



# **MULTI-ETHNIC STUDY OF ATHEROSCLEROSIS**

## **EXAM 7 Remote Visit**

### **Field Center Manual of Operations**

**June 23, 2023  
Version 1**

## MOP Version Change Log

Version Date	Summary of Changes

## **Multi-Ethnic Study of Atherosclerosis Exam 7 Field Center Manual of Operations for Remote Visits**

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# 1 OVERVIEW

The MESA Exam 7 Protocol includes a remote visit option to allow participation for those who are unable or unwilling to come to the clinic and do not want field center technicians to come to their home. Remote visits improve retention rates and provide an additional way to help keep participants connected to MESA. In general, it may take more than one remote visit to complete the examination.

As we continue, keep the above in mind when you perform the procedures on those gracious and willing participants. The ultimate value of this study depends on *you* and on the quality of the data that you collect.

## 1.1 Purpose and Objectives

The purpose and objectives of the MESA Exam 7 are described in detail in the main Exam 7 Manual of Operations.

## 1.2 How to use this manual

This manual contains step-by-step instructions for completing all the components in MESA Exam 7 during a remote visit. Many of the steps and procedures are the same as in the clinic visit; thus, where appropriate, the main manual of operation should be consulted.

You should carefully study all sections that relate to procedures that you will be performing, and you should keep this manual handy as a reference. If you have questions about anything in the manual, please direct them to your Study Coordinator or the MESA Coordinating Center.

# 2 EQUIPMENT AND SUPPLIES

Most supplies and equipment needed for the Exam 7 remote visit are the same as those used in the clinic visit. The following supplies and equipment should be ready for the remote visit:

### Exam equipment & supplies

Item	Procedure
Tablet PC computer and power cord	General
T-Mobile Wi-Fi Hotspot	General
Paper (PDF) copies of questionnaires and forms (backup)	General
Participant retention blanket	General
Participant retention tote bag	General
Remote Consent form in the appropriate language (and participant folders/files)	Consent
UBACC Questions	Consent
Current version of Prescriber's Digital Reference (pdr.net)_	Medications
Mod C: VCog Video Cognitive Battery	Cognitive Assessment
Printed MESA Mind Cognitive Testing CRFs	Cognitive Assessment
Stopwatch	Cognitive Assessment
MESA MIND VCog Visual Stimuli PowerPoint	Cognitive Assessment
Audio recorder	Cognitive Assessment

**These materials should be mailed to the participant prior to the first remote visit:**

Item	Procedure
Consent forms in the appropriate language	Consent
Stamped/addressed return envelope for the consent form	Consent
GrandPad with instructions for use	General/Cog Assessment

**Ancillary study equipment and supplies to be Mailed to the participant:**

Item	Procedure
GrandPad device and charger	Cognitive Assessment
VCog GrandPad Device Instructions	Cognitive Assessment
4 sheets of blank paper	Cognitive Assessment
Pen	Cognitive Assessment
Headphones – only for participants with hearing impairment	Cognitive Assessment
Participant Daily Diary	Home Monitors
GENEActiv Wrist Actigraphy Monitor	Wrist Actigraphy
PDI Sani-Cloth Disinfecting Wipes	Wrist Actigraphy
Participant Materials	Wrist Actigraphy
ActiGraph wGT3X-BT [30 monitors/FC]	Hip Monitor
ActiGraph belts or belt clips [1/participant]*	Hip Monitor
ActiLife 6 Lite License [1/FC] download	Hip Monitor
Neo Hub w/ 7 USB-NEO Cables [1/FC]	Hip Monitor
PDI Sani-Cloth Disinfecting Wipes	Hip Monitor
Prepaid mailers for returning monitors (e.g., Amazon Basics Poly Bubble Mailer, 8.5" x 12")	Hip Monitor
Participant Materials	Hip Monitor
Cardiac monitors (Cardea SOLO patch)	Heart Monitor Patch
Prepaid mailers for returning monitors	Heart Monitor Patch
Participant Materials	Heart Monitor Patch
Disposable razors to be used as needed	Heart Monitor Patch
Extra gauze pads to be used as needed	Heart Monitor Patch
Extra alcohol wipes to be used as needed	Heart Monitor Patch
Latex free gloves (small, medium, large sizes)	Heart Monitor Patch
Continuous glucose monitor sensors	Glucose Monitor
Continuous glucose monitor readers	Glucose Monitor
Adhesive patches	Glucose Monitor
Prepaid mailers for returning sensors	Glucose Monitor
Alcohol wipes	Glucose Monitor
Participant Materials	Glucose Monitor
Nox A1 device kit – Includes carrying case, Nox A1 device, SAS head cable, abdominal belt (ATC) cable, left (red) and right (blue body cables). Nonin WristOx unit with finger probe.	Polysomnography
Nox RIP belts (2 per study)	Polysomnography
Nox Nasal Cannula	Polysomnography
Nox Medical Bag 1 (contains electrodes, adhesive strips, alcohol wipes)	Polysomnography
2 AAA alkaline batteries for Nonin WristOx	Polysomnography

Item	Procedure
1AA Lithium battery for Nox A1 device	Polysomnography
Nox Cardboard Backing Sheet (color and shape-coded)	Polysomnography
Participant Instruction sheets	Polysomnography

### 3 EXAM 7 REMOTE VISIT PROCEDURES

#### 3.1 Summary of Exam 7 Remote Visit Components

The components below can be conducted at a remote visit. If feasible, the participant can also be invited to come to the clinic after the remote visit for scanning and/or other procedures that are not possible during a remote visit.

- Consent
- Cognitive Assessment using the GrandPad
- Questionnaires
- Monitor device placement and instructions
  - Hip activity monitor
  - Wrist activity monitor
  - Continuous glucose monitor
  - Heart Monitor Patch
  - Overnight Sleep Study (polysmnography)

Exam 7 components excluded from the remote visit include:

- Anthropometry, BP and Oximetry
- Spirometry
- All specimen collection including urine, hair, and nasal brushing sample collection
- Arterial stiffness
- Clinician Physical Exam
- Short Physical Performance Battery
- ABPM
- Lung CT
- Brain MRI
- Brain PET

#### 3.2 Data Collection Forms

All forms will be administered using the REDCap Data Collection system using a tablet PC, unless otherwise noted below.

*Study Tracking Forms:*

- Call Log
- Clinic Reception
- Participant Tracking
- Exit Report

*Exam Component Forms:*

- Medications
- Cognitive Function Testing Completion
- Neighborhood Questionnaire Completion

### *Participant Questionnaires:*

Questionnaires can be completed on paper, by phone, web survey, or during an interview

- Medical History
- Personal History
- Neighborhood Questionnaire
- Health & Life
- Sleep Questionnaire
- Family History
- Sleep Study PSG Questionnaire
- Environmental Exposures
- Daily Stress Survey (completed by phone survey if participant is going to do the Stress monitor)
- Participant Diary (completed on paper if participant is going to do the heart monitor patch, polysmnography, CGM, hip or wrist monitors)

### *Reading Center and Monitoring Exclusion & Completion Forms:*

- CGM Completion
- Hip and Wrist Activity Monitors Completion
- Stress Reactivity Completion
- Sleep PSG Tracking

## **3.3 Order of Exam Components**

The complete remote visit will require about 3 hours. Every effort should be made to perform all the components of the examination within during the remote visit. Field Centers may vary the exam sequence if needed.

Guidelines for the visit order are listed below. Many elements are left to the discretion of the individual field center.

1. Consent and participant questionnaires may be completed prior to the remote visit by phone, video visit, or using web surveys or mailed paper forms.
2. Questionnaires and other exam procedures may be administered at any time during the visit. During the interviews, make every effort to avoid distractions, ensure privacy, and maintain confidentiality for the participant.

## **3.4 Exam Component Selection Requirements and Prioritization**

Participants will be scheduled with the expectation that they will undergo ALL procedures and complete ALL questionnaires for which they are selected. However, for those few participants who are unable to participate fully, the following guidelines should be followed.

MESA MIND components: Participants with a MESA MIND Visit A diagnosis of dementia cannot participate in Remote Visit Exams.

MESA Sleep components: Participants are encouraged to complete the home sleep study and activity monitors. None are requirements for completing other MESA Sleep components.

MESA 24H-ACT components: The hip and wrist activity monitors must be worn together over

the same time period.

MESA Stress Reactivity: Participants must agree to complete both the heart monitor patch and the daily stress questionnaire.

## **4 PREPARING FOR THE EXAM 7 REMOTE VISIT**

### **4.1 Prior to the Remote Visit**

Remote Visit participants should be contacted first to describe the exam and complete the consent form. At this time, determine if the video visit will be conducted using the participant's own computer or via a GrandPad. Remote visits require a video visit. If no video option is available or the participant only plans to complete questionnaires, conduct a Phone Visit instead of a Remote Visit. See the Exam 7 MOP section X for phone visit components. Discuss which mobile monitors will be self-applied, who is available in the home to assist, and ensure all materials are sent to participant in time for the remote visit. Remote visits may be completed in two or more sessions as needed for completion of procedures.

### **4.2 Optional verbal consent for Exam 7 Questionnaires**

Participants may choose to complete questionnaires prior to consent. Document verbal consent using the procedure described in the Exam 7 MOP.

### **4.3 Pre-visit Reports and Forms**

Follow details described in the Exam 7 MOP

### **4.4 Completion of Forms at the Remote Visit**

Complete all forms using direct data entry into REDCap when at all possible. Have recently printed paper copies of all forms as back up if needed and be sure to enter data into REDCap as soon as possible.

## **5 EXAMINATION PROCEDURES**

### **5.1 Participant Reception and Consent**

The Check-In and Reception process is the first thing the participant experiences and sets the tone for the entire visit. The remote reception process is important in setting the participant's frame of mind for the rest of the exam day. Greet each participant warmly as soon as you arrive on the video session.

Refer to the Exam 7 Clinic Exam MOP for specific details about the reception and consent processes and entering the information into the REDCap database.

If non-participants are present during the visit, address the participant directly and do not encourage conversation with other persons. If necessary, ask that the participant be left alone for visit but to also remain available for assistance as needed.

### **5.2 Cognitive Assessment**

Cognitive assessment performed via video (VCog) using the GrandPad. Refer to the [MESA MIND VCog Testing MOP](#) for specific instructions.

### **5.3 Questionnaires**

The preferred method of questionnaire administration is to complete over Zoom via the participant's device or the

GrandPad, with the interviewer sharing the [survey mode](#) of the questionnaire. This way the participant can see the response options as you move along. If completing by phone only, consider mailing the paper forms in advance. Refer to the Exam 7 MOP for specific instructions for each questionnaire.

#### **5.4 Hip activity monitor**

The hip activity monitor is applied the same way in the home as in the clinic. Refer to the Exam 7 MOP for specific instructions.

#### **5.5 Wrist activity monitor**

The wrist activity monitor is applied the same way in the home as in the clinic. Refer to the Exam 7 MOP for specific instructions.

#### **5.6 Continuous glucose monitor**

The CGM is applied the same way in the home as in the clinic. Refer to the Exam 7 MOP for specific instructions.

#### **5.7 Heart Monitor Patch**

The heart patch monitor is applied the same way in the home as in the clinic. Refer to the Exam 7 MOP for specific instructions.

#### Additional Instructions for Remote Visits:

##### Mailing Heart Monitors

- Please attach a sticker that reads “Please DO NOT OPEN until your scheduled MESA remote visit” to each heart monitor that is mailed out. It is extremely important that participants do not open the heart monitor until the visit so as not to dry out the adhesive.
- Please also mail participants the “Cardea SOLO Remote Application Guide” packet in addition to the normal study brochure and phone survey reminder card.
- Don’t forget to send each participant a USPS envelope to return the heart monitor in after the study period.

##### Remote Heart Monitor Application

- To make application easier, we highly suggest that participants ask someone else in their household to attend the remote MESA visit to help apply the Cardea SOLO heart monitor.
- Please talk through each step in the heart monitor application process with the participant before having them do it.
- As participants (or family members that are assisting participants) complete each step, please watch carefully to make sure they are completing each step properly and offer feedback as necessary.
- When the monitor is applied on the participant, please have them bring the heart monitor close to the camera so you can observe the proper green light sequence after they press the button to activate.
- It is extremely important that the technician observes the correct green light sequence and that the exact date/time that the monitor is activated is recorded in REDCap and on the Cardea SOLO pouch.

#### **5.8 Home Sleep Study**

The sleep study equipment is configured for data collection and applied as described in the MESA Nox A1 Self-Applied System Appendix to this MOP.

#### **5.9 Post Exam Activities**

At the end of the exam, check the list of forms to be sure all are complete. If there are forms or procedures remaining, schedule a second remote visit, or if the participant is willing, to the clinic to complete the exam.

Describe what results the participant should expect and the timeline for receiving them.

Ask the participant if they have any questions at exam exit time. After you have answered any questions, thank the participant. Be sure they have a contact phone number in case questions arise while they wear the home monitors.

## **Appendix: MESA Self-Applied Home Sleep Study (SAS) Procedure**

### **Introduction**

The MESA Self-Applied Sleep Study (SAS) procedure is an alternative to the preferred MESA home sleep study procedure. The SAS is designed to be offered to participants who decline having the standard sleep study equipment applied during a clinic visit or during a visit by study staff to the home.

### **Staff training and certification**

Project staff who are already certified for sleep study data collection as described in the Home Sleep Study procedure (using gold cup electrodes) will not be required to certify in the SAS procedure. Staff from each site already certified in sleep study data collection will receive training from the SRC on all steps necessary to obtain high quality study data using the Nox SAS equipment. Training will include device initialization, device distribution and return, and instruction on SAS-specific device use procedures. All procedures for data download, proper cleaning, disinfection, and maintenance of equipment, and data transmission to the Coordinating Center (CC) for retrieval by the SRC are the same as those used for the standard home sleep study procedure. Staff who are not certified for sleep study data collection in the standard home sleep study procedure should not administer devices to study participants.

### **Software Requirements and Installation**

Noxturnal Research software must be installed to perform data collection using the Nox A1 Self-Applied System (SAS). This software allows configuration of the Nox A1 SAS device for data collection and download of data for studies that are collected using the Nox A1 SAS only. **NOTE: Noxturnal Research is only used with the Nox A1 SAS device kit for self-applied data collection. Noxturnal Research should NOT be used to configure devices for standard sleep study recording (i.e., equipment with EEG gold cups applied by the study staff).** Continue to use Noxturnal US software for collection of standard sleep study recordings.

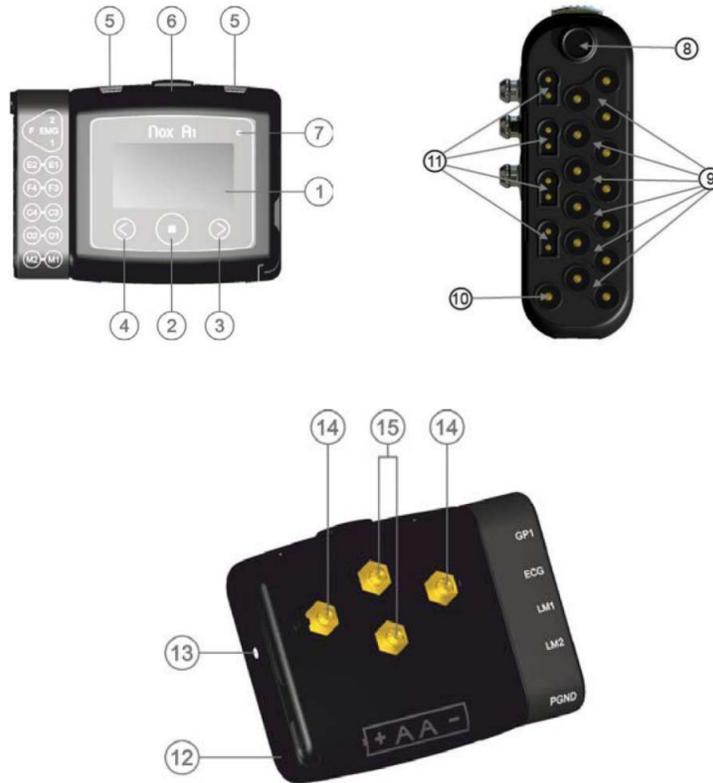
### **Download and Install Noxturnal Research**

Noxturnal Research software version 6.2.2.31544 and instructions for installing Noxturnal Research and activating the license can be found on Dropbox at [https://www.dropbox.com/sh/qxy0uua7albwg4q/AACHtRvc0Qw0LDSbUQ\\_RDoURa?dl=0](https://www.dropbox.com/sh/qxy0uua7albwg4q/AACHtRvc0Qw0LDSbUQ_RDoURa?dl=0). Email Dan Mobley at [dmobley@bwh.harvard.edu](mailto:dmobley@bwh.harvard.edu) if you require assistance installing and activating the software.

### **Equipment Description**

The Nox A1 device (Figure 1) is lightweight (5.8 ounces with battery installed) and can record 8 to 10 hours of data. The monitoring device was chosen because it can acquire high resolution signals through 32-bit signal processing and 256 kHz sampling on all channels with advanced noise reduction and anti-aliasing. A simplified frontal EEG and EOG system applied near the hairline using 5 self-adhesive electrodes will provide information on sleep-wake time and arousals. Respiratory data for identifying apneas and hypopneas consistent with American Academy of Sleep Medicine recommendations will be collected via a nasal pressure cannula and respiratory effort bands (high resolution thoracic and abdominal inductance plethysmography). Pulse oximetry will be collected via a wrist-worn Bluetooth-enabled finger pulse oximeter (Nonin Wrist-Ox2 model 3150, Figure 2) paired to the Nox A1 device. ECG data will be collected via 4 self-adhesive electrodes on the torso. The Nox A1 device is powered by a single Lithium AA battery, and the wrist-worn oximeter is powered by two AAA batteries. Nox supplies (including nasal cannula, effort belts, Nox Medical Bag 1, and cardboard backing sheets) are provided by the SRC as needed.

**Please note that each Nox A1s device is paired to a corresponding Nonin WristOx device, and these devices must remain together in the kits.** The Nox A1s device will only work with its paired Nonin WristOx device, and the devices should remain paired in their kits as distributed by the SRC unless the SRC provides guidance to change device pairings.



**Figure 1: Nox A1 Device**

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Source: *Nox Medical.*

Refer to the list below to identify parts of the Nox A1.

1. Device display
2. Middle push button/Power button
3. Forward push button
4. Backward push button
5. Clip strap loops (2, for clipping the device to clothing)
6. Microphone for recording respiratory sounds/snoring
7. Device status indicator light
8. Pressure port for connecting nasal cannula
- 9-11. Inputs for connecting SAS cable
12. Battery cover
13. Battery cover pin
14. Metal snaps (2) for connecting thorax effort belt
15. Metal snaps (2) for connecting abdominal cable for effort belt



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**Figure 2:** Nonin WristOx 3150 with finger pulse oximeter

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Source: Nonin Medical.

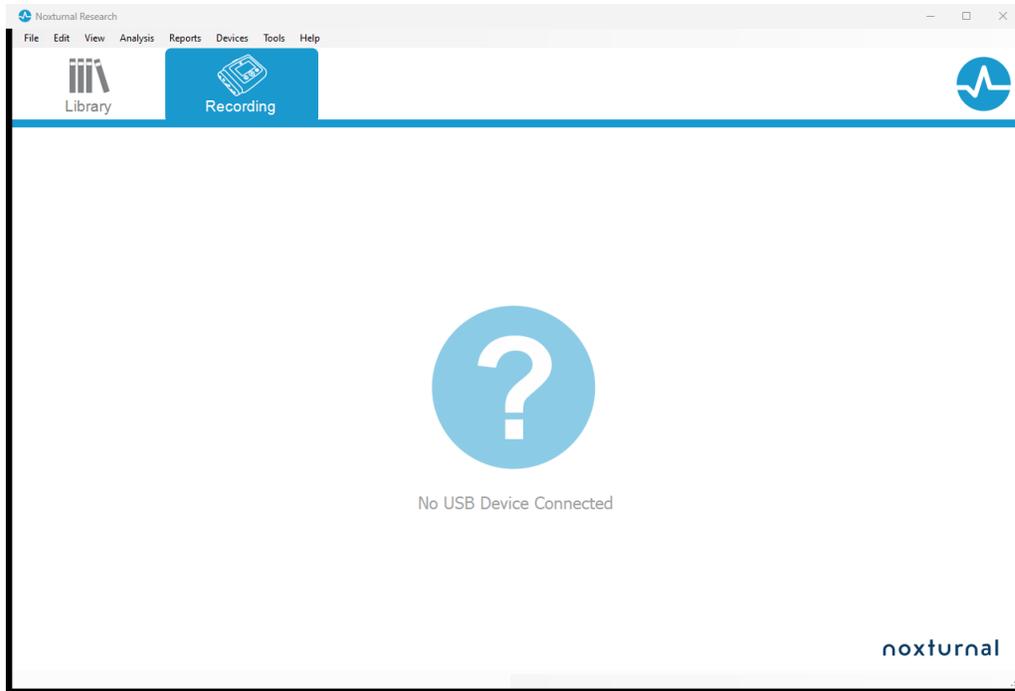
### **Battery Information**

**Nox A1s:** A single size AA lithium battery will be used to power the Nox A1s device. A new AA battery should be used for each recording. The battery will be inserted into the device after device configuration is complete and prior to providing the device to a participant. The used battery will be removed from the Nox A1s device after the device is returned to the center when the battery lid is opened to access the USB connector for data download. Please follow site specific guidance for disposal or recycling of AA lithium batteries.

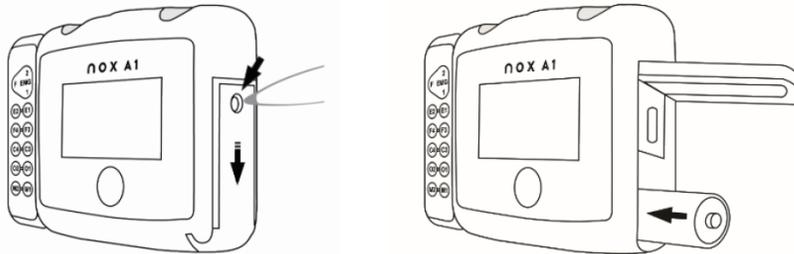
**Nonin WristOx:** Two alkaline AAA batteries will be used to power the Nonin WristOx. New batteries should be inserted into the WristOx at the time of Nox A1s device configuration. The used batteries will be removed from the Nox A1s device after the device is returned to the center. Please follow site specific guidance for disposal of AAA alkaline batteries.

### **Preparing the Nox A1s for Data Collection**

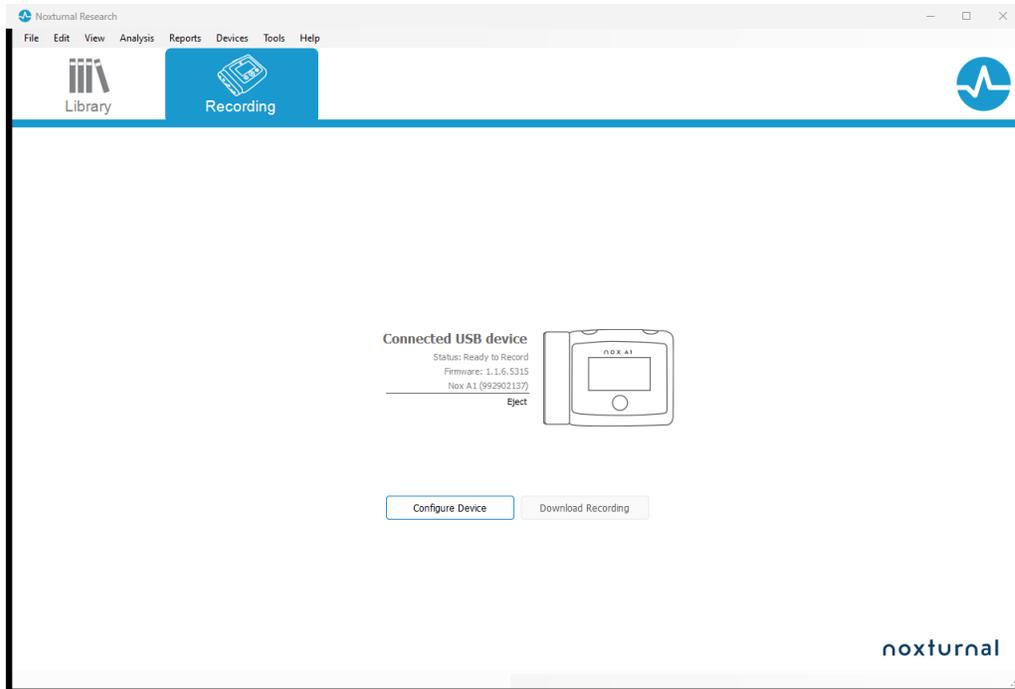
1. Start the Noxturnal Research application and select the “Recording” tab at the top of the screen.



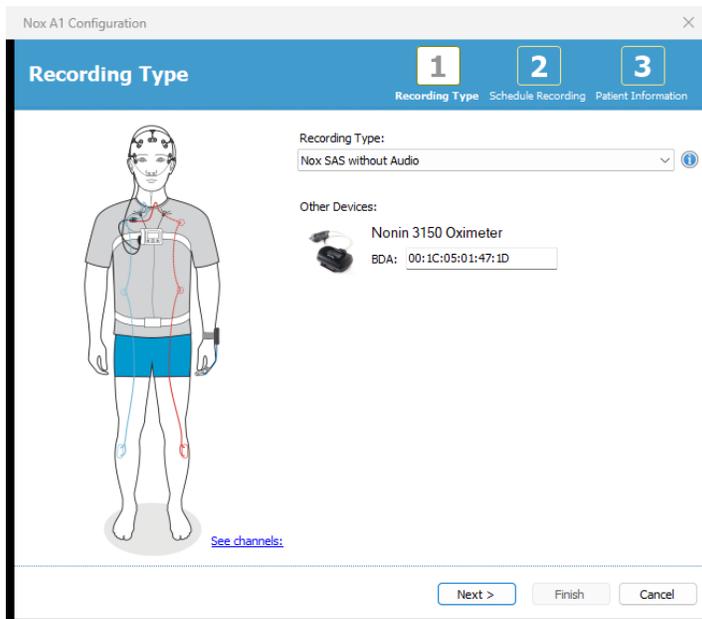
2. Connect the Nox A1 device to the computer with the supplied USB cable. To access the USB port on the Nox A1s device, use the Nox battery lid key to press the battery lid pin and gently slide the battery lid down, towards the bottom of the device. The battery lid door will open. A battery does not need to be inserted while the device is connected to the computer.



3. When the Nox A1 recorder is connected to the computer, the device display will turn on. After a series of brief tests, the “Device connected to PC” message will appear on the Nox A1 display. The Noxturnal Research software Recording tab will change to display the “Connected USB device” message and will show details about the connected Nox A1 device. Note: It can take several seconds for the software to recognize the device. If the software does not recognize the device after approximately 10 seconds, move the mouse pointer to the question mark on the “Recording” screen and click to scan for the Nox A1 device.

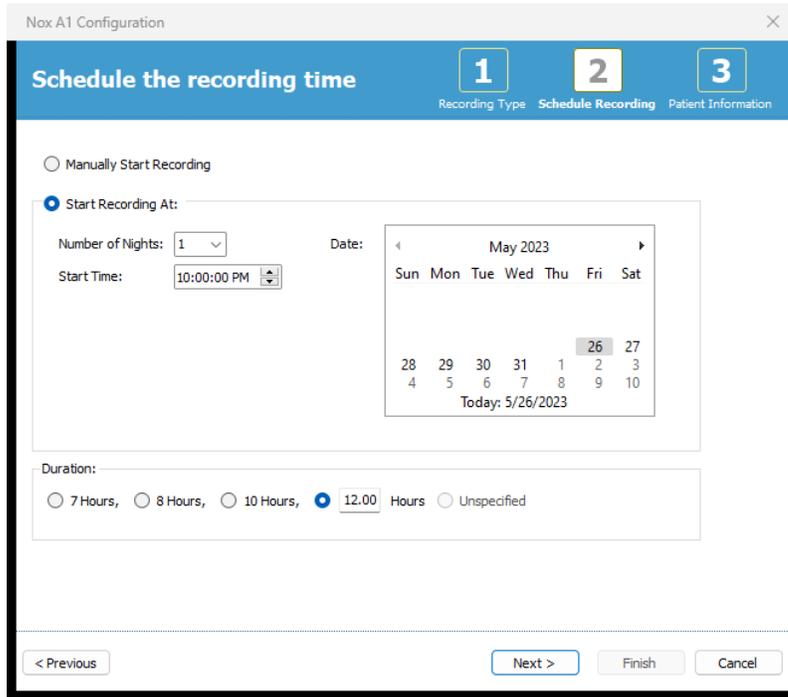


4. Click Configure Device. The Nox A1 Configuration “Recording Type” screen will display.
  - a. In the Recording Type field, select “Nox SAS without Audio”
  - b. In the BDA field, enter the BDA address found on the back of the Nonin WristOx. **NOTE: Unlike the Nox A1s device used in the standard home sleep study procedure, there is no “Pair with Oximeter” feature. It is very important to enter the BDA number correctly, or the oximeter will not collect data during the sleep study recording.**
  - c. Click Next.



5. The “Schedule the recording time” screen will display. Click the Start Recording At radio button to display the scheduling options. Set the options as follows:
  - a. Number of Nights: 1
  - b. Start Time: One hour prior to study participant’s reported bedtime.

- c. **Date:** Choose the date on the calendar for the date the sleep study will occur. Note that since the device is being provided for self-application via mail or another delivery service based on site preference, the night the recording is scheduled to occur must be very clear for the participant. Once configured, the recording date and time cannot be changed. The device must be reconfigured to change the recording date and time.
- d. **Duration:** Click the radio button next to the Hours box and enter 12.
- e. Click Next



- 6. The “Patient Information” screen will display. It is very important that no PHI is entered on this screen. Please enter only the following information in each field:
  - a. First: MESA technician ID number
  - b. Last: MESA participant ID
  - c. ID: MESA participant ID (enter a second time, do not copy and paste)
  - d. Leave all other fields as displayed and click Finish

Nox A1 Configuration

**Patient Information** 1 2 3  
Recording Type Schedule Recording Patient Information

Name  
First: 999 Last: 9912345 ID: 9912345

Gender  
 Male  
 Female

Date of Birth  
 1/ 1/1960  
 N/A

Body Metrics  
Height: [ ] cm Weight: [ ] kg BMI: [ ]

Tags  
[Click to edit tags...](#)

Notes  
[ ]

[Edit...](#) [change device pin...](#)

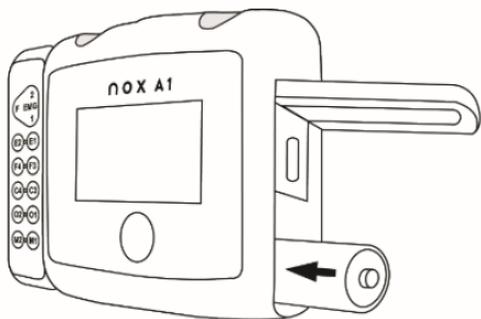
< Previous Finish Cancel

- The “Configuring Device for a New Recording” screen will display a progress bar during device configuration. When configuration of the Nox A1s is complete, the Device Configured message will display.



Finish

- Disconnect the device from the USB cable.
- If you are providing the device to the participant (e.g., by mail, courier or other method) within 24 hours of device configuration, proceed with inserting the battery into the Nox A1 device. If the device will be provided more than 24 hours after configuration, insert the battery just before the device is to leave the center. To insert the AA lithium battery into the Nox A1s device, insert the negative (flat end) of the battery into the battery slot first as shown in the image below. Gently close the battery compartment by pressing the lid back towards the device, then slide the battery lid back into position towards the top of the device.



10. The Nox A1s device configuration is now complete and ready for data collection.

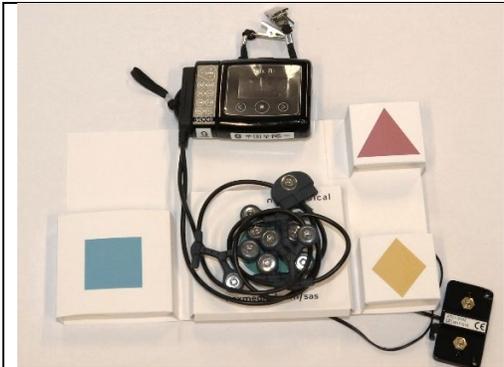
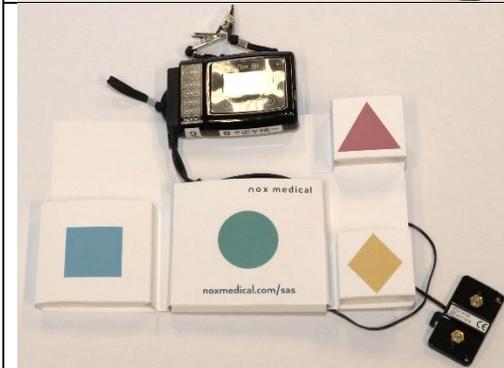
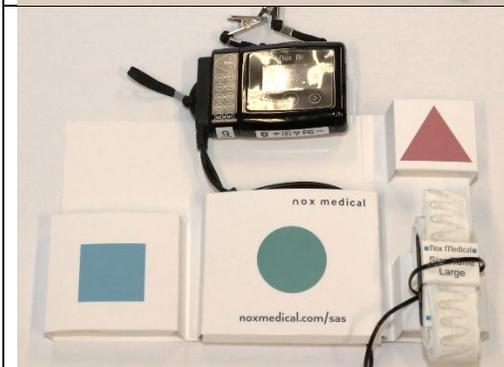
### ***Packaging the Nox A1 kit for In-Home Sleep Study Data Collection***

The SAS setup kit is composed of a Nox carrying bag and the following items:

- 1x Nox A1 recorder
- 1x Head cable
- 1x Red body cable
- 1x Blue body cable
- 1x ATC cable
- 1x Nasal cannula
- 2x RIP effort belts
- 1x Nonin Oximeter and finger probe cable
- 1x Nox Medical Bag 1 containing electrodes, adhesive strips, and alcohol wipes.
- 1x Cardboard backing sheet
- 1x Participant Instructions
- 1x AA Lithium battery for Nox A1 recorder
- 2x AAA alkaline batteries for oximeter

The device and supplies should be packed into the carrying bag as described below to facilitate self-application in the home.

	<ol style="list-style-type: none"> <li>1. The cardboard backing sheet holds the SAS setup to facilitate self-application by the participant. The cardboard backing sheet has: <ul style="list-style-type: none"> <li>• A fixture point (1) to fix it to the Nox A1 recorder</li> <li>• Green circle pocket (2) to hold the head cable</li> <li>• Yellow diamond pocket (3) to hold the abdomen RIP belt and ATC cable.</li> <li>• Red triangle pocket (4) to hold the thoracic RIP belt.</li> <li>• Blue square pocket (5) to hold the nasal cannula</li> </ul> </li> </ol>
	<ol style="list-style-type: none"> <li>2. Place a clean Nox A1 recorder which has been configured for recording and contains a Lithium AA battery and the cardboard backing sheet on a table.</li> </ol>
	<ol style="list-style-type: none"> <li>3. Turn the Nox A1 recorder so that the gold snap electrodes face you.</li> <li>4. Place the cardboard fixture point in the center of the device on the lower gold snap electrode.</li> </ol>
	<ol style="list-style-type: none"> <li>5. Fix the cardboard backing sheet by snapping the connector of the ATC cable over the two center snap electrodes on the Nox A1 recorder.</li> <li>6. Make sure the cable extends downwards from the recorder.</li> </ol>

 A photograph showing a black Nox A1 device with a head cable and a body cable. The cables are coiled on a white surface. To the right of the device are three white boxes with colored markers: a red triangle, a yellow diamond, and a green circle. A small black box with a green circle is also visible.	<p>7. Turn the Nox A1 device and the cardboard backing sheet over so that the front of the device and the colored shapes face you.</p> <p>8. Roll up the head cable and body cable connector so that it fits into the pocket labeled with the green circle.</p>
 A photograph showing the Nox A1 device and cables. The head cable is now placed inside the white box with the green circle. The body cable is still coiled on the surface.	<p>9. Place the head cable in the pocket labeled with the green circle.</p>
 A photograph showing the Nox A1 device and cables. The head cable is in the green circle pocket. A white abdomen RIP belt is being prepared, with one end snapped to the ATC cable.	<p>10. Prepare the abdomen RIP belt by snapping one end to the ATC cable and rolling the belt around the ATC connector.</p>
 A photograph showing the Nox A1 device and cables. The ATC cable and the rolled-up abdomen RIP belt are now placed inside the white box with the yellow diamond.	<p>11. Place the ATC cable and the rolled-up abdomen RIP belt in the pocket labeled with the yellow diamond.</p>

	<p>12. Prepare the chest RIP belt by connecting one end of the belt to the gold snap electrode on the same side as the battery door on the back of the Nox A1 recorder.</p> <p>13. Roll up the chest RIP belt.</p>
	<p>14. Place the rolled-up chest RIP belt in the pocket labeled with the red triangle.</p>
	<p>15. Make a small hole in the bag containing the nasal cannula.</p> <p>16. Pull the connector piece of the nasal cannula through the hole of the bag and connect it to the Nox A1 recorder port labeled “PRES” near the top of the recorder.</p>
	<p>17. Place the cannula bag in the pocket labeled with the blue square.</p>

	<p>18. The preparation of the SAS setup on the cardboard backing sheet is complete.</p>
	<p>19. Obtain a clean and empty Nox Medical carrying bag.</p>
	<p>20. Place a fully prepared SAS setup on a cardboard backing sheet in the bag. The cardboard backing sheet should contain:</p> <ul style="list-style-type: none"> <li>• Nox A1 recorder configured for the participant and containing Lithium AA battery.</li> <li>• Nasal cannula connected to the Nox A1 recorder.</li> <li>• Head cable connected to the Nox A1 recorder.</li> <li>• ATC cable connected to the Nox A1 recorder.</li> <li>• Abdomen RIP belt with one end connected to the ATC cable.</li> <li>• Chest RIP belt with one end connected to the Nox A1 recorder.</li> </ul>
	<p>21. Place the Nonin WristOx pulse oximeter containing fresh AAA batteries in the bag.</p> <p>22. The oximeter should be correctly configured to run with the Nox A1 recorder and must be the Nonin WristOx unit that is paired with the Nox A1 device.</p>

	<p>23. Place the red body cable and the blue body cable in the bag.</p>
	<p>24. Place the Nox Medical Bag 1, containing all the electrodes, adhesive strips, and alcohol wipes, in the bag.</p>
	<p>25. Place the printed participant instructions in the bag.</p>
	<p>26. Close and zip the bag. The Nox A1 sleep study kit is now ready to be given to the study participant.</p>

## Applying the Nox A1 Device for Sleep Study Data Collection

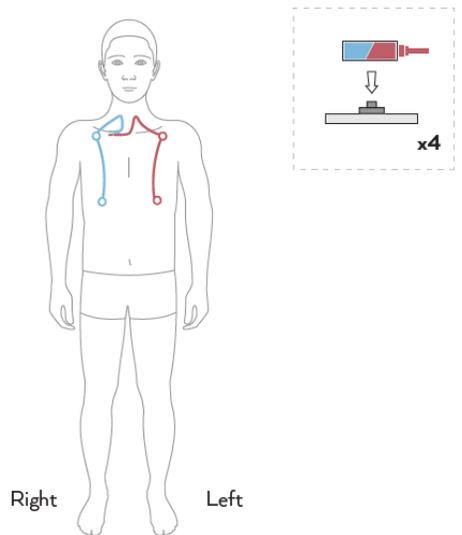
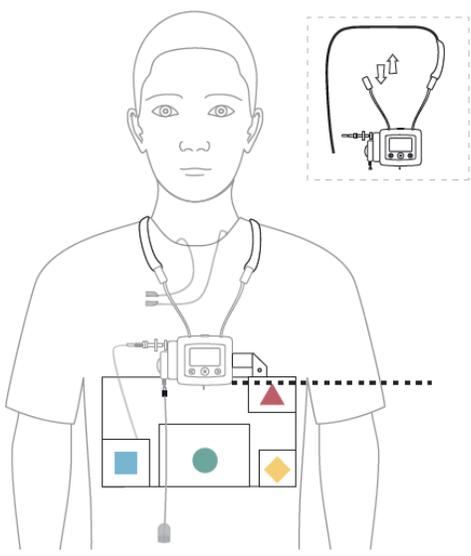
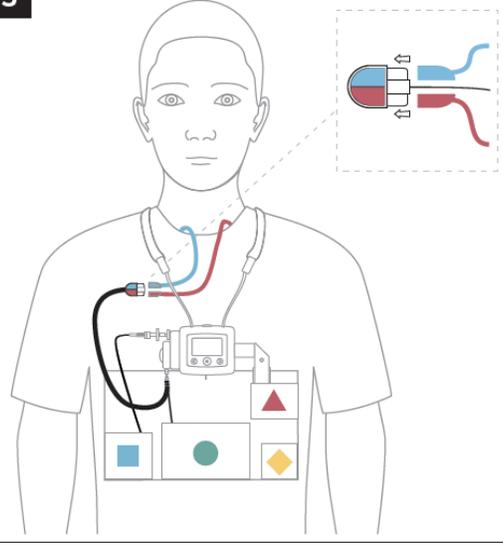
The following section describes how to instruct the participant to apply the device for in-home PSG data collection.

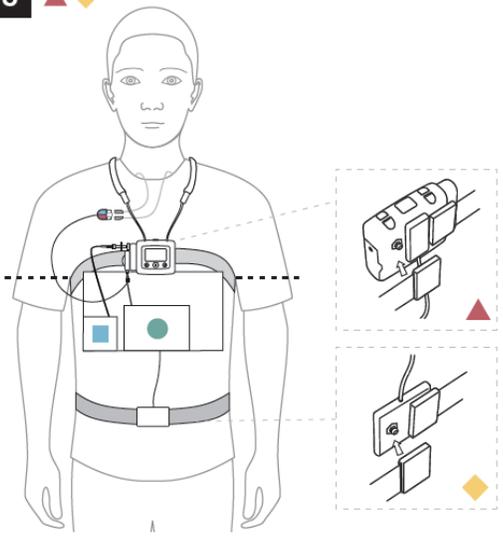
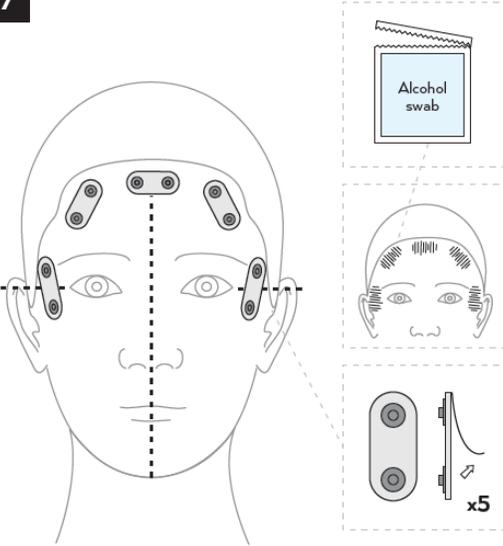
The Nox A1 Self-Applied Setup (SAS) kit supplies should be collected and available for use while instructing the participant on correct application of the Nox A1 device.

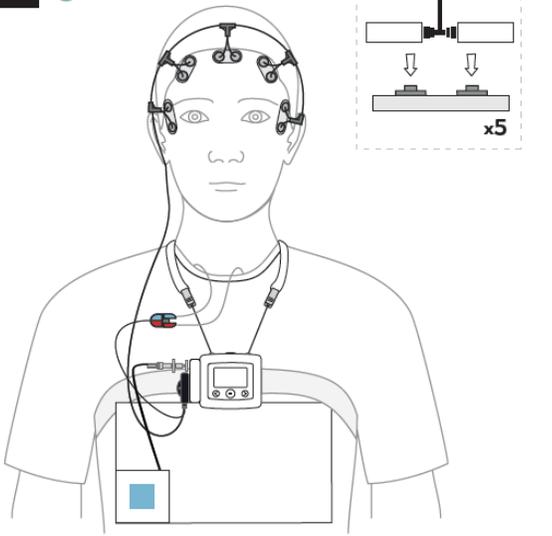
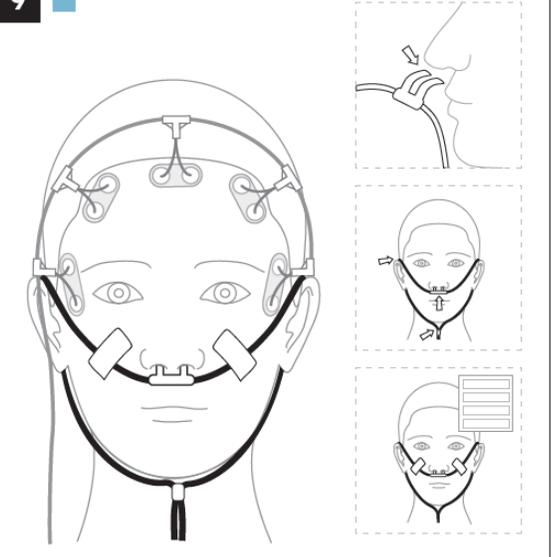
Study staff should request that the participant having an in-home sleep study be showered and dressed in comfortable clothing for sleeping prior to application of the Nox A1 device on the night of the study. The device and respiratory effort sensors should not be placed directly on the skin, so comfortable clothing for sleeping is recommended. The participant should be instructed to apply no lotions, moisturizers, or other types of creams prior to the study, as these items prevent the self-adhesive electrodes from properly adhering to the skin and cause interference with data collection. The Nox A1 device and kit contents can be used as described in the steps below to instruct the participant on proper device application and then packaged in the carry bag as described in the prior section.

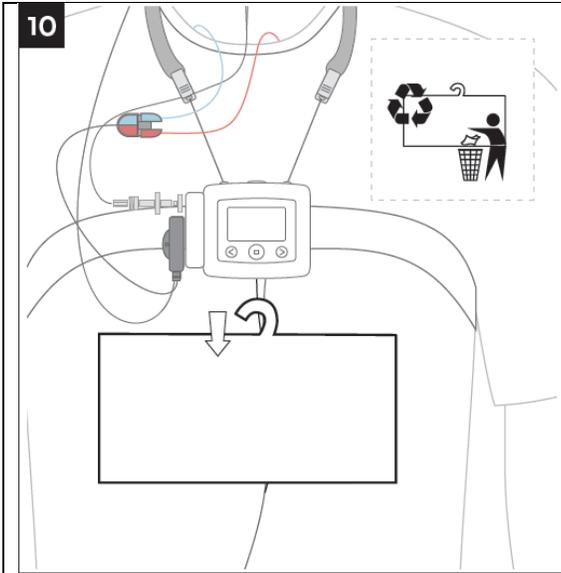
The following table provides step-by-step guidance for instructing the participant on proper Nox A1 SAS device application. The images on the left side of the table correspond to the images on the participant instruction sheet that will be included in the Nox A1 kit that the participant will receive. Please note that self-adhesive electrodes in the Nox Medical Bag 1 will not be applied during training or video instruction. Additionally, alcohol swabs, and adhesive strips from the Nox Medical Bag 1 in the participant kit should not be used while educating the participant. The steps requiring the use of supplies in Bag 1 should be clearly described, and a single sample Bag 1 can be opened in the clinic and the contents used for participant demonstration purposes. The same demonstration Bag 1 can be used for all demonstrations to participants who will use the kit in the home. For steps below that describe applying the self-adhesive sensors to the torso and forehead and then snapping the cables to the sensors, site staff can optionally open the Nox Medical Bag 1 and snap the self-adhesive electrodes to the cables for the participant. If the self-adhesive electrodes are attached to the cables for the participant, alter the description of the steps below appropriately during the instructional session.

<div style="background-color: black; color: white; padding: 2px; font-weight: bold; font-size: 1.2em;">2</div>	<ol style="list-style-type: none"> <li>1. Device application will take approximately 30 minutes and should be applied prior to bedtime. Open the Nox A1 carrying case and remove all supplies, placing them on a table or other surface for easy identification.</li> <li>2. Open Nox Medical Bag 1 and remove one alcohol swab pad and the 4 electrodes with a single snap.</li> <li>3. Open the alcohol swab pad and use it to gently clean the 4 areas shown in the image. Clean just below the left and right collarbones, and slightly below the bottom of the rib cage on both the left and right sides.</li> <li>4. Peel the self-adhesive electrodes from the backing paper and apply an electrode to each cleaned site as shown in the image.</li> </ol>
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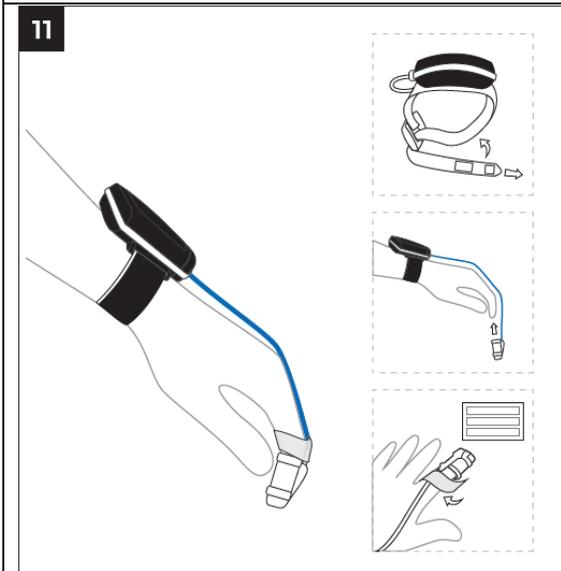
<p><b>3</b></p>  <p>Right Left</p>	<ol style="list-style-type: none"> <li>5. Locate the red body cable, used for the electrodes on the left side of the torso, and place the snaps inside the neck opening of the sleepwear so the cable and snap connectors are beneath the sleepwear. The red connector should remain outside the neck opening.</li> <li>6. Gently apply the bottom snap on the cable to the electrode below the rib cage on the left side of the body.</li> <li>7. Gently apply the upper snap on the cable to the electrode beneath the left collarbone.</li> <li>8. Repeat this procedure with the blue cable on the right side of the torso.</li> </ol>
<p><b>4</b></p> 	<ol style="list-style-type: none"> <li>9. The Nox A1 will have the cardboard backing sheet attached, as shown in the image, when the kit is unpacked in the participant's home. Carefully remove the Nox A1 device from the carrying case.</li> <li>10. Securely clip the Nox A1 device to the clothing near the neck as shown in the image. The clips will hold the Nox A1 device and cardboard backing sheet containing supplies securely in place.</li> </ol>
<p><b>5</b></p> 	<ol style="list-style-type: none"> <li>11. Remove the head and body connector cable from the pocket on the cardboard backing sheet labeled with the green circle.</li> <li>12. Connect the red left body cable and the blue right body cable to the corresponding red "L" and blue "R" connectors on the connector cable.</li> </ol>

<p><b>6</b> ▲ ◆</p> 	<ol style="list-style-type: none"> <li>13. Remove the chest effort belt from the pocket labeled with a red triangle on the cardboard backing sheet. The left end of the effort belt should already be attached to the left side of the Nox A1 device. The illustrations to the left are simply intended to show the location of the snaps and belt attachments on the back of the device and ATC cable.</li> <li>14. Wrap the effort band around the chest, passing it under the arms just beneath the armpits, and snap the effort belt to the snap connector on the back of the right side of the Nox A1 device.</li> <li>15. Remove the abdominal effort belt and the ATC cable from the pocket labeled with a yellow triangle on the cardboard backing sheet. The left end of the effort belt should already be attached to the left side of the ATC cable, and the ATC cable should already be attached to the Nox A1 device when unpacked in the home.</li> <li>16. Wrap the effort band around the abdomen, positioning the ATC connector and belt just beneath the umbilicus, and snap the effort belt to the snap connector on the back of the right side of the ATC cable.</li> <li>17. Adjust both effort bands so they fit snugly but are not too tight. Adjustments can be made by pulling the elastic belt material through the plastic loops next to any of the 4 snap connectors. The plastic “teeth” visible in each loop will prevent the belt from loosening.</li> </ol>
<p><b>7</b></p> 	<ol style="list-style-type: none"> <li>18. This step is performed only by the participant at home and not during the screening visit for participant's having an in-home study. For inpatients, apply the electrodes as described. Remove an alcohol swab pad from the Nox Medical Bag 1 and the 5 electrodes that each contain 2 snaps.</li> <li>19. Open the alcohol swab pad and use it to gently clean the 5 areas shown in the image. Clean 3 areas along the hairline of the forehead and clean the area next to each eye. The participant should be very careful not to get the alcohol swab pad too close to the eyes.</li> <li>20. Peel the self-adhesive electrodes from the paper backing and place them on the cleaned areas as shown in the image.             <ol style="list-style-type: none"> <li>a. Place one electrode at the top center of the forehead, with the center of the electrode along the midline of the</li> </ol> </li> </ol>

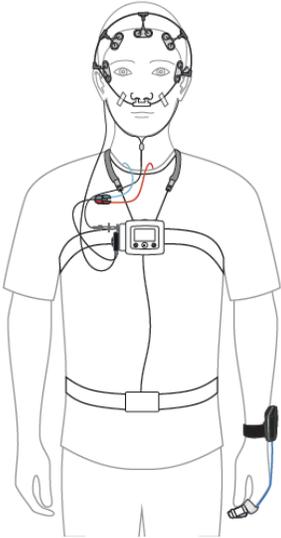
	<p>forehead (shown by the dotted line in the image).</p> <ol style="list-style-type: none"> <li>b. Place an electrode on either side of the center electrode.</li> <li>c. Place an electrode next to each eye, with the center of the electrode pad near the center of the corner of each eye (shown by the dotted lines next to the eyes in the image).</li> </ol>
<p><b>8</b> ●</p> 	<p>21. Beginning on the right side of the head, snap each pair of snaps on the head cable to the snaps on the 5 electrodes. Note that the cable should be positioned so that the snaps are toward the participant's face, and the cable is toward the back of the participant as shown in the image.</p> <ol style="list-style-type: none"> <li>a. The first 2 snaps will be attached to the electrode next to the right eye.</li> <li>b. The next 6 snaps will be attached to the electrodes along the hairline at the top of the forehead.</li> <li>c. The last 2 snaps will be attached to the electrode next to the left eye.</li> </ol>
<p><b>9</b> ■</p> 	<p>22. Remove the nasal cannula from the pocket labeled with the blue square on the cardboard backing sheet.</p> <p>23. Place the nasal prongs inside the nares with the prongs angled toward body.</p> <p>24. Loop the cannula tubing over each ear and, with the tubing beneath the jaw, adjust the slide on the tubing so that the cannula is secure but not tight.</p> <p>25. Remove the adhesive strips from the Nox Medical Bag 1. Place one strip over the tubing and secure it to the cheeks on each side of the nose as shown in the image. The adhesive strips will help prevent the nasal cannula from becoming dislodged during the night.</p>



26. Carefully pull down on and remove the cardboard backing sheet. The backing sheet can be discarded in the trash or placed in a recycling container.



- 27. Place the Nonin WristOx device on the non-dominant wrist. The device should fit like a wristwatch and is secured with the Velcro strap attached to the device. The strap should be adjusted so that the device is secure against the wrist but not uncomfortable or tight.
- 28. Place the finger probe on the finger that fits best into the soft tip sensor. The middle finger or ring finger is recommended. The fingertip should be near the end of the probe but should not extend through the opening at the end of the probe.
- 29. The largest part of the soft tip sensor, the raised square, should be positioned over the bed of the fingernail. Improper placement will result in an invalid recording, so proper placement is important.
- 30. Using an adhesive strip from the Nox Medical Bag 1, secure the cord of the finger probe cable by wrapping the adhesive strip around the finger just behind the soft tip sensor.
- 31. The participant should be instructed not to get the oximeter finger probe wet. If necessary, the finger probe can be removed to use the restroom and wash hands and then replaced.

<p>12 ✓</p> 	<p>32. The Nox A1 device application is complete.          33. The Nox A1 device is set to automatically start recording and will turn on and begin to record at the time programmed by the study staff member.          34. After the recording has started, a “Recording duration” message will be displayed with a timer that will display elapsed recording time.          35. The screen will automatically turn off, and a small green indicator light will periodically blink to indicate the recorder is running.          36. The participant is ready for bed and should be instructed to try and reapply any sensors that fall off during the night if they happen to wake up and notice that a sensor is off.</p>
<p>The morning after the sleep study:</p>	<p>37. When the participant wakes up and is ready to get out of bed for the day, they should follow the participant instruction sheet for removing all sensors and equipment and will place everything back into the carrying bag. The device will turn off automatically.          38. The device should be returned to the site per instructions provided by site staff.</p>

**Receiving and Cleaning/Disinfecting the Nox A1 kit**

Follow instructions in the primary MESA MOP for cleaning and disinfecting the Nox A1 unit. The nasal cannula, respiratory effort belts, and adhesive electrodes (if still connected to the head and body cables) are disposable. All other items are cleaned as described in the MOP.

**Downloading Sleep Study Data and Sending the Study to the Coordinating Center**

Follow instruction in the primary MESA MOP for downloading the sleep study from the Nox A1 device. Remember to use Noxturnal Research software and the mini-USB cable. Place the sleep study in a compressed folder, and upload to NextCloud per the usual procedure.