads.
- **Sandwich bags** = Bags will be used to separate wires for easy home application.

41.7 Participant Contradictions and Safety

Sleep monitoring is a non-invasive procedure with little to no risks. If there is any question as to the competency of the participant to receive and take home a NOX-T3 portable sleep monitor, the Center PI should be contacted.

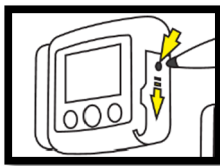
Personnel instructing/performing the sleep monitor setup for the L-PVDOMICS study should be trained in the appropriate placement of the electrode and leads, competent at using the necessary equipment, and familiar with this MOP.

41.8 Sleep Monitor Setup

The Noxturnal® software interacts with the NOX-T3 device for set-up and analysis. Minimum software version requirement of **4.4.214926** or above required. If higher, the images provided in this manual may appear different. Review the system requirements and contact your administrator if installation privileges are needed.

41.8.1 Using the Noxturnal® Software: Open the Noxturnal® application, . Navigate to the **Start Page**, this is where the user interfaces with the T3 devices and the recorded data. This sheet also guides the user through the most common tasks to perform in the application.

41.8.2 Connecting the T3 device: Start by connecting a T3 device to a USB cable to the computer. The USB connector is placed under the battery lid. To open the battery lid, press with a pen or similar tool on the battery lid pin and slide the battery lid downward.

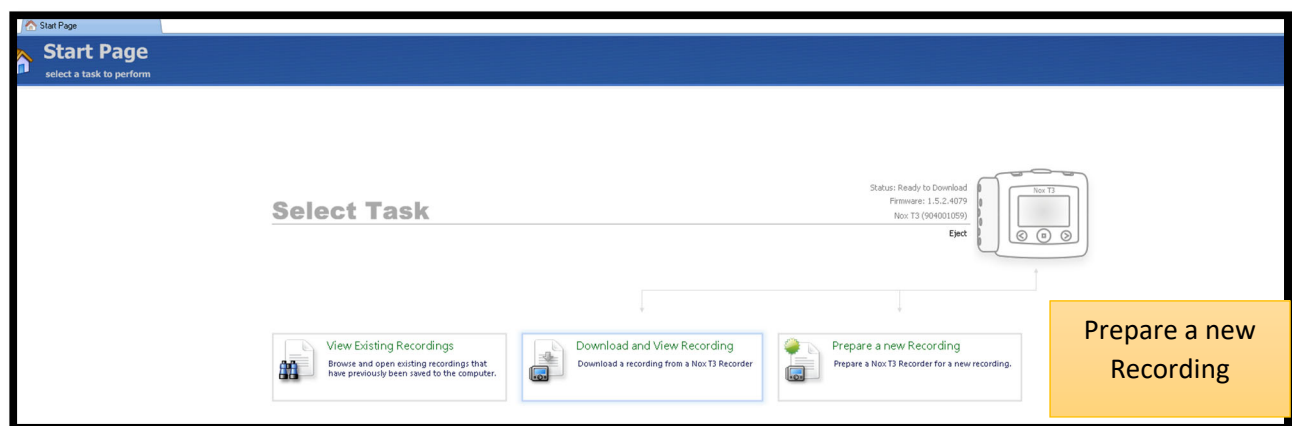


Refer to Preparing the NOX-T3 for new recordings:

<http://www.carefusion.com/our-company/video-gallery?video=4770674290001>

41.8.3 Create a new recording template: It is suggested to create a template for the initial set-up of each type of study. This is completed before setting up the device for patient use. **See Section 41.20** for instructions on how to create a new recording template before moving to the next step.

41.8.4 Once templates have been configured and you are ready to set up the device for a patient test, plug in the device and ensure it's recognized within the software.



41.8.4 Select 'Prepare a New Recording' and choose the correct Recording Template:

Configure Device for a New Recording

Select template and devices

1 Configuration 2 Schedule Recording 3 Patient Information

Recording Template:
T3 with ECG without CPAP (modified) [edit...](#)

Other Devices:
Nonin 3150 Oximeter
Pin: 462898

Channels:
Activity
Position
Thorax RIP
Abdomen R/L
Audio Volume
1: ECG
2: ECG

Channels selected to record

**Study Type:
Nasal Pressure,
PAP, Oximetry-
Only, or
Supplemental
Oxygen**

Nonin PIN located
on the back of the
Wrist OX

[Next >](#) [Finish](#) [Cancel](#)

The screen will show the configuration setup once you've selected the template. Confirm channels are correct in lower left corner.

Ensure NONIN 3150 PIN is correct and is paired with the T3 device.

Select 'Next' to schedule the recording.

41.9 Scheduling a Recording

After selecting the appropriate template (PAP, WITHOUT PAP, or Oximetry Only), select **next** to schedule the recording time. **Start recording option** to schedule a specific recording time. The device will turn itself on and automatically start recording at the specified time.

41.9.1 Start the device 30 minutes before the participant's anticipated scheduled time to bed and select the box (fourth option) for **24 Hours** duration:

Configure Device for a New Recording

1 2 3 4
Device Configuration Schedule Recording Battery Type Patient Information

☐ Manually Start Recording

☒ Start Recording At:

Number of Nights: 1 Date: July, 2016

Start Time: 10:00:00 PM

Sun	Mon	Tue	Wed	Thu	Fri	Sat
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31	1	2	3	4	5	6

Today: 7/1/2016

Duration:

☐ 7 Hours ☐ 8 Hours ☐ 10 Hours ☒ 24 Hours ☐ Unspecified

[Help](#)

< Previous Next > Finish Cancel

41.9.2 Click the **Next** button to continue to the participant information page and enter the participants' information including Study ID. Full Name will be the Center ID, ID will be the participant study ID and Date of Birth will be the date the device is initialized/set up, and the comments section will contain the study personnel name who set up the device.

Configure Device for a New Recording

1 2 3 4
Device Configuration Schedule Recording Battery Type Patient Information

Name

Full Name: Site ID: For example CCF ID: Participant ID

Gender

☒ Male ☐ Female

Date of Birth

☒ 7/1/2016 ☐ N/A

Body Metrics

Height: cm Weight: kg BMI:

Comments

Rawan Nawabit

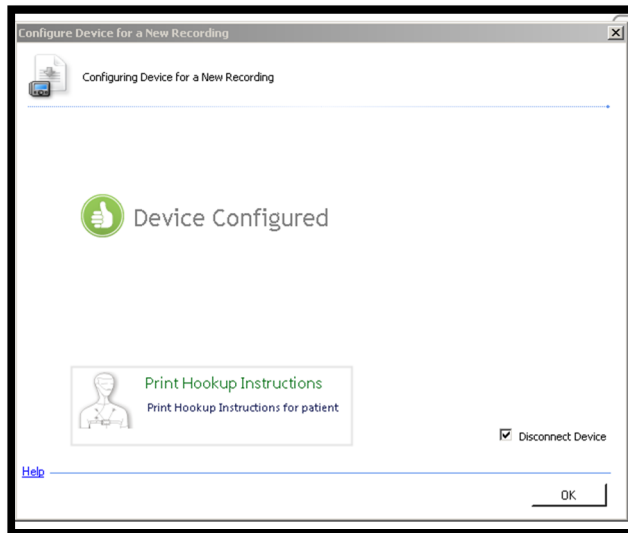
[Edit...](#)

[Help](#)

< Previous Finish Cancel

41.9.3 After entering the information, click the **Finish** button to send the configuration to the T3 device. Finally a confirmation page appears confirming the T3 device has been configured. Once you have completed the setup check the box at the lower left corner to disconnect the device.

Do not use the hook up instructions from the software, use the instructions located in the manual. This action will allow safe removal of the device from the computer.



41.9.4 Insert Battery into the Device:

Before you set-up or pack up the device for the participant:

***** It's important place a new battery into the device prior to each deployment. *****



41.10.1 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.

41.10. 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).

41.10. 3 Close the battery compartment by pressing the lid back towards the device without causing any strain, then slide

41.9.5 Nonin Pulse Oximeter: Insert two AAA batteries in the back of the device.

The oximeter will turn on once it has sensed a finger in the sensor.

41.12 Participant Preparation

41.12.1 Identify participant using two separate identifiers. Explain to the participant the rationale behind conducting the sleep study. (For example: *'The L-PVDOMICS study provides a platform to better understand the relationship of sleep apnea and pulmonary hypertension.'*)

41.12.2 Briefly explain the procedure and answer the participant's questions before the setup.

41.12.2.1 Explain that the sleep monitor requires access to the chest and chest wall, abdomen, head, and wrist and finger of the non-dominant hand.

41.12.2.2 Explain that wearing the device may be a little uncomfortable for some.

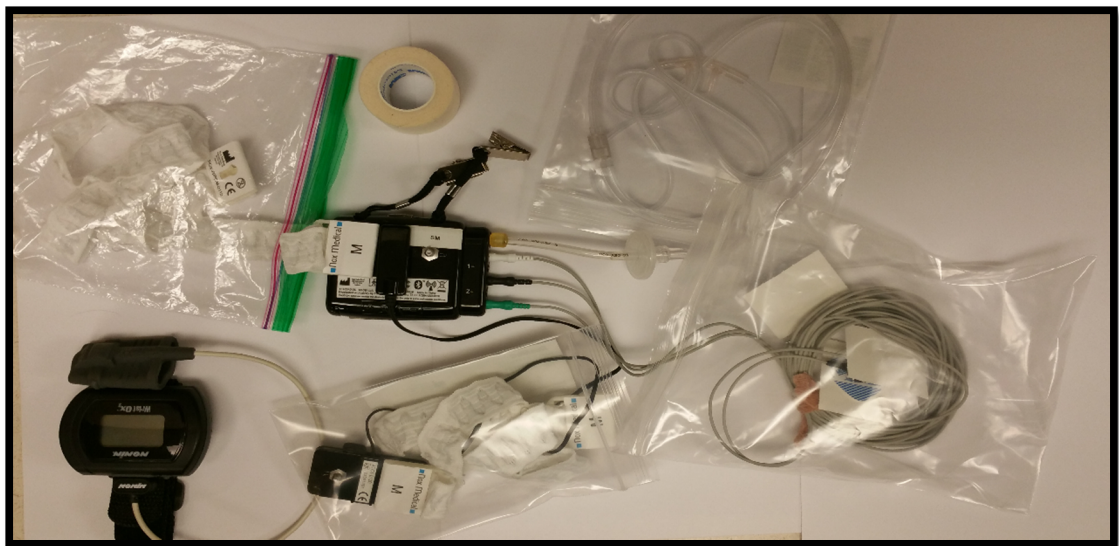
41.12.2.3 Explain that skin redness from the removal of the adhesive and temporary depigmentation under the area of ECG attachment may occur but it's rare.

41.12.3 Explain importance of completing and returning Form 551-Participant Sleep Study Questionnaire with the participant.

41.12.4 Instruct the participant on how to wear the device and allow the participant time to demonstrate applying the sensors before they leave the visit. The following video will aid in the demonstration, click on the link: https://www.youtube.com/watch?v=CteI_GhyP9g

A Carefusion 24-hour hotline is available for any technical support: **1-800-231-2466**, dial 1 at the prompt, and then 3 for sleep support.

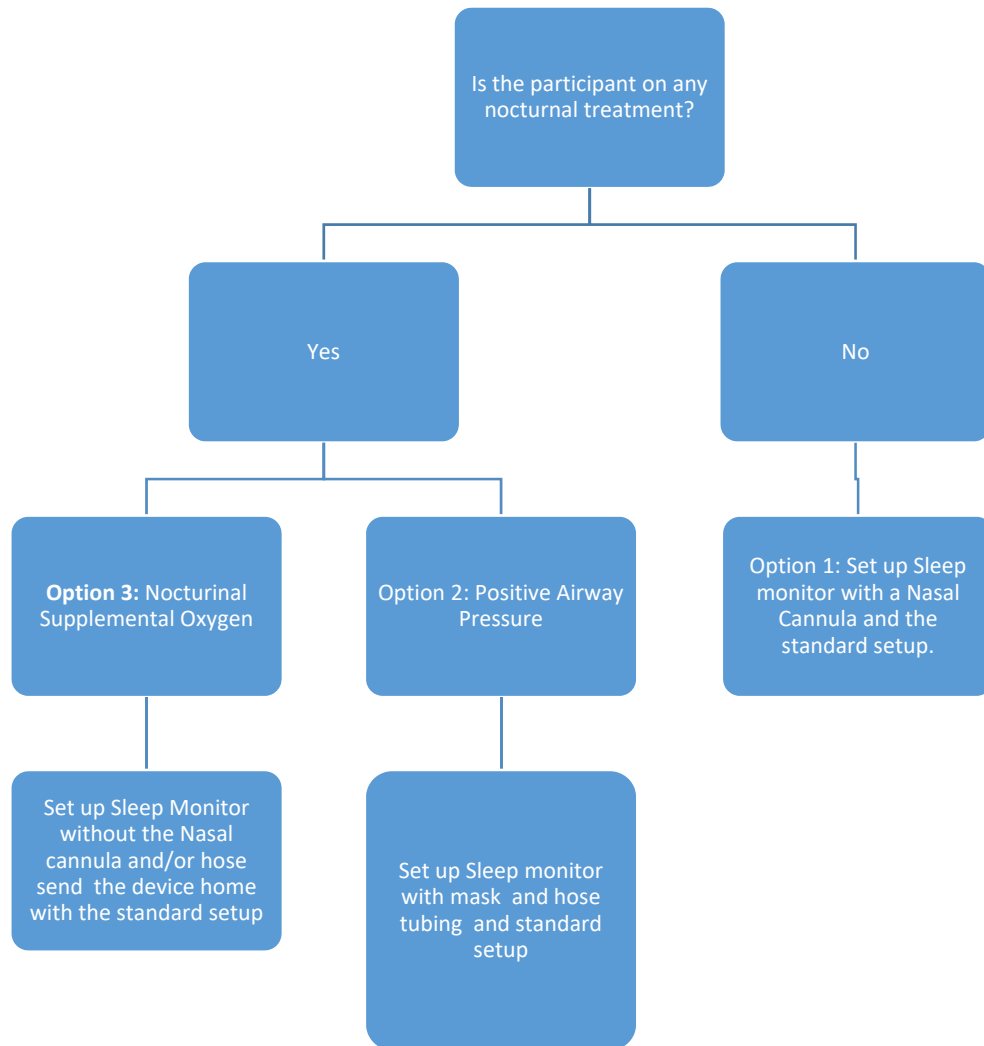
41.12.5 Place all items in the bag, and individually separate the wires in a zip lock bag while still attached to the device for easy application at home.



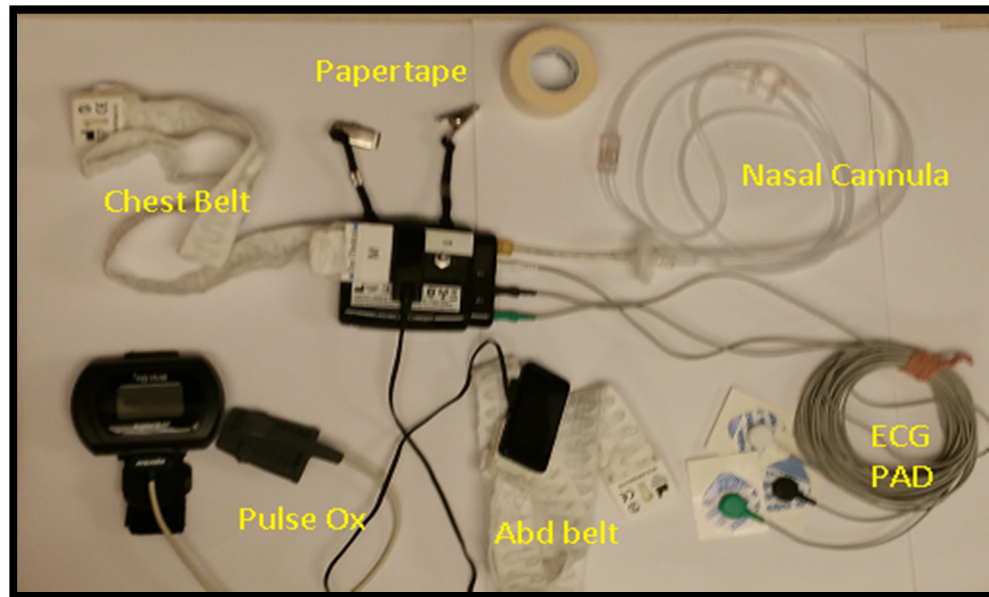
41.12.6 Place instructions, contact information, and the Sleep Questionnaire in the bag and instruct the participant to return everything with the equipment.

41.12.7 Units are returned to the clinic site using local center funds (by mail, courier or direct drop-off).

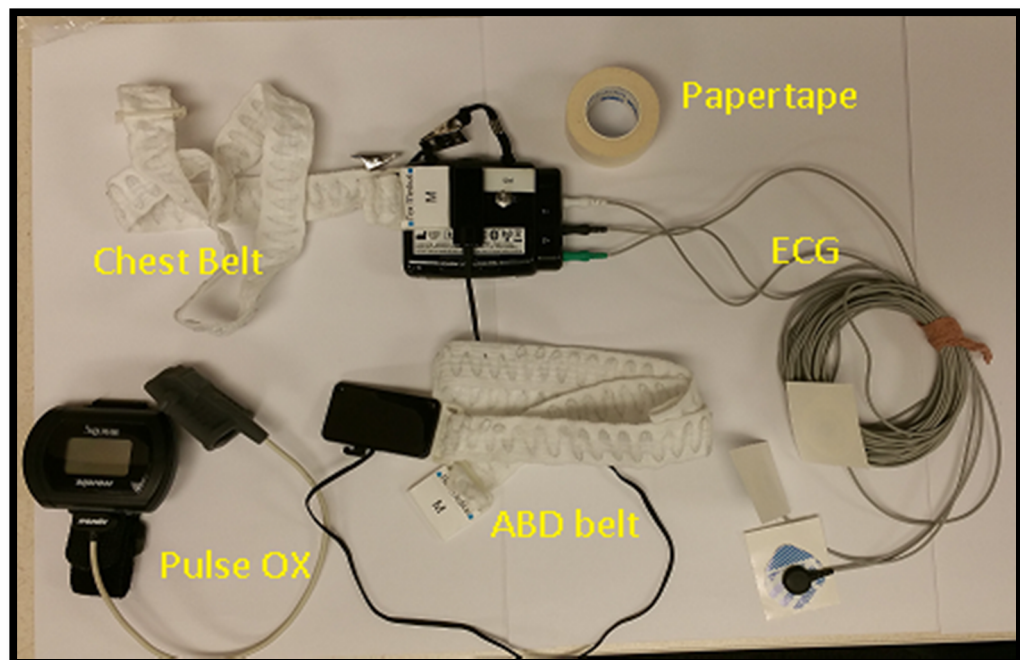
41.13 Sleep Recording Type Decision Flow:



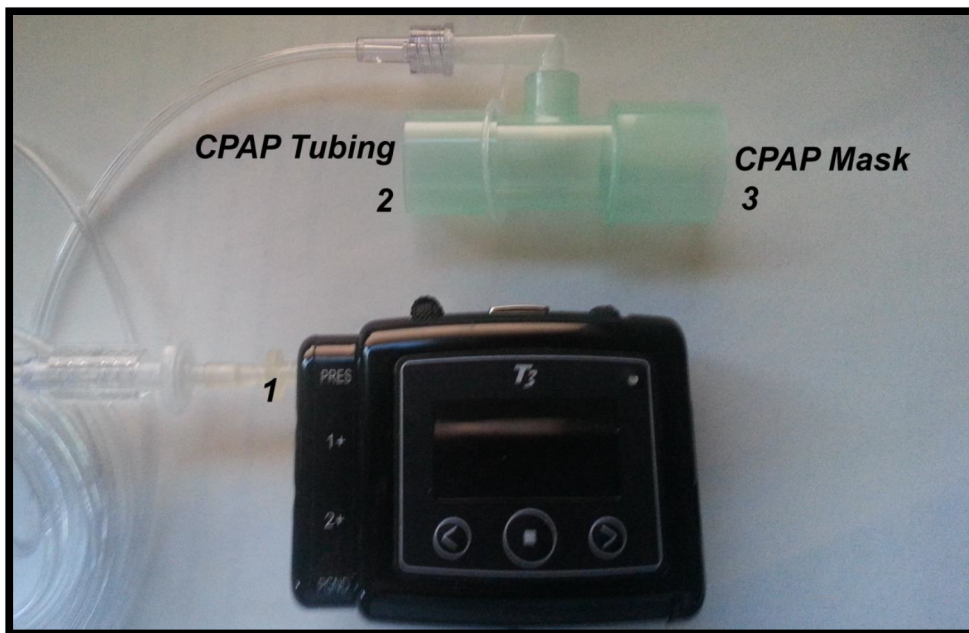
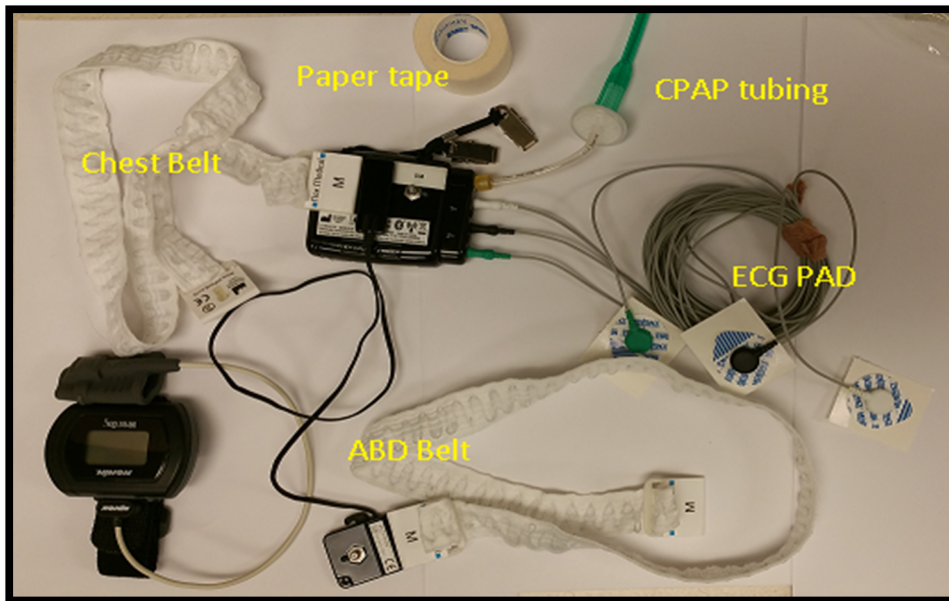
41.13.1 Standard set up for participant **without** nocturnal supplemental oxygen or positive airway pressure (PAP) treatment: Plug the snap wire leads into the ports labeled **1+**, **2+**, and **PGND**. Snap the **ECG Pads** at the end of the snap wire leads. Attach the Nasal Cannula into the **PRES** port. Snap one end of the **chest** belt into back of the device and snap one end of the **abdominal** belt into the external wire.



41.13.2 Standard setup for participant using supplemental **nocturnal oxygen**: Plug the snap wire leads into the ports labeled **1+**, **2+**, and **PGND**. Snap the **ECG Pads** at the end of the snap wire leads. Snap one end of the **chest** belt into back of the device and snap one end of the **abdominal** belt into the external wire.



41.13.3 Standard setup for participant using **PAP**: Plug the snap wire leads into the ports labeled **1+**, **2+**, and **PGND**. Snap the **ECG Pads** at the end of the snap wire leads. Attach the **PAP tubing** in to the **PRES** port. Snap one end of the **chest** belt into back of the device and snap one end of the **abdominal** belt into the external wire.



41.14 Returned Equipment Care Prior to Data Download

Returned Equipment

When the patient has returned the device, treat the container as if it were contaminated and allow it to sit for 72 hours before cleaning:

1. Don disposable gloves and a cloth mask to prevent contamination. Place the device on a non-porous surface, or on a disposable surface (Example: CHUX PAD), at a distance from food and normal work areas. Inspect the device and components for damage.
2. Discard the nasal cannula tubing, abdominal and thoracic belts, disposable wristband and any instruction materials within the package.
3. Clean the device and components based on the hospital-grade disinfectant used, take care and use a pre-cleaner prior to disinfecting if recommended by the manufacturer. Dampen a soft cloth with the non-corrosive hospital grade cleaner (Example: Cavicide) or use a disinfecting wipe.
 - a. It is optional clean the device twice, to ensure rigor of cleanliness, and to dispose of the used components in a trash bin outside of normal office workspaces such as in a laboratory or other sterile area.
4. CaviWipes are recommended for use and require a 1 minute wet time for proper disinfection without any pre-cleaning requirements as long as there is no visible soil on equipment. PLACE IN A “CLEAN” AREA and allow to dry.

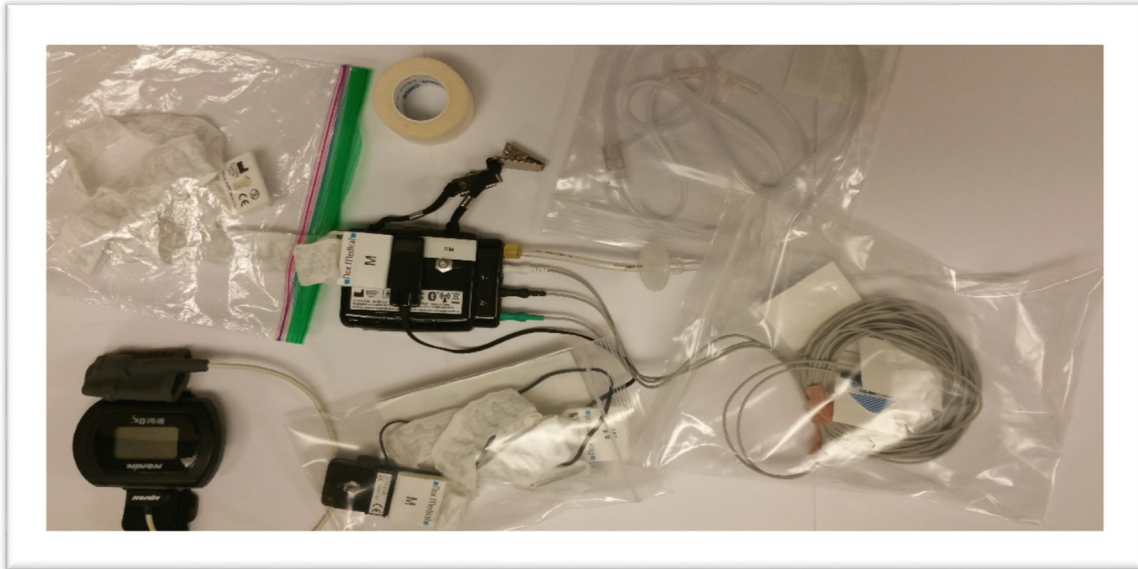
Do not spray the device/components or submerge in liquid as it is not waterproof. Take care to clean the outside without getting liquid into the holes on the device.



5. Clean the non-porous carrying case, or trash the disposable container (e.g. large plastic bag, box, or other as used) if used, ensuring the surface is wet for the designated amount of time. Place in a CLEAN area.
6. If CPAP adapter is used during the test, it should be submersed and hand-washed in 10% Bleach/90% water solution.
7. Take care not to re-contaminate a cleaned item by placing it in the contaminated area during the cleaning process.
8. Dispose of any contaminated materials. Remove the soiled gloves last using standard doffing PPE techniques.
9. Wash your hands before gathering device, transporting it to the workstation and downloading the data. Discard batteries (as appropriate).

Reusing Equipment

1. Place all clean wires in individual plastic bags, while still attached to the device, for easy application at home. Place this in a larger disposable or non-porous container.
 - a. If using a large plastic bag for transporting the device and components, it is recommended to use a bubble-wrap pouch around the device to prevent mechanical damage.



2. Place disposable instructions, contact information and the Sleep Questionnaire in a separate folder for the participant.
3. Belts, wristbands, and any tape provided should be single-use and disposable.
4. Instruct the participant to take care in transporting the device and in placing all equipment back into a non-porous (or disposable) container.

Cloth device carrying cases are not recommended for use.

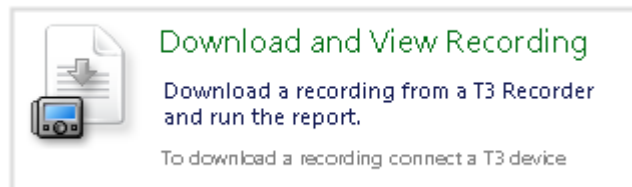
The sleep monitoring device and accessories should be stored in a clean, dry space. Each device will be tested for a minimum of 2 hours during normal work hours to assure all signals are working accurately before sleep data collection begins. All reusable components should be cleaned between participant uses.

41.15 Sleep Monitor Data Download

Downloading the recording:

After device and equipment are cleaned, download the recorded data from a T3 device to the computer connect the device to the USB port on the computer. Noxturnal® software automatically detects the device and displays information on the **Start Page**. Detection can take 2-4 seconds. If the T3 device is not detected, click the **Scan for Devices** link.

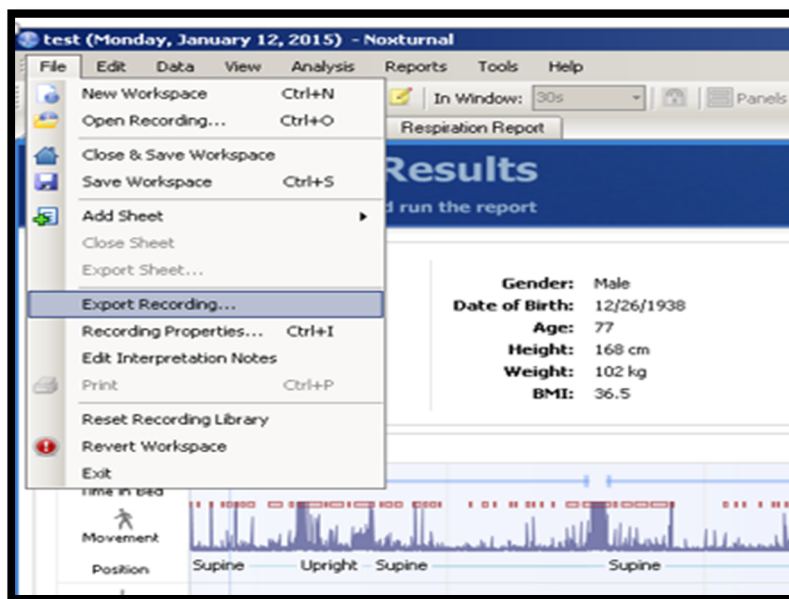
41.15.1 Click the **Download and View Recoding** button on the start page.



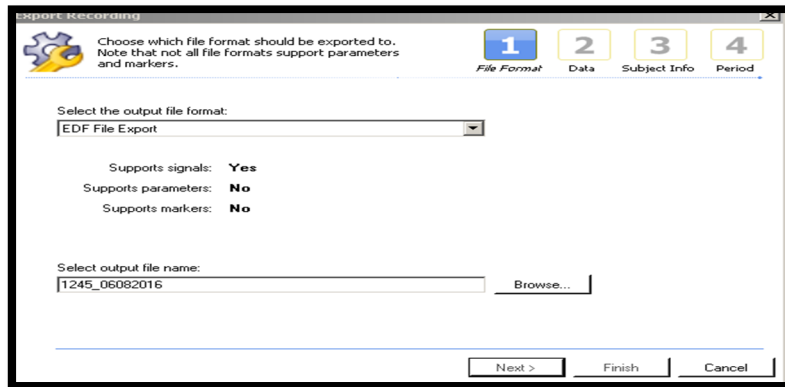
41.15.2 After download is completed, the recordings are automatically added to the recording library as a .ndb format. Always keep the original .ndb format separate from .edf recordings in case of file corruption. More information on converting file types below.

41.16 Converting a file to EDF format:

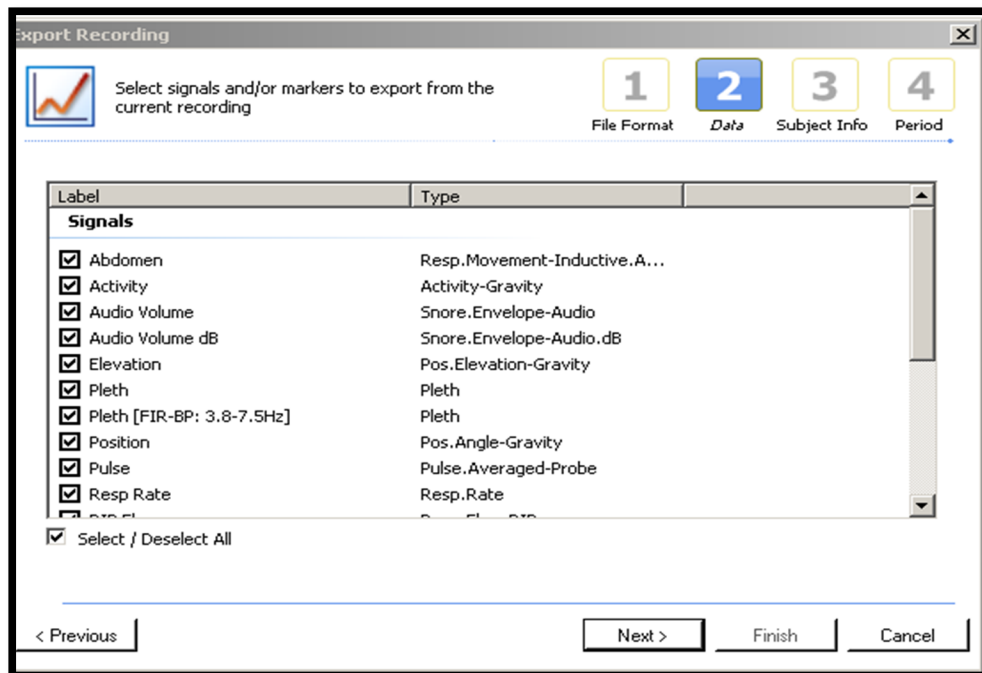
To convert the data file to .EDF, the data file must be opened. Locate the data file by moving the mouse to the top left corner and select **File, Open Recording**, or open from the Library screen if applicable. Once open, from the **File** drop down menu select **Export Recording**.



41.16.1 A wizard will appear, select EDF File Export, and click on **browse** to select the location of where you would like to place the EDF file. Enter the participant's ID with the date of recording night and then save. The data file name will be in the format: {LSleep}_[CR]_[staffusername]_[complete date of study].



41.16.2 Click on **next**. Place a ✓ mark in the select/deselect All option. All signals should have a ✓ mark next to them.



41.16.3 If the participant information is correct, select “**Use existing subject information**”. If not, select “**Create new subject**” and send an email to inform Samantha Wells wellss@ccf.org of the discrepancy with the participant file. Then select **Next**.

The screenshot shows the 'Export Recording' dialog box with the 'Subject Info' step selected. The dialog has a title bar 'Export Recording' and a close button. Below the title bar is a progress bar with four steps: 1. File Format, 2. Data, 3. Subject Info (highlighted), and 4. Period. The main area contains three radio button options: 'Use existing subject information' (selected), 'Create new subject information' (with fields for Name and ID), and 'Include no subject information'. At the bottom are buttons for '< Previous', 'Next >', 'Finish', and 'Cancel'.

41.16.4 Selecting a period to export: **Export whole recording** will be selected. Then select **Finish**

The screenshot shows the 'Export Recording' dialog box with the 'Period' step selected. The dialog has a title bar 'Export Recording' and a close button. Below the title bar is a progress bar with four steps: 1. File Format, 2. Data, 3. Subject Info, and 4. Period (highlighted). The main area contains two radio button options: 'Export active period' and 'Export whole recording' (selected). Below the 'Export whole recording' option, it says 'Whole Recording from 1/12/2015 10:00:00 PM to 1/14/2015 7:00:54 AM'. Below this is a 'Storage Capacity' section with a table showing 'Hard drive letter: C:\', 'Available disk space: 68.7 GB', and 'Estimated export capacity: 81.6 MB'. At the bottom are buttons for '< Previous', 'Finish', and 'Cancel'.

41.16.5 Right click on the folder to create a zip file and use the same naming scheme as above and log in to the secure FTP portal with previously assigned account name and password. Drag and drop file into the home directory for PVDOMICS on DCC server.
{LSleep}_[CR]_[staffusername]_[complete date of study].

41.17 Sleep Monitor Data Transmission

- Clinical Centers will transmit the home sleep monitor data to **SSH home directory**.
- All electronic data transmitted to the DCC must be stripped of all participant identifying information and saved with the unique Study ID.
- Log into SSH home directory and drop files into the PVDOMICS DCC server.
- If difficulties connecting or uploading are experienced, contact pvd-systems@bio.ri.ccf.org.

41.18 Retention of Data

The Clinical Center must retain original versions of the sleep recording data files that have been created by the download of the overnight study. It is preferred that the Center also retain copies of the EDF output files. Create one CD-ROM disk containing a copy of the original sleep recording and a copy of the converted EDF. The CD-ROM disk must be retained with the study documents in a secure location. These files are source documents and shall serve as “back up” files only.

41.19 Abbreviations and Acronyms

AASM	American Academy of Sleep Medicine
AHI	Apnea Hypopnea index
ASV	Adaptive- Servo Ventilation
BIPAP	Bilevel Positive Airway Pressure
CPAP	Continuous Positive Airway Pressure
EDF	European Data Format
HR	Heart rate
PAP	Positive Airway Pressure
PI	Principal Investigator
PM	Portable Monitor
TST	Total Sleep Time

41.20 Creating Device Profile Templates

Creating templates at the start of the study is helpful to ensure proper device set-up for each potential patient depending on the study type. For patients that wear oxygen or positive airway pressure (PAP), different settings will enable or disable channels on the device.

Follow steps 1-4 and 6 for each new recording template. Device Settings in Step 5 will change based on study type:

[Nasal Pressure setup](#)

[PAP patient setup](#)

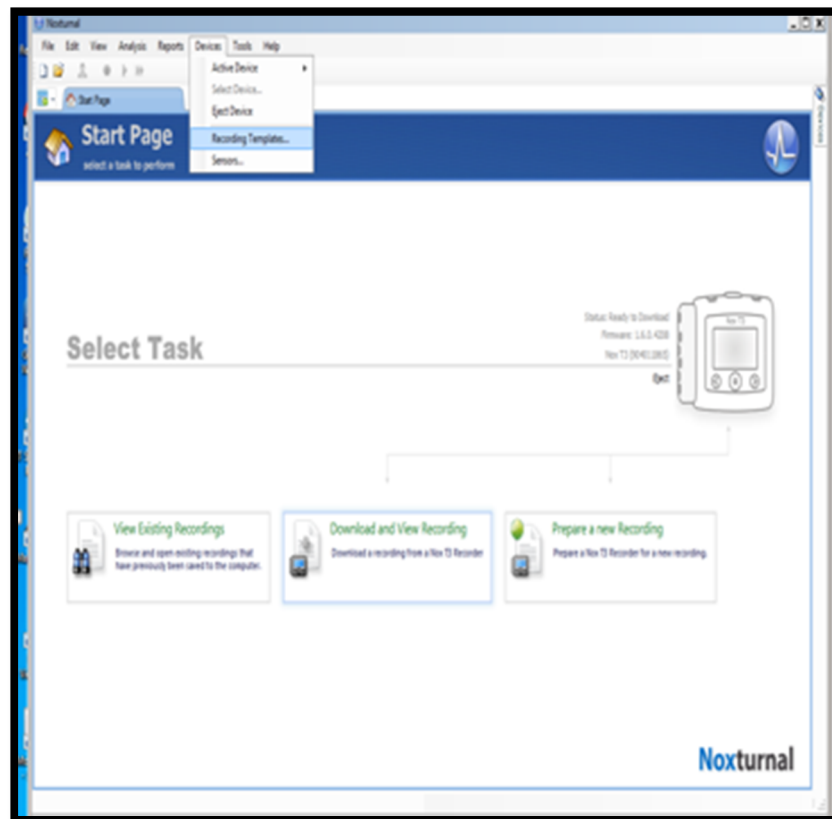
[Supplemental Oxygen patient setup](#)

[Oximetry Only patient setup](#)

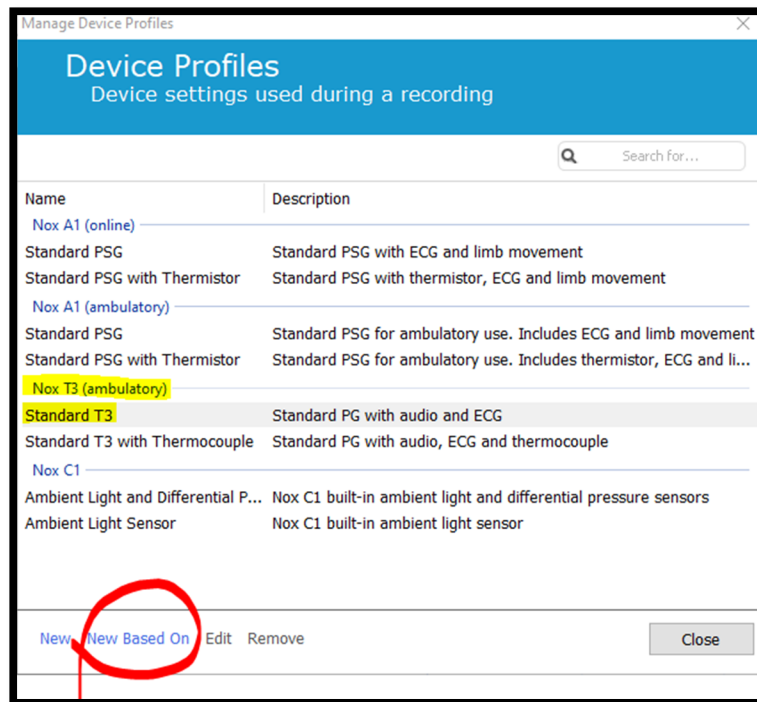
Step 1

Click on the tab marked “Devices.”

Select “Recording Templates” or “device profiles” depending on your software version.



Step 2



Click on "New based on" in the lower left corner

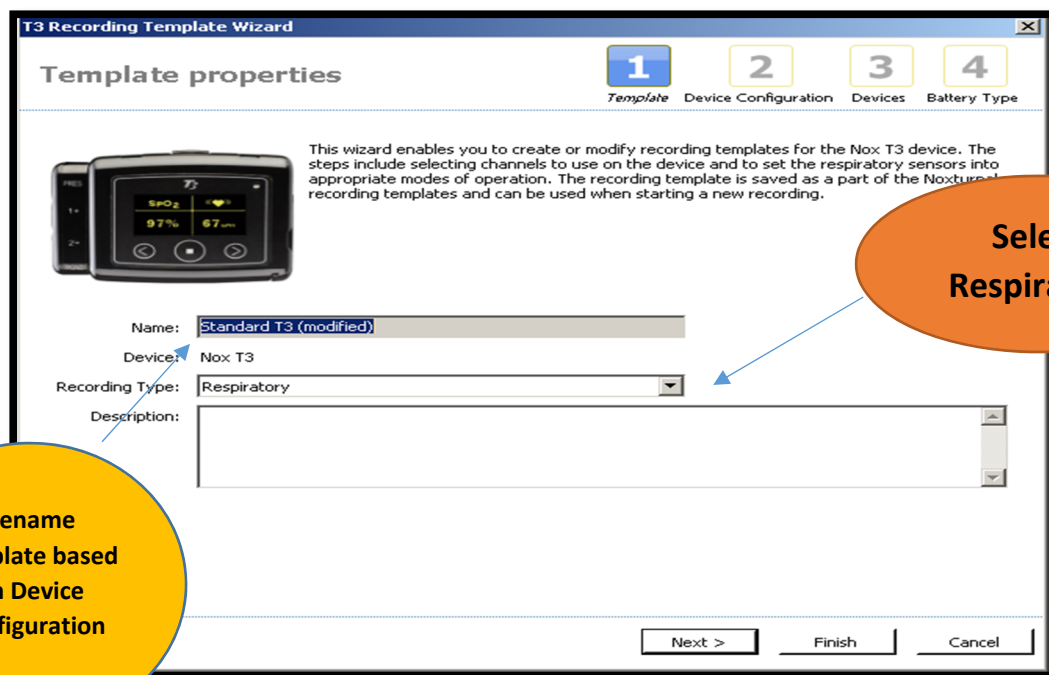
Select Nox T3 (ambulatory) Standard T3

A wizard will prompt

Step 3

Rename template based on the type of study from Device Configuration in step 5. [Nasal Pressure](#), [Mask Pressure](#), [Supplemental Oxygen](#), or [Oximetry Only patient setup](#).

Select Recording type as **Respiratory** from the drop down. Then select **Next**.



Step 4

Select the 'Recording Template' drop down to choose template name created above. Select 'Edit' to change the standard device configuration.

The screenshot shows a software window titled "Configure Device for a New Recording" with a close button (X) in the top right corner. The window is divided into three tabs: "1 Configuration" (active), "2 Schedule Recording", and "3 Patient Information". The main area is titled "Select template and devices". On the left, there is a diagram of a human figure with various sensors indicated: a chest strap, a wrist device, and a foot device. Below the diagram, a list of channels is shown: Activity, Position, Thorax RIP, Abdomen RIP, Audio Volume, Real Audio, Nasal Cannula, and 1: ECG. On the right, the "Recording Template:" is set to "Standard T3" with a dropdown arrow and an "edit..." link. Below this, the "Other Devices:" section shows a "Nonin 3150 Oximeter" with a "Pin:" field containing "462898". A yellow circle with the text "Select 'edit'" and an arrow points to the "edit..." link. At the bottom, there are three buttons: "Next >", "Finish", and "Cancel".

Step 5

Device Configurations

Follow steps 1-4 and 6 for each of these study types:

Configure Device: Nasal Pressure Cannula

Select Nasal
Flow

✓ Channel 1
ECG and
Channel 2
ECG and
uncheck
Audio
Recording,
and use
Standard for
Device display

The screenshot shows the 'Configure Device' window in the T3 Recording Template Wizard. The window has four tabs at the top: 1 Template, 2 Device Configuration (active), 3 Devices, and 4 Battery Type. On the left is a diagram of a person with a nasal cannula. Below the diagram, a list of channels includes Activity, Position, Thorax RIP, Abdomen RIP, Audio Volume, Nasal Cannula, 1: ECG, and 2: ECG. On the right, the 'Audio Recording' section has 'Enable Audio Playback' unchecked. The 'Cannula and/or Mask' section has 'Nasal Flow' checked and 'Mask Pressure' unchecked. The 'General purpose channels' section has 'Channel 1' and 'Channel 2' both set to 'ECG'. The 'Device display' section has 'Standard' selected. At the bottom are buttons for '< Previous', 'Next >', 'Finish', and 'Cancel'.

Proceed to Step 6 for remaining set-up instructions

Configure Device: Mask Pressure (PAP)

Select: “**Mask
Pressure.**”

✓ Channel 1/2
ECG

Use the Standard
Device display:

The screenshot shows the 'Configure Device' window in the T3 Recording Template Wizard. The window has four tabs at the top: 1 Template, 2 Device Configuration (active), 3 Devices, and 4 Battery Type. On the left is a diagram of a person wearing a PAP mask. Below the diagram, a list of channels includes Activity, Position, Thorax RIP, Abdomen RIP, Audio Volume, Mask Pressure, 1: ECG, and 2: ECG. On the right, the 'Audio Recording' section has 'Enable Audio Playback' unchecked. The 'Cannula and/or Mask' section has 'Nasal Flow' unchecked and 'Mask Pressure' checked. The 'General purpose channels' section has 'Channel 1' and 'Channel 2' both set to 'ECG'. The 'Device display' section has 'Standard' selected. At the bottom are buttons for '< Previous', 'Next >', 'Finish', and 'Cancel'.

Proceed to Step 6 for remaining set-up instructions

Configure Device: Supplemental Oxygen

Unselect “nasal flow”

Unselect “mask pressure”

✓ Channel ½ ECG

Standard device display

T3 Recording Template Wizard

Configure Device

1 Template 2 Device Configuration 3 Devices 4 Battery Type

Audio Recording

☐ Enable Audio Playback

Cannula and/or Mask

☐ Nasal Flow

☐ Mask Pressure

General purpose channels

☒ Channel 1: ECG

☒ Channel 2: ECG

Device display

Standard

Standard user interface. Shows signals and connection status.

Channels:

- Activity
- Position
- Thorax RIP
- Abdomen RIP
- Audio Volume
- 1: ECG
- 2: ECG

< Previous Next > Finish Cancel

Proceed to Step 6 for remaining set-up instructions

Configure Device: Oximetry Only

Unselect all channels and click next

T3 Recording Template Wizard

Configure Device

1 Template 2 Device Configuration 3 Devices 4 Battery Type

Audio Recording

☐ Enable Audio Playback

Cannula and/or Mask

☐ Nasal Flow

☐ Mask Pressure

General purpose channels

☐ Channel 1: Abdomen Piezo

☐ Channel 2: Abdomen Piezo

Device display

Standard

Standard user interface. Shows signals and connection status.

Channels:

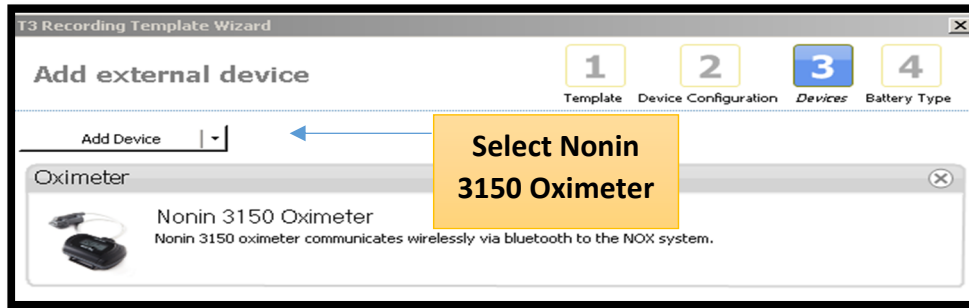
- Activity
- Position
- Thorax RIP
- Abdomen RIP
- Audio Volume
- 1: ECG
- 2: ECG

< Previous Next > Finish Cancel

Proceed to Step 6 for remaining set-up instructions

Step 6

Add External Device: Select from the drop down the type of Nonin oximeter device that will be used. Once the oximeter has been paired to the device, the device and oximeter will only interact with each other.



Select 'Next' to choose default battery type.

Battery Type: Select Alkaline Battery and click 'Finish.'

Template Saved

Now that each device configuration is created and saved as a template, they will appear in your Recording Templates (or Device Profiles) for NoxT3 Ambulatory Device when preparing a New Recording for a patient.

